Conditions for accreditation
Categories: All

1 Purpose

This document describes the terms for organizations that are accredited or are applying for accreditation. This document is valid from 25.04.2016. In this English version, the Norwegian word “presented” was translated into “submitted” in chapter 24.2. nr.7. This was corrected on 25.11.2016.

2 Table of contents

3 Introduction

Norwegian Accreditation (NA) is the national body for technical accreditation in Norway, and was created by The Royal Decree of 7 June 1991 (on the basis of Storting Proposition no.106 1989/90). NA is a government agency organized under the Ministry of Trade, Industry, and Fisheries (NFD). Accreditations are granted according to the Norwegian Act "Lov om det frie varebytte i EØS (EØS-vareloven)".

NA is given the authority to accredit the following types of activities:

- Calibration laboratories
- Testing laboratories (including medical laboratories)
- Inspection bodies
- Certification bodies
- Verification bodies for EU-ETS
- EMAS environmental verifiers
- Proficiency testing providers

NAs authority was extended by The Royal Decree of 7 October 1993 to include accreditation for OECD's Principles of Good Laboratory Practice (GLP). This type of accreditation is not covered by this document.

Accreditation comprises assessment of competence and may be granted to organizations that satisfy the requirements that apply to a certain type of activity, and is given for specified activities. NA maintains an up-to-date register of the activities covered by each individual accreditation. This register is available at www.akkreditert.no. Compliance with Norwegian legislation is assessed when it is necessary to determine whether an organization works in conformance with the terms of accreditation. It is the organization's responsibility to secure other licenses or authorizations necessary to conduct their activities. Accreditation does not replace such permissions.

4 Contact information for Norwegian Accreditation:

Norwegian Accreditation (NA)
P.O. Box 155
Lillestrøm bedriftssenter
2001 Lillestrøm

Telephone: +47 64 84 86 00

Visiting address: Skedsmogata 5, 2000 Lillestrøm

Internet address: www.akkreditert.no. The website has contact information for all employees at NA.

5 Obligation to fulfill the terms of accreditation

Accredited organizations shall comply with the current terms of accreditation at all times. It is the accredited organization's responsibility to stay informed about changes to the terms of accreditation.

Accredited organizations must conform to new terms or changes to existing terms within the deadlines stipulated by NA. Information about such changes are published on www.akkreditert.no within a reasonable time before they take effect.

6 Obligation to follow national laws and regulations

All accredited organizations are obligated to follow national laws and regulations. Where there is conflict between national laws and regulations with requirements for accreditation, national laws and regulations are applicable.

The accreditation body can report violations of laws and regulations to the appropriate authorities.

7 Requirements for accreditation

The requirements imposed by accreditation are defined in current versions of international standards for each type of activity (see the table below). In addition, there are mandatory documents published by the European cooperation for Accreditation – European Accreditation (EA) and the equivalent international cooperation for accreditation bodies International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF). These mandatory documents are specified in the sections pertaining to each type of accreditation. Furthermore, accredited organizations shall comply with any other requirements established by NA and that are defined or referred to within this document.

Accreditation standard	Title	Type of conformity assessment
NS-EN ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories	Testing and calibration
NS-EN ISO 15189	Medical laboratories – Requirements for quality and competence	Medical analyses
NS-EN ISO 22870 in combination with NS-EN ISO 15189	Point-of-care testing (POCT) – Requirements for quality and competence	Medical analyses
*NS-EN ISO/IEC 17043	Conformity assessment – General requirements for proficiency testing	Arrangement of proficiency testing / interlaboratory comparisons
NS-EN ISO/IEC 17020	Conformity assessment – Requirements for the operation of various types of bodies performing inspection	Inspection
NS-EN ISO/IEC 17021 ISO/IEC 17021-1	Conformity assessment – Requirements for bodies providing audit and certification of management systems (valid until 15.06.2017) Replaces NS-EN ISO/IEC 17021	Certification of management systems
NS-EN ISO/IEC 17024	Conformity assessment – General requirements for bodies operating certification of persons	Certification of persons
NS-EN ISO/IEC 17065	Conformity assessment – Requirements for bodies certifying products, processes and services	Certification of products, processes and services
NS-EN ISO 14065 EU Commission Regulation (EU) 600/2012	Greenhouse gases – Requirements for greenhouse gas validation and verification bodies for use in accreditation or other forms of recognition COMMISSION REGULATION (EU) No 600/2012 of 21 June 2012 on the verification of greenhouse gas emission reports and tonne-kilometre reports and the accreditation of verifiers pursuant to Directive 2003/87/EC of the European Parliament and of the Council	Verification of emission of greenhouse gases into the air EU ETS

Accreditation standard	Title	Type of conformity assessment
Pollution Control Act §52c	Act of 13 March 1981 No.6 Concerning Protection Against Pollution and Concerning Waste (Pollution Control Act)	Environmental verification
EU Regulation (EC) NO 1221/2009	REGULATION (EC) No 1221/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 November 2009 on the voluntary participation by organizations in a Community eco-management and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC	

*Is not currently covered by EA's multilateral agreement on mutual recognition of accreditation.

The following are mandatory for all organizations that are, or are applying for, accreditation from Norwegian Accreditation:

- Terms for use of Norwegian Accreditation's logo in accreditation marks and for references to accreditation and Good Laboratory Practice (GLP) (D00067)
- The Norwegian Regulation for Accreditation Fees (FOR-2013-07-01-821)

8 Guidance for accreditation requirements and the accreditation process

NA informs about the process that shall be followed for application to be accredited and how assessments are conducted (cf. Act of 10 February 1967 Relating to Procedure in Cases Concerning the Public Administration [Public Administration Act] §11, first and second paragraphs). When there is a need, there will be given an explanation of the requirements for accreditation for each type of activity.

