Guide for Norwegian Accreditation Assessors

Document category: Guide
Technical area: All

Purpose:
Guide for Norwegian Accreditation (NA) assessors when undertaking assessments.

Changes to this version:
The entire document has been rewritten. Changes to deadlines for assessment reports and monitoring of corrective action.

Content

1 FOREWORD

Both internal and external (contracted) assessors are used on accreditation projects. The assessor team usually comprises several assessors with different technical expertise to cover the scope of the accreditation/application for accreditation. The task of the assessors is to assess documentation and implementation of the applicant's management system, premises, equipment, expertise, and practice.

2 OBJECTIVE

This document is a guide for technical assessors (TA) and experts (TE) on assessments.

3 DEFINITIONS

Definitions and concepts in this document are in line with the definitions applied in accreditation standards.

3.1 Initial assessment

Initial assessment involves an assessment visit conducted by NA to the organisation that has applied for accreditation. The purpose of the visit is to verify that the organisation satisfies accreditation requirements. The entire management system, premises, equipment (if applicable) and expertise of staff are assessed.

3.2 Renewal of accreditation

Accreditation is normally issued for five years at a time and then has to be renewed. A renewal visit must be conducted, and this process must be completed no later than five years after accreditation was first awarded/most recently renewed. The renewal process is just as comprehensive as the process applicable to first-time accreditation.

3.3 Surveillance activities

Surveillance activities are activities performed to check that accredited organisations continue to satisfy accreditation requirements. Examples of such activities are:

- Surveillance visits with assessment of selected elements
- Document review
- Activities linked to accreditation in a new area
- Extraordinary visit
- Self-reporting/survey
- Participation in interlaboratory comparisons/proficiency testing
- Other activities
- Full review
- Observations

A full review is a visit that is just as comprehensive as a renewal and conducted in special cases.

4 ASSESSMENT

NA assesses the organisation's expertise according to accreditation requirements. NA uses follow-up and renewal visits to ensure that requirements are met over time. NA's assessors must assess whether the documentation/management system satisfies current requirements and whether the practice of the laboratory is in accordance with these requirements.

4.1 Scope of accreditation

Please see Conditions for accreditaiton.

4.2 Checklists (all types of assessment)

NA's document template must be used by TA when reviewing documentation.

4.3 Documentation from organisation

NA's project coordinator ensures that the assessor team obtains the required documentation from the organisation. See Conditions for accreditation. Review of documentation is used as a basis for planning the assessment.

4.4 Assessment preparation

The assessor team should clarify distribution of work and questions/problems, if applicable, in advance. The technical assessor (testing and calibration laboratories) sends proposals for demonstration of methods to the lead assessor (LA) two weeks prior to the assessment. The choice of focus areas is based on the criticality of the activity, results from previous assessments and when an accredited activity was last assessed. All accredited activities are assessed during an accreditation period.

Technical assessors may submit proposals, objections to agenda, clarifications etc.

4.5 Assessment

Assessment includes:

- Assessor meeting prior to assessment (if required).
- Opening meeting with members of the assessor team, organisation management and representatives from the organisation, if applicable.
- Assessment of the quality system, equipment, premises (if applicable) and work procedures as well as staff expertise.
- Internal meetings of the assessor team during the assessment to evaluate the progress of the assessment and to prepare for the final meeting.
- Final meeting with representatives of the organisation where any non-conformities are presented.

4.5.1 Conducting the assessment

The assessment shall be based on the accreditation requirements, relevant requirements from NA published on NA's website, relevant requirements from EA/ILAC/IAF, as well as any regulatory requirements. NA's assessors are expected to be familiar with the requirements, or to convey a need for information to NA.

All observations and conclusions must be objective. It must be possible to verify and test observations. Assessors must not propose solutions to non-conformities as this may threaten the impartiality of NA. Assessors must not act as consultants as this may also threaten the impartiality of NA. NA's assessment is based on random sampling. It will never be possible to assess all registrations in their entirety, and the selection of registrations that are requested must be based on an assessment of the risk of the outcome of the accredited activity and violation of the accreditation requirements.

Each assessor is responsible for assessing all available information before conclusions are drawn and observations are written down. Assessors must always be objective, friendly and open to accepting new solutions to problems as long as the accreditation requirements are met.

If it becomes clear during a visit that the system has not been implemented or that other serious defects exist which will make the visit pointless, the assessment may be discontinued. The organisation must be informed of the reason for this decision. See also NA's Condition for accreditation.

If areas that do not conform to requirements (non-conformities) are discovered, this should be communicated to the representative of the accredited organisation on an on-going basis.

4.5.2 Non-conformity reports

See Conditions for accreditation ([]D00072).[]

The non-conformity report should only contain factual descriptions of conditions related to the non-conformity with a specific paragraph in the accreditation standard, other applicable requirements or non-conformity with the organisation's own procedures.

All applicable points in the non-conformity report must be completed.
It is the responsibility of the lead assessor, with the support of the assessor team, to collect all identified non-conformities prior to the final meeting.

4.5.3 Final meeting with representatives of the organisation

The purpose of the final meeting is to sum up the results of the assessment for representatives of the organisation and to clarify any misunderstandings. The organisation can ask questions, but discussion about actual conditions is not desirable at the final meeting. Each assessor must make a brief presentation of his findings. The organisation is provided with a written list of recorded non-conformities.

