



A quick guide of regulations and standards applied for the supply chain of nuclear power plants and other installations in Brazil

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1. Introduction

Contributions for identifying configurations and governance mechanisms as key elements characterizing sustainable supply chain management in global supply chains and synthesizing their relationship with sustainability outcomes are very important [1]. Also the growing level of attention toward global warming, reduction of non-renewable resources and pollution calls manufacturing firms to implement sustainable and specifically green initiatives into their supply chains [2]. Incorporation of sustainability into quality and supply chain management was identified to be a highly emerging area with multi-dimensional (financial, ecologic and social) approaches highly in need for more sustainable supply chains [3]. In addition, the incorporation of the circular economy into supply chain management, known as circular supply chain management, needs to recognize enablers/drivers/critical success factors, barriers/obstacles, new circular business models and innovative frameworks [4].

Issues in the supply chain from various related factors as counterfeit, fraudulent, suspect items, logistics, legal barriers has increasingly become relevant to companies in many industries, while the nuclear industry represents the broad-structure supply chain driven by more complex products where materials, fuel and services are essential to the operation and maintenance of a nuclear facility, and their proper procurement contributes to safety and reliability [5], [6].

In recent years, both the construction and operation of nuclear power plants have experienced difficulties related to their supply chains, including project delays and even temporary shutdowns of reactors due to detection of counterfeit items, obsolescence of original technology and licensing to incorporate a greater amount of digital instrumentation and control technologies. The International Atomic Energy Agency (IAEA) supports the development of proactive management systems of supply chain [7]. Another issue in some Member States is the lack of original equipment suppliers and in some others, the will to set up a new localized supply chain. Recently, even COVID-19 has brought new challenges to the mobility of contractors [8].

The supply chain related guidance is found in many standards according to the phase and type of supply regulation and legal requirements. There are many different legislations, regulations and standards with specific vocabulary and concepts in use, and both suppliers and customers need to carefully analyze what complying with them means in practice. In order to fulfill this gap, this paper describes the applicable documentation applied for the nuclear power and other facilities supply chain in Brazil.

Regulations and laws are national responsibilities, when government, nuclear regulatory body and the operators have to be fulfilled by suppliers and it is not easy to understand and manage the contractual requirements when they are not common.

2. Methodology

This article is intended for potential external providers as a summary guide of regulatory, legal and quality assurance system requirements applied to the Brazilian nuclear supply chain. Often these requirements are not linked, so, providing to the users a quick information source, as potential service providers and/or manufacturers of important to nuclear safety items, through this document, will allow them gain knowledge from a source where is listed the required references adopted for the preparation of documents for most of bidding processes.

It was performed an evaluation of the current legal, regulatory and standards landscape with respect to supply chain applied in Brazil for nuclear power plants (NPPs) and other facilities with focus on suppliers for safety related items and services.

This research was made into parts. The first part presents current legal, regulatory and standards with respect to quality assurance system at nuclear facilities and their supply chain, describing the attributes of the Brazilian nuclear regulator with respect to quality assurance system. Following by a brief description and references applied for safety-related suppliers. Special topics includes non-nuclear Brazilian laws and oversight of suppliers as well. The final part summarize the mentioned documentation with the regulations, mandatory and non-mandatory standards for NPPs and for safety-related suppliers.

3. Results and Discussion

Hereafter the results of this research are shown followed by a brief discussion.

3.1 NPPs and Nuclear Facilities

The licensing process for nuclear installations in Brazil is regulated by CNEN-NE-1.04 (2002) “Licensing of Nuclear Facilities”[9]. This standard establishes in its items 6.2.1 and 8.1.2, that a Safety Analysis Report (SAR) of the nuclear installation be presented according to the respective established standard model, which shall contain the information from the applicant's and the main contractor's Quality Assurance Programs (QAPs), to be applied to important to safety items of the facility.

QAPs must be established according to CNEN-NN-1.16 (2000) “Quality Assurance for the Safety of Nuclear Power Plants and Other Facilities”[10]. CNEN-NN-1.16 (2000) determines the requirements to be met for establishing and implementing the Quality Assurance Systems for nuclear power plants, nuclear facilities and, as applicable, for radioactive facilities. This standard also determines how the QAPs shall be prepared and submitted to CNEN. This standard applies to activities that influence the quality of important to safety items.

