Shaw™ **Shaw Modular Solutions**

March 9, 2012

United States Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, DC 20555-0001

SUBJECT: REPLY TO NOTICES OF NONCONFORMANCE
NRC INSPECTION REPORT NO. 99901401/2011-202

Attached are the Shaw Modular Solutions (SMS) replies to the Notices of Nonconformance, in accordance with the directions provided in NRC Inspection Report 99901401/2011-202, dated January 6, 2012. SMS acknowledges and agrees with the Notices of Nonconformance, and thanks the NRC for accomplishing a thorough Inspection of the SMS Quality Assurance Program.

We understand the feedback received from the NRC during the Inspection and in the published Inspection Report. We take that feedback seriously, and have either completed or initiated comprehensive actions to remedy the specific observations provided and prevent their recurrence.

Over the past year, SMS has instituted numerous process, procedure and program improvements and has focused on ensuring a strong nuclear safety culture. While we believe that noteworthy progress has been made at SMS, we acknowledge that our Quality Assurance Program and its implementation are not yet at the level of maturity we desire. Your letter serves to remind us that we have continued opportunities to improve. SMS is committed to continuous improvement and has implemented several immediate corrective actions and ongoing improvements.

If you have any questions, please contact me.

Sincerely,

J. L. Ernst
Executive Vice President
Shaw Modular Solutions

C: E. H. Roach, Chief
Construction Mechanical Vendor Branch
Division of Construction Inspection & Operational Programs
Office of New Reactors

D. Chapman
K. David
G. Grant

Shaw Modular Solutions
3191 W. Lincoln Rd.
Lake Charles, LA 70605
337-562-3439 Main 337-562-3490 Fax

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NRO

SUBJECT: REPLY TO NOTICES OF NONCONFORMANCE
NRC INSPECTION REPORT NO. 99901401/2011-202

Attachments:

1. Reply to Nonconformance 99901401/2011-202-01
2. Reply to Nonconformance 99901401/2011-202-02
3. Reply to Nonconformance 99901401/2011-202-03
4. Reply to Nonconformance 99901401/2011-202-04
5. Reply to Nonconformance 99901401/2011-202-05
6. Reply to Nonconformance 99901401/2011-202-06
7. Reply to Nonconformance 99901401/2011-202-07
8. Reply to Nonconformance 99901401/2011-202-08
9. Reply to Nonconformance 99901401/2011-202-09

Shaw Modular Solutions
3191 W. Lincoln Rd.
Lake Charles, LA 70605
337-562-3439 Main 337-562-3490 Fax

ATTACHMENT 1
REPLY TO NONCONFORMANCE 99901401/2011-202-01

NONCONFORMANCE

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Shaw Modular Solutions (SMS) facility in Lake Charles, LA on November 14, 2011 through November 18, 2011, it appears that certain activities were not conducted in accordance with NRC requirements which were contractually imposed upon SMS by your customers or by NRC licensees:

A. Criterion II, "Quality Assurance Program", of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the Code of Federal Regulations (10CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," states, in part, that "The quality assurance program shall provide control over activities affecting the quality of the identified structures, systems and components, to an extent consistent with their importance to safety. The program shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test. The applicant shall regularly review the status and adequacy of the quality assurance program. Management of other organizations participating in the quality assurance program shall regularly review the status and adequacy of that part of the quality assurance program which they are executing."

   Section 2.4.1 of the SMS Quality Assurance Manual (QAM), Revision 3, dated January 4, 2011, states in part that, "The QAM is the top-tier program document at SMS, and defines the regulatory and industry standards to which SMS is committed. It serves as a high level description of the controls that will be established in procedures and implemented in order to ensure that the items and services produced by SMS are of the required quality."

   Contrary to the above, as of November 18, 2011, SMS failed to provide control over activities affecting quality in the SMS QAM and failed to define the regulatory and industry standards to which SMS is committed in the QAM. Specifically, the QAM does not contain the following:

   1. a description of the codes, procedures, regulations, standards, or other specific documents used to qualify personnel (e.g., audit personnel, inspectors, welders) performing activities affecting quality

2. the description of the alternative to use the accreditation provided by one of the domestic accrediting bodies instead of performing a commercial grade survey

3. a comprehensive list of the specific special processes performed at SMS

4. a description of the process for the preparation, issuance, distribution, and implementation of shop travelers for manufacturing operations

5. the general welding process requirements and limitations; and

6. the controls for performing non-destructive examination (NDE) activities and for qualification and certification of NDE personnel

This issue has been identified as Nonconformance 99901401/2011-202-01.

REASON FOR THE NONCOMPLIANCE

The QAM was written to provide a high level program description, with the intent and practice being to provide implementation details in supporting procedures. The details regarding compliance with regulations, standards and regulatory guidance to which SMS is committed were included in those procedures. SMS has since recognized that Revision 3 of the QAM did not provide adequate description to establish a bridge from the top-tier program document to the procedures that supported it. SMS was in the process of completing a significant revision (Revision 5) to its QAM at the time of the NRC Inspection.

For NRC information, Revision 4 of the QAM, while having been developed with a level of detail similar to Revision 5, had not been implemented at SMS. It had been through internal approval and had been accepted by the Authorized Nuclear Inspection (ANI) agency. Prior to receipt of contractually-required external approval, SMS entered into another revision cycle, thus Revision 4 was not implemented. This information is provided to explain the gap between Revisions 3 and 5 of the QAM.

