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# List of risks for accreditation processes and operation of national accreditation bodies

## **PURPOSE**

The main purpose of the document is to assist national accreditation bodies (NABs) in determining potential risks context that may be considered to comply with the relevant clauses of ISO/IEC 17011. The document provides two types of lists of risks. The first list of risks is related to operation of CABs, that NABs may consider when planning assessments, assessment programmes or scope extensions. The second list of risks is related to the management of NABs, operation of processes, with consideration the risks related to its competence, consistent operation and impartiality. These lists are not exhaustive, and each NAB needs to perform its own risk analysis. Other risks may also arise from the economic, legal or cultural circumstances specific for each country or NAB.

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## **1 GENERAL**

The standard ISO/IEC 17011:2017 provides new requirements concerning a “risk-based approach” for the accreditation processes, as well as concerning “risks” with regard to the operation of all processes of an accreditation body. Considering that the requirements of ISO/IEC 17011:2017 and Regulation (EC) 765/2008 remains mandatory for NAB, the main purpose of this document is to support the national accreditation body (NAB) in its risk-based approach by providing lists of possible risks that may be considered by the accreditation body.

## **2 RISKS FOR ACCREDITATION PROCESSES**

### **2.1 General**

The national accreditation body (NAB) is required to consider the risks related to the operation of a conformity assessment body (CAB) when planning assessments, assessment programmes or scope extensions, as referred to in ISO/IEC 17011 clause 7.4.6, 7.9.3 and 7.10.1.

A risk-based approach supports the objective of an assessment to take an appropriate, representative sample. Such an assessment concentrates on issues that are important at the current situation (occurring in internal and external environments relevant to the CAB) that may influence ongoing fulfilment of accreditation requirements by the CAB. In particular competence, consistent operation and impartiality that impacts conformity assessment activities (CAAs). NABs should consider the risks related to the CAB providing an invalid CAA, but also the impact of an invalid CAA on the CAB’s customers, stakeholders and public.

The use of a risk-based approach may influence the duration or frequency of assessments, choice of assessment technique and composition of the assessment team. The aim of a risk-based assessment is to optimize the value of the assessment and to provide justification for the duration or frequency of assessments, choosing the appropriate assessment technique and assessment team.

When preparing assessments, the NAB shall consider the risk associated with the activities, locations and personnel covered by the scope of accreditation, as well as related to operation and structure of the CAB. In this preparation the NAB may consider, but not be limited to, the risks listed in clause 2.2.

The assessment programme shall also take risks into consideration. Also, here the list of risks (clause 2.2) may be used to plan assessments (focus and case review), preparation time, assessment time and team.

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

When planning an assessment for cross-border accreditation the NAB should take also into account risks as referred to in EA-2/13.

Monitoring and revision of information about context of the risks is relevant for the process of risk-based approach assessment. As such it is recommended that the NAB regularly checks and updates its risk analysis of a CAB.

## 2.2 List of risks

When performing a risk evaluation of a CAB, the NAB is taking an educated and informed decision on the risk profile of the CAB, the outcome of which may be that the NAB varies its assessment approach. As such the NAB should always consider the primary purposes of accreditation (those being that accreditation provides confidence that the CAB is producing valid outcomes to its conformity assessment activities, is competent and operates with independence and impartiality) and be aware of its responsibility to provide confidence in the CAB to the CABs wider stakeholder community. To this end the NAB should consider the impact of the CAB conducting an invalid CAA as part of its risk evaluation.

The following table provides examples of risks related to operation of CAB that NAB may consider when evaluating the risk profile of the CAB.

