LIFE PRO ETV

How to become a verifier of the Environmental Technology Verification (ETV) scheme?

A primer

This project has received funding from the European Union's LIFE Programme under Project Number LIFE19 GIE/PL/000784 and is co-financed by the National Fund for Environmental Protection and Water Management, Poland and the Ministry of Agriculture, Hungary

NATIONAL FUND FOR ENVIRONMENTAL PROTECTION AND WATER MANAGEMENT

AGRÁRMINISZTÉRIUM

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TABLE OF CONTENTS

EXPLANATION OF ACRONYMS

Abbreviations and acronyms	Explanation
DanETV	national ETV programme in Denmark
EPD	Environmental Product Declaration
ETV	Environmental Technology Verification
GHG or GHGs	Greenhouse gas or Greenhouse gases
ILAC	International Laboratory Accreditation Cooperation
LCA	Life Cycle Assessment
NABs	National Accreditation Bodies
PEF	Product Environmental Footprint
TRL	Technology Readiness Level

1. INTRODUCTION

Environmental Technology Verification (ETV) has been designed as a voluntary environmental scheme tailored to address the performance demonstration needs of new and even disruptive, commercially ready environmental technologies. ETV provides a third-party verification of performance claims of new environmental technologies to deliver market-relevant and objective evidence about their technical and functional performance and the resulting environmental benefits to buyers, investors, and other stakeholders. In this way ETV ensures credibility and fosters trust in new environmental technologies. It enables stakeholders e.g. buyers, permitting and regulatory bodies, investors to make informed decisions, promotes market acceptance, and drives adoption of sustainable solutions, thus advancing environmental performance of industrial operations and their innovation.

ETV is based on a framework provided by 3 International Standards (Fig. 1):

- ISO 14034: 2016, Environmental management: Environmental Technology Verification. This standard serves as the main technical reference for ETV. It defines the principles, process and procedures and requirements of the ETV process. It also specifies, the following two standards to be applied when performing ETV as a framework ensuring quality and impartiality of the ETV process;
- ISO/IEC 17020:2012, Conformity assessment — Requirements for the operation of various types of bodies performing inspection. This standard specifies the requirements for the competence and impartiality of the entities (i.e. verifiers, sometimes also referred to as verification bodies) performing ETV;
- ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories. This standard defines the quality requirements of test data used to verify the performance of an environmental technology as a part of the technical requirements.

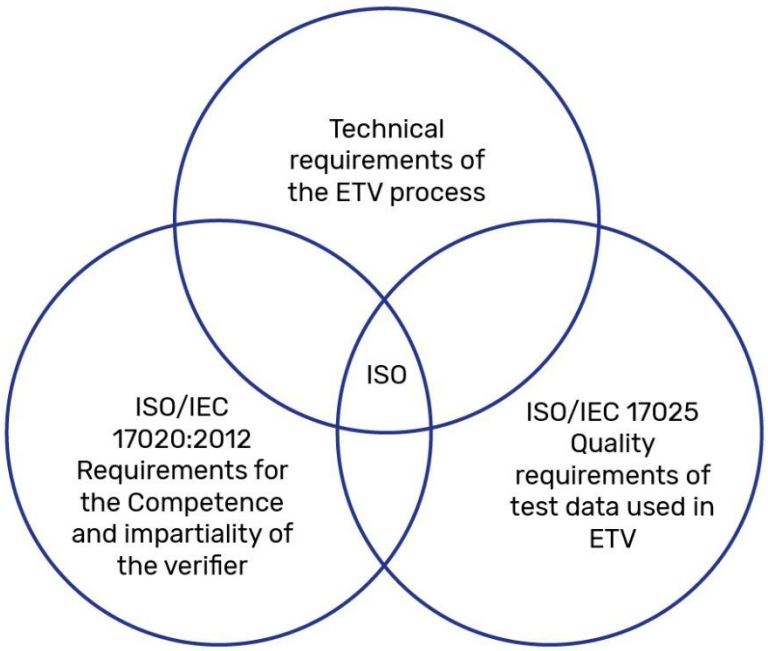

Figure 1. Overview of the ETV standardisation framework

In order to perform ETV in accordance to ISO 14034 requirements, the verifiers shall demonstrate compliance to the requirements of the International Standard ISO/IEC 17020:2012, Conformity assessment — Requirements for the operation of various types of bodies performing inspection for type A inspection body.

2. Scope and content of this Primer

This primer provides key information essential for the management and technical staff of an entity to consider when seeking to become a verifier to perform ETV compliant to the International Standard ISO 14034:2016. It focuses on some aspects specific to ETV as an inspection scheme and their implications for the organisation and operation of verifiers relevant to meet the accreditation requirements provided in ISO/IEC 1720:2016.

This primer covers:

- Management requirements
- Operational requirements
- Practical example/ case of a verifier quality management system documentation

This primer is not a substitute of the ISO 17020:2012 or ISO 14034 standard. It is neither intended to specify the accreditation requirements to ISO/IEC 17020:2012 for inspection bodies type A nor subtract from or modify the provisions of this standard, but only further explain and detail these provisions and requirements which are specific to the accreditation of ETV verifiers. The primer also supplements the information provided in ILAC document ILAC-P15:05/2020 Application of ISO/IEC 17020:2012 for the potential verifiers and clarifies some of the provisions and requirements of ISO 14034 for conducting the environmental technology verification process, particularly those that may not seem entirely clear.

The primer also does not provide documents or templates such as templates of quality manuals, operating procedures, working instructions, forms including templates of application form, verification plan, verification report and statement of verification.

3. Authorship

This document has been prepared in the framework of the LIFEproETV project by the following beneficiaries: the Institute for Ecology of Industrial Areas, Poland and ETA Danmark A/S, Denmark who are accredited ETV verifiers. It has been consulted with the members of EA Inspection Bodies Committee and RINA, Italy who is also an accredited ETV verifier and the Slovenian Institute of Civil Engineering (ZAG).

Organisations wishing to use this document or its parts must contain a statement acknowledging the LIFEproETV project and the mentioned beneficiaries' authorship of the document.

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4. Terminology

For the purposes of this document the terms and definitions given in ISO 14034 and ISO/IEC 17020:2012 and ISO/IEC 17011:2017 apply.

5. Understanding ETV in the context of ISO/IEC 17020:2012

It is essential that the entity seeking accreditation gets acquainted with this relationship between ISO/IEC 17020:2012 and ISO 14034:2016 to properly understand the context for accreditation. This section presents some general aspects of this relation.

Annex 1 to ISO 14034:2016 highlights key aspects between this standard and ISO/IEC 17020:2012 and this standards and explains the relationship between them (Table 1).

Table 1 - Key items of correspondence between ISO/IEC 17020:2012 and this document (source: ISO 14034:2016)

Clauses in ISO/IEC 17020:2012	Implications for this document
1 Scope	ISO/IEC 17020 applies to all activities performed in accordance with this document throughout the environmental technology verification
3.1 inspection examination of a product, process, service, or installation or their design and determination of its conformity with specific requirements or, on the basis of professional judgment, with general requirements	Although ISO/IEC 17020 refers to organizations performing inspection, it can be applied to organizations performing verification as described in this document. See definition of "verification" (3.2.1).
3.5 inspection body body that performs inspection	As defined in this document, verifiers can apply the ISO/IEC 17020 definition for inspection bodies. ISO/IEC 17020 refers to requirements for the operation of various types of bodies performing inspection, which, in this case, means verifiers. See definition of "verifier" (3.1.2).
3.6 inspection system rules, procedures, and management for carrying out inspection	In the context of ETV, this document can be considered an inspection system.
3.7 inspection scheme inspection system to which the same specified requirements, specific rules and procedures apply. NOTE 1 Inspection schemes can be operated at international, regional, national or sub-national level. NOTE 2 Schemes are sometimes also referred to as programmes. NOTE 3 Adapted from ISO/IEC 17000:2004, 2.8.	In the context of this document, ETV programmes, typically operating at a regional, national or international level, can be considered as an inspection scheme in accordance with ISO/IEC 17020.
4.1 Impartiality and independence	In the context of ETV, it is essential that activities performed by the verifier in accordance with this document are performed in an impartial and independent manner, in accordance with ISO/IEC 17020:2012, 4.1.
4.1.6 The inspection body shall be independent to the extent that is required with regard to the conditions under which it performs its services. Depending on these conditions, it shall meet the minimum requirements stipulated in Annex A, as outlined below. a) An inspection body providing third-party inspections shall meet the type A requirements of Clause A.1 (third-party inspection body).	For the purpose of Environmental technology verification, third-party verification, as defined in the requirements of ISO/IEC 17020:2012, Clause A.1 (Type A, inspection bodies), is recommended.
4.2 Confidentiality 4.2.1 The inspection body shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of inspection	The verifier needs to maintain the confidentiality of information as agreed with the applicant, including publication (see subclause 5.6.1 of this document) of verification report and statement.

Clauses in ISO/IEC 17020:2012	Implications for this document
activities. The inspection body shall inform the client, in advance, of the information it intends to place in the public domain. Except for information that the client makes publicly available, or when agreed between the inspection body and the client (e.g. for the purpose of responding to complaints), all other information is considered proprietary information and shall be regarded as confidential. NOTE Legally enforceable commitments can be, for example, contractual agreements. **4.2.2** When the inspection body is required by law or authorized by contractual commitments to release confidential information, the client or individual concerned shall, unless prohibited by law, be notified of the information provided. **4.2.3** Information about the client obtained from sources other than the client (e.g. complainant, regulators) shall be treated as confidential.	The verifier might be required to share confidential information with other organizations participating in environmental technology verification, in which case this clause applies.
5.1 Administrative requirements	The verifier is required to meet all requirements outlined in ISO/IEC 17020:2012, 5.1.
5.2.2 The inspection body shall be organized and managed so as to enable it to maintain the capability to perform its inspection activities. NOTE Inspection schemes can require that the inspection body participates in the exchange of technical experience with other inspection bodies in order to maintain this capability.	The verifier is required to meet all requirements outlined in ISO/IEC 17020:2012, 5.2. To maintain its capability of performing environmental technology verification, the verifier might be required to participate in the exchange of technical experience referred to in the note of this clause, including professional development and training activities. Such activities shall be documented in support of ISO/IEC 17020:2012, 5.1.3. (This is also true for ISO/IEC 17020:2012, 5.2.5 and 5.2.6.)
5.2.4 Where the inspection body forms a part of a legal entity performing other activities, the relationship between these other activities and inspection activities shall be defined.	The verifier and test body should be separate to ensure impartiality. It is possible however for the verifier and test body to be part of the same organization (legal entity) but the two entities need to demonstrate separation and impartiality.
6 Resource requirements	In the context of environmental technology verification, the human resources identified in ISO/IEC 17020:2012, Clause 6, are related to the verifier and other parties being subcontracted as per the verification process.
6.3 Subcontracting **6.3.1** The inspection body shall itself normally perform the inspections that it contracts to undertake. Where an inspection body subcontracts any part of the inspection, it shall ensure and be able to demonstrate that the subcontractor is competent to perform the activities in question and, where applicable,	When performing the environmental technology verification of environmental technology verification requires an activity to be performed by and subcontracted to parties other than the verifier, this is considered as subcontracting, as provided in this clause.

Clauses in ISO/IEC 17020:2012	Implications for this document
complies with the relevant requirements stipulated in this International Standard or in other relevant conformity assessment standards.	This also means that the verifier would be responsible for assuring the quality of the work submitted and performed by another party.
7 Process requirements	In the context of environmental technology verification, ISO/IEC 17020:2012, Clause 7, provides key information on the procedures defined in Clause 5 of this document, as well as mandatory part of the reporting.
7.1.1 The inspection body shall use the methods and procedures for inspection which are defined in the requirements against which inspection is to be performed. Where these are not defined, the inspection body shall develop specific methods and procedures to be used (see 7.1.3). The inspection body shall inform the client if the inspection method proposed by the client is considered to be inappropriate. NOTE The requirements against which the inspection is performed are normally specified in regulations, standards or specifications, inspection schemes or contracts. Specifications can include client or in-house requirements.	For the purposes of environmental technology verification, the overall requirements of this document, and, where applicable, additional requirements related to specific technologies being verified, could be considered as methods and procedures referenced to in ISO/IEC 17020:2012, 7.1.1.
7.1.2 The inspection body shall have and shall use adequate documented instructions on inspection planning and on sampling and inspection techniques, where the absence of such instructions could jeopardize the effectiveness of the inspection process. Where applicable, the inspection body shall have sufficient knowledge of statistical techniques to ensure statistically sound sampling procedures and the correct processing and interpretation of results.	This clause defines the requirements for the verification plan that include statistical and other methods that define the data-quality requirements. ISO/IEC 17020:2012, 7.1.2, applies particularly to subclauses 5.3 (Pre-verification) and 5.4 (Verification) of this document.
7.1.3 When the inspection body has to use inspection methods or procedures which are non-standard, such methods and procedures shall be appropriate and fully documented. NOTE A standard inspection method is one that has been published, for example, in international, regional or national standards, or by reputable technical organizations or by cooperation of several inspection bodies or in relevant scientific text or journals. This means that methods developed by any other means, including by the inspection body itself or by the client, are considered to be non-standard methods.	The verification requirements in this document should be considered as a standard inspection procedure, as referenced in the note to this clause. ISO/IEC 17020:2012, 7.1.3, generally applies to Clause 5 of this document.
7.1.6 When the inspection body uses information supplied by any other party as part of the inspection process, it shall verify the integrity of such information.	This requirement includes data submitted by a test body and ensures that the test body meets the requirements of ISO/IEC 17025.

