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CLIMA.B.2 – ETS (II): Implementation, Policy Support & ETS Registry

## Guidance Document

### The Accreditation and Verification Regulation - Relation between the AVR and EN ISO/IEC 17011

#### **AVR Key guidance note no. II.9, Version of 10 January 2022**

This document is part of a series of documents and templates provided by the Commission services for supporting the implementation of Commission Implementing Regulation (EU) No. 2018/2067 of 19 December 2018 on the verification of data and on the accreditation of verifiers pursuant to Directive 2003/87/EC of the European Parliament and of the Council.

The guidance represents the views of the Commission services at the time of publication. It is not legally binding.

This guidance document takes into account the discussions within meetings of the informal Technical Working Group on MRVA (Monitoring, Reporting, Verification and Accreditation) under the WGIII of the Climate Change Committee (CCC), as well as written comments received from stakeholders and experts from Member States.

*This guidance document was unanimously endorsed by the representatives of the Member States at the meeting of the Climate Change Committee on 19 September 2012.*

All guidance documents and templates can be downloaded from the documentation section of the Commission's website at the following address:

[https://ec.europa.eu/clima/eu-action/eu-emissions-trading-system-eu-ets/monitoring-reporting-and-verification-eu-ets-emissions\\_en#tab-0-1](https://ec.europa.eu/clima/eu-action/eu-emissions-trading-system-eu-ets/monitoring-reporting-and-verification-eu-ets-emissions_en#tab-0-1)

## Version History

Date	Version status	Remarks
19 September 2012	published	Endorsed by CCC on 19 September 2012
January 2022	re-published	<ul style="list-style-type: none"><li>• Updates to new Accreditation and Verification Regulation 2018/2067 that was amended by Commission Regulation 2020/2084. This includes revisions for the fourth trading period</li><li>• Updates as a result of revisions in ISO/IEC 17011:2017</li></ul>

## Background

This key guidance note is part of a suite of guidance documents developed by the Commission to explain the requirements of the EU ETS Regulation on Accreditation and Verification (AVR).<sup>1</sup> The suite of guidance documents consists of:

- an explanatory guidance on the articles of the AVR (EGD I), including a user manual providing an overview of the guidance documents and their interrelation with the relevant legislation;
- key guidance notes (KGN II) on specific verification and accreditation issues;
- a specific guidance (GD III) on the verification of aircraft operator's reports;
- templates for the verification report and information exchange requirements;
- exemplars consisting of filled-in templates, checklists or specific examples in the explanatory guidance or key guidance notes;
- frequently asked questions.

This key guidance note explains the requirements of EN ISO/IEC 17011 and how this standard relates to the AVR. In addition, explanation is provided on the application of the Accreditation Regulation 765/2008.<sup>2</sup> The note represents the views of the Commission services at the time of publication. It is not legally binding.

### 1. Relation between Accreditation Regulation 765/2008, the AVR and EN ISO/IEC 17011

Article 15 of the EU ETS Directive and the AVR have created an EU ETS specific accreditation scheme ensuring synergy with the accreditation framework established by the Accreditation Regulation 765/2008. The AVR contains EU ETS specific requirements on the accreditation process and the administrative measures to be imposed by National Accreditation Bodies (NABs), the structure of NABs, the competence and impartiality of NABs and their personnel as well as procedures to be implemented by the NABs. The comprehensive generic framework for accreditation established by Accreditation Regulation 765/2008 aims to harmonise the accreditation services performed by NABs across Europe. It covers the operation of accreditation in support of voluntary conformity assessment as well as conformity assessments required by legislation. It contains generic requirements on for example the structure of NABs, the competence and impartiality of NABs, non-competition of accreditation and cross-border accreditation. Synergy between the AVR and Accreditation regulation 765/2008 is reflected in Article 5 of the AVR.

Requirement	Location in AVR
<i>Where no specific provisions concerning the composition of the national accreditation bodies or the activities and requirements linked to accreditation are laid down in this Regulation, the relevant provisions of Regulation (EC) No 765/2008 shall apply.</i>	Article 5

<sup>1</sup> Commission Implementing Regulation (EU) 2018/2067 of 19 December 2018 on the verification of data and on the accreditation of verifiers pursuant to Directive 2003/87/EC of the European Parliament and of the Council as amended by Commission Implementing Regulation (EU) 2020/2084 of 14 December 2020: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02018R2067-20210101&from=EN>

<sup>2</sup> Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, OJ EU, L 218/30.

This means that the provisions of Accreditation Regulation 765/2008 related to accreditation which are not covered by the AVR, are applicable to EU ETS. This concerns the following provisions.

