

**United States Nuclear Regulatory Commission  
Attn: Document Control Desk  
Quality Assurance Vendor Inspection Branch  
Division of Construction Inspection and Operational Programs  
Office of New Reactors  
Washington, DC 20555-0001**

**December 17, 2014  
Reply to: SL-2786-0158**

**Subject: REPLY TO "NOTICE OF NONCONFORMANCE" - OREGON IRON WORKS**

**Reference: NUCLEAR REGULATORY COMMISSION INSPECTION REPORT OF  
OREGON IRON WORKS NO. 99901448/2014-201 AND 99901449/2014-201 AND  
NOTICE OF NONCONFORMANCE**

Dear Mr. Roach:

In response to the referenced NRC Inspection Report, Oregon Iron Works (OIW) provides the attached reply. In accordance with the instructions provided with the Inspection Report we offer three attachments, one addressing each finding. The attachments include: 1) the reason for the noncompliance, 2) corrective steps that have been taken and results achieved, 3) the corrective steps that will be taken to avoid noncompliances and 4) the date when your corrective action will be completed. An "Extent of Condition" Review has been completed and documented for each noncompliance.

OIW accepts the Nonconformances as described in the inspection report. We have worked diligently to understand the underlying causes of each noncompliance and initiate meaningful corrective actions. A consistent theme is that our procedural controls and documentation have not kept pace with our growth. We are committed to correcting these issues and we are engaging both in-house expertise and industry experts in our efforts to do so. Our efforts include comprehensive continuous improvement initiatives which result in a stronger program.

Sincerely,  
**OREGON IRON WORKS, INC.**



Dean Hudson  
Quality Assurance Manager, Nuclear Products Division

Attachment(s): Attachment 1: NON 99901448/2014-201-01 and NON 99901449/2014-201-01  
Attachment 2: NON 99901448/2014-201-02 and NON 99901449/2014-201-02  
Attachment 3: NON 99901448/2014-201-03 and NON 99901449/2014-201-03

cc: Jonathan Ortega-Luciano, P.E., Quality and Vendor Inspection Branch, US NRC  
Bradley D. Dunkin, OIW Vice President, Nuclear Products Division

**ATTACHMENT 1**

**NUCLEAR REGULATORY COMMISSION INSPECTION REPORT OF  
OREGON IRON WORKS NO. 99901448/2014-201 AND 99901449/2014-201  
Notice Of Nonconformance: 99901448/2014-201-01 and 99901449/2014-201-01**

A. Criterion XVI, "Corrective Action," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the Code of Federal Regulations (10 CFR) Part 50.

*OIW did not ensure that conditions adverse to quality, such as deficiencies and nonconformances were promptly documented and corrected. In addition, OIW's records did not always document the current status, plan of action, or commitments for work in progress to correct problems and prevent recurrence.*

Specifically,

1. "... OIW documented in NPD-CAR-14-34 that an internal audit identified that that a third party vendor, Cal-Cert, was used to determine the weight of rebar ... installed in CA20 module, which was not in the scope of their accreditation. ... OIW corrective actions failed to identify for the evaluation of scope of supply and method of verification to establish Cal-Cert as an appropriate provider of weight measurement services to verify the density of the rebar."
2. "OIW ... initiated NPD-CAR-13-31 which identified an issue associated with the temporary storage of measuring and test equipment (M&TE). The NRC inspection team identified that NPD-CAR-13-31 did not identify any proposed corrective actions to address the temporary storage of M&TE and that no objective evidence was found to demonstrate the action(s) taken by OIW to correct this issue."
3. "OIW documented in NPD-CAR-14-33 that an internal audit identified that OIW was using a light meter which had been calibrated by a calibration laboratory that was neither audited nor dedicated by OIW for their calibration services. The NRC inspection team identified that NPD-CAR-14-33 did not identify any proposed corrective actions to address the inadequate procurement of commercial grade calibration services used for a light meter and that no objective evidence was found to demonstrate the action(s) taken by OIW to correct this issue."

