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CHALLENGES IN THE IMPLEMENTATION OF A QUALITY MANAGEMENT SYSTEM APPLIED TO RADIOMETRIC ANALYSES

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ABSTRACT

The concept of quality in laboratories has been well established as an essential factor in the world of analytical techniques and the search for reliable results. Since its first version published in 1999, the ISO/IEC 17025 has been applied in the industrial and research fields, in a wide range of laboratorial analyses. However, the implementation of a Quality Management System (QMS) still poses great challenges at many institutions and companies. The purpose of this work is to expose the constraints related to the implementation of ISO/IEC 17025 applied to analytical assays of radionuclides, which was accomplished by studying the case of the Poços de Caldas Laboratory of the Brazilian Commission for Nuclear Energy. In this lab, a project of accreditation of techniques involving determination of radionuclides in water, soil, sediment and food samples has been conducted since 2011. The challenges presented by this project arise from two main? facets such as the administrative one, in which the governmental nature of the institution translates into unleveled availability of financial resources; or the organizational one, whereas QMS requires inevitable changes in the organizational culture. It is important to point out that when it comes to accreditation of analysis involving radioactive elements, many aspects must be treated with special attention due to the their very particular nature. Among these concerns are the determination of analysis uncertainties, accessibility to international proficiency studies (required by the system, yet not so commonly offered in the case of radionuclides), international radioactive sample and CRM transportation, the study of parameters on the validation of analytical methods and finally the lack of documentation and specialized personnel regarding quality issues of radiometric measurements. Through an effective management system, the institution is overcoming these challenges, moving toward the ISO/IEC 17025 accreditation.

1. INTRODUCTION

The association of reliability and excellence to the globalized and ever demanding world of products and services has moved from what could have started as a desire to unarguable necessity. The search for quality is not quite recent, once it can be traced back to the 1920s (not coincidently, the assembly line era), with the publication of *The Control of Quality in Manufacturing*, by G. S. Radford [1]. As the concept progresses in time – evidenced, for instance, by the application of statistics to quality control in the 1930s and the use of quality management to boost production in postwar Japan – it becomes more and more difficult to ignore it in view of competitive markets and well informed consumers. Quality nowadays is no longer a competitive asset, as the market assumed a punitive role to organizations not compromised to offer products and services expected by their customers [2].

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Nearly a century later, the concern for quality in laboratories has been established as an essential factor in the world of analytical techniques and the search for reliable results. Since its first version published in 1999, the ISO/IEC 17025 – General requirements for the competence of testing and calibration laboratories – has been applied in the industrial and research fields, in a wide range of laboratorial analyses.

The idea of maintaining a system where information and procedures are well defined, controlled and documented is especially attractive to the nuclear field, today facing a wave of retirement of its senior professionals and experts, being therefore a great beneficiary of a philosophy that may prevent the loss of knowledge. Moreover, institutions related to the field such as analytical laboratories, which deliver results and deal with issues regarding all nuclear, have acquired a very significant role in regards to society, governments and regulatory bodies when presenting new discoveries and reporting results that could affected the lives of all [3].

With all this in mind, although this necessity has been accepted worldwide and the quality at work philosophy has been well instituted, the actual implementation of a Quality Management System (QMS) still poses great challenges at many institutions and companies, including the ones of the nuclear area. Being ISO/IEC 17025 a standard divided in two specific kinds of requirements (managerial and technical), constraints related to different aspects naturally arise [4].

The purpose of this work is to approach this reality by discussing the implementation of ISO/IEC 17025 applied at analytical assays of radionuclides in the Poços de Caldas Laboratory of the Brazilian Commission for Nuclear Energy (CNEN/LAPOC), focusing on the challenges faced by the organization in regards to this quality system.

2. THE ORGANIZATION

With a 40-year tradition, the Laboratory of Poços de Caldas (LAPOC) was inaugurated in 1974 by the Brazilian Commission for Nuclear Energy (CNEN). As a pilot plant, it was aimed at the development of technologies related to extractive metallurgical processes applied to uranium and thorium – running continuously for 14 years. Today, incorporated by the Radioprotection and Nuclear Safety Division, LAPOC develops work at different fronts, such as inspections of radionuclide associated ore mining operations, environmental monitoring of stable and radioactive species found in and around waste facilities and research projects of nuclear interest, especially related to radioactive waste.

Today the Laboratory partakes into a Quality Management System project begun in 2011, seeking accreditation through the validation of an array of techniques of chemical and radiometric analysis of environmental samples from water, soil and sediment. Combining the efforts of three internal sectors (Analytical Chemistry, Radiochemistry and Radon labs), the team works towards validation of 15 analytical methods.

3. DISCUSSION

3.1. Funding

The first challenge to any laboratory pursuing accreditation concerns overall costs of implementation and later quality control [4]. The situation may be especially critical to public organizations, which are usually highly dependent on government controlled budgets. As such organization, the Laboratory of Poços de Caldas was faced with this fundamental difficulty. The need for investments on lab updating, purchase of new equipment and reference materials, staff training, calibration services and consulting could only be met through submission of a project (designed by researchers of the institution) to a third party state level research funding agency. Although LAPOC was successfully granted the financial means to execute the project, expenses associated with maintenance and continuous improvement of the system virtually never cease (and may actually keep growing by the further adding of new assays to an accredited scope). Therefore, management of finances may easily become a challenge of its own – one of constant presence.