The European Cooperation for Accreditation (EA), International Cooperation for Laboratory Accreditation (ILAC) and International Accreditation Forum (IAF) have published guidance documents that are recommended for use. For EMAS III and EU ETS, there are guides published by the EU. References to these guides are available at www.akkreditert.no. Where such guidance documents are published, organizations can fulfill the requirements for accreditation by either following the guides or by documenting that the requirements are maintained in an equal or better manner.

NA arranges information meetings and courses where the requirements and process for accreditation and assessment are explained. Information is also provided in the document «Information for organizations applying for accreditation» (NA Doc 4).

9 Disclosure of information requirements regarding changes

Accredited organizations shall inform NA about changes that can have significant impact on how the organization fulfills the necessary requirements and other terms and conditions associated with accreditation. If possible, such information should be disclosed to NA before the changes take effect.

Significant changes may include:

- Changes in ownership (legal entity), name, email address, visiting or mailing address, telephone number
- Organizational changes such as administrative and technical management (including personnel responsible for specific technical disciplines), quality manager, personnel responsible for validation or technical opinions
- Changes in the management system if they may affect compliance with the terms and conditions of accreditation
- Significant changes is national and international standards used for testing, calibrations, certifying, or inspection; or other significant changes in methods (note special rules for organizations with flexible accreditation scope)
- Restrictions on the scope of accreditation, including failure to maintain sufficient expertise for each individual accredited activity
- Changes in location where critical activities are performed (cf. ILAC /IAF A5 «IAF/ILAC Multi-Lateral Mutual Recognition Arrangement (Arrangements): Application of ISO/IEC 17011») as described in various sections of this document
- Changes in calibration, testing, and inspection facilities. This may include equipment, laboratory environment, and other resources.
- Other significant changes.

When moving accredited activities to a new location, necessary plans and documentation showing the suitability of the new location must be sent to NA in advance and approved before accredited results can once again be reported. NA evaluates each case individually whether it is necessary for an on-site assessment of conformity with accreditation requirements and terms or if it is sufficient with submission of documentation for the planned changes.

10 Fees and costs

Costs related to NA's services are billed to the accredited organization or applicant in accordance with the Norwegian Regulation for Accreditation Fees (FOR-2013-07-01-821).

11 Facilitation and preparation for assessment

Organizations are obligated to facilitate and cooperate to provide a constructive environment for effective assessment visits. This applies to both assessment at the accredited organization's premises and for observation of the accredited organization's activities at their customer's premises. This shall be made clear in agreements between the accredited organization and its customers.

Applicants and accredited organizations are obligated to provide NA access to premises and documentation pertaining to operation of the accredited legal entity and which are necessary to assess if the organization fulfills the terms for accreditation. Access to said premises and documentation shall apply for NA's employees as well for assessors and experts that are contracted by NA and are accepted by the accredited organization. Such access may also include associated entities that are not part of the legal entity that is accredited if NA determines this is necessary.

An organization's key personnel shall be made available to NA's assessors during an assessment visit unless otherwise agreed upon with NA's lead assessor. A representative from the organization's management shall be present for the assessment visit's closing meeting where the assessors' conclusions are reviewed and any nonconformities presented.

12 Requirements for accredited certificates and reports

Accredited certificates and reports issued by accredited organizations shall satisfy the requirements set for such documents in relevant accreditation standards. To be recognized as accredited, certificates and reports must also include the following:

- Name and address of the accredited organization
- The organization's accreditation mark, including the accreditation number (a reference to the organization's accreditation with NA)

An accredited certificate issued by an accredited certification body shall only describe conformity with the requirements of the standards or normative documents that the body is accredited for.

An accredited calibration certificate, test report, or inspection report shall contain accredited results. They can also include results from activities that the organization is not accredited for. In such cases it shall be clearly indicated which activities are accredited and which are not accredited.

13 Duration of accreditation

An accreditation is valid for five years from the date of the Grant of Accreditation or re-assessment of accreditation. This is provided that the organization satisfies the requirements and terms that apply for the relevant accreditation. All nonconformities found during an initial assessment (including extensions of the scope of accreditation), surveillance activities, and re-assessment must be satisfactorily corrected before accreditation can be granted, maintained, or renewed.

Accreditations that have expired are no longer valid. The accreditation period of five years cannot be extended.

14 Assessment, surveillance and renewal of accreditation

An accreditation is subject to surveillance throughout the accreditation period. In the first accreditation period, NA conducts annual surveillance assessments approximately 12 months between each visit. Surveillance visits are normally less extensive compared to initial assessments and re-assessments. Re-assessments shall be carried out approximately six months before the end of the accreditation period so that the organization has reasonable time to correct any nonconformities before the accreditation expires.

Following a re-assessment visit, NA establishes surveillance plans for each individual accreditation. This takes into account experiences from the previous accreditation period, the organization's ability to implement satisfactory corrective actions within stipulated deadlines, and the complexity and dynamics of the scope of accreditation. It shall not go longer than 18 months between consecutive assessment visits. If deemed necessary, NA may require extraordinary assessments in addition to planned surveillance and re-assessments.

