BJRS

BRAZILIAN JOURNAL
OF
RADIATION SCIENCES
06-03 (2018) 01-13

SBPR
Sociedade Brasileira de Proteção Radiológica

ISO/IEC 17025 accreditation of radiation measurement tests in the Brazilian National Commission for Nuclear Energy – Laboratory of Poços de Caldas

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ABSTRACT

This paper describes the implementation process of a Quality Management System (QMS) at the Laboratory of Poços de Caldas (LAPOC – Brazil), aiming for ABNT NBR ISO/IEC 17025 accreditation. As the scope consisted of both chemical and radiation test methods (for which only a few labs worldwide are accredited), this initiative turned into a challenging endeavor for the organization. In this sense, critical aspects on the development of a QMS are emphasized. Although the standard comprises a complex set of management and technical requirements, LAPOC's approach to achieve accreditation is presented as two main branches: documentation development and method validation/uncertainty estimation/traceability. Those aspects are the ones that most challenged the accreditation team, deserving a separate discussion, though. Upon the successful conclusion of its quality assurance project, LAPOC became the national pioneer in the field of accredited radiation measurements. This case study may be inspiring to other governmental institutions that struggle to obtain accreditation of radioanalytical test methods in an environment of low resource availability and restricted manpower. The most important learning points of this process are presented as a conclusion.

Accepted for publication 2018-05-15

Keywords: quality management system, ABNT NBR ISO/IEC 17025:2005, accreditation, radiation measurement, method validation

1. INTRODUCTION

In the last few years, ABNT NBR ISO/IEC 17025 accreditation has been essential for analytical labs looking to meet customer expectations [1]. The number of laboratories that will implement a Quality Management System (QMS) is expected to significantly grow in the coming years, since more and more national authorities and customers request the accreditation of the laboratories carrying measurements for them [2]. There are more benefits in running a testing lab based on the requisites of this standard via a consistent QMS. At first, the core features of any QMS (such as standardization, continuous improvement, customer focus and good performance procedures to guarantee reliability of the measurement data) are conducive to a better understanding of organizational processes, as well as to a more stable operational routine [3]. Albano and Faustini [4] presented the positive influence of an accredited quality system in analytical labs, through the performance of Brazilian laboratories in a proficiency testing (PT) scheme of physico-chemical water analysis. Moreover, the need for improvement of public reliability on measurement results is another key aspect to analytical labs worldwide that cannot be neglected [5]. In this sense, the challenge posed by the accreditation project of the Laboratory of Poços de Caldas (LAPOC), as a technical unit of the Brazilian National Commission for Nuclear Energy (CNEN), was held as a strategic initiative.

