# THE MANAGEMENT SYSTEM EVOLUTION OF RESEARCH NUCLEAR REACTOR IEA-R1

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## ABSTRACT

The IEA-R1 is the first research nuclear reactor in Brazil and since its inauguration in 1957, has been regularly used mainly for R&D, teaching and production of some radioisotopes for medical and other purpose. Until 1999 the IEA-R1 reactor adopted a Quality Assurance Program based on the Brazilian regulatory body standard (Brazilian Nuclear Energy Commission - CNEN) CNEN NN 1.16 and the IAEA Guide SS 50 CQ to control quality and safety requirements, quality procedures and records. In 2001 the Research Reactor Center (CRPq) has began to implement a Quality Management System (QMS) focused on "Operation and Maintenance of the IEA-R1 Research Reactor and Irradiation Services". In 2002 this facility obtained its first NBR ISO 9001:2000 certification on this scope. The present work relates the stages involving the implementation of QMS of IEA-R1 reactor since it started operation until now, reporting the mainly difficulties and results obtained.

## 1. Brief Historical - Quality

Since the start up, operational and managerial activities carried out in the IEA-R1 reactor has been controlled by the people in charge, but only in the latest years this process was done in a systematized way. During the period of 1957 to 1999, the facility adopted the concepts of Quality Control (1984) and Quality Assurance (1994) of the IAEA standards and guides and American standards.

In 1997, following a world tendency, the Nuclear and Energy Research Institute (IPEN), adopted for one of its units, Radiopharmaceutical Center (CR), one of the unique suppliers of radiopharmaceuticals in Brazil, the NBR ISO 9002:1994 [1] model to Quality Assurance of this product, including Good Manufacturing Practices requirements and other regulatory requirements applicable to radioactive facility. In this way, IPEN obtained its first NBR ISO 9002 certification for the scope "Radiopharmaceutical Production and Control".

The following step was to certify the internal suppliers of raw material for that Center. As IEA-R1 supplies samarium and iodine to CR, in 2001 has began the modification of the IEA-R1 Quality Assurance Program to a Quality Management System (QMS) based on ISO standards.

As general guideline the IPEN designed a Quality Management System based on NBR ISO 9004:2000 [2] to define the general directives to IEA-R1 reactor and other facilities and services comply with the CR requirements. This model is internationally recognized and allows a relative easy integration with requirements of other conformance standards (environmental, occupational health, safety and social responsibility) since some of them are common and others can be incorporated without compromise the system structure. To obtain and maintain the Quality Management Systems certification of each specific scope it was adopted the NBR ISO 9001:2000 [3].

As a general rule, the programs related with environmental, safety and radioprotection aspects to comply with legal and corporative requirements are implemented in an isolated way by few specialists that are no involved with the Management System. The result is a no integrated system to manage all important aspects in the organization. A way to solve these problems is to implement an Integrated Management System with the objective of identify and structure the legal and other subscripted requirements and to extend the system to

