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A025 Audit Report Writing Guide

Modifications: p. 2

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1. Aim

The purpose of this guide is to clarify the expectations of OLAS with respect to the contents of the audit report by giving you practical advice and examples or counterexamples.

This is to facilitate reading and understanding of audit reports by CABs, members of the Accreditation Committee and OLAS.

2. Writing tips

2.1. <u>Assessment plan Audit program</u>

The audit program is established by the team leader in consultation with the technical assessors and sent to the CAB and to OLAS at least 2 weeks 5 working days before the assessment, in accordance with procedure "P002 - Performing assessments". If a technical assessor acts alone, he has to establish his own assessment plan applying the same principles.

- **Witness assessments**: if foreseen, they must be clearly indicated in the assessment <u>plan program</u>;
- Extensions or additions within the flexible scope: if requested, they must be clearly identified (the necessary information is provided by the accreditation manager in the mission order);
- Findings to be closed of the previous assessment(s): it is recommended to indicate them in the assessment plan audit program.



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- Reference to the chapters of the standard
- Indication of witness assessments
- Identification of extensions
- Reference to the findings to be cleared
- Plan a wrap-up meeting at the end of the day for assessments lasting several days.

Date and time:	Reference section:	Names of assessors:	Persons encountered:
	Quality assessment according to ISO 17020 : 2012		
14h00 - 17h00	Facilities and equipment (6.2), Complaints and appeals (7.5 & 7.6), Management review (8.5), Internal audits (8.6), Corrective actions (8.7), Preventive actions (8.8)	Team leader	Quality manager
	Follow-up of findings n°1/4, 3/4 and 4/4 of the previous assessment		
141.00	Technical witness assessment: periodic inspections of lifts		m 1 : 1
14h00 - 17h00	Place : MUDAM (Musée d'Arts Modernes) Luxembourg	Technical assessor TA1	Technical manager and technicians
	Follow-up of finding n°2/4 of the previous assessment		
14h00	Technical witness assessment: air sampling before removal of	Technical	Technical
17h00	asbestos (extension) Place : to be defined	assessor TA2	manager and technicians
17h00 - 17h15	Intermediate wrap-up meeting: Feedback from assessors and any findings encountered during the first day of audit. Comments of the auditees.	Team leader Technical assessor TA1 Technical assessor TA2	All the staff of the organisation is invited to participate



Limit information to schedules and persons encountered

Date and time:	Reference section:	Names of assessors:	Persons encountered:
14h00 - 17h00	Quality assessment	Team leader	Quality manager
14h00 - 17h00	Technical assessment	Technical assessor TA1	Technical manager and technicians
14h00 - 17h00	Technical assessment	Technical assessor TA2	Technical manager and technicians



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2.2. Summaries and conclusions of assessment

The team leader draws up the audit report. He integrates the "synthesis of the technical auditor" part(s).

When on-site witness assessments are conducted, the part "Observation on realization of audits/inspection/sampling... on-site" is to be copied and completed for each witness assessments performed.

The template "F003A - ISO / IEC 17025, 17020 and 17065 Audit Report" contains sections specifically dedicated to laboratories, inspection bodies and certification bodies that should only be commented upon when applicable. Apart from these parts, all boxes in the audit report shall be commented.

Please avoid removing boxes or changing the structure of the audit report.

Some topics in the report may not be commented by all auditors or audited at each audit. In this case please clearly indicate "not examined or "not applicable".

It is possible to refer to the part of another assessor if a topic has not been examined. For key topics such as "Management of staff competence" it is important, however, that each assessor gives his or her point of view on the issue. The quality assessor from the point of view of the system (policies, procedure, criteria for qualification, maintaining competence, supervision of skills, training...), the technical assessor from the technical point of view in relation with the accredited domain.



Explain why a box in the report is not commented



been audited

Subcontracting (competent/accredited, contract + confidentiality and impartiality, information of clients, records)

(§ 4.5 ISO 17025 - § 6.3 ISO 17020 - § 6.2.2 ISO 17065)

« not applicable » / « not concerned »

or

« not examined »

or

« see report of the technical assessor »

Subcontracting (competent/accredited, contract + confidentiality and impartiality, information of clients, records)

(§ 4.5 ISO 17025 - § 6.3 ISO 17020 - § 6.2.2 ISO 17065)



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In your comments, please quote the audit evidence and, at the end of each section, please decide on compliance with the requirements. If appropriate, please identify strong points or areas for improvement.