CORRECTIVE STEPS THAT HAVE BEEN TAKEN AND RESULTS ACHIEVED

This condition was documented in SMS Corrective Action Report (CAR) 11-485. At the time of the NRC Inspection, Revision 5 to the QAM had been developed; had been through internal approval; had been accepted by the Authorized Nuclear Inspection agency; and was in the final stages of external approval.

Subsequent to the NRC Inspection, SMS received the contractually-required external approval of the QAM, Revision 5. SMS personnel training to Revision 5 was conducted, and QAM Revision 5 is currently in use. This extensive revision of the QAM contains a significantly greater level of detail than Revision 3.

CORRECTIVE STEPS THAT WILL BE TAKEN TO AVOID NONCOMPLIANCE

SMS has reviewed Revision 5 to ensure that the six topics discussed in the Notice of Nonconformance are sufficiently addressed. This review concluded that, with the exception of addressing the general welding processes for non-ASME Code Section III welding, Revision 5 of the QAM now establishes compliance with the requirements to provide control over activities affecting quality and provides a bridge between the top-tier program document and implementing procedures.

Upon successful completion of an ASME survey the week of February 27, 2012, SMS has revised its QAM to clarify the ASME scope of work and address the area related to non-ASME Section III welding processes.

While the QAM was being revised, SMS determined that procedures prescribing the non-ASME Code Section III welding processes at SMS contained the level of detail necessary to effectively implement the welding processes.

DATE WHEN CORRECTIVE ACTIONS WILL BE COMPLETED

The QAM revision will be issued for use, with requisite training complete, by March 29, 2012.

ATTACHMENT 2
REPLY TO NONCONFORMANCE 99901401/2011-202-02

NONCONFORMANCE

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Shaw Modular Solutions (SMS) facility in Lake Charles, LA on November 14, 2011 through November 18, 2011, it appears that certain activities were not conducted in accordance with NRC requirements which were contractually imposed upon SMS by your customers or by NRC licensees:

B. Criterion II of Appendix B to 10CFR50 states, in part, that "the program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained."

   Section 6.1.1 of the SMS Quality Procedure QP-G-02, "Training", Revision 7, dated October 20, 2011, states, in part, that "SMS personnel who manage or perform activities affecting quality shall receive, prior to performing said activities Quality Assurance Indoctrination and specific training on the SMS procedures and requirements that they will be responsible for managing and/or implementing."

   Section 6.3.3 of QP-QA-01, "Qualification of Auditors", Revision 5, dated September 29, 2011, states, in part, that "Lead Auditors who fail to maintain their proficiency for a period of two years or more shall require requalification. Requalification shall include re-training in accordance with Paragraph 6.2.2, participation as an Auditor in at least one nuclear QA audit, and reexamination in accordance with Step 6.2.4." Section 6.1.7 states, in part, that training "for non-Lead Auditor personnel, orientation/training shall be documented on the QA Auditor Training Record."

Contrary to the above, as of November 18, 2011, SMS failed to provide indoctrination and training to personnel who (1) manage or implement activities affecting quality, and (2) adequately document the training of auditors and to appropriately re-qualify a lead auditor in accordance with SMS procedures. Specifically, SMS failed to: 1) provide indoctrination and training to the SMS Senior Vice President on SMS Procedure QP-G-15a, "10CFR Part 21 and 10CFR50.55(e) Compliance," Revision 3, dated January 4, 2011, and the Corrective Action Manager on QP-G-15, "Control of Nonconforming Items,"

Revision 4, dated September 21, 2011; 2) re-qualify an employee as a lead auditor in 2009 consistent with all of the requirements for requalification as stated in QP- QA-01;

and 3) document the training records for two auditors as required by QP-QA-01.

This issue has been identified as Nonconformance 99901401/2011-202-02.

REASON FOR THE NONCOMPLIANCE

The Senior Vice President (SVP) had not received training to procedure QP-G-15a because it was not recognized that the SVP needed this training. QP-G-15a states that the Director, Quality Assurance/Quality Control (QA/QC) is responsible for ensuring the requirements of the procedure are met. Management and implementation of the SMS program for compliance with 10CFR21 has been performed by the Director, QA/QC. However, while the Director, QA/QC has substantial responsibility for implementation of this procedure, the SVP retains some responsibilities, and should have received the training.

During investigation of this nonconforming condition, SMS identified that the SMS Corrective Action Manager had received training to QP-G-15, Revision 4 on August 26, 2011. However, a copy of the archived training record was not provided to the NRC during the inspection. This investigation revealed that the training matrix that was reviewed during the NRC Inspection contained the position of Corrective Action Manager without listing specific training for the position. A Corrective Action Report was initiated; an extent of condition evaluation was completed to identify any other job positions for which training was not yet identified; and it was determined that the governing procedure did not specifically define a process for identifying training requirements for newly-created job positions, such as the Corrective Action Manager, on the matrix.

An employee was re-qualified and certified as a Lead Auditor without fulfilling all the requirements in the SMS procedure because certifying management (the SVP) believed that the employee's years of nuclear industry experience, coupled with having authored the SMS QA program, the Lead Auditor examination and answer key were sufficient bases for requalification and certification. The employee involved was the Director, QA/QC. This decision was documented on the employee's certification record. After a different test had been authored by another individual, the Director, QA/QC took and passed the examination, and his certification file reflects this.