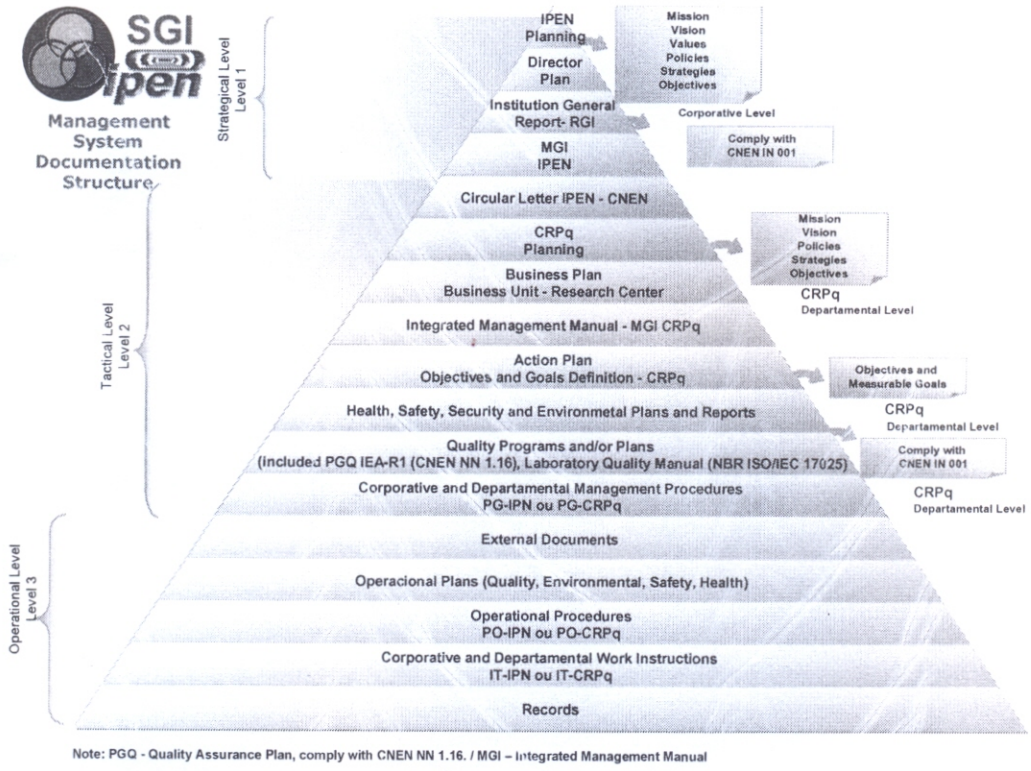


**Figure 2.** QMS Documentation Structure

## 2.4. Training and awareness

During the implementation of the QMS people must be convinced about the advantages of the change, mainly in relation to follow procedures and to keep records. At the beginning people thought the QMS was only bureaucracy and paper generation. After that some people started to see the QMS as a tool to identify problems or improvements in the processes and become more involved in it. In an organization like IPEN people have different comprehension levels of the QMS, then it is necessary to maintain activities (formal and informal meetings, talking) to ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the QMS objectives

It was observed that though people were trained some of them continue no working as was established. It is looking for other forms to improve the training efficacy.

## 2.5. Continuous Improvement

A periodic review of the performance of the QMS is carried out by means of:

- Independent assessment (internal and by external organisms and surveillance) and self-assesment (systematic and detailed review of the results obtained by the organization and CRPq, including results related to QMS).
- Regular meetings of the Board of Director of IPEN and CRPq to assess the implementation level and performance of the QMS and its continuous improvement.

### 2.5.1. Audits

Internal and external audits (system and technical audits) are performed (as scheduled) to verify if the QMS comply with all requirements and to identify occasional non conformance or improvement aspects. They follow corporative procedure and are done by trained and independent people. Although internal audit process has been considered a strong point of the QMS by external auditors, there are some weak points in the process related to safety

between CRPq specific process and IPEN processes called corporative (sale, procurement and purchasing, document control, non conformance control, corrective, preventive and improvement actions, audit, management review) to assure the coherence between them.
The QMS of CRPq follows two directive levels: corporative (established for all the organization) and sectorial (specific for requirements applicable to CRPq). It was also considered the regulatory, legislative requirements applicable to nuclear and radioactive facilities established by the regulatory body in the CNEN IN 001:1994 [5], CNEN NN 1.16 [6] and other applicable standards.
The main difficulty found in these phase was to convince people and manager to change their own way of work and adopt the corporative directives. The challenger was to wear down the natural resistance of people to changes.

## 2.2. Organization and Responsibility

CRPq is part of the IPEN organizational chart and is composed by a managerial body formed by one General Manager and three Managers. It is advised by a Consultive Council (on technical matters), an Internal Safety Committee (on safety and radioprotection matters), a Management Representative - MR (on QMS matters) and assisted for several IPEN departments, responsible by corporative processes: sale, procurement and purchasing, costumer relationship, audit, training. It is also assisted by a resident Radioprotection Team.
The Direction of CRPq responds to the Board of Directors of IPEN. All responsibilities are clearly defined and documented in procedure.
Some difficulties were identified in relation to organization and responsibility definition:

- Directors and Managers come from research areas and in some cases presents a lack of competence to lead with some managerial aspects of the QMS;
- In some areas the managers are defined considering the people and no the process. This is a cultural aspect of the organization. There is resistance in organizational changes;
- There is a reduced number of people directly involved in the QMS, considering the size and the activities developed by the organization;
- Organization changes without analysis of the impact of these changes on processes and business, mainly related to Directors and Managers.

## 2.3. Process Mapping and Documentation

The definition, mapping, interaction study and documentation related to processes, mainly the corporative ones, were done by working groups composed by representative of each area involved in the processes.
In the case of reactor operational procedures, the documentation was prepared by people that carried out the operations with the supervision of the MR, based on the documentation previously submitted to regulatory body to obtain the Operation Authorization (SAR – Safety Analysis Report based on IAEA Safety Series No. 35-G1 – 1994 [7]).
The documentation system that supports the QMS is composed by approximately 150 documents, including: Business and Action Plans, Quality Manual, Quality Assurance Program (focused in item important to safety), Safety Analysis Report and Procedures (in three levels: strategic, tactic and operational). Besides the documentation generated internally in CRPq, the QMS utilizes the documentation that supports the QMS of IPEN relative to corporative directives. The documentation structure is presented in **Figure 2**.
The major difficult in this process is to identify the details to be included in order to comply with all requirements and to share this knowledge.

environmental and safety issues. **Figure 1** shows how these aspects are treated by IPEN and its departments, in a simple and schematic way.
In this context, the IPEN through the Research Reactor Center (CRPq) since 2001 is implementing and maintaining a Quality Management System (QMS) based on NBR ISO 9001:2000 to the activities related with **"Operation and Maintenance of the IEA-R1 Reactor and Irradiation Services"**. This QMS was certified in 2002 and the certification was maintained or renewed in the following years. It is planned to adequate this QMS to new requirements of the NBR ISO 9001:2008 [4] (published in December 2008).