<b>Accreditation Regulation 765/2008</b>	<b>Application to EU ETS</b>
Article 4(1): single NAB per MS	Each Member State must appoint a single NAB. All accreditation services covered by Accreditation Regulation 765/2008 but also the services covered by the AVR must be provided by this single NAB.
Article 4(4): Information on recourse to another NAB	Article 56 of the AVR requires MS to have recourse to the NAB of another MS if the MS considers it economically not meaningful or sustainable to appoint a NAB or to provide EU ETS accreditation services. In those cases Article 4(4) AR regulation 765/2008 must be followed. The Commission must draw up a list of Member States that have had recourse to the NAB of another MS
Article 4(7) Working on a non-for profit basis	NABs shall operate on a not-for-profit basis.
Article 4(9) Financial and personnel resources	Each Member State shall ensure that its NAB has the appropriate financial and personnel resources for the proper performance of its tasks, including the fulfillment of special tasks such as activities for European and international accreditation cooperation and activities that are required to support public policy and which are not self-financing.  This will concern not only resources for EU ETS accreditation but also the other accreditation services of the NAB.
Article 5(2)	In the case that an MS decides to apply certification of natural persons, that MS has to provide the necessary evidence to the Commission and to the other MS (please see the key guidance note on certification KGN II.11)
Article 5(5) resolution of appeals	Article 54(4) of the AVR requires MS to establish procedures for the resolution of appeals on administrative measures. If appeals concern decisions of the NAB other than decisions on administrative measures, MS are required to establish procedures for the resolution of those appeals according to Article 5(5) of Accreditation Regulation 765/2008.
Article 6 non-competition	NAB shall not compete with verifiers nor shall NAB compete with other NABs. Only under certain conditions are NABs permitted to operate across national borders. See below.
Part of Article 7(1) Cross border accreditation	The verifier can only request accreditation by the NAB of the MS in which it is established (or with the NAB to which that MS has recourse if that MS does not have a NAB). The situation for EU ETS in which an MS can have such recourse is regulated in Article 56 of the AVR.  In exceptional cases the verifier may request accreditation by an NAB other than is mentioned above: <ul style="list-style-type: none"> <li>▪ If the MS in which the verifier is established has decided not to establish a NAB and has had no recourse to the NAB of another MS;</li> <li>▪ If the NAB of the MS in which the verifier is established does not perform EU ETS accreditation services and that MS has sought no recourse in another MS;</li> <li>▪ If the NAB of the MS in which the verifier is established has not successfully undergone a peer evaluation.</li> </ul>

Accreditation Regulation 765/2008	Application to EU ETS
Article 7(2)	If an NAB receives a request for cross-border accreditation as outlined above, it must inform the NAB of the MS in which the requesting verifier is established. In such cases the NAB of the MS in which the verifier is established may participate as an observer.
Article 8 requirements on accreditation bodies	<p>The requirements concern:</p> <ul style="list-style-type: none"> <li>▪ ensuring that the decision on accreditation is taken by competent persons different from those who carried out the assessment;</li> <li>▪ having adequate arrangements to safeguard the confidentiality of information obtained;</li> <li>▪ identifying verification activities for which it is competent to perform accreditation;</li> <li>▪ setting up procedures to ensure efficient management and appropriate internal controls;</li> <li>▪ having a number of competent personnel at its disposal that is sufficient for the proper performance of its tasks;</li> <li>▪ documenting the duties, responsibilities and authorities of personnel who could affect the quality of assessment and the decision on accreditation;</li> <li>▪ establishing, implementing and maintaining procedures for monitoring the performance and competence of the personnel involved;</li> <li>▪ publishing audited annual accounts prepared in accordance with generally accepted accounting principles.</li> </ul> <p>The requirements in Article 8(1), (2) and (10) of AR regulation 765/2008 are covered in the AVR.</p>
Article 9	NABs must have in place the necessary procedures to deal with complaints against verifiers that they have accredited.
Article 12 Information obligation	This article concerns general information requirements that are applicable to all conformity assessment activities that are carried out by NABs.

## 2. EN ISO/IEC 17011

The AVR prescribes the application of a harmonised standard in EU ETS accreditation scheme.

