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QUALITY ASSURANCE REQUIREMENTS FOR DEDICATION PROCESS IN ANGRA 1

Ana Rosa Baliza[1], Youssef Morghi[2]

[1]Eletrobrás Termonuclear S.A. - ELETRONUCLEAR
Departamento GQO.G
Rodovia Procurador Haroldo Fernandes Duarte - BR101/RJ,S/N km 521,56 – Itaorna
23948–000 Angra dos Reis – RJ
baliza@eletronuclear.gov.br

[2] Centro de Desenvolvimento da Tecnologia Nuclear (CDTN / CNEN - MG)
Av. Presidente Antônio Carlos, 6.627
Campus da UFMG - Pampulha
31270-901 Belo Horizonte - Minas Gerais, Brasil
ymo@cdtn.br

ABSTRACT

In Brazil the regulatory body is CNEN (Comissão Nacional de Energia Nuclear), according to its requirements, when there is not a Brazilian standard, the utilities shall follow the requirements of the designer. For Angra 1, the designer is an American company – Westinghouse. So, the requirements for dedication of U.S. NRC (United States Nuclear Regulatory Commission) shall be applied, these requirements are in 10CFR21 - REPORTING OF DEFECTS AND NONCOMPLIANCE.
According to 10CFR21, when applied to nuclear power plants licensed dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a quality assurance program standard for nuclear power plant. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses by the purchaser or third-party dedicating entity.

1. INTRODUCTION

Dedication of Commercial Grade Items (CGI) if conducted properly, provides reasonable assurance that a commercial grade item can be used as a basic component and will perform its intended safety related function and, in this respect, is deemed equivalent to an item designed and manufactured under 10 CFR Part 50 Appendix B [1].

When an intensive construction cycle of the new NPPs in the U.S.A. was completed, many equipment manufacturers either disappeared from the market or they abandoned their product lines that were designed and manufactured under 10 CFR Part 50 Appendix B quality assurance program. The quality assurance as defined by 10 CFR Part 50 Appendix B comprises all those planned and systematic actions necessary to provide adequate confidence that a Structure, System or Component (SSC) will perform satisfactorily in service. In many

cases, suppliers/developers concluded that continuing business orders were inadequate to justify the costs associated with maintaining a strict QA program.

The operating Nuclear Power Plants (NPPs) faced the problem related to the availability of qualified equipment, components and spare parts. The US NRC (Nuclear Regulatory Commission) recognized that problem in 10CFR21[2] and required a commercial grade item to be dedicated before it could be used as a basic component.

After that, the "Dedication of CGI" has been widely used mostly for relatively simple mechanical, electrical, and I&C components and spare parts. In order to provide guidance to the dedication process, EPRI has issued some documents to support the industries.

Angra 1 NPP was designed and built by an American company - Westinghouse, so the rules of the U.S. NRC (United States Nuclear Regulatory Commission) are adopted in conjunction with the rules of CNEN. This statement is based on the requirements of the CNEN NE 1.04 [3] standard: "6.5.1 - Items shall be designed, manufactured, assembled, built, tested and inspected in accordance with standards compatible with the importance of the safety function to be performed.
6.5.2 - In applying the provisions of section 6.5.1, shall be adopted current Brazilian codes and standards. When Brazilian standards could not be used, preferably, Codes, Guides and Recommendations of the International Atomic Energy Agency shall be used and, in their lack, international standards shall be used, provided that such rules and regulations are accepted by CNEN. "

The Quality Assurance Standard for Brazilian NPP is CNEN NN 1.16 [4]. This standard meets the 18 BR described in 10 CFR 50 Appendix B [1][5].

2. DEFINITION

To understand the dedication process is important to know some definition:

Basic component (10CFR21)
(i) When applied to nuclear power plants basic component means a structure, system, or component, or part thereof that affects its safety function necessary to assure:
(A) The integrity of the reactor coolant pressure boundary;
(B) The capability to shut down the reactor and maintain it in a safe shutdown condition; or
(C) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures.