The audit-specific training for the auditors was not documented on the procedurally-required form due to individual error. The procedural direction of QP-QA-01 was clear; the individual had received training to the procedure; the required audit training had occurred prior to the associated audits having been performed; and the individual forgot to document the training as required.

CORRECTIVE STEPS THAT HAVE BEEN TAKEN AND RESULTS ACHIEVED

These conditions were documented in SMS Corrective Action Reports (CAR) 11-484 and 11-455. The training matrix issue that was identified during the investigation was documented on CAR 12-054.

The Executive Vice President, Senior Vice President and new Director, QA/QC have received documented training to procedure QP-G-15a.

The training matrix has been revised to include the training requirements for the Corrective Action Manager, and other newly-created job positions that appeared on the matrix.

The individual who had not taken an examination prior to re-qualification had taken and passed an examination. This individual has been issued a new certification. No other personnel have been certified as Lead Auditors without having taken an examination.

Training of the two auditors has been documented on the procedurally-required form. An extent of condition evaluation was completed. One additional auditor was identified as not having had the procedurally-required training document completed, and this was also corrected.

Procedure QP-G-02 (Training) has been revised to address requirements associated with identification of required training for newly-created job positions on the training matrix.

The need for individuals who perform or manage activities affecting quality, to receive training to the procedures they either perform or manage, has been reinforced in writing to SMS Management.

The need to ensure that an audit team is prepared for an audit (which includes verification that required training documentation has been completed) has been reinforced in writing to SMS Lead Auditors.

The requirement for verbatim procedure compliance has been reinforced in writing to the Manager, Quality Assurance.

CORRECTIVE STEPS THAT WILL BE TAKEN TO AVOID NONCOMPLIANCE

No further corrective actions are necessary.

DATE WHEN CORRECTIVE ACTIONS WILL BE COMPLETED

Corrective actions are complete.

ATTACHMENT 3
REPLY TO NONCONFORMANCE 99901401/2011-202-03

NONCONFORMANCE

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Shaw Modular Solutions (SMS) facility in Lake Charles, LA on November 14, 2011 through November 18, 2011, it appears that certain activities were not conducted in accordance with NRC requirements which were contractually imposed upon SMS by your customers or by NRC licensees:

C. Criterion III, "Design Control", of Appendix B to 10CFR50 states, in part, that "measures shall be established to assure that applicable regulatory requirements and the design basis...are correctly translated into specifications, drawings, procedures, and instructions. These measures shall include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled.

   Design changes, including field changes, shall be subject to design control measures commensurate with those applied to the original design and be approved by the organization that performed the original design unless the applicant designates another responsible organization."

   Section 6.4.2.1 of QP-G-05a-00, "Detailed Drawings", Revision 0, dated January 11, 2011, states, in part, that "the Product Manager may red line detailed drawings in order to correct and/or incorporate design criteria. Product Manager shall confirm with the Detailer Manager that the red line change is in accordance with the approved design document prior to change."

   Westinghouse Specification APP-GA-G1-001 states, in part, that "Temporary bracing must be color coded and identified as such to alert fabricators that removal is required after installation in the plant."

   Contrary to the above, as of November 18, 2011, SMS failed to ensure that design changes were subject to the design control measures commensurate with those applied to the original design, SMS procedure QP-G-05a-00, and Westinghouse Specification APP-GA-G1-001. Specifically, the SMS Product Manager redlined detailed drawing APP-CA20-S5-02-000-0201, revision 0, dated April 11, 2011, to add supports to module CA20-02; however, the Product Manager failed to confirm with the Detailer manager that the redline changes were in accordance with the approved drawings prior to change. In addition, the redlined drawings did not in any way indicate that the subject angle iron supports were to be considered temporary.

This issue had been identified as Nonconformance 99901401/2011-202-03.

REASON FOR THE NONCOMPLIANCE

AP1000 CA20 Notes (APP-CA20-S5Y-00003) provide allowance to install temporary bracing as deemed necessary, and that the bracing must be removed prior to installation unless otherwise agreed. SMS invoked this allowance to install bracing, to facilitate maintaining fabrication tolerances. Discussions on making this bracing permanent were ongoing between SMS, Shaw Nuclear Services (SNS) and Westinghouse. These discussions represented an in-process design evolution that coincided with the timing of the NRC Inspection.

During this in-process design evolution, the controls at SMS (i.e., red-lined drawing and shop traveler change) for the temporary bracing were not effectively implemented in that neither the drawing red-line nor the traveler change identified the bracing as being temporary, and color-coding was not prescribed. This lack of specification was influenced by the in-process design evolution discussions and SMS anticipation that the bracing was going to be identified as permanent. The Product Manager notified the Detailer Manager of the red-line, but did not receive a response indicating the confirmation that the redline changes were in accordance with the approved drawings prior to the change. This occurred due to the Product Manager's interpretation that the procedure (QP-G-05a) requirement's intent was to notify the Detailer Manager.

CORRECTIVE STEPS THAT HAVE BEEN TAKEN AND RESULTS ACHIEVED

This condition was documented in SMS Corrective Action Report (CAR) 11-450. The red-line drawing was corrected to identify the bracing as temporary, and the bracing was color-coded to identify its temporary status once received at the jobsite.

