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Supplement 6 to EA-2/02 EA Procedure for the evaluation of a National Accreditation Body

Guidance on file review during a peer evaluation process

PURPOSE

This document provides EA guidance on the selection of files, how to review and report on the files selected during a peer evaluation.

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

The peer evaluation is the process of evaluation of a national accreditation body (NAB) by other national accreditation bodies according to EA-2/02 - EA Procedure for the evaluation of a National Accreditation Body.

The peer evaluation shall ascertain whether the NABs operate in compliance with the requirements laid down in EN ISO/IEC 17011 and in EA-1/06 and, when applicable, the supplementary requirements defined in EA mandatory documents and in Global Accreditation Cooperation Incorporated¹ documents endorsed by EA as mandatory for the accreditation schemes the NAB is competent to perform accreditation.

During the peer evaluations several evaluation techniques are used such as file reviews, interviews, on-site observation of committee meetings and witnessing of NABs while performing assessments.

The file review has proved to be a valuable technique to collect sufficient information about the processing of applications, the assessments and decision-making process of the NABs. However, the practices of the evaluators may differ, and therefore, there is a need for harmonization of the approach for sampling the files, how to review the files selected, and how to report about their evaluation.

2. PURPOSE

This document describes the criteria for sampling the files and provides guidance on how to review the files selected, and how to report about their evaluation in the framework of the peer evaluation process.

3. REFERENCES

- EN ISO/IEC 17011 - Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies
- EA-1/06 - EA multilateral agreement - Criteria for signing - Policy and procedures for development
- EA-2/02 - EA Procedure for the evaluation of a National Accreditation Body
- EA-2/02 S3 - Risk-based approach for the planning of a peer evaluation

¹ or IAF and/or ILAC documents as applicable at the time the assessment under review was conducted.

4. SAMPLING OF THE FILES

4.1 General

The file reviews aim at:

- confirming that the NAB's procedures are applied competently and in accordance with the requirements applicable to NABs;
- collecting representative information related to the NAB's operation in the respective accreditation schemes;
- confirming effective implementation of actions in response to nonconformities raised during the previous peer evaluation.

Time and language constraints as well as the very nature of the files may restrict the number of files being reviewed.

The selection shall however, applying the risk analysis ensure a representative sampling of:

- the level 4 and 5 activities of the EA MLA (see 4.2)
- the different types of assessments (see 4.3)
- assessors and persons in charge of the management of files (see 4.4).

A preliminary selection should be part of the team member preparation based on a review of the information publicly available from the NAB's webpage, but the selection will normally be finalized during the peer evaluation itself.

4.2 Sampling of level 42 and 52 activities

In order to take a representative sample of level 4 and 5 activities, at least the following information should be taken into account:

- the statistical information provided by the NAB and the technical fields pre-selected by the Team Leader in the application review;
- the risk-assessment performed by the Team Leader;
- the information included in the previous peer evaluation report;
- any decision of EA MAC with respect to the objectives of the evaluation;
- findings and critical issues raised at previous peer evaluations regarding specific levels 4 and 5 activities;
- new introduced level 4 and 5 activities, if the case;

² Level 4 and level 5 are the levels of the EA MLA as it is described in Table 1 of EA-1/06.

- significant changes to level 4 and 5 activities, (including those added to the NABs Global Accreditation Cooperation Incorporated MLA scope since the last peer evaluation), if the case;
- the level 4 and 5 activities, not yet covered in previous peer evaluation;
- a considerable increase of the number of accreditations for specific level 4 and 5 activities;
- recent complaints and appeals;
- mandatory documents adopted by EA for the accreditation of specific conformity assessment schemes;
- requirements by third parties, in particular regulators (i.e. accreditation for notification purposes) and/or conformity assessment schemes endorsed by EA/ Global Accreditation Cooperation Incorporated.

4.3 Sampling of the different types of assessments including specific assessment cases

The selected files should, as far as possible, cover different types of assessments and relevant accreditation decisions, and special cases such as:

- initial accreditation or reassessment;
- surveillance assessment;
- extension assessment;
- use of different assessment techniques, like remote assessment or witnessing;
- transition to new or revised accreditation standards, conformity assessment schemes or other international requirements;
- cross-frontier activities;
- multi-site CABs;
- accreditation with flexible scope;
- use of foreign external assessors;
- complaints or appeals in regard to specific level 4 and 5 activities;
- the refusal, reduction, suspension or withdrawal of accreditation;
- notification of changes.

