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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: <a href="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</a>

# **Version History**

Date	Version status	Remarks
19 September 2012	published	Endorsed by CCC on 19 September 2012
January 2022	re-published	<ul> <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
Where no specific provisions concerning the composition of the national	Article 5
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.	

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<sup>&</sup>lt;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: <a href="https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02018R2067-20210101&from=EN">https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02018R2067-20210101&from=EN</a>

<sup>&</sup>lt;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.

Accreditation Regulation	Application to EU ETS
765/2008	
Article 4(1): single	Each Member State must appoint a single NAB. All accreditation services
NAB per MS	covered by Accreditation Regulation 765/2008 but also the services
	covered by the AVR must be provided by this single NAB.
Article 4(4):	Article 56 of the AVR requires MS to have recourse to the NAB of another
Information on	MS if the MS considers it economically not meaningful or sustainable to
recourse to another	appoint a NAB or to provide EU ETS accreditation services. In those cases
NAB	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	NABs shall operate on a not-for-profit basis.
on a non-for profit	
basis	
Article 4(9) Financial	Each Member State shall ensure that its NAB has the appropriate financial
and personnel	and personnel resources for the proper performance of its tasks, including
resources	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)	Article 54(4) of the AVR requires MS to establish procedures for the
resolution of appeals	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-	NAB shall not compete with verifiers nor shall NAB compete with other
competition	NABs. Only under certain conditions are NABs permitted to operate across
	national borders. See below.
Part of Article 7(1)	The verifier can only request accreditation by the NAB of the MS in which it
Cross border	is established (or with the NAB to which that MS has recourse if that MS
accreditation	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:
	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;
	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;
	If the NAB of the MS in which the verifier is established has not
	successfully undergone a peer evaluation.

Accreditation Regulation 765/2008	Application to EU ETS
Article 7(2)  Article 8	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.  The requirements concern:
requirements on accreditation bodies	<ul> <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> <li>The requirements in Article 8(1), (2) and (10) of AR regulation 765/2008 are covered in the AVR.</li> </ul>
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
With respect to the minimum requirements for accreditation, and the	Annex III
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.	

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.



#### 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.

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	The NAB should have ultimate responsibility and
on accreditation and administrative measures	take the final decisions.

Art. 55(5) AVR

Art. 57(3) AVR

Art. 8(3) AR 765/ 2008

Requirement in EN ISO/IEC 17011	Explanation in relation to AVR	
The NAB must describe its legal status <sup>3</sup> and	It should be clear that the structure,	A.+ F7/2)
have formal rules for the appointment, terms	responsibilities and tasks of the NAB are	Art. 57(3) AVR
of reference, committees and persons	distinguishable from those of the CA and those of	AVI
involved in the accreditation	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	Documentation of the roles and responsibilities	
organisation structure as well as roles and	should not only include the personnel of the NAB	
responsibilities of top management and	itself, but also contracted persons and	
personnel used, including those persons	subcontracted bodies.	
involved in the accreditation process	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	EU ETS specific requirements on competence	Art. 59
to carry out accreditation	have been included in the AVR.	AVR
The NAB must have sufficient liability	This provisions is important to avoid potential	
coverage and have not only the human	conflicts of interest and to minimise the risks to	
resources but also the financial resources	impartiality.	
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.		

# 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.

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

Art. 57

(2) AVR

Art. 57(2)

**AVR** 

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

<sup>&</sup>lt;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	The applicants must meet the EU ETS specific
non-discriminatory and accreditation services	requirements when submitting the application.
should be accessible to all applicants. <sup>5</sup>	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	EU ETS specific competence requirements have
administrative measures has to be taken by	been laid down in Article 59 and 60 of the AVR.
competent personnel.	been faid down in Article 33 and 60 of the AVI.
In some cases a NAB can be related to another	For EU ETS it should be noted that the NAB must
organisation by common ownership or	be clearly distinguished from the CA for EU ETS
contractual agreements. In those cases the	and other national authorities.
NAB must ensure that the activities of its	and other national dathernies.
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>	
A related body may only offer consultancy	
services under certain conditions:	
Different top management	
<ul> <li>Different personnel involved in the decision</li> </ul>	
on accreditation	
<ul> <li>No possiblity to influence the outcome of an</li> </ul>	
assessment for accreditation and effective	
mechanisms in place to avoid such influence	
<ul> <li>Distinctly different name, logos and symbols</li> </ul>	
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,	Managing potential conflicts of interest not only
monitor and document on an ongoing basis	involves identifying and analysing potential
the relationships with related organisations	conflict of interest situations but also making the

Art. 46 AVR

<sup>&</sup>lt;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>&</sup>lt;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	necessary arrangements to avoid those situations
interests exist. These risks to impartiality	arising.
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.	