The Brazilian standard CNEN-NN-1.16 (2000) address the graded approach in item 4.1.2.7, where it describes that the applicant shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirements' importance to safety.

CNEN NN 1.16 (item 4.6) refers to measures to include or reference applicable regulatory requirements, design bases, and other necessary requirements in the procurement documents of material, equipment, and services by the licensee or its contractors or subcontractors. This includes, if necessary, the requirement of a Quality Assurance Program for contractors or subcontractors.

If it is allowed in contract, the Quality Assurance requirements are applied to subcontractors.

It is also mentioned that the licensee applicant may delegate to other organizations the task of establishing and implementing parts of the QAS for the enterprise, but shall remain fully responsible to CNEN for its effectiveness, without any harm to the legal liabilities of the applicant or its contractors.

CNEN-NE-1.26 (1997) “Safety in the Operation of Nucleoelectric Plants” establishes the minimum requirements necessary to ensure that the operation of nuclear power plants is maintained without undue risk to the health and safety of the population and to the environment [11]. It is established in this standard that the operating organization shall establish a Quality Assurance Program for the commissioning and operation of the plant, covering all activities that may have an influence on the quality and safety operation of the plant according to CNEN-NN-1.16 (2000).

CNEN-NE-1.28 (1999) “Qualification and Performance of Independent Technical Supervision Bodies in Nucleoelectric Plants and Other Installations” regulates independent technical supervision in nuclear power plants and other nuclear or radioactive installations, to be carried out by an Independent Technical Supervisory Body (ITSB), when specified by the designer [12]. The ITSB is able to perform the compliance control of the design documents used for manufacturing and to proceed with the qualification and monitoring of the qualification conditions of suppliers, regarding services and important to safety items, where the provisions of CNEN-NN-1.16 (2000) are respected.

3.2 Suppliers of Safety-related items or services

The Brazilian standard CNEN-NN-1.16 (2000) requires the control of purchased items and services. CNEN-NN-1.16 (2000) in item 4.6.2 indicates that the capability of suppliers to provide items or services in accordance with procurement documents must be assessed during supplier selection. As appropriate, according to CNEN-NN-1.16 (2000) item 4.6.2.2, historical data on quality performance in similar procurement activities; the use of supporting documents of the current quality of the supplier; source evaluation of the technical capacity and of the supplier Quality Assurance System, and product evaluation by sampling, are acceptable forms of supplier evaluation.

The first nuclear power plant in commercial operation in Brazil, Angra 1, was designed by Westinghouse Electric in the USA and because of it, the USNRC requirements based on ASME NQA-1 or USNRC 10CFR50 Appendix B (see Table 1) are applicable to the supplier’s Quality Assurance System. Similarly, for Angra 2, designed by Siemens/KWU in Germany, the requirements of KTA 1401 (see Table 1) for Quality Assurance are accepted. For Angra 3, a project similar to Angra 2, are also applied the same requirements [13]. The CNEN-NN-1.16 standard is the official document issued by the Brazilian regulatory body and most of national suppliers for safety items shall implement a Quality Assurance System and/or be audited according to its requirements.

3.3 Regulatory body and Technical Supervisory Body

Other entities other than the contractor can also interact with suppliers, such as auditing, performing on-site inspections and/or surveys, including access to the production line, test labs and documentation. The design documents, such as technical specifications, establishes hold points where it is necessary testimony to be signed by specialists or independent inspectors. Independent inspectors, if applicable also can verify data books.

The regulatory body plays a role in the licensing process, including the evaluation of main safety-related suppliers. The Quality Assurance Program of the licensee and main suppliers are submitted to the regulatory body knowledge and acceptance previously to the activities which they refer as required by CNEN-NN-1.16 (2000) item 4.2.1. The evaluation of QAPs are performed by documental analysis and by performance based audits. The regulatory body periodically analyzes and request in a planned and systematic manner the updated Quality Assurance Program in the several stages of the project.

