Challenges for the integration of ISO/IEC 17025

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Resumo:
Os laboratórios que prestam serviços de calibração de instrumentos de medição e ensaios de equipamentos, devem implementar um sistema de gestão de qualidade baseado na norma *ISO/IEC 17025*. A sua acreditação leva ao reconhecimento das competências técnicas e qualificações necessárias à garantia da obtenção de resultados válidos e fiáveis. Todavia, hoje as organizações estão sujeitas a um variado leque de outras exigências que tornam vital a implementação de um sistema integrado de gestão (qualidade, ambiente e segurança) para o seu bom desempenho. O presente trabalho foi desenvolvido numa entidade acreditada pelo *IPAC* – Instituto Português de Acreditação – para a prestação de serviços tanto ao nível da calibração de instrumentos de medição como para a realização de testes quer em diversos equipamentos elétricos (eletrodomésticos, comerciais e industriais) quer no âmbito do comportamento mecânico de diversos tipos de componentes estruturais, com vista à marcação *CE*. Inicialmente foi analisado o sistema de gestão implementado no âmbito da norma *ISO/IEC 17025*:2005. Esta análise teve como objetivo identificar quais os requisitos a implementar de acordo com as normas, *ISO/IEC 17025:2017; ISO 9001:2015 e OHSAS 18001:2007* de modo a definir
estratégias conducentes à atualização do sistema existente. Sendo um estudo de caso, limitado à realidade de um laboratório de ensaios e calibração, os resultados do presente trabalho são um contributo para a implementação de um sistema integrado de gestão em instituições idênticas, acreditadas pela norma *ISO*/*IEC* 17025, pretendendo ser ainda, um auxiliar para a transposição para a nova versão da *ISO*/*IEC* 17025:2017.

Palavras-chave: *ISO*/*IEC* 17025, *ISO* 9001:2015, *OHSAS* 18001:2007, Sistemas integrados de gestão.

Abstract:
Laboratories providing metrological calibration and equipment testing services shall implement a quality management system based on *ISO*/*IEC* 17025 standard. Such accreditation leads to the acceptance of the technical competencies and qualifications required to ensure the obtaining of valid and reliable results. However, organizations are presently subject to a wide range of other requirements making think over the implementation of an integrated management system (quality, environment and safety), which is vital to ensure good performance.

Present work results are coming from a study performed in an entity accredited by the *IPAC* (Portuguese Accreditation Institute) for the provision of services related to either metrological calibration or to performing several types of tests. Aiming to make the *CE* marking, the testing laboratory is geared to perform tests on electrical equipment (appliance, commercial and industrial holds) as well as on mechanical behaviour of several types of structural components. Initially, the management system was analysed under *ISO*/*IEC* 17025:2005. In order to understand the strategies leading to the implementation of an integrated system, were identified the requirements to be implemented according to *ISO*/*IEC* 17025:2017. *ISO* 9001:2015 and *OHSAS* 18001:2007. As a case study, limited to the reality of calibration and testing laboratories accredited by *ISO*/*IEC* 17025:2005, the results of present work can contribute for the update of the accredited system according to the new version of *ISO*/*IEC* 17025:2017 or to the implementation of an integrated management system in identical institutions.

Keywords: Integrated Management System, *ISO*/*IEC* 17025, *ISO* 9001:2015, *OHSAS* 18001:2007.

1. Introduction

Calibration and testing laboratories provide important services to industry/markets and consumers. Calibration and testing laboratories in order to demonstrate that they carry out their activities in an impartial, independent, and technically adequate manner, must be accredited according to *ISO*/*IEC* 17025 (Papadakis, Krokos and Trapalis, 2017). *ISO*/*IEC* 17025 is an "Accreditation" standard authorizing the laboratory to issue "Certifications" *i.e.* recognizing the qualifications and capabilities of laboratory to issue authentication certificates for the calibrations and tests performed. The certification and accreditation of management systems are activities differing in relation to the objectives and their respective references. According to *ISO* 9000, the certification (of management systems, products and people) is one of the activities of conformity assessment. On the other hand, accreditation is the recognition of the technical competence to perform conformity assessment activities, according to the same standard (Barradas and Sampaio, 2013).