*(Note: this table does not provide an exhaustive list of potential risks, neither should every risk listed be considered as being applicable to every CAB or NAB)*

*(Note: It is recognised that for several of the risks identified the NAB may not be able to perform a risk evaluation for that particular risk when the CAB is new to them. NABs should make best endeavours and perform the evaluation on information they know or can easily determine. The absence of information to make a risk evaluation can be considered a risk in itself)*

Risk area	Risks to the fulfilment the accreditation requirements by CAB
<b>Activities</b>	<ul style="list-style-type: none"> <li>• complexity of the scope of accreditation (e.g. number of different competences required by the NAB to cover the scope);</li> <li>• organisation of CAB (e.g. number of sites, geographical distribution, foreign sites, multiple management system for different departments/standards);</li> <li>• complexity and criticality of external (legal) requirements and rules (national and EU) for specific sector (e.g. diversity of regulatory texts and requirements);</li> <li>• general levels of competence and compliance in the sector the CAB operates in (e.g. critical findings, complaints, market surveillance that occur in CABs operating in the same sector);</li> <li>• volume and frequency of services provided to clients i.e. number of certificates, testing reports etc.;</li> <li>• the proportion of the market share held by the CAB;</li> <li>• outsourcing of activities that form part of the CAA process including use of use agencies, auditing companies, franchisees etc.);</li> <li>• performing other activities which can possibly interfere or conflict with CAAs (e.g. consultancy, regulatory activities –</li> </ul>

Risk area	Risks to the fulfilment the accreditation requirements by CAB
	<p>both legislative and executive, manufacture of product under test);</p> <ul style="list-style-type: none"> <li>• changes to factors critical to the ongoing validity of CAAs the CAB is accredited for, such as: <ul style="list-style-type: none"> <li>- company ownership;</li> <li>- key personnel;</li> <li>- location;</li> <li>- equipment.</li> </ul> </li> <li>• use of remote working/virtual locations (i.e. when individuals spend a high proportion of their time working independently away from a centralised location);</li> <li>• CAB operates a flexible scope;</li> <li>• historical performance in external monitoring activities (e.g. proficiency testing or interlaboratory comparisons);</li> <li>• historical performance on the effective and prompt clearance of non-conformities;</li> <li>• historical performance in conducting effective root cause analysis;</li> <li>• historical performance in relation to significant non-conformities;</li> <li>• history of sanctions (full or partial) e.g. suspension, scope reduction, etc.;</li> <li>• history of requiring supplementary or extraordinary assessments during the accreditation cycle;</li> <li>• upheld complaints, sector feedback, whistleblowing, etc. in relation to the operation of the CAB.</li> </ul>
<b>Personnel</b>	<ul style="list-style-type: none"> <li>• competence and experience of CAB's personnel;</li> <li>• turnover of CAB's personnel (in comparison to industry norms);</li> <li>• resource capacity and capability to provide CAAs in timely and competent manner;</li> <li>• ratio of newly employed to experienced personnel for specific functions (especially related to conformity assessments activities).</li> </ul>
<b>Locations</b>	<ul style="list-style-type: none"> <li>• level of control and monitoring demonstrated by the CAB for any satellite location;</li> </ul>

Risk area	Risks to the fulfilment the accreditation requirements by CAB
	<ul style="list-style-type: none"> <li>• criticality of activities performed at satellite locations (e.g. process development and approval, contract review, decision making, competence approval and monitoring of personnel);</li> <li>• type of location – permanent, temporary, mobile;</li> <li>• geographical spread of locations results in differences in language and culture, particularly consistency in application of policies, procedures &amp; methods.</li> </ul>

### **3 RISK RELATED TO MANAGEMENT OF NATIONAL ACCREDITATION BODIES**

#### **3.1 General**

According to the ISO/IEC 17011 the NAB is required to:

- establish documented procedures to identify opportunities for improvement and to identify risks and take appropriate actions (see also 4.4). (ref. 9.6);
- continually improve effectiveness of its management system in accordance with the requirements of the standard (ref. 9.2.2);
- perform management review to identify actions related to improvement its management system and services. It shall consider, among other inputs to management reviews, status of actions taken to address identified risks and opportunities. (ref. 9.8.2).