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Notice Of Nonconformance: 99901448/2014-201-01 and 99901449/2014-201-01**

**Oregon Iron Works Response**

**NPD-CAR-14-086**

**NPD-CAR-14-098**

**NPD-CAR-14-099**

**Reason for the Noncompliance**

The NRC identified three conditions where inadequate causal analysis was performed, documentation was insufficient and/or untimely, or appropriate corrective actions were not identified. Our evaluation has determined the following reasons for the noncompliance:

First, OIW procedures, forms, and training did not provide adequate guidance to personnel developing corrective actions or performing root cause analysis. OIW had previously provided specialized training in causal analysis to select individuals within our organization; however, this training was provided through various methods and not directly incorporated into OIW processes. Further, our procedures and forms did not provide adequate detail to ensure consistency and describe proper documentation requirements for RCAs and Corrective Actions.

Second, OIW did not have an adequate formal mechanism for status tracking and did not measure against explicit timeframes or milestones. With an ineffective tracking mechanism, timeliness was impossible to monitor much less manage. (Reference NPD-CAR-14-099)

**Corrective Steps Taken and the Results Achieved**

Interim instructions were developed for RCA analysis, Non Conformance Report (NCR) Control and Corrective Actions. These instructions are considered interim pending a comprehensive review of all affected procedures to be completed 03/31/2015. Training for NCR Instruction was completed on 11/10/2014, and the training for Corrective Action Instruction was completed 11/6/2014. Training for RCA Analysis Instruction has been performed for senior RCA personnel, and will be completed by 1/9/2015 for the remainder of the RCA staff.

A complete re-write of the Corrective Action Form includes appropriate prompts and step-by-step training guidance to develop the desired level of consistency. The CAR Form also includes specific sections for documenting immediate corrective actions, extent of condition, extent of cause, and requirements for objective evidence. This form has been distributed, training conducted, and is currently in use for all Corrective Actions dated after 11/6/2014.

Additionally, a CAR folder checklist has been added to all open CAR files as a secondary safeguard to ensure the requirements have been fulfilled prior to closure. Completed 11/20/14.

The OIW Corrective Action Manager has completed TapRooT training and all future causal analysis after Implementation is complete will be evaluated and documented using the TapRooT system. Implementation and documentation of causal analysis through TapRooT will facilitate consistent and appropriate corrective action development. Training of 15 additional personnel is taking place for all RCA personnel the week of 12/15/2014 and will be completed 12/19/2014.



An Effectiveness Review has been included as a required milestone as part of OIW's Corrective Action Status Tracking Tool. This review is scheduled to occur 120 days after closure of each CAR. Completed 10/7/2014.

Automated milestone dates have been incorporated within existing tracking mechanisms for each corrective action to provide due date expectations for all CARs. Completed 10/7/2014.

### **Corrective Steps to Prevent Future Noncompliance**

As part of OIW's CAR Number NPD-CAR-14-024, OIW will develop and document a comprehensive Corrective Action Procedure to incorporate the timeliness requirements, objective classification of CARs, and further expand on the scope, definitions, and responsibilities outlined within the Interim Corrective Action Instruction. (ETC 1/9/2015)

An Effectiveness Review Instruction will be written to detail the requirements for performing Effectiveness Reviews. The reviews will be completed for any CARs which are listed as "due" upon completion of the instruction and training. (ETC 1/23/2015)

### **Due Dates for Actions Yet to be Completed**

- ETC ... 12/19/2014 – RCA TapRoot training for 15 additional personnel
- ETC ... 12/19/2014 – Cornerstone CAR (CAR-14-041) for M&TE processes due.
- ETC ... 01/09/2015 – Comprehensive Corrective Action Procedure
- ETC ... 01/23/2015 – Complete Effectiveness Review Instruction & Perform Effectiveness Reviews to verify "appropriate action."

### **Results of Extent of Condition**

An Extent of Condition review for specific items identified below was completed to assure that nonconforming conditions did not affect hardware.

Item 1 ... The NRC identified inappropriate controls associated with testing of rebar. OIW purchased and dedicated appropriate scales to perform testing in house. All materials have been retested with the exception of those in transit and no issues have been identified. Completed 11/24/2014. Appropriate documentation has been included in the material data packages.