4.6 Reporting after the assessment

Technical assessors must write their own reports after the assessment visit and send them to lead assessor for approval no later than three working days after the assessment. The report shall provide a basis for decisions, most often reasons for maintaining, expanding or renewing accreditation, and less often reasons for suspending or withdrawing accreditation. The reports are expected to provide a sufficiently documented basis for personnel who were not involved in the assessment activity. The organisation has the opportunity to point out any errors in the report.

4.7 Correction of non-conformities (all assessments)

The organisation must submit documentation that shows that every non-conformity in the category of very serious or serious has undergone a satisfactory root cause analysis and has been satisfactorily remedied prior to the set deadline.
The TA assesses the documentation of corrective action and gives the reasons for his/her recommendations as to whether the non-conformity should be closed. The reasons must refer to the submitted root cause analysis and corrective action.

4.8 Surveillance, extension, renewal

4.8.1 Surveillance

The purpose of surveillance is to determine whether an organisation meets the accreditation requirements. During the first accreditation period (five years), ordinary surveillance visits should normally be conducted every year within 12 months of the previous visit. All elements in the accreditation standard must be assessed during the accreditation period. Lead assessor gives notice that specific areas are to be assessed if this is deemed necessary. At the end of the assessment, a non-conformity report and assessment reports are prepared.

The following elements are assessed during all surveillance visits

Technical assessor/expert (laboratory):

- Training and approval of new staff
- Maintenance of expertise, testing experience
- Measurement uncertainty
- Equipment maintenance
- Measurement traceability
- Quality assurance of results (verification cards)
- Test reports and calibration certificates
- Vertical audit
- Impartiality
- Follow-up on non-conformities from previous visit

Technical assessor/expert (inspection, certification, technical checks and verification):
Elements to be assessed – see tasks under p. 5.2

4.8.2 Extension

When application is made for an extension to the scope of accreditation, an assessment will be made during a visit as to whether the accreditation conditions for the extension have been satisfied. Such a visit will often coincide with the ordinary surveillance visit.

The organisation can apply for an extension during the entire accreditation period, and in some cases, it will not be appropriate to wait until a surveillance/renewal visit. The extension can be assessed in the form of a document review, and the technical assessor will then assess the relevant submitted documentation, write an assessment report and register any non-conformities. Assessment reports from document reviews are not as comprehensive as reports from on-site visits, but all relevant required elements must be reviewed and described in the report. Non-conformities recorded in the document review are handled in the same way as non-conformities recorded during surveillance/renewal visits.

4.8.3 Renewal and full review

Upon renewal and complete review, assessment is performed as for a first-time accreditation and is reported in the same way as other assessments.

5 QUESTIONS

5.1 Prior to assessment or observation

Laboratories

- Review technical procedures.
- Assess uncertainty estimates/budgets in connection with individual methods, and the use of these in connection with the presentation of results.
- Review and evaluate five-year plan and results from participation in interlaboratory comparison/proficiency testing programme.
- Assess the laboratory's system for achieving traceability of measurement results.
- Assess the laboratory's use of internal and external quality controls.
- Assess the expertise of technical staff with regard to training, maintenance and development.
- Give feedback to LA if defects of decisive importance are discovered in the documentation that the laboratory must correct before the assessment.
- Notify LA well in advance of the assessment, no later than two weeks, about the tests/calibrations that are to be demonstrated during the assessment.

Inspection, certification, technical checks and verification:

- Review technical procedures and standards within the technical area.
- Assess whether the skills/skills requirements and the technical content of the procedures are satisfactory.
- Assess whether the product standards/normative documents against which certified products are to be measured are sufficiently specific - see IAF GD 5
- Assess whether the product standards/normative documents or other inspection methods or procedures by which the inspection is to be performed are adequate.
- Assess examination papers and answers.

5.2 During assessment or observation

Laboratories

- Assess the technical expertise of staff
- Assess the suitability of the equipment for its intended use, calibration and maintenance status and labelling of the equipment. Check that all equipment is satisfactorily recorded in the equipment register.
- Assess the appropriateness of the laboratory premises for the calibration/testing for which accreditation has been applied/granted. Check that the required environmental parameters are recorded, and that the laboratory has a system in place for monitoring the results of such measurements.
- Observe whether calibration/testing takes place according to the described procedures.
- Assess the laboratory's use of internal and external quality controls.
- Assess the traceability of the individual methods, use of calibration and/or certified reference material and/or other.

Inspection, certification, technical checks and verification:

- Assess defined skills requirements
- Assess the expertise of staff involved in certification activities (CVs, training, approval/authorisation, monitoring of staff)

- Assess routines to ensure impartiality
- Assess process requirements from application to issued certificate – vertical audit
- Assess examination papers and answers, coverage matrices for examination paper bank (PERS)
- Follow-up on comments and corrective actions for non-conformities provided on previous visits (if applicable)

Reference is also made to Procedure A19 Cert p. 4.3. regarding tasks and execution of observations.

5.3 After assessment or observation

- Write a report and send to the lead assessor within three working days of the visit unless otherwise agreed. The report must contain references to all non-conformities.
- After observing the certification body's audit work in a specific company, a report must be prepared.
- Assess the received documentation for corrective action and send the assessment to the lead assessor normally within three days of receipt of documentation.
- LA: Inform the organisation of the result of the assessments normally within one week of receipt of documentation: Where applicable, set a deadline for the next round.

6 REFERENCES

D00072 Conditions for accreditation