Also, the previous edition of ISO/IEC 17011:2004 included elements of a risk-based approach – for example by carrying out preventive action to eliminate potential nonconformities, analysing any nonconformities that do occur, and taking action to prevent recurrence that is appropriate for the effects of the nonconformity.

The NAB needs to analyse its context i.e. internal and external environment and identify issues that may influence its objectives and strategic goals or influence intended results of the management system.

When analysing external environment the NAB should consider issues both on national and international level:

- legal environment (e.g. EU and national legislation and other requirements for accreditation body – standards, EA/IAF/ILAC mandatory documents, scheme owner’s requirements, contractual arrangements etc.),
- economic environment (e.g. employment, income, indicators, that influence the CAB’s interest in accreditation in regulatory and voluntary area),
- cultural and social environment (e.g. practices, customs and behaviours, interaction between people and institutions),
- technological environment (e.g. IT, communication and transport technologies that may influence accreditation activity).

When analysing operation on international level the accreditation body need to consider:

- purpose of EA, IAF and ILAC MLA/MRA Agreements aiming in the international acceptance of accreditation activities and acceptance of its accredited CAB's results;
- if applicable, providing accreditation abroad according to the cross-frontier rules.

When analysing internal environment the NAB should consider issues related to its values, competence, resources and performance. As described in clause 4.4 of ISO/IEC 17011 the NAB especially needs to analyse issues related to impartiality.

Understanding needs and expectations of interested parties enhances the ability of the NAB to provide accreditation activity according to its objectives and goals. Monitoring and revision of information about these interested parties and their requirements is relevant for the process of risk identification.

The purpose of a procedure (ref.9.6) is to set up a process for identification of the factors that could cause NAB's processes and its management system to deviate from the planned results, and to put in place preventive controls to minimize negative effects or to make maximum use of opportunities as they arise. The NAB is expected to plan and implement actions to address risks and opportunities for improvement.

Although clause 9.6 specifies that NAB shall identify opportunities for improvement and identify risks and take appropriate actions, there is no requirement for formal methods for risk management or a documented risk management process. The NAB can decide whether or not to develop a more extensive risk management methodology, e.g. through the application of other guidance or standards (e.g. ISO 31000).

The NAB can establish a general procedure which refers to management of risks or it could be included as a part of its relevant procedures. The NAB may use for that purpose internal audits and management reviews procedures. The identification of risks and improvements for its operations and subsequent actions dealing with them should be also part of setting goals and objectives for processes. The NAB shall also define in its procedures rules for retaining documented information as evidence of its determination of risks.

If the NAB performs risk analyses for other reasons (e.g. antibribery management system) it should consider using a combined approach if possible.

### **3.2 List of risks for impartiality of national accreditation body**

According to ISO/IEC 17011 accreditation shall be provided in an impartial manner. The risks below may arise from NAB's activities including any conflicts arising from its relationships or from the relationships of its personnel. The following list of risks provides examples of risks that NAB may consider but not be limited to.

*Note 1: This list is not exhaustive, and the risks listed should not be considered as being applicable to every NAB.*

*Note 2: Some of the risks for impartiality may also be considered by the NAB as a risk for confidentiality.*