Audit reports are among the most important records in the OLAS management system. After the completion of the audit they are the only written record and they must allow the members of the accreditation committee and OLAS to make a decision on the accreditation of the concerned organisation on the basis of factual elements.

Audit evidences are also important to demonstrate the value of the accreditation issued by OLAS when needed (appeal of a decision, complaint against a CAB, etc.).

It may be necessary to trace which files were examined by OLAS and on what basis an accreditation decision was taken. For this reason, it is important that the "Management of staff competence" and on-site observations (witness) sections are well supported in the audit reports.



Comment on the documents examined (content, compliance, any sensitive points or areas for improvement). If appropriate, make the link with the finding sheets.

Management of staff competence (contract, training, qualification, authorization, competence and performance, records...) (§ 5.2 ISO 17025 - § 6.1 ISO 17020 - § 6.1 ISO 17065)

The procedure for managing staff skills are documented in P001_Competence Management_v03.

Initial authorisation of staff is a rigorous process. It is based on specific criteria, with partial authorisations.

The files reviewed were complete and supported by satisfactory evidence. Seen by sampling:

- The personal file of Mrs. Schmit (technical manager): hired on 01/01/2017, diplomas, authorisation to practice from 01/01/2016, and trainings.
- The file on maintenance of skills of Mr Dupont (technician, metrology manager) for the various tests in terms of authorisation and monitoring of skills (document XY v.03 of 01/01/2018).

Area for improvement: validation of the cards of authorization with the visa of the interested ones.

Satisfactory evaluation of the 2016 training plan and its follow-up (document F001 v.02).

Conclusion: The situation is overall satisfactory, the finding **AB 1/10 (non-conformity)** has been observed: The CAB has not defined the criteria to enable and verify the maintenance of skills of its staff for the activity XY.



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- major non-

conformity [



Leave out the examined audit evidence

Management of staff competence (contract, training, qualification, authorization, competence and performance, records...) (§ 5.2 ISO 17025 - § 6.1 ISO 17020 - § 6.1 ISO 17065)

The audited staffs are technically competent.

Documents on authorization, training and maintenance of skills documents are kept up to date.



List the examined documents without any explanation of their compliance

Management of staff competence (contract, training, qualification, authorization, competence and performance, records...) (§ 5.2 ISO 17025 - § 6.1 ISO 17020 - § 6.1 ISO 17065)

- 2018 Training Plan

Finding:

- Procedure P001 v.03
- personal file of Mrs Schmit
- maintenance of skills of Mr Dupont

- remark

Please do write your comments and finding sheets in a factual manner, without giving advice or providing in the report the solutions to the findings.



Factual description of the findings, without proposing a solution.

Paragraph cited:					
This non-conformity relates to:	- application	- documentation			
Description of finding:					
The newly added parameters in the scope of accreditation are not included in the internal audit program.					

- non-conformity



Wording of the finding including the way to process it

Finding:	- remark	- non-conformity	- major non-conformity
Paragraph cited:			
This non- conformity relates to:	- application	- documentation	

Description of finding:

The newly added parameters in the scope of accreditation are not yet included in the internal audit program. The service should draw the internal auditor's attention to the new parameters so that they can be audited (validation files, interlaboratory tests, staff competence, relevance of the procedure, etc.).



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Mandatory EA, ILAC or IAF documents form part of the requirements to be audited in the same way as the accreditation standard.

As a signatory of EA, IAC and IAF mutual recognition agreements, OLAS must demonstrate that these documents are taken into account during audits.

Although the requirements are partially redundant with the requirements of the accreditation standard, it is essential that you make a clear statement that you have considered these documents.