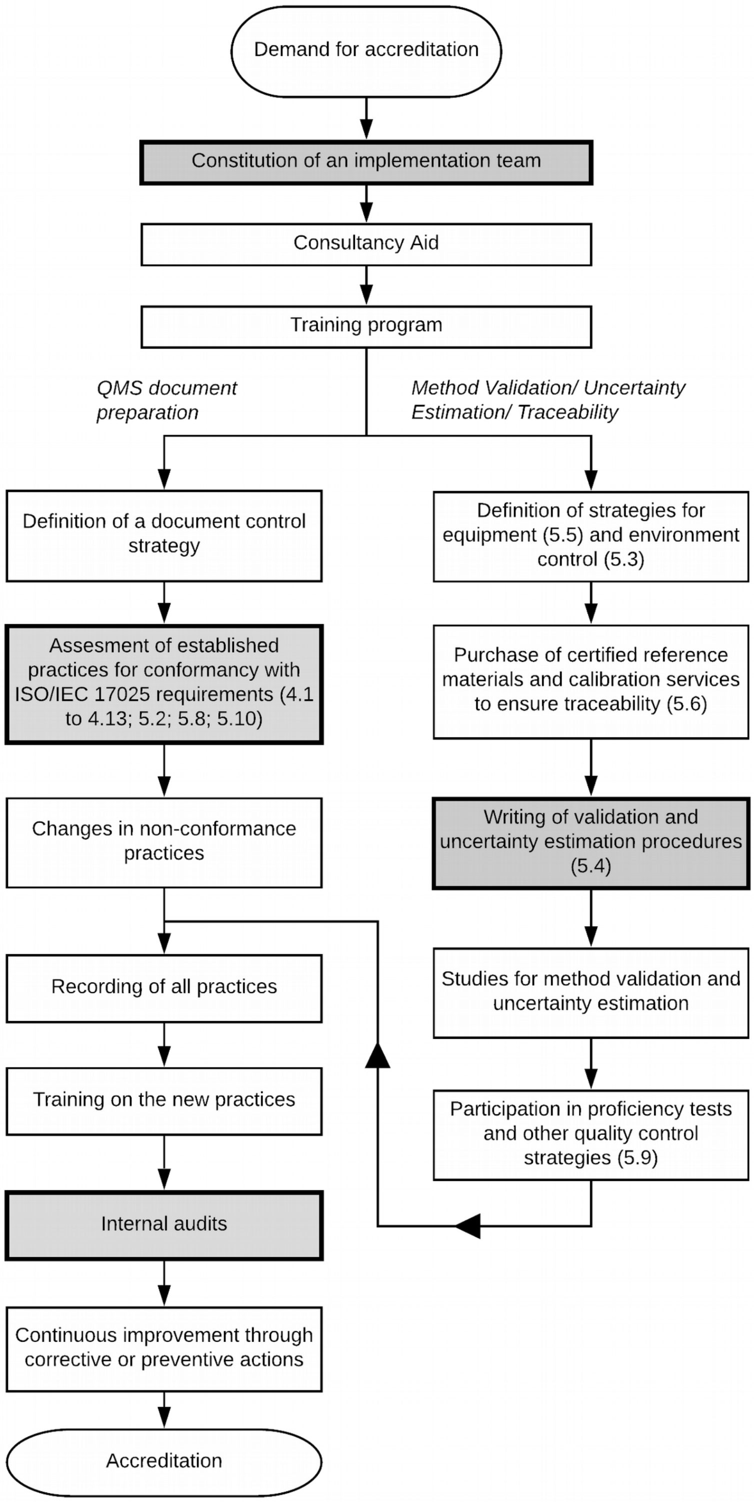
LAPOC is a governmental laboratory focused on safety assessments in the nuclear field. There is a legal framework to be followed that is not usually favorable to QMS implementation, as a public entity. Those legal requirements comprise, for instance: purchase at lowest costs, personnel hiring restrictions and people management policies centralized at federal level. However, LAPOC also performs inorganic chemical analysis and radiochemical test measurements, and acts on licensing, monitoring and decommissioning of nuclear facilities; control of nuclear materials; radio-ecological research and general assessment of environmental impacts from radiation. Facilities at LAPOC are equipped for the determination of chemical and radioactive species in foodstuff and environmental samples, through the techniques of gamma spectrometry, liquid scintillation counting, alpha spectrometry, atomic spectroscopy and induced coupled plasma-mass spectrometry (ICP-MS).

2. MATERIALS AND METHODS

The implementation process was initiated in 2010, through the indication of a staff member for the role of the quality manager. A quality manager must be carefully selected and empowered in order to conceive and implement a QMS.

The next step was to hire an experienced professional or even a specialized company that provided technical support for accreditation. At first glance, every quality system standard is a set of requirements of difficult interpretation, lacking a defined pathway for implementation [6]. Consultancy settled this issue, by providing a roadmap that led project team efforts into the development of a reliable QMS. Figure 1 indicates the steps adopted in LAPOC that allowed the institution to be accredited, which can be regarded as a pathway for other labs willing to follow the same strategies discussed on this paper. Critical steps, according to LAPOC's experience, were shaded in gray on this figure.