ISO/*IEC* 17025 (*ISO*/*IEC*, 2005) is specifically addressed to relevant aspects related to laboratory skill to produce precise, accurate test and calibration data, including:

- ↓ Technical competency of staff;
- ↓ Validity and appropriateness of measurement methods;
- ↓ Traceability of measurement and calibration to national standards;
- ↓ Appropriate application and measurement uncertainty;
- ↓ Suitability, calibration, and maintenance of test equipment;
- ↓ The testing environment;
- ↓ Sampling, handling, and transportation of test items;
- ↓ Quality assurance of test, inspection, or calibration data.

However, customer complaints regarding both the response times and the quality of the services provided are more frequent than the expected. *ISO* 9001 (*ISO*, 2015) can relate the quality and reliability of a service possibly expected by customers from a testing service provider without evaluating its technical competence. Therefore, the assessment based on *ISO* 9001 is insufficient to guarantee simultaneously the accuracy, reliability and validity of a test, inspection, or calibration performed by an entity. Thinking in direct effect on own profitability and consequently in client satisfaction, the testing providers betake frequently *ISO* 9001 certification in addition to *ISO*/*IEC* 17025 accreditation. Having a quality management system implemented in according to *ISO* 9001 and *ISO*/*IEC* 17025, the testing providers can guarantee to customers a greater technical sensitivity and, in addition, demonstrate the own quality of services.

Privileging the making broader decisions with particular emphasis on the environmental and social implications, stakeholders require nowadays adoptions of more holistic views to guarantee the business success (Rocha, Searcy and Karapetrovic, 2007). When anorganization already has a management system such as *ISO*/*IEC* 17025 and wants to be certified by multiple standards, the integration management systems must be considered, according to Jonker & Karapetrovic (2004). This means that quality, environment, safety and other management systems are seen as different forms of the same system (Jonker and Karapetrovic, 2004). So, through the integration of management systems, organizations can provide customers with efficiency of their services and ensure the efficiency of their resources, bringing multiple benefits such as "internal cohesion benefits", "benefits related to best use of the systems", "strategic organizational benefits" and "system performance benefits" (Simon, Karapetrovic and Casadesús, 2012).

The recent version *ISO*/*IEC* 17025:2017 (*ISO*/*IEC*, 2017) now matches the newer standards such as *ISO* 9001:2015 (Tranchard, 2017):

- ↓ Adopts the same High-Level Structure as *ISO* 9001:2015, adding terms and definitions as other *ISO* management system standards;
- ↓ The risk-based thinking applied in this edition permit some reduction in prescriptive requirements and their replacement by performance-based requirements;
- ↓ A "laboratory" is clearly defined now;
- ↓ The requirements relating to impartiality, confidentiality, complaints / appeals and management systems were adopted;
- ↓ The requirements relating to "Purchasing services and supplies" and "Subcontracting of tests and calibrations" were combined;
- ↓ Increases focus on process management, with greater emphasis on producing desired outputs.
- ↓ Greater emphasis on leadership engagement.

This paper intends to show the list of requirements to be introduced in either calibration or testing laboratories, accredited through *ISO*/*IEC* 17025:2005, in order to define the strategy to implement an integrated management system or the transition to the new *ISO*/*IEC* 17025:2017.

2. Research methodology

The main objective of present paper is to evaluate the integration of management systems in laboratories (*ISO*/*IEC* 17025, *ISO* 9001:2015 and *OHSAS* 18001:2007), taking into account the opportunity introduced by the new version of 17025 standard (*ISO*/*IEC*, 2017). In order to do so, according Yin, (2018) was carried out a case study approach, descriptive, that was consisted of an applied qualitative exploratory study resulting from a fieldwork that sought through data collection in an entity, accredited by *IPAC,* to provide calibration and testing activities. To protect confidentiality, the entity name will not be mentioned.

In order to establish the validity and reliability of the case study results, multiple sources of evidence (interviews with managers and collaborators, information from reports and other documentation resources) were used (Barbour, 2002). Moreover, an active corroboration on the interpretation of data between the authors and the organization interviewed was maintained (Yin, 2018).