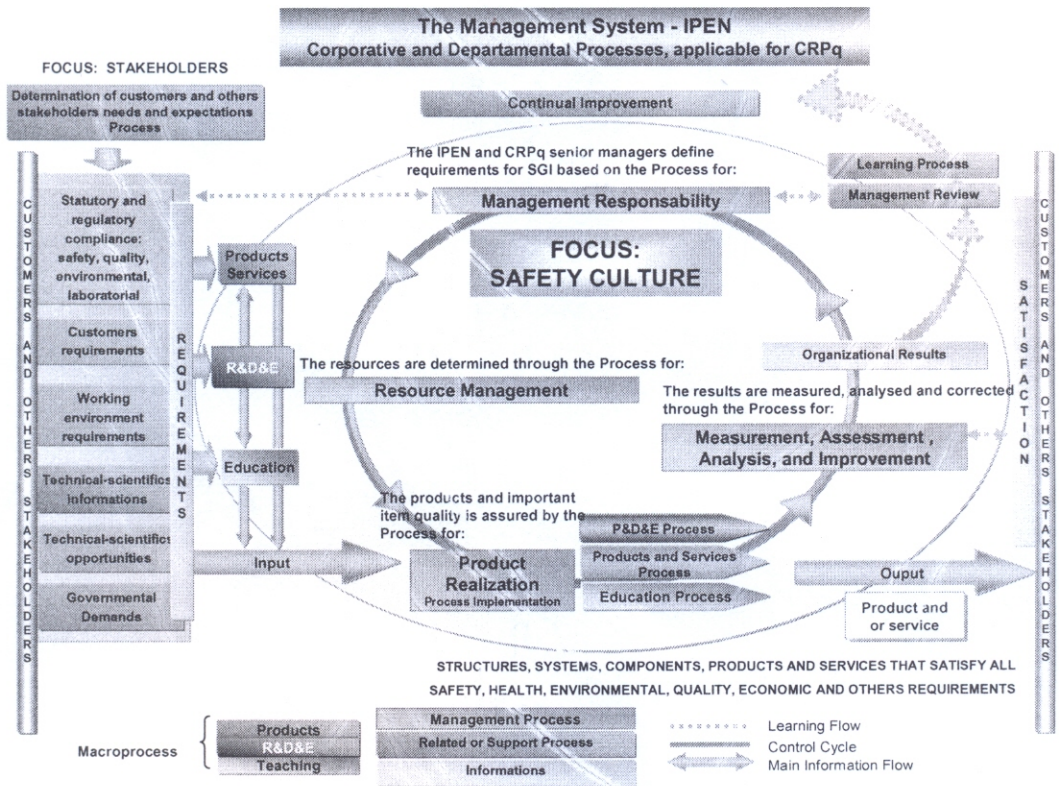


**Figure 1.** Process approach adopted by QMS-CRPq

## 2. Main process involved and achieved results

In the strategic plan development for IPEN and CRPq Mission, Vision, Values and Objectives were established, the main Policies were defined and a Business Plan was elaborated. This included the quality planning that culminated in the QMS implementation. The main phases of the QMS implementation were structure redefinition; reviewing, mapping, interaction and documentation of the main process; organization and responsibility redefinition considering the necessary competences to these processes; training and awareness; implementation of the policies and processes, independent assessment (internal and external audits; surveillance); management system review and continuous improvement in all phases.
Although the activities have always carried out observing the established safety criteria, until the implementation of the QMS the records and controls (analysis, approval criterion) were not clearly defined and documented, they were depended on people experience and knowledge. IPEN and CRPq workers had no idea how they could influence in the processes, improving safe, time and cost.

### 2.1 QMS structure definition

Following the NBR ISO 9001:2000 proposal, the QMS was structure adopting the process approach showed in **Figure 1**. After several leadership meetings it was defined the interface

aspect audits, mainly in relation to SAR assessment, due to the lack of competence in safety concepts of the auditors team.
The QMS of CRPq has been externally audit since 2002 by Fundação Carlos Alberto Vanzolini, a Brazilian Certify Organism. This QMS was NBR ISO 9001:2000 certified in 2002 and the certification was maintained or renewed in the following years. It is intended next audit would be done based on NBR ISO 9001:2008[4], approved in December 2008.

### 2.5.2. Management Review

Results, weak points and improvement aspects have been systematically reviewed in two level meetings: IPEN to corporative processes and CRPq to specific process. Directors, Managers, personal in charge of the each process and direction representative (RD) participate of these meetings.

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