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Evolution of Quality Management System at the Ruđer Bošković Institute

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***Abstract* – Requests for laboratory accreditation according to the ISO/IEC 17025 standard have become more and more frequent, both to commercial and scientific laboratories. Although Ruđer Bošković Institute (RBI) is a scientific institute whose primary role is scientific research, it also provides professional services to public/customers. Traditionally, these services were not expected to be accredited. However, customers' needs changed and the need for accredited services provided by the RBI's laboratories emerged. Therefore, the need for quality management system (QMS) complying with the ISO/IEC 17025 standard's requirements occurred at RBI. Development of the QMS at Ruđer Bošković Institute has been presented from different perspectives, long-term and short-term, and the time needed for its development was given in years, or working hours where possible. Its evolution in phases, from the initial idea through establishing and implementation of different QMSs in individual laboratories to establishing and implementation of the uniform QMS at the Institute level applicable to all RBI laboratories preparing for accreditation, is presented. The longest phase was the first phase of the awareness development and the emerging of the idea for the need of QMS and laboratory accreditation. The first critical point was the necessity of the first laboratory QMS and obtaining of the first certificate of accreditation in 2008. The second critical point was in 2015 when favourable conditions for establishing the QMS at the RBI level were met and the uniform QMS was established and its implementation began. Validity of the RBI's uniform QMS was confirmed in 2017 when the first laboratory obtained accreditation based on this system. Altogether, approximately 20–25 years were needed from the initial idea to proven successful application of the uniform RBI's QMS. At RBI, only selected commercial services are subjected to accreditation, while flexibility needed for scientific research is maintained. The regulator's and large customers' requests for accredited services were the principal motivation for QMS establishing and its implementation and, accordingly, for laboratory accreditation.**

Keywords – Accreditation, ISO/IEC 17025, Public research institute, Quality management system (QMS), Testing laboratory.

I. INTRODUCTION

Primary roles of research institutes and higher education institutions are scientific research and education, while professional services and consultancies to public, industry, governmental agencies, and other society sectors are secondary. However, the aspect of professional services is becoming increasingly important and demanding in scientific laboratories providing testing and calibration services due to customers' requirements. Parallel to usual requirements regarding service or product characteristics, scientific laboratories are faced with additional requirements regarding implementation of quality management system (QMS). In the case of testing and calibration laboratories, a QMS according to the ISO/IEC 17025 international standard is expected. Quality management or quality assurance systems according to the ISO 9001 standard or Good Manufacturing Practice (GMP) may be expected as well. These additional requirements may pose significant difficulties to scientific laboratories due to specifically flexible manner of work in scientific research as opposed to highly ordered and, sometimes, rather routine work for services provided in accordance to the QMS and a related international standard [1]. Additionally, laboratories in one research institute or a higher education institution often cover various areas of research and expertise making it even more demanding to establish a uniform QMS applicable to all required laboratories. It should also be taken into account that quality and the QMS are not considered a priority in most scientific organizations. Only approximately 20 % of the total number of accreditations for testing and calibration laboratories in Croatia are accreditations granted to laboratories in the science and higher education system [2]. It is, therefore, in many cases difficult to introduce a QMS in research institutes' and higher educations' laboratories. Consequently, establishing and implementing a QMS in a scientific laboratory, organization, or in a part of organization is a very laborious and time-consuming

process.

From this, some questions arise: How to establish and implement a QMS in a scientific or higher education laboratory?, How much time is needed to establish and implement a QMS in a scientific or higher education laboratory?. To answer these questions, an example from Ruđer Bošković Institute (RBI) is presented. It is a public scientific institute, the largest scientific institution in Croatia with approximately 900 employees, of which more than 500 work in the areas of natural, biomedical, technical, biotechnical and biotechnological sciences [3]. The RBI's example is not intended to serve as a guide for other scientific/higher education laboratories, since each laboratory works in different circumstances and adapt to them. The aim is to present the RBI's experience in order to give an insight in QMS establishing and implementation in the context of scientific institution. The purpose is to realistically present the amount of effort, perseverance and patience needed to establish and implement a functional QMS at an institute/organization level in order to help other organizations avoid unrealistic expectations. Phases of QMS evolution and its implementation are presented, some critical points and difficulties are discussed and both long- and short-term development of the QMS and its application at the laboratory and the Institute levels are shown.

