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Maliaño, 30/06/2016

ASUNTO/SUBJECT Reply to a Notice of Non Conformance.

In response to the US NRC letter dated June 9<sup>th</sup> 2016, relative to the inspection performed at Equipos Nucleares S.A on April 25-29 April 2016, this letter addresses the reason for non compliance, corrective actions to resolve the deficiencies, actions to avoid recurrence, status and timeline for resolving the Non Conformances reported in Inspection report No. 99901379/2016-201.

Information below shall be managed in accordance with Ensa Corrective Action program and resolved through Corrective Action reports CAR 86/16, CAR 87/16 and CAR 88/16, issued for Nonconformances 99901379/2016-201-01, 99901379/2016-201-02 and 99901379/2016-201-03 respectively.

Should you request any clarification or further information, please do not hesitate to contact me.

Yours Faithfully,

Raúl Marcos.

Cc: Chief Quality Assurance Vendor Inspection Branch-2, Division of Construction Inspection and Operational Program, Office of New Reactors.

Nonconformance 99901379/2016-201-01.

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Criterion III, "Design Control," of Appendix B, "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Title 10 of the Code of Federal Regulations (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," states, in part, that "Measures shall also 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."

Section 4.2, "Use of Unqualified Source Material," of ENSA's General Procedures (GP) Manual GP.08.20, "Commercial Grade Dedication Program," Revision 2, dated February 23, 2015, states, in part, that "Use of Unqualified Source Material as defined in ASME Section III is not considered Commercial Grade Dedication if applied within ASME III boundaries and follows requirements sets forth in NCA 3855.5. The process to provide compliance with this section is documented through a MIP. In the event that the metallic raw material is to be used in other safety related applications outside the ASME III scope, the dedication process is performed following Section 8 of Quality Assurance Manual for Unqualified Source Material."

Contrary to the above, as of April 29, 2016, ENSA failed to ensure the selection and review for suitability of application of materials that are essential to the safety-related functions of structures, systems, and components. Specifically, ENSA's Material Inspection Plan (MIP) OBV2MIP001, "Certification Compliance with 10 CFR 50 Appendix B, 10 CFR 21, and Westinghouse Specification A105C01-GEN Revision B, of Carbon Steel forged Flanges SA-105," did not establish and document the sample testing population for the acceptance of material critical characteristics used for the commercial-grade dedication of the feed water ring (FWR) assembly inspection port slip-on and blind flange SA-105 carbon steel material. In addition, ENSA did not verify that the supplier had quality controls in place to ensure heat traceability of the material. ENSA performed material testing verification on a limited sample of the 25 pieces received from multiple heats of material. Furthermore, ENSA's certified material test reports incorrectly stated that all the test results were in compliance with the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21, "Reporting of Defects and Noncompliance." During the inspection, the NRC inspection team determined that the safety-related supplier of the flange material was removed from ENSA's Qualified Vendors List and thus required the flange material to be accepted under ENSA's commercial-grade dedication program or the process for utilization of unqualified source material process of Section III, "Rules for Construction of Nuclear Facility Components," of the American Society of Mechanical Engineers Boiler and Pressure Vessel Code. Industry operating experience has shown that leaking FWR inspection port covers have led to water hammer events that distorted the supports of the FWR.

This issue has been identified as Nonconformance 99901379/2016-201-01.

- Reason for non compliance  
Incorrect communication of approval plan for material testing to the customer. The document OBV2MIP001 which describes the sequence and testing required for acceptance of material purchased was submitted to customer for approval without a definition of the sampling basis and approval purpose.
- Corrective steps that have been and the results achieved



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- Ensa shall issue a Non-Conformity Report (NCR) to document and address non-conforming condition disposition reported. Addenda) and the Code Federal Regulations 10 CFR Part 50 App. B and 10 CFR Part 21.

Status: NCR 0BV2/057 issued, submitted to Customer approval and closed.  
Due date: Performed.

- Westinghouse shall take ownership for commercial dedication program of material affected. Material shall be tested in accordance with Westinghouse commercial grade dedication program.

Status: Westinghouse commercial dedication instruction CDI number BV2-RSG-CDI-001 Rev 1 issued.  
Due date: Performed.

- The re-testing process shall be supported with a review of the supplier's written procedures for identifying source materials in a manner that provides traceability to the Certified Material Test Reports (CMTR's). Ensa shall verify on-site the compliance with these procedures.

Status: Supplier written procedures verified on site to ensure traceability process.  
Due date: Performed.

- Determine Extent of Condition: Ensa shall determine if there are more items in a similar condition to the ones described in this CAR

Status: Extend of condition performed with no identification of similar condition on other items.  
Due date: Performed.

- Corrective steps that will be to avoid further noncompliance
  - To perform a Stand Down to affected areas (Engineering and Quality Assurance Supplies Control) on the requirements of ASME NCA-3855.5 and EPRI 5652 requirements for explanation of the issue.

Status: Stand down to Quality Assurance Supplies Control performed.  
Due date: Engineering shutdown scheduled to July 8<sup>th</sup> 2016.