Requirement	Location in AVR
<i>With respect to the minimum requirements for accreditation, and the requirements for accreditation bodies, the harmonised standard pursuant to Regulation (EC) No 765/2008 concerning general requirements for accreditation bodies accrediting conformity assessment bodies shall apply.</i>	Annex III

On 16 June 2009 a reference to EN ISO/IEC 17011 was published in the Official Journal of the European Union making it a harmonised standard. This standard was updated in 2017 and this updated EN ISO/IEC 17011 standard was harmonised on the 9<sup>th</sup> of March 2018. By referring in Annex III to the exact title of EN ISO/IEC 17011, this standard is applicable to NABs and should be read in conjunction with the EU ETS specific requirements in the AVR.

EN ISO/IEC 17011 provides general requirements for NABs assessing and accrediting conformity assessment bodies (i.e. verifiers for EU ETS). These requirements concern not

only the accreditation process but also the structure of the NAB, impartiality and competence of a NAB, management and internal controls, procedures, subcontracting, appeals and complaints. Where needed, EU ETS specific requirements have been incorporated in the AVR.

NABs have to meet these EU ETS specific requirements and EN ISO/IEC 17011 and carry out the accreditation activities in line with these requirements.


Most of the revisions in the updated EN ISO/IEC 17011 build on the provisions that were already in place in 2009. On some aspects additional clarifications are provided, for example

- additional requirements on impartiality;
- more clear and detailed requirements on competence;
- additional rules on confidentiality of information during the verification;
- clarifications on verifier’s appeal and complaint procedures and the management system.

Some provisions in EN ISO/IEC 17011 offer flexibility and room for interpretation: e.g. scope of accreditation. However, further specification has been provided in the EU ETS specific accreditation scheme laid down in the AVR: e.g. predefined accreditation scope in Annex I of the AVR, requirement for NABs to assess the actual performance of (lead) assessors and EU ETS specific requirements on competence, organisation and impartiality of the AVR according to Article 45 of the AVR.

### 3. EN ISO/IEC 17011 requirements in relation to AVR

The following sections outline how EN ISO/IEC 17011 should be interpreted in relation to the AVR and EU ETS.

Please note that this guidance does not portray the full text of EN ISO/IEC 17011 because of copyright reasons. For a complete overview of the requirements the standard itself must be consulted.	
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#### 3.1 Legal status and structure of an NAB

The AVR as well as Accreditation Regulation 765/2008 contain specific requirements on the structure of the NAB:

- The NAB must have public authority;
- The structure, responsibilities and tasks of the NAB must be clearly distinguished from those of the Competent Authority for EU ETS and other national authorities. This means that the responsibilities between the NAB and the CA should not be intertwined and the relations between those organisations should be distinct;
- A clear delineation of the responsibilities within the NAB is important. Decisions on the accreditation and administrative measures must be taken by persons that are different from persons that carried out assessments.

Art. 55(5)  
AVR

Art. 57(3)  
AVR

Art. 8(3)  
AR 765/  
2008

To underpin those specific requirements in both regulations, the requirements of EN ISO/IEC 17011 on the legal status and structure of the NAB must be met. The table below only reflects the most relevant requirements.

Requirement in EN ISO/IEC 17011	Explanation in relation to AVR
The NAB must be a registered legal entity	
The NAB must be responsible for its decisions on accreditation and administrative measures	The NAB should have ultimate responsibility and take the final decisions.

Requirement in EN ISO/IEC 17011	Explanation in relation to AVR
The NAB must describe its legal status <sup>3</sup> and have formal rules for the appointment, terms of reference, committees and persons involved in the accreditation	It should be clear that the structure, responsibilities and tasks of the NAB are distinguishable from those of the CA and those of other national authorities.
The NAB must identify its top management having overall authority and responsibility for the policies, finances and activities mentioned in EN ISO/IEC 17011 <sup>4</sup>	
The NAB must document its legal and organisation structure as well as roles and responsibilities of top management and personnel used, including those persons involved in the accreditation process	Documentation of the roles and responsibilities should not only include the personnel of the NAB itself, but also contracted persons and subcontracted bodies.  This is of particular relevance for assessing the impartiality and independence of a NAB. Actual or apparent conflict of interest should be avoided between the NAB and other organisations
The NAB must have the necessary expertise to carry out accreditation	EU ETS specific requirements on competence have been included in the AVR.
The NAB must have sufficient liability coverage and have not only the human resources but also the financial resources required for the operation of accreditation activities. This should be demonstrated by records and/or documents. The NAB has to evaluate the risks arising from its activities and implement measures to cover liabilities.	This provisions is important to avoid potential conflicts of interest and to minimise the risks to impartiality.