List the assessed EA, ILAC and IAF documents. Comment on compliance and refer to any findings. Respect of applicable EA, IAF and ILAC requirements:

List of assessed EA, ILAC et IAF documents:

- EA-2/17 EA document on accreditation for notification purposes
- IAF MD1 Certification of multiple sites based on sampling
- IAF MD5 Determination of Audit Time of Quality and Environmental Management Systems
- IAF MD 19 Audit and Certification of a Management System operated by a Multi-Site Organization

Comment: the observed situation complies with the requirements above, except for IAF MD1 (finding AB2).



Remain vague about considering EA, ILAC and IAF documents

Respect of applicable EA, IAF and ILAC requirements:

NTR / Nothing To Report

2.3. Definitions and writing of audit findings

Major non-conformity

Major gap detected in the CAB's organization presenting a serious risk to the reliability of results and/or decisions.

Non-conformity

Gap detected in the CAB's organization resulting from a requirement in the frame of reference, which has not or has only partially been dealt with, but which does not have any direct impact on the reliability of the results and/or decisions.

Comment

Concerns an arrangement needed to be further formalised or specified.

Major non-conformities, non-conformities and **comments** are all reported on finding sheets. In accordance with procedure P002, CABs must take a corrective action for them.



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Strong areas

Practices that meet the requirements of the standard, going beyond what is requested and:

- provide additional information, and/or
- are particularly innovative, and/or
- are particularly efficient.

Sensitive areas

Sensitive areas represent:

- subjects or areas related to the identified findings, and/or
- "minor" deviations, not to be qualified as findings. However, they are practices that, if they persist, could become findings in future audits.

Strong areas and **sensitive areas** are reported in the corresponding cases of the assessment report.

Area for improvement

It is a way of thinking about a practice with a view to improving it and/or making it more efficient. The areas for improvement shall be limited to the cases discussed during the audit and shall be formulated in a general way, without giving specific advice.

Not to be confused with a sensitive point.

If appropriate, please indicate **areas for improvement** in the body of the report, in the boxes dealing with the concerned requirements.



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2.4. Finding and corrective action sheets

Regardless of the type of finding, please do always comment the box "Motivation of the classification of the finding".

Definitions and treatment of findings are described in detail in procedure P002. For remarks or simple non-conformities, **please explain why the risk is limited**.

Where a finding is blocking because it presents a serious risk to the reliability of the results or decisions, please classify it as a "major non-conformity" – also when the concerned activity is requested for extension of the scope and is not yet covered by the current accreditation.



Weigh the risk in case of a remark or non-conformity.

Finding:	- remark 🛚	- non-conformity	- major non- conformity	
Paragraph cited:	§ 5.9.1			
This non-conformity relates to:	- application 🔀	- documentation		
Description of find	ling:			
Following a stock shortage of the internal standard for method XX, the laboratory did not perform the internal quality controls for 3 weeks (an average of 100 samples are analysed per day).				
Motivation of the classification of the finding: please describe the context and the risk associated with the finding:				
In this case the risk is low because it is a production quality control laboratory and the results remain within the usual acceptance limits.				



Indicate that there is a risk on the reliability of the results for a remark or a simple non-conformity.

Finding:	- remark 🛚	- non-conformity	- major non- conformity
Paragraph cited:	§ 5.9.1		
This non- conformity relates to:	- application 🖂	- documentation	

Description of finding:

Following a stock shortage of the internal standard for method XX, the laboratory did not perform the internal quality controls for 3 weeks (an average of 100 samples are analysed per day).

Motivation of the classification of the finding: please describe the context and the risk associated with the finding:

Risk on the reliability of the results.



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In the finding sheets, please indicate the relevant paragraph(s) of the standard in a precise manner.



Indicate the relevant paragraph (s) of the standard in a precise manner.

Finding:	- remark	- non-conformity 🛚	- major non- conformity	
Paragraph cited	§ 5.4.5.2			
This non- conformity relates to:	- application	- documentation		
Description of fine	ling:			
The validation file for the analysis of XXX dated 01.01.2018 does not contain any data on trueness.				
Motivation of the classification of the finding: please describe the context and the risk associated with the finding:				
xxx				



Indicate a whole chapter of the standards as the relevant paragraph.

