

## **DEVELOPMENT OF A QUALITY MANAGEMENT SYSTEM FOR BRAZILIAN NUCLEAR INSTALLATIONS**

**Eduardo Kibrit<sup>1</sup> and Desirée Moraes Zouain<sup>2</sup>**

<sup>1</sup> Centro Tecnológico da Marinha em São Paulo – CTMSP  
Departamento da Qualidade  
Av. Prof. Lineu Prestes, 2468  
05508-000 São Paulo, SP  
edkibrit@yahoo.com.br

<sup>2</sup> Instituto de Pesquisas Energéticas e Nucleares (IPEN / CNEN - SP)  
Divisão de Planejamento e Inovação Tecnológica  
Av. Prof. Lineu Prestes 2242  
05508-000 São Paulo, SP  
dmzouain@ipen.br

### **ABSTRACT**

The present work is a proposal for developing a quality management system for Brazilian nuclear installations, based on applicable standards.

The standard ISO 9001:2000 [4] establishes general requirements for the implementation of a quality management system in all kinds of organizations. The standard IAEA 50-C/SG-Q [1] establishes general requirements for the implementation of a quality assurance system in nuclear installations. The standard CNEN-NN-1.16 [5] establishes the regulating requirements for the quality assurance systems and programs of nuclear installations, for licensing and authorization for operation of these installations in Brazil.

The revision of standard IAEA 50-C/SG-Q [1], to be replaced by IAEA DS 338 [2] and IAEA DPP 349 [3], introduces the concept of "Integrated Management System" for the nuclear area, in preference to the concept of "Quality Assurance". This approach is incorporated with the current tendency, because it guides the system to manage, in an integrated way, the requirements of quality, safety, health, environment, security and economics of the installation.

The results of the characterization of the quality management systems established in the applicable standards are presented, with the determination of the common and conflicting points among them. Referring data to quality assurance program/quality management system in some nuclear installations of IAEA Member States are also presented.

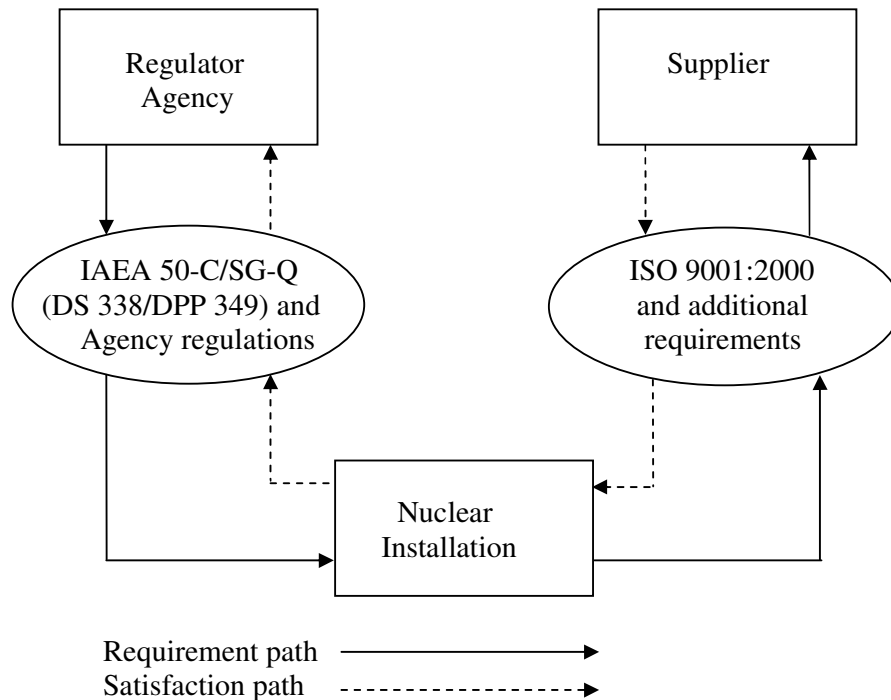
### **1. INTRODUCTION**

Publication IAEA 50-C/SG-Q [1] establishes the nuclear safety requirements at the nuclear utility–regulator interface. Publication ISO 9001:2000 [4], is often used to define the quality management system requirements at the utility–supplier interface. Publication CNEN-NN-1.16 [5] establishes the regulating requirements for the quality assurance systems and programs of nuclear installations, for licensing and authorization for operation of these installations in Brazil, and is used together with IAEA 50-C/SG-Q [1], at the nuclear utility–regulator interface.