Art. 57(3)  
AVR

Art. 59  
AVR

### 3.2 Impartiality and independence

The AVR contains EU ETS specific requirements on the impartiality and independence of the NAB. One of the key requirements is that the NAB must not offer or provide any activities provided by the verifier, and that it is independent from the verifier. Nor shall the NAB carry out consultancy services, own shares or otherwise have a financial or managerial interest in a verifier. During the accreditation process the NAB must therefore take special care not to provide consultancy to the verifier. These AVR requirements are further elaborated in EN ISO/IEC 17011. The table below portrays the most relevant provisions on impartiality.

Art. 57(2)  
AVR

Requirement in EN ISO/IEC 17011	Explanation in relation to AVR
The accreditation body should be structured in such a way as to safeguard impartiality. Where the NAB is part of a larger entity, its organisation should be such that accreditation can be provided in an impartial manner	The NAB should be independent from the verifier and the CA.

Art. 57  
(2) AVR

<sup>3</sup> Including names of owners or names of persons that are in control of the accreditation body.

<sup>4</sup> This includes for example, development of policies, monitoring the implementation of policies and procedures, supervision of finances of the accreditation body, decisions on accreditation, assessments and activities in the accreditation process, addressing complaints and appeals in a timely manner, making sure that there are adequate resources and that procedures and management systems are in place to effectively manage accreditation process, proper delegation of the responsibilities involved and safeguarding impartiality of the accreditation body and its personnel.

Requirement in EN ISO/IEC 17011	Explanation in relation to AVR
The NAB's policies and procedures must be non-discriminatory and accreditation services should be accessible to all applicants. <sup>5</sup>	The applicants must meet the EU ETS specific requirements when submitting the application.
All NAB personnel and committees that could influence the accreditation process must act objectively, be impartial and be free from commercial, financial or other pressures that could cause risks to the impartiality of the NAB. The NAB is responsible for the impartiality of its accreditation activities	
Each decision on accreditation and administrative measures has to be taken by competent personnel.	EU ETS specific competence requirements have been laid down in Article 59 and 60 of the AVR.
<p>In some cases a NAB can be related to another organisation by common ownership or contractual agreements. In those cases the NAB must ensure that the activities of its related bodies do not compromise the confidentiality, objectivity and impartiality of the accreditation. There should be no relation between the NAB and the related body that would create an unacceptable risks to impartiality.<sup>6</sup></p> <p>A related body may only offer consultancy services under certain conditions:</p> <ul style="list-style-type: none"> <li>▪ Different top management</li> <li>▪ Different personnel involved in the decision on accreditation</li> <li>▪ No possibility to influence the outcome of an assessment for accreditation and effective mechanisms in place to avoid such influence</li> <li>▪ Distinctly different name, logos and symbols</li> </ul>	For EU ETS it should be noted that the NAB must be clearly distinguished from the CA for EU ETS and other national authorities.
An impartiality policy must be adopted which manages impartiality of accreditation activities, conflicts of interests and ensures objectivity of accreditation. The NAB must require personnel and committee members to inform the NAB of any conflict of interest if this arises.	
The NAB must identify, analyse, evaluate, monitor and document on an ongoing basis the relationships with related organisations	Managing potential conflicts of interest not only involves identifying and analysing potential conflict of interest situations but also making the

<sup>5</sup> The application of the application should have the appropriate scope of accreditation for which the verifier requests accreditation. This means that for example the size of the verifier should not determine whether the verifier will receive an accreditation. The NAB can refuse the request for accreditation if the verifier has committed fraud or did not comply with accreditation requirements.

<sup>6</sup> Some activities are not considered a risk to impartiality according to EN ISO/IEC 17011: e.g. giving training or education provided this training or education is based on generic information and available for the public. It should not present specific solutions or recommendations of improvement to verifiers.



Requirement in EN ISO/IEC 17011	Explanation in relation to AVR
and determine whether potential conflicts of interests exist. These risks to impartiality should be documented. If there are conflicts of interest, these have to be addressed by the NAB. The NAB should show how these risks can be eliminated or mitigated. <sup>7</sup> If there are any residual risks, the top management will assess if this risk is acceptable. If an unacceptable risk to impartiality is identified and this cannot be mitigated to an acceptable level, the NAB should not grant an accreditation.	necessary arrangements to avoid those situations arising.

### 3.3 Competence

The AVR contains EU ETS specific requirements on the competence of the assessment team and the membership of that team: the assessors, the lead assessors and the technical experts. Furthermore specific competence requirements have been included on internal reviewers and persons taking the decision on granting, extending and/or renewing the accreditation. EN ISO/IEC 17011 elaborates further on the availability of human resources and the generic competence of the parties involved.