#### Nonconformance 99901379/2016-201-02.

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 5.10, "Draining and Drying," of ENSA's Specification No. 0BV2CS601, "Hydrostatic Pressure Test," Revision 1, dated November 25, 2015, states that "Draining and drying of the



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secondary chamber of the Steam Generator shall be as described in the specification No. 0BV2FS503." Specification No. 0BV2CS601 also provides quantitative values such as pressure and temperature of hydrostatic test and water chemistry criteria before and after the hydrostatic test.

Contrary to the above, as of April 29, 2016, ENSA failed to assure that special processes were controlled and accomplished using qualified procedures in accordance with specifications and acceptance criteria. Specifically, ENSA used several open flame gas burners that were installed underneath the secondary side of the steam generators to facilitate final drying and vacuuming after the secondary side hydrostatic pressure test, without a qualified procedure for this activity. ENSA Specifications Nos. 0BV2CS601 and 0BV2FS503, "Draining and Drying of the Secondary Side," Revision 1, dated September 30, 2015, did not provide instructions, specifications, controls and/or acceptance criteria for the heating process. By not having a qualified procedure, ENSA could not determine the maximum temperature the steam generators experienced during the heating process which could last up to a week. Excessive heating of the steam generators could create warping and affect the materials and dimensional tolerances (e.g. distortion) of the steam generator components.

This issue has been identified as Nonconformance 99901379/2016-201-02.

- Reason for non compliance

This heating process is performed to maintain the ambient temperature, or slightly higher, in order to increase the dew point of the air inside the steam generator during the air vacuuming (per section 3.2 of 0BV2FS503) and prior to the injection of hot nitrogen inside the RSG (per section 3.3 of 0BV2FS503). The purpose of this heating is to avoid the freezing of the remaining inside humidity during the vacuuming process (water freezes above 0°C (32 F) when the ambient pressure decreases). Thus, this heating process facilitates the draining and vacuuming process of the inside of the RSG prior to the filling of the RSG with nitrogen.

The draining and drying of the component is carried out in accordance with the provisions of the IPP/HR (traveler) 3BV2-40A01 rev. 02 (Hydrostatic Pressure Test of Secondary and Primary Side) and the main applicable process specification 0BV2FS503 rev. 01. Such procedure, or other applicable documents in the IPP/traveler, does not specifically mention the option of heating up the component and does not provide guidance on the temperature controls when performing this process.

- Corrective steps that have been and the results achieved

To justify that heating performed in the conditions reported does not affect property materials or dimensional tolerances.

Status: To be performed.  
Due date: July 30<sup>th</sup> 2016.

- Corrective steps that will be to avoid further noncompliance

- To issue a Lesson Learned to revise the applicable specification for this process in order to include provisions for the heating of the component to achieve a better result during the vacuuming and drying process. These provisions shall also include controls to ensure the temperature is within a certain range.



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Status: To be performed.  
Due date: 30<sup>th</sup> July, 2016.

- To perform a Stand Down to the Shop personnel on the use and adherence to procedures. The stand down shall include an explanation of the issue identified in this CAR and the actions taken to avoid recurrence.

Status: To be performed  
Due date: 15<sup>th</sup> August, 2016.

#### Nonconformance 99901379/2016-201-03.

Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50, states, in part, that "Measures shall be established assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. 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 April 29, 2016, ENSA failed to establish adequate measures to obtain objective evidence of quality furnished by the contractor or subcontractor. Specifically, ENSA did not provide adequate documented objective evidence in their external audit reports of material and service suppliers to provide reasonable assurance that the suppliers had implemented an Appendix B to 10 CFR Part 50 and 10 CFR Part 21, "Reporting of Defects and Noncompliance," programs for the supply of safety-related basic components. For a sample of 11 audits reviewed by the NRC inspection team, the evaluation of the suppliers' 10 CFR Part 21 programs and associated implementing procedures did not demonstrate adequate compliance with the requirements of 10 CFR Part 21.

This issue has been identified as Nonconformance 99901379/2016-201-03.

- Reason for non compliance  
Inadequate review and approval of 10CFR21 requirements implementation on suppliers program.
- Corrective steps that have been and the results achieved
  - Ensa Suppliers qualified under 10CFR50 Ap B and 10CFR21 whose 10CFR21 procedure does not correctly address 10CFR21 requirements shall be requested to modify the procedure accordingly.

Status: In process  
Due date: November 30<sup>th</sup>, 2016.

- Corrective steps that will be to avoid further noncompliance
  - Applicable check list for auditing suppliers in accordance with 10CFR50 Ap B and 10CFR21 shall be revised to tighten the criteria to be checked during audits.



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Status: To be performed  
Due date: July 15<sup>th</sup>, 2016.

- Lead Auditors shall be indoctrinated regarding content and timeline requirements as per 10CFR21 to be included specifically checked during audits or procedures review.

Status: Indoctrination regarding 10CFR21 requirements and approach from a vendor standpoint performed.  
Due date: Performed

- A package documentation shall be prepared to be delivered to supplier in order to facilitate correct understanding of 10CFR21 and 10CFR50 Ap B requirements.

Status: To be performed  
Due date: August 30<sup>th</sup>, 2016.