According to Yin (2018), the theoretical framework was supported by the literature review, carried out in the structuring phase. Initially, the *QSM* (Quality System Management) already

implemented in both calibration and testing departments with basis on the *ISO*/*IEC* 17025:2005 standard was analysed. In the data collection, semi-structured interviews were performed to the managers and collaborators of laboratories as well as the direct observation technique was considered too. In order to understand the updating process to an integrating system according to the *ISO*/*IEC* 17025:2005, *ISO* 9001:2015 and *OHSAS* 18001:2007 (*BSI*, 2007) standards, the list of requirements to be introduced to the current system was stablished. Being aware of the multiple factors to be balanced in the phase analysis, a useful category matrix was generated. In the evaluation phase, there was a disposition of evidence within the categories in the matrices, facilitating thus the definition of the strategy to be implemented.

3. Results

Interviews were performed to quality manager, to responsible for metrology and testing laboratories and staff, due to their relevance in current performance and, above all, in planning and implementing phases of the desired Integrated Management System. Those interviews was structured based on documentation analyses as well as the direct observation (as for instance, procedures, process maps and audit reports) evidencing, or not, the compliances with the requirements standard of the implemented quality system, based on *ISO*/*IEC* 17025:2005. Documented evidences were found in general accordance with the requirements stablished by *ISO*/*IEC* 17025:2005, as expected.

The studied entity intends to implement an Integrated Management System, including *ISO* 9001:2015 and *OHSAS* 18001:2007 into the currently accredited system *ISO*/*IEC* 17025:2005. Given the new revision of standard 17025, structurally approaching it to *ISO* 9001:2015 and introducing the risk-based thinking. Such system integration may be easier if it is carried out concurrently with the upgrade of the already accredited quality system.

In order to evaluate the organizational context on a risk-based thinking, a *SWOT* analysis (Table 1) was performed allowing the study of internal and external environment of the concerned entity.

The analysis shows that the entity under study should start by clearly establish a structured management philosophy in order to take advantage in market consolidation or in the business expansion, specifically exporting their services. So, *ISO* 9001:2015 is highly recommended in order to support and assist the management, considering the clients satisfaction. On the other side, the compliance of the requirements imposed by national law in terms of health and safety at work also contribute to the intended integration of the standards above mentioned (*ISO*/*IEC* 17025:2005; *ISO* 9001:2015 and *OHSAS* 18001:2007).

Table 1 – *SWOT* analysis

Strength	**Weaknesses**
Good institutional image Associative link to an IES Testing laboratory with international visibility Direct export potential in the testing laboratory - for instance CE marking; ENEC. Scope of accreditation areas Stabilized staff	The systematic and structured management philosophy is barely perceptible Absence of clear definition to the promotional strategy Absence of a specific procedure to the staff performance assessment
Opportunities	**Treats**
Growth of national exports of electrical equipment to major markets (eg the Middle East) Possibility of penetration in the Iberian market through the agreement with the LCIE Equipment calibration needs in new areas of activity - energy management; wind cluster; food safety; health and distribution of medicines Growing globalization of the testing market - Re- industrialization in the EU member states	Entities accredited only as OVM - Metrological Verification Bodies may extend their accreditations to areas of industrial metrology Possibility for large customers to use Community funds to build internal calibration capacity

Attending to the *QSM* implemented with basis on the *ISO*/*IEC* 17025:2005 a checklist was drawn up with all the necessary requirements for integration with *ISO* 9001:2015 and *OHSAS* 18001:2007. The documentation was then reviewed to understand gaps needed to be met in this checklist. Table 2 shows relationship between management requirements of those standards.

