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U.S. Nuclear Regulatory Commission

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ASUNTO/SUBJECT

Reply to a Notice of Non Conformance – Ensa's response to the US NRC inspection report No. 99901379/2016-201 and Notice of Nonconformance.

Relative to the US NRC letter requesting clarification on the following two items, this letter provides response to the information required.

Items:

1. Your response to NONs 99901379/2016-201-01 and 99901379/2016-201-02 states that as part of your corrective actions that will be taken to avoid further noncompliance, Equipos Nucleares, S.A (ENSA) will perform "stand down" of several activities. Please clarify what is meant by the term "stand down."
2. Your response to NON 99901379/2016-201-03 states that as part of your corrective actions performed to avoid further noncompliance, ENSA will prepare and deliver to its suppliers a package documentation to facilitate correct understanding of Title 10 of the Code of Federal Regulations (10 CFR) Part 21 and Appendix B to 10 CFR Part 50 requirements. Please provide a detailed description of what the package documentation will include and what does ENSA expect its suppliers will do with this package documentation.

Clarification:

1. The term stand down refers to a training session to personnel involved that included the following information:
 - a. Description of the Non Conformance and specific details of material specification and contractual requirements.
 - b. Cause analysis
 - c. Human Performance factors that influenced on the occurrence of the Non Conformity reported.
 - d. Technical training describing in detail the process for applying Unqualified Source Material (NCA 3855.5) and EPRI 5652 and sampling basis requested in both cases.
 - e. Description of correction actions to be implemented for acceptability of items.



f. Descriptions of impact and costs incurred to correct the Non Conformity identified.

2. The package documentation includes the following documents:

- a. Copy of 10CFR50 Ap B requirements, together with an additional document highlighting the key points to reinforce the quality program to comply with nuclear industry requirements and expectations.
- b. Copy of 10CFR21, together with an additional document providing clarification on the following.
 - i. Quality Program provisions to address 10CFR21 requirements.
 - ii. Description of timeline requirements for reporting.
 - iii. Posting requirements, posting example is provided.
 - iv. Training requirements, training example is provided.
 - v. Reportability requirements, as per 10CFR21, par 21.21 a) and b).
 - vi. Examples of 10CFR21 reports.

The purpose of this documentation is to provide guidance to vendors for clarifying and developing 10CFR50 Ap B program requirements. On the other hand, Ensa expects that vendors increase safety awareness and reportability about material and process produced and specifically, get an actual knowledge about 10CFR21 scope and procedural guidance to proceed in potential situations that may arise.

Should you request 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.