The revision of IAEA 50-C/SG-Q [1], to be replaced by IAEA DS 338 [2] and IAEA DPP 349 [3], introduces the concept of "Integrated Management System" for the nuclear area, in preference to the concept of "Quality Assurance". This approach is incorporated with the current tendency, because it guides the system to manage, in an integrated way, the requirements of quality, safety, health, environment, security and economics of the installation.

In general, the nuclear facilities of IAEA Member States have their quality management system established by standards IAEA 50-C/SG-Q [1], ISO 9001:2000 [4] and regulations of their own government regulator agency, for obtaining their operation license. Two interfaces are observed.

The first interface is between the nuclear installation and the government regulator agency. The latter hopes that the nuclear installation develops and implements a quality management system, assisting to the requirements of the standards IAEA 50-C/SG-Q [1] and regulations established by the agency. The second interface is between the nuclear installation and the suppliers of items and services that developed a quality management system in conformity with ISO 9001:2000 [4]. Figure 1 shows these interfaces and the application of IAEA 50-C/SG-Q [1] and ISO 9001:2000 [4].



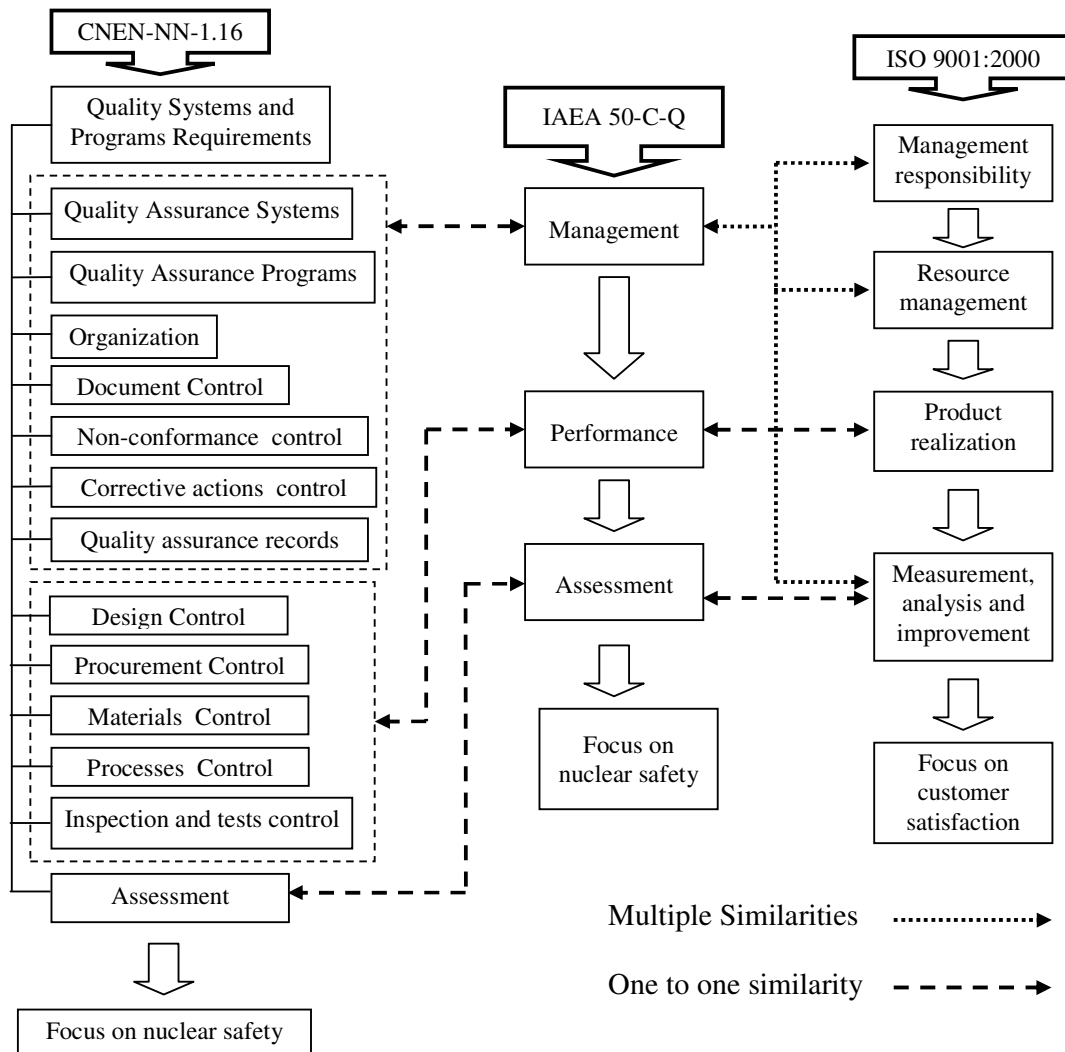
**Figure 1. Interfaces of a Nuclear Installation and the application of IAEA 50-C/SG-Q [1] and ISO 9001:2000 [4].**