The list of requirements stablished to be introduced to the current system were basically the requirements from *ISO* 9001:2015, such as:

↓ Organizational roles;

↓ Leadership and commitment to quality management system;

↓ Scope of quality system;

↓ Quality policy and objectives;

↓ Process approach;

↓ Actions address to risks and opportunities;

↓ Planning changings;

↓ Control of documentation;

↓ Customer communications;

↓ Requirements of products and services

↓ Etc…

Table 2 –Management requirements *ISO*/*IEC* 17025:2005 vs *ISO* 9001:2015 vs *OHSAS* 18001:2007

ISO/*IEC* 17025:2005		*ISO* 9001:2015		*OHSAS* 18001:2007	
4.1	Organization	4,1; 4.4; 5.1; 5.1.1; 5.3; 7.1.3; 7.2; 7.3; 7.4; 8.1; 8.5.3;	Understanding the organization and its context; Quality management system and its process; Leadership and commitment; Organizational roles, responsibilities and authorities; Infrastructure; Competence; Awareness; Communication; Operational planning and control; Property bellowing to customers or external providers;	4.1; 4.4.3; 4.4.4	General requirements; Communication, participation and consultation; Documentation
4.2	Management system	4.2; 4.3; 5.1; 5.1.1; 5.2; 5.3; 6.1; 6.2; 6.3; 7.1; 7.1.1; 7.1.2; 7.5; 7.5.1; 8.1; 8.5.1;	Understanding the needs and expectations of interested parties; Determining the scope of the quality management system; Leadership and commitment; Quality policy; Organizational roles, responsibilities and authorities; Actions to address risks and opportunities; Quality objectives and planning to achieve them; Planning of changes; General; People; Documented Information; General; Operational planning and control; Control of production and service provision;	4.3.1; 4.3.2; 4.3.3; 4.4.1; 4.4.4; 4.4.5; 4.5.4;	Hazard identification, risk assessment and determining controls; Legal and other requirements; Objectives and programme(s); Resources, roles, responsibility, accountability and authority; Documentation; Control of documents; Control of records;
4.3	Document control	7.1.1; 7.1.2; 7.5.2; 7.5.3;	General; People; Creating and updating;		
4.4	Review of requests, tenders and contracts	5.1.2; 7.1.1; 8.2; 8.2.1; 8.2.2; 8.2.3;	Customer focus; General; Control of documented information; Determination or requirements for products and services; Customer communication; Determination of requirements related to products and services; Review of requests, tenders, and contracts;		
4.5	Subcontracting of tests and calibrations	8.2.1; 8.6;	Customer communication; Release of products and services;		
4.6	Purchasing services and supplies	7.1.3; 8.4; 8.4.1; 8.4.2; 8.4.3; 8.5; 8.5.4; 8.6;	Infrastructure; Control of externally provided products and services; General; Type and extent of control of external provision; Information for external providers; Production and service provision; Preservation; Release of products and services;		
4.7	Service to customer	7.1.1; 7.1.2; 8.2.1	Customer communication; General; People;		
4.8	Complains	8.2.1	Customer communication;		
4.9	Control of non-conforming testing and/or calibration work	6.1; 8.6; 10.1; 10.2;	Actions to address risks and opportunities; Release of products and services; Nonconformity and corrective action;	4.4.6; 4.5.3	Operational control; Incident investigation, nonconformity, corrective and preventive action;
4.10	Improvement	7.1.1; 7.1.2; 9.1.1; 9.1; 9.1.2; 9.1.3; 10.1; 10.3;	General; People; Monitoring, measurement, analysis and evaluation; Customer satisfaction; Analysis and evaluation; Continual Improvement;	4.5.1; 4.5.2; 4.5.3	Performance measurement and monitoring; Evaluation of compliance; Incident investigation, nonconformity, corrective and preventive action;
4.1	Corrective action	6.1; 10.2	Actions to address risks and opportunities; Nonconformity and corrective action;		