Figure 1: *QMS steps adopted by LAPOC aiming ABNT NBR ISO/IEC 17025:2005 accreditation.*


Demand for accreditation
Constitution of an implementation team
Consultancy Aid
Training program
QMS document preparation
Method Validation/ Uncertainty Estimation/ Traceability
Definition of a document control strategy
Assesment of established practices for conformancy with ISO/IEC 17025 requirements (4.1 to 4.13; 5.2; 5.8; 5.10)
Changes in non-conformance practices
Recording of all practices
Training on the new practices
Internal audits
Continuous improvement through corrective or preventive actions
Accreditation
Definition of strategies for equipment (5.5) and environment control (5.3)
Purchase of certified reference materials and calibration services to ensure traceability (5.6)
Writing of validation and uncertainty estimation procedures (5.4)
Studies for method validation and uncertainty estimation
Participation in proficiency tests and other quality control strategies (5.9)

A training program was provided to all staff involved in the process, as a way to offer the necessary information to create a new work concept. That information was presented in a pace that respected each one's capabilities, as some old beliefs and deep-rooted habits had to be reviewed and replaced for new practices aiming the establishment of a consistent QMS. Many organizations fail in this aspect, by trying to speed up this process [7]. The following training courses were then offered in a 2-year time frame: interpretation of ABNT NBR ISO / IEC 17025:2005 requirements; metrological reliability; uncertainty estimation and internal audits.

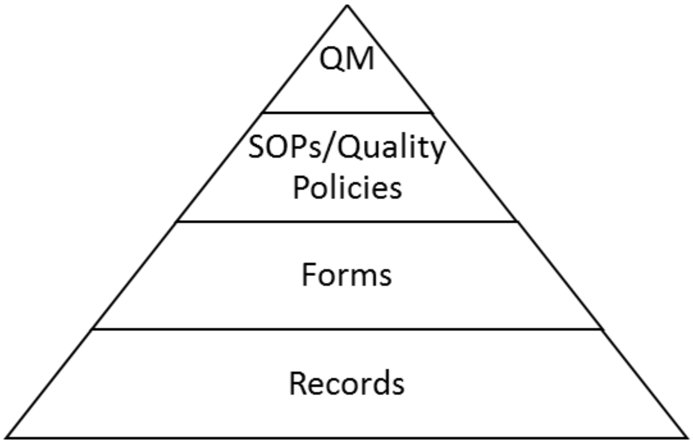
Meanwhile, the implementation process itself was split in two branches (i) QMS documentation development and (ii) methods validation/uncertainty estimation/traceability. Those two fronts will be discussed separately, due to the singular nature of each.

2.1. QMS documentation development

The QMS was described in a single quality manual (QM) that includes LAPOC's quality policy, as well as quality procedures highlights. Standard operating procedures (SOPs) and quality policies were organized in a single document category. Figure 2 represents the hierarchy adopted by LAPOC documentation, whose basis is comprised by records resulting from activities described in the procedures.

Although many commercial software products are available for document control, the lack of a local Information Technology assistance group motivated a low-cost solution for documents approval and distribution. It entailed uploads of digitally signed pdf files stored on a private network area. Afterwards, the documentation structure moved to a hybrid pattern, in which technical operation procedures were distributed both in electronic and physical formats.

Figure 2: *Documental Structure of LAPOC Quality Management System.*



After the establishment of a documentation structure and distribution platform, procedures addressing each standard requirement were written and reviewed. Documents were written in order to register the corresponding process in the required extension. Before documenting, practical issues must be assessed and altered, when necessary, to attend the requisite in question. This approach is important to engage people by valuing each staff member´s experience.

Personnel, reporting of results and handling of test items (requisites 5.2, 5.10 and 5.8 of ABNT ISO/IEC 17025, respectively) were also tackled on this phase of the project.

2.2. Method validation/uncertainty estimation/traceability

QMS documentation development, method validation, uncertainty estimation and traceability studies were simultaneously carried out. The first concern was to find suitable reference materials (supplied by ISO 17034 accredited producers, when available) to be used in the test methods to be accredited. Actions for (i) equipment control (registry of lab equipment in the QMS and the establishment of a maintenance and calibration program) and (ii) environmental conditions (monitoring of temperature and humidity in instrument rooms) were defined to attend corresponding requisites of ABNT ISO/IEC 17025. Analytical methods were technically reviewed before validation in the light of updated references and standards. Lab personnel demonstrated resistance to this approach, as the team had no experience on working with quality standards on a formal manner. As a matter of fact, radiometric measurement methods were validated as non-standard procedures. Subsequently, a validation procedure had to be written. This procedure was based on the guidance for analytical methods validation of the Brazilian national accreditation body (INMETRO) [8], which is strongly focused on chemical measurements. Robustness, linear working range, detection/quantification limit, precision and accuracy were the assessment parameters included in LAPOC's validation procedure. Based on this procedure, all methods were validated and the records obtained were kept as an evidence of that.