4.4 Sampling of accreditation staff

The sampling of files should allow for the evaluation of the level of management of the accreditation process by:

- NAB accreditation staff, including external persons or committees involved in decision-making;
- external assessors/experts including foreign assessors/experts (from other NABs);

- newly recruited personnel involved in the accreditation process;
- the available resources for each specific field, i.e. enough experience and appropriate competences in case of few or high number of accredited conformity assessment bodies (CABs), i.e. enough staff members internal and external, case managers, assessors, etc.

5. REVIEW OF THE FILES

5.1 Methodology and time limit for file review

File review shall be such as to focus on those aspects of the accreditation process that have an important impact on the NAB's activities (see also par. 5.2 below).

It is important to highlight that a deep and proper preparation of the evaluation shall be done by the evaluators by review of the documents received with the self-assessment report. File review includes interviews with the NAB's staff in charge of the selected files; interviews of concerned assessors can be considered if feasible. The evaluators should identify the critical points for discussion and clarification and the points to be verified by file review and/or by interview.

At least one file shall be evaluated in depth for the whole process (vertical approach) and depending on the results, the review of the other selected files can focus on specific steps of the process (horizontal approach).

Considering time constraints, a reasonable time for a comprehensive file review may vary depending on the complexity of the file and the review itself (e.g. need of translation); however, it is not expected to take more than four hours to complete in order to ensure the evaluator has time to cover all selected files. In some situation file review could be planned in advance to optimise the time for on-site evaluation (see risk assessment performed by Team Leader).

Apart from examining the information on the CAB available from the website, the Team Member (TM) should not ask further information/documents in advance to the NAB. In case specific information or evidence cannot be directly provided by the evaluated NAB during the interviews and in order to save time, the evaluator will consider reviewing different files in parallel.

5.2 What are the essential steps to review

Depending on the specificities of the file, the evaluators should identify the critical points for discussion and clarification.

It is however recommended to focus at least on the following elements:

General

- Were the requirements of EN ISO/IEC 17011 and other applicable requirements with regard to the accreditation process met?
- Were the steps of the NAB's accreditation processes/procedures followed?
- Is the NAB applying a risk-based approach at all stages of the process?
- Does the personnel involved in the application review, selection of the team members, document review, assessment, reviewing of the assessment reports and decision making

have the appropriate knowledge, skills and qualifications and are the competences of this personnel monitored?

Application stage

- Was the application review appropriately performed and registered?
- Were all necessary documents required, received and reviewed?

Assessment planning

- Are there activity data collected from CAB (e.g. volume of activity, nb of people involved in the activity, countries where the CAB is active...) to design the assessment program (and the assessment plan)? Do the data collected support the risk-based approach used to design the assessment program?
- Was the planning of the assessment appropriate (sampling, composition/ competence/ impartiality of the team, duration, definition of tasks and assessment techniques, locations, information to the CAB and to the team)?
- Is a detailed assessment plan available?
- Is the mark properly used by the CAB's and assessed by the NAB?

Assessment documentation

- Were the assessment non-conformities relevant and adequately managed by the CAB and evaluated by the NAB (content, cause and extent, actions, closing)?
- Does the report clearly indicate what has been done during the assessment and includes conclusions with regard to the fulfilment of the applicable requirements?

Decision-making

- Was the information collected in the assessment report and used for decision making sufficient to support the accreditation decision?
- Was the decision consistent with the outcome of the assessment and taken without any undue delay and communicated to the CAB?
- Were negative decisions or decisions on condition duly motivated?
- Is there evidence of competence of decision-makers?

Assessment program and accreditation cycle

- Was the assessment programme followed and adequately designed/revised (risk-based approach – coverage of the scope).

Accreditation information

- Does the content of the accreditation documents (certificate – scope) comply with the relevant requirements?
- Is the information on the accredited CAB publicly available and up to date?

Peer evaluators notes made during the evaluation should be detailed enough in order to be able to support the conclusions of the team and should be stored until the final decision is made by MAC (i.e. to answer any request from the MAC Task Force Group or to clarify any issue that might be raised after the peer evaluation).

6. REPORTING ON THE REVIEW OF FILES

The aim of the evaluation report is to support the decision-making process by providing the MAC with:

- information on the implementation of policies and procedures of the NAB supported by evidence gathered during the peer evaluation process;
- evidence that a representative sampling of the NAB activities has been covered during the peer evaluation.

The evaluators should report both on the compliance and the non-compliance and confirm the on-going compliance of the NAB with the applicable requirements, giving confidence to regulators, scheme owners, stakeholders and the business community in certificates and reports issued by conformity assessment bodies under the different fields (conformity assessment activities) of the EA MLA.