Item 2 ... The NRC identified that corrective actions in NPD-CAR-13-031 regarding storage of M&TE were ineffective. An extent of condition for M&TE Storage was performed on 10/16/2014. Unsatisfactory conditions have been addressed and objective evidence have been submitted to our customer and accepted.

Item 3 ... The NRC identified inadequate corrective actions in NPD-CAR-14-033 regarding calibration of a light meters used for assuring appropriate light levels for NDT inspection. All light meters have been calibrated using an accredited laboratory. We have evaluated all light meter utilization for CA\_20 Modules and found no issues.

**END OF ATTACHMENT 1**



**ATTACHMENT 2**

**NUCLEAR REGULATORY COMMISSION INSPECTION REPORT OF  
OREGON IRON WORKS NO. 99901448/2014-201 AND 99901449/2014-201  
Notice Of Nonconformance: 99901448/2014-201-02 and 99901449/2014-201-02**

B. Criterion III, "Design Control," of Appendix B to 10 CFR Part 50 states, in part, that "Measures shall be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems and components."

Criterion VII of Appendix B to 10 CFR Part 50 states, in part, that "These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery."

*"Contrary to the above, as of September 26, 2014, OIW failed to ensure the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems, and components. Additionally, OIW failed to establish appropriate measures that included provisions for source evaluation of subcontractors."*

Specifically,

1. OIW, as a dedicating entity failed to perform a technical evaluation to justify that the selection of critical characteristics for dedication of various components such as plates, rebar, weld wires, and metallurgical testing services used as basic components installed in CA20 module assemblies would provide reasonable assurance that they would perform their intended safety functions. The NRC inspection team identified six examples of plates, rebar, weld wires, and metallurgical testing services that were procured as commercial-grade and then inadequately dedicated to be used as safety-related components by OIW.
2. OIW failed to perform a technical evaluation to identify additional technical requirements such as tolerances, accuracies, ranges over which the item is to be calibrated, specific industry standards to be used, etc., to be included in the purchase order for commercial calibration services....
3. OIW failed to perform and document adequate engineering justification to support their determination of the dedication sampling plan. The NRC inspection team identified several examples of plates, rebar, weld wires, and testing services that were procured as commercial grade items and then inadequately sampled as part of the dedication process to be used as safety-related components by OIW.
4. OIW failed to conduct a commercial-grade survey or source surveillance to verify that American Steel Portland, Industrial Welding Services, Inc., and Professional Services Inc.'s quality programs included the requisite processes, such as material traceability and lot and batch controls, for the control of critical characteristics necessary to provide reasonable assurance that commercial-grade materials and services to be used as basic components will perform their intended safety function



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**Oregon Iron Works Response**

**NPD-CAR-14-046**

**NPD-CAR-14-083**

**NPD-CAR-14-101**

**Reason for the Nonconformance**

Oregon Iron Works (OIW) developed and submitted a Commercial Grade Dedication procedure with associated plans to our customer for review. Our procedure required OIW, as the “dedicator,” to perform technical evaluations as appropriate to the product and method of dedication. However, the procedure did not sufficiently detail the documentation requirements of engineering Technical Evaluations, justification for sampling plans, commercial-grade surveys and source surveillance.

Additionally, OIW failed to comply with the procedure by allowing Buyer-provided technical evaluations to be incorporated into the commercial grade dedication packages as a stand-alone document. OIW engineering did not perform the Technical Evaluation or document our analysis of the Buyer-provided information in order to achieve reasonable assurance the evaluations were sufficient. This nonconformance was the result of inadequate training and insufficient procedure development by OIW.

**Corrective Steps Taken and the Results Achieved**

OIW procedure QP-2786-(07)-10 has been revised to clarify the responsibility for Technical Evaluations. The procedure also clarifies engineering justification required for sampling plans, commercial-grade surveys, and source surveillances. Completed 10/15/2014.

The CGD Plan form has been revised to more clearly identify evaluation of technical requirements and specifically addresses dedication of services. Completed 10/15/2014.

Training has been conducted on 12/5/2014 with necessary personnel and documented within NPD-CAR-14-046.