II. RELATED RESULTS IN THE LITERATURE

Numerous authors from different types of institutions, including science and research laboratories, reported their experience with establishing and implementation of the ISO/IEC 17025 standard [4-10] as well as ISO 9001 and ISO 15189 or their unification and integration in one system [11-13]. Some of them are presented at a laboratory level, concentrating only on the operational phases of establishing and implementing the QMS and obtaining the certificate of accreditation [4, 6, 8, 9]. It was found that laboratories providing tests/calibrations and working in the area of research and development and/or teaching needed two to eight years to establish and implement a QMS and to be granted a certificate of accreditation. Other authors presented an evolution of QMS at an institutional level [5, 7, 10, 13], which included strategic decisions concerning several laboratories. However, data on the long-term development of QMSs are scarce. On the other hand, unification of already existing QMSs according to different standards took just nine months in the case of Department of Public Health Laboratories in Israel, after all interested parties agreed to it [13]. Some laboratories used help from consultants in the process of establishing and implementing a QMS, which proved very useful or even essential in some cases [6, 8, 9, 11].

Laboratories and their institutions faced various difficulties in the process of establishing, implementation or unification of QMSs such as: resistance from the personnel, lack of financial resources, personnel, time, institutional support or quality related knowledge, and reconciling scientific and commercial work [1, 5, 8, 9, 12, 13, 14].

III. DESCRIPTION OF THE METHOD

Development of RBI QMS is shown in both long- and short-term contexts (from decades to years and months) and from a single laboratory level to the Institute level. It is divided in phases on a yearly basis. Working hours (or months) for some phases or tasks are also given where possible. This was the case when only one person was responsible for execution of activities and working hours could be easily recorded. Working hours included analysis of ISO/IEC 17025 standard's and other relevant documents' requirements, QMS documentation preparation and its implementation, holding of educations and creation of systematic archives (both in paper and electronic). Preparations for educations, forms functionality testing and unplanned meetings and consultations were not included in working hours. Where precise working hours regarding the QMS were not recorded, estimates based on available data were given if possible. QMS concept and its documentation hierarchy are also presented. The extent of QMS documentation from different phases is compared as well.

IV. RESULTS AND DISCUSSIONS

Development of RBI QMS according to ISO/IEC 17025 is presented through different phases.

Phase I: Awareness development (1990s–2007)

The beginning of this phase is not clear, but it can be placed in the 1990s when the idea of a possible need for accreditation started to emerge in only one or few laboratories due to customer's suggestions. Since, at that time, accreditation was unknown at the RBI, some time was needed to understand and accept the idea. The difficulty was even greater, considering that resistance to accreditation is not an isolated behaviour in scientific community [8, 9]. Taking this into account and the fact that accreditation was not yet strictly demanded, but only suggested, from the customers, this phase was the longest one of all phases. It lasted 10 years or more. However, it is important that the idea of accreditation was finally understood and accepted at a laboratory level, representing the first step towards the laboratory/RBI QMS. Some attempts of establishing a single laboratory QMS were undertaken in this phase, but the system was never completed and implemented.

Phase II: Accreditation in individual laboratories – non-unified QMSs (2008–2012)

The first critical point, which designated transition to phase II, was a strict demand from customers for accreditation in a defined deadline. This left no space for

inactivity in concerned laboratories and forced them to establish and implement a QMS the best they could and knew. Since both time and personnel knowledge on accreditation/quality were limited, external consultant was hired for help and guidance. The first laboratory to obtain accreditation was the Laboratory for Radioecology (accreditation granted in 2008) [3], which produced the QMS documentation in just few months. It was followed by the Secondary Standard Dosimetry Laboratory (SSDL, accreditation granted in 2009) and Division of Radiation Protection (DRP, accreditation granted in 2012) [3]. Consultant's services were used in LRE even after accreditation was granted (until June 2011). These three laboratories developed separate QMSs covering the whole ISO/IEC 17025 standard, which means that the QMS documentation was duplicated.

The main characteristic of this phase is establishment and implementation of non-unified and unconnected QMSs in different laboratories. It is important because the foundations of the future RBI QMS were set then in LRE, although not even the idea of a joint RBI QMS existed at the time. The QMS documentation structure was defined and it was generally maintained throughout subsequent phases. The structure was hierarchical, encompassing the quality manual (QM) as the highest-level document, followed by standard operating procedures (SOP), working instructions (WI) and forms (F). Documents and records were retained in paper and electronic form, but it was not consistently archived. All mandatory and relevant policies and organizational scheme were given in the laboratory quality manual. The laboratory quality manager and his/her deputy were appointed by the RBI director.