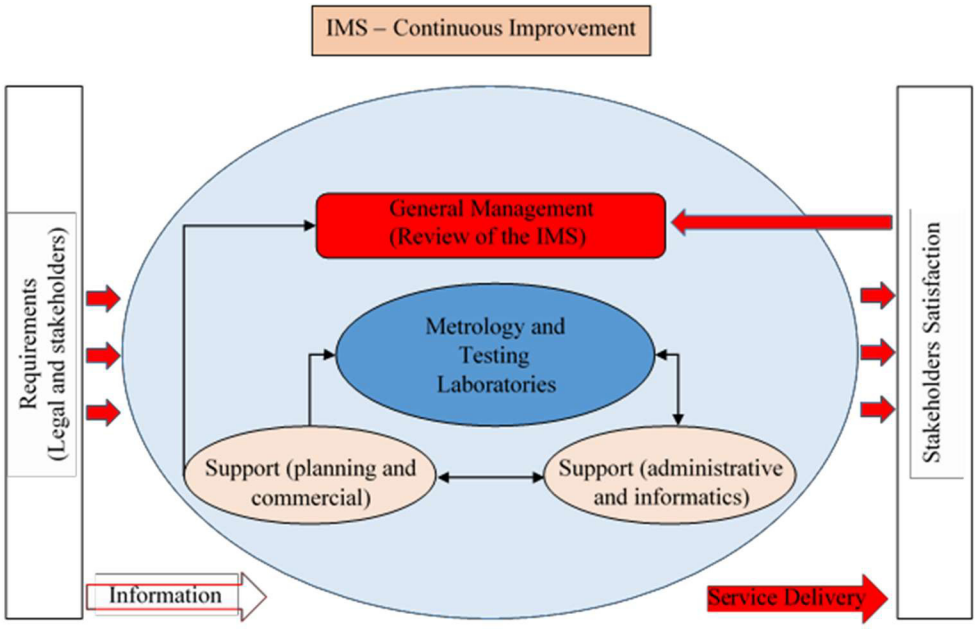
4.11					
4.12	Preventive action	7.5.2; 7.5.3; 8.5.4; 10.2; 10.3;	Creating and updating; Control of documented information; Preservation; Nonconformity and corrective action; Continual improvement;		
4.13	Control of records				
4.14	Internal audits	9.1.1; 9.2;	General; Internal audit	4.5.5	Internal audits
4.15	Management review	5.1; 5.1.2 9.3.1; 9.3.2	Leadership and commitment for the quality management system	4.1; 4.2; 4.6	General Requirements; OH&S Policy

Note: Underlined numbers identify correspondence between *ISO* 9001: 2015 and *OHSAS*18001: 2007

3.1. Strategy to be implemented

Process approach help to understand the capabilities of organization, assisting in the definition of the system objectives and actions to achieve them. On the other hand, process approach can facilitate the implementation of any management system. Organizational processes have been identified in order to establish relations between them, to operate as an integrate complete system (Figure 1)

