

ISSN 2270-5658 Volume 2, Issue 1 2023

## The International Journal of Conformity Assessment

#### An Issue Dedicated to Risk Management

- How Do Accreditation Bodies Manage Risk Associated with the Accreditation Business? By L H D Bandusoma
- Comparison of International Maritime Organization (IMO) Member State Audit Scheme (IMSAS) with ISO/IEC 17000 Conformity Assessment Standards Series and ISO 19011 By Vasileios Lymperopoulos, and Sotirios Karagiannis
- Risk Management, Conformity Assessment, and Evaluation of Organizational Intelligence in Scenarios of Change and Crisis By Nicola Gigante
- 'Risky Business': A Comprehensive Risk Analysis of an Accreditation Body By Dr. George Anastasopoulos, Patrick McCullen, and Harry Makam
- Accreditation of Agri-Food and Medical Laboratories in the UEMOA Region: An Opportunity for the Promotion of Sustainable Public Health By Marcel Gbaguidi, Kafui Codjo Kouassi, and Amadou Diop
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Journal Dedicated to Testing, Inspection, Certification, and Accreditation Published by the International Accreditation Service (IAS)



#### 2 The International Journal of Conformity Assessment

The International Journal of Conformity Assessment (IJCA) is an international, peerreviewed journal for conformity assessment academics and practitioners. IJCA aims to contribute substantially to the fields of testing. inspection, certification, and accreditation by providing a high-quality medium for the dissemination of new knowledge and methods. Among IJCA's targeted audience are conformity assessment scholars, practitioners, and other interested groups and individuals. Main conformity assessment fields covered are testing and calibration laboratories, inspection agencies, product certification bodies, management system certification bodies, organizations offering certification of persons, and training course developers and providers.

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ISSN: 2770-5658



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#### ISSN: 2770-5658

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## Message from IAS President

As the world slowly emerges from the pandemic shock, and most of us are trying to adjust to the new shift in our work-paradigm as well as ensure that the "old order" continues to function within the guardrails of norms and standards, a nagging question emerges: How do we calibrate this shift without adding to the associated risks? Conformity assessment organizations, as well, have had to



quickly manage this risk-paradigm shift due to the ever-changing expectations of clients, markets, and regulators. This issue of the International Journal of Conformity Assessment (IJCA) is intended to address risk from current and prospective viewpoints.

Our intent in supporting this professional publication in the conformity assessment space is to bring critical analysis to a wider audience beyond the conformity assessment community. In my everyday interactions with regulators and consumers, it is clear that the work of the conformity assessment community is now integral to quality of life and safety in virtually all supply-chain sectors. Products and services delivered to meet customer and regulatory requirements and expectations are inherently modulated by risk-based decisions. As an accreditation body, IAS wakes up each morning with the same burden to balance risks with rewards. Our daily calling is to address these risks in practical and operational terms. I am sure you would agree that building upon this awareness and developing risk-based tools and approaches ensure those guardrails continue to be in place and guarantee our goal to deliver a safer and better product and/or service is essentially maintained.

We invite you to share your feedback on this issue and contribute to our shared efforts through this publication.

(Ley nather

Raj Nathan President, IAS May 2023

## From the IJCA Executive Editor's Desk

Dear Readers,

It is my pleasure to introduce this second issue of the International Journal of Conformity Assessment (IJCA). The journal's inaugural issue has already generated considerable interest, and we hope this current issue will further expand this interest. Launching this new journal has been a wonderful

experience, and it would not have been possible without the outstanding contributions from the conformity assessment community.

Conformity assessment costs money and takes time—amounts that need to be balanced against the applicable risks. As the nature of the product or service becomes more complex and the risks become higher, conformity assessment activities will become more complex and extensive. This second issue of the IJCA contains, among other content, selected papers related to risk management in conformity assessment. Taken together, the articles in this issue represent the wide variety of international and multi-sector uses of risk management in conformity assessment, while building on and expanding the range of themes, research areas, and activities explored in the first issue. In the pages that follow, we will explore together how risk management can be applied in the conformity assessment world.

This second issue owes much to many people. Thanks are due to our publication and marketing team, which is helping us during this initial phase of the journal, as well as to members of the editorial team who have worked hard to make this issue a reality. Their professionalism and attention to detail have made this second issue a real pleasure to see. Thanks also to all the technical reviewers who have so generously given their time and expertise to guarantee high quality. I also wish to thank the support of IAS staff for their continuous efforts to ensure the timely completion of various administrative tasks.

I hope that you will enjoy reading this second issue of IJCA and that you find these articles useful to inspire your research in the vibrant area of conformity assessment. I invite you to submit your best papers for publication.

With my kindest regards,

Dr. George Anastasopoulos Executive Editor, IJCA May 2023





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DOI: doi.org/10.55459/IJCA/v2i1/LHDB

## How Do Accreditation Bodies Manage Risk Associated with the Accreditation Business?

#### WILL ISO/IEC 17011:2017 HELP TO MANAGE THE RISKS?

By L H D Bandusoma, Deputy Director (Accreditation), Sri Lanka Accreditation Board (SLAB)

#### -ABSTRACT-

Among other factors, accreditation-focused entities operating various accreditation schemes for conformity assessment bodies are expected to fulfill requirements of international standard ISO/IEC 17011:2017 (Conformity Assessment – Requirements for accreditation bodies providing conformity assessment). Consideration should be made of legal requirements. Additional requirements of the International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC) as well as the requirements of scheme owners, such as CORSIA and GLOBAL G.A.P, etc., should adhere to the word "risk," which appears in different places of the ISO/IEC 17011:2017.

The main objective of ISO/IEC 17011:2017 is to ensure competence, consistent operation, and impartiality of accreditation bodies accrediting conformity assessment bodies. The term "risk" is defined as the "effect of uncertainty on objectives" (ISO 31000:2018, clause 3.1). Therefore, it is required to consider all possible uncertainties by accreditation bodies (ABs) and initiate suitable actions to prevent or mitigate such risks. Mandatory documents (MDs) published by the International Accreditation Forum (IAF) have addressed how accreditation bodies should consider risks when they operate specific accreditation schemes, such as EMS, FSMS, QMS, OH&SMS, etc. There are no common viewpoints published or discussed in relation to the risks associated with accreditation bodies.

This aims to create awareness of possible risks associated with accreditation bodies and share experiences with examples of cases on how accreditation bodies react to uncertain situations with respect to achieving the intended objectives of ISO/IEC 17011.

Keywords: ISO/IEC 17011:2017, Conformity Assessment Bodies (CABs), Accreditation Bodies, risk management, Riskbased Assessment Techniques, International Accreditation Forum, International Laboratory Accreditation Cooperation, ISO 31000:2018

#### Introduction

In the accreditation and conformity assessment arena, the organizational lifecycle is surrounded by risk. Often, it is too sensitive to identify the sources of risk and determine the frequency of occurrence and consequences. Meanwhile, compliance and quality are the most fundamental commitments of an organization and must be managed very sensitively. Among other factors, accreditation-focused entities operating various accreditation schemes for conformity assessment bodies are expected to fulfill requirements of international standard ISO/IEC 17011:2017 (Conformity Assessment -Requirements for accreditation bodies providing conformity assessment). Consideration should be made of legal requirements. Additional requirements of the International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC) as well as the requirements of scheme owners, such as CORSIA and GLOBAL G.A.P, etc., should adhere to the word "risk," which appears in different places of the ISO/IEC 17011:2017.

According to the ISO 31000:2018 (Risk Management Guidelines) published by the International Standard Organization, the word "risk" is defined as the "effect of uncertainty on objectives." The ISO 31000:2018 standard is a generic yardstick of product excellence, and it provides a common approach for managing risk encountered by any organization operating under any context regardless of the size, type of industry, or sector.

In the global ecosystem of accreditation of conformity assessment bodies, the organizational life cycle of an accreditation-providing institute is also surrounded by risk. However, it is too sensitive to identify the sources of risk and determine the frequency of occurrence and its consequences. Therefore, the attempt made in this document is to explore how accreditation-providing institutes could manage associated risks with their accreditation processes and comply with the ISO/IEC 17011, ILAC, and IAF requirements. The outcome of this article would be a comprehensive review of ISO/ IEC 17011:2017, ILAC, and IAF requirements and identify the risk-based approaches for providing accreditation services.

An effect is a deviation from the expected and it can be positive, negative, or both. Likewise, it can address, create, or result in both opportunities and threats. The most common and general risks associated with accreditation-providing entities are the requirements for the management of risks. These risks associated with accreditation bodies (ABs) are highlighted under different clauses of ISO/IEC 17011:2017 as shown in Table 01.

Clause number of ISO/IEC 17011:2017	Requirement	Common approaches of ABs to comply with the requirements
4.4.6	AB shall have a process to identify, analyze, evaluate, treat, monitor and document on an ongoing risk factor posed towards the key objective of impartiality. These factors are those arising from related activities and relationships associated with the internal management processes, including those associated with the client. Note: Risks to impartiality can be from ownership, governance, management, personnel, shared resources, finances, contracts, outsourcing, training, marketing, payment of sales commissions, personal friendships, or other inducements for referral, etc.	Impartiality is one of the major pillars of the credible accreditation process. Therefore, ABs pay due attention to identifying threats to impartiality through a systematic and ongoing process and management of identified threats in an unbiased manner. ABs introduce policies, controls, and procedures to avoid potential threats, and continuously review and monitor. If there are any unacceptable risks to impartiality, ABs do not provide accreditation.
4.4.7	Where any risks to impartiality are identified, document how AB eliminates such risks.	
4.4.8	Top management shall review residual risks.	
4.4.9/4.4.13	When unacceptable risks are identified and cannot be mitigated to an acceptable level, accreditation shall not be provided.	
4.5.2	Evaluate risks arising from its activities and have arrangements to cover liabilities.	Through professional indemnity insurance coverage, reserves allocated and shown in accounts. Also, through governmental ABs, sometimes by the nature of their establishment or regulations, liabilities arising from accreditation activities are covered. In addition, the terms and conditions of ABs have a requirement for conformity assessment bodies (CABs) to obtain insurance coverage or keep dedicated reserves.
7.4.6	In selecting the activities to be assessed, AB shall consider the risk associated with the activities, locations, and personnel covered by its scope of accreditation.	Incorporation of mandatory requirements from International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC) into ABs' assessment- related process and introduction of own policies and procedures to minimize risk associated with ABs' activities.
7.9.3	Scope of accreditation shall be assessed taking all factors of risk into consideration.	ABs defined their own policies on the assessment of the scope of CABs and determine the CAB's competence before granting accreditation. Application of different assessment techniques, use of EQA results, and application of mandatory documents of IAF for witnessing.
9.6	Documented procedures for identifying opportunities for improvement, identifying risks, and taking appropriate and timely actions to preempt jeopardizing of required standards.	Continuous monitoring of the conformity assessment and accreditation world to identify new developments, changes, use of the experience gained through operating accreditation schemes, feedback of interested parties, monitoring and evaluating of the performance of personnel involved in the accreditation activities and accredited conformity assessment bodies, review of all steps of the accreditation process, and conducting a preliminary review of risks.

#### TABLE 01: CLAUSES OF ISO/IEC 17011:2017 CONSIST OF REQUIREMENTS WITH THE WORD "RISK"

## Is it Adequate to Focus Only on Clauses Having the Word "Risk?"

Anyone interested solely in the objective of complying with the requirements of ISO/IEC17011 and who operates an accreditation scheme may assume that the fulfillment of minimum requirements is adequate. Such a false belief, however, will contribute towards creating an uncertain situation for the AB.

#### **Making Information Available Publicly**

At the very beginning of the accreditation process, availability of and reading, as well as understanding with clarity the rules, procedures, terms and conditions of ABs for accreditation, complaints, and appeals, etc. (clause 8.2.1-b of ISO/IEC 17011) as well as legally enforceable agreements to be entered between AB and CAB, and information about the accreditation body (clause 8.2.1-a of ISO/IEC 17011) paves the way for creating mutual understanding. This background is necessary to clear doubts that could lead to creating diverse situations associated with the term ("risk") as relevant to the accreditation process. This is equally applicable to the postaccreditation phase as well. Therefore, ABs are required to publicly avail their terms and conditions. rules, procedures, accreditation agreements, and requirements for each accreditation scheme in order to disseminate information to all interested parties to ensure transparency. The goals towards achieving this transparency should be established as gate watcher processes in every stage of the accreditation awarding undertaking.

#### **Case example on websites**

A review of the websites of accreditation bodies - those who act as full members of ILAC and IAF and regional member bodies – was done prior to developing this concept paper. This case study relates to websites and will look at the negative aspects to prevent such in actuality. What is often noted is that some websites are not user-friendly. Most documents offer information in the local language alone and translating them credibly into the global business language of English is generally not carried out. Usually, websites do not have search functions updated and prove redundant. Non-availability of up-to-date documents and information from accredited organizations is a key hindrance. Data protection issues surface when web management is outscored to external parties. Issues related to the management of backup records must be monitored carefully.

The ISO/IEC 17011:2017, clause 4.2 requires ABs to formulate a legally enforceable agreement with each CAB that covers the obligations of ABs as well as CABs, including the use of the legally protected accreditation symbol and claims. This is to prevent misuse or misleading of interested parties. Compliance with clauses 4.2 and 4.3 of ISO/IEC 17011 minimizes the risks towards ABs.

Nonavailability of Terms and Conditions for maintaining accreditation and accreditation agreement prior to application in the websites was identified as a common discrepancy of many accreditation bodies.

Clause 8.2.2 of ISO/IEC 17011 requires ABs to make available accreditation information as required in clause 7.8.1. This concerns information on suspension and withdrawal, including dates and scopes. Compliance with this requirement reduces the risk for ABs due to misuse of accreditation status. This provision is an added advantage for interested parties, including regulators, to make decisions that will help in building confidence of accredited conformity assessment services.

Relative to the introduction of the dedicated section on the official website and listing all accredited organizations (clients), scopes, and validity timeframes, making this information as freely downloadable documents/information is generally carried out by most accreditation bodies. With the current ICT developments, designing userfriendly instant search options or advanced filtering options to provide information about accredited organizations is now becoming a trend in the accreditation world. Networking of accreditation bodies with regulators and stakeholders is paramount to getting the expected outcome from accreditation services, especially for those with international recognition.

Uncertainties associated with sustainability, recognition, and expansions of accreditation activities could be minimized when ABs comply with all requirements in relation to publicly available information. This contributes to achieving the objectives in relation to the ILAC tagline: "Accreditation: Delivering Global Confidence."

## Address the Risks Associated with Impartiality and Confidentiality

Publicly available impartiality policy (clause 4.4.3 of ISO/IEC 17011) is a top management commitment towards impartiality to ensure that accreditation

activities are carried out devoid of bias, management of conflict of interest (CoI), and objectivity of accreditation activities. ABs are required to introduce an effective and practical mechanism to gather information on internal and external personnel of the AB and their relationships with CABs and involvements. Prevention of CoI situations are very important in the accreditation process as it is a higher risk component and will impact the credibility of the accreditation process.

ABs are required to identify, analyze, evaluate, treat, monitor, and document on an ongoing basis the risks to impartiality arising from their activities and relationships (clause 4.4.6 of ISO/IEC 17011). Note 1 under the same clause explains the sources of risks as guidance for ABs to evaluate potential risks to impartiality. Figure 01 shows main sources of risks to impartiality and process of management of impartiality risks. When ABs identify potential threats/risks to impartiality, appropriate actions are taken to eliminate or minimize the impact of such. However, there may be residual risks that can be acceptable to some extent, which can be reviewed and monitored continuously by the management. However, sometimes, there may be identifiable risks that are unacceptable, as these are direct threats to impartiality. Under such a situation, ABs do not provide accreditation.

#### **Risks Associated with Confidentiality**

Self-declarations from internal and external personnel at a defined frequency, obtaining consent from CABs and assessment teams before each assessment, collecting information on consultants for management system development (also towards assessing criteria such as conflict of interest), internal auditing, training, etc. at the application stage as part of an application are commonly used methods by ABs to gather information to determine potential Col. Clause 6.2.2 of ISO/IEC 17011 requires ABs to have enforceable agreements with their personnel to address aspects of impartiality



and confidentiality. Thus, it requires personnel to disclose to the AB regarding existing, prior, or enforceable relationships, which may lead to bias and thus compromise impartiality. Moreover, clause 8.1.1 of ISO/IEC 17011 requires ABs to be responsible through legally enforceable agreements for the management of all information obtained or created during the accreditation process.