Clauses in ISO/IEC 17020:2012	Implications for this document
	This also applies to sub-contracting by the verifier in accordance with ISO/IEC 17020:2012, 6.3.
7.4 Inspection reports and inspection certificates 7.4.2 Any inspection report/certificate shall include all of the following: identification of the issuing body; unique identification and date of issue; date(s) of inspection; identification of the item(s) inspected; signature or other indication of approval, by authorized personnel; a statement of conformity where applicable; the inspection results, except where detailed in accordance with 7.4.3.	The requirements for the content of the verification report and statement, as outlined in subclause 5.5 of this document, include the minimum requirements identified in ISO/IEC 17020:2012, 7.4.2. NOTE For the purposes of this document, the verification statement is the equivalent of the inspection certificate and the verification report is the equivalent of the inspection report.
7.4.3 An inspection body shall issue an inspection certificate that does not include the inspection results [see 7.4.2 g)] only when the inspection body can also produce an inspection report containing the inspection results, and when both the inspection certificate and inspection report are traceable to each other.	The verification statement should include a summary of the verification results, as provided in subclause 5.5 of this document, the full results being included in the verification report in accordance with this clause.
7.5 Complaints and appeals 7.6 Complaints and appeals process	Any complaints and appeals in accordance with this document should encompass the requirements identified in ISO/IEC 17020:2012, 7.5 and 7.6.
8 Management system requirements	In the context of ETV, activities performed by any party in accordance with this document should follow the management system requirements described in ISO/IEC 17020:2012, Clause 8.

In the introduction of ISO 17020:2012, it is explained that this International Standard covers the activities of inspection bodies whose work can include the examination of materials, products, installations, plants, processes, work procedures or services, and the determination of their conformity with requirements and the subsequent reporting of results of these activities to clients and, when required, to authorities.

In the meaning of ISO 14034, these activities cover the examination of environmental technologies to verify their performance declared by technology providers, manufacturers developers and other parties legally authorised by them to apply for ETV. The conformity with the requirements shall be understood as the verification of an environmental technology performance declared by the applicants.

Moreover, the introduction states that inspection can concern all stages during the lifetime of these items, including the design stage. Such work normally requires the exercise of professional judgement in performing inspection, in particular when assessing conformity with general requirements. In the meaning of ISO 14034, ETV involves the assessment of the conformity of technology design with the performance claim and therefore requires professional judgment. This is achieved by verification of parameters that are related to the performance of a technology and its environmental added value. These parameters must be quantifiable and measurable through testing. The environmental added value is considered from a life-cycle perspective, i.e. taking into account the main benefits and impacts during the life cycle of the technology, but with a simplified approach.

Furthermore, the introduction also states that inspection activities can overlap with testing and certification activities where these activities have common characteristics. However, an important difference is that many types of inspection involve professional judgment to determine acceptability

against general requirements, for which reason the inspection body needs the necessary competence to perform the task. In the meaning of ISO 14034, and as indicated above, verification of performance of an environmental technology is based on the interpretation and assessment of test data based on professional judgment. The verifier shall not perform any testing activities. The testing activities which serve to generate the test data for the need to verify the performance of an environmental technology shall be performed by test bodies independent from the verifier compliant to the requirements of ISO/IEC 17025. Therefore, the verifier shall demonstrate the competencies to perform interpretation and assessment of such test data, including quality aspects, relevant to verify the performance of an environmental technology not in the testing itself.

Also, the environmental technologies which performance is to be verified under ETV may differ a lot in terms of technology type, intended application and performance parameters and each of them requires an individual verification approach. Clause 4.1 of ISO 14034 defines the principles of ETV, including flexibility (Clause 4.1.5): To maximize the utility of results, environmental technology verification allows for flexibility in the specification of the performance parameters and test methods. This is achieved through a dialogue between the applicant and the verifier.

The flexibility principle and the innovation-oriented approach of ISO 14034 creates accreditation challenges for both verifiers. These challenges refer in particular to understanding the provisions and requirements specified in ISO 17020:2012: Clause 3 Terms and definitions, Clause 5 Structural requirements, Clause 6 Resource requirement, Clause 7 Process requirements when applying ISO 14034.

6. THE ROLE OF THE VERIFIER IN THE VERIFICATION PROCESS COMPLIANT TO ISO 14034

Besides the context and specificity of using ISO 14034 as an inspection scheme in the meaning of ISO/IEC 17020:2012, the entity should also get an understanding on its roles, tasks and responsibilities in the verification process in order to define appropriate inspection methods, procedures and other relevant documentation. This section provides general information of the roles and responsibilities of the verifier in the verification process

The diagram below (Fig.2) presents an overview of the roles of the applicant, verifier and test body throughout the ETV process.

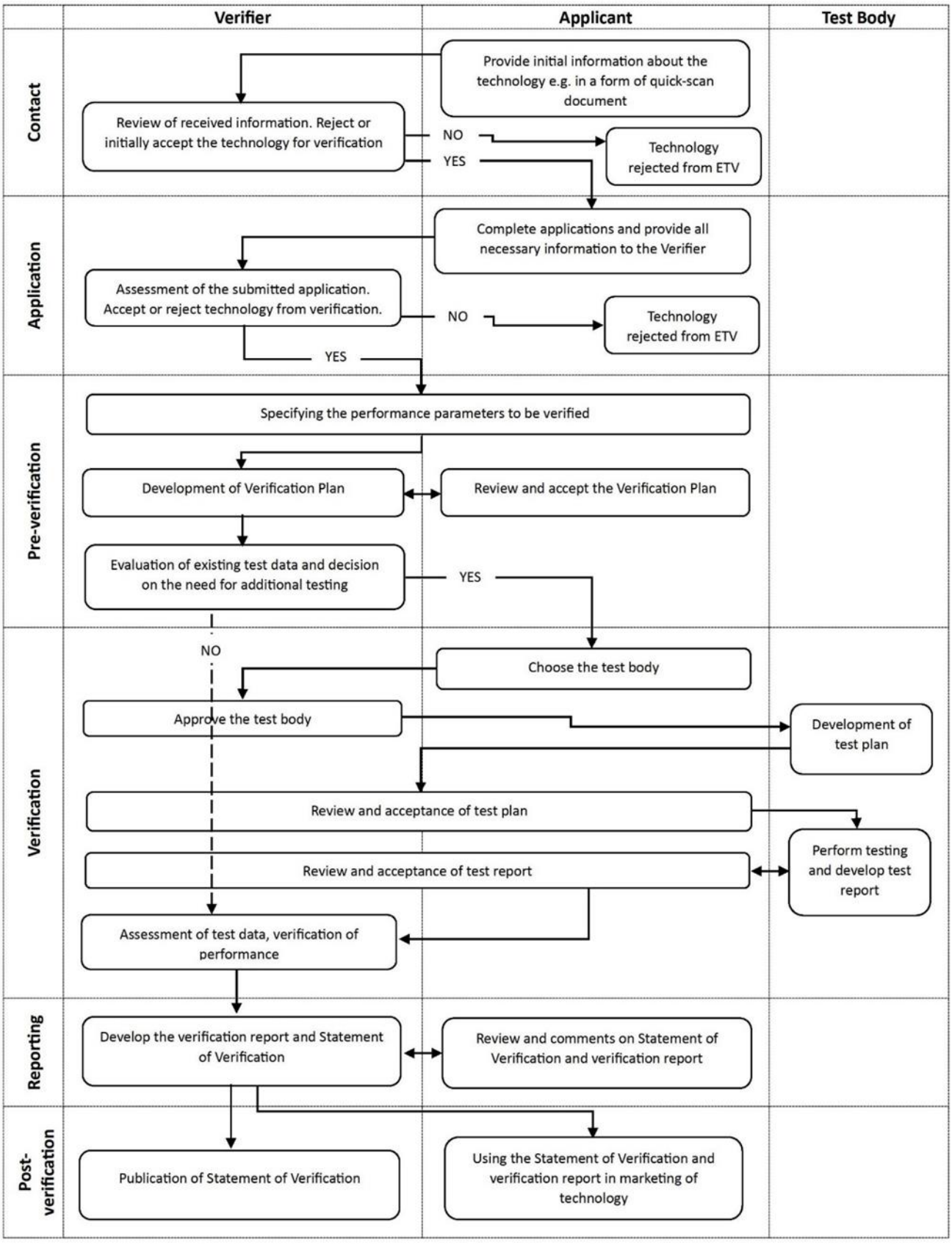


Figure 2. Overview of the roles of: ETV applicant, verifier and test body in the steps of the ETV process.

The following roles and responsibilities of the verifier should be reflected in the operational procedures of the verifier pertaining to ISO 14034:

CONTACT

At the contact step (optional) the verifier is responsible for:

- ensuring that the information provided by the applicant is sufficient, relevant and adequate to:

    - make an initial check if the technology is potentially eligible for ETV;
    - understand of the applicant's expectations concerning the verification;
    - make decision about the ability and competencies to perform the requested verification (e.g. if the technology falls in the scope of accreditation of the Verification Body);
- providing feedback to the applicant on whether a technology considered to be proposed for verification potentially meets ETV application requirements;
- providing recommendations relevant to meet formal and technical requirements of the ETV application including technology description, definition of the performance claim and additional testing needs.
- Inform the applicant about verification expenses.

APPLICATION

At the application stage, the verifier is responsible for:

- entering into a contractual arrangement with the applicant ensuring that the confidentiality aspects are properly addressed;
- providing guidance on the development of the application within the limits of impartiality;
- performing a formal review of the application to check the completeness of the information provided by the applicant;
- performing a technical review of the application in order to decide about the eligibility of the presented technology for ETV, and in particular:
    - if the technology fulfils the definition of environmental technology;
    - the proposed performance claim for the intended application of the technology addresses the needs of the interested parties;
    - the information on the technology is sufficient to review the performance claim. This includes an indicative assessment of the applicability of the existing test data provided by the Applicant to substantiate the claimed performance;
- communicate to the applicant:
    - any issues resulting from the formal and technical review of the application including requests for additional clarification or providing additional information;
    - the decision on acceptance or rejection of the technology for verification with due justification.

PRE-VERIFICATION

At the pre-verification stage, the verifier is responsible for:

- defining the final set of parameters to be verified in consensus with the applicant that is relevant and sufficient for the verification of the claimed performance of the technology, and its environmental added value, if applicable, including their numerical values and ranges, conditions, assumptions and limitations and test methods, prior to the development of the verification plan;
- agreeing on the additional parameters pertaining to the technology and its performance relevant for interested parties that will not be verified but included in the verification plan, report and Statement of Verification at the responsibility of the applicant;
- development of the verification plan and presenting it for approval to the applicant.

VERIFICATION

At the verification stage, the verifier is responsible for:

- assessing the test data provided by the applicant that were generated prior to verification and deciding on their acceptance for the verification of performance claim;

- communicating the assessment result to the applicant together with the need of performing additional testing, if relevant;
- if additional testing is needed:
  - approval of the test body;
  - approval of the test plan;
  - performing the test system assessment to ensure test data quality;
  - approval of the test report;
- assessment of the test data against the performance specified in the verification plan and confirmation of the achieved performance.

REPORTING

At the reporting stage, the verifier is responsible for:

- development of a verification report presenting the verification activities and the confirmed performance;
- development of a Statement of Verification summarising the verification activities and the confirmed performance;
- presenting the verification report and Statement of Verification for review and comments to the applicant;
- considering the applicant's comments as deemed appropriate.

POST-VERIFICATION

At the post-verification stage, the verifier is responsible for:

- publishing at a minimum the Statement of Verification in a publicly available domain (e.g. verifier's website);
- if a notification has been provided by the applicant about the change in the conditions as per technology verification:
  - determine the impact of these changes on the verified performance of the technology to the verification conditions;
  - decide about the validity of the Statement of verification and verification report;
  - communicate the decision to the Applicant.