This was the first module with temporary bracing installed, and there was, therefore, no impact on previously-shipped AP1000 modules. SMS has confirmed that, for modules with bracing already installed, controls are in place (appropriately red-lined drawings, shop travelers requiring color-coding).

The requirement for verbatim procedure compliance has been reinforced in writing to the Product Manager.

Procedure QP-G-05a has been revised to clarify the roles/responsibilities of the Product Manager.

CORRECTIVE STEPS THAT WILL BE TAKEN TO AVOID NONCOMPLIANCE

No further corrective actions are necessary.

DATE WHEN CORRECTIVE ACTIONS WILL BE COMPLETED

Corrective actions are complete.

ATTACHMENT 4
REPLY TO NONCONFORMANCE 99901401/2011-202-04

NONCONFORMANCE

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Shaw Modular Solutions (SMS) facility in Lake Charles, LA on November 14, 2011 through November 18, 2011, it appears that certain activities were not conducted in accordance with NRC requirements which were contractually imposed upon SMS by your customers or by NRC licensees:

D. Criterion IV, "Procurement Document Control," of Appendix B to 10CFR50 state, in part, that "Measures shall be established to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the applicant or by its contractors or subcontractors."

   Contrary to the above, as of November 18, 2011, SMS failed to include the applicable technical requirements in procurement documents which are necessary to assure that adequate quality is suitably included or referenced. Specifically, SMS included the alternative to use laboratories accredited by the National Voluntary Laboratory Accreditation Program, the American Association for Laboratory Accreditation, and other domestic accrediting bodies for commercial calibration services in safety-related purchase orders without requiring the dedication of the calibration service.

This issue has been identified as Nonconformance 99901401/2011-202-04.

REASON FOR THE NONCOMPLIANCE

Investigation into this issue revealed that the SMS purchase order attachment that prescribes Quality Assurance requirements had been revised to include a paragraph that allows the alternative to use laboratories accredited by the National Voluntary Laboratory Accreditation Program, the American Association for Laboratory Accreditation, and other domestic accrediting bodies for commercial calibration services in lieu of survey and audit of suppliers of calibration services. This purchase order attachment was revised concurrent with SMS development of the SMS ASME Section III Quality Assurance Program, and reflected the alternative as defined in ASME Section III, NCA-3855.3(c). This paragraph does not specify that the supplier must dedicate these commercial calibration services notwithstanding the fact that accreditation can be used in lieu of survey or audit.

However, the SMS purchase order attachment contains a general provision requiring suppliers who plan to purchase a commercial grade item or service and dedicate it for use in support of safety related applications to have a dedication program. Because the purchase of calibration services from an accredited lab is a commercial service, this provision requiring a dedication program would apply.

SMS recognizes that, in practice, SMS and some of its suppliers misunderstood NRC guidance and policy information related to the acceptable use of recognized accredited commercial grade calibration providers. Although SMS purchase orders required the dedication of commercial grade items and services, SMS and its suppliers did not apply the dedication requirements to commercial grade calibration services.

CORRECTIVE STEPS THAT HAVE BEEN TAKEN AND RESULTS ACHIEVED

This condition was documented in SMS Corrective Action Report (CAR) 11-448.

SMS has discontinued use of the SMS purchase order attachment that included the alternative to use laboratories accredited by the National Voluntary Laboratory Accreditation Program, the American Association for Laboratory Accreditation, and other domestic accrediting bodies for commercial calibration services in safety-related purchase orders.

SMS completed an extent of condition determination to identify purchase orders that contained the alternative to use accredited commercial calibration providers. These purchase orders have been revised to remove this alternative.

In addition to the three suppliers identified during the NRC inspection, the extent of condition determination identified one supplier to whom SMS had issued purchase orders that included the alternative to use accredited commercial calibration providers. Thus, SMS had issued the purchase order attachment to a total of four suppliers.

The four suppliers who received purchase orders that included the alternative to use accredited commercial calibration providers have been contacted. These suppliers have been advised of the SMS Notice of Nonconformance, and have been reminded of the requirement to dedicate commercial calibration services. The suppliers have provided SMS information regarding their practices. SMS has evaluated the information provided by the four suppliers. The following information is provided with respect to each of the four suppliers.

1) One supplier (identified in the NRC Inspection Report) performs Commercial Grade Dedication (CGD) on Measuring & Test Equipment (M&TE) calibrated by commercial calibration laboratories. SMS has reviewed

examples of the CGD performed by this supplier and found the examples to be satisfactory. Thus, no further action is necessary for this supplier.

2) One supplier (identified in the NRC Inspection Report) uses audited, approved suppliers for calibration services. SMS has reviewed examples of this supplier's documentation used to approve suppliers for calibration services, including an audit report and checklist for one of their calibration laboratories. This documentation is satisfactory and no further action is necessary for this supplier.
3) One supplier (not identified in the NRC Inspection Report) uses two calipers in support of inspections for SMS work. This supplier had been using commercial calibration laboratories without dedicating the calibration services. SMS evaluated the supplier's calibration documentation for the two calipers against a commercial grade dedication plan SMS developed for internal evaluation related to Notice of Nonconformance 99901401/2011-202-06. This evaluation concluded that there are no gaps between this supplier's calibration documentation and the SMS dedication plan for commercial calibration services. It was concluded that M&TE from this supplier, while not having been appropriately dedicated by the supplier, has been adequately calibrated, and therefore, there has been no impact on previously-shipped AP1000 modules.
4) One supplier (identified in the NRC Inspection Report) had been using commercial calibration services without dedicating the calibration services. SMS evaluated calibration documentation from this supplier against a commercial grade dedication plan SMS developed for internal evaluation related to Notice of Nonconformance 99901401/2011-202-06. This evaluation concluded that there are no gaps between the supplier's calibration documentation and the SMS dedication plan for commercial calibration services. It was concluded that M&TE from this supplier has been adequately calibrated, and therefore, there has been no impact on previously-shipped AP1000 modules.