Uncertainty was estimated for each test method, based on the Guide to the Expression of Uncertainty in Measurement (GUM) [9] or Kragten approach [10]. Upon validating test methods by studying the parameters mentioned according to INMETRO guide [8] and reporting them, LAPOC took part of proficiency testing programs to evaluate their reliability. Among those programs, Era's Radionuclides in Soil m-RaD program; Rede Metrológica RS Environmental Test Methods Proficiency Program; AQC (Quality Consult) 17-CS1 metals in contaminated soil and, finally, PNI (Brazilian National Intercomparison Program) organized by Instituto de Radioproteção e Dosimetria (IRD) can be mentioned. For all parameters comprising LAPOC's scope of accreditation, satisfactory results were obtained on those programs.

Quality Assurance/Quality Control (QA/QC) strategies, especially the ones involving control charts, were implemented to ensure measurement results were obtained at a required quality level, that is, 95% confidence interval. Hence, LAPOC's validation approach was then aligned to the Analytical Quality Assurance Cycle (AQAC) proposed by Olivares and Lopes [11]. AQAC includes three main elements: validation, uncertainty estimation and QA/QC strategies, connected through the use of calibrated instruments and certified reference materials.

2.3. QMS implementation and auditing

Upon conclusion of validation studies and QMS documentation development, lab personnel were trained on the primary versions of the procedures to effectively run the system. The first internal audit was conducted at the end of 2013 and formal accreditation was requested to the Brazilian national accreditation body on mid-2014. Accreditation audit took place in late 2016, allowing LAPOC to be formally accredited on January, 2017. The initial scope covers a set of 4 radiation measurement test methods (Radium-226, Radium-228 and Lead-210 activity evaluation in soil and sediment and Cesium-137 activity measurement in foodstuff by gamma spectrometry) and 11 chemical test methods (Uranium, Thorium, Cadmium, Lead, Copper, Nickel, Arsenic, Selenium and Mercury determination in environmental samples by atomic spectroscopy techniques and induced coupled plasma – mass spectrometry).

3. RESULTS AND DISCUSSION

Only a few articles describing ABNT NBR ISO/IEC 17025 accreditation processes in radiation measurement labs were found in the literature [12-17]. As stated by Vajda *et al.* [12], the sophisticated nature of radioanalytical work presumes a research-oriented activity, with a constant method development dynamics for special sample analysis. Hence, a feasible QMS for such laboratories must take this feature into account as a rigid method standardization approach may not work accordingly. The challenge in implementing a QMS for this unique environment is to balance those aspects.

Another important point to be emphasized is the choice of an appropriate quality manager. The project development pointed out that, more than just a project leader, the manager must combine key competences for a successful achievement. Therefore, this professional must be a goal-oriented and tenacious person, exhibiting suitable technical knowledge on the test methods as well as good interpersonal and negotiation skills. Those attributes are fundamental to tackle all issues related to the complex process of ABNT NBR ISO/IEC 17025 accreditation. This way, a QMS fitted to the institution's culture must be built.

In spite of the general quality leap brought by the implementation of an ABNT NBR ISO/IEC 17025 QMS, any postulant to accreditation must be aware that quality requires a sometimes-significant capital expenditure. The discussion on the ideal quality level to satisfy the customer's needs at its lowest cost isn't recent [3] but must be considered by the quality manager in conjunction to top management on the planning phase of the accreditation process. At LAPOC, it was defined that research projects would initially fund the accreditation process. Hence, the institution enrolled in 4 different research projects. This apparently positive aspect had as its main drawback an expense of teammate energy and time to manage those funding projects, as well as a larger accreditation scope to handle. Moreover, the progress of funding projects was not time-convergent.

In LAPOC, the same difficulties reported by Chung at al. [14] were experienced: technicians felt that documentation required excessive effort whereas technical managers were afraid of not having time (and maybe freedom) to conduct a creative analytical work. In this sense, open communication was the strategy adopted by the quality manager to handle lab staff fear of the upcoming changes. Besides, the advantages attained by QMS implementation (traceability, organization, availability of information and resources to work and positive customer feedback) were easily realized by lab personnel, keeping the team on the right track to formal accreditation.