7. GENERAL QUALIFICATION REQUIREMENTS OF THE VERIFIER

To become a verifier i.e. a body performing verification compliant to ISO 14034, the entity shall:

1. be established under national law and have legal personality;
2. be considered an inspection body type A within the meaning of ISO/IEC 17020 by means of accreditation. The accreditation shall be granted by National Accreditation Bodies (NABs) established under national law. In the case of the EU Member States, the NABs shall be established under national law in application of Regulation (EC) No765/2008. The NABs shall comply with the requirements of ISO/IEC 17011 and hold signatory status in the Multilateral Agreement for accreditation of inspection bodies to ISO/IEC 17020;

NOTE 1: It is essential that the National Accreditation Body has an accreditation scheme in place to grant accreditation to an entity to perform ETV compliant to ISO 14034.

NOTE 2: The accreditation by NAB should be granted before any verification process is started and accomplished.

3. the standard ISO 14034 shall be part of the documentation describing its inspection activities;

4. define the technical scope of the inspection activities minimum at the level of technology area, or a specific technology groups/ types (see section 12 Explanations concerning the scope of accreditation/activity scope of the verifier);
5. not be involved in the design, manufacture or construction, sale, installation, use or maintenance of the specific environmental technology applying for verification to the entity concerned, or represent the parties involved in such activities;
6. have a complete documentation describing its functions with an indication of the scope of its activities;
7. guarantee the confidentiality of the information obtained in the course of its inspection activities;
8. be organised in a way enabling it to maintain its capacity to carry out its activities at all times;
9. if performing other services (e.g. certification, testing), clearly define the interrelationship between verification and these services;
10. employ on a permanent basis a technical manager (by whatever name this position is called), who is suitably qualified and experienced and who assumes overall responsibility for carrying out inspection activities. The qualifications should include a proof of competence pertaining to ISO/IEC 17020:2012 (for example a completed training course with a certificate), a proof of competence pertaining to ISO/IEC 17025 (for example a completed training course including also internal audit skills with a certificate) relevant for assessment of test data quality, a proof of competence in ISO 14034.
11. describe all staff categories affecting the quality of inspection services including requirements concerning education, training, technical knowledge and experience,
12. have an effective, fully documented quality system appropriate to the type, scope and volume of work performed;
13. have a sufficient number of staff whose range of skills enables them to carry out their normal activities;
14. have a description of the procedures by which it carries out its verifications, ensuring clarity and reproducibility of those procedures;
15. have adequate procedures for reviewing and recording the results of verification activities;
16. have adequate insurance to cover liability for verification activities.

8. BEFORE APPLYING FOR ACCREDITATION

These 4 key steps that must be taken by the entity seeking accreditation to become a verifier in the meaning of ISO 14034. They are presented below

Step 1 Contact with NAB

Before applying for accreditation, the entity shall contact the National Accreditation Body if a relevant accreditation scheme pertaining to ISO 14034 is available or needs to be developed first. While most of the National Accreditation Bodies offers accreditations for compliance to ISO/IEC 17020, a scheme dedicated specifically to ISO 14034 may not be available at hand. Therefore, an initial contact with the relevant NAB is essential.

Step 2 Gather and consult relevant reference documents

Entities seeking accreditation shall obligatorily consult the following key documents:

- ISO 14034: 2016, Environmental management: Environmental Technology Verification. This standard serves as the main technical reference for ETV. It defines the principles, process and procedures and requirements of the ETV process. It also specifies the following two standards to be applied when performing ETV as a framework ensuring quality and impartiality of the ETV process;
- ISO/IEC 17020:2012, Conformity assessment — Requirements for the operation of various types of bodies performing inspection. This standard specifies the requirements for the competence and impartiality of the entities (i.e. verifiers, sometimes also referred to as verification bodies) performing ETV;
- ILAC P15:05/2020 Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies
- Any other documents issued by relevant NAB that complements the aforementioned ILAC document.

Additional information/guidance material helping understand ETV is provided by:

- the General Verification Protocol v.1.3 of the EU Environmental Technology Verification Programme (EU ETV) and related guidance documents developed by the Technical Working Groups established under this programme, however with this reservation that these documents are not binding in any way and may serve for informative purposes only as the EU ETV Programme is no longer effective.
- an ETV-specific guidance concerning accreditation of ETV verifiers provided by the LIFEproETV project.

Step 3 Develop application file

Besides the application documentation related to the formal requirements of the accreditation application specified by NABS including a contractual arrangement, the core part of the application file is a completely documented quality and management system of the verifier including such documents as for example quality manual, procedures, forms and where applicable, work instructions or guidance documents, etc.

The guiding standard for the development of the system documentation shall be based on the requirements of ISO/IEC 17020:2012, with further specifications concerning type A inspection bodies provided therein.

There are four main clauses in ISO/IEC 17020:2012 which specify the key requirements that the verifier shall satisfy:

- General requirements (Clause 4)
- Structural requirements (Clause 5)
- Resource requirements (Clause 6)
- Process requirements (Clause 7)
- Management requirements (Clause 8)

Annex 1 of ISO/IEC 17020:2012 details further the requirements for independence requirements for verifiers including these referring to inspection body type A which a verifier performing ETV compliant to ISO 14034 must satisfy.

ISO/IEC 17020:2012 Clauses 4,5,6 and 8 refer to the impartiality, organisation of the verifiers and its effectiveness, resources needed, the staff and its competencies, reporting and the overall management of the verifier.

Clause 7 addresses the operational aspects related to the performance of ETV. These requirements shall be provided based on the verification process and procedures specified in ISO 14034 and more specifically on ISO 14034 Clause 5 and its sub-clauses Application (Sub-clause 5.2), Pre-verification (Sub-clause 5.3), Verification (Sub-clause 5.4), Verification (Sub-clause 5.5), Post-verification (Sub-clause 5.6).

ISO/IEC 17025 shall be referred to in the procedures pertaining to Verification (Sub-clause 5.4).

Each system and the supporting documentation basically consist of 2 sets of procedures and related documents:

- set 1: procedures and documentation resulting from ISO /IEC 17020: 2012 requirements (Clauses 4, 5,6,8)
- set 2: procedures and documentation describing the inspection methods which shall comply with ISO 14034

Depending on whether the accreditation scope addresses a very specific type or group of environmental technologies e.g. 3rd generation biofuels or is defined in a broader way e.g. water and wastewater treatment technologies, the entity may organise its system either with a set of operational procedures applying to all groups of technologies/ technology areas that the accreditation is sought (Fig. 3). The later may apply especially to these entities who consider a high level of specialisation of their inspection activities.

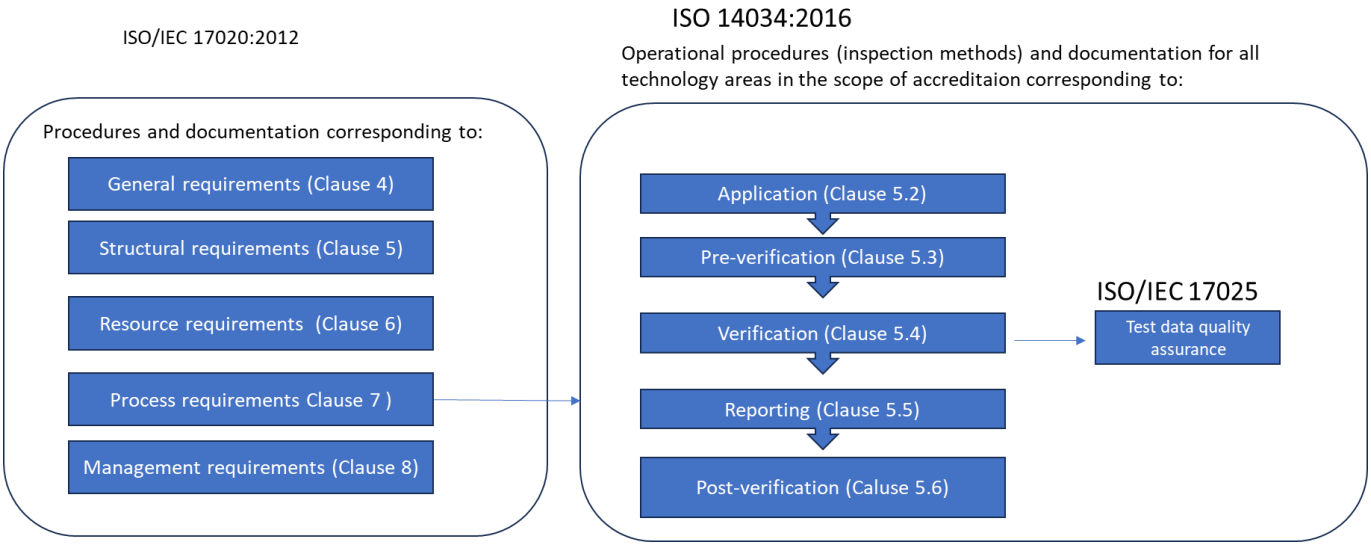


Figure 3. Procedures organisation

Step 3 Ensure sufficient and competent human resources

The entity should build a team of experts constituting the human resources of the verifier following the requirements of Sub-clause 6.1 of ISO 17020:2012. To build the team qualification requirements, the entity shall define the qualification requirements.

The team may be based on permanent personnel and external personnel, but at a minimum the personnel responsible for management, including technical management and quality assurance should be permanent.

External personnel may include for example technical experts (inspectors) with adequate, sufficient and proven qualifications and competencies including expertise in technology areas/types/groups corresponding with the accreditation scope to perform ETV compliant to ISO 14034.

Establishing such resources may require the organisation of /participation in training courses prior to application for accreditation as a basis for personnel qualification.

Step 4 Perform an internal audit

Prior to submitting the accreditation application file, the entity should perform an internal audit to assess the competence of your organization's quality and management system as well as overall performance of the planned arrangements. The purpose of this audit should be to ensure that the entity complies to the requirements of ISO/IEC 17020:2012 and ISO 14034 requirements in terms of competences and identify areas where improvements are still needed.

The internal audit should cover system audit and process audit. The system audit should focus on the entity's management system as a whole, and compare the planning activities and ISO/IEC 17020:2012 type A inspection body system requirements to ensure that each clause or requirement specified in Clauses 4-8 has been implemented. The process audit should verify if the processes of the management system and the operational procedures resulting from ISO 14034 are performing and producing in accordance with desired outcomes (see also roles and responsibilities of the verifier) and identify any opportunities for improvement and possible corrective actions before applying for accreditation.

The results of the audit should be documented as it is subject for inspection of the NAB.

9. APPLICATION OF ISO/IEC 17020:2012 TO ISO 14034

The International Standard ISO/IEC 17020:2012 together with ILAC guidance ILAC P15:05/2020 provide the generic framework for developing and documenting a system based on which the entity is to manage and operate its processes while ensuring impartiality and competence. There are however certain aspects that are specific to ISO 14034 which require additional explanation in order to be considered to in the verifier's system.

This section provides explanations to the selected Clauses and/or sub-clauses of ISO 17020:2012 concerning their application to ISO 14034.

Clause 4: General requirements

Sub-clause 4.1 Impartiality and independence

Point 4.1.6 of ISO 17020:2012 states that the inspection body shall be independent to the extent that is required with regard to the conditions under which it performs its services. ETV process and procedures as defined in ISO 14034 are designed as third-party verification of performance of environmental technologies. To ensure this condition, Annex A (informative) to ISO 14034 states that for the purpose of performing ETV, it is recommended that the verifier complies to the requirements defined in ISO/IEC 17020:2012, Clause A.1 (Type A, inspection bodies). It means, that unless compliance to the ISO/IEC 17020:2012 requirements for type A inspection bodies is demonstrated by means of accreditation by a relevant National Accreditation Body, the verifier shall not perform ETV.

For accreditation application it implies that the assessment of the competences and the processes of the entity is based on the analysis of the system documentation rather than a performed environmental technology verification process as this will not be possible unless the entity gets accredited.

Clause 5: Structural requirements

Sub-clause 5.2 Organisation and management

Point 5.2.4 of ISO 17020:12 refers to defining the other activities then inspection of the legal entity to which belongs inspection body and the relationship between these other activities and inspection to prove the impartiality and lack of interest of the inspection body.

In practice, entities seeking accreditation to become ETV verifiers may perform also other activities related to testing, certification or performing research and development activities. In any of these cases the absence of conflict of interest and independence must be demonstrated. It refers both to the organisation units of the entity performing these activities as well as the personnel.

The entity should provide a mechanism in the management system for an in-depth of analysis of the relations of these activities and the planned inspection activity including identification of general risks for impartiality resulting from performance of other activities as well as per each case of technology verification.

Point 5.2.5 of ISO 17020:12 refers to the technical competences of technical managers in the inspection body. It specifies that the technical manager should have overall responsibility to ensure that the inspection activities are carried out in accordance with this International Standard. In the case of the verifier, this requirement refers to the technical competence of the manager to ensure an overall responsibility that ETV is performed in accordance to the requirements of ISO 14034.