Phase III: Transitional phase (2013–2014)

This phase refers to redesign of the LRE's QMS and its subsequent review and validation. Use of the existing LRE's QMS (2008–2012 period) showed that the system was chaotic and incomplete in some situations, which caused difficulties in everyday work and acted as a source of nonconforming work. Therefore, the laboratory quality manager proposed a QMS redesign to meet the laboratory needs. It was accepted and, at the beginning of 2013, the quality manager started with redesign, which included transformation of some processes as well as of the whole QMS documentation. All existing documents, from quality manual to forms, were thoroughly studied and reworked to fulfil all ISO/IEC 17025 standard requirements and to satisfy the needs of everyday work. Useful parts of documentation were used for new documents, while others were removed. Some documents were withdrawn from use, many were merged in one document, revised and supplemented and some completely new documents were prepared in order to cover all requests of the ISO/IEC 17025 standard. External documents were checked as well (60–70 documents). All missing documents were acquired and all documents were studied, implemented in new documentation, labelled, registered and archived. 4.5 months (954 working hours) were needed to complete the QMS documentation and another 3.5 months (493 working hours) to implement this documentation. Implementation encompassed preparation of records, establishing systematic and easily utilizable archives (in paper and electronic), change of laboratory practices where necessary and training of personnel. No negative impact of this redesign and of new QMS implementation was observed on the ongoing processes and activities. The QMS redesign resulted in significant reduction of QMS documentation volume, while its applicability in laboratory activities was significantly improved because the whole system was aligned with the laboratory work. Summary of the LRE QMS documentation reduction is given in Table 1.

Table 1. LRE QMS documentation reduction after redesign in 2013.

Parameter / Comment	Reduction
Number of document pages, without Fs / QM+SOP+WI	39 %
Number of documents, without Fs / QM+SOP+WI	58 %
Number of forms / There were 15 forms for test reports only. They were replaced with 2 fully functional forms for test reports.	26 %
Number of all documents / QM+SOP+WI+F	37 %

However, it should be noted that not all documents were reviewed and revised and that some parts of the LRE QMS were not redesigned. These parts refer to technical activities concerning test methods for which the laboratory quality manager was not responsible and the responsible persons refused to review processes and documents under their responsibility.

Management review was conducted after new QMS was implemented in LRE and no significant deficiencies were found. Additionally, the whole redesigned system was reviewed in 2014 to make the final adjustments and controls. It took additional 6.5 months. Finally, the validity of this transformed QMS was confirmed by the national accreditation body and the interested customer. Both parties were satisfied with the system.

Phase IV: Establishment and implementation of joint RBI QMS (2015–2017)

The second critical point in RBI QMS evolution happened in 2015 when favourable conditions for its establishing were met: the growing and urgent need for accreditation at RBI, available personnel with knowledge about accreditation/quality and, most importantly, support of the RBI director. The idea of a joint RBI QMS appeared

several years earlier, but the circumstances were not favourable.

Due to urgent need for accreditation in the Laboratory for Physical Chemistry and Aquatic Systems (LPCAS), it was agreed with the RBI director that the best approach would be to establish a joint RBI QMS and implement it in LPCAS by August 2015 and in all future laboratories seeking accreditation. RBI quality manager was given a task to establish a joint RBI QMS and to help the LPCAS with QMS implementation and accreditation application. A new concept of laboratory QMS consisting of two parts was adopted: joint RBI QMS as a general (non-specific) part applicable to any RBI laboratory and specific laboratory documentation (SD) covering specific laboratory activities or processes as a second part. Only the two parts combined form a complete laboratory QMS. This concept is shown in Fig. 1.

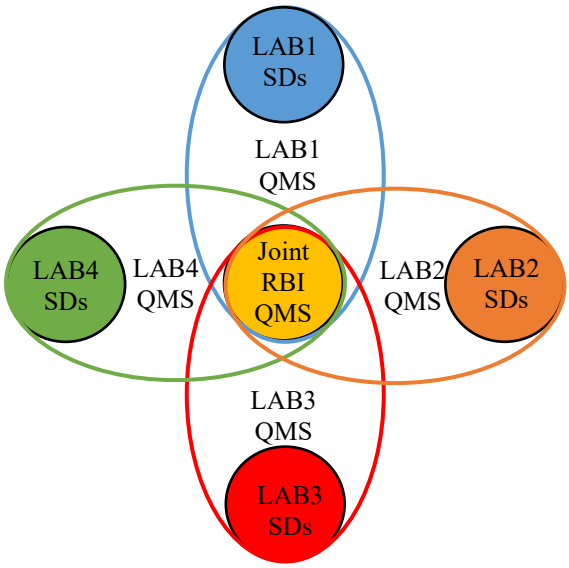

Fig. 1. Concept of the laboratory QMS that includes the joint RBI QMS and specific laboratory documentation (SD); LAB – laboratory