#### 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	impartiality of the personnel within the NAB.
authorities	
Each person must commit himself formally to	This could be rules on confidentiality, impartiality,
comply with the rules of the NAB	specific requirements in the accreditation process
	etc.

For each particular assessment, the NAB appoints an assessment team that consist of a lead Art. 59 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.

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

AVR

Art. 60(3)

<sup>&</sup>lt;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	This concerns the scope of accreditation
accreditation each assessor and technical expert is	listed in Annex I of the AVR.
competent to operate.	

# 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;8
- 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.

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

Art. 59(1)

(b) AVR

Art. 59(1)

(a) AVR

Art. 59(1) (c) AVR <u>Lead assessors</u> 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

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

Art. 59(3) AVR

Art. 60(2)

**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.

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:

Art. 61 AVR

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

- 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	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.
	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.
	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.
Establishing	Activities related to the control of documents include:
procedures to	<ul> <li>approving documents for adequacy prior to issue;</li> </ul>
control all	<ul> <li>reviewing, updating and re-approving documents;</li> </ul>
documents that relate to	<ul> <li>ensuring that changes and the current revision status of documents are identified;</li> </ul>
accreditation	<ul> <li>ensuring that relevant versions of applicable documents are available to</li> </ul>
activities	personnel and contracted persons;
	<ul> <li>ensuring that documents remain legible and readily identifiable;</li> </ul>
	<ul> <li>preventing unintended use of obsolete documents, and applying suitable</li> </ul>
	identification to them if they are retained for any purpose;
	<ul> <li>safeguarding, where relevant, the confidentiality of documents.</li> </ul>
Establishment of	Records shall include not only personnel records but also records on
procedures for the	verifiers involved, including records on complaints, appeals etc
identification,	

<sup>&</sup>lt;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.

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Procedure in	Explanation of activities in procedures in relation to AVR
EN ISO/IEC 17011	,
collection, indexing,	According to EN ISO/IEC 17011 access to records should be consistent with
accessing, filing,	confidentiality agreements.
storage, protection,	, ,
retrieval,	
maintenance and	
disposal of records.	
This also includes	
procedures to define	
controls needed for	
these activities	
Establishing	
procedures for	
retaining records for	
a period consistent	
with its contractual	
and legal obligations	
Establishing	The procedure should include requirements on how to proceed when non-
procedures for the	conformities are identified (e.g. determining the root causes of non-
identification and	conformity, correcting non-conformities, assessing the need for actions to
management of non-	ensure that non-conformities do not recur, determining the actions needed
conformities in the NAB's own	and implementing corrections in a timely manner; recording the results of
	actions taken; reviewing the effectiveness of corrective actions).
operations	Non-conformities are any non-compliance with the AVR.
	When taking corrective actions these must be appropriate to the impact of
	the problems encountered.
Establishing	The procedure should include requirements on how to take preventive
procedures to	actions to eliminate the root causes of potential non-conformities. This
identify	involves:
opportunities for	<ul> <li>identifying potential non-conformities and their root causes;</li> </ul>
improvement and to	<ul> <li>determining and implementing preventive actions needed;</li> </ul>
take preventive	<ul> <li>recording results of actions taken; and</li> </ul>
actions to eliminate	<ul> <li>reviewing the effectiveness of preventive actions taken.</li> </ul>
the causes of	Preventive actions taken shall be appropriate to the impact of the
potential non-	potential problems.
conformities	
Establishing	EN ISO/IEC 17011 contains requirements on how to carry out internal
procedures for	audits which should be reflected in the procedures for internal audits.
internal audits to	Internal audits shall be performed at least once a year unless the NAB can
verify conformity	demonstrate that its management system has been effectively
with the	implemented and has proven its stability. In that case the NAB may reduce
requirements of the	the frequency of the audits. For internal audits, an audit programme must
AVR and that the	be developed, taking into consideration the importance of the processes
management system	and areas to be audited, as well as the results of previous audits. EN
is implemented and maintained	ISO/IEC 17011 contains further requirements on how to conduct internal
mamilameu	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
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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	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:  decide on the validity of the complaint;  ensure that the verifier concerned is given the opportunity to submit its observations;  take appropriate actions to address the complaint;  record the complaint and action taken; and  respond to the complainant.  EN ISO/IEC 17011 requires the decision on complaints to be made. reviewed and approved by persons not involved in the accreditation activities concerned.
Establishing a procedure to receive, evaluate and make decisions on appeals	<ul> <li>The activities related to address appeals are:</li> <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> <li>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.</li> </ul>

# 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

Art. 62 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 Reponsibilities 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.