In addition, Accreditation Regulation 765/2008 requires the NAB to have a sufficient number of competent personnel at its disposal for the proper performance of its tasks. This includes access to a sufficient number of assessors, lead assessors and technical experts. Other relevant provisions on personnel associated with NABs are:

Requirement in EN ISO/IEC 17011	Explanation in relation to AVR
The NAB clarifies to each person the extent and limits of their duties, responsibilities and authorities	The aim is to ensure the competence and impartiality of the personnel within the NAB.
Each person must commit himself formally to comply with the rules of the NAB	This could be rules on confidentiality, impartiality, specific requirements in the accreditation process etc.

For each particular assessment, the NAB appoints an assessment team that consist of a lead assessor and, where necessary, a suitable number of assessors and technical experts. Lead assessors lead the assessment team whereas assessors carry out their activities under the direction of lead assessors. Technical experts can be involved to provide detailed knowledge and expertise on a specific subject matter. This could be language, specific technical knowledge, data and information auditing expertise, IT expertise and any other expertise for which the lead assessor or assessor need support. Technical experts carry out their tasks under the direction and full responsibility of the lead assessor of the assessment team.

Art. 59  
AVR

Art. 60(3)  
AVR

When selecting the team, the NAB shall ensure that the team includes at least one person with knowledge of GHG monitoring and reporting that is relevant for the scope of accreditation. The team must have the competence and understanding required to assess the verification activities carried out for the installation or aircraft operator. This will enable

Art. 58(2)  
AVR

<sup>7</sup> This should also cover potential risks within the NAB and from other persons, bodies or organisations related to the NAB.

the assessment team to assess the performance of the verifier (e.g. how the verifier checks the application of the monitoring methodology, how the verifier carries out data sampling in a refinery etc). The NAB must also ensure that members of the assessment team act in an impartial and non-discriminatory manner. EN ISO/IEC 17011 requires team members to inform the NAB, prior to the assessment, of existing relations and potential conflict of interests with the verifier.

To facilitate the selection of the team, the NAB must undertake certain measures outlined in the table below.

Requirement in EN ISO/IEC 17011	Explanation in relation to AVR
The NAB must have processes to ensure that its personnel is competent to carry out accreditation activities. The NAB must outline for each activity in the accreditation process the qualifications, experience and competence required, and the initial and ongoing training required.	
The NAB must establish procedures for selecting, training and formally approving assessors and technical experts used in the assessment process. The NAB shall identify training needs and provide training opportunities for personnel	
The NAB must identify for which scope of accreditation each assessor and technical expert is competent to operate.	This concerns the scope of accreditation listed in Annex I of the AVR.

Assessors have to meet the following competence requirements: they must:

- be familiar with the accreditation procedures, accreditation criteria and other relevant requirements and guidance documents;
- have undergone a relevant assessor or lead assessor training;
- have a thorough knowledge of the relevant assessment methods, including risk based assessment principles and business environment of verifiers;
- be able to communicate effectively in the required languages;
- have appropriate personal attributes: e.g. being observant, ethical, decisive, self reliant;<sup>8</sup>
- have knowledge of the EU ETS Directive; the MRR and the AVR; NAB procedures and requirements based on EN ISO/IEC 17011; EN ISO 17029; EN ISO/IEC 14065 and 14064-3; other relevant legislation (e.g. complementary national legislation); and the guidance developed by the European Commission to support the interpretation of the MRR and the AVR. When the NAB assesses verifiers carrying out verification of allocation data, assessors also must have knowledge of the Free Allocation Rules, Implementing Regulation on annual activity level data and relevant guidance on both regulations;
- have knowledge of data and information auditing obtained through training or have access to a person that has such knowledge and experience. Data and information auditing knowledge means knowledge of, for example, data and information auditing methodologies, including the application of materiality levels and assessing the materiality of misstatements; analysing inherent and control risks; sampling techniques and assessing data flow, control system, procedures for control activities, IT systems etc.

**Art. 59(1)  
(a) AVR**

**Art. 59(1)  
(b) AVR**

**Art. 59(1)  
(c) AVR**

<sup>8</sup> Personal attributes mentioned in ISO/IEC 14066.

Lead assessors have to meet the same competence requirements as assessors and shall be able to demonstrate competence to lead an assessment team and be responsible for carrying out an assessment in line with the AVR.

Art. 59(2)  
AVR

Internal reviewers and persons taking decisions on granting, extending and renewing the accreditation, must meet the same competence requirements as assessors and have sufficient knowledge and experience to evaluate the accreditation.