For assessments of organizations that have more than one critical location where accredited activities are carried out, the main office shall be assessed at all assessments. New sites shall be assessed before they can be taken into the scope of accreditation and assessed at least once in the course of an accreditation period. This is in accordance with the requirements for accreditation bodies issued by ILAC and IAF and described in the document "IAF-ILAC A5".

The entire scope of accreditation shall be assessed at least once in the course of an accreditation period.

NA conducts observations of accredited certifications and inspections. This means that NA's assessors observe the certification/inspection body's personnel while they perform their work at a customer. Corresponding observations are conducted for laboratories where accredited services are performed externally at a customer.

NA may conduct unannounced assessments if there is suspicion of serious violations of the terms of accreditation.

15 Nonconformities with the requirements and terms for accreditation

Nonconformities are issued if NA's assessors identify conditions that do not conform with the requirements and terms for each type of accreditation. Nonconformities are categorized as "minor", "significant", or "very serious" in accordance with the severity that NA's assessors consider the nonconformity to be. All nonconformities must be satisfactorily corrected before accreditation can be granted, maintained, or renewed.

If necessary after an assessment, NA will explain/elaborate on each nonconformity and why they were issued, i.e. what is the specific reason for nonconformity with the stipulated requirement. However, NA's assessors cannot recommend how organizations implement corrective actions for nonconformities. Implementation of corrective actions is part of the competence that accredited organizations shall hold and be assessed by NA's assessors.

NA sets deadlines for implementation of corrective actions for nonconformities. Completion of root cause analysis and satisfactory correction of nonconformities must be documented. For very serious nonconformities, NA may require organizations to withdraw accredited calibration certificates, test reports, certificates, licenses, verification rapports, or inspection reports (cf. The Norwegian Act "Lov om det frie varebytte i EØS" [EU Regulation no. 765/2008] Chapter II article 5 no. 4, ref. paragraph 17 on sanctions)

If necessary, NA may conduct extraordinary assessment visits or observations to assess if implemented corrective actions are effective and work as intended in order to determine if a nonconformity has been satisfactorily corrected.

Corrective actions shall be accepted by NA before accreditation is granted/maintained/renewed. This is done by closing nonconformities. The following deadlines apply for the submission of documentation of corrective actions:

- Initial assessment: normally 12 weeks
- Surveillance visit: normally 6 weeks
- Renewal assessment: normally 6 weeks
- Extension of scope: normally 12 weeks
- Shorter deadline for very serious nonconformities (normally 2 weeks).

If the conditions underlying the establishment of a nonconformity are not considered to be corrected or the root cause analysis is not deemed to be satisfactory by submitted documentation, NA's assessors will request new documentation of revised corrective actions / root cause analysis. If a nonconformity is not considered to be satisfactorily corrected after the third submission of documentation, the accreditation normally will be wholly or partially suspended until the pertinent conditions are adequately corrected, see section 17 about sanctions.

16 Documentation for Norwegian Accreditation's assessors

16.1 Deadlines for disclosure of documentation

Documentation shall be made available for NA's assessors within a reasonable time before an assessment visit and/or observation. This means that the documentation and applications shall be sent to NA (as attachments in e-mail, memory stick, on paper, etc.), or in another suitable manner be made available for assessors (e.g. by access to the organization's management system via internet). In order that assessors shall have enough time to prepare for assessments and observations, there are established deadlines for disclosure of documentation to the assessors. These deadlines are:

- Initial assessment: no later than 8 weeks before the date of assessment
- Surveillance visit: no later than 4 weeks before the date of assessment
- Renewal assessment: no later than 4 weeks before the date of assessment
- Extension of scope: no later than 8 weeks before the date of assessment
- Plans for audits that certification bodies and verification bodies shall perform in the coming year within the scope of accreditation shall be sent to NA by November 1 (for the first half of the year) and May 1 (for the second half of the year).
- Upon request by NA, inspection bodies shall send an overview of planned inspections.

16.2 Documentation for lead assessors

Lead assessors shall at a minimum be given access to:

- The management system with relevant procedures and documentation
- Completed compliance list / checklist for the relevant accreditation standard/requirements
- Overview of documents and forms that comprise the management system
- Documented competence in relation to competence criteria, such as CV
- Audit program and reports from the previous year's internal audits
- Report from the management review
- Information about changes since the last visit, e.g. organization, personnel, locales/facilities, equipment/instruments
- For laboratories: completed application for the scope of accreditation
- Certification bodies shall submit an overview of planned certification activities within the deadlines described in section 24
- For certification bodies and verification bodies: competence criteria for each scheme
- For verification bodies: see specific terms in section 27

16.3 Documents for technical assessors and technical experts

Technical assessors and experts shall at a minimum have access to:

- Relevant sections of the management system with technical procedures and documentation (including completed compliance list / checklist for the applicable accreditation standard/requirements)
- Overview of documents and forms in the management system
- Description of relevant education and work experience (CV) for key personnel
- Information about changes since the last assessment visit
- An overview of relevant methods/instruments, when applicable
- For laboratories: an overview of participation in interlaboratory comparisons and reports from validation/verification of methods
- For certification and verification bodies: competence criteria for each scheme
- For inspection bodies: Upon request, an overview of accredited inspection reports issued since the previous assessment by NA

17 Archiving

The various accreditation standards require that different types of documentation are stored for a suitable period of time. Archiving of such documentation shall be adapted to the accredited organization's needs, as well as NA's needs for assessment of accredited activities since the last assessment visit. Storage of documentation shall be a minimum of three years, unless national legislation requires other time periods.