The suppliers discussed in 3) and 4) above have taken corrective actions and are now dedicating commercial calibration services. SMS has reviewed the suppliers' dedication procedures and has concluded that the procedures are adequate.

SMS personnel involved with the process of procuring commercial calibration services have received training to ensure that they understand the requirement to dedicate the results of those services. This training focused on the Notice of Nonconformance and the fact that calibration of M&TE is a safety related process, and calibration services need to be procured as either safety related, or as a Commercial Grade Service that must be dedicated.

As a pro-active measure, SMS contacted the remainder of its 10CFR50 Appendix B suppliers of safety related items and services who calibrate M&TE (i.e., those who did not receive the revised purchase order attachment) to advise them of the SMS Notice of Nonconformance, and to remind them of the requirement to dedicate commercial calibration services. SMS requested these suppliers to provide information as to how they procure calibration services. These suppliers have all responded to the SMS request. Four suppliers advised SMS that they do not dedicate commercial calibration services procured from laboratories accredited by the National Voluntary Laboratory Accreditation Program, the American Association for Laboratory Accreditation, and other domestic accrediting bodies for commercial calibration services. SMS has evaluated calibration documentation from these fours suppliers against a commercial grade dedication plan SMS developed for Notice of Nonconformance 99901401/2011-202-06. This evaluation concluded that there are no gaps between the suppliers' calibration documentation and the SMS dedication plan for commercial calibration services. SMS concluded that M&TE from these suppliers has been adequately calibrated, and therefore, there has been no impact on previously-shipped AP1000 modules. SMS has initiated CARs to these suppliers, to track their completion of corrective actions.

CORRECTIVE STEPS THAT WILL BE TAKEN TO AVOID NONCOMPLIANCE

SMS corrective actions are complete. Follow-on actions with suppliers will be tracked to completion in accordance with the normal SMS process.

DATE WHEN CORRECTIVE ACTIONS WILL BE COMPLETED

SMS corrective actions are complete.

ATTACHMENT 5
REPLY TO NONCONFORMANCE 99901401/2011-202-05

NONCONFORMANCE

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Shaw Modular Solutions (SMS) facility in Lake Charles, LA on November 14, 2011 through November 18, 2011, it appears that certain activities were not conducted in accordance with NRC requirements which were contractually imposed upon SMS by your customers or by NRC licensees:

E. Criterion IX, "Control of Special Processes," of Appendix B to 10 CFR Part 50 states that "Measures shall be established to assure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements."

   Section 9 of the SMS QAM states, in part, that "special processes, including welding, shall be performed by qualified personnel using qualified written procedures in accordance with applicable industry codes." Step 6.2 of QP-PC-04, "Welder/Operator Qualification-AWS," Revision 6, dated October 19, 2011, states, in part, that "if a welder successfully completes the required qualification tests, the welding engineer will initiate and update the welder qualification test record."

   Step 6.6 of QP-PC-04 states, in part, that "the Welder Qualification History Log shall be used to update and maintain the welder qualifications by the welding engineer, and used to track the welder qualifications and ensure that welders employed at SMS remain qualified." QP-PC-04 also state, in part, that "upon successful completion of qualification testing, a unique welder symbol stamp shall be provided to the welder."

   Contrary to the above, as of November 18, 2011, the SMS American Welding society (AWS) welder qualification program, including the welder qualification records and Welder Qualification History Log, did not provide adequate records to demonstrate that welding was accomplished by qualified personnel. Specifically, SMS failed to provide adequate records to demonstrate that 1) a welder listed in the Welder Qualification History Log was qualified in accordance with QP-PC-04, even though the welder failed the qualification test, 2) records contain evidence of welders maintaining their qualifications consistent with QP-PC-04 and, 3) welder qualifications for different stainless steel materials met the

requirements of AWS D1.6, "Structural Welding Code-Stainless Steel", 1999 Edition.

This issue has been identified as Nonconformance 99901401/2011-202-05.

REASON FOR THE NONCOMPLIANCE

Investigation of the issue regarding a welder who was listed as being qualified in accordance with QP-PC-04 and had failed a qualification test revealed that the affected individual had been qualified to the positions and material thickness being welded at SMS. However, the SMS Welding Engineer had not forwarded the welder's qualification record to the SMS records system. The test failure referenced in the above non-conformance occurred during general actions to upgrade the qualification of welders to a thicker material. The welder was not identified on the Welder/Welding Operator Qualification Roster as qualified to this thicker material and did not perform welds on this thicker material. The Welding Engineer did not forward the original qualification documents as required by procedure due to individual error, due in part to a lack of procedural detail in QP-PC-04 supporting timely processing and completion of new hire welder paper work.