Sources of risks	Potential risks to impartiality of the NAB
<b>Ownership</b>	<ul style="list-style-type: none"> <li>• being a part of larger organisation (public or private) that:                             <ul style="list-style-type: none"> <li>- provides conformity assessment activity,</li> <li>- provides consultancy,</li> <li>- is responsible for supervising or approving CABs for other purposes,</li> <li>- is involved in the regulation of CABs;</li> </ul> </li> <li>• holding shares or other financial or managerial benefits in relation to any CAB or body representing CABs;</li> <li>• relationship between owners, senior personnel or other controlling parties with organisations with an interest in the operation of the NAB (CABs, bodies representing CABs, governmental bodies supervising/regulating CABs).</li> </ul>
<b>Governance</b>	<ul style="list-style-type: none"> <li>• parallel supervision of NAB and CABs by the same supervising authority;</li> <li>• impartiality mechanism dominated by a single party and/or not providing objective and reliable evidence;</li> <li>• policies and the rules for accreditation disproportionately influenced of preponderant stakeholders;</li> <li>• bodies outside of the NAB having control of or significant influence of NAB policy or procedure, especially the accreditation decision making process.</li> </ul>
<b>Management</b>	<ul style="list-style-type: none"> <li>• conducting activities related to conformity assessment activity, which is subject to accreditation;</li> <li>• provision of services to CABs by NAB that may threaten independence and impartiality, such as: providing consultations, specific training, preparation of documentation, internal audits, etc.;</li> <li>• unequal treatment of CABs in the same sector, on areas such as:                             <ul style="list-style-type: none"> <li>- criteria for application acceptance,</li> <li>- price,</li> <li>- processes (e.g. turnaround times),</li> <li>- representation with the NAB;</li> </ul> </li> </ul>
<b>Personnel</b>	<ul style="list-style-type: none"> <li>• the remuneration of the personnel being dependent (in full or part) on:                             <ul style="list-style-type: none"> <li>- the conduct of CAB's assessments (e.g. assessment duration, number of nonconformities),</li> </ul> </li> </ul>

Sources of risks	Potential risks to impartiality of the NAB
	<ul style="list-style-type: none"> <li>- the successful outcome of a CABs application for accreditation or scope extension,</li> <li>- the gaining or retention of customers;</li> <li>• performing function in relation to the CAB, where the employee (internal, external or member of committee) combines relationships that may constitute a conflict of interest (e.g. family, financial, conducting activities for CAB by external auditors: training, consultations, internal audits, etc.);</li> <li>• professional co-operation (networks) among experts used by NAB, leading to familiarity and limited number of experts available in these fields;</li> <li>• threat to maintain objectivity in treating CABs with the referral status or where the results of an accredited CAB have remarkable economical influences;</li> <li>• participation of assessors (internal or external) in any part of the assessment process that were recently employed by the CAB in question (either permanently or as a contractor);</li> <li>• using the same assessor for the particular technical field of CAB activity over long period; repeated assessments or providing services to the same CAB leading to familiarity;</li> <li>• verification of own work when decision making on accreditation;</li> <li>• ethical principles are missing or interpreted differently by the personnel.</li> </ul>
<b>Shared Resources</b>	<ul style="list-style-type: none"> <li>• shared facilities or services with CABs or bodies representing CABs (e.g. offices, canteen, computer network, IT support, Finance team, Human Resources, etc);</li> <li>• using CABs' staff members as part-time assessors/experts.</li> </ul>
<b>Finances</b>	<ul style="list-style-type: none"> <li>• conducting profit-oriented activities;</li> <li>• financial dependence on the "large" CAB;</li> <li>• funding levels set by a third party without due consideration to volume of assessment required.</li> </ul>
<b>Contracts</b>	<ul style="list-style-type: none"> <li>• agreements with third parties to provides services (e.g. scheme owners) or providers of support services (e.g. IT hosting) which:               <ul style="list-style-type: none"> <li>- place constraints on the NABs operations,</li> <li>- place the responsibility for oversight onto a third party,</li> <li>- require the sharing of client confidential information.</li> </ul> </li> </ul>

Sources of risks	Potential risks to impartiality of the NAB
<b>Outsourcing</b>	<ul style="list-style-type: none"> <li>not ensuring an adequate level of independence and competence in accordance with the requirements of ISO/IEC 17011.</li> </ul>
<b>Training</b>	<ul style="list-style-type: none"> <li>provision of training that is tailored to the specific needs of a single CAB;</li> <li>personnel involved in training also involved in the assessment of CABs attending training courses.</li> </ul>
<b>Sales and Marketing</b>	<ul style="list-style-type: none"> <li>participating in promotional or communication activities arranged by CABs or suppliers to CABs;</li> <li>offering inducements to CABs to purchase services from the NAB.</li> </ul>

### 3.3 List of risks for processes

According to ISO/IEC 17011 accreditation shall be provided in a competent and consistent manner. The following list of risks for processes provides examples of risks related to competent and consistent manner that the NAB may consider, but not be limited to.

