



IAAC Guide for identifying risks in accreditation bodies

CLASSIFICATION

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Guide for identifying risks in accreditation bodies

1. Objective:

This document provides guidance on risk identification activities carried out by the ABs and serves as a supporting reference for peer evaluations that IAAC performs on ABs within the IAAC MLA activities.

2. Scope:

This document is applicable to the risk identification activities carried out by the ABs, and as reference support for peer evaluations that IAAC performs on CABs within the IAAC MLA activities.

3. Introduction:

ISO/IEC 17011:2017 includes the consideration of risks to impartiality (section 4.4), as well as new requirements related to risks to the ABs activities and its objectives (sections 4.5.2, 6.1.3.4 and 9.6), including opportunities for improvement (section 9.6), and other risks to the AB associated with the CABs (sections 7.4.6, 7.9.3 and 7.10.1).

The identification of these risks is an initial and critical step in order to consider them and, where appropriate, establish an adequate treatment for each of them within the AB, in accordance with the processes and procedures established by the AB (sections 4.4.6 for risks to impartiality and 9.6 in general).

ISO/IEC 17011:2017 refers to the following areas of potential risk that may be useful in the risk identification process:

- 1) Risks to the impartiality of the AB.
- 2) Risks (other than impartiality risks) associated with the activities of the AB and its objectives, including the expected results of its management system and processes.
- 3) Other risks for the AB related to CABs.

A risk-based approach supports the objective that an appropriate and representative sample be taken in an assessment, to demonstrate the technical competence of the CAB. This assessment focuses on issues that are important in the current situation (taking place in the internal and external context of the CAB) and may affect continued compliance with the accreditation requirements by CABs, in particular competence, consistent operation and impartiality that impacts conformity assessment activities. ABs should consider the risks associated with the CABs conducting a conformity assessment activity whose results are invalid (not intended for the original use), as well as its impact on the CABs' customers, stakeholders, and the general public.

4. Definitions and abbreviations:

For the purpose of this document, the terms and definitions included in ISO/IEC 17011 and ISO 31000 are applicable.

5. Description:

5.1 General

5.1.1 For risk identification, it may be useful to consider such identification from the following aspects:

- a) Risks to the impartiality of the AB.
- b) Risks (other than risks to impartiality), and opportunities associated with the activities of the AB and its objectives, including the expected results of its management system and processes.
- c) Other risks for the AB regarding the CABs.

5.1.2 For risk identification related to CABs, the AB should consider the fundamental objective of accreditation (give confidence that the CAB gives valid results in its conformity assessment activities, is competent and works with consistency and impartiality) and be aware of its responsibility to give confidence in the CAB to all stakeholders.

5.1.3 The risks that the AB should identify regarding CABs are risks for the AB¹, its impartiality, its objectives, its activities, etc.: these risks may be general, and considered for the CAB overall as applicable, or may be specific and associated with the activities, locations, application of requirements or scope of a CAB that is requesting accreditation or has been accredited.

5.1.4 ISO 31010 identifies and describes techniques and tools that may be used to manage risk (e.g. brainstorming, cause-effect analysis, failure mode and effect analysis, checklists, etc.)

5.1.5 To identify its risks, the AB should analyze its internal context (mission, vision and values, policies, objectives, culture, processes, organization, institutional environment, personnel, processes, material resources, etc.) and its external context² (legal requirements for the AB, legal requirements affecting CABs, international agreements, economic and financial, cultural and

¹ The risks of an AB related to a CAB in particular (which will be considered by the AB) should not be confused with the risks for the same CAB (the CAB itself should identify them and address them according to the requirements of the applicable accreditation standard.) Nevertheless, the risks for the CAB itself may be a useful source of information for the AB, among other things, to identify its risks regarding this CAB.

² The ISO 31000:2018, clause 5.4.1 describes some aspects to consider in the internal and external context analysis.

social, technological, market for CABs, competence regarding accreditation, requirements and expectations of stakeholders, etc.) and identify aspects that may affect the achievement of its objectives at the levels considered appropriate (e.g. strategic, operational, etc.), including the expected results of the management system.