(ii) Basic components are items designed and manufactured under a quality assurance program complying with 10 CFR 50 appendix B, or commercial grade items which have successfully completed the dedication process.

Certify of Conformance (ANSI N45.2.10-1973)
A written statement, signed by a qualifies party, certifying that the item or service comply with specific requirements.

Commercial grade item (10CFR21)
Commercial grade item means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).

Commercial Grade Survey versus audit
CGI Survey (EPRI Report NP-5652) – assesses the adequancy and effectiveness of commercial quality controls for manufacturing/service activities with respect to identified critical characteristics.
Audit (ANSI N 45.2.10) – an activity to determine, through investigation, the adequancy of, and adherence to, established procedures, instructions, specifications, codes and standards or other applicable contractual and licensing requirements, and the effectiveness of implementation.

Constructing or construction *(10CFR21)*
Means the analysis, design, manufacture, fabrication, placement, erection, installation, modification, inspection, or testing of a facility or activity which is subject to the regulations in this part and consulting services related to the facility or activity that are safety related.

Critical characteristics (10CFR21)
When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, critical characteristics are those important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function.

Dedication (10CFR21)
Is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR Part 50, appendix B, quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at hold points at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process shall be conducted in accordance with the applicable provisions of 10 CFR Part 50, appendix B. The process is considered complete when the item is designated for use as a basic component.

Dedicating entity (10CFR21)
Means the organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or the licensee itself. The dedicating entity, pursuant to § 21.21(c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process.

Procurement document (10CFR21)
Means a contract that defines the requirements which facilities or basic components shall meet in order to be considered acceptable by the purchaser.

Special Tests and Inspections (EPRI NP-5652)
Activities conducted during or after receipt of a Commercial Grade Item to verify one or more critical characteristics. (Method 1)

*Technical Evaluation (*EPRI NP-5652*)*
An evaluation performed to assure that the correct technical requirements for an item are specified in a procurement document.

3. AN OVERVEIW OF THE 18 BASIC REQUIREMENTS (BR) OF QUALITY ASSURANCE FOR NPP [5]

According to the definition of Dedication: *"In all cases, the dedication process shall be conducted in accordance with the applicable provisions of 10 CFR Part 50, appendix B.", s*o, it is important to know the requirements of 10 CFR 50 Appendix B.

The 10 CFR 50 Appendix B is the Quality Assurance document for U.S. nuclear facilities. This document establishes eighteen basic requirements (BR) to design, construction, manufacture and operation of structures, systems and components (SSC) related to safety.

The 18 BR describe "what" shall be done, but not "how" to do. In order to standardize the actions of nuclear facilities during 10 CFR 50 App B implementation, the industry has developed some documents, the main ones are: ASME NQA-1 (Quality Assurance Requirements for Nuclear Facility Applications), the series ANSI N 45.2 (Quality Assurance Program Requirements for Nuclear Facilities), IAEA Safety Standard Series – GS-R-3, GS-G3.1, GS-G-3.5, 50C/SG-Q and Safety Guide DS349. IAEA up to date the Safety Serie 50-C/SG-Q - Quality Assurance for Safety in Nuclear Power (1996) for GS-R-3, GS-G-3.1 and Safety Guide DS349: MS for Nuclear Installations. [6, 7, 8, 9, 10, 11, 12]

These standards clarify some concepts, include specific requirements (for example for nuclear softwares), introduce more details about the requirements and the most important is that they are approved by the regulatory body.

As described before, Angra 1 NPP was designed and built by Westinghouse, the rules of the U.S. NRC (United States Nuclear Regulatory Commission) and IAEA are adopted in conjunction with the rules of CNEN.

The Quality Assurance Standard for Brazilian NPP is CNEN NN 1.16 [4]. This standard meets the 18 BR described in 10 CFR 50 Appendix B [1].