Sources of risks	Potential risks to competent and consistent providing accreditation by the NAB
<b>Structure</b>	<ul style="list-style-type: none"> <li>lack of clear responsibility or authority for organisational or accreditation decisions;</li> <li>lack of clear responsibility or authority for personnel participating in accreditation process.</li> </ul>
<b>Resources</b>	<ul style="list-style-type: none"> <li>lack of sufficient competent and qualified resources to: <ul style="list-style-type: none"> <li>conduct required assessment activities,</li> <li>conduct assessment related activities (e.g. planning, evidence review, etc...),</li> <li>create and maintain NAB policy and procedure,</li> <li>provide oversight and monitoring of personnel;</li> </ul> </li> <li>use of low skilled or unqualified personnel in technical roles;</li> <li>incomplete or not relevant competence criteria for personnel assigned to each accreditation scheme (external requirements i.e. law, scheme owners);</li> <li>personnel (particularly technical) not maintaining as current relevant technical skills and knowledge, including assessment skills;</li> </ul>

Sources of risks	<b>Potential risks to competent and consistent providing accreditation by the NAB</b>
	<ul style="list-style-type: none"> <li>• turnover of personnel (i.e. higher than industry norms);</li> <li>• limited resources for new or niche accreditation schemes.</li> </ul>
<b>Accreditation processes</b>	<ul style="list-style-type: none"> <li>• lack of/insufficient access to information on CAB's operations to evaluate risks for assessment;</li> <li>• inconsistent use of the risk evaluation for determination of assessment duration, assessment technique and assessment team;</li> <li>• non-harmonised approach to assessment of CAB accredited for the same activities;</li> <li>• inconsistent and inadequate information presented in accreditation scope leading to inconsistent assessment.</li> </ul>
<b>Information</b>	<ul style="list-style-type: none"> <li>• inadequate protection of or uncontrolled access to information obtained or created during the accreditation process;</li> <li>• non-centralised systems for the collation and storage of assessment information;</li> <li>• maintaining current information on NAB's policies and procedures up to date and publicly available;</li> <li>• external assessors working in CABs may get information of accreditation process, which is not available to other CABs, risk of discriminatory treatment of CABs;</li> <li>• delays in publication of updates of accredited CAB directories and information on suspensions and withdrawals of accreditation (dates and scopes);</li> <li>• inadequate transition periods for implementation changes in accreditation requirements.</li> </ul>
<b>Management system</b>	<ul style="list-style-type: none"> <li>• development of policies and procedures not in accordance with relevant national laws, international standards etc.;</li> <li>• personnel not following the NAB's procedures sufficiently or appropriately;</li> <li>• taking inappropriate actions for the scope, range and impact of the problem, if it is discovered that personnel does not follow the procedures;</li> <li>• lack of access or difficulties to relevant versions of documents (internal and external) at places where the work is performed (internal staff, external assessors, member of committees);</li> </ul>

<b>Sources of risks</b>	<b>Potential risks to competent and consistent providing accreditation by the NAB</b>
	<ul style="list-style-type: none"><li>• risk for objectivity of the internal audit (e.g. being responsible for audited areas, working in projects groups responsible for audited areas);</li><li>• management system documentation is not unambiguous enough to enable harmonized way to work and procedures are not communicated with the personnel;</li><li>• no effective procedure to monitor that personnel follows NAB's procedures and to react if discovered that procedures are not followed.</li></ul>