When the AB operates different schemes, it may require the development of specific guidelines, rules, procedures, and frameworks to avoid the domination or influence of a single party of a particular sector in such activities. This will contribute towards avoiding the committees appointed for the purpose risking the AB's impartial service. Therefore, ABs take their maximum effort to ensure the participation of interested parties in the tasks of developing and defining policies, rules, and guidelines. This requirement is addressed under clauses 4.4.5 and 4.6.2 of ISO/IEC 17011. In general, major activities, such as the development of accreditation criteria, conducting assessments, and decision-making in relation to accreditation processes are carried out by different personnel and it ensures the impartiality of accreditation services.

#### TABLE 02: A COMPARISON OF TWO ACCREDITATION BODIES TO UNDERSTAND THE SIGNIFICANT VARIATIONS OF FULFILLMENT OF REQUIREMENTS IN RELATION TO RISKS TO IMPARTIALITY

Accreditation Body – A	Accreditation Body – B
AB conducts analysis of conflict of interest (CoI) once without considering the changes.	Review on an ongoing basis/ continuously.
No mechanisms to obtain relationships and involvements of personnel.	Self-declarations, code of ethics, and applications have provisions to declare relationships of CABs with consultants, internal auditors, and trainers, etc.
Notification of Assessment teams and their organizations to CAB; obtaining consent or confirmation of no objections for the assessment teams is not obtained each time.	Objections from CABs, if any, for assessment teams are obtained prior to appointing team members and dealt with as per ABs' policies and procedures.
Internal and external relationships of AB are not fully reviewed to identify Cols due to management, ownership, etc.	Analysis of internal and external relationships are collected and analyzed; actions are taken to prevent Cols.

When ABs evaluate conformity assessment schemes to determine the suitability as per ISO/IEC 17011, new IAF MD25:2022 (Criteria for Evaluation of Conformity Assessment Schemes) should be followed to determine its suitability and demonstrate that the review process is impartial.

In addition, compliance with the requirements of clauses 7.12.8 and 7.13.8 in relation to the handling of complaints and appeals, and clause 9.7.4-b relevant to internal auditors are also required to prevent risks arising due to self-reviews.

#### Can We Completely Remove Risks to Impartiality?

No we cannot, because there are risks remaining even after taking actions, called residual risk. Residual risk refers to those risks that remain after we addressed the identified risk. For those risks that we cannot eliminate after addressing it, we need to perform continuous monitoring to ensure that risk is controlled. Different approaches for monitoring include proper recording or documentation of activity to be reviewed or included in the Internal Audit schedule as well as management review meetings. Figure 02 illustrates the potential risks to impartiality and possible approaches to mitigate them.

#### **Case example: Identifying different approaches of ABs to manage risks to impartiality**

If we take two accreditation bodies as an example, we can see how different approaches are used to comply with the requirements and therefore, significant variations can be observed.

## Strategic Structuring of Accreditation Bodies and Competence Management

When AB structures its organization, placement of AB within the parent organization to prevent any impartiality-related risks and risks associated with the management of AB, is a demonstration of schemes operated by the AB. This consists of relationships with committees and their place within the ABs' structure, and demonstrates the interconnected roles of different categories of personnel. These are very important for an AB to identify potential risks and also demonstrate how the AB structure itself can support and prevent potential risks. This showcases and proves the suitability of the structure to ensure implementation of actions in relation to identified risks.

Clause 6.1 of ISO/IEC 17011:2017 requires ABs to implement a process to ascertain and certify that their personnel have the appropriate knowledge and

skills relevant to the accreditation schemes and the geographic areas in which they operate.

The existence of any significant gaps between requirements and the AB's process will create a risk associated with competency. Lack of required competency will impact significantly on the credibility of accreditation services offered by the AB. Therefore, defining competencerelated requirements for each personnel category (clause 6.1.2 of ISO/IEC 17011) includes selection, training, supervision, monitoring, and evaluation of competencies prior to authorization. These are to be included in the AB's competence management process (6.1.3 of ISO/IEC 17011). The application of different monitoring techniques in a planned manner would assist ABs to identify the competency gaps of individuals and minimize the risk associated with activities performed by such personnel (Ex. 6.1.5/6 of ISO/IEC 17011).

When there is higher turnover in a particular category or at the initial stage of launching a new scheme, ABs have higher competency-related risk than the management of well-established schemes with well-experienced personnel. In particular, global ABs are required to consider the risks associated with personnel operating from different countries, cultures, and the management of their competencies. To minimize risks associated with competency, ABs should consider increasing the frequencies of onsite monitoring and apply whatever different techniques (onsite observation/witnessing) are possible. These involve techniques associated with reporting, reviewing, and obtaining feedback and complaints, etc. to monitor the competency of personnel.

When an AB outsources its accreditation activities to other ABs or individuals associated with other ABs, the application of similar processes for competency management will prevent any potential risk. For all categories, the availability of written procedures, policies, guidelines, and instructions will contribute to preventing or minimizing risks associated with the performance of personnel (6.2.3, 6.4.5 of ISO/IEC 17011).

Due attention of ABs is required to ensure the availability of relevant and competent personnel for decision-making as well as handling of appeals. The absence of competent personnel in one or both activities is also a higher risk for the credibility of accreditation services. Therefore, the availability of competent personnel for decision-making and handling appeals will be helpful for ABs to manage their accreditation activities to achieve a minimum risk or no risk situation.

Failure to acquire the knowledge and skills required for personnel involved in specific accreditation schemes as defined by the scheme owner or relevant IAF documents (e.g., IAF MD14, Annex B for GHG as per ISO 14065, IAF MD13 for ISMS, clause MD 6.2.1 of IAF MD 16 for FSMS, and IAF MD 20) is considered a critical risk for the outcome of accreditation activities. Therefore, ABs are required to review relevant scheme criteria or IAF documents to identify specific requirements for knowledge and skills and comply with them. An example to show variation in complying with requirements is given in Table 03.

TABLE 03: VARIATIONS IN COMPLYING WITH THE
<b>REQUIREMENTS BY TWO ABs</b>

Accreditation Body – A	Accreditation Body – B
Competency requirements are defined in general. Therefore, it is very difficult to match the scope of CABs and assessors.	Competency requirements are defined to meet the required knowledge and skills to manage the scope of accreditation activities and each technical area. Required competencies can be sourced correctly and easily. The personnel who select the assessment team can easily judge the team competency.
Lack of effective process for competence evaluation to ensure that personnel are competent.	Use of different techniques, such as interviews, document review, onsite evaluations, shadow assessments, onsite mentoring, use of feedback and complaints, and review of reports are implemented, and records are also maintained.
Training needs are not identified considering the outcome of monitoring activities.	Use of outcome of monitoring activities and other sources for identification of training needs are available, and records are also maintained.
Feedback from peers is not obtained.	Feedback from peers is obtained and regular technical harmonization meetings are conducted to share important technical points.
The collection of up-to- date qualifications and affiliations is not evident.	Personnel files are maintained for each staff and up-to-date records are available.
Assessors are not trained to apply risk-based assessment techniques.	Assessors are trained to apply risk- based assessment techniques and develop personnel attributes.



#### **Managing Accreditation Process Effectively**

A typical process of an accreditation body for granting accreditation for conformity assessment bodies begins with the application from a conformity assessment body. In order to receive applications with the correct information, ABs post their set of requirements on their official websites. Figure 02, below, illustrates the different stages of the accreditation process (with important clause numbers of ISO/IEC 17011:2017) and the potential risks associated with each stage. Due attention to these potential risks by the staff of accreditation providing organizations in their day-to-day operations and incorporation of these potential risks into their policies and procedures with expected actions in different uncertain situations are required. Following with diligence these checks and balances will enable the smooth operation of accreditation services.

#### **Case examples**

Accreditation bodies make available accreditation requirements, normative documents, and application documents through their official websites. Most accreditation institutes operate accreditation schemes based on international, national, or regional standards. In comparison, some accreditationcertifying institutes operate accreditation schemes based on other conformity assessment schemes. The newly published IAF mandatory document (IAF MD25:2022 - Criteria for evaluation of Conformity Assessment Schemes) contains minimum requirements for conformity assessment schemes (CAS) to be applied by IAF member ABs when evaluating national, regional, or international CAS to ensure they meet requirements specified in ISO/IEC 17011, clause 4.6.3.

Accreditation bodies that operate accreditation for specific conformity assessment schemes owned by regulators and provide accreditation shall ensure that the requirements of conformity assessment schemes do not contradict the applicable international standards. Operating an accreditation scheme without a proper review would create inconsistencies with international standards. Ultimately, a comprehensive review of conformity assessment as indicated in IAF MD25 would minimize the risk associated with operating accreditation schemes introduced by scheme owners.

Accreditation bodies accept applications only from national economies fully aware of the relevant local context including the applicant conformity assessment and its history. However, ABs entertain applications from other countries that have a risk of granting accreditation for conformity assessment bodies operating under different cultures, legal frameworks, and minimum potential to monitor them and the misuse of accreditation status. If any CAB from another economy wishes to get accreditation due to the interest of customers or regulators, it should be done as per the ILAC guidelines of crossfrontier accreditation (ILAC G 21: Cross Frontier Accreditation-Principles for Cooperation).

IAF Mandatory Document (MD) Number	Title	Description (as given on IAF website)	Potential risks to AB and approaches to eliminate risks
IAF MD12:2016	Accreditation Assessment of Conformity Assessment Bodies with Activities in Multiple Countries	Provides requirements for the consistent application of clause 7 of ISO/IEC 17011 regarding an Accreditation Body (AB)'s Assessment of Conformity Assessment Bodies (CAB)'s that provide certification for countries outside the domestic territory in which their head office is located.	AB should design the application to obtain such activities from the application stage. Collaborate with local AB and regulators. Collect information on activities and continuous monitoring. Arrange witnessing/visits to branches.
IAF MD23:2018	Control of Entities Operating on Behalf of Accredited Management Systems Certification Bodies	This document relates to entities, performing and/or managing management system certification activities, on behalf of Certification Bodies (CBs) holding accreditation, which are not wholly or partly owned or employed by the CB.	AB should design the application to obtain such activities from the application stage. Collaborate with local AB and regulators. Collect information on activities and continuous monitoring. Arrange witnessing/visits to branches.

### TABLE 04: IMPORTANT IAF MANDATORY DOCUMENTS (MDs), WHICH ARE REQUIRED FOR ABs TO CONSIDER THE RISK IN THEIR ACCREDITATION PROCESS



Figure 03: Assessment techniques and risks in the relation accreditation process

The risk associated with the acceptance of applications from foreign countries would be minimized by working very closely with local accreditation bodies in the accreditation process. This is achieved by means of conducting joint assessments, the appointment of observers/ technical assessors/team leaders from the local AB, and other collaborations. Cooperation with local ABs benefits the foreign AB in terms of managing the cultural differences, local regulations as well as any possible misleading behaviors of the conformity assessment body.

Failure to gather information on branch officers, accredited scopes by other ABs, franchises, and the geographical locations where the Certification Body (CB) operates, etc., with the accreditation application of certification bodies with multiple locations (e.g., franchises in other countries with accreditation from other ABs), represents a higher risk. Thus, ABs accrediting certification bodies should design their application to gather information as well as make terms, conditions, rules, and procedures for governing certification bodies operating in other countries. In this scenario, due attention to the following IAF mandatory documents (MDs) given in Table 04 is required to prevent or minimize the risks towards accreditation bodies.

Preparation for assessment processes with effective resources to review the accreditation body to ensure the availability of competencies required to undertake an assessment in a timely manner also prevents any uncertainties in relation to the accreditation process. A proper review of the application and scope of CAB to identify required competencies and assessment durations and assessment techniques are the most vital steps in the accreditation procedures.

Team selection is based on the scope of accreditation to ensure team competency to undertake the assessment. The use of assessment techniques while applying the knowledge and experience of risk-based assessment principles plays a remarkable role in the accreditation provision undertaking.

An overall summary of risks associated with each step of the accreditation process and assessment techniques with reference to process requirements of ISO/IEC 17011:2017 is shown in Figure 03.

Selection and use of assessment techniques themselves pose a risk because if we missed out on an important technique during the assessment, we may not reach the expected outcome of the assessment. For example, in a laboratory assessment stage, failure to witness tests or calibrations will result in the assessment team not being able to give their recommendations on the performance based on accurate analysis of test/ calibration methods. The use of remote assessment techniques to observe the branch officers will give added value to the assessment outcome. ABs are required to have clear policies and procedures for planning and conducting assessments of a conformity assessment body operating within the main location and multisites. This basically consists of a range of aspects to be considered in order to minimize risk, for example, the selection of sites, selection of assessment techniques, the coverage of scope and personnel, and indication of all these points in the assessment program.

#### Application of Mandatory Requirements of International Accreditation Forum (IAF) for Witnessing to Manage Accreditation of Certification Bodies at Minimum Risk

The IAF MD16:2015 (Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification) has requirements for witnessing of FSMS certification bodies. Particularly, IAF MD16 allows the AB to consider other food safety-related management systems in relation to a specific food chain category for witnessing and office assessments as well as the decision-making process.

An AB has the choice to consider a particular food chain cluster, which includes one or more food chain categories, and grant accreditation after a one witnessing in the particular cluster. Even though this approach is allowed by the IAF MD16, ABs are required to consider the possible risks if the certification body does not have auditors, internal staff, and clients in relation to a specific food chain category. Because it is a risk for an AB to grant accreditation without witnessing for the cluster. So, Accreditation Bodies should at least conduct a file review of clients, auditors, and internal staff, and then decide whether the CB has the required competency to carry out certification activities.

The same approach should be applied when an accredited CB is requesting scope extension within a cluster already accredited. Of course, for a scope extension for a new cluster, IAF MD16 does not allow for granting accreditation without witnessing. In addition, when the accreditation body develops an assessment program, it is required to consider witnessing of cluster 2 every year and at least one witness within five years in other clusters. At minimum, witnessing should cover initial certification during the period. Due attention on requirements for witnessing given in IAF MD16 and consideration of potential risks for granting accreditation without witnessing is required for accreditation bodies operating an accreditation scheme for FSMS certification.

IAF MD17:2019 (Witnessing Activities for the Accreditation of Management Systems Certification Bodies), section 0.1 stated that "According to ISO/IEC 17011:2017 clause 7.4.4 and clause 7.4.5, Accreditation Bodies (ABs) are also required to establish documented procedures to assess the competence of conformity assessment body to perform all activities in its scope of accreditation irrespective of where these activities are performed, through the use of a combination of onsite assessments and other assessment techniques sufficient to provide confidence in the conformity with the relevant accreditation criteria. The assessment shall cover a sample of locations and personnel to determine the competence of the conformity assessment body to perform the activities covered by its scope of accreditation."

Under the management system certification, there are different certification schemes, such as QMS (Quality Management Systems), EMS (Environmental Management Systems), and OH & SMS (Occupational Health and Safety Management Systems) and many scope sectors, which come under different economic sectors/activities. These schemes support the competence of certification bodies to conduct audits under different technical scopes to be assessed by the accreditation body prior to grant accreditation. If the AB is not able to assess the competence of the certification body to carry out certification under all economic activities as per IAF ID1:2020 (IAF Informative Document for QMS and EMS Scopes of Accreditation), it will be a higher risk for the accreditation body.

However, it is not possible for an AB to conduct witness of all scope sectors. Therefore, the AB can get the advantage of technical clustering and identification of critical sectors as highlighted in IAF MD17 and use other assessment techniques as far as possible and practicable to assess the competence of certifications bodies rather than depending only on the witnessing. If an AB totally depends on the provisions of IAF MD17 and complies with it, the AB still has risk as there are some scope sectors within the clusters that have not been assessed properly. How can the AB avoid this risk? It is required to use other assessment techniques such as document review, interview, file review, remote assessments, etc. to determine the competence. Sometimes, ABs will take the risk and grant accreditation for noncritical sectors without auditors or clients based on their demonstrated competence to carry out certification in other related scope sectors. In such cases, ABs should use proper control over such scope sectors and make mandatory requirements on certification bodies. For example, ABs can grant accreditation for noncritical scopes without clients or auditors with a condition to conduct the witnessing when the CB has the first client in relation to a particular scope sector.