At the time of the NRC Inspection, SMS did not include welders' original qualification dates on the Welder/Welding Operator Qualification Roster. The actual qualification documentation in SMS archives was available to demonstrate an individual's original qualification date. SMS considered this practice to be adequate. SMS now understands that inclusion of welders' initial qualification date on a Welder or Welding Operator Qualification History Log (WQHL) provides a more comprehensive compilation of information and lessens the chances of overlooking information that could result in erroneous assignment of a welder to a specific task.

The practice of visually verifying welders' implementation of processes (and thereby, maintaining their qualifications) and documenting this on the roster, showing their last qualification date, was thought to be adequate at the time. SMS now understands that the roster in combination with the use of the newly developed WQHL, provides a more effective tool for ensuring that personnel qualifications are maintained current and lessens the chance of erroneously assigning a welder to a specific process.

The roster did not specifically differentiate between types of stainless steel because it was intended to be used as a tool by the Process Engineering Department. Their use was as a reference for Welding Procedure Specification (WPS) numbers, as opposed to specific material type, when developing shop travelers. This was thought to be adequate at the time. SMS now understands that separate identification of base materials on the roster will provide more comprehensive information and lessen the chance of error on the part of a user.

CORRECTIVE STEPS THAT HAVE BEEN TAKEN AND RESULTS ACHIEVED

These conditions were documented in SMS Corrective Action Reports (CAR) 11-439 and 11-460.

The original qualification documentation for the welder was submitted to the SMS records system for archiving. An extent of condition review of active and inactive welder qualifications for 2011 was completed.
QP-PC-04 has been modified to provide detailed steps for completing new hire paper work for welders.

The WQHL has been implemented and includes the following attributes: welders' qualification date, all subsequent requalification test dates, and qualification expiration date.

The roster now lists the WPS to which welders are qualified, plus the material type and filler material type for the WPS.

The requirement for verbatim procedure compliance has been reinforced in writing to the Welding Engineer.

In the extent of condition review for this issue, there were no instances identified where SMS practices related to the tracking and logging of welder qualifications resulted in unqualified welders performing work on safety related AP1000 modules. Thus, the issues identified in this Notice of Nonconformance did not have an impact on the quality of previously-shipped modules.

CORRECTIVE STEPS THAT WILL BE TAKEN TO AVOID NONCOMPLIANCE

QP-PC-04 is being revised to provide detailed steps for completing new hire paper work for welders, the roster and the Welder or Welding Operator Qualification History Log.

DATE WHEN CORRECTIVE ACTIONS WILL BE COMPLETED

Corrective actions will be complete by March 30, 2012.

ATTACHMENT 6
REPLY TO NONCONFORMANCE 99901401/2011-202-06

NONCONFORMANCE

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Shaw Modular Solutions (SMS) facility in Lake Charles, LA on November 14, 2011 through November 18, 2011, it appears that certain activities were not conducted in accordance with NRC requirements which were contractually imposed upon SMS by your customers or by NRC licensees:

F. Criterion XII, Control of Measuring and Test Equipment," of Appendix B to 10 CFR Part 50 states that "Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits."

   QP-G-12, "Control of Measuring and Test Equipment," Revision 3, dated September 13, 2011, states, in part, that "measuring and testing equipment (M&TE) requiring control and calibration include instruments or equipment used for testing, inspection, and calibration of other instruments, process verification, or data collection, for the purpose of determining compliance with established requirements. M&TE shall be labeled, tagged, or otherwise suitably marked, and documented on FRM-000120, "M&TE Inventory and Calibration Log," to indicate the item's unique identification, manufacturer's identification, serial numbers, frequency of calibration, its calibration date, and its next calibration due date."

   Contrary to the above, as of November 18, 2011, SMS failed to properly control and calibrate safety-related M&TE. Specifically, SMS used a commercial laboratory to calibrate some safety-related M&TE without dedicating the calibration service. In addition, a hardness tester used to perform portions of SMS Procedure QP-PC-31, "Distortion Correction Improvement Technique," Revision 0, dated August 18, 2011, did not have a calibration label and was not documented on the SMS M&TE Inventory and Calibration Log.

This issue has been identified as Nonconformance 99901401/2011-202-06.

REASON FOR THE NONCOMPLIANCE

The SMS Quality Assurance procedures provided the allowance for acceptance of nationally accredited commercial laboratories without performing commercial grade

dedication of the services because SMS misunderstood NRC guidance and policy information related to the acceptable use of recognized accredited commercial calibration providers.

The hardness tester was not in the SMS Measuring & Test Equipment (M&TE) program because it was not intended for use in the acceptance of safety related work products and, as such, SMS believed that it did not need to be included in the safety related M&TE program.

CORRECTIVE STEPS THAT HAVE BEEN TAKEN AND RESULTS ACHIEVED

These conditions were documented in SMS Corrective Action Reports (CAR) 11-448 and CAR 11-456.

A commercial grade dedication plan for commercial grade calibration services has been developed. M&TE at SMS that has been calibrated by accredited commercial calibration laboratories, without those services having been dedicated by SMS, has been identified. Calibration documentation for that M&TE has been evaluated against the dedication plan to determine whether any gaps exist between it and the dedication plan. This evaluation concluded that there are no gaps between the M&TE calibration documentation and the dedication plan for commercial calibration services. It was concluded that SMS M&TE was adequately calibrated, and therefore, there has been no impact on previously-shipped AP1000 modules.