The CNEN NN 1.16 standard presents 13 requirements, the 18 BR were reorganized. This standard is similar to 10CFR50 App B, i.e., it describes the Quality Assurance Requirements for Nuclear facilities in Brazil and it has the force of law. It applies: "activities affecting quality of items important to safety, developed in each of its various stages: site selection,

design, construction, commissioning, operation and decommissioning." (CNEN NN 1.16, 2000, p.4).

The table 1 shows the comparison between the 18 BR of the 10 CFR 50 App B and the CNEN NN 1.16 requirements.

Table 1 - Comparison between the requirements of CNEN NN 1.16 and 18 BR.

10 CFR 50 App B/ NQA-1	Requisitos CNEN NN 1.16
I – Organization	4.3
II - Quality assurance program	4.2
III – Design control	4.5
IV – Procurement Document control	4.6
V – Instructions, procedures and drawings	4.1.4
VI – Document control	4.4
VII – Control of purchase material, equipment, and services	4.6.3
VIII – Identification and control of materials, parts and components	4.7
IX – Control of special processes	4.8
X – Inspection	4.9 /4.9.1
XI – Test Control	4.9/4.9.2
XII – Control of measuring and test equipment	4.9.3
XIII – Handling, storage and shipping	4.7.2
XIV – Inspection, test and operation status	4.9/4.9.4
XV – Nonconforming materials, parts, or components	4.10
XVI – Corrective action	4.11
XVII – Quality assurance records	4.12
XVIII – Audits	4.13

4. DEDICATION PROCESS

The eight steps to conclude a CGI Dedication are:

Step 1 – Nuclear Procurement? Y/N
Step 2 – If Y, is it a SR item/service? Y/N
Step 3 – If Y, is it a CGI? Y/N
Step 4 – If Y, Identify Critical Characteristics (CCs)
Step 5 – Identify Acceptance Criteria for "ALL" CCs
Step 6 – Determine Method (s) of Dedication
Step 7 – Implement and record Verification of CCs
Step 8 – If all CCs are approved, Dedication is complete!

The NPP procuring an item or service that supports a nuclear safety function has two options to procure the item or service:

(i) The item or service shall be either procured or performed subject to the requirements of 10 CFR 50 App B, or

(ii) Be commercial grade dedicated in accordance with the requirements of 10 CFR 21.

If the option (i) is selected, the NPP procuring will use the Supplier List. But if option (ii) is selected, so there are two options – The NPP can perform the dedication process or can procure the item/service through a Dedicating Entity. So, the steps to procure one item or service that supports a nuclear safety function are:

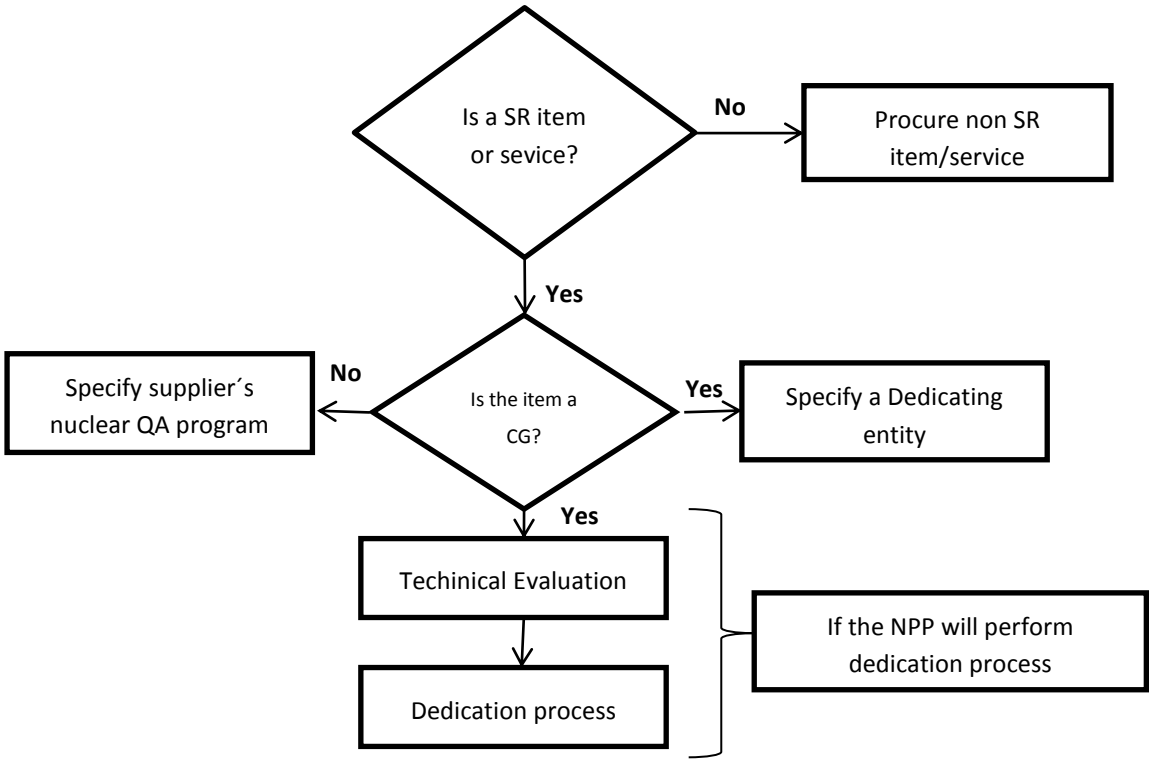

Figure 1 – Overview to procure one item or service that supports a nuclear safety function

The procurement document of an item or service that supports a nuclear safety function shall be according to 10 CFR 50 Appendix B – Requirement IV (control of documents of purchase - requisition / purchase order) and VII (control items purchased). The figure 2 shows the difference between these two requirements where the steps are controlled by the requisite IV are circled with dotted line and the full line are controlled by the requirement VII.