5.1.6 As a consequence of the risk identification that the AB carries out, the AB may define different actions to deal with the risks, in order to minimize or eliminate them, and where appropriate to improve the opportunities, in accordance with the processes and procedures that it has defined (ISO/IEC 17011:2017, 4.4.6 and 9.6).

5.1.7 The identification of risks by the AB regarding a specific CAB may cause the AB to change the focus of the assessment program and specific assessments.

5.1.8 The following sections, 5.2 to 5.4, give examples of related risks that the AB may consider when identifying its risks in each of the aspects indicated in section 5.1.3. These risks are not an exhaustive list of potential risks. Not all the items in the list apply to each AB, although the AB may consider the applicability of the examples.

5.1.9 For some of the identified risks, the AB may not be able to carry out a well-supported risk assessment when the CAB is new to the AB. The AB should do its best and carry out the assessment based on the information that it knows or can easily determine. The absence of information to carry out a risk assessment can be considered a risk in itself.

5.2 List of possible AB risks to the impartiality

5.2.1 When impartiality risks are to be identified, these should be considered with respect to different aspects in accordance with the requirements and notes of ISO/IEC 17011: 2017, 4.4³:

- a) **ISO/IEC 17011:2017, 4.4.2:** commercial, economic or other pressures compromise their impartiality to the AB.
- b) **ISO/IEC 17011:2017, 4.4.4:** undue commercial, financial, or other pressure on the personnel of the accreditation body and the committees.
- c) **ISO/IEC 17011:2017, 4.4.6:** NOTE 1 Sources of risk to the impartiality of the accreditation body.
- d) **ISO/IEC 17011:2017, 4.4.7:** Potential risks arising from within the accreditation body or from the activities of other persons, bodies, or organizations.
- e) **ISO/IEC 17011:2017, 4.4.10:** The policies, processes and procedures of the accreditation body.
- f) **ISO/IEC 17011:2017, 4.4.11** ... offer or provide services that affect their impartiality.

³ The following aspects are identified as risks or should be considered when risks to the AB's impartiality are analyzed, which are derived directly from the requirements of the standard regarding impartiality.

- g) **ISO/IEC 17011:2017, 4.4.13...** Present accreditation activities as related to consulting or other services that pose an unacceptable risk to impartiality...

5.2.2 The following table provides examples of risks that could be identified for an AB based on its specific characteristics. This list is not intended to be an exhaustive list of risks that an AB may identify.

Risk Source	Possible AB risk to the impartiality
Property	Being part of a larger organization (public or private) that: <ul style="list-style-type: none"> - Carries out conformity assessment activities. - Provides consulting to CABs, including specific training for the development and implementation of the management system, operating procedures and / or competence of a conformity assessment body. - It is responsible for supervising or approving CABs for other purposes. - It is involved in the regulation of CABs. - Carries out other activities that may pose a conflict of interest with the accreditation activities. - Has organizational control or has organizations that carry out the above activities.
Property	Possess shares or other financial or management benefits in relation to any CAB or organization that represents CABs.
Property	Owners, senior personnel or others who have control capacity over the AB or carry out accreditation activities, have a property relationship with organizations with an interest in the operation of the AB (CABs, organizations that represent CABs, government organizations that supervise or establish regulations for CABs)
Governance / Corporate Governance	AB and CAB parallel supervision by the same supervisory authority.
Governance / Corporate Governance	The impartiality mechanism is either single party dominated or does not have balanced stakeholder representation.
Governance / Corporate Governance	Accreditation policies, criteria and procedures are disproportionately influenced by prevailing stakeholders.
Governance / Corporate Governance	Bodies external to the AB have control over the AB or have a significant influence on policies and procedures, especially in the accreditation decision process.
Relations	The AB has relationships with other organizations (for example, suppliers, project partners, organizations whose personnel conducts assessments for the AB, etc.) that have interests in or provide services to CABs (e.g. consulting, specific training, internal audit, etc.)
Management	Carry out conformity assessment activities that are subject to accreditation.