Laboratories may prepare supplements, which are type of SDs, to RBI documents if they carry out some additional practice to that presented in RBI QMS documents. This additional practice must not be in collision with RBI practice. The hierarchy of documentation remained the same (QM, SOP, WI, F), but now it was applied at two levels: institute and laboratory. Institute quality manager is responsible for the institute level documentation and laboratory personnel for the laboratory level documentation. Any changes in the institute level documentation are communicated to the laboratory quality manager who implements them at the laboratory level. This way, duplication of documentation is avoided and the extent of documentation to be prepared and maintained by laboratories is significantly reduced. An example of such laboratory workload reduction is given by comparing the LRE QMS in its redesigned form with its possible transition to use of the joint RBI QMS in terms of SOPs and WIs preparation (Table 2.).

Table 2. Reduction of laboratory workload (SOPs and WIs preparation) by using the joint RBI QMS. LRE QMS accessed 21 January 2016, RBI QMS accessed 30 August 2017.

Need for supplement to RBI QMS document in laboratory	Fraction of RBI QMS documents
Direct application of document (no supplement necessary)	44 %
Minor laboratory supplement to RBI QMS document, if needed	12 %
Minor laboratory supplement to RBI QMS document necessary	40 %
Major laboratory supplement to RBI QMS document necessary	4 %

Additionally, 75 % of LRE forms could have been replaced by RBI QMS forms and immediately used without any restrictions, 8 % of LRE forms should have been prepared from already prepared RBI QMS templates and only 17 % should have been prepared completely in LRE because they refer to specific, technical laboratory work. Finally, the total workload reduction for complete LRE QMS documentation preparation and maintenance could have been reduced 60 % minimum by shifting the system to RBI QMS.

The whole RBI QMS was prepared and implemented in a little bit more than four months in 2015 (203 working hours). Altogether, 122 documents in 387 pages were prepared, of which 96 forms. Establishing the RBI QMS took significantly less time than establishing and implementing new, redesigned LRE system because the RBI system was based on redesigned LRE system. The LRE QMS was reworked in such a manner that its parts applicable to the whole Institute were retained and modified and parts specific for the laboratory were removed. All documents were adjusted for use at the Institute level and in any laboratory. Archives (in paper and electronic) and backup for RBI system documentation were established as well. A transitional period of two years (until 30 July 2017) was agreed with the RBI director, in which the LRE, SSDL and DRP were supposed to implement the joint RBI QMS and adjust their QMSs with it. However, all three laboratories refused and they still have their own QMSs disconnected from the RBI QMS.

Parallel to establishing the RBI QMS and implementing it at the Institute level, it was implemented in the LPCAS as well. Implementation in LPCAS and its preparation for accreditation application included preparation of documents in the laboratory, adjustment of laboratory processes and activities and internal educations of its personnel. RBI quality manager held internal

educations during 5.5 months (distributed in 16 individual meetings and 44 hours). Each clause of the ISO/IEC 17025 standard was covered separately. Standard's requirements, coverage of these requirements by the RBI QMS, use of RBI QMS documentation and records needed were explained. Additional meetings or consultations were also held after these educations, when necessary.

Considering that eight laboratories from six RBI divisions expressed their interest in accreditation according to ISO/IEC 17025 standard, the RBI quality manager concluded that it would be the most efficient to hold a joint education about RBI QMS application for all interested personnel at RBI. The education was held, from November 2015 to December 2016, as a cycle of 26 presentations covering all clauses of the ISO/IEC 17025 standard and associating parts of the RBI QMS. Questionnaires were given to participants at the end of education to gain some feedback from them in order to evaluate the approach applied.

During the 2016, the Laboratory for Low-Level Radioactivities (LLLR) also started to implement the joint RBI QMS. However, only about half of the RBI QMS was implemented in 2016 and 2017 before the implementation stopped because the QMS was not a priority at that time.

Phase V: Start of accreditations based on unified RBI QMS (2017)

Although accreditation in LPCAS was found urgent in 2015, application for accreditation was submitted only in January 2017. This marked a beginning of a new phase, because the joint RBI QMS and the concept of two-part laboratory QMS were to be validated by an external body, i.e. the national accreditation body, and accreditation applications started based on the unified joint RBI QMS, which was the purpose of this QMS. The validity of the concept and functionality of the RBI and LPCAS QMSs were confirmed by the assessment for initial accreditation performed by the national accreditation body in the LPCAS. LPCAS was granted the initial accreditation in October 2017 making it the first RBI laboratory to obtain accreditation using the joint RBI QMS.