XXX

Finding:	- remark	- non-conformity	- major non- conformity	
Paragraph cited:	§ 5.4			
This non- conformity relates to:	- application	- documentation		
Description of find	ling:			
The validation file for the analysis of XXX dated 01.01.2018 does not contain any data on trueness.				
Motivation of the classification of the finding: please describe the context and the risk associated with the finding:				



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The **corrective action sheets** shall directly follow the corresponding finding sheets.



Finding n°: AB 1/2

Corrective action n°: AB 1/2

Insert the corrective action sheets so that they follow the corresponding finding Finding n°: AB 2/2

Corrective action n°: AB 2/2

Finding n°: CD 1/1

Corrective action n°: CD 1/1



sheets

Finding n°: AB 1/2 Finding n°: AB 2/2

Include corrective action cards in bulk at the end of the report

Finding n°: CD 1/1

Corrective action n°

Corrective action n°: AB 1/2 Corrective action n°: AB 2/2 Corrective action n°: CD 1/1

A corrective action sheet has the same identification number as the corresponding finding sheet.



Finding n°: AB 1/2

Corrective action n°: AB 1/2

Label the corrective action sheets with the same numbers as the corresponding finding sheets Finding n°: AB 2/2

Corrective action n°: AB 2/2

Finding n°: CD 1/1

Corrective action n°: CD 1/1



Have an independent

numbering for

Finding n°: AB 1/2

Corrective action n°: OEC 1/3

Finding n°: AB 2/2

Corrective action n°: OEC 2/3

Finding n°: CD 1/1

Corrective action n°: OEC 3/3

corrective action sheets

2.5. Validated accreditation scope

Where the scope of accreditation requires changes, please identify them clearly (e.g. in colour) within the scope of accreditation at the end of the audit report.

Please do also refer to any changes to the scope in the box "Validation of the accreditation scope and the granted flexibility..." in the summary of the team leader.



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2.6. Modifications of the report

If major non-conformities are identified during an assessment, the organism has 3 months to send evidence of implementation of the corresponding corrective actions.

After reviewing evidence of corrective actions, the concerned assessors have to update the first version of the assessment report. In this second version of the report, please leave the original text and identify any additions (e.g. in colour and by indicating the date of the addition).

The following parts of the report have to be updated:

Corrective action sheet:

Please comment on the evidence reviewed and clearly indicate whether the finding can be considered as cleared from a documentary point of view (the application will be systematically verified at the next assessment).

- Final conclusion of the technical assessor regarding the technical competencies of the audited body:
 - Please update your conclusion considering the new items reviewed.
- Clear statement of the team leader as to the granting, maintaining, withdrawing, etc. of accreditation status:
 - If applicable, please indicate the new position of the audit team regarding the granting, maintenance, extension, withdrawal ... of accreditation.



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2.7. Report format

For the sake of clarity, please write in black, rather than using colours already used in the report template (such as blue in the template boxes).

Please do not include attendance lists and validated accreditation scope as images or pdf format in the report in Word format, in order to avoid creating a file that is too large.



Write comments in black

Finding:	- remark	- non-conformity	- major non- conformity ⊠	
Paragraph cited:	§ 5.4.5.2			
This non- conformity relates to:	- application 🛚	- documentation 🗵		
Description of find	ling:			
XXX				
Motivation of the classification of the finding: please describe the context and the risk associated with the finding:				
Risk on the reliability of the results.				



Write comments without clear distinction from the blue text of the report template.

Finding:	- remark	- non-conformity	- major non- conformity	
Paragraph cited:	§ 5.4.5.2			
This non- conformity relates to:	- application 🛚	- documentation 🗵		
Description of find	ling:			
XXX				
Motivation of the classification of the finding: please describe the context and the risk associated with the finding: Risk on the reliability of the results.				

2.8. Use of abbreviations

It is allowed to use abbreviations in reports.

Please define each abbreviation at least once in the document. If possible, the definition should be done the first time the abbreviation is used.



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This applies especially to abbreviations related to technical terms that are not easy to understand if the reader does not have extensive experience in the field.

The definition of an abbreviation could be done as follows:

- OLAS (Office Luxembourgeois d'Accréditation et de Surveillance)
- Institut Luxembourgeois de Normalisation, de l'Accréditation et de Surveillance (ILNAS).