Management	Provide services to CABs that may threaten impartiality such as: providing consulting services, preparing documentation, internal audits, etc.
Management	Carry out in the pre-assessment, consultancy from the evaluation team during evaluation.
Management	Unequal treatment of CABs in aspects such as: <ul style="list-style-type: none"> - criteria for accepting the application, - cost, - processes (e.g. response times), - representation in the AB.
Personnel	The personnel's salary depends (in whole or in part) on: <ul style="list-style-type: none"> - carrying out the assessments of CABs (e.g. duration of the evaluation, number of non-conformities), - the successful outcome of an application for accreditation of a CAB or scope extension. - client recruitment or retention.
Personnel	Carry out functions in relation to CABs, in which AB personnel (internal, external, member of a Committee) have relationships that pose a conflict of interest (e.g. family, financial, carry out activities for CABs by of external assessors or other personnel who carry out accreditation activities: training, consulting, internal audits, etc.; conflict relationships, previous or current litigation, competition, etc. should also be considered).
Personnel	Professional networks between experts used by the AB, leading to familiarity and a limited number of experts available in these fields.
Personnel	Threats to maintain objectivity when treating a CAB based on its status or when the results of an accredited CAB have significant economic and / or political influences.
Personnel	Participation of personnel (internal, external, member of a Committee) in any part of the assessment process or other accreditation activities, who were recently employed by the CAB in question (either permanently or as a contractor).
Personnel	Using the same evaluator for the particular technical field of CAB activity for a long period; repeated assessments or provision of services to the same CAB leading to familiarity.
Personnel	Verification of own work when making a decision about accreditation.
Personnel	There are no ethical principles, or they are interpreted differently by personnel.
Personnel	Recommend specific solutions to nonconformities or opportunities for improvement in evaluations
Shared resources	Shared resources or services with CABs or organizations representing CABs (e.g. offices, cafeteria, computer network, Information Technology support, Finance Team, Human Resources, equipment or samples that are

	used by the assessment team during the assessment - for example, provided by the NMI or by a regulatory authority, etc.).
Shared resources	Use of personnel from the CABs, NMIs personnel, as part-time assessors or technical experts, in decision-making processes, etc.
Finance	Carry out for-profit activities.
Finance	High percentage of AB's budget from accreditation to a single entity.
Finance	Funding levels set by a third party (members of board of directors, senior management, trustees, etc.) without taking proper account of the required evaluation volume.
Contracting	Agreements with third parties for the provision of services (for example, scheme owners) or support service providers (for example, IT hosting) that: <ul style="list-style-type: none"> - place restrictions on AB operations; - place the responsibility for supervision on a third party; - require sharing confidential customer information.
Outsourcing	Outsource without ensuring an adequate level of independence and competence in accordance with the requirements of ISO / IEC 17011.
Training	Impart training that provides specific solutions to a conformity assessment body in relation to the activities of that organization.
Training	The personnel who train are also involved in evaluating CABs participating in the training courses.
Sales and Accreditation promotion	Participate in promotional or communication activities organized by CABs or suppliers of CABs.
Sales and Accreditation promotion	Induce CABs to buy other AB services.
CAB Activities	Relationship of the CAB with organizations linked to the AB (for example, through projects that finance the AB, suppliers, etc.), if applicable.
CAB Activities	The CAB carries out or organizes activities in which the AB collaborates (for example: courses, conferences, projects, etc.)
CAB Personnel	Someone from the CAB participates in accreditation activities for the AB (As an evaluator, technical expert, in decision-making, etc.).

5.3 List of Risks (other than impartiality risks) associated with the activities of the AB and its objectives, including the expected results of its management system and processes

5.3.1 When risks, other than impartiality risks, associated with the activities of the AB and its objectives are to be identified (including the expected results of its management system and processes) these should be considered with respect to different aspects according to the requirements of ISO / IEC 17011:2017:

- a) **ISO/IEC 17011:2017, 4.5.2** The risks arising from its accreditation activities.

