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c.c.: Chief, Mechanical Vendor Branch  
Division of Construction Inspection and Operational  
Programs  
Office of New Reactors

**Subject: Reply to a Notice of Nonconformance**

**IBF ref.: QA1300020-NUC\_r00**

**Your ref.: NRC letter dated July 31, 2013**

**NRC Inspection Report No. 99901428/2013-201 and Notice of Nonconformance**

**Nonconformance No. 99901428/2013-201-02**

*Identification of Deficiency*

Criterion IV, "Procurement Document Control," of Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of production and Utilization Facilities," states, 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 June 21, 2013, IBF failed 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.

Specifically,

1. QSM Section 11 describes the control of purchased materials, equipment, and services and the ASME Section III NCA-3800 process for utilization of unqualified source material. The IBF QSM was written to specifically support ASME Section III NCA-3800 code implementation activities and includes specific controls that implement the quality program requirements to meet ASME requirements. However, the manual does not address implementing specific quality assurance requirements to support the supply of 10 CFR Part 50 Appendix B safety-related basic components as defined 10 CFR Part 21.

2. QSM Section 11 and PGQ-N40 define the requirements for procurement documentation; however, neither document requires the invocation of Appendix B to 10 CFR Part 50 or 10 CFR Part 21 for safety-related purchase orders. In addition, PGQ-N25 defines the responsibilities and methods for selection and qualification of materials, source materials, and services suppliers for nuclear components under ASME section III NCA-3800, but does not identify or reference Appendix B to 10 CFR Part 50 for these specific responsibilities and methods for procurement of safety-related basic components.

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### *Reason of noncompliance*

IBF Quality System Manual (QSM) and Quality Procedures (PGQ-N) were written to specifically support ASME Section III NCA-3800 code implementation activities and they include all specific controls that implement the quality program requirements to meet ASME requirements.

10 CFR Part 50 Appendix B was not explicitly invocated in QSM Section 11, PGQ-N40 and PGQ-N25 because IBF Program did not allow Procurement of Basic Component and managed Procurement of Commercial Grade only, in a way wrongly assumed to be in accordance with Commercial Grade Dedication requirements.

During NRC inspection, IBF issued a corrective action RAC1300031\_r01 to address this noncompliance.

### *Corrective actions*

IBF developed and implemented:

- an Appendix 01 to its QSM Ed. 01 Rev. 03 clearly specifying in detail all requirements additional to ASME NCA 3800 needed to be in compliance with 10CFR50 Appendix B.

Appendix 01 (sect. 2.2.4) manages also Procurement of Basic Component, possibility not prescribed in QSM Ed. 01 Rev. 03 and related PGQ-N.

- a specific procedure to cover Commercial Grade Dedication Process, collecting all Dedication Plans as attached (PGQ-N95).

### *Corrective actions scheduling*

All documents were issued.

Training course are running. Deadline: end of September.

Colnago, August 29, 2013

Sprenger Giancarlo

IBF QA / QC Director

Attached:

Rev. 00 of "Appendix 01 to Quality System Manual ed. 01 rev. 03"

PGQ-N95 rev 00 "Commercial Grade Dedication Management Procedure"