An organization's management system shall include a description of how long different types of documentation shall be stored.

18 Management of extraordinary events or circumstances

When extraordinary events occur (e.g. bankruptcy), the current version of the document "IAF ID 3 Informative Document for Management of Extraordinary Events or Circumstances Affecting Abs, CABs and Certified Organizations" shall be a guideline for handling of the situation. See www.iaf.nu for a link to the document.

19 Terms for transfer of accreditation

An accreditation may on application be transferred to another organization. In such cases, the following documentation must be sent to NA:

- Confirmation that the new/other organization will comply with the requirements and terms that apply for the type of accreditation
- Explanation of any measures taken so that the transfer will not mislead the market, if applicable
- Confirmation that the new/other organization will attend its obligations to customers and NA
- Confirmation that the transfer will not conflict with Norwegian law

Applications for transfer of an accreditation shall document compliance with the requirements/terms of accreditation. The application must be submitted within a reasonable amount of time for NA to evaluate and verify compliance with the applicable requirements/terms and accept the transfer of accreditation before the desired date of transfer. NA will determine if it is necessary to have an assessment of the new/other organization or if the transfer may be granted on the basis of submitted documentation.

20 Resignation and termination of accreditation

Accredited organizations may voluntarily resign their accreditation (wholly or partially) without cause with two months' written notice. NA may allow a shorter notice if deemed prudent. NA has the right to take measures to verify the accredited services rendered since the previous surveillance of the accreditation in question. Accrued expenses shall be covered in accordance with the Norwegian Regulation for Accreditation Fees (FOR-2013-07-01-821).

If an accredited organization is dissolved or declared bankrupt, the accreditation will be terminated immediately.

Changes in international accreditation standards and requirements may affect an individual organization's ability to be accredited. When this type of situation occurs, NA shall notify the accredited organization. Together with the organization and interested parties, NA shall discuss possibilities for continued accreditation. In addition, see section 14.

21 Sanctions for failure to comply with the terms of accreditation

21.1 Conditions that may lead to sanctions

NA may impose sanctions if the accredited legal entity no longer satisfies the terms for accreditation (cf. the Norwegian Act "EØS-vareloven" [Regulation No. 765/2008] Article 5 No. 4). The European and international cooperation for accreditation require that accreditation bodies impose sanctions in situations where an accredited legal entity does not operate in compliance with the requirements and terms that pertain to the applicable type of accreditation (cf. IAF MD 7 «Harmonization of sanctions»). Conditions that may lead to sanctions are:

- Failure to comply with the requirements of the applicable accreditation and/or other terms as they are described or referred to in this document).
- Failure to pay for NA's services (cf. The Norwegian Regulation for Accreditation Fees [FOR-2013-07-01-821])
- Misuse of accreditation and the accreditation mark (cf. Terms for use of Norwegian Accreditation's logo in accreditation marks and for references to accreditation and Good Laboratory Practice [GLP]).
- Inability or unwillingness to perform root cause analyses, initiate corrective actions and implement the necessary measures within the stipulated period of time (ref. section 14 of this document)
- Certification bodies use an accreditation standard for certification (accreditation standards are specified in section 3 of this document)
- Failure to comply with relevant national laws and regulations and/or EU directives and regulations applicable as requirements for the relevant type of accreditation
- Specific for verification bodies that are accredited for the EU-ETS scheme: If a member of the verification body's top management is found guilty of fraud, NA is obligated to terminate the accreditation. (cf. COMMISSION REGULATION (EU) No. 600/2012 for EU-ETS, Chapter IV Article 53 Section 3b).

21.2 Applicable types of sanctions

Applicable types of sanctions and/or actions are:

1. Imposition of correction of nonconformities and implementation of specified corrective actions within the given deadline
2. Intensified surveillance (including extraordinary visits and other actions deemed necessary)
3. Suspension of all or part of an accreditation
4. Termination of all or part of an accreditation
5. Legal actions

What type of sanction implemented will depend upon the severity of the situation, the organization's ability and willingness to investigate the circumstances and provide requested information in order to correct the situation, the organization's compliance with given deadlines, and whether or not it is a reoccurring situation. Normally, actions 1 and 2 above will be implemented before an accreditation is suspended. Correspondingly, action 3 will normally be implemented before an accreditation is terminated.

21.3 Suspension and the effect of suspension

Suspension is a decision for temporary withdrawal of an accreditation. The withdrawal may be for part or all of the accredited scope. An accredited organization may request voluntary suspension if it determines that it does not satisfy one or more of the requirements and terms for the applicable type of accreditation.

Before a decision on suspension is made, the interested organization will be informed and given a reasonable amount of time to comment and provide information that can clear up the identified situation. Notification of the decision shall normally be given in writing. For very serious nonconformities with the terms and requirements for the applicable type of accreditation, the lead assessor can initiate immediate suspension (cf. the Norwegian Act "EØS-vareloven" [Regulation No. 765/2008] Article 5 No. 4.) Note: for the EMAS scheme, immediate suspension is not possible (cf. Regulation [EC] No. 1221/2009 [EMAS III]).

A decision on suspension will be valid until the organization has corrected the conditions that formed the basis for the suspension and NA has performed the necessary actions to investigate if the organization now complies with the applicable terms and requirements. Which actions NA takes in connection with such investigations depend upon the type of offense and how long the suspension has been effective. A suspension is effective for a maximum of three months, with an option to extend for up to one year. Such extensions require an application from the suspended organization.