The evaluators should report on the conclusions of their review and should not duplicate parts of the text of the self-assessment report or of the NAB documentation.

The information collected during file reviews should be used to conclude on the evaluation and be included in:

- the conclusion boxes under each clause of EN ISO/IEC 17011;
- the conclusion boxes in the last section of the evaluation report concerning the implementation of EA, ILAC and IAF mandatory documents;
- the table concerning the handling of findings from the previous peer evaluation.

The text in the conclusion box under the clause of EN ISO/IEC 17011 filled by TMs (clauses assigned to the TMs by the TL) should be limited to essential information (it should be sufficient to write that the file reviews confirm the compliance of NABs operation with the applicable requirements for a NAB), with links to findings if any.

Examples of wording in the boxes under the clauses of EN ISO/IEC 17011 might be:

- *“the file reviews confirm the description hereabove (3 cases checked)”*
- *“the file reviews show that the time intervals for assessments are respected (checked on 4 cases)”*
- *“from the file reviews, it is confirmed that the use of the accreditation mark is checked during the assessments”*
- *“in several cases it was found that the accreditation certificate available on the website is not up to date with the latest accreditation decision (cf. NC #X)”*.

As complementary information, a detailed description of the extent and the result of the performed file review will be presented in a separate table (see Annex 1 below).

ANNEX 1 – REPORTING THE FILES REVIEWED

Note: The tables below for the Level 3 activities are intended solely as working templates for use by the peer evaluation teams. Following completion, the templates shall be submitted to the Secretariat for record-keeping purposes. The Secretariat shall maintain the completed templates as records of the respective evaluation. The filled in templates shall not constitute part of the peer evaluation report and shall not be considered or circulated as supporting documentation for decision-making by the MAC.

Each Team member is expected:

- for each file to tick the relevant box(es) and the points that have been the subject of a specific evaluation;
- to duplicate the relevant table as many times as necessary for each of the file reviewed.

Activity	CAB no.	Technical scope	CAB's structure and additional information	Assessment Type	Accreditation Process	Personnel Records	Assessment Program Compliance	Conclusion
CAL EN ISO/IEC 17025	CAL 1 ☐ Remote ☐ On-site	☐ Voluntary ☐ Regulated Technical field(s):	☐ Multisite ☐ Cross Frontier ☐ Flexible scope ☐ Reference to accreditation ☐ Other (see list in 4.3 of Guidance document on file review)	☐ Initial ☐ Surveillance ☐ Re-assessment ☐ Extension ☐ Other (see list in 4.3 of Guidance document on file review)	☐ Application review ☐ Assessment plan & report ☐ Decision & accreditation docs ☐ Assessment program elaboration ☐ Accreditation information ☐ Other ...	☐ NAB staff ☐ Assessor(s) ☐ Expert(s) ☐ Decision-maker(s)	☐ Time intervals respected ☐ Coverage of activities & sites ☐ Other	☐ Remarks (see Notes) ☐ No remarks
		<u>Notes</u> Add here remarks, where relevant, and references to any Finding NC/Cm #X, where applicable						