Art. 59(3)  
AVR

Technical experts must have:

- the competence required to support the lead assessor and assessor effectively on the subject matter for which his or hers knowledge and expertise is requested;
- knowledge of the EU ETS Directive, the MRR and the AVR, NAB procedures and requirements based on EN ISO/IEC 17011; EN ISO 17029; EN ISO/IEC 14065 and 14064-3; other relevant legislation (e.g. complementary national legislation); and the guidances developed by the European Commission to support the interpretation of the MRR and the AVR. Where it concerns verification of allocation data, knowledge of the Free Allocation Rules, Implementing Regulation on annual activity level data and relevant guidance on both regulations;
- a sufficient understanding of GHG verification activities.

Art. 60(2)  
AVR

To ensure that the NAB's personnel continue to meet these competence requirements, Article 8 of the AR regulation 765/2008 requires the NAB to establish, implement and maintain procedures for evaluating and monitoring the performance and competence of the personnel involved. EN ISO/IEC 17011 requires the NAB to have proper evaluation methods in place to monitor the competence of all personnel. As part of this process the NAB must review and evaluate the performance and competence of its personnel in order to identify training needs. The way persons are monitored should be determined based on how deeply they are involved in accreditation activities (e.g. frequency with which they carry out accreditation activities) and the level of risk concerned with their accreditation activities. As a result of this evaluation the NAB can recommend appropriate follow-up actions to improve the personnel's performance and request corrective action. EN ISO/IEC 17011 requires regular on-site observation of lead assessors and assessors in combination with review of assessment reports and feedback from personnel, the verifier and other interested parties such as operators of installations. The observation and monitoring of (lead) assessors should be done at regular intervals. In general this would occur every three years unless there is sufficient supporting evidence that the assessor and lead assessor are continuing to perform competently.

### **3.4 NAB's procedures**

In order to meet the key principles and requirements of Article 8 of the Accreditation Regulation 765/2008, the NAB must establish, implement and maintain the procedures and systems mentioned in EN ISO/IEC 17011. This involves the establishment and maintenance of the following:

- a management system;
- procedures for extending activities and responding to demands of interested parties;
- procedures to control all documents that relate to accreditation activities;

Art. 61  
AVR

- procedures for the identification, collection, indexing, accessing, filing, storage, maintenance and disposal of records;
- procedures for retaining records for a period consistent with its contractual and legal obligations;
- procedures for the identification and management of non-conformities<sup>9</sup> in the NAB's own operations;
- procedures to identify opportunities for improvement and to take preventive actions to eliminate the causes of potential non-conformities;
- procedures for internal audits to verify conformity with the requirements of the AVR and ensure that the management system is implemented and maintained;
- procedures to review the management system;
- procedure for dealing with complaints;
- procedure to address appeals.

The NAB can also implement a management system in line with ISO 9001 but in those cases it has to meet the same requirements on the management system. The table below gives an outline of EN ISO/IEC 17011 requirements, it does not entail a complete overview of all the requirements.

Procedure in EN ISO/IEC 17011	Explanation of activities in procedures in relation to AVR
Requirement to establish a management system	<p>A management system involves the NAB's top management defining, documenting, implementing and maintaining policies and objectives for its activities at all levels of the NAB.</p> <p>The management system should be appropriate to the type, range and volume of work performed. All applicable requirements of the AVR and EN ISO/IEC 17011 must be addressed either in a manual or in associated documents which are accessible to its personnel.</p> <p>The NAB must ensure that procedures needed for the management system are established and that reports are made to top management on the performance of the management system and any need for improvement. The NAB is required to continually improve effectiveness of its management system in line with the standard.</p>
Establishing procedures to control all documents that relate to accreditation activities	<p>Activities related to the control of documents include:</p> <ul style="list-style-type: none"> <li>▪ approving documents for adequacy prior to issue;</li> <li>▪ reviewing, updating and re-approving documents;</li> <li>▪ ensuring that changes and the current revision status of documents are identified;</li> <li>▪ ensuring that relevant versions of applicable documents are available to personnel and contracted persons;</li> <li>▪ ensuring that documents remain legible and readily identifiable;</li> <li>▪ preventing unintended use of obsolete documents, and applying suitable identification to them if they are retained for any purpose;</li> <li>▪ safeguarding, where relevant, the confidentiality of documents.</li> </ul>
Establishment of procedures for the identification,	Records shall include not only personnel records but also records on verifiers involved, including records on complaints, appeals etc..

<sup>9</sup> Non-conformities are any act or an omission of an act by the verifier that is contrary to the requirements of the regulation.