If corrective actions or other measures are not implemented in a satisfactory manner within the time limit set for the suspension (maximum one year), NA will terminate the accreditation.

Upon suspension of all or part of an accreditation, the accredited organization cannot offer or perform accredited services for the suspended activities. Accredited calibration certificates, test reports, inspection reports, verification reports or certificates within the areas covered by the suspension cannot be issued. New agreements cannot be entered into for certifications, inspections, or verifications. Affected customers shall be informed that the accreditation is suspended and what this entails for them.

Fees paid will not be refunded upon suspension (cf. The Norwegian Regulation for Accreditation Fees (FOR-2013-07-01-821). Annual fees must be paid as normal during the period of suspension (cf. § 2, third paragraph of the Regulation for Accreditation Fees). Accredited organizations are obligated to pay for all costs incurred.

Specific to accreditation of verification bodies for verification of emissions under the EU-ETS scheme (EU Regulation 600/2012 and ISO 14065): In cases where NA suspends all or part of such an accreditation, NA will inform the competent authority in the country that the verification body operates. The competent authority in Norway is the Norwegian Environment Agency. When the suspension is lifted, the same authorities shall be informed.

Specific for the EMAS scheme (Regulation [EC] No. 1221/2009 and Pollution Control Act §52c – EMAS III): In cases where NA suspends all or part of such an accreditation, NA will inform the licensing authority and competent authority. In Norway, these authorities are the Brønnøysund Register Center and Norwegian Environment Agency. When the suspension is lifted, the same authorities shall be informed.

21.4 Termination and the effect of termination

NA may decide upon termination of all or part of an accreditation if an organization does not want or is not able to correct the conditions that led to the suspension of the accreditation within the deadlines described in section 20.3. Furthermore, NA may decide upon termination of accreditation without prior suspension, complete or partial, if serious violations of compliance with the terms and requirements of the applicable type of accreditation are discovered. This may include conditions that NA perceives to make the organization unqualified to perform accredited services. An accredited organization may also terminate all or part of its accreditation. Such notifications of termination shall be done in writing.

Before a decision on termination is made, the interested organization will be informed and given a reasonable amount of time to comment and provide information that can clear up the identified situation. Notification of the decision for termination shall normally be given in writing.

Upon termination of an accreditation, an organization can no longer offer or perform accredited services for the accreditation (or part of accreditation) that has been terminated. The organization shall inform their customers in writing that the accreditation is terminated and what the consequences of the termination are.

An accreditation that is terminated in its entirety cannot be reinstated. If an organization wishes to be accredited again at a later time, accreditation must be reapplied for. Upon grant of a new accreditation, the organization will be assigned a new accreditation number.

Specific to certification bodies: all issued certificates with NA's accreditation mark or other references to accreditation from NA covered by the termination shall be recalled and destroyed. Confirmation of this along with a copy of the pertinent information shall be sent to Norwegian Accreditation.

NA normally stipulates a transitional period so that the certification body's customers may have an opportunity to find another certification body and continue to have valid accredited certification. Transfer of accredited certificates from one system certification body to another must happen in agreement with NA. In such cases, there are guidelines published in the document «IAF MD 2 Transfer of Accredited Certification of Management Systems». This document is available at www.iaf.nu.

Upon termination of an accredited certification body, the certification body is obligated to inform its customers about the termination and that they should contact another certification body (cf. IAF ID 3 Informative Document for Management of Extraordinary Events or Circumstances Affecting ABs, CABs and Certified Organizations»). This document is available at www.iaf.nu.

Specific to accreditation of verification bodies for verification of emissions under the EU-ETS scheme (EU Regulation 600/2012 and ISO 14065): In cases where NA terminates all or part of such an accreditation, NA will inform the competent authority in the country that the verification body operates. The competent authority in Norway is the Norwegian Environment Agency.

Specific for the EMAS scheme (Regulation [EC] No. 1221/2009 and Pollution Control Act §52c – EMAS III): In cases where NA terminates all or part of such an accreditation, NA will inform the licensing authority and competent authority. In Norway, these authorities are the Brønnøysund Register Center and Norwegian Environment Agency.

22 Rules for case management in Norwegian Accreditation

22.1 General rules for case management

The Act Relating to Procedure in Cases Concerning the Public Administration (Public Administration Act) and The Act Relating to the Right of Access to Documents Held by Public Authorities and Public Undertakings (Freedom of Information Act) generally apply to NA's operations, with certain exceptions for handling of complaints against decisions on accreditation (see section 22.2). This means that NA's operations are subject to the rules of public administrative procedures and transparency as required by law, with regulations.

NA's case management is further regulated by special rules in the Norwegian Act "EØS-vareloven". Amongst other things, these rules state that the national accreditation body shall have appropriate arrangements in order to secure confidential information it receives. Additional requirements include working in conformance with the international standard for accreditation bodies (ISO/IEC 17011) and the European and international agreements established by European Accreditation (EA), International Laboratory Accreditation Cooperation (ILAC), and International Accreditation Forum (IAF).

NA's case documents are generally open to the public. Requests for access to documents in cases where one is not an interested party is regulated by The Freedom of Information Act. Interested parties to a case are entitled to access (cf. Public Administration Act §18).

As a government agency, NA has the authority to restrict access to information according to existing legislative regulations. In the interests of whom the information concerns, NA is bound to confidentiality regarding personal matters, technical information and procedures, and operational or business information that is classified as important for competitive reasons (cf. Public Administration Act §13).