#### **Converting Risk to Financial Aspects**

Concerning the above background, if the accreditation-providing institution has a clear understanding of the big picture of risks arising from its activities, it is feasible to make an informed decision on the overall level of risk towards the AB and pass the liabilities that have arisen from its activities to another. This will necessitate making arrangements to obtain professional indemnity insurance coverage (may differ due to different regulatory frameworks) and/or allocate reserves, which can be used to cover liabilities arising from accreditation activities as required in clause 4.5.2 of ISO/IEC 17011:2017. A comparison between two ABs' approaches to fulfill the requirements is given in Table 05. According to the simple comparison in Table 05, Accreditation Body – A has taken many steps to cover liabilities arising from its activities, lowering the risk towards the AB.

#### TABLE 05: DIFFERENT APPROACHES OF ABs TO COVER LIABILITIES

Accreditation Body – A	Accreditation Body – B		
Covers liabilities from the following approaches:	Covers liabilities from the following approaches:		
Has obtained a professional	From the nature of		
indemnity coverage.	government and or regulations, liabilities are		
Have fixed deposits/reserves.	covered.		
The AB has made a	Professional indemnity		
requirement for CABs to	coverage is obtained.		
get insurance coverage to cover the liabilities from			
their conformity assessment			
services.			

#### **Effective Use of Quality Management System**

Clause 9 of ISO/IEC 17011 requires ABs to establish, document, implement, and maintain a management system capable of supporting and demonstrating the consistent achievement of the requirements of ISO/IEC 17011. The management system itself has a requirement (clause 9.6) for the improvement of accreditation activities and the management system through the identification of opportunities for improvement and risks. Therefore, ABs should pay due attention to reviewing ABs' accreditation activities and processes to identify potential risks in time and take appropriate actions to prevent any uncertain situation.

Use of management system tools, such as identification of nonconformities and taking corrective actions (clause 9.5 of ISO/IEC 17011), such as internal audit and management reviews, are also very important. If an AB is at the very initial stage (relevant even for a matured AB), it can increase the frequencies of internal audits and management reviews in order to minimize the impact of potential risks.

The implementation of document and record control procedures with adequate retention times to fulfill regulatory requirements and protection of records prevents risks in relation to the use of obsolete documents and updates the availability of required documents for operations.

#### Summary

ISO/IEC 17011:2017 is the international standard that stipulates requirements for accreditation bodies accrediting conformity assessment bodies. The requirements of the ISO/IEC 17011 are to ensure the competence, consistent operation, and impartiality of accreditation bodies throughout their accreditation activities. Any effect of uncertainty in those prime objectives of accreditation services could be considered as a risk for the accreditation body. The ISO/IEC 17011 has general, structural, resource, process, information, and management system requirements. At the implementation of all requirements by accreditation bodies, uncertain situations could occur that will impact prime objectives. The above technical discussion was developed based on ISO/IEC 17011, ILAC, and IAF requirements and guidance while incorporating the experience gained through operating activities of accreditation bodies, peer evaluations, and local and regional training and sessions on sharing experiences. Therefore, it is expected that there are many more examples that you may have experienced, which have not been covered in this short write-up.

#### Acknowledgement

I shall acknowledge the content taken directly from or references from ISO/IEC 17011:2017, ISO 31000, IAF Mandatory documents, official websites of ISO, ILAC and IAF was used in order to develop this write-up.

#### **Author Biography**

Mr. L H D Bandusoma is currently working as Deputy Director (Accreditation) of Sri Lanka Accreditation Board for Conformity Assessment (SLAB). Mr. Bandusoma is one of the pioneer members of SLAB and he counts over 15 years of experience with the SLAB. While covering duties of the Director/CEO, SLAB, he served as SLAB's official delegate for ILAC, APLAC from 2016-2018. He began his career in 2003 as Academic Instructor of University of Sri Jayewardenepura and then moved to Ministry of Science & Technology as Science & Technology Officer. Thereafter, with the inception of SLAB, in 2005 he joined the SLAB as Accreditation Officer and gradually rose to the level of Deputy Director (Accreditation). Mr. Bandusoma has a multidisciplinary education background. He holds a bachelor's degree in forestry and environmental science, a Master of Food Science & Technology from University of Sri Jayewardenepura (USJP), Master of Public Administration in e-Government, and Postgraduate Diploma in e-Government from Institute of Postgraduate Institute (PIM). He is a qualified auditor as per ISO 14001, Lead Peer Evaluator of APAC, and has participated in more than 10 evaluations in different ABs under APLAC/PAC as well as APAC. During this 17-year period, he was

involved in the development of accreditation schemes of SLAB and managed almost all accreditation schemes of SLAB currently covered under APAC MRA. He functioned as Technical Manager of Testing/ Calibration Laboratories, Certification Bodies, and at present functions as Technical Manager of Inspection, Proficiency Testing, Reference Materials and GLP schemes. Mr. Bandusoma is a member of National Mirror Committee on Environmental Management System, which is directly linked with ISO/TC 207 responsible for ISO 14000 series of standards, and he functions as a Visiting Lecturer of Corporate Environmental Management, EMS & QMS as per ISO 14001 & 9001 and Laboratory Quality Management at Faculty of Science & Faculty of Graduate Studies, University Sri Jayewardenepura.

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#### -ABSTRACT-

This study compares the International Maritime Organization (IMO) Member State Audit Scheme (IMSAS) and ISO/IEC 17000 series as well as ISO 19011. The part that we investigate in this paper is the marine industry audit cycle that the IMO Member State Audit Scheme uses, such as ISM code certification of the vessels over 500 Gross Tonnage (GT) and the IAF peer evaluation of its members' accreditation bodies. The reasoning for such effort is that both ISM code certification of the vessels over 500 GT and the IAF peer evaluation are long established and more mature assessment practices. The contribution of our study is to create a robust audit cycle for the IMO Member State Audit Scheme, which has not been examined in the literature

Keywords: IMO Mandatory Audit Scheme (IMSAS), IMO Instruments Implementation Code (III Code), conformity assessment standards, auditor, ISO/IEC 17020, ISO/IEC 17021, ISO/IEC 17065, ISO /IEC 17024, ISO 9000, ISO 19011



Comparison of International Maritime Organization (IMO) Member State Audit Scheme (IMSAS) with ISO/ IEC 17000 Conformity Assessment Standards Series and ISO 19011

By Vasileios Lymperopoulos, PhD (candidate), Bolton University, Mechanical Engineer, LiberoGroup; and Sotirios Karagiannis, PhD, New York College

#### Introduction

Since the inception of the International Maritime Organization (IMO) in 1948 [1], the maritime community has been looking for a vigorous system to prevent accidents, preserve the environment, and protect the assets. Hence, the role of IMO was to construct the framework for succeeding in this objective. Most of the legislations have been developed after the occurrence of major and well-known accidents [2], such as the chemical/oil tanker Amoco Cadiz, IMO 7336422, Liberiaflagged, American Bureau of Shipping-classed oil spill on the Brittany coast in March 1978, which caused the most massive oil pollution on record [3]; crude oil tanker Aegean Sea, IMO 7312452, a Greek-flagged shipwreck that occurred en route to the Repsol refinery in La Coruña, at the northwest of Spain near the harbor, when it encountered a heavy storm. The accident was partly due to bad weather conditions and possibly also to the poor condition of the ship [4]; the grounding of the crude oil tanker *Braer*, IMO 7377220, Liberia-flagged, on January 5, 1993, which resulted in the spilling of 80,000 tons of crude oil in the waters off Shetland [5]; oil tanker Erika, IMO 7377854, Malta-flagged, which on December 12, 1999, broke in two and sank after experiencing a heavy storm, releasing thousands of tons of oil into the sea, killing marine life and polluting the shores around Brittany, France [6]; oil tanker *Prestige*, IMO 7372141, Bahamian-flagged, which on November 13, 2002, carrying approximately 77,000 tons of heavy fuel oil, sank during a storm, after having burst a tank [7]. The important aspect on this casualty is that French, Spanish, and Portuguese member states, among others, refused to allow the ship to dock, resulting in considerable political and public outrage, which fueled the idea that some registries are unable to maintain a functioning administration and legal framework in order to meet their international law implementation and enforcement commitments.

However, the IMO has no enforcement or compliance monitoring function in this regard, and the flag, port, and coastline states' governments are responsible for implementing and enforcing such requirements. The member states are collectively responsible for implementing the regulations and legislations. The IMO and the European Commission (EU) have traditionally been concerned about member states' implementation and enforcement of international standards. Whereas some of the member states have a robust system for implementing the regulations of the IMO, others have a far less effective implementation.

In order to address this problem, the IMO has developed the International Safety Management (ISM) Code, which was introduced in 1998 [8]. This regulation requires each organization's management to take on more responsibility for overseeing occupational health and safety (OHS) on their ships to ensure the preservation of the environment and the protection of the asset [9]. Its adoption resulted in a big change from the old command and control system, which relied on inspections by inspectors from a ship's governing authority (Flag State) to assure statutory compliance. Instead, the ISM Code requires managers to establish work processes encompassing risk management and all the functionalities of a management system, such as continual improvement, internal audit, and management of competence. Nowadays, when the ISM Code can be considered as a mature management system for the maritime industry, it can be analyzed, and its contribution can be shown on a sample of 268 ship accidents over a period spanning before and after the implementation of the Code. It showed that the rate of incidents due to human error as opposed to other causes dropped from around 64 to 52 percent. The positive impact was particularly evident in the tanker and roll-onroll-off passenger sectors, where it dropped from around 84 to 55 percent [10].

In 2013, the IMO, having considered the added value of an effective management system such as ISM code, contemplated an audit scheme for the oversight of the member states regarding how they perform their duties and how they exercise their authority [11]. Although initially voluntary, it soon became mandatory and is based on peer evaluation between the member states.

Similar to the IMO, the accreditation and conformity assessment worlds have the International Accreditation Forum (IAF). IAF promotes a uniform global market by establishing a mutual recognition agreement among accrediting bodies, ensuring that the results given by conformity assessment entities accredited by IAF Accreditation Body (AB) members are universally recognized [12]. An appointed committee of peers evaluates ABs that are signatories to the IAF Multilateral Recognition Arrangement (MLA) on a regular basis to offer confidence in the administration of their accreditation programs.

To facilitate this goal, there have been some regional groups established in the peer evaluation process in order to lessen the cost of transporting auditors from the other side of the world. The IAF has regional clusters based on certain economies as follows:

- 1. Economy: Europe; the body responsible is European cooperation for Accreditation (EA)
- 2. Economy: Arab Region; the body responsible is Arab Accreditation Cooperation (ARAC)
- 3. Economy: Americas; the body responsible is InterAmerican Accreditation Cooperation (IAAC)
- 4. Economy: Africa; the body responsible is African

Accreditation Cooperation (AFRAC)

5. Economy: Pacific; the body responsible is Asia Pacific Accreditation Cooperation Incorporated (APAC)

Although the IMO audit scheme started on a voluntary basis, it has been made compulsory as of January 1, 2015 [13], when the International Maritime Organization urged the flag states to fully implement the adopted resolution. In terms of the above conventions and the mandatory IMO instruments, each state may act under the following three different capacities: First, as a flag state, which means that the vessels fly this country's flag; second, as a port state, which acts as a receiving country for foreign flagged vessels; and finally, as a coastal state in case the vessel is passing through that country's waters. The scheme also contains an auditors' manual, and the management of the process is being handled by the IMO as the central authority.

The scope of these audits covers the mandatory IMO instruments, which are the following conventions:

- 1. SOLAS 1974 [14]
- 2. MARPOL 73/78 [15]
- 3. STCW 1978 [16]
- 4. LL 66 [17]
- 5. Tonnage 1969 [18] and
- 6. COLREG 1972 [19]

#### **Analysis & Discussion**

The IMO has recognized two challenges facing the organization since the establishment of the Flag State Implementation (FSI) Sub-Committee in the early 1990s: the development of new policies and regulations, and

the need to ensure that existing policies and regulations were taken seriously and correctly implemented and enforced [20]. In 2013, the FSI Sub-Committee was renamed the Sub-Committee on Implementation of IMO Instruments (III). Consequently, the IMO created the IMO Instruments Implementation Code (also known as the III Code or IIIC). which is the backbone of the IMO Member State Audit Scheme. The III Code establishes a Code (set of rules) against which all member states are audited in order to determine their capability and resources to meet international responsibilities in the areas of port state, coastal state, and flag state.

As part of IMO audit process, this study will check the fit of the ISO/ IEC 17000 series as part of the member states' functions.

There are various gaps that need to be addressed in order to properly control the auditing process. To further complicate the matter, there are various management systems that may apply to handle this process. Such standards belong to the 17000 Series covering the conformity assessment field. For this purpose, the current paper will try to identify gaps between the standard practices of IMO with regards to the member state scheme and the conformity assessment series. The objective would be a linkage of the existing practices IMO is doing with the international practices.

The accreditation of Certification, Inspection, Verification, and Validation Bodies is a complex process. Its importance varies as the object of certification (system, product, person, or plant) and the object of verification and validation change – due to the generic nature of the normative references used.

To enhance the effectiveness and the credibility of the accreditation process, it is necessary to implement specific criteria which, without overstepping the intention and the words of the standard, foster full application on the part of accredited bodies, while at the same time providing unambiguous, objective, and impartial references for the assessments performed on such entities by Accreditation Bodies [21].

Currently, there are several important issues that need to be addressed, and which create confusion in the implementation and enforcement of the IMO Member States Audit Scheme. Ultimately, these issues obstruct the effectiveness and control of the auditing processes associated with maritime safety, environmental protection, and management of the human element. There are a few management system standards belonging to the 17000 Series covering the conformity assessment field, which may be applied as an effective solution to handle this process.

In accordance with the set of principles contained in paragraph 4.1.1 of the Procedures for the IMO Member State Audit [11] (part II), the Secretary-General has determined the audit schedule for implementation of audits under the mandatory Scheme (based on a random drawing of the names of member states and an associate member who have not completed an audit under the voluntary Scheme), followed by those member states and associate member states and associate member states and associate member states and associate member states and associate

a voluntary audit in the order in which they were previously audited. The audit schedule which is set out in the Annex 6 "Audit schedule for the mandatory Scheme" – presents the order of audits chronologically [22]. Cycle of audit should be determined for reassessment/reevaluation. The need for surveillance is necessary, whereas the requirements can be checked on a regular cycle. This is very important to maintain the validity of a report that acts as an existing statement of fact about the compliance level of a member state. Typically, each iteration of monitoring does not require a full repetition of the initial assessment to meet this demand [23].

Based on the overall audit schedule as defined by Resolution A1067, audits under the mandatory Scheme will be conducted at periodic intervals not exceeding seven years, a relatively relaxed way for continuous oversight of the maritime administrations. From the EU accreditation, the surveillance is being conducted over a four-year period, which is considered a long time [24].

It is worth mentioning that IMO has been exempted from the initial plan as included in the Annex 6 "Audit schedule for the mandatory Scheme" countries, such as Georgia, Angola, El Salvador, Colombia, Indonesia, and Cook Islands, which have volunteered to conduct the audit prior to it becoming mandatory. Additionally, these countries have postponed their mandatory audit, on the basis they have performed a voluntary one, until the rest of the maritime administrations finish with their audit obligations and the cycle starts over.

Based on ISO/IEC 17011:2017 [25], clause 7.9 mentions that an accreditation cycle, which is the third-party attestation for the carriage of specific conformity assessment tasks based on the competence of the organization, should not be longer than five (5) years. To determine this period, the risk of the associated conformity assessment should be taken into consideration.

In addition, a sample of the scope of accreditation should be assessed every two (2) years.

The ISM code mandates that a Safety Management Certificate (SMC) issued to a ship should be valid for no more than five (5) years and the validity of such certificate is subject to an intermediate verification between the second and third anniversary dates of the Safety Management Certificate (SMC) [26]. Another aspect that should be considered is the risk of failure of the member state to exercise its functions. The impact of a maritime accident is huge [27] and hence, the severity of the IMO audits in terms of global shipping for the safety and environmental protection is considerable.

#### **Conclusion** -

Proposition: There are two options, which based on the writers' opinion can be equivalent or ground for further study:

A. The cycle should be limited to four years with an intermediate audit, with the scope to sample some of the functions of the member state under each capacity (i.e., port state, flag state, coastal state). B. Alternatively, a five-year cycle with an intermediate audit, with the scope to full audit of the functions of the member state under each capacity (i.e., port state, flag state, coastal state).

As further study, we can propose the researchers go deeper on some case studies for member states. These case studies should be drowned from member states that have undergone the IMO member state audit, but conformity has not been fully achieved. This non-fulfillment of conformity can be shown by their overall performance in the global Port State Control databases and other third-party assessments, such as the International Chamber of Shipping (ICS) Annual Flag State Performance Report.