The regulatory body performs audits and inspections in main contractors performing safety related activities in order to fulfill the applicable requirements of the normative bases. Audits, when performed by the regulatory body, are witnessed by the licensee at the suppliers' site. Supplier audits and inspections are performed according to the Brazilian standard CNEN-NN-1.16 (2000), where it is addressed the graded approach in item 4.1.2.7.

The regulatory body performs the qualification of an entity as an Independent Technical Supervisory Body in a specific area of activity in nuclear power plants and other nuclear or radioactive installations, as appropriate, according to CNEN-NE-1.28.

For safety related items, some design documents for Angra 2 and Angra 3 components establish a third party authority to perform independent technical evaluation during fabrication of products, in accordance with material test specification. So, in order to fulfill this design requirement are included, on purchased orders, clauses with freedom access to manufacturing installations and source inspections. The third party authority is submitted to the knowledge and previous acceptance of the regulatory body in accordance with the requirements of CNEN-NE-1.28 "Qualification and Performance of Independent Technical Supervision Bodies in Nucleoelectric Plants and Other Facilities".

3.4 Brazilian structure of Quality Assurance System

See Table I for the documents related to the Brazilian structure of quality assurance system as described on the previously subsections of this paper.

Table I: Brazilian structure of quality assurance system

Regulation(s):	CNEN Resolution 15/99, published in Brazilian Federal Register on 09.21.1999, through CNEN Ordinance 17/00 on 04.03.2000
Mandatory standard(s) for NPPs:	<p>Norma CNEN-NE-1.04: LICENCIAMENTO DE INSTALAÇÕES NUCLEARES.</p> <p>Norma CNEN-NN-1.16: GARANTIA DA QUALIDADE PARA A SEGURANÇA DE USINAS NUCLEOELÉTRICAS E OUTRAS INSTALAÇÕES.</p> <p>Norma CNEN-NE-1.26: SEGURANÇA NA OPERAÇÃO DE USINAS NUCLEOELÉTRICAS.</p> <p>Norma CNEN-NE-1.28: QUALIFICAÇÃO E ATUAÇÃO DE ÓRGÃOS DE SUPERVISÃO TÉCNICA INDEPENDENTE EM USINAS NUCLEOELÉTRICAS E OUTRAS INSTALAÇÕES.</p>
Mandatory standard(s) for safety-related suppliers:	<p>Norma CNEN-NN-1.16: GARANTIA DA QUALIDADE PARA A SEGURANÇA DE USINAS NUCLEOELÉTRICAS E OUTRAS INSTALAÇÕES.</p> <p>The American Society of Mechanical Engineers, ASME NQA-1 standard - Quality Assurance Requirements for Nuclear Facility Applications.</p>

	<p>U.S. Nuclear Regulatory Commission, USNRC 10CFR50 Appendix B - Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants.</p> <p>U.S. Nuclear Regulatory Commission, USNRC 10CFR72 – Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related greater than Class C Waste - Subpart G - Quality Assurance.</p> <p>Kerntechnischer Ausschuss, KTA 1401 - General Requirements for the Quality Assurance.</p>
Non-mandatory standard(s) for NPPs:	International Atomic Energy Agency, IAEA Leadership and Management for Safety – General Safety Requirements No. GSR Part 2.
Non-mandatory standard(s) for safety-related suppliers:	<p>International Organization for Standardization, ISO 9001:2015 - Quality management systems – Requirements.</p> <p>International Organization for Standardization, ISO/IEC 17025:2017 - General requirements for the competence of testing and calibration laboratories.</p>

4. Conclusions

A brief description of laws, regulations and standards used in the nuclear supply chain was made to help newcomer suppliers from other backgrounds and/or countries to understand what is required in Brazil. The documents directly related to quality assurance systems, with focus on construction and operational nuclear power plants lifecycle phases and nuclear facilities were available. Mandatory and non-mandatory standards for safety-related suppliers were listed. As result, it is expected that potential newcomers players at supply chain should have a better performance when dealing with the Brazilian documentation applied for supplying products or providing services to nuclear power plants and other nuclear installations.

The regulatory body and its role in the qualification or licensing of suppliers providing safety-related products or services was also indicated in this article, when the Quality Assurance Program of the licensee and main suppliers are submitted to the regulatory body knowledge and acceptance previously to the activities they refer.

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