This includes information provided in documentation prepared by applicants and accredited organizations as a basis for accreditation, reports from NA's assessments, nonconformities registered during assessments at individual organizations, and other information that may be exempt from anyone other than the interested parties.

Decisions on accreditation are made by Norwegian Accreditation's personnel delegated this authority for a specific technical discipline or a specific type of accreditation. Decisions about accreditation are individual decisions. In accordance with chapter two of The Public Administration Act, regarding impartiality, decisions on accreditation will be made by another authorized person if the responsible person is considered to be biased in a case within their area of responsibility.

22.2 Complaints about decisions regarding accreditation

Complaints can be made against decisions on accreditation, renewal of accreditation, suspension of accreditation, termination of accreditation, extensions of accreditation scope, and reductions of accreditation scope by interested parties in a case or by others with legal interests in a case pursuant to The Public Administration Act §28 and the Norwegian Act "EØS-vareloven" §3. Such complaints shall be sent to NA and must be sent within three weeks from the day that the decision was received by the party making the complaint. The complaint shall state what decision it is made against or the desired changes in the decision, and the reasons cited for the complaint. The complaint shall be signed by the party making the complaint or an authorized representative of the legal entity making the complaint. The party making the complaint has the right to acquaint themselves with the case's documents.

If the decision is not changed after the complaint process is handled by NA, the complaint and accompanying documentation and information can be sent to NA's Appeals Committee. The Appeals Committee's recommendation is submitted to NA's Director for a final decision.

Other types of decisions may be complained against pursuant to The Public Administration Act, Chapter VI.

22.3 Complaints regarding other aspects of Norwegian Accreditation's services

Complaints regarding other aspects of accreditation may be sent to NA. Such complaints could be: delayed processing of applications for accreditation, costs and fees of accreditation, and work performed by accredited organizations.

23 Limitation of liability for Norwegian Accreditation

NA is not responsible for accredited organizations' obligations to their customers.

24 Specific requirements for testing, calibration, and medical laboratories

24.1 Specific requirements for laboratories

In addition to the terms set out in this document and accreditation standards ISO/IEC 17025 and ISO 15189, the following documents apply for accreditation of laboratories:

NA Doc 26a	Requirements for calibration and control of balances in accredited testing laboratories
NA Doc 26b	Traceability requirements of the temperature measurement for accredited laboratories
NA Doc 26c	Requirements for calibration and control of volumetric equipment for accredited testing laboratories
NA Doc 50	Flexible scope for testing laboratories
~~NA Doc 52~~	~~Angivelse av måleusikkerhet ved kalibreringer (Norwegian translation of EA-4/02)~~ (Withdrawn as of 01/01/2017 and is replaced by EA-4/02 and ILAC P14)
ILAC-P9	ILAC Policy for Participation in Proficiency Testing Activities
ILAC-P10	ILAC Policy on Traceability of Measurement Results
ILAC-P14	ILAC Policy for Uncertainty in Calibration
EA-4/02	Evaluation of the Uncertainty of Measurement In Calibration

When standard methods are revised, NA shall change the affected scope of accreditation within six months of publication. The change is handled in the same manner as other changes in the scope of accreditation. Information about the extent of changes in the standard and how these are to be implemented in each individual laboratory shall be sent to NA.

24.2 Specification of requirements for participation in interlaboratory comparisons (PT)

Specification of requirements for participation in interlaboratory comparisons (PT), as defined in «ILAC P9 ILAC Policy for Participation in Proficiency Testing Activities»:

1. The accreditation standards ISO/IEC 17025 and ISO 15189 indicate that participation in PT is a way to verify the competence and validity of test results. NA views participation in such activities as key for demonstration of competence and maintenance of competence in laboratories.
2. Where programs for such comparisons are available and appropriate, laboratories shall at a minimum participate in the comparison with satisfactory results before accreditation will be granted.
3. Accredited laboratories shall prepare plans for participation in interlaboratory comparisons that cover the entire period of accreditation.
4. The plans shall meet the need for participation in each discipline / parameter / type of testing / calibration object to document the quality of the laboratory's services. Risk analyses undertaken for calibrations/testing must be taken into account when making the plans.
5. When unsatisfactory results in PT occur, it is the laboratory's responsibility to implement appropriate corrective actions and confirm that the calibrations/tests are satisfactory. If a laboratory is unable to rectify the conditions that led to unsatisfactory results within a reasonable amount of time, NA shall be notified in writing with reference to the applicable testing/calibration.
6. NA evaluates plans for participation and the results achieved from PT in connection with assessments for each laboratory.
7. The scope and frequency for participation, results, and management of the results shall be presented to NA for assessment.
8. Where there has arisen doubts about the quality of the tests/calibrations issued by an accredited laboratory, NA may require results from PT and/or other quality controls to be sent to NA for evaluation between assessment visits.
9. For individual disciplines, NA may require participation in specific PT programs if mandated by regulatory authorities, industry, trade associations, EA, or other interested parties. NA may set the requirement for minimum frequency of participation.

In cases where participation in PT is not possible/suitable, a laboratory must use one or more of the following methods, in order of priority, to ensure control over quality of the results:

- Regular use of certified reference materials
- Regular use of reference materials
- Self-initiated comparisons of tests/calibrations with other laboratories that perform similar tests/calibrations.
- Repeated testing/calibration using the same method or different methods.