- b) **ISO/IEC 17011:2017, 6.1.3.4** Competence and performance of all personnel.
- c) **ISO/IEC 17011:2017, 9.6** Improvement opportunities and to identify risks (see also 4.4).
- d) **ISO/IEC 17011:2017, 9.8.2** Management review, status of actions to address risks and opportunities.

5.3.2 The following table provides examples of risks that could be identified for an AB based on its specific characteristics. This list is not intended to be an exhaustive list of risks that an AB may identify.

Risk source	Potencial risks associated with AB activities and objectives
External context: Political	Changes in the Government of the Country or in the Legislation applicable to Accreditation could affect the recognition of the AB at national and international level.
External context: Financial	The economic situation could mean a significant decrease in the accreditation activity and affect the economic viability of the AB.
External context: Regulatory Authorities	The national regulatory authorities do not use the AB's accreditation as a guarantee of confidence in the conformity assessment activities carried out by the CABs or consider it together with other unaccredited options, without recognizing any differential value.
External context: Disasters	Disasters (Pandemics, natural disasters, etc.) can affect the development of accreditation activities.
Financial / Legal responsibility	CABs do not carry out their conformity assessment activities adequately, and there may be legal or financial responsibility depending on their performance in accreditation activities.
Financial	The AB financial resources are not self-sufficient and are subject to the decisions of third parties outside the AB.
Financial	An economic crisis can affect the viability of maintaining the activities of the AB.
Objectives	Decisions, commitments, contracts that may have a negative impact on the fulfillment of the established objectives.
Structure	Lack of responsibility or authority for decision-making on accreditation or organization.
Structure	Lack of clear responsibility or authority for personnel participating in the accreditation process.
Structure	The AB uses parts of the structure (for example Procurement and Contracting, Human Resources, IT Support Services, etc.) of the legal entity in which it is located and these do not act in harmony with the Accreditation Management System.
Relations	The AB has signed agreements or covenants with Accreditation Scheme Owners, with regulatory authorities, etc., which could include aspects contrary to the requirements of the applicable IAAC, IAF or ILAC accreditation standards or international documents.

Resources	Lack of sufficient and qualified competent resources to: <ul style="list-style-type: none"> - carry out the required assessment activities. - carry out assessment-related activities (e.g. planning, reviews, etc.) - create and maintain AB procedures and policies. - Perform supervision and monitoring of personnel.
Resources	Use of unskilled or under qualified personnel in technical functions.
Resources	Incomplete or not relevant competence criteria for the personnel assigned to each accreditation scheme (external requirements, for example, regulatory, scheme owners).
Resources	Personnel, particularly technical personnel, who do not keep relevant technical skills and knowledge up-to-date, including assessment skills.
Resources	AB personnel turnover (e.g. higher than in industry).
Resources	AB personnel salary (for example, less than in the labor market)
Resources	Limited resources for new accreditation schemes or niches.
Resources	The person or Committee in charge of Decision Making does not have the necessary competence for this in any of the accreditation activities.
Resources	AB personnel lack appropriate knowledge and skills relevant to the geographic areas in which it operates
Accreditation requirements	Accreditation requirements defined in a way that can be understood differently between evaluators, and between evaluators and CABs, leading to non-homogeneous and discriminatory evaluations between the different CABs.
Accreditation procedures	Determining the suitability of conformity assessment schemes and / or accreditation applications is not adequate.
Accreditation processes	Insufficient or lack of access to information on the operations of the CABs to assess risks for the evaluation.
Accreditation processes	Inconsistent use of risk assessment to determine duration of assessment, assessment techniques, and assessment team.
Accreditation processes	There is no harmonized approach to assessing accredited CABs for the same activities.
Accreditation processes	The information presented in the scope of accreditation is inconsistent and inadequate leading to an inconsistent assessment.
Accreditation processes	Designation of assessment teams for the same type of CABs and similar scopes with disparate levels of competence that do not ensure adequate assessment in all cases.
Information	Inadequate protection of the information obtained or created during the accreditation process, or uncontrolled access to it.
Information	Non-centralized systems for the collection and storage of assessment information.
Information	Keeping information on ABs policies and procedures updated and publicly available.