#### **Author Biography**

The author, **Vasileios Lymperopoulos**, is a PhD candidate at Bolton University. Vasileios joined LiberoGroup in 2010. His background is Mechanical Engineer. Since 2011, Vasileios has been appointed Deputy Registrar under several International ship registries. Since 2013, he has worked as Certification Manager of LiberoAssurance - LiberoGroup affiliate company, which obtained accreditation from Hellenic Accreditation System (ESYD), the International Accreditation Service of United States (IAS), and Accredited Auditing firm (ASI). Being a lead management System Auditor for ISO 9001, ISO 14001, ISO 50001, ISO 45001, ISO 39001, ISO 22301, ISO 41001, ISO 55001, ISO 37001 as well as Appointed Flag State Surveyor, Auditor for ISM-ISPS-MLC, and Statutory Certification, Vasileios has deep knowledge in auditing, training, and surveying, is an Accident Investigator and Certified Designated Person Ashore (DPA), and he has performed audits on Maritime Training Centres and Recognized Organizations on behalf of Maritime Administrations.

The co-author, **Sotirios Karagiannis**, is Supervisor of Doctoral Studies at New York College of Greece and Research Associate at the Research Centre of Economic Analysis. He is also Senior Manager of the Global Investment & Innovation Incentives department at Deloitte Greece and an Economist, member of the Economic Chamber of Greece. Sotirios has significant professional experience in financial and business advisory for funding firms and leading large-scale investments in hospitality, logistics, manufacturing, and the energy sector under State Aid regulations, feasibility studies and business plans, financial modeling, market research, national or regional operational programs, as well as in supporting services for the use of tax incentives. During his professional career, he also gained a lot of expertise in the provision of consulting services to public authorities, he was a team member of several European cross-border research projects, and he participated as a team member providing technical assistance to the Recovery and Resilience Facility Agency, Ministry of Finance. Sotirios holds a degree in Mathematics from the University of Patras, MSc in Finance & Management from the University of Essex (UK), and a PhD (hon) in Applied Economics from the University of Peloponnese.

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DOI: doi.org/10.55459/IJCA/v2i1/NG

## Risk Management, Conformity Assessment, and Evaluation of Organizational Intelligence in Scenarios of Change and Crisis

By Nicola Gigante, Assessor of Accredia, Italian Accreditation Body

#### -ABSTRACT-

In an environment increasingly dominated by change and crisis, in which the organizations are required to readily adapt their management systems to new needs and emerging risks, the conformity assessment should itself be adaptive and always responsive to the growing complexity of its object. The article aims to explore this issue, first by addressing the topic of "organizational intelligence." In the second part, there is a focus on the evolution of the management system standards in a performance perspective, and on risk management as a countermeasure to the progressive reduction of the prescriptive approach. Finally, the idea of a "complexity assessment" is proposed, aimed at assessing not only the conformity to requirements within a stable and predictable framework, but also the adaptability and resilience of the organizations, in response to the traumatic transformations of the context.

Keywords: Risk management, organizational intelligence, conformity assessment, change, crisis, quality assurance, performance assurance, complexity assessment, ISO 9001:2015, ISO 17000, ISO 31000, IEC 31010, ISO 31050

#### Introduction

Is it possible to have confidence in the validity of conformity assessment, even when its object is rapidly changing? How can the ability of organizations to ensure the fulfillment of requirements be appraised in the presence of structural and traumatic crises, nowadays inevitable components of the broader context? How is it possible to reconcile the goal of performance assurance (for example, "quality assurance") with the concept of risk, and with that of its associated uncertainty? How should assessment tools evolve to match the growing complexity of the object activities?

The following considerations arise from these questions with the intention of contributing to the search for the right answers. First, to this end, the topic of "organizational intelligence" will be addressed. Subsequently, we will focus on the evolution in the sense of performance of the rules on management systems, and on risk management as a countermeasure to the progressive abandonment of the prescriptive approach. Finally, the idea of a "complexity assessment" will be proposed, aimed at assessing not only compliance with the requirements in a stable and predictable framework, but also the adaptability and resilience of organizations in the face of change and crisis.

#### **Organizations and Context Transformation**

Organizations are complex adaptive systems. Considering the sometimes-disruptive variations of the conditions that characterize their context, they will become increasingly able to regularly provide outputs conforming to the requirements and to deal advantageously with this variability.

To achieve this, organizations should possess, to the necessary degree:

- 1. An up-to-date knowledge of the framework of requirements, resulting from monitoring the expectations and requirements of the most critical and important interested parties, and of their evolution.
- 2. A clear understanding of the risks and opportunities associated with both the routine management of processes and their change, when necessary.

For the realities characterized by the unpredictability of the scenario, the risk-based approach and the adoption of tools to maximize the rationality of decisions will be decisive. The management system will be more useful and effective the better it can regulate on this basis the organizational reactions in unforeseen events and crises.

Operationally, a management system should include tools for:

- The management of the consolidated part of the processes (for example, procedures for the routine management of infrastructures, or for the control of typical courses of action).
- 2. Detecting changes in the context, both internal and external (for example, those necessary to monitor the evolution of requirements and expectations, or to promptly recognize and evaluate unexpected situations).
- Making decisions and for carrying out consequent actions in the face of non-routine and unforeseen events, emergencies, etc.

In other words, an organization should be able to respond in a coherent way to the evolution and changes to the context, to the extent that it can demonstrate:

**Diligence** in applying the rules governing the predictable and stable components of the processes.

**Attention** to the scenario, to rapidly identify changes.

**Ability** to readily and effectively adapt its course of action, in the face of the variations.

Added to these "virtues," which are essential in a "physiologically" changing context, is one that is indispensable for dealing with any crisis scenarios: the transformative capacity, that is, an organization's ability to apply drastic and immediate changes when new, unpredictable, and even traumatic circumstances occur in the business environment.

The adaptability and transformative capacity of an organization will involve creativity, as an aptitude for elaborating original solutions, and could be summed up in the unifying concept of "organizational intelligence."

#### The New Performance Approach and Risk-based Thinking in Management System Standards

It is well known that the management of an organization is enhanced if it is based on tested and recognized models, such as those codified by the rules on management systems. They do not introduce new solutions for organizational management compared to the consolidated framework of business management tools, but instead establish a structured system of requirements, the application of which can help organizations to implement these tools regularly and with a view to continuous improvement, and to demonstrate their effective and regular application externally.

Given the changeable nature of the "ecosystem" mentioned above, the latest generation standards on management systems, including those for the accreditation of Conformity Assessment Bodies, require organizations, more than in the past, to contextualize their management system and to define the rules of organizational behaviour. The validity of the management system standards in supporting the definition and effective implementation of policies, and the achievement of objectives, today lies precisely in their reduced prescriptiveness, and therefore in their "unspoken" attributes (i.e., those spaces not covered by requirements, which the users of the standards themselves can fill). Therefore, there is less rigidity of the requirements and greater freedom on the part of organizations in designing and establishing their own specific management system. This enhanced freedom, however, must be supported by:

- Greater managerial competence, to respond to the request for a more evolved planning capacity.
- Greater responsibility of organizations in guaranteeing the effectiveness of the "selfregulation" process and in demonstrating, internally and externally, the suitability of the "self-defined" requirements.

It will be possible to demonstrate if each of the solutions identified by the organizations — within the new and wider margins of discretion mentioned above — will emerge as the result of a logical, traceable path, along which both the inputs taken as the basis for each decision and the understanding of the possible consequences will result from a correct management of the risk.





All this implies a "cultural" transformation, which the definition of "risk-based thinking" used by ISO 9001:2015 and taken up as part of the ISO 17000<sup>1</sup> series standards, effectively summarizes.

The adoption of risk-based thinking will serve not only to build, apply, and improve a management system aimed at the result, but also to make the logical process that generated it feasible, enabling effective conformity assessment.

Regarding the way to apply risk-based thinking, the standards in question (in line with the new performance approach) do not provide specific solutions. In general, simple, small-size organizations with consolidated technologies, characterized by a stable/predictable external/ internal context, will not need sophisticated tools to put risk-based thinking into practice. Instead, in larger and more complex organizations its implementation should be more structured and will involve the implementation of specific methods, tools, and skills. For them, the main normative reference to systematically address risk management is found in the standards developed by the ISO/TC 262 Technical Committee, particularly in the following:

- ISO 31000 Risk management Guidelines
- IEC 31010 Risk management Risk assessment techniques

• ISO 31050 - Guidance for managing emerging risks to enhance resilience (currently under development)

 the risk-based thinking applied in this edition has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements;

#### **Conformity Assessment in the Scenarios of Change and Crisis**

As an essential part of the conformity assessment, the new emphasis on the evolution of management systems requires assessment processes capable of providing a reliable estimate of the organization's ability to maintain and increase the performance of its management system amid changing conditions.

In addition to the ability to apply the requirements and to improve continuously, depending on the changes in the context and the framework of expectations, the organization should demonstrate the following conditions:

- The capacity to innovate, when the context and the framework of expectations require alternative propositions of product/service, or rethinking of processes (for example, to increase the chances of success in a competitive context).
- The capacity for transformation, in the event of radical changes in the context and in the requirement framework that oblige the organization to rethink/modify itself (for example, in the presence of a crisis or structural changes in the scenario).

Thus, the assessment should include an appraisal of these capacities, i.e., an assessment of the organization's "intelligence," as well as its "diligence." This is a task that is difficult to perform using metrics, and which, due to having highcomplexity systems as its object, cannot in general be based on a purely deterministic approach. The assessment of the "new" management systems, and of future ones already emerging in the debate on possible revisions of the applicable ISO standards<sup>2</sup>, will require the assessor to have a growing ability to understand and critically examine organizational behaviour, allowing for the consideration of whether it responds primarily to criteria of rationality and reasonableness, including behaviours in place to effectively react to any (now widely experienced) economic, health, geopolitical, climatic, energy, etc. crisis scenarios. This will enable the formulation of reliable judgments on the resilience and transformation capacity of the organization under assessment.

<sup>1</sup> See ISO 9001.2015 - Quality Management Systems - requirements. A.4 Risk-based thinking: "... The risk-based thinking applied in this International Standard has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements. There is greater flexibility than in ISO 9001:2008 in the requirements for processes, documented information, and organizational responsibilities." See EN ISO/IEC 17025, December 2017 - General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2017 - Foreword): "...This third edition cancels and replaces the second edition (ISO/IEC 17025:2005), which has been technically revised. The main changes compared to the previous edition are as follows:

<sup>-</sup> there is greater flexibility than in the previous edition in the requirements for processes, procedures, documented information and organizational responsibilities; ...".

<sup>2</sup> See the works of the Technical Group ISO/TC 176/TG04 "Emerging trends in quality" and the current debate in the same area on the topic "Quality 4.0."

Based on this increased capacity, the assessment must consist of a valid logical and socio-technical analysis of the management system and, consistent with the criteria of risk-based thinking, carefully examine the objective reasons for organizational decisions before their implementation. The key question of the assessor must be: "Why?" Only after having obtained objectively valid answers on a logical and technical level will the assessor be able to proceed with the search for evidence of a regular and effective application of decisions.

This "leap in complexity" will make the performance of the assessment less feasible through the accurate application of pre-established protocols, thereby increasing the possibility that its essential objective (providing a valid measure of the state of the management system) may not be reached. In other words, with the new "performance" approach and with the pressure of crisis scenarios, the "uncertainty" associated with the outcome of the assessment could grow.

To reduce this uncertainty and the associated risk that the assessment itself will not generate "value" or worse, produce misleading information (similar to management systems that must apply the logic of risk), we should deal with the increased danger that the result of the assessment does not correspond to the actual state of conformity of the "measurand."3 To this end, the components of this uncertainty will be identified, as for any measurement process, and the right countermeasures for its containment within acceptable limits will be implemented. Among them, the assessment process will need to be based on greater "evaluative intelligence" (meaning, among other things, the ability of the assessors to use their logical-deductive skills in understanding the complexity of the organization and its context, and in the assessment of decision-making processes, from the strategic to the operative level); and greater technical-managerial competence of the assessors Since the need for higher performance on the part of the assessment team is less easily met by drawing on the knowledge of only one or a few assessors, a more frequent and broader involvement of specialists and interested parties in support of the team should be taken into consideration.

This should be part of a more interdisciplinary, dynamic, and inclusive approach to the entire

management of the assessment program, as a basis for a conformity assessment that is itself adaptive and always responsive to the increasing complexity of its object tasks.

**Figure 1** (below) summarizes and aims to detail the assessment scenario, highlighting the needs for change deriving from the context according to: an increasing order of complexity; the corresponding qualities that an "adaptive" organization must have to satisfy these needs; the results deriving from the application of these skills; and the list (simplified and not exhaustive) of the corresponding areas of focus of the assessment. It should be noted that this is a broad outline scheme, presented with the aim of illustrating more clearly the functional relationship between some of the main concepts described up to now.



#### answers and focus areas of the assessment

#### **Author Biography**

**Nicola Gigante** holds degrees in architecture and sociology (respectively from Polytechnic of Turin and University of Urbino). He is assessor of Accredia, Italian Accreditation Body, with more than 1,600 assessments provided by the CABs and the certified organizations. Nicola is also assessor for CEN-CENELEC, and convenor and member of many ISO Technical Committees and Technical Groups.

<sup>3</sup> Ref. International Vocabulary of Metrology — Basic and general concepts and associated terms (VIM). Third Edition 2008: 2.3 (2.6) measurand: quantity intended to be measured.

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DOI: doi.org/10.55459/IJCA/v2i1/GA.PM.HM

## 'Risky Business': A Comprehensive Risk Analysis of an Accreditation Body

By Dr. George Anastasopoulos, Senior Vice President, IAS; Patrick McCullen, Senior Program Manager, Management System Certification Bodies, IAS; and Harry Makam, Accreditation Program Officer, IAS

#### -ABSTRACT-

Risk assessment and risk-based thinking are both key aspects considering the multi-faceted activities inherent in Conformity Assessment. As an Accreditation Body (AB), risk assessment is used to ensure a consistent, data-based approach towards accreditation of conformity assessment bodies.

The following paper presents methodology, lessons learned, and best practices found while conducting risk management at the AB level within the Global Conformity Assessment industry. It provides a framework for conducting a Modified Fink Risk Assessment and Analysis for use by various organizations, including accreditation and conformity assessment bodies, such as testing and calibration laboratories, inspection agencies, product and personnel certification bodies, management system certification bodies, etc.

Keywords: Accreditation body, risk assessment, risk analysis, risk-based thinking, conformity assessment bodies, ISO/IEC 17011, likelihood, contingency plan, mitigation plan, Fink method, impact score

#### Definitions

- 1. **Risk:** Effect of uncertainty on objectives (see ISO 31000:2018).
- 2. **Risk Assessment:** A set of techniques and methods on the system level to predict future events and their consequences.
- 3. **Mitigation:** The action of reducing the severity, seriousness, or painfulness of something (Oxford Dictionary).
- 4. **Contingency:** A provision for an unforeseen event or circumstance (Oxford Dictionary).
- 5. Crisis Impact Value (CIV): Value used to quantify and convey the "Likelihood" and "Impact" of a given risk.
- 6. **Likelihood:** The probability of occurrence of a given risk or situation.
- 7. **Impact:** The potential severity of consequences of a given risk or situation.
- 8. **Conformity Assessment:** Demonstration that specified requirements relating to a product, process, system, person, or body are fulfilled (See ISO/IEC 17000:2004).
- Accreditation: Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks (see ISO/ IEC 17011:2017).

#### Introduction

According to clause 4.4.6 of ISO/IEC 17011:2017, the accreditation body "shall have a process to identify, analyze, evaluate, treat, monitor and document on an ongoing basis the risks to impartiality arising from its activities." However, risk-based thinking doesn't stop with impartiality considerations. In fact, the ISO/IEC 17011:2017 standard mentions "risk" a total of 21 times throughout the document. Accreditation bodies, and accredited conformity assessment bodies, must consider the impact of risk on all activities on an ongoing basis.

This risk assessment and analysis deals strictly with the impartiality/business risks related to the ongoing sustainability of the International Accreditation Service, Inc. (IAS) as a global conformity assessment accreditation provider. The below analysis considers IAS-specific risks related to seven broad categorizations related to the overall organization:

- 1. General and Administrative
- 2. Global Business
- 3. IT Systems
- 4. Assessment Resources
- 5. IAS Policies, Procedures, and Processes
- 6. Conflicts of Interest/Impartiality
- 7. Miscellaneous

#### Risk Management and ISO/IEC 17011:2017

ISO/IEC 17011:2017 is the International Standard (IS) used by regional cooperations to conduct peer evaluations of ABs worldwide. If an AB wishes to be recognized under the IAF or ILAC multilateral agreements, they must be prepared to demonstrate compliance with ISO/IEC 17011:2017 to their local regional accreditation groups. One significant aspect of operating an internationally recognized AB is implementing the risk management requirements found in the Standard.