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Activity	CAB no.	Technical scope	CAB's structure and additional information	Assessment Type	Accreditation Process	Personnel Records	Assessment Program Compliance	Conclusion
TEST EN ISO/IEC 17025	TEST 1 ☐ Remote ☐ On-site	☐ Voluntary ☐ Regulated Technical field(s):	☐ Multisite ☐ Cross Frontier ☐ Flexible scope ☐ Reference to accreditation ☐ Other (see list in 4.3 of Guidance document on file review)	☐ Initial ☐ Surveillance ☐ Re-assessment ☐ Extension ☐ Other (see list in 4.3 of Guidance document on file review)	☐ Application review ☐ Assessment plan & report ☐ Decision & accreditation docs ☐ Assessment program elaboration ☐ Accreditation information ☐ Other ...	☐ NAB staff ☐ Assessor(s) ☐ Expert(s) ☐ Decision-maker(s)	☐ Time intervals respected ☐ Coverage of activities & sites ☐ Other	☐ Remarks (see Notes) ☐ No remarks
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Activity	CAB no.	Technical scope	CAB's structure and additional information	Assessment Type	Accreditation Process	Personnel Records	Assessment Program Compliance	Conclusion
MED EN ISO 15189	MED 1 ☐ Remote ☐ On-site	☐ Voluntary ☐ Regulated Technical field(s):	☐ Multisite ☐ Cross Frontier ☐ Flexible scope ☐ Reference to accreditation ☐ Other (see list in 4.3 of Guidance document on file review)	☐ Initial ☐ Surveillance ☐ Re-assessment ☐ Extension ☐ Other (see list in 4.3 of Guidance document on file review)	☐ Application review ☐ Assessment plan & report ☐ Decision & accreditation docs ☐ Assessment program elaboration ☐ Accreditation information ☐ Other ...	☐ NAB staff ☐ Assessor(s) ☐ Expert(s) ☐ Decision-maker(s)	☐ Time intervals respected ☐ Coverage of activities & sites ☐ Other	☐ Remarks (see Notes) ☐ No remarks
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Activity	CAB no.	Technical scope	CAB's structure and additional information	Assessment Type	Accreditation Process	Personnel Records	Assessment Program Compliance	Conclusion
INSP EN ISO/IEC 17020	INSP 1 ☐ Remote ☐ On-site	☐ Voluntary ☐ Regulated Technical field(s):	☐ Multisite ☐ Cross Frontier ☐ Flexible scope ☐ Reference to accreditation ☐ Other (see list in 4.3 of Guidance document on file review)	☐ Initial ☐ Surveillance ☐ Re-assessment ☐ Extension ☐ Other (see list in 4.3 of Guidance document on file review)	☐ Application review ☐ Assessment plan & report ☐ Decision & accreditation docs ☐ Assessment program elaboration ☐ Accreditation information ☐ Other ...	☐ NAB staff ☐ Assessor(s) ☐ Expert(s) ☐ Decision-maker(s)	☐ Time intervals respected ☐ Coverage of activities & sites ☐ Other	☐ Remarks (see Notes) ☐ No remarks
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Activity	CAB no.	Technical scope	CAB's structure and additional information	Assessment Type	Accreditation Process	Personnel Records	Assessment Program Compliance	Conclusion
PTP EN ISO/IEC 17043	PTP 1 ☐ Remote ☐ On-site	☐ Voluntary ☐ Regulated Technical field(s):	☐ Multisite ☐ Cross Frontier ☐ Flexible scope ☐ Reference to accreditation ☐ Other (see list in 4.3 of Guidance document on file review)	☐ Initial ☐ Surveillance ☐ Re-assessment ☐ Extension ☐ Other (see list in 4.3 of Guidance document on file review)	☐ Application review ☐ Assessment plan & report ☐ Decision & accreditation docs ☐ Assessment program elaboration ☐ Accreditation information ☐ Other ...	☐ NAB staff ☐ Assessor(s) ☐ Expert(s) ☐ Decision-maker(s)	☐ Time intervals respected ☐ Coverage of activities & sites ☐ Other	☐ Remarks (see Notes) ☐ No remarks
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Activity	CAB no.	Technical scope	CAB's structure and additional information	Assessment Type	Accreditation Process	Personnel Records	Assessment Program Compliance	Conclusion
RMP EN ISO 17034	RMP 1 ☐ Remote ☐ On-site	☐ Voluntary ☐ Regulated Technical field(s):	☐ Multisite ☐ Cross Frontier ☐ Flexible scope ☐ Reference to accreditation ☐ Other (see list in 4.3 of Guidance document on file review)	☐ Initial ☐ Surveillance ☐ Re-assessment ☐ Extension ☐ Other (see list in 4.3 of Guidance document on file review)	☐ Application review ☐ Assessment plan & report ☐ Decision & accreditation docs ☐ Assessment program elaboration ☐ Accreditation information ☐ Other ...	☐ NAB staff ☐ Assessor(s) ☐ Expert(s) ☐ Decision-maker(s)	☐ Time intervals respected ☐ Coverage of activities & sites ☐ Other	☐ Remarks (see Notes) ☐ No remarks
		Notes Add here remarks, where relevant, and references to any Finding NC/Cm #X, where applicable						