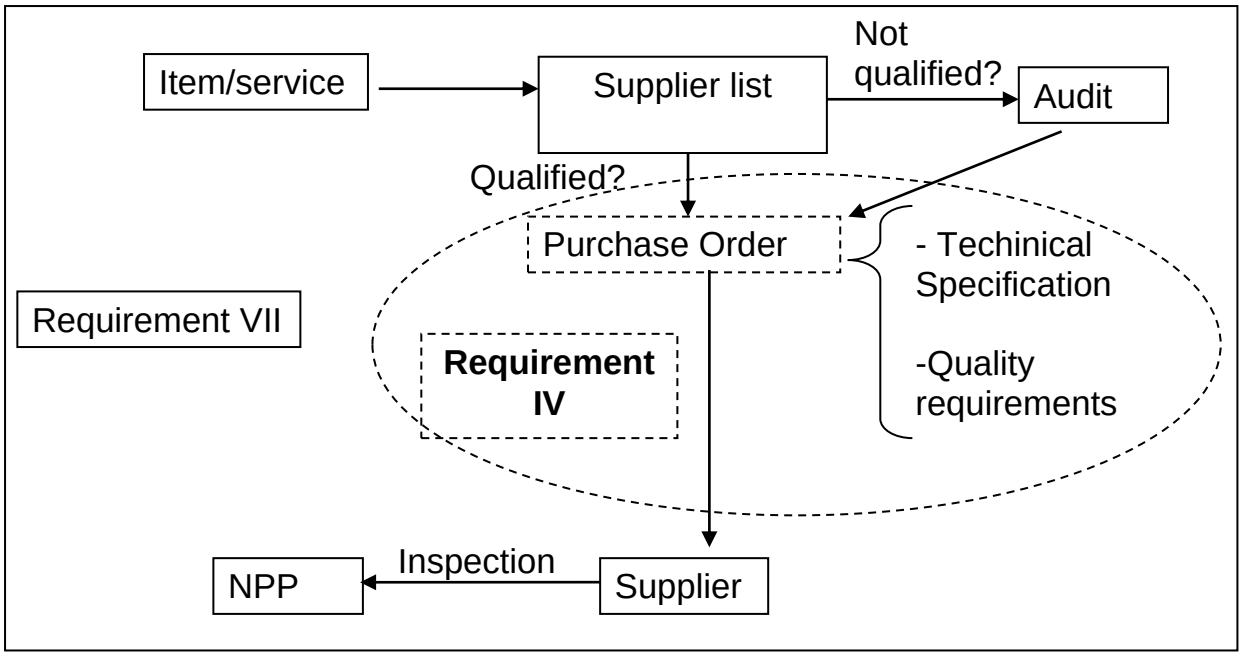

Figure 2 - Difference between requirements IV (control of documents of purchase - request) and VII (control items purchased). [5]

When the NPP decide to procure a CG item or service, all the items of 10CR50 App B shall be follow, the steps are:

1) Define the responsibilities, according to 10 CFR App B requirement I: Authority and duties of persons and organizations performing quality-related activities shall be clearly established and delineated in writing. Define that individual that performs verification or checking of any activity adequacy, during the dedication, by individuals others than originator of original activity. It is important to remember that personnel performing QA functions are independent of cost and scheduling when it comes to safety considerations. Identify major organizations participating and their responsibility.

2) Define the Quality Assurance Program (QAP), according to 10 CFR App B requirement II: Establish the program, identify the structure, system and components (SR item) and/or SR service to be covered, define the controlled conditions (For exemple: Special process, document, records, design, inspection, tests, audits).

3) Define the control of design requirements according to 10 CFR App B requirement III: start the technical evaluation defining/selecting the design basis, regulatory requirements and quality standard into design documents, i.e., define the technical specification. Define the critical characteristics (control of design requirements, including deviations), select material, equipment and processes. Control of design change.

4) The purchase order (PO) shall be according to the 10 CFR 50 App B requirement IV, as described before, the PO should include or reference regulatory, technical specification (critical characteristic and appropriate details), quality requirements. Require that the supplier has an appropriate QA program – 10 CFR 50 App B and 10

CFR 21. Require that the supplier to impose applicable technical and quality requirements on subcontractors.

5) The dedication activities shall be done through documented and approved Instruction, procedures and drawings according to 10 CFR 50 App B requirement V. The instruction, procedure and drawing shall be used appropriate to the circumstances and the appropriate acceptance criteria shall be included in the instruction, procedure and drawing.

6) All the documents used on dedication shall be controlled according to 10 CFR 50 App B requirement VI, i.e., documents are reviewed for adequacy, documents are used where the prescribed activities are performed, documents are distributed and controlled so that only correct and current revisions are used.

During a dedication, the expectation of Documentation for each method of dedication (see the item 7) is in Table 2:

Tabela 2 - Expectation of documentation for each method of dedication

10 CFR 21	Documentation [13]
Identifying the critical characteristics of the item and verifying their acceptability by inspection tests or analyses performed by the purchase or third-party dedicating entity delivery	The CGI Plan (CDP). The completed Special test and Inspection Plan. The results of the tests and inspection records. The certificate of personnel, material, equipment.
Commercial Grade Surveys	The CGI Plan (CDP) The CGI Survey Report (specific to the item/service procured and their critical characteristics). The sub-supplier is on the dedication entity´s "Approved Supplier List". The PO, wich includes the specific controls for all applicable CCs. The sub-supplier´s certification to the P.O. requirements.
Product inspections or witness at designated hold points at the manufacturer´s facility	The CDP. The source verification plan, with documented, quantified results. The dedication entity's P.O., including provisions for Rights of Access and Hold Points. Source Verification and "Permission to Ship". Copies of Supplier's actual test report (as applicable)
Analysis of historical records for acceptable performance	Documented acceptable supplier and item performance. Historical performance and credit for success in industry product test, non-nuclear codes and standards, other industry data – aerospace, automobilist, etc.