The word "risk" can be found 21 times throughout the Standard. However, it is not enough to do a simple word search and note "risky" areas. Instead, conformity assessment professionals must operate under the paradigm of risk-based thinking (RBT). RBT supposes that in every situation, there are risks, and there are opportunities. Practitioners of risk assessment must constantly be on the lookout for these risks and opportunities and should take measures to either mitigate the risks, or, capitalize on the opportunities. From an AB standpoint, RBT should pervade business and technical decision making. Is this application for accreditation going to present the AB with untenable risk? Is the decision to not use checklists going to present an untenable risk? What opportunities does it present? How can this situation be used to make the AB better? What are some measuring the AB can take to reduce the likelihood and/or impact of the risk? These are all good examples of guestions that should arise from RBT.



#### **Risk Management Is Also Important for Conformity Assessment Bodies (CABs)**

Risk management is equally as important for CABs. Below are the mandatory requirements for risk management that can be found in the various standards, for example:

Clauses 5.2.3, 6.2.1, 7.2.9, 9.1.4.2, and 10.2.5.2 of ISO/ IEC 17021-1:2015

Clauses 4.2.3, 4.2.4, and 4.2.11 of ISO/IEC 17065:2012

Clauses 9.4.9 and 9.6.3 of ISO/IEC 17024:2012

Clause 4.1.3 of ISO/IEC 17020:2012

Clauses 4.1.4, 7.8.6.1, 7.10.1, 8.5, and 8.9.2 of ISO/IEC 17025:2017

There are many sections within the Standard that require risk management, even where it isn't expressly written. For instance, a management system's certification body must consider risk when determining audit time and practice risk management when it sets procedures for the determination of audit time. The CAB decides, based on appetite for risk, what is an adequate justification for reduction or increase in audit time. Similarly, a testing laboratory may need to consider the level of risk (to the public, to the lab, to the UUT) associated with a specific statement of conformity and practice risk management by establishing risk levels associated with the specific scope of testing.

In any situation, appropriate risk management ensures that personnel at all levels of an organization are aware of, working to mitigate or take advantage of, and constantly identifying and analyzing associated risks and opportunities that otherwise may go unnoticed until they develop into a crisis or a lost opportunity.

#### Why Risk Management?

First, appropriate risk management is the key to any successful business. Risk management is critical to those that wish to operate their business from a proactive, rather than a reactive standpoint. Risk management is also crucial to ongoing improvement within an organization. Understanding the risks and opportunities presented by different situations allows for the development of mitigation and contingency plans for the risks, and strategy and tactics for the opportunities. This highlights a very important concept when considering risk management; it is very difficult to eliminate a specific risk or guarantee a specific opportunity. Instead, we reduce/increase one, or both of the following factors:

**Likelihood of Occurrence**: On a scale of 1% to 100%, what is the likelihood of this risk/opportunity happening?

**Impact:** On a scale of 1 to 10, what is the impact should this risk/opportunity happen?

However, before arriving at the point of developing mitigation and contingency plans and truly managing one's risks, one must first identify the risks; analyze them to determine the above factors; prioritize the list so that the most important, most likely, and higher impact risks are identified; and quantify the data. This is what is known as conducting a risk assessment.

#### Methodology

Following a modified Fink approach, this risk assessment/analysis was initiated by first seeking input from IAS personnel to ascertain the top risks as perceived by the various staff members. Consideration was also given to various risk registers and internationally accepted methodologies when developing this risk assessment (see, for example: EA-2/19 INF:2020 – List of Risks for Accreditation Processes and Operation of National Accreditation Bodies and ISO 31000:2018 – Risk Management -Guidelines).

After receiving the first round of feedback, risks were divided into seven broad categories referenced above. After categorization, "like risks" were combined to bring the overall list to a more manageable level. At this point, the refined lists were recirculated to staff and all individuals were asked to estimate:

- A. The likelihood of the risk materializing (1% [Not Likely] – 100% [Extremely Likely])
- B. The impact should the risk materialize (1 [No Impact] – 10 [Significant Impact])

for each risk presented in the refined lists for each broad category with the aim of calculating Crisis Impact Values (CIVs) for each identified risk.

Responses were received from nearly all staff included in the poll, and CIVs were calculated for each risk presented. Risks were ordered according to CIV (largest to smallest) and those risks falling within the medium to high risk levels (CIV>250) were isolated. Each risk value was plotted on a risk matrix



to provide visual representation of where each risk falls on the graph, per category (see next section).

The next step in the process was to define and draft both mitigation and contingency plans for each identified risk.

A mitigation plan is enacted to reduce the likelihood and/or impact of a specific risk; it is synonymous with a preventive action.

A contingency plan is enacted to respond to a crisis arising due to a specific risk; it is synonymous with a corrective action.

To identify appropriate mitigation/contingency plans, the risks that were classified as medium to high from each category were sent to all relevant staff based on areas of responsibility, and staff were asked to answer the following two questions, per risk:

- A. What preventive actions do you propose to reduce the likelihood and/or impact, if possible, of this risk? (i.e., mitigation plan/action)?
- B. What actions do you propose if the risk escalates into a crisis (i.e., contingency plan/ action)?

Once staff responded to this request, responses were compared, "like suggestions" were combined, and the final mitigation/contingency plans were presented for analysis in the subsequent sections of this document.



Based on the mitigation and contingency plans discussed in section 4 below, the top management and managers related to each department were tasked with defining the allocation of resources for implementation of the selected proposed actions. These mitigation/contingency measures are reviewed on an ongoing basis for continued effectiveness throughout the lifecycle of the organization. Based on the review of these actions and their effectiveness, IAS continues to make changes based on feedback data received.

#### **Risk Assessment and Analysis Methods**

#### **Step 1: Information Gathering**

Understanding the business and associated interested parties is a critical first step in risk assessment. (For the remainder of this paper, risk(s) is used interchangeably for risk/opportunity.) Practitioners should consider, for example:

- 1. What are some important aspects of the business? Is it product-based, service-based, or both? What is the level of public scrutiny? Is the business sector regulated? Is it dangerous? Does it use contract workers? What is the level of associated liability?
- 2. Who are the interested parties related to the business? Staff? Customers? The public? Regulators? Industry groups? Governments?

Then, form a group of the identified interested parties, provide a brief on the business (generated by asking question 1, if needed), and ask the interested parties to identify risks anticipated within the business. This can be accomplished quite simply using email, and does not need to be a lengthy, highly technical process. Seeking input from individuals at all levels within an organization (e.g., administration, technical, management, finance, etc.), including external individuals (e.g., trade groups, regulators, subject matter experts, etc.) when appropriate, helps ensure that the business is considered from many different perspectives, increasing the likelihood that relevant risks will be identified and reported.

#### **Step 2: Categorization and Combination of Risks**

Upon collecting the responses, the next step is to create broad categories based on the various risks received. This allows for combination of "like risks" helping to reduce the overall workload and duplicate analysis later. Categories should make sense for the business, and some example categories are as follows: regulatory risks, IT systems risks, conflict of interest/impartiality risks, resource risks, domestic business risks, international business risks, and policy, procedure, or process risks. Once broad categories have been identified, risks can be grouped under each of the categories. During the grouping process, if "like risks," or, risks that are similar in subject, are discovered, they can be combined to reduce the overall list of risks. For example, "loss of internet connectivity while traveling," and "inability to connect to IT systems while on the road" can be combined into "loss of internet connectivity while traveling." Here is another example where two similar risks can be combined: "Inability to complete jobsite projects in allocated time" and "Not enough time to complete complicated paperwork while at a jobsite." In this case, they may be combined into a single risk that addresses both of the individual ones: "Complicated paperwork requires too much time while on the jobsite, which prevents project completion." In this case, one risk was a cause of the other. It is very important to consider risks from a holistic point of view as in many cases, risks are related to one another.

#### Step 3: Ascertain Impact/Likelihood of Each Risk

Now that risks have been categorized and combined, where appropriate, the next step is to seek interested party input for the Impact (1-10) and Likelihood of Occurrence (1% to 100%) of each risk. Like step 1, this can be easily accomplished via email and should not be a lengthy or highly technical process. Simply arrange the risks according to category, identify the most relevant interested parties for each category, and ask them to report:

A. What they think the Impact of each risk is on a scale of 1 to 10, and

B. What they think the Likelihood of Occurrence of each risk is on a scale of 1% to 100%

For example:

Category	Risk	Impact (1-10)	Likelihood (1% to 100%)
Travel	Loss of internet connectivity while traveling	?	?
	National lockdown in response to pandemic	?	?
Service Completion	Complicated paperwork requires too much time while on the jobsite, which prevents project completion	?	?
Administrative	Contract employees do not submit pay cards on time	?	?

Once interested parties have responded with their input, the next step is to combine responses to arrive at average values for each aspect for each risk.

#### **Step 4: Quantify Data and Plot Visually**

While the responses received for many of the risks may seem to indicate a straightforward hierarchy, it is important to double check preliminary results by plotting the risks and calculating values for each risk. Once responses are received from all interested parties, calculate the average values for both Impact and Likelihood for each of the risks on the list. Once in a single list, with one value for Impact and one value for Likelihood for each of the risks, they can be plotted on a graph similar to the one below:



TABLE 1.

As you can see, the X axis is the Impact, while the Y axis is the Likelihood. For example, compare the below table with the following graph:

TABL	E.	2.
TADE		

Risk Identifier	Category	Risk	Impact (1-10)	Likelihood (1% to 100%)
A	Travel	Loss of internet connectivity while traveling	6	70
В		National lockdown in response to pandemic	7	80
С	Service Comple- tion	Complicated paperwork requires too much time while on the jobsite, which prevents project completion	8	20
D	Adminis- trative	Contract employees do not submit pay cards on time	3	30



Figure 2

The above graph also demonstrates the four risk level zones. After plotting the two values on the graph, each risk falls within a different zone. Risk A is considered high – medium risk, risk B is considered high risk, risk C is considered medium risk, and risk D is considered low risk. For these four risks, it is quite clear where they fall on the graph; however, what happens when Impact and Likelihood numbers are far closer together? Consider the following graph and table:



#### Figure 3

The above risks have Impact and Likelihood values so close together, it is difficult to see which risk is more critical. For this situation, calculate the Impact Value (IV) of each risk. To arrive at the IV, multiply the Impact, by the Likelihood; see the far-right column for calculated IVs.

TABLE 3.

Risk Iden- tifier	Cate- gory	Risk	Impact (1-10)	Like- lihood (1% to 100%)	Impact Value (Impact x Likelihood = IV)
A	Travel	Loss of inter- net connec- tivity while traveling	6.2	75	465
В		National lockdown in response to pandemic	6.3	72	453.6
С	Service Com- pletion	Complicated paperwork requires too much time while on the jobsite, which pre- vents project completion	6.9	70	483
D	Admin- istrative	Contract em- ployees do not submit pay cards on time	6.4	74	473.6

After calculating IV for each of the risks, reorganize them so that they appear in ranked order. Considering the above results, risk C has the highest value, which indicates that it is the most critical of the four example risks. See below for a reorganized ranked list based on IV:

TABLE 4.				
Ranked Order	<b>Risk Identifier</b>	IV		
1	С	483		
2	D	473.6		
3	А	465		
4	В	453.6		

## Step 5: Identify Acceptable Risk Level (ARL) and Risks Exceeding ARL

Upon arriving at a hierarchical list of risks and after plotting risks on a graph to see where they fall within the four risk zones, organizations should identify an Acceptable Risk Level (ARL). This level can be identified generally based on the four risk zones; for example, all risks falling within the medium and low risk zones are acceptable, or, it can be identified more granularly based on a specific IV; for example, all risks with an IV less than 400 are acceptable. Once the ARL has been identified, note the risks that fall above the ARL. These are the risks that require treatment. See below for an example:

ARL = Risks < IV=400

IABLE 5.			
Ranked Order	Risk Identifier	IV	Treatment Required?
1	С	483	Yes
2	D	473.6	Yes
3	A	465	Yes
4	В	453.6	Yes
5	E	419	Yes
6	Н	400.2	Yes
7	F	398	No
8	G	350.4	No
9	I	343	No
10	J	320.5	No

#### Step 6: Circulate Risks Exceeding ARL Back to Interested Parties and Ask for Mitigation/ Contingency Plans

Take the list of risks requiring treatment and recirculate to the interested parties and ask for suggested mitigation and contingency plans for each risk. While like before, this should not be a time-consuming and highly technical process, it may require more clarification to the interested parties regarding what is expected for the plans. A mitigation plan is a plan that:

A. Reduces the Likelihood of Occurrence of the risk

or

B. Reduces the Impact of the risk

or

C. Reduces both the Likelihood of Occurrence and Impact of the risk

A mitigation plan is a plan that is instituted immediately and is typically used to achieve A through C before a risk evolves into a crisis.

A contingency plan is a plan that can be instituted in case the specific risk evolves into a crisis and typically reduces the Impact, or longevity of the crisis, as it is too late at this point to reduce the Likelihood of Occurrence.

To use terms familiar to the conformity assessment industry, a mitigation plan can be considered preventive action; whereas, a contingency plan can be considered corrective action/correction.

#### Step 7: Combine and Select Proposed Mitigation/ Contingency Plans

Once responses to the latest query have been received, like what was done with the risks during step 2, mitigation and contingency plans should be reviewed, analyzed, and combined where appropriate. For example, for the same risk, two similar mitigation plans may be proposed:

Risk	Party A Proposed Mitigation	Party B Proposed Mitigation	
Loss of internet connectivity while traveling	Ensure air/ground transport has available Wi-Fi before booking ticket	Carry cellular plan- based internet hotspot-capable device	

TARI F 6

These two mitigation plans may be combined to read: Ensure air/ground transport has available and reliable Wi-Fi before booking ticket; if not or if questionable, carry cellular plan-based internet hotspot-capable device as backup. The combined mitigation plan takes both suggestions and increases their reduction to Likelihood of Occurrence by providing a two-pronged response rather than a single pronged response.

Once mitigation and contingency plans have been reviewed, analyzed, and combined where

appropriate, decide on a final list of plans for each risk to be presented to top management. There are many different factors to consider when deciding on a final list, for example: Is this mitigation/ contingency cost effective? Does either plan require hiring of additional personnel? What is a tentative timeframe for implementation of each plan? Does each plan truly address the root cause of the risk, or does it merely treat a symptom? It is expected that different organizations may arrive at very different criteria regarding feasibility of different mitigation/ contingency plans.

#### Step 8: Management Review to Decide on Appropriate Mitigation/Contingency Plans, Implementation, and Evaluation of Residual Risk

Top management should be engaged to decide on which mitigation/contingency plans should be implemented to treat each of the risks. This is very commonly achieved through a risk discussion during the already planned management review meeting; however, this could certainly necessitate an individual meeting in many cases as well. Once management has selected the plans they wish to implement, the organization then implements them. As discussed previously, very rarely do mitigation plans eliminate a risk entirely; instead, they reduce either the Impact or Likelihood of Occurrence. This means that even after implementing the plans, residual risk exists. Depending on how successful the implementation and execution of the plans are, there may be the same or less residual risk. To calculate residual risk, follow a very similar process as was described for the initial information gathering phase:

- 1. Circulate a list of the risks and a brief description of the mitigation that was implemented.
- 2. Ask interested parties to consider the mitigation and to re-enter revised values for Impact and Likelihood of Occurrence.
- 3. Replot and re-run the IV for each of the risks to arrive at the residual risk level.
- 4. If residual risk is acceptable, document the justification for acceptability.
- 5. If residual risk is unacceptable, repeat the entire exercise and attempt new mitigation measures until such time that the residual risk is deemed acceptable.