Since the planned verifier's inspection activity (scope of accreditation) may cover verification of performance of a broad range of technologies i.e. products, processes or services categorised as environmental technologies in the meaning of ISO 14034. Therefore, the technical manager should primarily demonstrate technical competence in the overall organisation and implementation of a verification process in line with ISO 14034 requirements allowing for the selection, involvement and coordination of work of inspectors with expertise relevant and adequate to specific technologies which

performance is subject to verification. The process for selection of inspectors together with their competence requirements should be defined and documented as a procedure for personnel management.

Point 5.2.6 require that the inspection body shall have one or more named person who will deputize in the absence of any technical manager responsible for ongoing inspection activities. The deputy technical manager may also be a person from the verifier's external personnel who demonstrates competence in ETV process required for the technical manager. The rules for nomination of the deputy and required scope of competences of the deputy should be defined and documented.

Clause 6: Resource requirements

Sub-clause 6.1 Personnel

Point 6.1.5 refers to the procedures for selecting, training, formally authorizing, and monitoring inspectors and other personnel involved in inspection activities. The area of the verifier's activity can cover a broad range of environmental technologies even if their application is defined, although following the process and procedures of ISO 14034, each verification is unique. The technology and its performance to be verified determine the selection of verification personnel with specific competences. Therefore, the competence required in point 6.1.5 shall refer to ability to select, deliver ETV procedures training and authorize competent personnel to perform specific verification works to the performance claim of verified technology. The verifier should put in place an appropriate procedure for selecting verification personnel that ensure that the personnel selected to perform a specific verification are competent to perform it. The procedure for recruiting the verification personnel (who may be also external experts) shall be documented and guarantee that the personnel selected to perform a specific verification demonstrates adequate, sufficient and relevant knowledge and experience covering existing as well as emerging technical and environmental aspects concerning technologies in the area to which a specific technology to be verified belongs.

Annex 1 provides guidance on the capabilities required from a verifier to demonstrate competence to conduct verifications compliant to ISO 14034.

Point 6.1.6 (c) refers to training requirements of the inspection personnel concerning continuing training to keep pace with developing technology and inspection methods. For the needs of applying ISO 14034 this requirements should be limited to inspection methods only as it is not the verifier's role to follow the developments in the area of environmental technologies.

It is the responsibility of the verification personnel to follow the technology developments and reflect this knowledge by means of updates of proofs (projects performed, publications etc) provided to demonstrate their technical competences. The verifier shall have appropriate documented procedures for acquiring an updated information on the current competences of the inspectors.

Point 6.1.9 requires that each inspector shall be observed on-site, unless there is sufficient supporting evidence that the inspector is continuing to perform competently. This requirement has a limited application in the case of ISO 14034. Verification of performance is carried out based on the analysis of test data which typically has a form a desk study. On-site activities can include site visits or performance of a test system assessment which generated the test data for the needs of performance verification in order to make decision on the test data acceptance (Clause 5.4.2 of ISO 14034).

Sub-clause 6.2 Facilities and equipment - This sub-clause is typically not applicable for ETV verifiers.

Sub-clause 6.3 Subcontracting - There is a rather low chance that verification activities will be subcontracted to another ETV verifier and therefore this requirement may be omitted unless such an approach is clearly established.

Clause 7 Process requirements

Subclause 7.1 Inspection methods and procedures

Point 7.1.2 states that the verifier should have adequate documented instructions on control and control techniques including sufficient knowledge of statistical techniques to ensure statistically valid sampling procedures and correct processing and interpretation of results.

The verification process and the related verification procedures should be based on the requirements in ISO 14034. However, accreditation bodies may require specific working instructions for technology areas or groups for which the potential verifier seeks accreditation. These instructions are intended to support the verification of technologies belonging to these technology groups/areas. Verification instructions should include a reference to area-specific legislation if relevant.

The verifier does not perform testing of the verified technology. In some cases, however, the sampling may refer to the selection of the items for inspection for example if the verification refers to items produced in series or a new material. The operational procedure referring to pre-verification including the development of the verification plan should however include the requirements to provide specific methods to be used, including sampling, test and calculation methods, determination of uncertainty and statistical methods etc. It could be addressed for example in a work instruction for the development of a verification plan or a template of the verification plan as well as in the process documents (procedure, work instruction) related to the acceptance of the test data (see Sub-clause 5.4.2 of ISO 14034:2016).

Subclause 7.4 Inspection reports and inspection certificates

Point 7.4.2 refers to the content of the inspection reports and inspection statements. Sub-clause 5.5 of ISO 14034 specifies the minimum requirements concerning the content of the verification report and verification statement. These requirements include additional content requirements to those specified in 7.4.2. Point 7.4.2 (c) refers to the date(s) of inspection which corresponds with the date of verification (point 5.5.1 (d) in ISO 14034). The verification process is typically extended in time and can involve several months. Therefore, the requirement concerning the specification of the date(s) of inspection shall reflect this fact.

The verifier should use application submission date by the applicant as the start date of the inspection and the date of the acceptance of the verification report and statement of verification by the applicant as the end date of inspection.

Moreover, Sub-clause 5.6 of ISO 14034 requires that the statement of verification shall be made publicly available. The verifier is responsible for publication at a minimum of the statement of verification in a publicly available domain (e.g. at own web site) and therefore shall have appropriate procedures in place demonstrating compliance to this requirement.

10. CLARIFICATION ON THE APPLICATION OF SOME REQUIREMENTS OF ISO 14034

Subclause 5.2 Application

Point 5.2.1 Application requirements list all information what the applicant should provide with application for verification, that include the information on relevant alternative of the technology its relevant performance and environmental impacts. It is recommended that the comparison of the technology being sought for verification with an alternative technology for the assessment of the environmental added value should be made by the applicant in terms of the whole life cycle of the technology. The comparison should be made on a numerical basis to assess the environmental added value of the technology put forward for verification. The verifier should define the procedures that allow assessing at the application stage whether a technology has an environmental added value according to or not. On this basis, the verifier should issue a decision to recommend technology for verification, refuse

to verify or not recommend the technology for verification. These procedures can be based on the guidance presented in Annex 2.

Note 1. It is recommended that the verifier consults with the applicant prior to the application preparation and evaluation stage, with the aim of obtaining basic information on the technology from the applicant to enable the verifier to decide on the verifier's ability to enter into a verification contract. This would include determining whether the technology being considered for verification meets basic criteria such as market readiness, can be an environmental technology in the sense of the standard, the applicant has the rights to the technology and is within the scope of the verifier's accreditation.

Note 2. It is recommended that the verifier may provide technical support in the preparation of the final application. The verifier may include such tasks in the contract with the applicant.

Subclause 5.3 Pre-verification

Point 5.3.2 Verification planning describes what the verification plan should contain. Subsection (g) should include specification of the requirements for the test data such as:

- general description of the testing activities (e.g. continuous or batch testing, scale, testing methods, etc.);
- scale (i.e. laboratory / simulated environment / field) and the actual matrix used for testing, which should be the same matrix for which the verification parameters have been defined;
- parameters to be measured;
- methods to be used, including sampling, equipment requirements (e.g. type and frequency of calibration), analytical samples or standards, test and calculation methods, uncertainty determination and statistical methods;
- testing conditions;
- data management;
- quality assurance, including test system auditing where applicable;
- content of the test report.

The sample structure of the verification plan is presented in Annex 3

Note: If the technology to be verified is installed and operated in the field, the verifier should ensure that the test facility's choice of site does not involve any commercial or other interests that could affect the test results. In particular, the verifier should make sure that the field site is not dependent on the applicant. If a site dependent on the applicant is the only option available, the use of the site should be justified in the test plan and the verifier should make sure that the test body implements precautions, such as access logging, to ensure and document that the test results were not unduly influenced.

Subclause 5.4 Verification

Point 5.4.2 Acceptance of existing test data explain under what conditions the data which were generated prior verification can be accepted. In addition to listed conditions the acceptance of existing test data should be accompanied with the test plan and test report which comply with verification plan. The verifier should have appropriate procedures in place to evaluate existing test data against the parameter requirements, methods, quality and target values set for the verification. The preparation of procedures for the evaluation and possible acceptance of existing test data can be based on the guidance presented in Annex 4.

Note: In some cases, existing test data developed by the test body may have been generated for conditions other than those specified in the claim. In this case, the performance claim may be modified by the applicant in consultation with the verifier to match the existing data, in which case additional testing may not be needed

Point 5.4.3 Generation of additional test data. The test plan(s) based on the verification plan must be prepared by the test body prior testing and approved by both the verifier and the applicant. The verifier should have in place the procedures for onsite auditing of technology testing and test system of the test body. The verifier should be competent in this regards. The preparation of procedures for auditing test bodies can be based on the guidelines presented in Annex 5.

Point 5.4.4 Confirmation of performance. In some cases, the technology performance achieved, as verified using the test data qualified to be used for verification, may not match the performance originally anticipated by the applicant in the performance claim provided in the application. In such a case, the actually achieved performance should be considered the verified performance and be confirmed and documented by the verifier.

11. EXPLANATIONS CONCERNING THE SCOPE OF ACCREDITATION/ACTIVITY SCOPE OF THE VERIFIER

ISO 14034 applies to any technology which complies to the definition of an environmental technology as indicated above and in particular to new, often disruptive technical solutions.

The entity may define the accreditation scope broadly to cover a variety or selected technology areas or in a very specific way choosing a concrete type of technology e.g. nanofiltration systems.

In any case however, when defining the accreditation scope, the entity should maintain a balance between a certain level of flexibility allowing new environmental technologies related to specific fields of application to be verified while ensuring that:

- it is sufficiently precise that potential clients may establish accurately and unambiguously the general field of inspection, it's type and range,
- the flexibility does not significantly change the competences, skills, resources and methodologies required for the inspection activity.

At a minimum the scope of accreditation shall define the area of environmental technologies application. The areas of environmental technology applications may be defined as follows:

- water,
- materials, waste and resources
- energy
- soil and groundwater
- cleaner production and processes
- agriculture
- air

The proposed scope of accreditation should be extensively discussed with NAB relevant to grant accreditation as it determines on the one hand the technical competences (especially personnel requirements) that the entity applying for accreditation shall demonstrate while on the other the need for the NAB to tailor the accreditation scheme including also technical assessors competent for the technology area/type.

12. PRACTICAL EXAMPLE OF VERIFIER'S QUALITY MANAGEMENT SYSTEM (QMS)

This section presents some practical examples of a quality management system (QMS) that an entity seeking accreditation to become ETV verifier may consider when developing own system.

The presented case study of a verifier's QMS system is not aimed to serve as a demonstration of satisfying the requirements of ISO/IEC 17020:2012 but only to showcase the elements of such system and how they could be organised.
The QMS typically includes the following 3 core elements:

- a quality manual
- procedures
- quality records

Figure 4 presents an overview of a potential QMS structure.

Figure 4. An overview of core elements of a quality management system of the verifier.

12.1. Quality manual

According to ISO/IEC 17020:2012 Clause 5.2 Organisation and management, the inspection body should have in place a documentation presenting how its quality management system is structured, organised and managed. Although a Quality Manual is not specifically indicated as an obligatory document presenting all these aspects, it is however the most practical option. The manual should combine and describe details on the key aspects required in ISO/IEC 17020:2012 Clauses 4-8 as well as aspects related to performance of verification processes resulting from ISO 14034:2016. The manual should not provide detailed description of the individual procedures but provide a general understanding how these procedures are used in the management and operation of the organisation with reference to these procedures. Example below presents an outline of the Quality Manual content.

1. GENERAL INFORMATION ABOUT ENVIRONMENTAL TECHNOLOGY VERIFIER

- Background information,
- Organisational structure of the verifier,
- Scope of activity,
- Assurance of obligations/liability.

2. QUALITY MANAGEMENT SYSTEM OVERVIEW

- Description of processes performed by the verifier, documentation and records of the quality management system including a list and reference to the procedures
- Description of the documentation supervision

- Description on how the records will be supervised

3.RESPONSIBILITIES IN THE QMS

- Commitment and engagement of the entity's management
- Reviews/Audits of the QMS
- Description on how the client's needs orientation will be addressed
- Quality policy and impartiality policy including quality objectives
- Specification responsibilities of the verifier's management staff

4. RESOURCE MANAGEMENT

- Description of how resources adequate to the performance of the verifiers activities will be ensured
- Description of human resources including staff qualifications, roles and responsibilities of the staff members, staff training
- Description of the infrastructure and equipment of the verifier to be used in the activities
- Description how an adequate work environment of the verifier will be ensured

5. VERIFICATION OF ENVIRONMENTAL

- Description of the processes related to/involving the client including initial contact (technology quick scan review if applicable) application review, communication with the client, contractual arrangements, confidentiality maintenance)
- Planning of verifications (costs, timelines definition) including description of verifier's procurement and purchase processes of resources necessary to perform verification, if relevant
- Environmental Technology Verification Process:
  - How the verification process is to be supervised and by whom
  - Ownership of the applicant: how the documentation and items of inspection belonging to the client (ETV applicant) are handled
  - Description of the core technology verification process with focus on application, verification planning, verification, post verification
  - Organisation of verification staff,
  - How the evaluation of the test system generating data to verify performance of a technology is performed,
  - Assessment of the validity of the Statements of Verification,
  - Handling of complaints and appeals.