The hardness testers have been included in the SMS M&TE program and have been calibrated. The "as found" condition for the hardness testers was acceptable.

SMS personnel involved with the process of procuring commercial calibration services have received training to ensure that they understand the requirement to dedicate the results of those services. This training focused on the Notice of Nonconformance and the fact that calibration of M&TE is a safety related process, and calibration services need to be procured as either safety related, or as a Commercial Grade Service that must be dedicated.

CORRECTIVE STEPS THAT WILL BE TAKEN TO AVOID NONCOMPLIANCE

No further corrective actions are necessary.

DATE WHEN CORRECTIVE ACTIONS WILL BE COMPLETED

Corrective actions are complete.

ATTACHMENT 7
REPLY TO NONCONFORMANCE 99901401/2011-202-07

NONCONFORMANCE

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Shaw Modular Solutions (SMS) facility in Lake Charles, LA, on November 14, 2011 through November 18, 2011, it appears that certain activities were not conducted in accordance with NRC requirements which were contractually imposed upon SMS by your customers or by NRC licensees:

G. Criterion XV, "Nonconforming Materials, Parts or Components," of Appendix B to 10CFR50 states that "Measures shall be established to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation.

   These measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures."

   Section 15 of the SMS QAM states, in part, that "items that do not conform to specified requirements shall be controlled to prevent inadvertent installation or use, and further processing beyond a point where the non-conforming condition can no longer be corrected. Controls shall provide for identification, documentation, segregation (when practical), evaluation, disposition of nonconforming items, and notification to affected organizations."

   Step 6.1.6 of QP-G-15 states, in part, that "Further processing of work on the nonconforming item shall cease until such time as the item or material is released for further work." In addition, Step 6.1.14 of QP-G-15 states, in part, that "work shall not progress beyond the point specified in the Conditional Release."

   Contrary to the above, as of November 18, 2011, SMS failed to control a sub-module that had open nonconformances identified on it. Specifically, SMS failed to identify all open nonconformance packages related to a sub-module in the work package at the sub-module (i.e., no identification at the sub-module that work could continue). In addition, for nonconformances with a conditional release, SMS failed to identify in the work package the point that work may continue at the sub-module.

This issue has been identified as Nonconformance 99901401/2011-202-07.

REASON FOR THE NONCOMPLIANCE

There was a lack of specific direction in the implementing procedures with regard to what actions are to be, or may be, taken when a nonconforming condition is identified on a sub-module. The procedures and corresponding practice were previously thought to be adequate. SMS now recognizes that, as the SMS organization, scope of work and procedures evolve, procedures need to describe activities at a level of detail that will enable appropriately trained and qualified personnel to consistently understand and implement those activities.

CORRECTIVE STEPS THAT HAVE BEEN TAKEN AND RESULTS ACHIEVED

These conditions were documented in SMS Corrective Action Reports (CAR) 11-440, 11-446, 11-452 and 12-076. CAR 12-076 was written subsequent to the NRC inspection, but prior to procedure changes made to address this non-conformance, and identifies, in part, similar issues to those identified in the NRC inspection report. CARs 11-446 and 11-452 addressed the programmatic elements of the issue identified in this non-conformance. CARs 11-440 and 12-076 (in part) are specific examples of conditions that resulted as a consequence of the programmatic issues identified in CARs 11-446 and 11-452.

To address the programmatic issues identified in this nonconformance, procedures QP-G-15 and QP-PC-06 (section 6.11) have been revised to add Conditional Release process controls, including instruction to specify the work sequences that may be completed and what sequence not to proceed past, related to a Conditional Release that affects a shop traveler. The revision to procedure QP-G-15 clarified that work does not need to stop on the entire item (module) when the nonconforming condition only applies to a specific portion of that module.

Final acceptance of products, including preparation, review and approval of final documentation packages prior to shipment, includes verification that nonconformance reports associated with those products have been satisfactorily closed. Therefore, this issue did not have an impact on previously-shipped AP1000 modules.

The responsibility to stop and notify supervision if procedures are observed that have vague directions, in order that clarification may be added, has been reinforced in writing to SMS personnel.

CORRECTIVE STEPS THAT WILL BE TAKEN TO AVOID NONCOMPLIANCE

No further corrective actions are necessary.

DATE WHEN CORRECTIVE ACTIONS WILL BE COMPLETED

Corrective actions are complete.

ATTACHMENT 8
REPLY TO NONCONFORMANCE 99901401/2011-202-08

NONCONFORMANCE

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Shaw Modular Solutions (SMS) facility in Lake Charles, LA, on November 14, 2011 through November 18, 2011, it appears that certain activities were not conducted in accordance with NRC requirements which were contractually imposed upon SMS by your customers or by NRC licensees:

H. Criterion XVI, "Corrective Action," in Appendix B to 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, the measures shall assure that the cause of the condition is determined and corrective action taken to prevent repetition. The identification of the significant condition adverse to quality, 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 QAM states, in part, that "Conditions adverse to quality shall be identified promptly and corrected as soon as practicable. In the case of a significant condition adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management. Completion of corrective actions shall be verified."