There should be visible movement of the risks on the graph when they are replotted post-mitigation. For

example, recall the graph with A, B, C, and D shown in Step 4:



Now, suppose mitigation measures have been implemented for each risk, as below:

Risk A: Mitigation measure successfully implemented to reduce Likelihood of Occurrence

Risk B: Mitigation measure successfully implemented to reduce Impact

Risk C: Mitigation measure successfully implemented to reduce Likelihood of Occurrence and Impact

Risk D: Mitigation measure not successfully implemented to reduce either factor

The movement of the risks on the graph would appear like this:



In Figure 5, A2, B2, and C2 are the newly calculated IVs after implementation of the respective mitigation plans. Reducing Likelihood of Occurrence moves the risks in a vertical direction (A), reducing Impact moves the risks in a horizontal direction (B), and reducing both the Impact and the Likelihood of Occurrence moves the risks in a diagonal direction (C). For risk D, the mitigation plan failed to address either the Impact, or the Likelihood of Occurrence, so, the risk plot did not move. The same can be seen mathematically if comparing the IVs previously calculated vs. the IVs calculated post-mitigation.

After rerunning the numbers and finding that residual risk is acceptable, document the justification for acceptability. After rerunning the numbers and finding that residual risk remains unacceptable, repeat the process again until arriving at acceptable residual risk.

#### Step 9: Plan, Do, Check, Act

Like nearly everything in conformity assessment, risk assessment and analysis is not a one-time operation. Instead, it is a continuous process that must be re-done whenever significant changes to the organization, or organizational context occur. There is no magic number or frequency that dictates ideal intervals of risk assessment and analysis. Instead, it is up to the organization to define when, why, and how risk assessment and analysis will take place.

#### **Other Considerations**

Read on for additional discussion regarding other considerations that were not covered in the above methods section.

#### **Extended Impact Score**

Wherein this paper the value for Impact of each risk was requested simply by asking for an answer on a scale of 1 to 10, it may be valuable to use a more extensive method to ascertain Impact. In order to find the Extended Impact Score, instead of simply asking interested parties for a number between 1 and 10, ask the following five questions:

- 1. If the crisis escalates in intensity, how intense might it get for you?
- 2. To what extend would the crisis fall under someone's watchful eye, such as the news media or some government regulatory agency?
- 3. To what extent would the crisis interfere with the normal operations of your business?
- 4. To what extent would your company's public image and/or your personal reputation be damaged in the event of the potential crisis?

5. In the event of the potential crisis, to what extent will your company's bottom line be damaged?

Respondents should answer with a value between 1 and 10 for each of the five questions. Then, the practitioner takes these values and calculates the average to arrive at a single value for Impact. This could provide a more insightful value for Impact based on the position of the individual within the organization.

#### Significance/Importance Factors

Another aspect of the modified Fink approach to risk assessment and analysis is the inclusion of Significance or Importance Factors. These factors can be used to add a weighted approach towards the original risk assessment and analysis of Impact and should be between 1 and 5. For example, an organization may identify that the CEO of the organization has more of a holistic understanding of the organization, compared to, for example, an employee who works in the warehousing and shipping department. In this case, the organization may assign a Significance Factor of 5 to the CEO, and a Significance Factor of 1 to the warehousing/ shipping employee. After receiving the anticipated Impact values for each risk from each employee, the practitioner would multiply each value by the relevant Significance Factor. For example:

ТΔ	RI	F	7
-			

Risk	CEO Impact Response	Warehousing/Shipping Employee Impact Response
Loss of internet connectivity while traveling	5	5

While both have used 5 as the anticipated impact, the CEO's Significance Factor is 5, while the warehousing/shipping employee's Significance Factor is 1. Notice below how the CEO's answer now carries far more weight than that of the warehousing/shipping employee:

TABLE 8.

Risk	CEO Impact Response	Warehousing/Shipping Employee Impact Response
Loss of internet connectivity while traveling	5(SF=5)	5(SF=1)
Recalculated with Significance Factor	25	5

This will skew the data based on the weighted response, which may better serve the practitioner

in some cases. In some situations, it makes sense to use this additional factor, in others, it may not; it is completely up to the organization and risk assessment practitioners to decide. As a final example, if the risk is one having to do with overall finance of the company, it makes sense for the CEO to have a greater Significance Factor than the warehousing/shipping employee; however, if the risk is one that has to do specifically with warehousing or shipping of products, perhaps the opposite may be true and the warehousing/shipping employee should have the greater Significance Factor.

#### **Graphical Representation of Data**

A picture is worth a thousand words. This phrase is constantly repeated in marketing, sales, finance, data management, and many other professional courses and collections of best practices. The same holds true for risk assessment and analysis. If results can be demonstrated, rather than written, often, the audience will better understand the data. Further, presenting data graphically saves all parties time and effort.

#### **Categorization of Risks**

Categorization of risks can be both a positive and a negative influence on risk assessment and analysis. While categories help reduce duplicate work and combining similar or like risks may help reduce the number of items in a risk assessment, there is a chance that when combined, the "essence" of a specific risk is lost. Perception is a very personal process. If practitioners are not entirely clear on the subject and "essence" of the risk being proposed, the point of the risk may be lost due to perceptional differences. If practitioners are unsure of the specific meaning of a risk, conferring with the interested party that reported the risk is certainly advised. This concept also holds true when combining like mitigation or contingency plans and should be considered at every turn of the risk assessment and analysis. Perception is a powerful factor that could have far-flung influences on your overall process if not appropriately considered and controlled.

#### **Contingency Plans**

This paper briefly discussed contingency plans as the focus was more on risk assessment and analysis, rather than on risk management. Contingency plans are often more associated with overall risk management as they are not something that get immediately implemented like a mitigation plan. Instead, they are held in reserve should the need arise to implement them in response to a crisis. A good contingency plan consists of a correction (immediate action), corrective action (planned, phased action), root cause analysis (to understand why and how the crisis happened), and mitigation options for the future (to prevent recurrence or reduce the impact or likelihood of recurrence).

#### Examples of Risks Relevant to Accreditation Bodies and Conformity Assessment Bodies



**Risk 1:** Lack of staff to support ongoing growth, current operations, vacation time, back-up personnel, and increased staff competence needs

Mitigation Plan	Contingency Plan	
Cross-training of staff	Hire existing contractors as full-time staff	
Hire more contract staff	Utilize contracted assessors	
Contingency plans for absences	Involve retired staff knowledgeable in the respective processes	
Designated back-ups for each position	Cross train existing employees	
Hire more full-time technical staff (consider temp to hire)	Hire more contract employees	
Hire another full-time administrative staff person (consider temp to hire)	Hire temporary employees	
Clear demarcations for staff responsibilities, and reorganizing organizational structure	Bring additional management and technical personnel to help on contingency	

#### Risk 2: Health risks (i.e., COVID-19)

Mitigation Plan	Contingency Plan
Ask assessors and all traveling people to have travel insurance, especially when traveling to high-risk (related to health) countries	Remote assessment to be administered
Provide instructions to staff/assessors	Stop all travel
Maintain work-at-home options	Senior management team will be immediately activated to ensure safety with company policies, like all planned contingencies
No onsite assessment to be planned until COVID-19 subsides	
Introduce a crisis management team	
Have back-ups/deputies for key positions	
Encourage staff to work on OneDrive rather than personal computer, to ensure access to important data	

#### Risk 3: Slow reaction time from IT development team

Mitigation Plan	Contingency Plan	
Set standards of service for IT development requests	Hire external contractor for IT development	
Frequent meetings with IT, following up on their tasks	Prepare a continuity plan utilizing alternate resource	
Evaluation of IT as external supplier	Ensure that the work-around tools and process are available and staff have been trained to deploy them when IT tools are delayed or lacking	
Hire a full-time IT person	IT team needs to have a contractor who can provide support in their absence	
	Cross train existing employees with an aptitude for IT or hire more IT- savvy contractors	

#### Risk 4: Assessors cannot access appropriate resources/IT systems when needed

Mitigation Plan	Contingency Plan
Issue a "portal map" or "troubleshooting" guide	Use paper copies of documentation/resources
Training on the IT system to be made mandatory for each assessor either during inception or on an ongoing basis	Ensure that alternative options (back to paper, spreadsheets, etc.) can be quickly enabled if portal system goes down, etc.)
Introduce help center for end users	Continue utilization of existing assessment processes using Google Docs and Dropbox, and limit access to company resources/IT systems to accreditation program manager
Upload and provide access to assessors to rules, policies, procedures, and previous assessments documentation	
Formally evaluate the need for assessors in each program to have access to the IT system resources	
Assign specific staff who can help assessors	
Make use of IT OneDrive	

#### **Risk 5:** Fraudulent behavior: CABs issuing false reports/certificates, incorrect use of logo

Mitigation Plan	Contingency Plan
Educate clients with interactive resources	Suspend suspicious CABs until further notice
Continually review possible mechanisms to help prevent fraudulent behavior	If identified during assessment, lead assessor to inform client about required actions. Include it in his/her report to IAS
Lead assessors and IAS staff should be trained on how to handle such cases	IAS program manager try to resolve the issue with client and inform IAS top management
Make fraudulent accreditation claims public on IAS website, train assessors on logo requirements, and make sure correct usage is checked with every assessment	Suspend, investigate and cancel, if needed
Unannounced assessments	Take legal action if needed per IAS top management decision
Increase frequency of visits on CABs identified as "bad actors"	
Conduct ongoing surveillance activities (not just surveillance assessment) as specified in 17021-1	

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#### **Acknowledgement**

The creation of this paper is due to the contributions made by IAS staff. Without them, this paper would not have been possible. We sincerely thank them for all their thoughts and efforts throughout the process.

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committees who developed the new ISO 9001 and ISO/IEC 17025. He was awarded the EOO Presidential Georges Borel Award for international achievements in quality. He presented lectures related to Accreditation, Conformity Assessment, Management Systems, BPR, Telecoms-FTTH-IT and Process Auditing. He participated in consulting and research projects in the USA, European Union, and many other countries worldwide.



Patrick McCullen serves as the Senior Program Manager of the Management System Certification Body at International Accreditation Service (IAS). After a number of jobs within the construction, service, and manufacturing industries spanning 10 years, Patrick

McCullen joined IAS in December, 2014. Since that time, he has held a number of roles within the company serving the Testing Laboratory, Calibration Laboratory, and Management Systems Certification Body programs. Patrick has his bachelor's degree in English and an MBA in Engineering Management. He has 8+ years' experience in the accreditation body realm and regularly conducts assessments for the ISO/IEC 17021-1 program. He participates in various international committees/ working groups including the APAC Business Continuity Management Systems Working Group as well as the APAC Management Systems Committee and the IAF Remote Assessment Task Force. Patrick is a provisional evaluator for APAC in ISO 9001:2015, ISO 14001:2015 and ISO 45001:2018. He is a high-energy facilitator for multiple IAS training programs and greatly enjoys the interactive nature of the IAS learning model and being able to network with international colleagues. Patrick has also delivered a number of presentations at conferences such as the Measurement Science Conference, NCSLI, APAC, and ASQ.

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Accreditation Program Officer at International Accreditation Service (IAS). He has his BS in Forensic Science from the University of Nebraska - Lincoln. He is also an EPA Microbiology Lab Certification Officer and has performed numerous assessments on testing



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## **Section B**

an informative section that includes general articles, announcements, white papers, etc.

## Accreditation of Agri-Food and Medical Laboratories in the UEMOA Region: An Opportunity for the Promotion of Sustainable Public Health

By Marcel Gbaguidi, Resident Representative and Director General of the West African Accreditation System (SOAC-WAAS); Kafui Codjo Kouassi, Associate Professor in Biochemistry – Nutrition and Conformity Assessment/University of Lomé (Togo); and Amadou Diop, SOAC-WAAS National Accreditation Focal Point in Mali

#### -ABSTRACT-

In an increasingly changing and demanding world, Quality Infrastructure is an instrument that is both important and essential in a context marked by health, environmental, economic, and social issues. Among the pillars of Quality Infrastructure, accreditation plays an important role, ensuring the technical competence and integrity of bodies offering conformity assessment services, such as testing, medical testing, calibration, certification, inspection, and validation/ verification based on recognized international standards.

The objective of this article is to highlight the importance and role of the *Système Ouest Africain d'Accréditation*/West African Accreditation System (SOAC-WAAS) in preserving and promoting the health of populations and the competitiveness of West African economies.

Given the importance of accreditation, the West African Economic and Monetary Union (UEMOA) that gathers eight countries (Benin, Burkina Faso, Côte d'Ivoire, Guinea Bissau, Mali, Niger, Senegal, and Togo) created, in 2005, SOAC-WAAS, a multi-economy accreditation body. The latter is the only authorized accreditation body for the eight UEMOA member states. Its mission is to deliver and promote accreditation in the community area, particularly through the issuance of accreditation certificates to conformity assessment bodies (CABs). To date, SOAC-WAAS has accredited forty-six (46) conformity assessment bodies, including four (4) calibration laboratories, three (3) certification bodies, and thirty-nine (39) testing laboratories. Among the SOAC accredited testing laboratories, one (1) is in the field of forensics and ten (10) are medical laboratories. Fourteen (14) testing laboratories and the three (3) accredited certification bodies are operating in the agri-food sector.

This result, which is certainly insufficient for the entire UEMOA region, is still encouraging and contributes to the preservation of health and protection of the population, particularly with regard to accredited agri-food and medical testing laboratories.

Keywords: Accreditation, laboratories, public health, Agri-food, UEMOA, ECOWAS



#### Introduction

In a constantly changing and demanding world, Quality Infrastructure is an instrument that is both important and essential in a context marked by health, environmental, economic, and social issues. Quality Infrastructure corresponds to the entire institutional framework required to establish and implement standardization, metrology, accreditation, and conformity assessment services based on internationally recognized standards.

These international standards include the following: ISO IEC 17065 for the accreditation of product certification bodies: ISO IEC 17020 for the accreditation of inspection bodies; ISO IEC 17025 for the accreditation of testing and calibration laboratories: and ISO 15189 for the accreditation of medical laboratories. The implementation of the requirements of these standards by accredited conformity assessment bodies (CABs) quarantees consumer health. as well as product safety and suitability for use. Unfortunately. on the African continent. accreditation is one of the weak links of Quality Infrastructure.<sup>1</sup> Given its important role, African leaders created in 2010 the

1 Development of Accreditation in Africa (AFRAC, 2020)

African Accreditation Cooperation (AFRAC) of which the West African Accreditation System (SOAC-WAAS) is a member. AFRAC has around 20 members, including 13 accreditation bodies.

In West Africa, Quality Infrastructure has evolved a lot over the past ten years, with the existence today of the Economic **Community of West African States** (ECOWAS) Regional Accreditation System (ECORAS), composed in particular of the SOAC-WAAS for the eight UEMOA States, **NiNAS** (Nigerian Accreditation Body), and GhaNAS (Ghanaian Accreditation Body). SOAC-WAAS was created in 2005 by Regulation No. 01/2005/CM/ UEMOA, on the Scheme for the harmonization of Accreditation, Certification, Standardization, and Metrology activities in the UEMOA region, revised in 2010. This organization is essential for the UEMOA region, which abounds with agri-food industries and medical laboratories. Indeed. **UEMOA** industrial production index increased by 5.4% in 2018 thanks to the improvement in manufacturing industries (+10.2%) driven by chemicals (+26.2%), but also food and drink (+14.5%). These products need to be tested by ISO/IEC 17025 accredited laboratories to, in particular, ensure the health security<sup>2</sup> of our populations and facilitate exports within and outside Africa. Regarding aid in the diagnosis and monitoring of non-communicable diseases (e.g., diabetes, arterial hypertension, obesity) and those transmissible (e.g., COVID-19, malaria, HIV, and tuberculosis),

very few laboratories are ISO 15189 accredited.<sup>3</sup>

The objective of this article is to highlight the importance and the role of SOAC-WAAS accreditation in the preservation and promotion of the health of populations as well as the competitiveness of West African economies.

Among the pillars of Quality Infrastructure, accreditation plays an important role, making it possible to ensure the technical competence and integrity of bodies offering conformity assessment services on the basis of recognized international standards.

#### **Missions of SOAC-WAAS**

The mission of SOAC-WAAS is to promote accreditation in the UEMOA region, in particular through the issuance of accreditation certificates to conformity assessment bodies (CABs).

#### Organizations Accredited by SOAC-WAAS: Advantages and Opportunities

To date, SOAC-WAAS has accredited forty-six (46) conformity assessment bodies, including four (4) calibration laboratories, three (3) certification bodies, and thirty-nine (39) testing laboratories. Among the SOACaccredited testing laboratories, one (1) is in the field of forensics and ten (10) are medical laboratories. Fourteen (14) testing laboratories and the three (3) accredited certification bodies are operating in the agri-food sector.