3.2. Management

When quality is envisioned as a result of an operational policy (management), other than just the application of techniques [1], the system demands a highly capacitated and involved manager, who is able to lead, motivate, gather efforts and delegate responsibilities throughout the entire process. These qualities become even more important when a deep change of attitude on the part of the staff must take place in the daily routines of the organization. To meet these essential aspects, the role of manager was assigned to a researcher with not only previous experience on quality systems field, but with a high degree on the field of Chemistry (which was an asset to the technical side of the endeavor) and personal / leadership skills that promoted the much needed initial involvement of collaborators at all levels of the Laboratory.

3.3. Organizational culture

The change of the organizational culture of a workplace may possibly be the hardest intangible obstacle to overcome as well as one of the longest processes the entire body must endure when it comes to implementing a quality system. Factors such as deep-rooted working habits, lack of pertinent information, resistance to change and loss of motivation at work are common at many organizations today, as they were part of the reality of the Laboratory in question. With these facts considered, the management action plan used to tackle this classical threat was based on an early involvement of the entire staff (in especial the technicians, who were to be responsible for executing the analytical methods). The atmosphere of the major changes that would take place at LAPOC was created early in the process, consisting on the promotion of events such as lectures and training courses on Quality Management Systems (QMS), ISO/IEC 17025, its concept, history and requirements. The efforts included frequent internal department meetings as well as involvement on an individual level during the development of operational procedures. The decision to consult the workers during the design of procedures that were pertinent to their own work routine was a successful empowerment strategy so much for involvement as for building the technical aspect of the system.

3.4. Human resources

As part of the reality of many Brazilian public institutions, the lack of human resources may hinder such projects, as QMS inevitably demand a high amount of work which must be distributed among collaborators. The detailed and precise nature of quality development and maintenance, as well as management, should not be concentrated on the shoulders of a few if the system is to be implemented successfully. Another aspect of human resources pertains to capacitation of internal auditors – essential to accreditation by a national authority. Therefore, the elevated retirement rate of LAPOC's workforce in the upcoming years can be appointed as a critical problem to the Laboratory – a situation not yet solved.

3.5. Consulting/Documentation

The process of documentation (writing technical and managerial procedures and designing documents and forms) must start early in the project, as it comprehends a heavy work load. Here, a consulting service may enter as a valuable ally, aiding at the development of an activity that is frequently challenging for its complexity, extent and detailing. The goal of LAPOC in that sense was to find a consultant fit for the organization's reality, which translated into experience with governmental institutions, good availability (geographically accessible) and financial suitability. A knowledgeable professional with all the desired requisites was hired, attending to the management team throughout this entire phase, in addition to instruct norm interpretation and auditing courses for all collaborators.

3.6. Technical aspects

The technical sphere of the implementation project (associated to the competence of staff, methodology and testing/calibration of equipment) deserves full attention right from the beginning of the process. As a study involving Brazilian accredited laboratories has indicated, the most difficult requirements to be applied are the items *validation of methods*, *estimation of uncertainty of measurement* and *assuring the quality of test calibration results* [3], which are, no surprisingly, critical to quality control. At LAPOC, the aspect of calibration was a source of concern that persisted for a considerable amount of time. As it would make sense within the entire philosophy here discussed, the organization would only hire equipment calibration services from ISO 17025 certified providers. Ironically, it is unfortunate to point out that not all companies live up to their "certified status". As a result of this type of situation, the Laboratory suffered quite a few drawbacks such as damaged equipment returning from these services as well as internal difficulties in carrying out routine scale validation procedures due to poor calibration. This example elucidated the need for careful consideration when associating internal quality to external services. The matter was only solved when the management opted for a change of calibration company and hired an expert who provided training on the subject.

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3.8. Radiometric methods

When it comes to methodologies involving the analysis of radionuclides, some critical aspects of validation pose great challenges to laboratories seeking accreditation. One important element to be assessed is the estimation of uncertainty. In addition to the lack of a standard process to calculate this parameter, the very particular nature of radioactive species contribute to an unusual behavior (when compared to other chemical elements), rendering this estimation process an even more rigorous treatment. At LAPOC, the efforts included the careful study of the calculation process provided by the software of the measuring equipment (gamma ray spectrometers) and manual verification of the above estimation method by researchers with expertise on this area.

Another constraint commonly faced by nuclear laboratories relates to proficiency testing. As a requirement of the norm, and a means of confirming competence in analytical procedures, intercomparison exercises at international level bring even higher credibility to the organization. However, these exercises are not yet commonly offered for radionuclides analyses today. This lack of variety in the field of intercomparison becomes a negative aspect of analytical method validation in the nuclear field. Another issue is the lack of ISO/IEC 17043:2010 [6] accredited providers of proficiency testing schemes for radiometric measurements.

The nuclear institutions seeking accreditation face yet other limitations that are pertinent to their area, such as the unavailability of required certified reference materials (such as ISO Guides 34), in the case, again, of radionuclides. As a real, tangible obstacle to the process of validation of methods, the laboratory may have to find not very satisfactory alternatives in order to comply with the requirements. Finally, it can be pointed out that an even more general challenge persists to these institutions, which is the shy amount of references in literature related to the validation of radiometric methodologies.

4. CONCLUSIONS

By taking into account all management and technical aspects elucidated in this study and by looking closely at the very core of quality concepts, it becomes clear that the efforts towards

establishing and maintaining a Quality Management System is an ever continuous process - one that constantly demands careful attention and presents opportunities for improvement. The case of the Poços de Caldas Laboratory of the Brazilian Commission for Nuclear Energy well exemplifies the overall situation today faced by many laboratories. Despite all the constraints presented, this Laboratory overcame major challenges as it is moving towards ISO 17025 accreditation by the National Institute of Metrology, Quality and Technology (Inmetro).

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