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# **Supplement 3 to EA-2/02 EA Procedure for the evaluation of a National Accreditation Body**

## **Risk-based approach for the planning of a peer evaluation**

### ***PURPOSE***

This document describes the risk-based approach used for the planning of a peer evaluation, considering the indicators specific to a national accreditation body.

### *Authorship*

This document has been prepared by the EA MLA Council (MAC).

### *Official language*

The text may be translated into other languages as required. The English language version remains the definitive version.

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## **1. INTRODUCTION**

Each national accreditation body (NAB) is unique and differs from other national accreditation bodies in terms of complexity, experience, stability, maturity and other individual framework conditions.

The evaluation of NABs shall create trust to the whole market in their ability to fulfil the relevant requirements. Accordingly, the efforts to be considered for an evaluation of an individual NAB shall reflect the individual degree of complexity, extent of experience as well as reached stability and maturity.

This document defines risk-indicators that reflect the above-mentioned complexity, experience, stability, and maturity of individual NABs. These risk indicators shall be taken into account during the planning stage of an evaluation. During a risk assessment performed by the team leader with support by the EA Secretariat the risk indicators are reviewed regarding their applicability and are correlated to mitigation actions that are suitable to address the risk indicators. It depends strongly to the overall picture of the individual NAB whether mitigation actions are necessary and which of them are suitable.

The aim of this document is not to establish a mechanistic approach where each risk indicator is strictly correlated to a specific mitigation action.

The task of the team leader who is responsible for performing the risk assessment is a kind of professional judgement, taking the whole picture of a NAB under evaluation into account. The document is a guide for team leaders, to help them in the planning of an effective and efficient peer evaluation by correlating applicable risk indicators with suitable mitigation actions.

Depending on the result of the risk assessment, the framework conditions of the peer evaluations (PE) will be determined on a case-by-case basis.

## **2. FRAMEWORK CONDITIONS FOR THE IMPLEMENTATION OF THE RISK APPROACH**

- Transparent to all parties involved;
- Create trust in the PE-system for all stakeholders (regulators, scheme owners, public, etc.);
- No contradiction to the current mandatory framework conditions as defined in IAF/ILAC A2 and EA-2/02;
- As simple as possible;
- Fit for purpose and should not result in unnecessary costs.

## **3. RISK INDICATORS TO BE CONSIDERED IN THE PLANNING OF A PEER EVALUATION**

This chapter lists the issues and the risks that should be at least considered when planning a peer evaluation:

Risk Indicator	Explanation
Number of sites of the NAB	<ul style="list-style-type: none"> <li>• increased complexity of the NAB to safeguard common processes and effective implementation of NAB's quality management at each site</li> <li>• risk of not having enough time for an effective peer evaluation and coverage of NABs sites with individual personnel or activities performed at each site</li> </ul>
Number of internal technical staff <sup>1</sup> of the NAB <sup>2</sup>	<p><u>High number</u></p> <ul style="list-style-type: none"> <li>• increased complexity in managing an organisation with a high number of technical staff, divided in different organisational units over different hierarchy levels, if applicable</li> <li>• risk of not having enough time for evaluating the above-mentioned complexity and for interviews with a representative number of staff</li> </ul> <p><u>Low number</u></p> <ul style="list-style-type: none"> <li>• increased complexity/risk because of large areas of responsibility for individual staff members</li> <li>• risk of not having enough contact persons/interview partners for the team members This will complicate the PE as team members may need to interview the same person simultaneously.</li> </ul>
Number of accredited conformity assessment bodies (CABs) per Level 3 accreditation standard <sup>3 4</sup>	<ul style="list-style-type: none"> <li>• risk of not having enough time for reviewing/witnessing a representative sample of accreditation files/assessments, especially if the range of technical fields is divers</li> </ul>
Extension of level 3 standards or level 4 sets of supplementary requirements	<ul style="list-style-type: none"> <li>• risk of not having enough time available for sampling new schemes and evaluate their implementation in the NAB</li> <li>• risk of not having the needed competence among TMs when an extension is requested by the NAB.</li> </ul>
Significant increase or decrease of the no. of CABs for a specific level 3 standard from the last PE	<ul style="list-style-type: none"> <li>• increased complexity to manage significant increase or decrease of CABs for a specific Level 3 standard</li> <li>• risk of not having enough time to address the above-mentioned situations during the evaluation</li> </ul>

<sup>1</sup> Personnel with significant responsibility according to ISO/IEC 17011 Annex A, Table A.1

<sup>2</sup> The number and type of staff in relation to the number of customers has to be taken into account when performing the risk assessment. When reviewing the number of technical personnel, the relation to the number of CABs and the distribution of staff to the different level 3 standards to be evaluated should be considered.

<sup>3</sup> Correlated to the number of technical staff who are responsible for managing the accreditation files of the CABs

<sup>4</sup> Diversity of technical fields may be an additional risk indicator and could be considered.