Figure 1 also applies to a nuclear installation operating in Brazil. The Regulator Agency is the National Commission of Nuclear Energy (CNEN), which requires that the nuclear installation implements and maintains a quality assurance program in conformance to standard CNEN-NN-1.16 [5].

## 2. MAJOR DIFFERENCES AND CORRELATIONS AMONG THE APPLICABLE STANDARDS

### 2.1. Structure and Focus

Figure 2 highlights the similarities of structure and the differences of focus among IAEA 50-C/SG-Q [1], ISO 9001:2000 [4], and CNEN-NN-1.16 [5]. Both IAEA and CNEN standards distinguish between management, performance and assessment, the ISO standard between management responsibility, resource management, product realization, and measurement, analysis and improvement.



**Figure 2. Similarities of structure and the differences of focus among IAEA 50-C/SG-Q [1], ISO 9001:2000 [4], and CNEN-NN-1.16 [5].**

The focuses of IAEA 50-C-Q [1] and CNEN-NN-1.16 [5] are on achieving nuclear safety, the focus of ISO 9001:2000 is on achieving customer satisfaction.

In IAEA 50-C-Q [1] and CNEN-NN-1.16 [5] the terms ‘quality assurance’ and ‘quality assurance program’ are used. The term ‘quality assurance’ is no longer used in ISO 9001:2000.

The term ‘quality management system’ used in ISO 9001:2000 is equivalent to the term ‘quality assurance program’ as used in IAEA 50-C-Q [1] and CNEN-NN1.16 [5].

All applicable standards, IAEA 50-C-Q [1], CNEN-NN-1.16 [5], and ISO 9001:2000 [4], utilize a quality management system approach and require that the quality management system shall focus on continual improvement.

## **2.2. Correlation Among the Basic Requirements of the IAEA CODE 50-C-Q [1], CNEN-NN-1.16 [5] and ISO 9001:2000 [4]**

In general the basic requirements of the IAEA Code 50-C-Q [1] and CNEN-NN-1.16 [5] are addressed by one or more clauses of ISO 9001:2000 [4]. The following clauses of ISO 9001:2000 [4] are not specifically addressed within IAEA 50-C-Q [1] and CNEN-NN-1.16 [5]:

- Clause 5.2: Customer focus;
- Clause 5.5.3: Internal communication;
- Clause 7.5.4: Customer property;
- Clause 8.2.1: Customer satisfaction.