Procedure in EN ISO/IEC 17011	Explanation of activities in procedures in relation to AVR
collection, indexing, accessing, filing, storage, protection, retrieval, maintenance and disposal of records. This also includes procedures to define controls needed for these activities	According to EN ISO/IEC 17011 access to records should be consistent with confidentiality agreements.
Establishing procedures for retaining records for a period consistent with its contractual and legal obligations	
Establishing procedures for the identification and management of non-conformities in the NAB's own operations	<p>The procedure should include requirements on how to proceed when non-conformities are identified (e.g. determining the root causes of non-conformity, correcting non-conformities, assessing the need for actions to ensure that non-conformities do not recur, determining the actions needed and implementing corrections in a timely manner; recording the results of actions taken; reviewing the effectiveness of corrective actions).</p> <p>Non-conformities are any non-compliance with the AVR.</p> <p>When taking corrective actions these must be appropriate to the impact of the problems encountered.</p>
Establishing procedures to identify opportunities for improvement and to take preventive actions to eliminate the causes of potential non-conformities	<p>The procedure should include requirements on how to take preventive actions to eliminate the root causes of potential non-conformities. This involves:</p> <ul style="list-style-type: none"> <li>▪ identifying potential non-conformities and their root causes;</li> <li>▪ determining and implementing preventive actions needed;</li> <li>▪ recording results of actions taken; and</li> <li>▪ reviewing the effectiveness of preventive actions taken.</li> </ul> <p>Preventive actions taken shall be appropriate to the impact of the potential problems.</p>
Establishing procedures for internal audits to verify conformity with the requirements of the AVR and that the management system is implemented and maintained	<p>EN ISO/IEC 17011 contains requirements on how to carry out internal audits which should be reflected in the procedures for internal audits. Internal audits shall be performed at least once a year unless the NAB can demonstrate that its management system has been effectively implemented and has proven its stability. In that case the NAB may reduce the frequency of the audits. For internal audits, an audit programme must be developed, taking into consideration the importance of the processes and areas to be audited, as well as the results of previous audits. EN ISO/IEC 17011 contains further requirements on how to conduct internal audits (e.g. using competent personnel, having the internal audits performed by personnel different from those performing the activity to be audited, informing the responsible persons of the outcome of the internal audit, actions to be taken as a result of internal audits in a timely and</p>

**Art. 3(13)  
AVR**

Procedure in EN ISO/IEC 17011	Explanation of activities in procedures in relation to AVR
	appropriate manner, identification of opportunities for improvement).
Establishing procedures to review the management system	Management systems must be reviewed at planned intervals to ensure their continuing adequacy and effectiveness. These reviews shall take place at least once a year, as appropriate. EN ISO/IEC 17011 specifies the inputs for such a review, e.g. results of audits, results of peer reviews, trends in non-conformities, feedback of interested parties, new areas of accreditation, the status of actions to address risks and opportunities, follow-up actions from earlier management reviews, changes that could affect the management system, analysis of appeals and complaints. Outputs of the review of the management system include for example improvement of the management system and accreditation process, need for resources and defining or redefining policies, goals and objectives.
Establishing a procedure for receiving, evaluating and making decisions on complaints	<p>The activities related to dealing with complaints is regulated in the AVR. Where the NAB has received a complaint concerning the verifier it shall, within a reasonable time but no later than 3 months after receipt of the complaint:</p> <ul style="list-style-type: none"> <li>▪ decide on the validity of the complaint;</li> <li>▪ ensure that the verifier concerned is given the opportunity to submit its observations;</li> <li>▪ take appropriate actions to address the complaint;</li> <li>▪ record the complaint and action taken; and</li> <li>▪ respond to the complainant.</li> </ul> <p>EN ISO/IEC 17011 requires the decision on complaints to be made, reviewed and approved by persons not involved in the accreditation activities concerned.</p>
Establishing a procedure to receive, evaluate and make decisions on appeals	<p>The activities related to address appeals are:</p> <ul style="list-style-type: none"> <li>▪ appointing a person or group of persons to investigate the appeal. These persons shall be competent and independent of the subject of the appeal;</li> <li>▪ deciding on the validity of the appeal;</li> <li>▪ informing the verifier of the NAB's final decision;</li> <li>▪ taking follow-up action where required; and</li> <li>▪ keeping records of all appeals, of final decisions, and of follow-up actions taken.</li> </ul> <p>EN ISO/IEC 17011 states that the decision on appeal should be made, reviewed and approved by persons that are not involved in the accreditation activities concerned.</p>

Art. 62  
AVR

### 3.5 Subcontracting and contracting personnel

Subcontracting or outsourcing means that contract arrangements have been made with another external organisation to deliver parts of the accreditation services. The NAB maintains the final responsibility. Contracting persons means hiring persons to carry out certain activities internally for the NAB, but under the direction and full responsibility of the NAB itself. EN ISO/IEC 17011 clearly states that contracting individual assessors and technical experts to carry out activities does not constitute subcontracting or outsourcing. As the AVR requires the NAB to take all final decisions pertaining to accreditation of verifiers, subcontracting or outsourcing of decisions on accreditation is not allowed. The persons making accreditation decisions should therefore be working in the NAB.