Risk Indicator	Explanation
Needs of interpreter/s for interviews with NAB`s staff	<ul style="list-style-type: none"> <li>• risk of not having enough time required for an effective peer evaluation (e.g. interviews with staff or for reviewing files)</li> </ul>
Cross frontier activities	<ul style="list-style-type: none"> <li>• increased complexity within the NAB to manage the needed collaboration (subcontracting) with different local NABs according to EA-2/13</li> <li>• risk of not having enough time dedicated to the evaluation of the NAB`s assessments and accreditation activities performed abroad.</li> </ul>
Stability, maturity of NAB	<ul style="list-style-type: none"> <li>• risk of facing a NAB with unexperienced staff, high staff turnover, inconsistent approach in the application of the accreditation procedures, low involvement in international committees and WGs, low capacity to contribute in peer evaluations, unsatisfactory results of previous evaluations, (i.e. number<sup>5</sup> and seriousness of previous findings, commitment in identifying and implementing corrective actions), collaboration with Team Leader (TL), with the Multilateral Agreement Council (MAC) and the Secretariat, complaints and appeals, follow up or extraordinary evaluation.</li> <li>• risk of not having enough time for an effective peer evaluation and coverage of NAB`s stability and maturity issues</li> </ul>

#### 4. RISKS MITIGATION IN THE PLANNING OF THE PEER EVALUATION

The variables listed and explained below may be applied as a result of the risk assessment to mitigate/consider the applicable risk indicators for the planning of a specific evaluation.

Depending on the results of the risk assessment, the specific evaluation of the NAB will be associated with more or less effort.

##### 4.1 Team composition

The team composition is one key variable for an evaluation. The standard approach is one Team Member (TM) for each Level 2/3 combination. For exceptionally low complexity and stable/mature NABs a decrease of TMs may be taken into account by appointing one TM for two Level 3 standards or two TMs for 3 Level 3 standards.

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<sup>5</sup> The number of findings is just an indication, it is one of the factors considered but it is not decisive for the final outcome of the risk assessment.

For higher complex/risk NABs a selection of experienced TMs<sup>6</sup> should be considered or in exceptional cases an additional TM may be appointed.

If needed appointment of TMs with specific level 4 competence in relation to specific extensions may be taken into account.

The appointment of TM Trainees may also be suitable to mitigate existing complexity/risks or to have the necessary competence within the team.

If communication between the NAB's staff and the team is likely to be a burden at least one or two members of the team (which may not be the TL) should be familiar with the language of the NAB under evaluation.

## 4.2 Duration of the evaluation and evaluation method

The team requires sufficient time to conduct a rigorous peer evaluation and effectively cover the complexity/risks referenced in section 3. There are several opportunities regarding the planning of the peer evaluation that are directly or indirectly related to the time that is available to the team/to certain team members. Among others the main opportunities are:

- Make use of remote evaluation techniques prior to the on-site peer evaluation week (e.g. TM for file review, TL for specific risk indicators); This additional time will not reduce the time allocated for the TM during the peer evaluation week.
- Witnessing prior to the evaluation will lead to more time flexibility during the evaluation week to be used for other purposes;
- See also the variables below.

## 4.3 Split evaluation

Consider a split evaluation when, among others:

- a) there is a limited number of staff to be interviewed at the NAB;
- b) a high effort of coordination for the TL is foreseen during the PE week;
- c) more time is needed by the TL to evaluate the NAB in sufficient depth (i.e. when high complexity/specific risks are identified).

## 4.4 Witnessing

Set the appropriate level of witnessing depending on the risk assessment and according to the following criteria:

- a) Witnessing in advance:
  - this will allow the TM to select the appropriate assessment activity in a specific field to be witnessed;

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<sup>6</sup> A TM is considered experienced when he/she has participated in more than 3 peer evaluations.

- this possibility provides more time for the TM to evaluate the activities of the NAB in sufficient depth and gives more flexibility during the on-site evaluation week.
- b) Decide upon one day witness instead of two days per level 3 standard (as long as in line with IAF/ILAC A2);
- c) In exceptional cases, increase the level of witnessing (in advance) mentioned in EA-2/02 per level 3 standard.

#### **4.5 Increase or decrease the file review**

Depending on the outcome of the risk assessment, increase or decrease the number of files to be reviewed (directly correlated to the variables above).

### **5. PROCEDURAL ASPECTS AND GENERAL CONSIDERATIONS**

- a) The risk assessment is to be performed once, during the application review, using with the information available at that time – using the specific form “*Risk assessment for the planning of the peer evaluation*”.
- b) The main inputs for the planning of the peer evaluation are the information on the structure and activities of the NAB, the statistical information, the results and experience of the previous evaluations, complaints and information received by the EA Secretariat etc.
- c) Decision on the application review remains with the TL and the Secretariat. Feedback from the NAB under evaluation will be considered as necessary.
- d) Regarding the assessment of risks, the TL together with the Secretariat have some flexibility when planning a peer evaluation. They may conclude about how to address specific risks within the planning of the peer evaluation.
- e) In order to harmonize the application of the risk approach as much as possible, the Secretariat will consider the risk-assessment carried out by the Team Leader and will provide him/her with information on the actions already taken for other NABs facing similar situations. The Team Leader will consider the information provided by the Secretariat for the final outcome of the risk-assessment.
- f) A regular peer evaluation of a NAB should not exceed one week on-site (5 days).