The revised CGD procedure and associated form has been submitted to our customer for review. All customer provided comments or suggestions have been resolved in the approved. Completed 11/5/2014.

**Corrective Steps to Prevent Future Noncompliance**

OIW’s procedural revisions and training are complete. We anticipate that all future dedication activities will be fully compliant. Due to the reliance on customer approval as a contributor to the noncompliance, OIW will gage the effectiveness of this process through independent audits performed by industry experts.

We will obtain a secondary third-party review of new dedications throughout first quarter of 2015 to assure that our CGD packages are complete and meet the NRC and EPRI guidelines. This review is above and beyond our procedure requirements and is designed to demonstrate effectiveness. Results will be documented as part of NPD-CAR-14-083. Objective evidence of this review will be documented in the applicable dedication package.



### **Due Dates for Actions Yet to be Completed**

Engineering will review all dedication packages associated with CA20. Engineering will also perform Technical Evaluations and supplement each package, as necessary, to document the required justification for sampling plans, commercial-grade surveys and source surveillances performed. Extent of Condition review of Technical Evaluation adequacy will be completed by 12/23/2014. All dedication packages are being reviewed and documentation will be added to each dedication package and included within NPD-CAR-14-101.

- ETC ... 12/23/2014 – Third party review of all Technical Evaluation for CA20
- ETC ... 03/31/2015 – Third party evaluations of all new OIW Dedication plans.

### **Results of Extent of Condition**

A preliminary Extent of Condition review by Oregon Iron Works has been completed to assure that nonconforming conditions do not affect hardware. Every dedication package applicable to CA20 performance is being re-evaluated by a third party Engineering firm as additional assurance. ETC 12/23/2014. Specific deficiencies have been addressed as below and there are no remaining deficiencies to report at this time.

Item 1 ... The NRC identified six examples of improper Technical Evaluation of components installed in CA20 module assemblies. All dedication packages for CA20 components are being reviewed for appropriate Technical Identification of Critical Characteristics. For materials no evidence of missed Critical Characteristics has been identified to date.

Item 2 ... The NRC identified improper evaluation of the requirements for dedicating calibration activities. Calibration activities found to be improperly dedicated will be re-performed with a revised dedication plan in accordance with the new procedure.

Item 3 ... The NRC identified the OIW failure to document the Technical Evaluation and justification of the sampling plan used for dedication activities. Each dedication package has been revised to include the justification for sampling plan choice.

Item 4 ... The NRC identified that Commercial Grade Surveys were not documented in the Technical Evaluation or dedication package to verify that the supplier had adequate controls in place to control Critical Characteristics. Our evaluation revealed one survey that should have been conducted, but was not. That survey has been completed and documented. Each dedication package has been revised to document the survey, audit or surveillance employed to justify sampling. There are no deficiencies to report.

**END OF ATTACHMENT 2**



**ATTACHMENT 3**

**NUCLEAR REGULATORY COMMISSION INSPECTION REPORT OF  
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Notice Of Nonconformance: 99901448/2014-201-03 and 99901449/2014-201-03**

C. Criterion XV, “Nonconforming Materials, Parts or Components,” of Appendix B 10 CFR Part 50 states, in part, that “Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures.”

Criterion XVII, “Quality Assurance Records,” of Appendix B states, in part, that “Sufficient records shall be maintained to furnish evidence of activities affecting quality. Records shall be identifiable and retrievable.”

Section 15 of OIW’s Quality Assurance Manual, Issue 3, Revision 1, dated July 18, 2014, states, in part, that “... a nonconformance and its disposition shall be documented on a Nonconformance Report, and that proposed disposition shall be made by a Project Engineer or Project Manager.” It further states that Nonconformance Reports are maintained as Quality Records in accordance with Section 17 of OIW’s Quality Assurance Manual, which states, in part, that “...records are preserved and controlled.”