6. QUALITY CONTROL OF VERIFICATION

- Description on how the quality of the verification outputs: Verification Report and Statements of verification is ensured e.g. internal and external reviews and how the non-conformities are handled and supervised,
- Description on how the identified non-conformities are supervised and handled,

7. MONITORING AND AUDITING OF VERIFIER'S OPERATIONS

- Monitoring of the operation of the quality management system
- Review and examination of the clients (ETV applicant's) opinion
- Audits of the quality management system operation

8. IMPROVING THE QMS

- Methods of QMS improvement, planning improvement

12.2. Impartiality policy and quality policy

These are typically two short documents presenting the commitment of the top management of the entity to ensure impartiality and quality of the performed activities and their continuous improvement. The quality policy should define quality objectives.

12.3. Management procedures

These procedures should specify how the management operations of the verifier are organised and supervised in relation to ISO/IEC 17020:2012 requirements. The set of procedures and corresponding documents may include the following ones

- Control of documents
- Control of quality records
- Internal audits
- Dealing with a non-compliant product
- Corrective and preventive actions
- Management review
- Personnel organisation
- Risk management
- Handling of complaints and appeals

12.4. Operational procedures

This set of procedures should specify how the verification process compliant to ISO 14034 is implemented. The set of procedures and corresponding documents may include those presented in the table 2.

Table 2 - Examples of verification process procedures compliant to ISO 14034

Procedure	Purpose/Description
Contact with applicant	Purpose: Pre check of the eligibility of the technology for verification from the viewpoint with the verifier (compliance to the accreditation scope) the technology, initial check of the technology eligibility for ETV Procedure also compliant to ISO/IEC 17020:2015 Sub-clause 7.1.5 requirement to ensure if the work to be performed by the verifier is within its expertise and that the organization has adequate resources to meet the requirements. The procedure may be supported with an initial contact form e.g. a quick scan.
Contractual arrangements	Purpose: enter into a contractual arrangement with the applicant (a requirement also under ISO 17020). The procedure typically includes a template of the contract or at a minimum a working instruction specifying the key elements of the contract.
Application: formal and technical review	Purpose: acquire relevant and sufficient information about the technology and the ETV applicant enabling a final decision on the eligibility of a technology for verification. This procedure addresses the formal and technical review of the application. The procedure should be accompanied by

Procedure	Purpose/Description
	a template of an application form. It may also include the following working instructions related to: • Assessment of formal requirements • Assessment of the environmental added value of a technology (eligibility criterion) • Assessment of the initial performance claim relevance • Initial assessment of the applicability of the existing test data for ETV
Verification planning: specification of parameters to be verified and development of the verification plan	Purpose: specify parameters relevant to verify the performance claim to be verified and based on it develop a detailed plan of the verification, , define the quality requirements specific for the verification. The procedure typically includes a template of a verification plan and may be accompanied by the following working instructions: • Definition of parameters and their values and their numerical values for verification, • Development of a test design including quality requirements
Verification	Purpose: verify the performance claim based on test data. The procedure may be accompanied by the following working instructions • Assessment of test data compliance to verification plan requirements • test system assessment for compliance to ISO/IEC 17025 requirements
Post verification	Purpose: development of the verification report and statement of verification This procedure should include templates of verification report and statement of verification. It may also include working instruction providing more details on what and how should be described in both documents.
Assessment of the verification statement validity	Purpose: assessing, upon applicant's request, if the changes to the conditions for which the verification has been performed affect the validity of the issued statement of verification. The procedure may include a template for an application for assessing the validity of the verification statement

13. REFERENCES

ISO/IEC 17020:2012 Conformity assessment – Requirements for the operation of various types of bodies performing inspection

ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories

ISO 14034: 2016 Environmental Management: Environmental Technology Verification

Guidelines on assessing the environmental added value of an environmental technology in a lifecycle perspective at the proposal stage, Guidance document 004/2016, adopted on the 26/01/2016, Version 1.0, EU Environmental Technology Verification Pilot Programme Guidance Document.

Guidelines on the Acceptance of Existing Test Data, Guidance document 005/2016, adopted on 07/06/2016, Version 1.0, EU Environmental Technology Verification Pilot Programme Guidance Document.

Guidelines on Auditing Test Bodies, Guidance document 009/2016, adopted on 06/06/2016, Version 1.0, EU Environmental Technology Verification Pilot Programme Guidance Document.

General Verification Protocol (GVP), Version 1.3, 1st April 2018, EU Environmental Technology Verification Pilot Programme

ANNEX 1. GUIDANCE FOR DEMONSTRATING COMPETENCE OF THE VERIFIER TO CONDUCT VERIFICATIONS COMPLIANT TO ISO 14034

1. The verifier should be able to identify possible risks and benefits of innovative or non-standard technologies and translate possible risks into technical criteria to assess the behaviour and performance of the technology in relation to the applicant's performance claim.

   To be able to identify and prioritise risks associated with innovative technologies, verifiers must have the following skills or qualifications:
   - in-depth knowledge of the relevant standards, procedures and other requirements to be followed;
   - an understanding of the technological areas covered by their scope of accreditation;
   - In-depth technical knowledge of the technology being verified;
   - in-depth knowledge of specific risk areas, technical aspects of the technology and specialised scientific fields (e.g. drinking water treatment requirements);
   - knowledge of stakeholder views and measures to ensure their balanced consideration;
   - the means to consider the risks associated with the management of the overall process, the specific requirements of the verification, impartiality and quality assurance.

   This knowledge and understanding may be contained in the verifier's own organisation or, in part, in the network of external bodies that the verifier actively manages or works with in a professional manner.

2. The verifier should be able to design and validate appropriate methods (e.g. tests, simulations or calculations) to assess and verify performance, taking into account the state of the art, including justification for the selection and application of technical criteria.

   To develop appropriate methods, the verifier should:
   - have experts (directly employed or contracted) with knowledge of the technologies and their applications in the domains of the verifier's expertise;
   - have experts (directly employed or contracted) with knowledge of best practice in assessment and verification methods for such technologies and products;
   - ensure that all personnel involved in verification have an objective approach, are impartial in their professional judgement and are able to work with other verification bodies and external organisations and expert groups in a balanced, consensus-based and technically competent manner to agree on a plan that takes into account production, operational and regulatory requirements.

3. The verifier should be able to verify the performance of the technology based on the agreed methods and technical criteria and provide a concrete implementation of the results in the form of a verification statement as requested by the applicant.

   In order to carry out a technology verification, the verifier should:
   - comply with the applicable procedures and rules;
   - have an in-depth knowledge of the technology field and the conditions of use relevant to the technology being verified;
   - have experts (directly employed or contracted) with the experience to assess conformity or non-conformity with the technical criteria and regulations that apply to the technology and its use.

   Experts should have proven knowledge of:
   - processes and procedures for handling ETV applications;

- the technology and the specific technology area;
- the market and user needs for the specific technology area;
- the environmental implications of the use of the technology from a life cycle perspective;
- relevant applicable test methods;
- statistical methods to evaluate test results and calculations.

The expert's expertise can be documented through written conclusions, professional achievements and other objective evidence based on the expert's CV, publications and other relevant documentation.

4. The verifier should ensure consistency, reliability, objectivity and traceability of its work by applying appropriate governance principles.

   Verifiers should follow the procedures described in ISO 14034 and have documented management procedures to ensure:

   - Sound contract offer and review practice - ability to pursue requests from applicants, identify resources and determine time requirements leading to a contract offer to the client that clearly defines the scope of work, responsibilities of both the verifier and client and associated fees;
   - Objectivity and impartiality - having policies and procedures in place to ensure the objectivity of the verification work, ensuring independence from any special interests;
   - Document control - having a document control system to ensure that all documents relevant to the verification procedure are recorded, traceable, maintained and retained;
   - Confidentiality - having policies and procedures to ensure the protection and non-disclosure of confidential information of which the verifier or any of its partners become aware during the assessment and verification procedure;
   - -Appropriate staff qualification - having policies and procedures for the assessment and qualification of experts (continuously or on a case-by-case basis), together with the development and implementation of plans for the development/updating of experts' knowledge;
   - Appropriate validation - having policies and procedures to ensure that validation of verification and related decisions and documents is carried out by staff independent of those who carried out the testing and evaluation of the technology or product;
   - Sound internal audit and management review practice - having policies and procedures to ensure that compliance with management procedures is regularly monitored and that any non-compliance is resolved by management;
   - Notification of changes - having policies and procedures for notifying clients of changes that the verifier intends to make to assessment and verification requirements;
   - Handling appeals - having policies and procedures in place to ensure that customer appeals or complaints are dealt with in an objective manner and that records of both the appeal and any follow-up are maintained;

Quality assurance - having policies and procedures to ensure compliance with the quality requirements of ISO 17020 for the verifier and ISO 17025 for the test data.

ANNEX 2. GUIDELINES ON ASSESSING THE ENVIRONMENTAL ADDED VALUE OF AN ENVIRONMENTAL TECHNOLOGY IN A LIFE-CYCLE PERSPECTIVE AT THE APPLICATION STAGE

This guideline is based on the Guidelines on assessing the environmental added value of an environmental technology in a life-cycle perspective at the proposal stage, Version 1.0 2014, produced by the EU ETV Technical Working Groups, chaired by the JRC, under the auspices of DG Environment for the EU Environmental Technology Verification Pilot Programme.

Scope

According to the definition of innovative environmental technologies, this tool has to allow a comparative assessment with a *'relevant alternative'* so that the key environmental aspects can be identified in a simple and qualitative way.

The guidelines below will provide a "*life-cycle perspective*" approach, meaning that the assessment should focus as much as possible on a holistic view of the environmental pressures of a technology during its entire life-cycle. If results from life-cycle inventories (LCI) or assessments (LCA) are available, then they can be used but the life-cycle perspective approach used for ETV does not require any life-cycle assessments or calculations on the impact of the technology. The "life-cycle perspective" should help at least to qualitatively determine if a technology provides an environmental added-value at the cost of much higher use of consumables, energy or water, or at the cost of higher pollution in other aspects of its life-cycle, when compared to a relevant alternative.

Defining the relevant alternative

In order to determine the environmental advantages and disadvantages of each new technology according to the definitions provided in ISO14034, the Applicant needs to designate the *'relevant alternative(s)'* against which a qualitative comparison (quantitative if data is available) can be made. The Verifier can then accept the proposed relevant alternative or suggest a different one, based on its experience. If no appropriate relevant alternatives are found, the verifier can take into account the EU/country legal requirements..

It is not always an easy process to determine what the relevant alternative should be, but in principle it should be the answer to the following question:

If the applicant's technology would not be available, what would be the alternative(s)?

Below are a set of criteria that can be used by the applicant or the verifier to choose the best relevant alternative.

- The relevant alternative should perform an identical or similar function and achieve a similar end-result than the technology under verification. The technology and the relevant alternative could be:
    - Very similar technologies, e.g., a pump and a more efficient pump
    - Very different technologies, e.g., a UV water disinfection system and a sand filter
    - An association of technologies working in sequence to produce a similar ultimate function, e.g. a sorting procedure including dismantlement can be an alternative to a crusher.

    The verifier will confirm whether this alternative is appropriate, or whether a more suitable technology should be used based on existing operational technologies for the targeted market.

- The relevant alternative should refer to a technology that is both current and commercially available. It should be legal and accepted by the end-users on the specific targeted market. In some very dynamic fields, the relevant alternative could also be defined as the state of the art in that particular topic or application. However, it should be noted that if the state of the art for that field yields already a significantly high level of environmental added-value, then a comparison should be weighed with care as a lower performance could be equally acceptable and still overall positive. For example, in the case of an advanced wastewater treatment process, such as a granular activated sludge process, the choice would be between a conventional wastewater treatment process such as activated sludge, which would be the standard process, or for example choosing another system of granular sludge that would be the current state of the art.

- If the technology is a similar or improved version of something already on the market, then the relevant alternative should be the already existing version of this technology on the market unless this technology is not sufficiently widespread or accepted. For example, in the case of a new versatile LED lamp, the relevant alternative could be another type of LED lighting or fluorescent lighting (which is maybe the more widespread solution) depending on the particular application.