Art. 57(4)  
AVR

If the NAB is making use of subcontracting or outsourcing for parts of the accreditation activities, it must have a policy describing the conditions under which subcontracting may take place. This includes a properly documented agreement covering confidentiality of data and addressing conflicts of interests.

When subcontracting takes place, the NAB must take full responsibility for all subcontracted assessments and shall itself have competence and final responsibility in the decision-making. The NAB has to ensure that the subcontracted or outsourced body is competent and will comply with the AVR. Furthermore EN ISO/IEC 17011 requires the NAB to obtain the written consent of the verifier to use a particular subcontractor.

The NAB has to have a procedure for approving and monitoring the organisations that carry out outsourced or subcontracted activities for the accreditation process.

### **3.6 Records**

The NAB must keep up to date records on each person involved in the accreditation process. This includes records related to the competence process, and the competence of lead assessors, assessors and technical experts (e.g. educational qualifications and professional status, training, experience and competence of persons in assessments and for specific assessment tasks as well as results of regular monitoring of their competence), records related to the impartiality of personnel, records on contracted personnel, subcontracted activities, records on verifiers, documentation on appeals, complaints and corrective action. The records should also include this information for subcontracted or outsourced personnel.

**Art. 63  
AVR**

Data to be maintained on verifiers include relevant correspondence, assessment records, records of relevant committee discussions, and copies of accreditation certificates; all such data must be held securely. The data should be recorded at least for the previous and current accreditation cycle.

### **3.7 Public information and confidentiality**

On a regular basis the NAB must make publicly available, and provide up-to-date information about the process of accreditation services. EN ISO/IEC 17011 outlines examples of information concerned, e.g.:

**Art. 64  
AVR**

- information about the authority under which the NAB carries out its activities;
- information on how the NAB receives financial support;
- information on the NAB's rights and obligations and the NAB's activities other than accreditation;
- information on international recognition arrangements;
- detailed information about its assessment and accreditation processes, including arrangements for granting, maintaining, extending, reducing, suspending and withdrawing accreditation;
- a document or reference documents containing the requirements for an application for accreditation or extension(s) of accreditation, as well as other requirements for accreditation, including technical requirements specific to each field of accreditation, where applicable;
- general information about the fees relating to the accreditation;
- a description of the rights and obligations of verifiers;

- information on the accredited verifiers such as name and address of each accredited verifier; dates on which the accreditation is granted and on which date the accreditation will expire; scopes of accreditation, condensed or in full. If only condensed scopes are provided, information shall be given on how to obtain full scopes;
- accreditation certificates and administrative measures imposed;
- information on making and addressing complaints and launching appeals;
- changes to the requirements of the accreditation;
- Information on the use of accreditation symbols.

Some of the information can be included in the database that each NAB has to set up. Only in rare cases may access to the aforementioned information be limited on request by the verifier.

**Art. 76  
AVR**

The NAB must make adequate arrangements to safeguard the confidentiality of information. The NAB and its personnel shall not disclose confidential information about a particular verifier outside the NAB without the written consent of the verifier, except when the AVR, Directive 2003/4/EC or other law requires such information to be disclosed without consent.

**Art. 64(2)  
AVR**

### ***3.8 Responsibilities of verifiers***

The verifier has certain responsibilities. According to EN ISO/IEC 17011 the NAB requires the verifier to conform to specific requirements: e.g. providing access to relevant locations, providing access to information mentioned in Article 8 of the Accreditation Regulation 765/2008, arranging witness audits, informing the NAB without delay of significant changes related to the status and operation of the NAB (e.g. changes to the scope of accreditation, changes in resources and verifier's premises), not using accreditation in such a manner so as to bring the NAB into disreputation.

### ***3.9 Reference to accreditation and use of accreditation symbols***

EN ISO/IEC 17011 requires the NAB to have a policy governing the protection and use of its accreditation symbols intended for use by its accredited verifiers to indicate the accredited status of those verifiers. EN ISO/IEC 17011 includes specific requirements to ensure the correctness of data and avoid any misuse of the accreditation symbols.