

MANAGEMENT QUALITY SYSTEM IMPLEMENTATION IN THE LNMRI RADIONUCLIDE GROUP BASED ON ISO/IEC 17025 REQUIREMENTS

*Estela Maria de Oliveira*¹, *José U. Delgado*², *Carlos José da Silva*³, *Maria Antonieta R. R. Di Prinzio*⁴, *Maura Julia Camara da Silva Bragança*⁵, *Maria Elizabeth Dias Acar*⁶

¹LNMRI/IRD/CNEN, Rio de Janeiro, Brasil estela@ird.gov.br

²LNMRI/IRD/CNEN, Rio de Janeiro, Brasil delgado@ird.gov.br

³LNMRI/IRD/CNEN, Rio de Janeiro, Brasil carlos@ird.gov.br

⁴LNMRI/IRD/CNEN, Rio de Janeiro, Brasil tuna@ird.gov.br

⁵LNMRI/IRD/CNEN, Rio de Janeiro, Brasil maura@ird.gov.br

⁶SEGEQ/IRD/CNEN, Rio de Janeiro, Brasil acar@ird.gov.br

Abstract: In recent times, the Ionizing Radiation Metrology Laboratory implemented the ISO/IEC 17025 requirements for the radioactive source production and calibration services. To this a peer-review process was done in the main measurement systems of the laboratory. This work describes with details the structure of quality system adopted as well as the action plan and non-conformities.

Keywords: Quality management, peer review, quality policy

1. RADIONUCLIDE METROLOGY SERVICE

The Radionuclide Metrology Service, created in 1973, belongs to the National Metrology Laboratory of Ionizing Radiations (LNMRI) of the Dosimetry and Radioprotection Institute (IRD). In 1989, by delegation of INMETRO (National Institute for Metrology, Standardization and Industrial Quality), the metrology activities of IRD made up the National Metrology Laboratory of Ionizing Radiations [1].

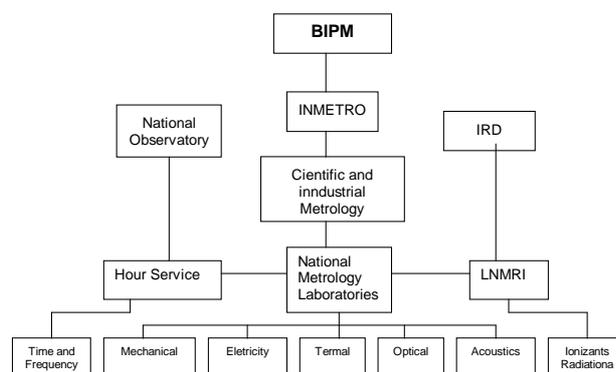
LNMRI together with the laboratories at INMETRO (for quantities in the fields of mechanical, electricity, thermal, optical and acoustics) and at the National Observatory (for time and frequency), makes up the National Metrology Laboratory (LNM) of Brazil, as defined by resolution 03/89 of the National Council of Metrology (CONMETRO), according Figure 1.

The Mutual Recognition Arrangement (MRA) was signed in October 1999 by the directors of the national metrology institutes of thirty-eight Member States of the Metre Convention. It is an arrangement between national metrology institutes which specifies terms for the mutual recognition of national measurement standards and for recognition of the validity of calibration and measurement certificates issued by national metrology institutes.

The MRA by means of key comparisons, demanding that each laboratory operate a quality system applied to the

calibration services, which establishes the metrological equivalence among standards and certificates [2]. To this the NMI's must adopt the requirements of ISO/IEC 17025 Standard as the main document [3].

Figure 1. The structure of metrology in Brazil.



This work shows the results obtained during and after the quality system implementation, which was adopted in radionuclide metrology, based on non-conformities detected in internal audits, peer review and, consequently, their action plans.

2. IMPLEMENTATION OF QUALITY MANAGEMENT SYSTEM

In IRD there are two kinds of services. One is the essay and calibration service and the other is the inspection service.