In the field of trade, particularly with regard to agri-food products, the challenges related to quality explain, today, the difficulties of access and placing safe West African products on the local, regional, and international markets. At this level, accredited testing laboratories in the agrifood sector play an important role in terms of assessing the conformity of such products with normative requirements. These testing laboratories most often support certification and/ or inspection bodies to certify products' conformity. Trade in agri-food products is of growing importance in the UEMOA economies. UEMOA's extracommunity trade is much more oriented towards the European Union and represents 31.4%<sup>4</sup> of total trade with other partners. More than three quarters  $(3/4)^5$ of the value of exports remains concentrated on raw materials, in particular agricultural and food products. Given the requirements of international markets, particularly European ones, the trade in these products is encountering major exportrelated constraints. These are, among others, the low quality of exported products, the lack of professionalism of the actors, the weakness of the professional organizations of the sectors, and the non-compliance of the products with the regulatory and commercial requirements for export on the international markets. These requirements, therefore, most often constitute Technical Barriers to Trade (TBT) and shortcomings in compliance with sanitary and phytosanitary

<sup>2</sup> https://www.unido.org/sites/default/ files/2007-11/71767\_TCB\_No.02.Promouvoir\_ lacces\_des\_produits\_agroalimentaires\_de\_lU-EMOA\_au\_marche\_de\_lUnion\_europeenne\_0. pdf

<sup>3</sup> https://www.linfodrome.com/ sante/58079-covid-19-accreditation-et-securite-des-laboratoires-de-biologie-medicale-dans-l-espace-uemoa-et-cedeao-une-structure-renforce \_ free-of-charge-the-capacity-of-about-thirtytechnicians

<sup>4</sup> UEMOA Trade Surveillance Report, 2016 5 UEMOA Trade Policy Review, 2017





(SPS) measures. An accreditation body that has signed international recognition agreements, such as SOAC-WAAS, therefore contributes to removing these constraints.

#### International Recognition of SOAC-WAAS by ILAC and AFRAC

International recognition of conformity assessment results is an essential principle that explains the existence of international umbrella organizations in terms of accreditation, such as the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF). This recognition is formalized by the signing of mutual recognition arrangements by accreditation bodies, after they have been submitted beforehand to a rigorous evaluation of their working method by peers.

Thus, aware of the need to allow the laboratories it accredits to be able to have their results recognized throughout the world, SOAC-WAAS has embarked on peer evaluation process. This process resulted in the signing of the mutual recognition agreements of AFRAC and those of ILAC, for the benefit of SOAC-WAAS accredited calibration, testing, and medical laboratories.<sup>6</sup>

For medical laboratories, it notably makes it possible to guarantee the reliability of the analysis. Also, the patients concerned are exempted from additional analysis in the country of destination. The reliability of the medical tests, granted by an accreditation, is also a guarantee of a better diagnosis and therapeutic followup.

For testing and calibration laboratories, the international recognition of SOAC-WAAS authorizes the acceptance of their results at the international level. This increases consumer confidence in products from West Africa, and, from a trade point of view, contributes to increasing trade by reducing nontariff barriers. It is in view of the mechanism for recognizing the results of conformity assessment that Article 6 of the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT) provides that:

"... Members shall ensure. whenever possible, that the results of conformity assessment procedures of other Members are accepted, even where those procedures differ from their own, provided that they are satisfied that such procedures provide assurance of compliance with applicable technical regulations and standards equivalent to their own procedures ..."

One of the instruments that supports this provision is the accreditation of conformity assessment bodies (Article 6.1.1 of the TBT Agreement).<sup>7</sup>

At the African level, the framework of the African Continental Free Trade Area in Africa (AfCFTA), Annex 6, on Technical Barriers to Trade (TBT), provides in its article 9 that:

"... the States parties are responsible for promoting and facilitating the use of accredited conformity assessment bodies as tools to facilitate trade within the AfCFTA on the continent, etc."<sup>8</sup>

The international recognition of the results of SOAC-WAASaccredited CABs thus plays a decisive role in the framework of trade cooperation between West Africa and its partners, such as the European Union and the United States of America. It participates, for example,

<sup>6</sup> https://www.soacwaas.org/reconnaissance-internationale-du-SOAC.html

<sup>7</sup> WTO Agreement on Technical Barriers to Trade (TBT)

<sup>8</sup> Annex 6 of the AfCFTA Protocol on Trade in Goods

in ensuring better access for West African productions to the markets of these two key partners within the framework, in particular, of the Economic Partnership Agreement (EPA) (Europe) and the African Growth and Opportunity Act (AGOA) (USA).

#### Proficiency Testing and SOAC-WAAS Accreditation: Issues and Relevant Provisions

Proficiency testing or interlaboratory comparison is one of the main levers for ensuring the performance of testing and calibration laboratories. To this end, the inter-laboratory comparison tests are requirements of international standards, such as ISO/IEC 17025, ISO 15189, and ISO/IEC 17020. Thus, SOAC-WAAS has contractual documents setting the requirements for the interlaboratory comparison tests' performance, in accordance with the requirements of ILAC,9 AFRAC,<sup>10</sup> and ISO/IEC 17011.<sup>11</sup>

Inter-laboratory comparisons are organized by proficiency testing providers who should ideally meet the requirements of ISO/IEC 17043 standard.<sup>12</sup> These proficiency testing bodies play an indispensable role in the accreditation process. It is clear that there are very few of this type of CABs in West Africa. Laboratories are often forced to resort to extra-regional inter-

laboratory comparisons, which entails additional costs. To overcome this lack of proficiency testing bodies, the West African Quality System Program (WAQSP) of UEMOA and the Economic Community of West African States (ECOWAS) have initiated activities to promote this specific conformity assessment service. The WAQSP (2014-2019) was funded, in part, by the European Union and executed by the United Nations Industrial Development Organization (UNIDO). In addition, the Community Metrology Committee (ECOMET) was created by ECOWAS Council of Ministers in 2013, along with other attributions in the field of scientific and industrial metrology, to "organize and promote the participation of laboratories in inter-comparisons and support the free movement of metrological artefacts used for comparisons."13

In the UEMOA region, interlaboratory comparisons have been initiated, particularly in Togo. A national proficiency testing program<sup>14</sup> for medical laboratories was implemented in 2016 by the Ministry of Health. This program, supported by the Mérieux Foundation, was carried out by the West African Network of Medical Laboratories (RESAOLAB) and involved 11 government laboratories. The objective of this program was to evaluate the performance of 18 clinical biochemistry examinations.

In order to develop accreditation in West Africa, the governments of the States are called upon to redouble their efforts for the development of inter-laboratory comparisons and/or proficiency tests in order to support the accreditation of laboratories. Also, at the regional level, the two Commissions, namely that of UEMOA and that of ECOWAS, must continue to promote accreditation, in particular by supporting proficiency testing activities in the member states.

#### **Contribution of the Governments of the UEMOA Region**

Governments, through public policies, ensure the protection of populations. As such, they use accreditation as an instrument allowing, on the one hand, the support of the regulators, and on the other hand, as a support for the achievement of well-being (health, environment, safety, etc.). It should be noted that in the UEMOA region, the Republic of Côte d'Ivoire has already a regulation that makes the accreditation of CABs mandatory; this is Decree No. 2014-461 on the terms of application of the Law n°2013 – 866 of December 23, 2013 relating to standardization and quality. In this example, this regulation used accreditation to ensure protection of populations.

In addition, the accreditation of CABs supports the implementation of effective product controls by the competent authorities of UEMOA member states, particularly in the sanitary and phytosanitary field.

#### Conclusion

Accreditation constitutes an important pillar of Quality Infrastructure and contributes to the achievement of the Sustainable Development Goals (SDGs), in particular the protection

<sup>9</sup> ILAC P10, ILAC Policy on Traceability of Measurement Results & ILAC P14, ILAC Policy for Uncertainty in Calibration 10 TP003-01 AFRAC Guidelines on the Method for Stating Test and Calibration Results 11 Conformity assessment - Requirements for accreditation bodies accrediting conformity

assessment bodies 12 Conformity assessment - General requirements for proficiency testing

<sup>13</sup> Regulation C/REG.12/06/17 on the organization and functioning of the Community Metrology Committee

<sup>14</sup> The Togo national proficiency test pilot program for basic clinical chemistry tests, African Journal of Laboratory Medicine, June 2022

of the health of populations and animals, and the preservation of the environment. In addition. the accreditation of CABs is an effective tool in terms of public health and for increasing trade in the UEMOA and ECOWAS region. This is why SOAC-WAAS will fully play its role in order to make available. in West Africa. world-class and affordable accreditation services. To this end, the commitment and support of UEMOA and ECOWAS member states, as well as the two Commissions, must be required to support SOAC-WAAS, but also NiNAS and GhaNAS in the dynamics of strengthening public health and food safety, as well as the development of fair trade.

#### **Author Biographies**

**Marcel Gbaguidi,** from Senegal, is specialized in International Trade and Quality Management (Master Lille1 University, France, MBA from Institut Supérieur de Management, Senegal). He is evolving since 25 years on quality infrastructure issues. In this capacity, he worked, as a consultant, for many agencies, including the French Development Agency (AFD), the World Health Organization (WHO), the World Bank (WB), the International Trade Center (ITC), the EU TBT project on SPS / TBT Agreements, etc., and particularly for the West Africa Quality Infrastructure Programs, executed by the United Nations Industrial Development Organization (UNIDO) and with which he has been committed since 2008. He has held, among other responsibilities, that of expert in quality infrastructure, Head of sub office / chief technical expert of UNIDO West Africa Quality Infrastructure Programs. Since 2018, he has been appointed as Director General of SOAC, the West Africa Multi- economies Accreditation Body, which was developed with UNIDO support. Since November 2021, he has held the position of Resident Representative of SOAC-WAAS following the establishment of the latter as an international organization with diplomatic status in Côte d'Ivoire.

**Kafui Codjo Kouassi,** a Togolese national, initially trained as an engineer in medical testing with a unique PhD in biochemistry/ nutrition and a DUAP (Diplôme Universitaire d'Approfondissement Professionnel-Responsable Qualité of Nancy-1 in France). He has been evolving for more than 10 years in the field of quality, providing training and auditing missions sponsored by UNIDO, SOAC-WAAS, WAQSP, etc. Since 2014, Mr. Kouassi has been a teacher-researcher at the University of Lomé (Togo). He is currently an associate professor at this university. Since 2017, he has been chairing the ECOWAS Community Conformity Assessment Committee (ECOCONF).

Amadou Diop, currently the National Accreditation Focal Point of SOAC-WAAS in Mali, is a graduate of the École Nationale d'Administration (ENA) of Mali and holds a post-graduate degree from the University of Lund in Politics, Commercial Law and International Trade Law. A Malian national, Mr. Diop is also a member of the ECOWAS Community Conformity Assessment Committee (ECOCONF).

He works as an expert for UNIDO, particularly on the development of technical regulations and standardization in the ECOWAS region and on SPS issues. He is also a consultant to the International Trade Centre (ITC) on technical barriers to trade issues (standards, conformity assessment, and regulations) related to AfCFTA and women traders' empowerment.



DOI: doi.org/10.55459/IJCA/v2i1/VM

## Experience in Implementing ISO 15189:2012 Accreditation at Chimera Transplant Research Foundation: A Molecular Testing Laboratory

By Dr. Vikash C Mishra, Dinesh Chandra, and Dr. Vimarsh Raina

#### -ABSTRACT-

ISO15189:2012 is a formal recognition by an authorized national accreditation body that a testing laboratory is competent to carry out specific tasks according to the standard. This article aims to share the experience of reaching ISO 15189:2012 accreditation at Chimera labs. A gap analysis was performed, followed by the preparation and implementation of policies and procedures for the effective implementation of QMS. After six months of intensive work, including mentoring activities, the laboratory was ISO 15189 accredited in the field of medical genetics and related HLA and immunogenetics by the National Accreditation Board for Testing and Calibration Laboratories, India. Our experience suggests that the implementation of a quality management system is possible even in small-sized laboratories with the help of skilled manpower and supportive management.

Keywords: ISO15189, ISO15189:2012, accreditation, NABL

#### Introduction

Chimera Transplant Research Foundation (CTRF) was established in December 2012 and serves to provide cost-effective and quality diagnostic and consulting aid for successful transplant operations to tertiary care hospitals. Since its foundation, CTRF has seen steady growth, serving more than 28,000 patients all over the country. Expertise in transplant immunology and DNA analysis makes CTRF the leader in the niche segment and helps hospitals fulfill the legal formalities of a transplant while complying with all legalities.

The current globally accepted standard for medical laboratory practice is ISO 15189 (medical laboratories), which was developed by the International Organization for Standardization [1]. ISO 15189 accreditation enables the medical testing laboratory to demonstrate to its clients the effectiveness and reliability of the services [2]. The content of ISO 15189 is broadly categorized into two sections: management requirements and technical requirements. The accreditation will help any testing laboratory in its international recognition, continual improvement, and enhanced customer confidence and satisfaction. Hence, being in the arena of medical testing laboratories, we had planned for the accreditation of ISO 15189:2012 in mid-2013. The following will attempt to summarize the author's experience with ISO 15189 accreditation at Chimera labs and the implementation of an effective quality management system (QMS).

#### **Material and Methods**

#### **Gap Analysis**

The gap analysis of the available resources of the laboratory was done to get the baseline information for the effective implementation of the quality management system. This was done by comparing the existing resources from the ISO 15189:2012 standard. This gap analysis resulted in several nonconformities and broadly included the absence of established policies and standard operating procedures, due to a lack of knowledge about the ISO 15189 standard. All this information was recorded and presented to management for making an action plan to overcome these issues.

#### Implementation of an Effective Quality Management System per ISO 15189

Management appointed a trained and experienced laboratory director and quality manager for the preparation and implementation of the quality management system. All the policies, procedures, and records were prepared and maintained as per the standard in coordination with the quality manager and laboratory director at Chimera labs.

#### Internal Audit

An internal audit was done once all the preparation had been completed by a trained ISO 15189:2012 external auditor. Despite intensive preparations, six non-conformities were observed. After the closure of these non-conformities, management decided to apply four tests under the scope of accreditation for ISO 15189.



#### Results

#### **Quality Management System**

The preparation of the accreditation resulted in an effective Quality Management System supported by the policies, procedures and records as per the standard ISO 15189:2012.

#### ISO 15189:2012 Accreditation

After intensive preparation and management approval, the procedure of accreditation was started by submitting of application form in the field of medical genetics and related HLA and immunogenetics in September 2014. The onsite pre-assessment was done in January 2015. A total of six nonconformities were identified after the inspection. All the nonconformities were closed satisfactorily within the provided time frame and the laboratory was recommended for final assessment. The first assessment was done in April 2015 and four tests were recommended for the scope of accreditation in the field of medical genetics and related HLA and immunogenetics by the National Accreditation Board for Testing and Calibration Laboratories(NABL), India [3]. The total numbers of nonconformities observed were nine. At present, 25 tests are under the scope of accreditation for ISO 15189:2012. A total of four onsite and three desktop assessments were done for the continuation of accreditation

#### Discussion

Implementation of ISO 15189:2012 in the laboratory was a wonderful experience and produced a need to maintain quality for the tests under the scope of accreditation, which ultimately benefits the end user (e.g., patient, clinician). Continuous monitoring of all the policies, procedures, quality objectives and quality indicators is done at regular intervals to maintain the QMS as per ISO 15189:2012.

#### Management Review Meeting (MRM)

MRM is conducted every year in the CTRF lab and output from the management review is incorporated into a record. MRM is one of the key factors for improving the system.

#### Internal Audit

The laboratory has derived a procedure for conducting internal audits. The audits are conducted on an annual basis. During the internal audits, all the quality activities of the laboratory functions are assessed.

#### Interlaboratory Comparison or EQAS Participation

The CTRF has a protocol to assure the quality of all examination procedures being performed in the laboratory. To achieve this, the lab participates preferably in an External Quality Assessment (EQA) proficiency testing program. In the case that EQAS is not available nationally or suitable for the particular testing, the laboratory sends the sample for a proficiency check to the other NABL accredited (ISO15189) laboratories.

As per the policy, the lab regularly accomplishes trend analysis of quality objectives and quality or key performance indicators, vendor evaluation, document review, and internal audit. The laboratory director and quality manager of the laboratory play a pivotal role in the effective implementation of the QMS. Regular mentorship by the laboratory director and quality manager with strong leadership skills transformed the laboratory into a quality-driven organization. CTRF conducts weekly seminars for regular updates on its associates on recent advances in the field of transplant immunology. The weekly seminar is conducted by each of the associates on a rotating basis. These weekly sessions contribute to over-development of each associate by updating their scientific knowledge and enhancing their skill sets.