Once an accreditation process is a project that requires extra financial input (beyond the usual lab budget), funding had to be obtained from different sources such as research agencies. LAPOC became involved with four independent accreditation projects, focusing on different extents of test methods. Although this approach increased the financial income for LAPOC, the initial accreditation scope turned into a complex endeavor for an institution without a QMS established.

Another issue to be overcome in LAPOC's QMS implementation process was the restricted manpower available for analytical work and management. This question led to a work function overlap for some employees, in a similar way described by Zapata-García *at al.* [15], as the quality manager acted as the technical manager of Analytical Chemistry lab while LAPOC's director was also in charge of the Radiochemistry lab. As a result, the implementation process took longer (3 years) than initially expected (2 years).

Moreover, the inclusion of radiation measurement test methods in the scope of accreditation constituted another challenging aspect for LAPOC. The singularities of those methods and the limited expertise in this field were reasons for that.

A key point to strengthen LAPOC's QMS efficacy were the inputs provided by internal audits. Among the four internal audits performed along the way, three of them were conducted by ABNT NBR ISO/IEC 17025 external experienced auditors. In the internal audits, some important structural faults were detected and solved in time, prior to the formal audit. However, it stands to reason that no QMS implementation will result in a perfect system at first, regardless of the efforts in the planning phase.

4. CONCLUSION

At the successful end of the accreditation process, the main learning points can be summarized as follows:

• Implementing an ABNT NBR ISO/IEC 17025 QMS on a radioanalytical lab was a project of singular nature, due to the sophisticated essence of radioanalytical work;

• LAPOC's QMS conception demanded dedication from quality and technical managers. In this project, it was observed that dispersing team energy to manage funding projects or other activities reduced its effectiveness and made accreditation a more distant target;

• Special attention should be spent on helping people to change their mindset towards accreditation, in order to promote a genuine cultural change aligned to ABNT NBR ISO/IEC 17025 requirements;

• Internal audits comprised an important tool that allows improvement opportunities on the system, especially if conducted by experienced auditors;

• The benefits brought by the implementation of a QMS boosted lab personnel confidence on their own work. They also triggered the pursuing for a natural expansion of accreditation scope to fulfil new customer needs, as accreditation is a continuous improvement process and not a goal achieved once forever, in the same way as reported by Lopes *et al.* [16].

• Good performance and reliability were important goals achieved by LAPOC as a global result of the accreditation process.

• New work concepts widespread by QMS development result in valuable knowledge to the ones involved in the project, which may be helpful to the undersized community of radioanalytical labs.

Finally, the authors fully endorse the belief that significant work is necessary to develop an ABNT NBR ISO/IEC 17025 QMS. The benefits delivered by the achievement of accreditation are worthwhile, though. Upon the successful conclusion of its accreditation project, LAPOC was made a member of the Brazilian Network of Test Method Laboratories (RBLE), thus becoming the national pioneer in the field of accredited radiation measurements [18].

ACKNOWLEDGMENT

The authors acknowledge financial support from Fundação de Amparo a Pesquisa do Estado de Minas Gerais (FAPEMIG – Process APQ-04824-10), International Atomic Energy Agency (Project BRA 9057), Poços de Caldas Department of Electricity and Distribution/ National Electric Energy Agency - Brazil (Process 01346.00019/2014-11) and Financiadora de Estudos e Projetos (FINEP) by Sistema Brasileiro de Tecnologia (SIBRATEC) project. Thanks are due to all LAPOC employees involved in the accreditation process.

REFERENCES

[1] ABNT - Associação Brasileira de Normas Técnicas/ ISO – International Organization for Standardization/ IEC -International Electrotechnical Commission. **ABNT NBR ISO/IEC 17025:2005 -** Requisitos Gerais para Competência de Laboratórios de Ensaio e Calibração**.** Rio de Janeiro: ABNT, 2005. 31 p.

[2] BAKER, M. Quality time. It may not be sexy, but the quality process is becoming a crucial part of lab life. **Nature, v. 529**, p. 456–458, 2016.