7) According to 10 CFR 21, the dedication shall be done under some methods:

(a) Identifying the critical characteristics of the item and verifying their acceptability by inspection tests or analyses performed by the purchase or third-party dedicating entity delivery (According to EPRI NP-5652, it is method 1)

Supplementing, as necessary, by one or more of the following:

(b) Commercial Grade Surveys (According to EPRI NP-5652, it is method 2, the Nuclear Procurement Issues Committee (NUPIC) has established a checklist, NRC published the IP 38703 and IP 43004).

(c) Product inspections or witness at designated hold points at the manufacturer´s facility (According to EPRI NP-5652, it is method 3)

(d) Analysis of historical records for acceptable performance (According to EPRI NP-5652, it is method 4)

All this methods are either described in 10 CFR 50 App B requirement VII, the table 3 shows the comparison:

Table 3 – Comparison between the 10 CFR 50 App B requirement VII, 10 CFR 21 and EPRI NP-5652

10 CFR 50 App B requirement VII	10 CFR 21	EPRI NP-5652
Receipt inspection of products upon delivery	Identifying the critical characteristics of the item and verifying their acceptability by inspection tests or analyses performed by the purchase or third-party dedicating entity delivery	Method 1 – Special Tests, Inspections or Analyses
Source evaluation and selection	Commercial Grade Surveys	Method 2 – Commercial Grade Survey of Supplier
Source inspection	Product inspections or witness at designated hold points at the manufacturer´s facility	Method 3 – Source Verification
Review of objective evidence of quality provided by the supplier	Analysis of historical records for acceptable performance	Method 4 – Acceptable supplier/Item performance record

It is important to understand that according to 10 CFR 21, method 1 is required, however, EPRI Guideline NP-5652 suggests any one or a combination of Methods 1, 2, 3 and 4. But to a NPP, the regulatory requirement is 10 CFR 21, so during a dedication, method 1 needs to be planned and attended, if the NPP can't attend this, it shall send a documented justification to be approved by the regulatory body. EPRI Guideline NP-5652 is not a regulatory document, it is an industrial guideline.
And it is important too, the dedication entity looks for others applicable requirements published by the regulatory body, for example, NRC published one Generic Letter on March 21, 1989 - Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products (Generic Letter 89-02) the follow [14]:

"C. Dedication Programs

It is each licensee's responsibility to provide reasonable assurance that nonconforming products are not introduced into their plants. Dedication programs that ensure the adequacy of critical parameters of products used in safety-related applications can also contribute to the identification of counterfeit or fraudulently marketed vendor products.

The NRC staff believes that licensees who use methods similar to those described in EPRI NP-5652 "Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety-related Applications (NCIG-07)," to verify the critical characteristics of commercial-grade items intended for safety related applications have the basis for effective dedication programs.

Properly implemented, the EPRI guidelines, as modified below, establish methods which satisfy existing requirements of Appendix B to 10 CFR Part 50 as they apply to the dedication process of commercial-grade items.

1. Acceptance Method 2, "Commercial-Grade Survey of Supplier," should not be employed as the basis for accepting items from suppliers with undocumented commercial quality control programs or with programs that do not effectively implement their own necessary controls. Likewise, Method 2 should not be employed as the basis for accepting items from distributors unless the survey includes the part manufacturer(s) and the survey confirms adequate controls by both the distributor and the part manufacturer(s).

2. Acceptance Method 4, "Acceptable Supplier/Item Performance Record," should not be employed alone unless:

a. The established historical record is based on industry-wide performance data that is directly applicable to the item's critical characteristics and the intended safety-related application; and

b. The manufacturer's measures for the control of design, process, and material changes have been adequately implemented as verified by audit (multi-licensee team audits are acceptable)."

Other important issues in 10 CFR 50 App B requirement VII to dedication are:

- Documented evidence of conformance of purchased items is to be available at the site prior to installation and use.

- Effectiveness of control of quality by suppliers is assessed periodically based on the importance and complexity of the products or services.

8) During the dedication, it shall provide traceability to items, establish identification and control system designed to prevent the use of incorrect or defective item and maintain identification of an item (heat number, part number, serial number, etc.), according the 10 CFR 50 App B requirement VIII.