- If the applicant's technology is a completely new solution for a certain problem, then the relevant alternative is not using this technology at all. For example, in the case of an entirely new process for recycling a certain waste that was never previously recycled, the relevant alternative could be the disposal without recycling, such as landfill, incineration etc. The relevant alternative must also be aligned with the EU or each country's legal requirements for that particular situation.

- Preferably, the relevant alternative should be recognised as having the highest possible general level of environmental protection but also a fair market acceptance. This is to avoid making comparisons with technologies that are so innovative and so advantageous in providing an environmental added-value that the assessment does not truly reflect the advantages in comparison to what is commonly used in the market. In the case where all alternatives provide a poor level of environmental protection, then one should choose the one with the least harmful pressures. For example, if the market offers technologies that are either non-energy efficient or energy-efficient and if both are current, then the relevant alternative should be energy-efficient.

System boundaries

The tool used in these guidelines simplifies the life-cycle of the technology into 4 stages

Extraction, refining, processing, transformation and transport of natural resources (raw materials, energy)

Every aspect of all activities involved before the manufacture of the technology's equipment or products; this is likely to include the extraction, treatment, transformation and processing of natural resources (raw materials, energy) together, where appropriate, with the production of any remote components. By definition, this also includes all of the raw materials, the energy and water used and all waste or emissions released to the environment during these activities.

- **Manufacturing of parts, components, machinery and of products**

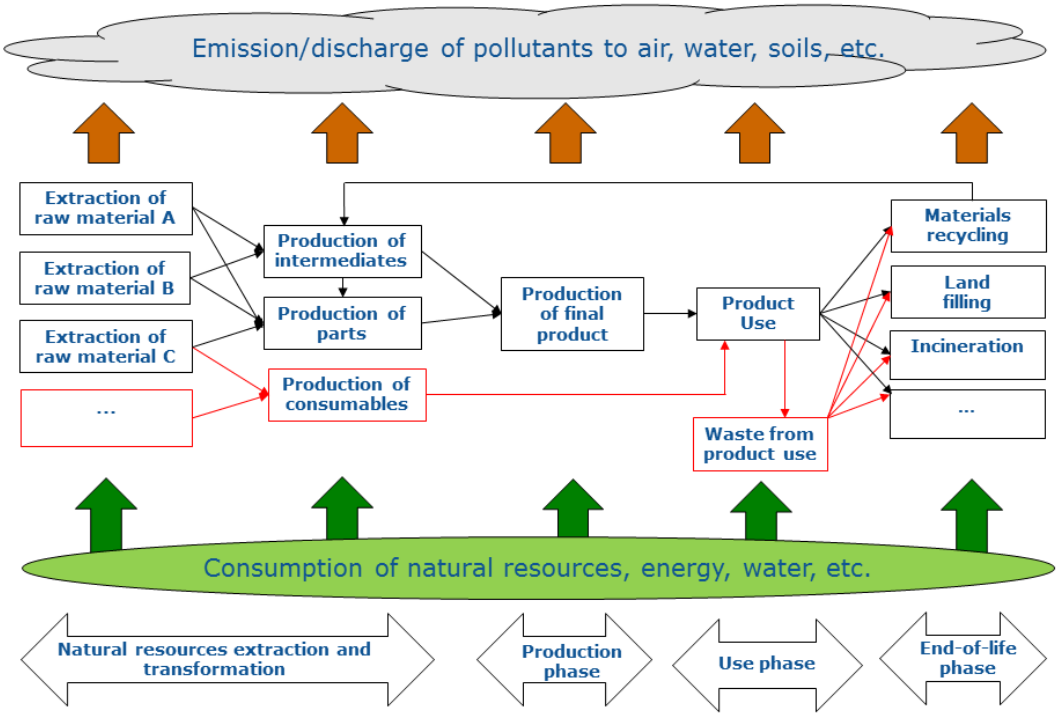
Every aspect of all activities involved in the production of the technology. In general, it is expected that this will include the production of most if not all sub-assemblies. This also includes all of the water, energy and consumables used, together with all of the emissions and all of the products and wastes. This will generally occur on production sites operated by sub-contractors or under control of the applicant

- **Use and maintenance phase of a product, a process or a service**

Every aspect of the use of and maintenance of an equipment and/or a product by the client/end-user, including consumables and where applicable their life-cycle, and all raw materials, energy and water used for its functioning, as well as all the emissions, products and waste streams.

- **End of life of an equipment or of a product**

Every aspect of all activities involved in the 'End of Life' of a product or an equipment, when it is discarded by the client/end-user, including its recycling, dismantling, reusability and/or disposal of all components. As above, this also includes all of the water, energy and consumables used, together with all types of emissions, all of the products and wastes.



Life-cycle stages of a product or a process. The elements in black picture a simple product that does not require consumables for its operation and does not generate waste. The elements in red picture a more complex situation where the product (or process) requires consumables for its operation (e.g., filters, oil) and generate waste (e.g., wasted filters, waste oil). These elements may have to be taken into consideration in a life-cycle perspective of the technology

The applicant helped or not by the VERIFIER, will then need to provide the following in the application template:

1. **Define the important phases for this technology.** For each of the above-mentioned stages, the applicant will identify if this phase is likely to present significant differences from an environmental perspective in comparison to the relevant alternative.

2. **For each important phase, provide qualitative or quantitative information for the various environmental criteria described in section 4.** In some instances the applicant may be unable to provide information for one or more of the stages. This is the case when he can justify or provide convincing evidence that:

    - the technology will lead to environmental pressures/impacts that are not significantly different than those of the relevant alternative
    - those environmental pressures/impacts are negligible compared to those of the other phases
    - the information is not available or not relevant for the considered technology

3. **Information should be available for at least the manufacturing and use phases.** It is expected that for the manufacturing and use stages the applicant will normally possess relevant information, as designer and manufacturer of the technology

The following considerations could be useful when filling the necessary information:

- **Lack of information, especially concerning raw materials, sub-assemblies and components.** It is understood that the applicant may not have access to full details of the all of the activities described in the four stages above, especially where materials or sub-assemblies are produced by others in the supply chain, and for activities involved in the 'end of life' stage (perhaps in other countries). In these cases, if specific information is not available, consideration should be given to the materials, 'substances' and processes involved in these stages - based on generic information that is reasonably available. For example, if it is known that a sub-assembly requires specific raw materials, unless particular information is available it could be assumed that these will be sourced from the country which is the major producer of those materials, using the methods and processes which are prevalent in that country.

- **Important environmental parameters should be included in the verification.** If some environmental parameters are considered important, they should be considered for inclusion in the verification. If after verification there is still uncertainty about potentially important environmental factors, this should appear in the verification statement.

The focus on the life-cycle stages could be different whether a product, a process or a service is being verified and depending on the innovative characteristics of the technology. E.g., if a technology is innovative because it uses biodegradable materials instead of conventional materials, then, apart from the information on the manufacture and use phases, the applicant shall provide information for the "extraction, refining, processing and transport of natural resources" stage and for the "end of life" of this technology. On the other hand, if the technology proposed will use a manufacturing process different from the relevant alternatives so as to increase its efficiency during the use phase, but the natural resources used are similar to the relevant alternatives, the key stages would then be the manufacturing and the use phase. For both these phases the applicant shall indicate the differences with the relevant alternative but may indicate that for the natural resources extraction the technology would be similar to the relevant alternative although specifying that he has no precise information to confirm this.

List of environmental criteria

For each of the relevant stages, identified in the previous section, information should be provided by the applicant pertaining to a series of environmental parameters.

For the relevant stages identified in the previous section, the applicant shall provide at least qualitative information and when possible quantitative information on the environmental criteria listed below as long as relevant for the technology in question (to be determined in cooperation with verifier). To facilitate the qualitative process, the information may be provided in relation to standard knowledge available for the relevant alternative or it may be provided in absolute terms and the verifier could use its expertise to assess how this information compares to the relevant alternative.

- **Emission of pollutants to air**

Identify or quantify additional, increased, reduced or removed air pollutants including green-house gas emissions vs. the relevant alternative.

- **Emission of pollutants to water**

Identify or quantify additional, increased, reduced or removed water pollutants vs. the relevant alternative.

- **Emission of pollutants to soil**

Identify or quantify additional, increased, reduced or removed soil pollutants vs. the relevant alternative.

- **Consumption of natural resources**

Identify differences in consumption of rare raw material required for the process vs. the relevant alternative.

- **Energy consumption**

Identify differences in energy consumption and in energy sources (indicate differences in use of non-renewable or renewable energy) vs. the relevant alternative.

- **Water consumption and related processes**

Identify differences in the consumption or the use of water vs. the relevant alternative but also the quality of the water used and the necessary treatment before and after use. This section includes process water, but also water used in bulk such as cooling water.

- **Production of non-hazardous waste**

Identify or quantify any additional, increased, reduced or removed non- hazardous waste vs. the relevant alternative.

- **Production of hazardous waste**

Identify or quantify any additional, increased, reduced or removed hazardous waste vs. the relevant alternative.

If relevant, additional information on the productivity of the technology should also be provided, namely:

- **Production efficiency – productivity**

Indicate any significant differences in productivity of the technology vs. the relevant alternative. The proposed technology could have a higher performance but at the expense of a lower productivity or vice-versa (e.g.: for recycling, ratio of substance recycled vs. quantity of substance contained in the waste; for a ion-exchange resin, the treated flow rate).

- **Production efficiency – final quality**

Indicate the differences in the quality of the final product vs. the relevant alternative. The technology could be more environmentally beneficial but resulting in a product that is of lower quality that the relevant alternative (e.g. for recycling: the level of purity of the recovered substance; or for a particular material such as a plastic: a material that costs less energy to make but that resulted in lower quality characteristics).

For any relevant item, the Applicant should provide enough information in order to allow the verifier to understand the nature and magnitude of potential environmental pressure/impacts. However it is acceptable under certain items for the Applicant to demonstrate or provide supporting information, that a particular item is not relevant or that it has no significant impact on the environment.

The Applicant may also provide extra information that might be useful for the assessment relating to economic, social and safety aspects – if they are not already included in the "potential to meet user needs" section – so as to justify or complement the information provided for environmental criteria. For example, a technology might be proposed that has little or no environmental benefits in comparison to the already commercially available alternatives but that provides greater social, economic or safety benefits and therefore could be equally recommended for ETV since it could improve the availability or acceptance of environmental technologies.

The applicant should, as far as possible, provide relevant documentation to support the information provided in the tables, especially when this information is crucial for the evaluation. The verifiers are expected to scrutinise the reliability of the information provided and request supporting information when needed.

Based on experience, the TWGs will progressively determine which aspects have to be investigated for different kind of technologies, in order to simplify the work of the applicants and the verifiers.

Assessment of the environmental added-value

It is the responsibility of the applicant to provide sufficient and relevant information about the technology. Based on the information provided, the verifier will assess the environmental added-value of the technology. This assessment will be provided to the Applicant, for information, discussion and in order that improvements may be made where appropriate.

This assessment will serve as an aid so as to confirm the decision at the eligibility stage of:

i) recommending a verification; ii) not recommending a verification since the environmental added value does not seem to justify the need for an ETV; iii) refusing the verification due to serious environmental issues (noncompliance with the definition of environmental technology).

Each item of information will be 'scored' on the following basis:

- Major negative differences in comparison to the relevant alternative (--)
- Significant negative differences in comparison to the relevant alternative (-)
- No significant differences in comparison to the relevant alternative (0)
- Significant positive differences in comparison to the relevant alternative (+)
- Major positive differences in comparison to the relevant alternative (++)
- Not relevant (NR)
- Not available (NA)

The results can be compiled in the following table:

	Raw materials extraction phase	Manufacturing phase	Use phase	End of life phase
Emission of green-house gas				
Emission of pollutants to air				
Emission of pollutants to water				
Emission of pollutants to soil				
Raw materials consumption				
Energy consumption				
Water consumption				
Production of non-hazardous waste				
Production of hazardous waste				
Production efficiency – productivity				
Production efficiency – final quality				

The scoring will then be evaluated in the following way:

1. Has the applicant provided sufficient information to draft a conclusion? Does the VERIFIER judge that the key points related to this technology have been addressed?

- Yes: *Proceed to point 2*.
- No: Can this be improved using the Verifiers expertise and/or in further discussions with the applicant?
    - Yes: *Review application.*
    - No: Is there a good justification for the absence of all the necessary information, e.g., if a technology has not yet been tested in full-scale or even at prototype level, but lab-scale research data indicates promising environmental benefits?
        - Yes: *Proceed to point 2.*
            - No: *Defer the application and recommend that the applicant returns when adequate information is available.*

2. Are there severe negative aspects identified (--)?

- No: *Proceed to point 3.*
- Yes: Are there more than 2 severe negative aspects (--)?
    - Yes: Are there sufficient environmental benefits (++) or any special circumstances that can justify the poor environmental performance in some criteria?