Phase VI: Harmonization of RBI QMS with the ISO/IEC 17025:2017 edition (2019–2020)

Once established and implemented, each QMS must be maintained. With the edition of the ISO/IEC 17025:2017 standard, it meant that the whole RBI QMS and the LPCAS QMS must be harmonized with the new standard edition to fulfil all its requirements. The RBI quality manager had the task to harmonize the RBI QMS and the LPCAS quality manager to harmonize the laboratory SDs and implement changes into laboratory practice. Harmonization included examining the new standard to detect new requirements, QMSs documentation review and revision, internal educations for LPCAS quality manager about new or changed requirements of the standard, about revised RBI QMS documentation and about risk/opportunity assessment, and, finally, application of revised documentation in LPCAS and at RBI. This was executed from October 2019 to April 2020 in a very intensive pace (approx. 1000–1500 working hours) because the whole documentation structure was changed to follow the structure of the standard. However, the hierarchy of documentation remained the same, with one change. Quality manual was removed from the QMS, both RBI and laboratory, since the 2017 edition of the ISO/IEC 17025 standard no longer requires one. The rest of documentation hierarchy remained unchanged at both RBI and laboratory levels. All relevant information contained in previous QMs were incorporated in adequate SOPs or presented in records. The most significant, and the most feared by the laboratory personnel, novelty in the new edition of the standard was risk assessment. Although not required by the standard, a joint RBI QMS SOP for risks and opportunities and associated forms were prepared to facilitate the risk and opportunity assessment and because the RBI quality manager had the needed knowledge, while the LPCAS quality manager had no experience regarding risk assessment. A simple process encompassing risk/opportunity identification, analysis, evaluation, treatment and efficiency evaluation of undertaken actions was established. Lists of risks and opportunities were prepared as well as plans and actions for their treatment. Responsibilities and deadlines for execution of actions were assigned. No assessment methodology is chosen at the RBI level. It is left to laboratories, but for the beginning, simple tools (e.g. SWOT analysis) were suggested during training until some experience is gained in practice. At the end, risk and opportunity assessment proved not to be complicated, it was easily understood and applied and well accepted in both the LPCAS and later in the LLLR. As a result of successfully revised RBI and LPCAS QMSs and their implementation, LPCAS submitted an application for assessment by the national accreditation body according to the ISO/IEC 17025: 2017 standard in April 2020.

In the meantime, new circumstances have arisen for the LLLR. Accreditation now became an imperative due to customers' demands. Therefore, the existing partial laboratory QMS was urgently transitioned to newly harmonized joint RBI QMS and the missing parts of the LLLR QMS were established and implemented using the RBI QMS as a basis. This was executed from May to July 2020 in order to submit the application for the initial accreditation by the end of July, which was achieved.

Validation of the harmonized RBI QMS and the laboratory QMSs has been done internally by internal audits. They yet has to be validated externally by the national accreditation body. It is expected to be successful.

V. CONCLUSIONS AND OUTLOOK

A bottom-up QMS development at the scientific

institute is presented in six phases. It is obvious that its development is not straightforward and planned, but that it reacted to circumstances and evolved accordingly. It is, therefore, not surprising that it took 20–25 years from the initial idea of accreditation to successful implementation of the joint Institute QMS. Phase of the awareness development (phase I) lasted the longest. It could be attributed to the fact that commercial services, and accreditation accordingly, are not a priority in a scientific institution. Phase II designated final acceptance of accreditation in some laboratories, triggered by customers' requests. The motivation for accreditation were always firm customers' requests. The following phases were rather intensive (especially phases III, IV and VI), when necessary changes in the QMS and their implementation were performed in months of intensive work. It can be stated that these activities were conducted in campaigns. It is important that only commercial services be accredited, while scientific flexibility is maintained. Contrary to many opinions, accreditation and science do not have to be in conflict. Just the opposite, they can support each other.

Support and determination of management are extremely important for the QMS establishment and implementation. These are the heads of laboratories at the laboratory levels and the RBI director at the institute level. They have a significant role in overcoming personnel resistance to accreditation and in making strategic decisions in accordance with the Institute vision. One of such decisions is to or not to implement the joint RBI QMS in all accredited laboratories (old and new ones). Implementation of joint RBI QMS in all accredited laboratories with no exceptions might be the next (seventh) phase in RBI QMS evolution. It is expected that a lot of time will pass before this phase begins, and, if it begins, it will surely take a long period to execute all activities properly. In the meantime, the existing RBI QMS must be maintained and improved to serve its purpose. With the rising number of accredited laboratories at the RBI, it is expected that accreditation and quality will be more understood and accepted at the whole RBI.

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