*Contrary to the above, as of September 26, 2014, OIW failed to review, disposition, and appropriately document resolution on several nonconforming items and was unable to retrieve some nonconformance reports.*

Specifically,

1. On February 28, 2014, nonconformance reports NPD-NCR-14-032 and NPD-NCR-14-033 were generated to document that during recalibration the “as found” condition of four calibrated tools was identified as being outside of specified tolerances. On July 30, 2014, NPD-NCR-14-236 documented an additional calibrated item that was identified “as found” out of tolerance. The NRC inspection team did not identify any objective evidence to demonstrate that OIW had performed an evaluation of usage, the extent of condition, or dispositioned the item identified as nonconforming.
2. OIW could not retrieve nonconformance reports NPD-NCR-14-032, NPD-NCR-14-033, and NPD-NCR-14-236 when the inspectors requested them for review.



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**Oregon Iron Works Response**

**NPD-CAR-14-084**

**NPD-CAR-14-100**

**Reason for the Nonconformance**

The NRC identified three conditions where NCRs had not been evaluated and dispositioned properly and two more that could not be produced in a timely manner for review. This Nonconformance is the result of inadequate procedural controls and training. OIW has experienced explosive growth in the last 12 months. Legacy procedures and training materials did not keep up with the addition of new people and the enhanced rigor demanded of the commercial nuclear industry.

Our legacy procedure did not provide adequate specificity and control to prevent this nonconformance. Existing procedures relied on specific individuals writing and controlling the NCR process. As work expanded, more personnel were needed to support that effort. Existing training was inadequate to meet the needs of expanded program.

**Corrective Steps Taken and the Results Achieved**

An NCR instruction has been developed, approved, and all affected staff have been trained in its use. Completed on 11/10/2014. This instruction facilitates consistency among newly generated NCRs.

An Extent of Condition, as part of NPD-CAR-14-084, has been completed to ensure all NCR and CAR documents are properly located and stored.

An Extent of Condition for all M&TE used on CA20 has been completed. No findings or discrepancies have been identified. Eighteen tools have been found to be out of calibration, though none have been utilized on CA20. Each tool has been evaluated and results included within NPD-CAR-14-100, Rev 1.

OIW initiated NPD-CAR-14-100 to document the lack of technical justification, disposition, and extent of condition on NCRs. NCR Instruction QI-NPD-(15)-01 was revised on 10/29/2014 to clarify these requirements when generating NCRs. Training has been provided as of 11/10/2014.

**Corrective Steps to Prevent Future Noncompliance**

OIW initiated NPD-CAR-14-084 to document the inability to retrieve NCR documents. NCR Instruction QI-NPD-(15)-01 was revised on 10/29/2014 to add the requirement for the assigned QAE to pull a list of all open NCRs for that project number once every month. Training has been provided as of 11/10/2014.

OIW also initiated NPD-CAR-14-093 to review NCR procedures and instructions for cohesiveness and develop an interim NCR process instruction. While the interim NCR instruction satisfies the immediate need for consistency in generating and dispositioning NCRs, the comprehensive NCR procedure would require a detailed review to be performed against all associated procedures within our Quality Program. This comprehensive procedure revision will be vetted with industry experts and peer reviewed.



**Due Dates for Actions Yet to be Completed**

- ETC ... 1/23/2015 – Review all NCRs identified as incomplete for appropriate technical justification. Document appropriate review and analysis.
- ETC ... 1/23/2015 – Document and perform necessary customer notifications or component actions.
- ETC ... 1/23/2015 – Complete comprehensive NCR procedure emphasizing “auditable” documentation, consistency and completeness.
- ETC ... 2/06/2015 – Perform Training on comprehensive NCR procedure revision.
- ETC ... 2/13/2015 – Close NPD-CAR-14-100

**Results of Extent of Condition**

An Extent of Condition review for specific items identified below is being performed to assure that nonconforming conditions did not affect hardware.

Item 1 ... We have evaluated every NCR resulting in a “use-as-is” or “repair” disposition for its effect on hardware. All such NCRs are submitted to the Buyer for disposition and are included within the data package for affected deliverables. There are no undocumented CA20 related deficiencies to report.

Item 2 ... All NCRs will be evaluated for completeness of documentation, proper storage and retrieval. Documentation will be provided within NPD-CAR-14-100. This action will be completed no later than 1/12/2014.

**END OF ATTACHMENT 3**