9) If the dedication of a item/service require welding, heat treating, nondestructive testing, i.e., special process, so it shall be done according the 10 CFR App B requirement IX. It is necessary establish measures to assure that the special process are controlled, provide qualified procedures and personnel, meet applicable codes, standards, specifications, criteria and any special requirements.

10) All the inspection that are done to check critical characteristics shall attend the 10 CFR App B requirement X, it is important to remember that the persons performing inspection can't be the same that performed the activity.

11) The tests performed to check critical characteristics shall attend the 10 CFR App B requirement XI. The tests procedure shall include requirements and acceptance limits from applicable technical specification (design documents). These tests shall be carried out under suitable environmental conditions and document test results and retain records.

12) The tool, gages, instruments and other measuring and testing devices used in dedication shall be controlled, calibrated and adjusted at specified periods to assure that M&TE is accurate within appropriate limits. The control of measuring and test equipment (M&TE) shall be according to 10 CFR 50 App B requirement XII.

13) Measures to prevent damage and/or deterioration of dedication item shall be establish. That includes proper control of handling, storage, shipping, cleaning and preservation activities according the requirement XIII of 10 CFR 50 App B.

14) According the requirement XIV of 10 CFR 50 App B, measures shall be established to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed during the dedication.

15) During the dedication, all nonconformance shall be controlled according to 10 CFR 50 App B requirement XV. Procedures for identification, segregation, disposition and notification shall be documented. (If it's a dedication entity, the requirements of 10 CFR 21 – notification shall be followed!).

16) When a nonconformance is identify, a corrective or preventive action shall be provide, according to 10 CFR 50 App B requirement XVI : Measures shall be established to assure that conditions adverse to quality(failures, malfunctions, deficiencies, deviations, defective) and nonconformances are corrected. The corrective action taken shall be documented and reported to appropriate levels of management.

17) All the activities affecting the quality during the dedication shall be recorded, according to 10 CFR 50 App B requirement XVII : Records shall be identifiable and retrievable. requirements concerning record retention, such as duration, location, and assigned responsibility shall be established. Sufficient records shall be maintained to furnish evidence of activities affecting quality during the dedication. The records shall include at least the following: results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses, qualifications of personnel, procedures, and equipment. Inspection and test records shall, as a minimum, identify the inspector

or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted.

18) The Dedication shall be in the Quality Assurance Audit Program and the requirement XVIII of 10 CFR 50 App B shall be attended. The audit shall follow a written procedure or checklist, auditors shall be trained and should not have direct responsibility in the areas being audited. The result of the audit shall be documented and follow-up actions shall be performed when appropriate.

19) Specific technical requirements are not described on 10CFR50 App B and 10CFR21. Technical standard, codes, specification shall be followed during dedication of item or service, and the dedication entity shall use the correct edition of these technical documents, according regulatory body.

20) EPRI has updated the guidelines for dedication, where the document 3002002982 - Upgraded Commercial Grade Dedication Guidance supersedes NP-5652 and TR-102260, Published September 5, 2014, NEI submitted to NRC for review September 17, 2014 and NRC Draft Regulatory Guide 1292 ("Sampling and Dedication of Commercial Grade Items") is being prepared.

5. CONCLUSIONS

As shown in table 1, CNEN NN 1.16 presents the same QA requirement as 10 CFR 50 App B. If the dedication entity is a Brazilian company, so it can follow the requirements of CNEN NN 1.16. The industrial QA standards must be applied because they are updated, clarify some specific requirements and are approved by the Regulatory Body.

During a dedication process, it is important to follow updated technical standards, codes, specification, according the approval of the regulatory body.

The dedication is an important process to NPP since many suppliers concluded that continuing business orders were inadequate to justify the costs associated with maintaining a QA program according to 10 CFR 50 App B.

A new revision about dedication needs to be done, to understand the changes on EPRI documentation and to understand the rules of NRC on RG 1292 that is being prepared.

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