Information	External assessment work in CABs and may obtain information from the accreditation process that is not available to other CABs, at the risk of discriminatory treatment of other CABs.
Information	Delays in publishing updates to the directories of accredited CABs and information on suspensions or withdrawals of accreditation (dates and scope).
Information	Inadequate transition periods for the implementation of changes in accreditation requirements.
Management systems	Development of policies and procedures that are not in accordance with applicable national laws, international standards, etc.
Management systems	The defined accreditation management system does not contemplate, or does not do so adequately, all the requirements of the ISO / IEC 17011 standard and applicable documents of international agreements.
Management systems	Personnel who do not adequately follow AB procedures.
Management systems	Take inappropriate actions for the scope, range, and impact of the problem, in case of discovering that the personnel are not following the procedures.
Management systems	Lack of access or difficulties to access the applicable versions of the documents (internal and external) in the places where the work is carried out by internal personnel, assessors or other external personnel and members of committees.
Management systems	Risk of lack of objectivity in an internal audit (for example, being carried out by those responsible for the audited areas, working in groups of projects responsible for the audited areas).
Management systems	The documentation of the management system has ambiguities that do not allow a harmonized way of working and the procedures are not communicated to the personnel.
Management systems	The management system has contradictions between different documents that deal with the same issue.
Management systems	There is no effective procedure to monitor that personnel follow AB procedures and to react if procedures are found not to be followed.

5.4 Other risks to AB associated with CABs

5.4.1 When other risks to AB associated with CABs are to be identified, these should be considered with respect to different aspects according to the requirements of ISO/IEC 17011:2017:

- a) **ISO/IEC 17011:2017, 7.4.6** Selecting the activities to be assessed.
- b) **ISO/IEC 17011:2017, 7.9.3** The assessment program.
- c) **ISO/IEC 17011:2017, 7.10.1** Expand the scope of accreditation, and consider the corresponding requirements defined in sections 7.3 to 7.9.

5.4.2 The use of a risk-based approach may affect the duration or frequency of assessments, the choice of the assessment technique, and the composition of the assessment team. The objective of a risk-based approach is to optimize the value of the assessment and to help justify the duration or frequency of assessments, choosing the appropriate assessment technique and assessment team.

When the AB prepares assessments, it should consider the risk associated with the activities, locations, and personnel covered by the scope of accreditation, as well as issues related to the operation and structure of the CAB. In this preparation, the AB may consider, but is not limited to, the risks listed in clause 5.

The assessment program should also take risks into account. The list of risks in section 5 can be used to plan assessments, to define the assessment's preparation time, time to perform the assessment, and to appoint the assessment team.

When a CAB wishes to extend the scope of its accreditation, the AB should also consider other risks in the same way as when planning other assessments. However, the emphasis may vary and the impact on the duration of assessments, choice of assessment technique, and assessment team may vary for different types of assessments.

Monitoring and reviewing information regarding the context of organizations is relevant to accreditation activities with a risk-based approach, therefore it is recommended that the AB regularly reviews its risk analysis, both for the AB itself and for each CAB⁴.

5.4.3 The following table provides examples of risks that could be identified for a CAB based on its specific characteristics. This list is not intended to be an exhaustive list of risks that an AB might identify, and that, likewise, could eventually affect the assessment program and assessment, including the activities to be assessed and the assessment techniques to be used.