24.3 Specification of requirements for metrological traceability

Specification of requirements for metrological traceability are defined in ISO/IEC 17025, ISO 15189, and ILAC P10 “ILAC Policy on Traceability of Measurement Results”.

24.3.1 Specific to calibration laboratories

Equipment used to perform accredited calibrations shall be calibrated by:

- A national metrology institute (NMI) that offers the appropriate calibration and is a signatory to CIPM’s MRA. An overview of services covered by CIPM’s MRA can be found in BIPM’s Key Comparison Database (KCDB) http://kcdb.bipm.org/.

Or

- A calibration laboratory that offers the appropriate service and is accredited by an accreditation body that is a signatory to ILAC’s MRA for accreditation of calibration laboratories or otherwise recognized by ILAC. This includes all accreditation bodies that are signatory to the corresponding regional multilateral agreements within EA, APLAC, AFRAC, ARAC and IAAC. Information about which accreditation bodies this applies to is available on ILAC’s website (http://ilac.org/).

Calibration laboratories that use calibrations as described above are considered to satisfy the requirements of metrological traceability given in ISO/IEC 17025.

If the calibration services listed above are not available, NA may accept the following documentation of calibration:

- A NMI offering services that are suitable for the purpose, but is not covered by CIPM’s MRA.

Or

- A calibration laboratory offering services suitable for the purpose, but is not accredited and therefore is not covered by ILAC’s MRA or otherwise recognized by ILAC.

In such cases and situations where traceability to SI units is not possible, the laboratory shall submit sufficient documentation for metrological traceability and uncertainty of measurement in calibration to NA. The documentation must show that the calibration meets the requirements of metrological traceability. This includes documentation of the uncertainty of measurement and the procedure for the calibration.

24.3.2 Specific to testing laboratories and medical laboratories

If an instrument used for accredited testing significantly contributes to the total uncertainty of the test, the requirements of metrological traceability for calibration laboratories is valid.

If an instrument has an insignificant contribution to the total uncertainty of the test, sufficient documentation of its evaluation shall be submitted to NA.

Provided that adequate technical expertise is available in the laboratory/organization, calibration of its own equipment can be performed by internal personnel. In such cases, the laboratory/organization must have detailed procedures for calibration. Measurement of uncertainty must be calculated according to “Evaluation of the Uncertainty of Measurement In Calibration” (EA-4/02 / ILAC-P14) as for calibration laboratories. Participation in interlaboratory comparisons is also required.

24.3.3 Metrological traceability via reference materials

Certified reference materials (CRM) and reference materials (RM) produced by accredited suppliers of such materials are considered to satisfy the requirements of metrological traceability. The same applies for RM with values included in JCTLM's database where:

- The values are determined by a NMI and included in BIPM KCDB
- Or the values are determined by a producer of RM that is accredited for these determinations.

CRM and RM produced by producers of reference materials that do not satisfy the above criteria are considered to be critical materials and services in the context of accreditation. When using such materials, the laboratory must document or otherwise demonstrate that each CRM or RM is suitable for the intended application, as required by ISO/IEC 17025 and ISO 15189.

24.4 Specification of requirements for calculation/estimation of the uncertainty of measurement in calibration and testing

Calibration laboratories shall calculate uncertainty for their calibrations in accordance with EA-4/02 and ILAC P14.

Testing laboratories and medical laboratories shall calculate/estimate uncertainty for their test results whenever this is possible. Uncertainty in testing is normally reported with the coverage factor k=2 / 95% confidence interval. Exceptions from this shall be mathematically proven / technically justified.

25 Specific requirements for certification bodies and environmental verifiers (EMAS)

25.1 General conditions

In addition to the terms set out in this document, accreditation standards, Norwegian law, and EU directives and regulations, there are extra terms and requirements valid for each of the various certification schemes.

Certification bodies shall plan their certification activities according to relevant EA and IAF MD documents.

As a part of the assessment of certification bodies, observations of the certification body's activities shall be conducted. For selection of observations, the following criteria are used:

- The organization's scope of accreditation
- The number of certificates issued by the organization
- The number of certificates outside of Norway
- The number of audit managers / resources that perform certification activities
- Results from previous observations
- The certification scheme's specific requirements

If the accredited body has certificates outside of Norway, observations can be conducted in the applicable countries regardless of critical locations. For certification bodies with locations performing key activities, the requirements in IAF/ILAC A5 are valid.

Certification bodies are obligated in their contracts with customers to allow NA the opportunity to conduct observations. NA shall be free to select desired observations.

Accredited certification bodies are obligated to maintain an updated list of their issued accredited certifications and EMAS approvals. This list shall also be made available to NA upon request.

In accordance with IAF MD 15, accredited certification bodies shall identify:

- Countries outside of Norway into which accredited certificates are issued and the number of certificates issued in each country
- Countries in which the certification body operates from a fixed office location that performs any certification activities
- Countries in which the certification body has remote personnel that perform any certification activities
- Which fixed office locations are responsible for performing and/or managing key activities as defined in IAF/ILAC A5, or from where remote personnel performing key activities are managed
- The certification organ's arrangements for managing all activities that are performed from a foreign fixed office location or by remote personnel.

25.2 Accreditation of management system certification bodies and environmental verifiers (EMAS)

Plans for audits within the scope of accreditation shall be submitted to NA by November 1 for the first half of the year and May 1 for the second half. The plans shall include which industry the customers belong to, audit personnel, scheduled time points, which standard is the basis for certification, and which geographical and administrative locations will be audited.