Activity	CAB no.	Technical scope	CAB's structure and additional information	Assessment Type	Accreditation Process	Personnel Records	Assessment Program Compliance	Conclusion
MSC EN ISO/IEC 17021-1	MSC 1 ☐ Remote ☐ On-site	☐ Voluntary ☐ Regulated Technical field(s):	☐ Multisite ☐ Cross Frontier ☐ Flexible scope ☐ Reference to accreditation ☐ Other (see list in 4.3 of Guidance document on file review)	☐ Initial ☐ Surveillance ☐ Re-assessment ☐ Extension ☐ Other (see list in 4.3 of Guidance document on file review)	☐ Application review ☐ Assessment plan & report ☐ Decision & accreditation docs ☐ Assessment program elaboration ☐ Accreditation information ☐ Other ...	☐ NAB staff ☐ Assessor(s) ☐ Expert(s) ☐ Decision-maker(s)	☐ Time intervals respected ☐ Coverage of activities & sites ☐ Other	☐ Remarks (see Notes) ☐ No remarks
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Activity	CAB no.	Technical scope	CAB's structure and additional information	Assessment Type	Accreditation Process	Personnel Records	Assessment Program Compliance	Conclusion
PROD EN ISO/IEC 17065	PROD 1 ☐ Remote ☐ On-site	☐ Voluntary ☐ Regulated Technical field(s):	☐ Multisite ☐ Cross Frontier ☐ Flexible scope ☐ Reference to accreditation ☐ Other (see list in 4.3 of Guidance document on file review)	☐ Initial ☐ Surveillance ☐ Re-assessment ☐ Extension ☐ Other (see list in 4.3 of Guidance document on file review)	☐ Application review ☐ Assessment plan & report ☐ Decision & accreditation docs ☐ Assessment program elaboration ☐ Accreditation information ☐ Other ...	☐ NAB staff ☐ Assessor(s) ☐ Expert(s) ☐ Decision-maker(s)	☐ Time intervals respected ☐ Coverage of activities & sites ☐ Other	☐ Remarks (see Notes) ☐ No remarks
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Activity	CAB no.	Technical scope	CAB's structure and additional information	Assessment Type	Accreditation Process	Personnel Records	Assessment Program Compliance	Conclusion
PERS EN ISO/IEC 17024	PERS 1 ☐ Remote ☐ On-site	☐ Voluntary ☐ Regulated Technical field(s):	☐ Multisite ☐ Cross Frontier ☐ Flexible scope ☐ Reference to accreditation ☐ Other (see list in 4.3 of Guidance document on file review)	☐ Initial ☐ Surveillance ☐ Re-assessment ☐ Extension ☐ Other (see list in 4.3 of Guidance document on file review)	☐ Application review ☐ Assessment plan & report ☐ Decision & accreditation docs ☐ Assessment program elaboration ☐ Accreditation information ☐ Other ...	☐ NAB staff ☐ Assessor(s) ☐ Expert(s) ☐ Decision-maker(s)	☐ Time intervals respected ☐ Coverage of activities & sites ☐ Other	☐ Remarks (see Notes) ☐ No remarks
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Activity	CAB no.	Technical scope	CAB's structure and additional information	Assessment Type	Accreditation Process	Personnel Records	Assessment Program Compliance	Conclusion
V&V EN ISO/IEC 17029	V&V 1 ☐ Remote ☐ On-site	☐ Voluntary ☐ Regulated Technical field(s):	☐ Multisite ☐ Cross Frontier ☐ Flexible scope ☐ Reference to accreditation ☐ Other (see list in 4.3 of Guidance document on file review)	☐ Initial ☐ Surveillance ☐ Re-assessment ☐ Extension ☐ Other (see list in 4.3 of Guidance document on file review)	☐ Application review ☐ Assessment plan & report ☐ Decision & accreditation docs ☐ Assessment program elaboration ☐ Accreditation information ☐ Other ...	☐ NAB staff ☐ Assessor(s) ☐ Expert(s) ☐ Decision-maker(s)	☐ Time intervals respected ☐ Coverage of activities & sites ☐ Other	☐ Remarks (see Notes) ☐ No remarks
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Activity	CAB no.	Technical scope	CAB's structure and additional information	Assessment Type	Accreditation Process	Personnel Records	Assessment Program Compliance	Conclusion
BIO EN ISO 20387	BIO 1 ☐ Remote ☐ On-site	☐ Voluntary ☐ Regulated Technical field(s):	☐ Multisite ☐ Cross Frontier ☐ Flexible scope ☐ Reference to accreditation ☐ Other (see list in 4.3 of Guidance document on file review)	☐ Initial ☐ Surveillance ☐ Re-assessment ☐ Extension ☐ Other (see list in 4.3 of Guidance document on file review)	☐ Application review ☐ Assessment plan & report ☐ Decision & accreditation docs ☐ Assessment program elaboration ☐ Accreditation information ☐ Other ...	☐ NAB staff ☐ Assessor(s) ☐ Expert(s) ☐ Decision-maker(s)	☐ Time intervals respected ☐ Coverage of activities & sites ☐ Other	☐ Remarks (see Notes) ☐ No remarks
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