Risk Source	Potential AB risks associated with CABs
CAB Activities	Complexity of the accreditation scope (for example, number of different competencies required by the CAB to cover the scope).
CAB Activities	Degree of novelty of the scope of accreditation (for example, there is no one accredited by the AB, in the country, in the region, in the world)
CAB Activities	Organization of the CAB (for example, number of locations, geographic distribution, locations abroad, multiple management system for different departments or standards, places where critical activities are carried out)

⁴ Regarding surveillance of CABs, the AB may choose to maintain information regularly updated on the risks that the CAB itself has identified, although these do not have to coincide with the risks that the AB identifies for that CAB (which are the risks for the AB related to that CAB).

CAB Activities	Complexity and criticality of external legal requirements and rules (national and international for the scope of the CAB) for a specific sector (for example, diversity of texts and regulatory requirements)
CAB Activities	General levels of competence and compliance in the sector in which the CAB works (for example, findings, complaints, market surveillance that exists for CABs working in the same sector).
CAB Activities	Volume and frequency of customer services, for example, number of certificates, test reports, etc.
CAB Activities	The proportion of the market that the CAB has.
CAB Activities	Relationship of the CAB with the regulatory authority, where appropriate, for activities included in the scope of accreditation.
CAB Activities	Outsourcing of activities that are part of the conformity assessment process, including the use of consultancies, temporary employment agencies, auditing companies, franchisees, etc.
CAB Activities	Carry out other activities that may possibly interfere or conflict with conformity assessment activities (for example, consulting, legislative and executive regulatory activities, manufacturing of the product under test).
CAB Activities	Changes in factors critical to the continued validity of conformity assessment activities for which the CAB is accredited, such as: <ul style="list-style-type: none"> - Property of the organization; - key personnel; - location; - teams.
CAB Activities	Use of remote virtual / work locations (for example, when individuals spend a high portion of their time working independently outside of a centralized location).
CAB Activities	The CAB works with a flexible scope.
CAB Activities	Historical performance in external monitoring activities (e.g. proficiency testing or interlaboratory comparisons).
CAB Activities	Historical performance on the effective and quick resolution of non-conformities.
CAB Activities	Historical performance in conducting effective root cause analyzes.
CAB Activities	Historical performance regarding significant non-conformities.
CAB Activities	Sanctions history (full or partial) e.g. suspension, scope reduction etc.
CAB Activities	History of supplemental or extraordinary evaluations during the accreditation cycle.
CAB Activities	Complaints received, feedback from the sector, complaints, etc., regarding the CAB's operation.
CAB Activities	The CAB holds accreditations from other accreditation bodies.
CAB Personnel	Competence and experience of CAB personnel
CAB Personnel	CAB personnel turnover (compared to the labor market)

CAB Personnel	CAB personnel salaries (compared to the labor market)
CAB Personnel	Resource capacity and ability to provide conformity assessment activities on time and competitively.
CAB Personnel	Ratio of new employees to experienced personnel for specific functions (especially related to conformity assessment activities).
CAB Locations	Level of control and monitoring carried out by the CAB at any satellite location.
CAB Locations	Criticality of activities carried out at satellite locations (for example, process development and approval, contract review, decision making, competence approval, and personnel monitoring).
CAB Locations	Location type: permanent, temporary, mobile.
CAB Locations	Geographical dispersion of locations involving differences in language and culture, and in particular consistency in the application of policies, procedures and methods.
CAB Locations	Possible natural disasters that could affect the activities of the CAB and the evaluations: earthquakes, volcanic eruptions, storms and hurricanes, etc.
CAB Locations	Epidemics that specifically affect CAB locations
CAB Locations	Travel or trade restrictions that may affect CAB activities and evaluations
Evaluation Techniques	Plan and apply evaluation techniques that are not appropriate for CAB activities, personnel, and locations (for example, remote evaluations that do not allow achievement of the intended objectives of the planned evaluation within the evaluation program).

References:

[1] ISO/IEC 17011:2017: *Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies*

[2] ISO 31000:2018 *Risk Management. Guidelines*

[3] EA -2/19 INF *List of risks for accreditation processes and operation of national accreditation bodies*

[4] EA-2/13 *EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation between EA Members, 5.4, 6.3.1*