- Yes: *Not recommend pursuing an ETV but should leave the decision up to the applicant as long as he is aware of the risks and the implications of continuing with the verification, and that he is informed that the negative aspects identified should be included in the verification*

- No: *Refuse the technology for ETV*

- **No**: Are there sufficient positive aspects that balance the negative environmental pressures (should have at least the same number of important environmental benefits (++) than major negative aspects or an overall significantly better performance than the relevant alternative for all other criteria (+))?

  - **Yes**: *Recommend pursuing an ETV as long as the applicant is informed that the negative aspects identified should be included in the verification*

  - **No**: Are any of these important negative aspects sufficiently severe to risk the reputation of ETV and to outweigh any positive environmental benefit?

    - **No**: *Not recommend pursuing an ETV but should leave the decision up to the applicant as long as he is aware of the risks and the implications of continuing with the verification*

    - **Yes**: *Refuse the technology for ETV*

3. Does the technology proposed present any environmental added value in comparison to its relevant alternative (+)?

- No: Are there any other reasons, for instance related to social, economic or safety, that strongly support the suitability of verifying this technology, in particular if the relevant alternative chosen is already proving a high level of environmental protection?

  - **Yes,** there are several other reasons such as relevance to the market, lower costs, higher safety level or higher social acceptance: *Recommend pursuing an ETV as long as the applicant is informed that any negative aspects identified should figure in the verification as well.*

  - **No**: Are there any negative aspects in comparison with the relevant alternative?

    - **Yes**: *Not recommend pursuing an ETV but should leave the decision up to the applicant as long as he is aware of the risks and the implications of continuing with the verification.*

    - **No**: *Recommend pursuing an ETV, in particular in situations where the relevant alternative is already providing a high level of environmental protection*

- **Yes**: Are there any negative aspects in comparison with the relevant alternative?

  - **No**: *Recommend pursuing an ETV*

  - **Yes**: Do the negative aspects qualitatively outweigh the positive environmental aspects?

    - **No,** the environmental added value seems to be far greater than any negative aspect identified, especially in situations where the relevant alternative already provides a high degree of environmental protection: *Recommend pursuing an ETV as long as the applicant is informed that any negative aspects identified should figure in the verification as well.*

    - **Yes,** the quantity and significance of the negative aspects identified partly or greatly overweighs the only/few environmental benefits: *Not recommend pursuing an ETV but should leave the decision up to the applicant as long as he is aware of the risks and the implications of continuing with the verification.*

This scoring is proposed as a guide to decision and should not be substituted to the Verifiers knowledge and judgement of the specific technology at hand.

ANNEX 3. SAMPLE STRUCTURE OF THE VERIFICATION PLAN

1. Identification of the verifier:
   - Organisation name,
   - Address of the physical location,
   - Organisation registration number,
   - Organisation contact,
   - Accreditation status,
   - Phone number,
   - Email address,
   - Website.
2. Identification of the applicant:
   - Organisation name,
   - Address of the physical location,
   - Organisation registration number,
   - Organisation contact,
   - Phone number,
   - Email address,
   - Website.
3. Unique identification of the verification plan and date of issue:
   A unique verification plan document number should be assigned.
4. Person(s) responsible for verification: contact details of persons responsible for verification
5. Description of the technology:
   - Brief description of the technology and its technical and scientific principles,
   - Intended application including matrix, purpose, technologies, technical conditions,
   - Key environmental impacts and emissions (including anticipated environmental benefits),
   - Market readiness, etc.
6. Technical and operational organisation of the planned verification.
   A description specifying the steps of the verification, verification logistics, roles and responsibilities of the involved bodies (including the applicant), specification of experts involved, information on data files or documentation needed from the applicant and test body, etc.
7. List of performance parameters, their assigned numerical values and the description of how they will be verified; technical and operational details of the planned verification.
   A table listing the performance parameters with their numerical values, along with details on how these performance parameters should be evaluated and verified.
8. Requirements for the test data, including quality and quantity and test conditions;
9. Methods for the assessment of the test data and their quality. Requirements for the management of test data and data storage, as well as information on how performance parameter values will be calculated based on the raw measurement data, including calculation methods, statistical methods, assessment of uncertainty, confidence levels, etc.

Information pertaining to test data quality should also describe the means for evaluating test quality (e.g. a test system assessment for compliance to ISO 17025 requirements).

ANNEX 4. GUIDELINES ON THE ACCEPTANCE OF EXISTING TEST DATA

This guideline is based on the Guidelines on the Acceptance of Existing Test Data, Version 1.0 2015, produced by the EU ETV Technical Working Groups, chaired by the JRC, under the auspices of DG Environment for the EU Environmental Technology Verification Pilot Programme.

The clause 5.4.2 of ISO 14034 describes under which circumstances the existing test data can be accepted for verification.

The existing test data shall meet the following requirements:

a) are relevant for the performance to be verified;

b) are produced and reported according to the requirements of ISO/IEC 17025;

c) meet the requirements specified in the verification plan.

Submited information with the existing test data shall include sufficient information for assessment, i.e. a clear indication of the object of testing to enable tracing to which object of testing the data refers to e.g. a commercial name of the technology, an identification number or applicable version, and the full address and status (e.g. independent/dependent, certifications and accreditations etc.) of the data supplier and of any third parties involved (e.g. test design, witnesses etc). The test plan and test report shall be provided along with any other information covering in substance the content.

The verifier shall assess the existing test data to qualify for performance verification considering the following requirements:

- The test data are relevant, sufficient and adequate for the performance to be verified i.e. they correspond to the parameters, methods and target values of the specified performance parameters to be verified;
- The test data are produced and reported according to the requirements of ISO/IEC 17025 for example a detailed test plan that was followed during the testing and a test report are available, the quality assurance and control measures implemented during the testing comply with the requirements of ISO/IEC 17025, the testing was performed in a way ensuring its impartiality, etc;
- The test data meet the requirements specified in the verification plan e.g. they were produced with the same test methods as the ones specified for performance parameters to be verified and generated in testing conditions corresponding to the intended application (and purpose and matrix) defined for the verified technology and its performance together with the operational parameters, assumptions, constraints and limitations applying to the performance claim;
- Test data is provided in a format that allows assessment against the above mentioned requirements.

This assessment is done through the "test system assessment". Without an ISO/IEC 17025 accreditation valid at the moment of the testing covering the tests under consideration, then test system assessment has to include a "test system audit" which includes the review of relevant procedures, observation of actual practices and evaluation of the test performance. Where applicable, the audit may also include examination of control data for the relevant period, participation in proficiency testing and/or control of measurement device calibration. The main difference with new data is that, in the case of existing data, the verifier has to consider the situation at the moment of testing and not the current one, which can make things more complicated and uncertain.

Evaluation of the test and quality management systems

As indicated above, without an ISO/IEC 17025 accreditation valid at the moment of the testing covering the tests under consideration, then test system assessment has to include a "test system audit". The test system audit is meant to help the verifier in evaluating the suitability of the quality management and the test systems.

Here are the circumstances under which it is considered justified not to perform the 'test system audit' for existing data:

a. At the time of testing, the test body was ISO / IEC 17025 accredited for the methods of testing and calibration relevant for the verification process
b. At the time of testing, the test body was ISO / IEC 17025 accredited for tests that are very similar to those involved in the verification process, in that they provide data of the same quality.
c. When the verifier has positively audited the test body for identical or very similar tests, within a period of 12 months before or after the tests, and has sufficient confidence in the quality of the test system for the tests at hand.

It has to be noted that this audit is more complicated to perform and may be less conclusive when the tests are old (more than 1-2 years), as the situation of the test body may have changed (new personnel, new procedures, new equipment….) Auditing the current situation would not reflect the situation that prevailed when the existing data were generated. Therefore the verifier would have to consult the archives of the test body to find out what situation prevailed at that time, a difficult and time consuming task. It has to be stressed that ETV is directed at innovative technologies, and therefore it is not very suited for situations where data are particularly old. One could wonder the relevance and feasibility of evaluating data that are particularly old, although old data with very good quality records could still be considered as valid (risk based assessment).

A good practice would be that the applicant anticipatively invites the verifier to perform a test system audit before or during the tests (i.e. before the start of the verification and in the context of a specific contractual arrangement). The verifier could then use the collected information during the verification process (see witness check below).

When the test system does not exist anymore (e.g. test facilities have been dismantled), the audit shall include at least an in-depth desk review of the test body QA documentation related to tests performed, in force at the time of testing. Whenever possible and relevant, the desk review shall be accompanied by on site observations performed at the place of testing.

The above mentioned QA documentation is made of procedures and records (staff training and qualification, calibration of instruments, measurement and data logs, tractability sheets, non-conformities, test methods and method validation reports…). If such documentation is not available or not suitable/sufficient, the data cannot be accepted.

The audit should also examine the reliability of the tests by reviewing past records documenting the reliability of the data produced by the test body (e.g., laboratory control data for relevant period, evaluation of data from laboratory participation in proficiency test and control of calibration of online measurement devices,…).

Since the audit is similar for both new and existing data, the specific guidance document related to auditing of test bodies should be used.

The core point is that the verifier possesses sufficient evidence to be confident that the tests have been carried out properly and in line with the verification plan and the test plan, e.g. by qualified personnel, using adequate and properly calibrated instruments, following appropriate methods, using suitable sampling and data management procedures etc.

The results of this assessment are reported in Verification Report and Verification Statement.

Appropriate Test methods

The test data shall be collected using robust and appropriate measurement methods and sampling/reporting procedures in order to make sure that the figures correctly reflect the parameters to be assessed. The test method shall be in line with the requirements of the verification plan

In cases where the existing data have been produced using non-standard methods, the documented evidence supporting the(se) method(s) shall be provided. The verifier shall evaluate the suitability of the method, paying special attention to elements including: method validation, skills, traceability etc. This evaluation may include consultation with relevant test laboratories while respecting the necessary confidentiality requirements. The result of this evaluation shall be documented in verification plan

Final evaluation of existing test data

As indicated earlier, the data and accompanying documentation must be sufficient and provided in the appropriate format in order to allow this evaluation.

Meeting the requirements of the verification plan is an essential requirement. Deviations to the Verification plan have to be reported and evaluated. Deviations that are not judged acceptable to the verification body shall lead to the rejection of the data, possibly after a dialogue with the applicant. This requirement is not discussed further here, because it derives directly from the Verification plan, which should provide the method or criteria for evaluating the compliance of data with requirements.

Besides the Verification plan requirements, the verifier should have a critical look at the existing data, examining in particular whether the data are:

- reliable, i.e. collected using appropriate methods and procedures and within an appropriate quality system
- of sufficient quality, e.g. within the sufficient level of precision,
- relevant, i.e. related to the current version of the technology (and not to an outdated version), but also reflecting adequately the verification parameters set out in the verification plan,
- complete, i.e. covering all the relevant parameters including environmental and performance parameters. (NB: incomplete existing data does not necessarily have to be rejected, provided it can be complemented by new data).

If an important parameter is missing from the data sets, the existing data may have to be rejected. For instance if ambient temperature influences the performance of an energy saving device, but ambient temperature was not monitored during testing, then the data should not be used for the verification, or only with extreme caution and with the necessary caveats in the verification report and verification statement.

A statistical analysis has to be performed in order to determine the validity of the results, e.g. are the standard deviation and confidence intervals within acceptable limits, are there outliers etc.? In principle adequate acceptance criteria should have been developed in the verification plan A separate guidance document addresses the statistical evaluation of the results.

All the relevant new and existing data that have been collected have to be presented and discussed. Partial or selective elimination of data is not allowed unless there is a good reason for doing so, e.g. in the case of outliers that can be attributed to experimental errors. When such a situation occurs, this shall be acknowledged and duly justified in the Test and Verification reports and, if potentially impacting the conclusions of the verification, in the Verification Statement.

The 'tools' presented below allow deeper insight in the acceptability of the existing data. To the extent possible, their eventual usage should be anticipated in the verification plan.

Spot checks

The terms 'spot check' refer to the random checking of a certain portion of the data. For example it can be considered advisable that between 5-10% of the existing data for each claim is checked. The checks should concern all the steps where the introduction of an error is possible. It can be for example the

transcription of raw data into a spreadsheet, or the statistical calculations and interpolations carried out by the test body.

If a mistake is identified, its origin should be investigated and, when possible, the values should be corrected. In this situation, a broader range of data should be checked in order to detect other possible mistakes. Eventually, a complete check may be needed in cases where several mistakes are identified.

Correction of mistakes can only be done once their source is identified and one is sure that the corrected dataset adequately reflects the situation. Such corrections have to be reported in the Verification plan, or in the verification report where applicable.