Regular customer feedback is taken to measure what clinicians think about the laboratory services,

which has revealed that clinicians at the hospital were able to trust and make clinical decisions supported by laboratory results.

Formal recognition of the competence of a conformity assessment body for ISO 15189:2012 has many advantages including robust QMS, assurance of accurate and reliable results, and enhanced customer confidence and satisfaction, which ultimately results in a potential increase in business for the laboratory.

#### Conclusion

Our experience suggests that implementation of a QMS is possible – even in resource-limited small size laboratories such as ours – when adequately supported by management. Achieving effective implementation of the ISO 15189 standard requires trained and well-motivated laboratory associates. Regular trend analysis of all objectives and guality indicators is necessary and should be done by laboratory professionals trained in QMS who have implemented the system. Additionally, skilled, motivated associates and supportive management are keys to achieving and implementing an ISO15189 accreditation. Each medical testing laboratory should go for ISO 1589:2012 accreditation as it offers international recognition resulting in access to the global market and, finally, improved customer acquisition and satisfaction.

#### Source of funding: None

**Conflicts of interest:** There is no conflict of interest.



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**Dr. Vikash C Mishra** (Ph.D. Biotechnology) is working as a quality Manager at Chimera Transplant Research Foundation (<u>www.chimeralabs.org</u>), New Delhi, India. He has more than 12 years of working experience in the area of transplant immunology and immunogenetics. He has a keen interest in translating healthcare research for the benefit of the masses. He has in-depth knowledge of ISO 15189:2012 guidelines He has more than 30 research articles in peer-reviewed international journals with a high impact factor. He is an advisory member of Chimera EQAS (<u>https://eqas.in/</u>) and also a member of the Genebandhu ethics committee (<u>http://ethicsindia.org.</u> in/)."



**Dinesh Chandra** received his master of science in Biotechnology and has been associated with Chimera Transplant Research Foundation since 2016. He has good hands-on experience in histocompatibility testing. He is also the assistant quality manager of the laboratory . He has more than 15 research articles in peer-reviewed international journals with a high impact factor.

Dr. Vimarsh Raina received his specialization (MD) in Pathology from Davanand Medical College, Ludhiana (Punjab), India. He also holds a Post Graduate Diploma in Hospital Administration from the University of Delhi. He is leading Molecular Pathologist of South East Asia and healthcare industry veteran with over 30 years of experience in conceptualising and building India's fastest growing throughput diagnostic service and an international stem cell donor registry, over 200 publications, 2 book chapters, 4 patents and is an ISO 15189 auditor. Dr. Raina recently won the BMJ South Asia "Healthcare Innovation of the Year 2018" Award. He has been honored for his social enterprise and his commitment towards humanity and was conferred the "Abhinav Gupta Samman". He is sought after speaker in International Pathology meetings and conferences.

He strongly believes that the field of medical sciences is one which is extremely dynamic and undergoes constant transformation. Therefore he advocates that clinical application of medical knowledge needs to consider the changes in societal needs and demands. **Dr. Vimarsh Raina** is the founder and medical director of **Genebandhu**-an adult stem cell donor not for profit social enterprise that is part of the World Bone Marrow Donors Association (WMDA). This Network connects voluntary stem cell donors globally with patients having life threatening diseases like Blood Cancer.

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#### DOI: doi.org/10.55459/IJCA/v2i1/SCSR

## Risks and Opportunities: An Assessor's Perspective of ISO/IEC 17025 Expectations

By Dr. S.C. Soundar Rajan, Advisor, Dr. Amin Controllers Pvt. Ltd.

#### -ABSTRACT-

For many laboratories as well as the assessors of testing and calibration laboratories, there has been a lack of clarity about the specific intentions of ISO/IEC 17025:2017 under the topic "Risks and Opportunities" in clause 8.5. This paper presents the author's understanding and perception of the standard.

Keywords: ISO/IEC 17025:2017, risks and opportunities, testing and calibration laboratories, accreditation body, National Accreditation Board for Testing and Calibration Laboratories

The author has dealt extensively with the standard ISO/IEC 17025, both as a member of the laboratories for which he has worked and also as an assessor evaluating several other laboratories on behalf of the National Board for Testing and Calibration Laboratories, India. The author admits that when he first read the 2017 version of the standard, he was at a loss to understand why ISO/IEC 17025 felt it necessary to include the topic "Risks and Opportunities" in clause 8.5 and what exactly the standard expects from laboratories. He wondered what risks a laboratory could undertake that might result in producing unreliable, unsure or unacceptable results.

Unsure of how to interpret clause 8.5, the author used to avoid analyzing it extensively in his assessment undertakings. In the laboratories he worked or guided, he allowed the laboratories to merely copy from other laboratories simply to satisfy the assessment process. He found it amusing that several laboratories produced documents containing a big list of risks associated with laboratory activities and how they are mitigated and even accorded grading to the potential risks. The identified risks included factors such as inadequate/improper training to personnel, lacking or expired calibration of measuring equipment, unavailability or inappropriate CRM, nonparticipation in interlaboratory and proficiency testing programs, and similar. He noted that some laboratories even included risks to impartiality, though this topic is covered under a different clause in the standard, and he was further intrigued that even a grade was accorded for the risk

to impartiality.

## Laboratories Are Missing the Point of ISO/IEC 17025

The author feels these so-called risks are not risks, rather they are clearly nonconforming acts, which are not allowed to happen and several laboratories failed to understand the same. Such nonconformities can generate unreliable and questionable results. These so-called risks are potential threats for laboratories and can cause them to lose their credibility. The author thinks that these laboratories did not seem to be able to differentiate between risk assessment and risk mitigation as dealt with in other situations and "Risks and Opportunities" as dealt with in ISO/IEC 17025.

It took guite a long time for the author to understand the essence of this clause. Clarity finally dawned on him when he revisited the 2005 version of the standard for some other purpose and chanced to read Note 3 under clause 5.4.5.3. And then when he again read the 2017 version of the standard, Clause 8.5, Note 2 under 8.5.3, it dawned on him that that ISO/IEC 17025 talks about risks that open doors for increased, improved, or new business opportunities for laboratories, out of the risks the laboratories are prepared to undertake. He feels that several laboratories missed this point. The standard allows or even probably seemed to encourage laboratories to be innovative and undertake conscious, calculated, measurable risks whenever certain situations demand the same and to cater to the needs of the customer and effectively serve the intended purpose for which such risks are undertaken.

The author recalls several situations in his career when laboratories were compelled or obligated to undertake testing for which there may not have been any existing standard or published material and public domain information was not readily available.

Such problems manifest in different ways. In a production plant, the process could be impacted by unexpected behavior, maybe due to variations in the input materials or the loss of valuables into discards (e.g., slag or dross). In trade, unexpected contamination during transport or handling is very common. Sometimes, unexpected developments may happen due to accidental or deliberate contaminations. Even if these types of problems had been handled at another time, such information may not be readily available in the public domain. In all these situations, the laboratories were under pressure and had an obligation to conduct studies or investigations to develop methods of testing and achieve possible conclusions and solutions. Laboratory personnel have to use all their experience and knowledge to first understand the problem, to identify the possible ways and test methods that can provide conclusions.

#### Clear Understanding Is Critical for Reliable Results

The author has witnessed such unexpected requirements in his experience. One recent example involved a wheat export from India to Italy where the consignment was rejected at the discharge port, citing the presence of rubella, a disease never expected on a food grain. Now who knows, to be on the safe side a country might make it a norm to test a wheat export for this disease. Similarly, this happened with testing for melamine, which began with milk then extended to every food commodity, and also testing for Sudan dyes, which started off with chili powder and then other food products.

While working out test methods for such situations, which the author terms as challenges, a certain amount of risk is involved, since there is no prior history and no reference samples or reference standards for comparison. Reliability of the results can be achieved only by a clear understanding of the situation, products and test methods. Sometimes, it could be a small deviation from a standard method as such deviations are allowed per ISO/IEC 17025, provided the deviation has been documented, technically justified and accepted by the customer. It also could be an established method (or combination of established methods) used for some other purpose and applied for the present needs to the situation or requirement. At times, it could result in an entirely new laboratory developed method. All the laboratory is expected to do in such situations is validate the method in as many ways as possible to support confidence in the results.

Validation of such laboratory-developed methods is possible only through:

- a. understanding the theoretical principles of the method and practical experience;
- b. systematically assessing the factors influencing the result;
- c. confirming no interference from the matrix of the sample or test object;
- d. ascertaining the measurement range, precision, and robustness;
- e. evaluating measurement uncertainty; and finally,
- f. ascertaining whether the performance characteristic of the validated method is relevant to the intended need and consistent with specific requirements.

The above validation adequately satisfies the requirement of ISO/IEC 17025:2017, Note 2 under Clause 7.2.2.1.

Though antiquated now, the statement in the 2005 version of ISO/IEC 17025 in Note 3, Clause 5.4.5.3 is practical and sensible and holds relevance in this regard. It states: "Validation is always a balance between costs, risks and technical possibilities. There are many cases in which the range and uncertainty of the values (e.g., accuracy, detection limit, selectivity, linearity, repeatability, reproducibility, robustness and cross-sensitivity) can only be given in a simplified way due to lack of information."



#### **Risk Unlocks Opportunity ... but Diligence Is Key to Avoiding Potential Impacts**

When a laboratory takes risks, this also creates an opportunity to expand the scope of activities, addressing new customers, new technologies, and other opportunities to meet customer needs. (Note 2 of Clause 8.5.2.)

But while taking risks, laboratories should maintain compliance with all other requirements of ISO/IEC 17025 (e.g., calibration of measuring equipment, purity of chemicals and reagents used, traceability to SI units, personnel training, etc.). Quality assurance activities such as intralaboratory comparison, as well as parallel and rechecking of tested samples as blind samples should be carried out to build and increase confidence.

The note under Clause 8.5.2 seems to indicate it is not mandatory for a laboratory to always undertake risks. However, if the laboratory is willing to take risks (aka challenges), it should be able to assess the potential impact of the risk on the validity of laboratory results and take care to prevent or reduce undesired impacts and potential failures in the laboratory activities. The risks taken should be identifiable and measurable in order to identify potential impacts.

In the following, the author presents a few examples in his experience, just merely to illustrate the concept of risk and opportunity.

A customer was using Muriate of Potash procured from a supplier, and he suspected the presence of ammonia. He approached the laboratory to ascertain and determine the ammonia content. This request was unusual since no one expected to test ammonia in Muriate of Potash and no standard refers to such a test. The laboratory worked out a method and confirmed the presence of ammonium salt. Since the method involved the distillation of ammonia and then Nessler's method of determination, which are established methods, the laboratory was confident in its results. The laboratory was sure that the risk levels were very low or practically nil. The supplier, who never believed there could be ammonia in his product, initially guestioned the results. But the laboratory could demonstrate the same to his satisfaction. The laboratory won a new customer, which further extended to others in the field, creating more opportunities for the laboratory.

While working in the zinc-lead industry, a sudden requirement came up because of some process problem to estimate/determine the unburnt carbon levels in Waelz kiln slag. The laboratory was aware the slag contains constituents such as sulphides, so direct ignition was ruled out. It worked out a method wherein the sulphides in the sample were first decomposed using dilute acids (combination of hydrochloric and nitric acids) at low temperatures, and then the dried residue was re-ignited and the carbon content was arrived at based on the final loss of ignition. In this case, certain risks were taken by way of assuming that all sulphides are such, which get broken down with dilute acid digestion, and that carbon remains unaffected at that stage. Based on the inputs of the raw material, the laboratory was confident the slag would not contain such sulphides (e.g., chalcopyrite), which do not decompose with dilute acids. Based on the chemical behavior of carbon, the laboratory was confident the carbon was not affected by dilute acids at the temperatures they were using. The laboratory discussed these risks with the plant personnel and the management. After further studies of the process behavior, the plant personnel on their own confirmed the laboratory findings seemed to be in order. Plant and management personnel were happy that the laboratory could offer some useful information, which helped in controlling/improving the process.

Another example centers on the deviation of a standard method. When the author joined the process lab, the lead refinery samples were being tested by atomic absorption spectroscopy. The refinery plant was complaining that the feedback from the laboratory was slow in the copper removal stage, because a lot of fuel was wasted keeping the kettle hot and also there was a possible reversion of copper from dross back to lead metal while waiting for the result. The first stage of lead refining involved copper removal as copper dross. The refinery plant was not interested in the exact values of copper in the copper drossing stage and once the copper is confirmed to have come down to less than 100 gpt (grams per metric ton or parts per million), the process would proceed for the next stage of refining.

To hasten process feedback, instead of running copper standards each time along with samples and then arriving at the exact values, the laboratory worked out a reference lead sample with an established value of 90 gpt copper. The laboratory processed this reference sample along with process samples. Once the absorbance of the sample was seen to be less than the reference, the laboratory would clear the sample reporting as <100 gpt copper, without actually arriving at the exact values. This reduced the feedback time by more than 50% and helped to decrease process costs by way of fuel savings and also possible reversion of copper from dross to the lead metal. Since adequate margin was given in the reference sample and also taking into consideration the uncertainties involved, the laboratory was sure the risk factor was very low.

#### ISO/IEC 17025 Encourages Risk-Taking to Meet Customer Needs and Other Requirements

Now, one question arises as to whether the standard ISO/IEC 17025 expects a laboratory to take risks and attempt such testing, which is not in the laboratory's regular range of activities. Certain laboratories may not be willing to undertake risks, maybe because of regulatory requirements (e.g., government laboratories), and others may not be willing because they just do not want to take any risks. The answer to this question lies in Clause 8.5.2, where the standard seems to say it is not mandatory. The author believes that it is left to laboratories to decide on the same. But in case the laboratory is willing to take risks, to create more business opportunities or expand its customer base, it should document addressing the requirements of clauses 8.5.1 and 8.5.2 and also include the range of activities as required in Clause 5.3.

One potential problem is when concerned parties/ customers expect the laboratories to be accredited for such tests, making the laboratories obliged to seek test accreditation. One point of concern is whether the accreditation body (and the assessors who assist the accreditation body) will be satisfied with the validation carried out by the laboratory for such tests, which need specific expertise to assess and confirm. Some accreditation bodies also mandate that laboratories should participate in interlaboratory or proficiency testing (PT) programs for all tests sought for accreditation. This is not always feasible, since there may not be any PT programs for such tests, and an interlaboratory testing is not always possible since there may not be other laboratories capable or willing to undertake such tests. Also, the seeking laboratory may not be prepared to share its in-house-developed method with others. This is an area accreditation bodies should ponder further in order to arrive at a logical decision.

The author's perception of what ISO/IEC 17025 (2017) intends in Clause 8.5 is that laboratories should be innovative and capable of undertaking conscious, calculated and measurable risks at times when a situation demands it. Laboratories are also expected to address customer needs effectively and meaningfully. Undertaking such risks can unlock opportunities for laboratories to expand areas of activity and also increase business opportunities.

#### Acknowledgments

The author thanks Dr. Amin Controllers Pvt. Ltd., Mumbai, India, for the opportunity to analyze ISO/IEC 17025, and for their support and encouragement. He also thanks India's National Accreditation Board for Testing and Calibration Laboratories for allowing him to assist in assessing several laboratories for ISO/ IEC 17025.

#### **Author Biography**

S.C. Soundar Rajan holds a doctorate in analytical chemistry and has several research publications to his credit. His career highlights include working for Hindustan Zinc Limited, a premier company in India producing zinc, lead, silver, and cadmium metals for 19 years, both in research and development and also in process control laboratories. He subsequently worked with two reputable inspection companies, Intertek Testing Services and Dr. Amin Controllers Pvt. Ltd., for 13 years. Presently, he continues to work as an advisor for Dr. Amin Controllers Pvt. Ltd., in Mumbai, India. Other professional achievements include providing guidance to a few candidates seeking doctorate and M.Phil degrees at Andhra University in India. He also served on India's National Accreditation Board for Testing and Calibration Laboratories (NABL) as an assessor, mostly for ISO/IEC 17025 and to some extent for ISO 17034 and ISO 17043 standards.









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August 8-9	Understanding ISO/IEC 17025 for Testing and Calibration Labs	Americas
August 15-16	Understanding ISO/IEC 17065 for Product Certification Bodies	Americas
September 6-7	Introduction and refresher to ISO/IEC 17020 for Inspection Agencies	Middle East India and South Asia
September 13-14	Understanding ISO/IEC 17025 for Testing and Calibration Labs	Middle East India and South Asia
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