[3] GITLOW, H. S. **Quality management systems: a practical guide.** Boca Raton: CRC Press, 2001. p. 19-28

[4] ALBANO, F. M.; FAUSTINI, L. H. The influence of a quality system according to ABNT NBR ISO/IEC 17025 on the performance of Brazilian laboratories in proficiency testing in the environmental area. **Accred Qual Assur**, v. 21, p. 19-23, 2016

[5] IAEA - International Atomic Energy Agency. **Quality system implementation for nuclear analytical techniques**. IAEA-TCS-24. Vienna: IAEA, 2004. 91p.

[6] BODE, P.; HEYDORN, K.; INNES, R. W.; WOOD, R; ZEISLER, R. Basic steps towards a self-sustainable quality system and laboratory accreditation. **Accred Qual Assur**, v. 3, p. 197-202, 1998.

[7] JEROME, S. M.; JUDGE, S. M. Accreditation to ISO 17025:2005 for the Radioactivity Metrology Group of the UK's National Physical Laboratory. **Journal of Radioanalytical and Nuclear Chemistry**, v. 273, p. 353-355, 2008

[8] INMETRO – Instituto Nacional de Metrologia. **DOQ-CGCRE-008 rev. 05 - Orientação sobre validação de métodos analíticos.** Rio de Janeiro: INMETRO, 2016. 20p. Available at: <http:// www.inmetro.gov.br/credenciamento/organismos/doc_organismos.asp? tOrganismo=CalibEnsaios>Last accessed: 31 Oct. 2017

[9] BIPM, IEC, IFCC, ISO, IUPAC, IUPAP and OIML. **Evaluation of measurement data—guide to the expression of uncertainty in measurement JCGM 100:2008.** BIPM: Se`vres, 1995. 120 p. Available at: <http://www.bipm.org/en/publications/guides/gum.html>. Last accessed: 15 May 2018

[10] KRAGTEN, J. Calculating standard deviations and confidence intervals with a universally applicable spreadsheet technique. **Analyst**,. v. 119, p. 2161-2166, 1994

[11] OLIVARES, I. R. B.; LOPES, F. A. Essential steps to providing reliable results using the Analytical Quality Assurance Cycle. **TrAC Trends in Analytical Chemistry**, v. 35, p. 109–121, 2012

[12] VAJDA, N.; BALLA, M.; MOLNAR, Z.; BODIZS, D. On the way to formal accreditation. **Accred Qual Assur**, v. 10, p. 599–602, 2006

[13] RESNIZKY, S. M.; PL´A, R. R.; JASAN, R. C.; HEVIA, S. E.; MORENO M. A.; INVENIZZI R. The experience of accreditation of an analytical laboratory at the Argentine Atomic Energy Commission. **Accred Qual Assur**, v. 10, p. 590–593, 2006

[14] CHUNG, K. H.; CHO,I G. S.; LEE, W.; CHO, Y. H.; LEE, C. W. Implementation of ABNT NBR ISO/IEC 17025 standard in a nuclear analytical laboratory: the KAERI experience. **Accred Qual Assur,** v. 10, p. 603–605, 2006

[15] ZAPATA-GARCÍA, D.; LLAURADÓ, M.; RAURET ,G. Experience of implementing ISO 17025 for the accreditation of a university testing laboratory. **Accred Qual Assur,** v. 12, p. 317–322, 2007.

[16] LOPES, I.; SANTOS, L.; PEREIRA, M. F.; VAZ, P.; ALVES, J. G. Implementation of the quality management system at the Laboratory of Radiological Protection and Safety (LPSR) in Portugal. **Accred Qual Assur**, v. 19, p. 355–360, 2014

[17] LOPEZ, M. A.; MARTI,N R.; HERNANDEZ, C.; NAVARRO, J. F.; NAVARRO, T.; PEREZ, B.; SIERRA, I. The challenge of CIEMAT internal dosimetry service for accreditation according to ISO/IEC 17025 standard, for in vivo and in vitro monitoring and dose assessment of internal exposures. **Radiat Prot Dosimetry**, v. 170, p. 31-34, 2016.

[18] INMETRO – Instituto Nacional de Metrologia. **LAPOC Accreditation Scope**. Rio de Janeiro: INMETRO, 2017. 4p. Available at: <http://www.inmetro.gov.br/laboratorios/rble/docs/CRL1225.pdf>. Last accessed: 15 May 2018