### **2.2.1. Overall considerations of the applicable standards**

The IAEA Code 50-C-Q [1] and CNEN-NN-1.16 [5] provide the basic requirements to be adopted for establishing and implementing quality assurance programs/quality management systems related to the safety of nuclear power plants and other nuclear installations.

The objectives of the IAEA Code and CNEN-NN-1.16 [5] are to establish basic requirements for quality assurance in order to enhance nuclear safety by continually improving the methods employed to achieve quality. The Code and CNEN-NN-1.16 [5] recognize that all work is a process that can be planned, performed, assessed and improved.

ISO 9001:2000 [4] specifies requirements for a quality management system that can be used for internal application by organizations, or for certification or contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

In summary, the IAEA Code 50-C-Q [1] and CNEN-NN-1.16 [5] are focused on meeting the overall safety requirements for the plant, personnel and society in general, whilst ISO 9001:2000 [4] is focused on satisfying the requirements of the customer.

## **2.2.2. Additional conceptual requirements of the applicable standards**

### **2.2.2.1. Grading**

The IAEA Code 50-C-Q [1] and CNEN-NN-1.16 [5] recommend a graded approach for the application of quality assurance during the various stages of a nuclear power plant life cycle. All items, services and processes require various controls to ensure that they perform correctly. The grading process is a means of determining the types and extent of controls to be applied to specific items, services and processes.

ISO 9001:2000 [4] does not specifically address a graded approach for applying the controls specified in the quality system.

### **2.2.2.2. Independence of inspection and testing personnel**

The IAEA Code 50-C-Q [1] and CNEN-NN-1.16 [5] require that inspection and testing of specified items, services and processes shall be conducted using established acceptance and performance criteria. The level of inspection and testing and the degree of independence of personnel shall be established.

ISO 9001:2000 [4] does not specifically cover the independence of inspection and testing personnel.

## **3. QUALITY ASSURANCE PROGRAMS/QUALITY MANAGEMENT SYSTEMS IN NUCLEAR INSTALLATIONS OF IAEA MEMBER STATES**

All IAEA Member States have established their own national laws and regulations in nuclear power, and those laws and regulations, related to nuclear safety, are mostly based upon IAEA Safety Standards.

Nuclear installations of many IAEA Member States have incorporated IAEA 50-C/SG-Q [1] in their quality assurance program/quality management system. This is the case of Argentina, Brazil, China, Czech Republic, Hungary, India, Indonesia, Republic of Korea, Mexico, Pakistan, Romania, Slovakia, Spain, Turkey, Ukraine and USA.

## **4. CONCLUSIONS**

Since IAEA 50-C/SG-Q [1] is being superseded and will be replaced by IAEA DS 338 [2] and IAEA DPP 349 [3], it is advisable that all quality assurance programs/quality management systems, already implemented by nuclear installations of IAEA Member States, should be revised to comply with the new IAEA quality management systems requirements.

## ACKNOWLEDGMENTS

I would like to thank PhD Desirée Moraes Zouain, who guides me in my master's degree dissertation at Institute of Energy and Nuclear Researches (IPEN), and encouraged me to participate in this event.

## REFERENCES

1. IAEA, *Safety Series No. 50-C/SG-Q - Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations - Code and Safety Guides Q1-Q14*, IAEA, Austria (1996).
2. IAEA, *Safety Standards Series DS338 Draft 7 - Management Systems - Revision of Safety Series 50-C-Q / 50-SG-Q1 to Q7*, IAEA, Austria (2005).
3. IAEA, *Safety Guide DPP 349 Revision 0 - Management Systems for Nuclear Facilities - Revision of Safety Series 50-SG-Q8 to Q14*, IAEA, Austria (2003).
4. ISO, *ISO 9001 - Quality Management Systems – Requirements*, ISO, Switzerland (2000).
5. CNEN, *CNEN-NN-1.16 - Quality Assurance for Nuclear Power Plants, and other Nuclear Installations*, D.O.U., Brasil (1999).