   Contrary to the above, as of November 18, 2011, SMS failed to promptly correct conditions adverse to quality. Specifically, SMS had not closed 72 out of 561 corrective action requests CARs by the established due date or establish new due dates for completion of corrective actions.

This issue has been identified as Nonconformance 99901401/2011-202-08.

REASON FOR THE NONCOMPLIANCE

The SMS Corrective Action procedure (QP-G-16) includes controls regarding the timely response and implementation of actions related to Corrective Action Reports (CAR). It includes directions for requesting and granting of extensions to response or action completion due dates. It includes provisions for escalation of overdue CARs to progressively higher levels of management for action. This procedural

direction has not been followed to ensure that conditions adverse to quality are corrected in a timely manner.

A Root Cause Analysis (RCA) was performed on the Corrective Action Program (CAP). With respect to timeliness of responding to and closing out corrective actions, it was determined that management has not effectively enforced the procedural standards for meeting due dates, due in part to a lack of a tracking mechanism for management to know what is coming due in their group, and insufficient resources in the Corrective Action group, causing a bottleneck to program administration and corrective action closeout.

CORRECTIVE STEPS THAT HAVE BEEN TAKEN AND RESULTS ACHIEVED

This condition was documented in SMS Corrective Action Report (CAR) 11-315.

Specific to implementing the procedural controls that are presently in place and address timeliness, requesting/receiving extensions (to response and/or action completion dates), plus CAR escalation for failure to meet due dates or request/receive extensions, the following actions have occurred.

CARs addressing SMS conditions adverse to quality with overdue responses and/or actions have been identified and have been either responded to, acted upon, or received an approved extension. SMS is manually tracking and monitoring CARs for upcoming response or actions due dates, to ensure that due dates are known and met, or receive an approved extension. SMS Management is meeting on a regular basis to oversee the status of CARs and extension requests.

The responsibilities related to the timely correction of conditions adverse to quality, and procedural requirements for meeting due dates or obtaining approved extensions has been reinforced in writing to SMS Management.

As a compensatory action related to CAR 11-315, a review of open CARs was completed to determine if any CARs might have an impact on modules being fabricated. For any CARs identified as having a potential to impact fabrication, each was evaluated to ensure that any compensatory or remedial actions were completed prior to SMS shipment of any potentially-affected module. The scope of this evaluation addressed previously-shipped modules also. This evaluation concluded that there has been no impact on previously-shipped AP1000 modules.

CORRECTIVE STEPS THAT WILL BE TAKEN TO AVOID NONCOMPLIANCE

SMS is identifying and deploying resources needed (additional personnel, electronic tracking system and training) to support short and long term program remediation

and process improvements.

A Corrective Action Review Board (CARB) is being established to oversee CAP activities and status. This CARB represents the formalization of the SMS Management oversight that is currently occurring.

DATE WHEN CORRECTIVE ACTIONS WILL BE COMPLETED

SMS will complete its transition, including procedure revisions, CARB establishment, and training, to an electronic tracking system, by August 31, 2012.

ATTACHMENT 9
REPLY TO NONCONFORMANCE 99901401/2011-202-09

NONCONFORMANCE

Based on the results of a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the Shaw Modular Solutions (SMS) facility in Lake Charles, LA, on November 14, 2011 through November 18, 2011, it appears that certain activities were not conducted in accordance with NRC requirements which were contractually imposed upon SMS by your customers or by NRC licensees:

I. Criterion XVI in 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."

   Several purchase orders from Shaw Nuclear Services (SNS) to SMS state, in part that "Conditions adverse to quality identified through the individual work processes are to be periodically reviewed to identify the presence of adverse trends."

   QP-G-16, "Corrective Action," Revision 4, dated August 31, 2010, defines conditions adverse to quality as an all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items and nonconformances. In addition, QP-G-16 states that the Manager QA is responsible for assessing and reporting identified trends.

   Contrary to the above, as of November 18, 2011, SMS failed to perform a trend analysis of conditions adverse to quality as required by the SNS purchase orders.

This issue has been identified as Nonconformance 99901401/2011-202-09.

REASON FOR THE NONCOMPLIANCE

The SMS Corrective Action Program (CAP) as prescribed in procedure QP-G-16 has not been completely implemented with regard to trending analysis. A Root Cause Analysis (RCA) was performed on the CAP. With respect to not implementing the trending process as required by contract, it was determined that the CAP system (procedures, process/people/training) was not adequate to fully implement a trending program. Additionally, there was insufficient engagement in the CAP by SMS Senior Management.

CORRECTIVE STEPS THAT HAVE BEEN TAKEN AND RESULTS ACHIEVED

This condition was documented in SMS Corrective Action Report (CAR) 11-315.

An interim, manual trending methodology has been established until electronic trending is in place. Results of this trending will be presented to SMS Management at regularly-scheduled meetings.

CORRECTIVE STEPS THAT WILL BE TAKEN TO AVOID NONCOMPLIANCE

SMS is identifying and deploying resources needed (additional personnel, electronic tracking system and training) to support both short and long-term program remediation and process improvement.

A Corrective Action Review Board (CARB) is being established to oversee CAP activities and status. This CARB represents the formalization of the SMS Management oversight that is currently occurring.

DATE WHEN CORRECTIVE ACTIONS WILL BE COMPLETED

SMS will complete its transition, including procedure revisions, CARB establishment, and training, to electronic trending by August 31, 2012.