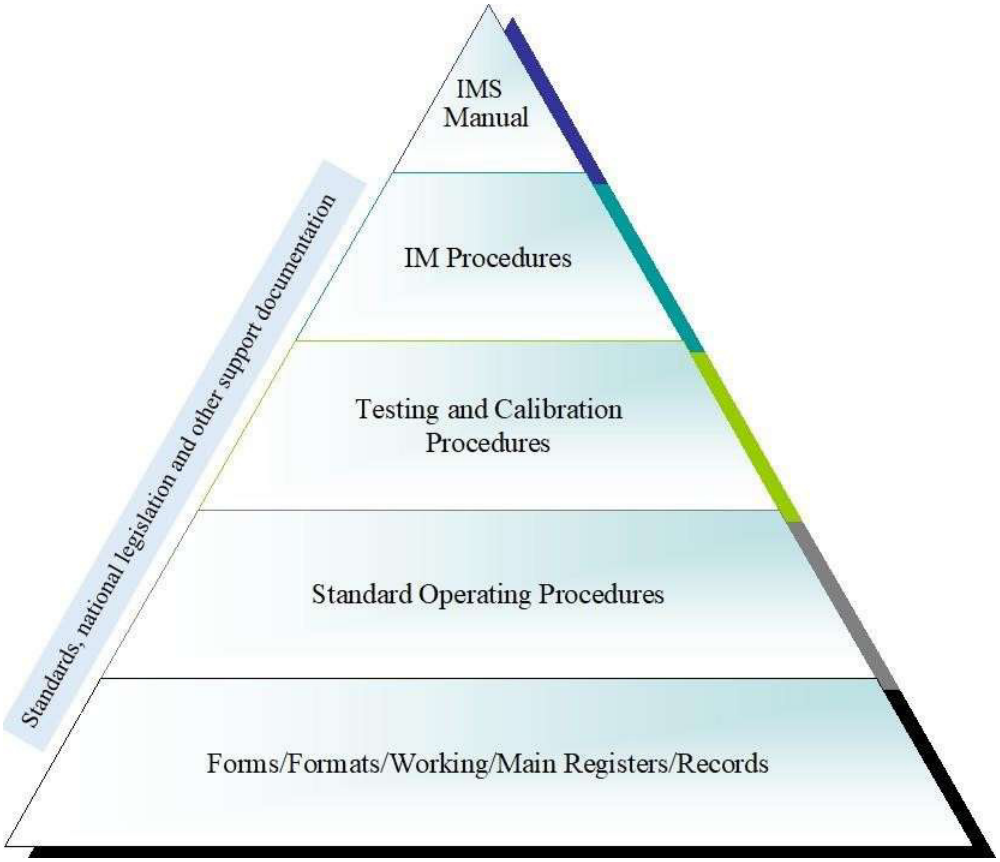
Figure 1 – Map of processes



The definition of quality policy and objectives help to support the management philosophy, allowing the establishment of values, mission and vision in order to define strategies and their implementation.

The success in the implementation of an integrated management system putting on action the strategies and tactics leading to continuous improvement within the organization, can only be achieved with an effective document management. For such purpose, the hierarchically definition of documentation is fundamental. Attempting to the actual reality of the studied entity, the suggested documentation includes Manual of Integrated Management System, Quality Policy, Quality Objectives, Control of Records, Control of Nonconforming Products, Preventive and Corrective Actions. Figure 2 illustrates the hierarchy of the suggested documentation.

Figure 2 – Hierarchy of the documentation.



Even without having implemented a management system dedicated to safety and health at work, the studied entity reveals a responsible attitude in this context confirmed by the compliance with the legal requirements. Was verified the existence of a risk assessment report in the work-stations, defining the objective, responsibilities and describing the fields of application. The probable risks in the organization were already identified and classified, according to the disability, exposure, competence and intervention levels. However, were not identified any references to prevention or control actions. With the documental system suggested, these gaps can be eliminated through compliance with the requirements of *OSHAS* 1801:2017.

With the implementation of the integrated system, the transposition to *ISO*/*IEC* 17025:2017 will be simplified as the general, structural, resources and processes requirements will be naturally fulfilled. As is clear from the previously referred, the new version of the standard promotes the risk based thinking and presents a different structure to the previous one, but most of the changes introduced are of an editorial nature. Therefore, at least, the general requirements focused on competence of the laboratories may be considered already documented.

On the other hand, the requirements related to the concepts of impartiality and confidentiality as well as the identification of risk and opportunities for continuous improvement should be subject to specific treatment, even taking into account the fulfilment of the requirements of *ISO* 9001:2015 standard. Therefore, the risk analysis as well as adequateness of the resulting actions should be reflected in the management system after the transposition process. Deciding which risks and opportunities need to be addressed the management system will become more effective. The gain in management effectiveness will be translated into the improvement of results and in the prediction of negative effects.

4. Conclusions

A study was carried out at a laboratory services entity, accredited according to *ISO*/*IEC* 17025:2005, in order to understand the actual quality management system and to define the implementation of an *IMS* - Integrated Management System based on the requirements of *ISO* 9001:2015, *OHSAS* 18001:2007 and *ISO*/*IEC* 17025.

A Correspondence Matrix was established considering the integration of *ISO* 9001:2015, *OHSAS* 18001:2007 and *ISO*/*IEC* 17025, in order to generate an *ISM* including the adequate requirements to ensure both effective management and the satisfaction of customers and own staff.

An integrated system based on *ISO* 9001:2015 results in the establishment of a well-founded management philosophy that will be translated into the improvement of results and in the prediction of negative effects.

Based on an integrated system with *ISO* 9001:2015, *OHSAS* 18001:2007 and *ISO*/*IEC* 17025:2005, the transposition to *ISO*/*IEC* 17025:2017 standard should develop without major disturbances.

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