The essay and calibration services must adopted the requirements of ISO/IEC 17025 Standard as the main document and the inspection services must adopted the requirements of ISO/IEC 17020 Standard.

To attend the requirements of ISO/IEC 17025 Standard and the requirements of ISO/IEC 17020 Standard, the Quality Management System of IRD is organized in eight

modules which six are relative with the common requirements to the both norms (Corporative Modules). There are two modules that attend the requirements of each one of the norms (Specific module of Essay and Calibration Service and specific module of Inspection Service). Figure 2 shows the structure of IRD Quality Management System.

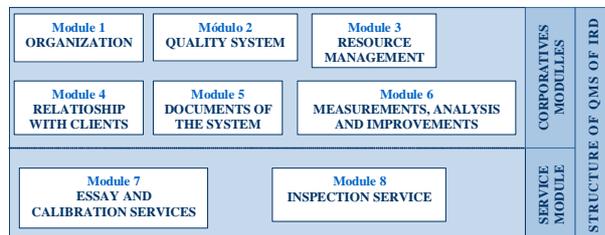


Figure 2. Structure of Quality Management System (QMS) of IRD.

In the Quality Manual of IRD each module of the Quality Management System is treated in a specific topic.

The quality program consisted in the register and control of documentation, training program, internal audits, management review, service users, supplier evaluation, etc, as showed below.

2.1 Documents

The documents of IRD quality management was divided in 4 groups:

- Quality manual, corporate (13) and radionuclide group procedures (15), and registry forms;
- External documents (standard and technical application, especifications, etc.);
- Other documents (tables, graphics, draws, etc.) and,
- Registers

2.2 Training Program

First, the radionuclide team had trained guided to the knowledge about ISO/IEC 17025 Standard. Some persons of the laboratory were chosen to be trained in internal audit programs.

2.3 Internal Audits

In order to follow the implementation of the management quality system, it is conducted an internal audit once a year. This process is responsible for detect non-conformities and recommendations. But there are also non-conformities identified by internal activities.

Both kind of non-conformities are evaluated in an own form and correctives actions are generated as soon as possible.

This quality system predicts a meeting of critical analysis once a year, chaired by the IRD Director. Then, the results are compared with the proposed aims and new goals are established.

2.4 About peer review

To attend the demands of SIM/BIPM (Sistema Interamericano de Metrologia/Bureau International des Poids et Mesures), the services of the laboratory were submitted to a peer review, where the laboratory received 2 international auditors. These experts not only evaluated technical aspects but also management requirements. The technical expert was from LNHB/BNM-France, and the system expert was from IPQ/Portugal. The peer review happened in septembre 2004.

2.5 Results

Table 1 shows the number of non-conformities detected in each internal audit and the non-conformities detected in internal activities.

Table1. Non-conformities detected in internal audits and in internal activities.

Year	Non conformities
2004	Internal activities: 07
	Internal audit: 19
2005	Internal activities: 03
	Internal audit: 11
2006	Internal audit will be made in june 2006

At the end of peer review, the experts presented 9 recommendations and 10 suggestions for the radionuclide group. Next, the radionuclide group presented an action plan to the experts and they approved it.

The result of peer review evaluation was submitted and approved in the meeting of SIM that happened in Venezuela in November 2004 [4].

Recommendations and suggestions were solved in the determined time.

3. CONCLUSIONS

The implementation of the management quality was just possible due to the commitment and involvement of the technical body and administrative staff.

The main difficult of this implementation was to conciliate two norms in the same Quality Management System.

This implementation carried out improvement in all tasks of radionuclide calibration services. These improvements can be observed in different steps of the radionuclide calibration process, such as:

- control of documents and recordings
- issue of calibration certificates
- training of the human resources
- relationship with users
- new systematic to evaluate and expressing the measurement uncertainties
- better radionuclide laboratory performance concerning of the results of intercomparisons

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