In accordance with IAF MD 15, accredited system certification bodies shall report the following by May 1:

- Number of accredited certificates valid at the end of December
- Number of auditors
- Number of transfers accepted
- Number of overdue audits
- Number of auditor-days delivered

EMAS verifiers shall inform NA at least four weeks before planned EMAS verifications.

Organizations accredited as a certification body for environmental management systems or environmental verifier shall notify NA if the certification body or environmental verifier has received a complaint or other critical remark from an environmental agency regarding an ISO 14001 certification or EMAS approval.

In addition to the requirements described in section 1 of this document, accredited environmental verifiers (EMAS) shall comply with the requirements in chapter five of EC Regulation 1221/2009 (EMAS III).

Certificates, issued by an organization which later received accreditation as a certification organ, can be converted to accredited certificates if:

- After the organization was accredited, it has performed at least one follow-up of the certificate holder
- The certificate is given a new date of issue
- The certification is part of the current scope of accreditation for the certification body, and
- There have not been any significant changes in the certification scheme since the certificate was issued or the previously mentioned follow-up showed that the necessary requirements are satisfied

Expired certificates cannot be converted.

Accredited system certification bodies are obligated to only issue accredited certificates for certification schemes/standards where the body is accredited (effective as of November 1, 2016).

Transfer of certificates from one certification organ to another is not allowed according to the requirements defined in IAF MD 2.

Applicants and accredited system certification bodies shall ensure that NA can conduct observations of a sample of audits the body performs. The choice and scope of observations conducted are carried out according to IAF MD 17. NA normally conducts one observation for each system standard per year. Sector-specific requirements apply and may override the aforementioned terms and requirements.

For observations, the following shall be submitted to NA:

- CVs of auditors
- Audit reports from the previous audit (if applicable)
- The organization's procedures for audits
- Justification for changing the industry code (if applicable)
- Issued certificate
- Qualification criteria for the audit team
- Calculation of the required audit time in accordance with IAF MD 11 for integrated management systems
- Calculation of sampling in accordance with IAF MD 1
- For ISO 9001 and ISO 14001; calculation of audit duration in auditor days in accordance with IAF MD 5
- Any other documentation required for the organization to be audited (management system, internal audit reports, etc.)

25.3 Accreditation of product conformity certification bodies

Applicants and accredited product conformity certification bodies shall ensure that NA can conduct observations of the certification body's audit at manufacturers, if there is a license agreement. The same applies to observations of the certification body's monitoring of subcontractors, if the subcontractors are not accredited.

Each product area (related products, technical processes, and competence) shall normally be observed once before accreditation can be granted and again over the course of the accreditation period.

For certification of services and processes, observations must be performed of the certification body's monitoring of customers.

25.4 Accreditation of certification bodies of persons

Applicants and accredited certification bodies of persons shall ensure that NA can conduct observations of examinations of candidates and the certification body's monitoring of subcontractors / teaching activities.

Observations in this context can be:

- Review of exam questions and answers
- Observations of examinations

The certification body for each certification scheme shall normally be observed once before accreditation can be granted and again over the course of the accreditation period.

Certificates for persons cannot be transferred from one accredited certification body to another.

26 Specific requirements for inspection bodies

In cases where testing is performed as a part of an inspection, the relevant requirements for testing laboratories apply.

Each technical area for inspection shall normally be observed once before an accreditation can be granted and again over the course of the accreditation period. NA is free to select which inspections/inspectors are to be observed.

A specification of how requirements in 17020 shall be interpreted is given in ILAC-P15 (Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies).

27 Specific requirements for proficiency testing providers (ISO 17043)

The definition for accreditation scope is set to a level of detail equivalent to testing and calibration laboratories.

Proficiency testing providers shall maintain a publicly available list over the specific proficiency test programs they offer.

The measurements that form the basis for reference values shall, if possible, be performed as accredited tests or calibrations.

In addition, PT providers shall inform NA when:

a) changing/replacement of key personnel concerning statistical analysis

b) change of subcontractors (such changes shall be approved by NA before they can be initiated)

28 Specific requirements for EU-ETS (ISO 14065 and Regulation 600/2012)

By November 15 of each year, accredited verification bodies shall submit the following information to NA (cf. Regulation 600/2012 Article 76):

- A list over planned verifications (dates and locations)
- Address list and contact persons for organizations to be verified (referred to as operators or aircraft operators in Regulation 600/2012 Article 76)

When there are changes in the information listed above, these changes shall be reported to NA immediately, no later than two weeks after the changes are confirmed by the verification body.

In connection with each assessment, NA shall conduct observations of the applicable verifications performed by the verification body.

Assessments performed by NA are based on the requirements described in:

- EU Regulation 601/2012
- EU Regulation 600/2012,
- EUs key guidance documents
- EA 6/03 M:2013 EA Document for recognition of verifiers under EU ETS Directive
- IAF MD6: Application of ISO 14065

EU Regulation 600/2012 Article 53 describes the accreditation body's obligations for disclosure of information for changes in accredited scope.

29 References

The Norwegian Act «Lov om det frie varebytte i EØS (EØS-vareloven)»
The Pollution Control Act §52

Norwegian legislation is available at www.lovdata.no

EA documents are available at www.european-accreditation.org

EU regulations are available at www.eurlex.eu

EU-ETS Key guidance documents: http://ec.europa.eu/clima/policies/ets/monitoring/documentation_en.htm

IAF documents are available at www.iaf.nu

ILAC documents are available at www.ilac.org