If errors cannot be corrected satisfactorily, or if the errors cast doubt on the reliability of the data, then the existing data should be rejected, partially or totally. However errors that will not influence the conclusion of the whole verification can be tolerated but should be reported anyway, with the reason for accepting them. For example, if there is doubt whether the value of 1 sample out of 50 samples is 782,8 or 788,8. The impact of the error on the value of that particular sample is less than 1% and the impact on the average value of all samples is less than 0,015 %. If the required precision for this particular test is 1%, the error can be tolerated.

Witness checks

This covers several possibilities:

A visit to the test body's premises and evaluate 'quantitatively' the 'performance' of the tests. Typically this would involve repeating some tests using the same methods and procedures as for the existing data and see whether any significant difference arise. Samples with known properties could be tested in order to determine the accuracy of the measurement chain (e.g. actual detection limit and precision). The checks may focus on the measurement devices that have been used in order to determine the repeatability and accuracy of the results.

Alternatively, this may refer to the witnessing by the verifier of the tests performed before the start of the verification, while respecting the conditions of independence between verifier, applicant and test body. The observations (e.g. evidence that quality assurance and testing procedures have been respected and possible deviations) made by the verifier on this occasion would then be included in the elements used by the verifier to evaluate the existing data.

Conditional acceptance of existing data

Conditional acceptance of existing data is a powerful tool to ensure suitability of the existing data. Typically, conditional acceptance may be linked to additional testing confirming the existing data or to the execution of the test system audit. When the new tests show significant differences with the existing data, the reasons need to be investigated and, when applicable, the existing data should be rejected. This leads to an iterative verification process.

Conditional acceptance may also be linked to the successful outcome of the spot checks, the witness checks, and/or the test system audit mentioned above. If case the test system audit could not be carried out before the finalisation of the verification plan then conditional acceptance of the existing data is necessary.

In the case of conditional acceptance, this provisional conclusion about the acceptance of existing data should be reported in the verification plan with the conditions attached to the acceptance explicitly and clearly mentioned. The conclusion on the possible need for further tests, should logically be also conditional. The final conclusion on the acceptance of existing data should in this case be reported in the verification report, together with the results of spot checks, witness checks and/or test system audit where relevant and any other check or assessment of the existing data undertaken after the verification plan stage.

In principle, the acceptance should remain conditional until the verifier has examined all evidence supplied by the applicant, gathered all elements needed to perform the verification, including results from any tests, checks and audits, and has made sure that all requirements related to existing data are met, i.e. in most cases until the verification report is finalised and approved.

ANNEX 5. GUIDELINES ON AUDITING TEST BODIES

This guideline is based on the Guidelines on Auditing Test Bodies*, Version 1.0 2016, produced by the EU ETV Technical Working Groups, chaired by the JRC, under the auspices of DG Environment for the EU Environmental Technology Verification Pilot Programme.*

Audit procedure

It is recommended to perform the test performance audit in several steps:

1. preliminary assessment, for example through a questionnaire to be filled by the test body. If available, the reviews of the test plan and of the test report can also provide valuable pre-audit information. Thanks to the preliminary assessment, some potential gaps can be identified, the test body is given a chance to perform corrections, and then the detailed audit can be performed.

2. Desk review: review of the QMS and test procedures. It can be performed remotely (off-site) if all procedures and manuals can be made available to the verifier. It can be facilitated using a dedicated check list. This can be seen as the "say what you do" part of the audit.

Those two steps could allow to focus the scope of investigations to be performed on-site in the third step, in a risk-based perspective, as explained above.

3. On-site observations: control of the adequate implementation in practice of the QMS and test procedures, performed on-site. This can be seen as the "do what you say" part of the audit. It aims at obtaining confirmation of proper implementation of the procedures that can influence the outcome of the tests: is there evidence that the test body adequately follows these procedures? It will notably look at the suitability of the measurement method, the test system, and test operators, by examining the test in operation, methods, equipment, data quality control and review, and operator understanding and competence.

A more detailed audit procedure can be recommended as follows:

phase 1: preliminary assessment	1. Test body fills-in the questionnaire (see annex for typical questions)
	2. Verifier reviews questionnaire (and other relevant material like test plan and test report if available)
	3. Verifier gets further insight via remote phone and/or video conference
	4. The verifier identifies possible 'gaps'
	5. If no significant gaps, the audits can be further carried out (go to step 10)
	6. If important gaps are identified, verifier discusses with test body how to fill the gaps
	7. Test body take steps to fill the gaps
	8. Test body informs verifier about steps taken
	9. Verifier approves or requires further work (back to step 5)

Phase 2: detailed assessment	10. In-depth review of quality documentation based on the results of the preliminary assessment
	11. Scope of on-site investigations is decided

Phase 3: On-site visit	11. Verifier goes on-site and performs the necessary observations 12. Verifier collets test performance data

Audits conclusion	13. Verifier performs overall assessment based on audit(s) results and other sources of information (documentation) 14. If the outcome is negative then back to step 6, or another test body has to be designated by the proposer (extreme case).

How many audits?

As many test system audits have to be carried out as necessary. If there is one test body, then it is expected that in most instances one audit will be enough, but here are instances that can justify carrying additional audits:

- If the verification involves more than one test system. This would be the case for example when different tests are planned at different moments with different personal, different measurement equipment, maybe in different locations. Note that it may be possible to cover several test systems in a single on-site visit, depending on the availability of the test systems at the moment and place of the audit.
- When measurements span over a long period and when there is not sufficient evidence to demonstrate that the quality of data can be maintained (e.g. lack of either internal or external audits).
- When a first audit results in a negative outcome, a second audit may be required in order to control the improvements put in place by the test body as a result of the first audit.
- When there are doubts about the qualifications of a test body, the verifier may decide to come on site several times to witness the key phases of the testing procedure.
- When time did not allow to collect all required information during a first visit, or when the assessment of collected evidence reveals a need for further on-site investigations.
- When questions/doubts arise as a result of issues found in the test plan and /or report.

Technically, some of these instances can be seen as one audit split in several test site visits. The last instance (questions/doubts as a result of issues found in the test plan and /or report) implies that additional audits may have to be decided even at the end of the verification process.

When to conduct an audit?

It is possible to conduct the test system audit before, during or after the tests. The options can be combined.

Before testing (pre-qualification audit)

Conducting an audit before testing allows identify in advance potential weaknesses in the quality or the test and quality management systems, and could allow to propose possible areas of improvement.

For instance this audit may be relevant when there are doubts about the competence/suitability of a given test body (e.g. Test body unknown to the verifier, poor reputation, test body has little experience in the domain of the tests to be performed…). In the worst case it could allow to rule out an unqualified test body. If needed, the audit can even be performed before the test body elaborates the test plan, with a

view to make sure that the test body does not engage in significant work without then proposer/verifier having sufficient evidence about test body suitability. Otherwise it is recommended to wait for the test plan before carrying the audit, as the test plan could contain useful information related to quality assurance issues.

It is advised to complement this audit with an on-site visit during testing, unless the audit findings provide high confidence in the capability of the test body to conduct the considered tests and to produce reliable and reproducible results. However, an audit before testing is not likely to be sufficient if at the time of the audit the test body is not carrying out tests that are similar to the tests planned in the verification. In such case, a second audit during testing is required

During testing (standard audit)

Conducting this audit allows to witness to operation of the test body for the specific tests at hand, and therefore to make pertinent observations about the relevant testing and quality management practices. In case of serious concerns, test results already obtained may have to be rejected. It is therefore recommended to perform the audit early in the testing process.

After testing (ex-post audit)

An ex-post audit comes generally as an additional audit that is supplementary to other audit(s) already performed. It can provide great benefits for example with selective and limited retesting, to determine the reproducibility, and/or parallel tests comparing measurements with those from an accredited test laboratory.

If no other audit is carried, then the ex-post audit should also look at current practices related to similar tests, and include an in-depth auditing of records related the period in which the tests have been carried out. Interview with personnel that was involved in the testing is also useful, if these personnel are still present. The ex-post audit can be used for instance in the case of existing data (data produced before the verification started).

Nb: In case of existing data, the ex-post audit is the normal situation. See the guidance document on existing data for more information.

What kind of evidence is needed?

The test system audits should be performed by collecting different types of objective evidence, for instance:

Desk review:

- Questionnaire (check-list)
- Relevant manuals and procedures and other documents
- Previous audit results and recommendations (internal and/or third parties)
- Test performance data: Laboratory control data for relevant period, reports of laboratory participation in proficiency testing etc.

On-site observations

- Examination of records (staff training and qualification, calibration of instruments, measurement and data logs, tractability sheets, non-conformities, method validation reports)
- Staff interview
- Examination of test equipment and premises
- Observation of practices (e.g. witnessing the tests and other relevant activities such as calibration, filling in of records, sample handling, data handling).

Moreover, the review of the test plan and test report, if available, is expected to deliver useful pre-audit information, e.g.:

- Which tests are covered by a ISO 17025 accreditation?

- Which tests follow recognized methods?
- What are the quality insurance measure foreseen?
- Does the test plan/report refer to internal procedures?
- Do the test plan/report provide the relevant information about staff, measurement devices, test site, calibrations etc. ?

The relevant documents shall be used as main reference against which to make observations: test plan/report, Verification plan, internal quality procedures relevant to the tests at hand, applicable standards and methods etc.

It may be useful to let investigations go beyond the tests at hand, in order to obtain confidence that the test body has a proven track record of good practices in various domains of testing. This is particularly true when the test body has little experience in the tests at hand.

The in-depth and exhaustiveness of the audit have to be tailored to each specific situation. In particular if there is satisfactory evidence of sound and robust procedures being well enforced, the number of spot checks can be reduced. In the opposite case, the number of checks has to be increased (e.g. verify that ALL relevant instruments have been properly calibrated).

Duration of the audit

The duration of the test system audit will depend on the complexity of the tests and of the test system, the qualifications of the test body and its experience with the considered tests, previous audit experience with the same test body, and verifier's own experience with such audits. For a verifier's first audits of this kind, 3-days duration for on-site observations is advised, to be progressively reduced according to experience if deemed advisable.

Another element to consider is the duration of the tests themselves. If their duration is limited (e.g. one to two days or less) then it may be worth to include in the audit the witnessing of the whole tests. This is all the more relevant when there is lack of evidence that the test body does have sound, robust and well-enforced quality and test procedures.

The audit involves some preliminary work, as well as an assessment of the collected evidence and the drafting of a report. This does not need to be performed on-site, and is not included in the three days duration mentioned above. The total effort for the audit could therefore be one week, but it could be also less or more, depending on the complexity and other factors highlighted above.

What to audit?

As indicated earlier, the test system audit has three components.

a) Quality Management System (QMS) component

In case of ISO 9001 certification, the QMS component of the audit may be simplified: after a satisfactory desk review of QMS procedures, the verifier may consider that the QMS requirements, or part of them, do not need to be verified on-site.

b) Test system component

The audit shall cover key factors that contribute to measurement reliability. The main question is "what could affect the quality of the result?" The factors to consider are:

- Competence of personnel
- Accommodation and environmental conditions
- Test methods and method validation
- Equipment
- Metrological traceability
- Sampling
- Handling of test and calibration items

- Quality of test and calibration results
- Reporting

The importance of those various factors has to be assessed according to the context, and the focus of the audit has to be adjusted accordingly. For example, is calibration crucial, is the personal quite familiar with those tests, is there a complex data transmission chain, are samples likely to deteriorate etc ?

When performing the audit, a special attention to the requirements of the Verification plan and the test plan is needed.

c) Test performance component

The test performance component of the audit aims at answering the following question: is there quantitative evidence of the reliability of the tests? This can be achieved through the review of relevant documentation e.g. calibration data, laboratory control data for relevant period, laboratory participation in proficiency testing, limited retesting to determine the reproducibility, parallel testing for comparing measurements with those from an accredited test laboratory etc. Whether this requires a site visit has to be determined on a case-by-case basis.

Outcome of the audit

One important objective of the test system audit is to obtain satisfactory evidence that sound and relevant procedures exist and that they are efficiently enforced. This will give confidence that tests will be performed appropriately even when the auditor has left the test premises. If procedures are poorly designed and/or enforcement level is weak, then the consequences have to be fully evaluated.

Overall, in case of doubtful audit outcomes, at least the following questions need to be addressed:

- Are test results already obtained valid?
- Is the test body allowed to proceed with testing?
- Are improvements required?
- Is supplementary testing required?
- Is another audit needed?
- Is it needed to witness all tests?
- How will this be reflected in the outcome of the verification itself (i.e..in the Verification Report and in the Statement of Verification) ?

In the worst case, the test body has to be considered as not qualified and therefore the proposer has to designate another test body.

Audit reporting

A summary of collected the evidence and test system audit conclusions shall be compiled in an audit report. The report structure should be in line with the elements audited (e.g. items listed in section 0 above).

The outcome of the audits including possible deviations has to be outlined in the Verification Report and in the Statement of Verification. To provide additional credibility to the verification, the audit report should be attached as an appendix to the verification report.