



EU Environmental Technology
Verification pilot programme

General Verification Protocol

Version 1.0 – December 15th, 2011

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Part A: Environmental Technology Verification pilot programme

A.I Introduction

Europe and the rest of the world are confronted with urgent environmental challenges such as climate change, the unsustainable use of resources and loss of biodiversity. Environmental technologies have a role to play in addressing these challenges and, at the same time, can contribute positively to competitiveness and growth.

The objective of Environmental Technology Verification (ETV) is to promote environmental technologies by providing technology developers, manufacturers and investors access to third-party validation of the performance of innovative environmental technologies.

At a European level, the European Commission launched a voluntary scheme for ETV on an experimental basis: the EU ETV pilot programme.

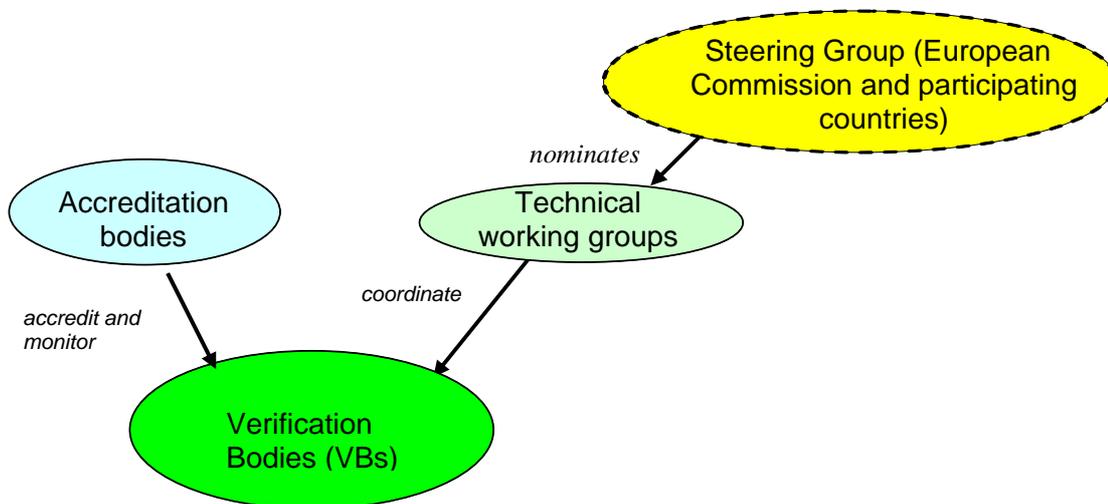
This General Verification Protocol (GVP) has been drafted to support the development and implementation of this initiative. This GVP consists of three sections and supporting documents within appendices:

- Part A: Environmental Technology Verification pilot programme
- Part B: Verification procedure
- Part C: Quality management

The GVP is to serve as the main technical reference for the implementation of ETV procedures and the coordination at a European level.

Implementing this GVP will lead to independent and credible information and data on new environmental technologies, by verifying that performance claims put forward by technology developers and manufacturers are complete, fair and based on reliable test results. Mutual recognition of Statements of Verification in the European Union is ensured by following the procedures as laid down in this GVP.

The management organisation of the EU ETV pilot programme is presented in the following figure. Roles and responsibilities are described in the next paragraphs.



A.I.1 Objectives and principles

The general objective of ETV is to promote innovative environmental technologies, which have the potential to contribute to the efficient use of natural resources and to a high level of environmental protection.

This objective will be pursued by giving technology developers and manufacturers the opportunity to apply for verification of the technical performance and potential environmental impacts of environmental technologies, using scientifically sound procedures, and by providing reliable information on environmental technologies to the potential investors, purchasers and users of these technologies.

The ETV pilot programme is to follow adequate standards of quality; organisations undertaking the verification of environmental technologies under the ETV pilot programme must be accredited by national accreditation bodies, as described in this GVP and following the approach of the 'New Legal Framework' defined by Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and Regulation (EC) No 765/2008.

A.I.2 Scope

An innovative environmental technology may be presented for verification under the EU ETV pilot programme by any legal entity established in or outside the European Union, hereinafter referred to as 'the proposer', if the technology fulfils the following criteria:

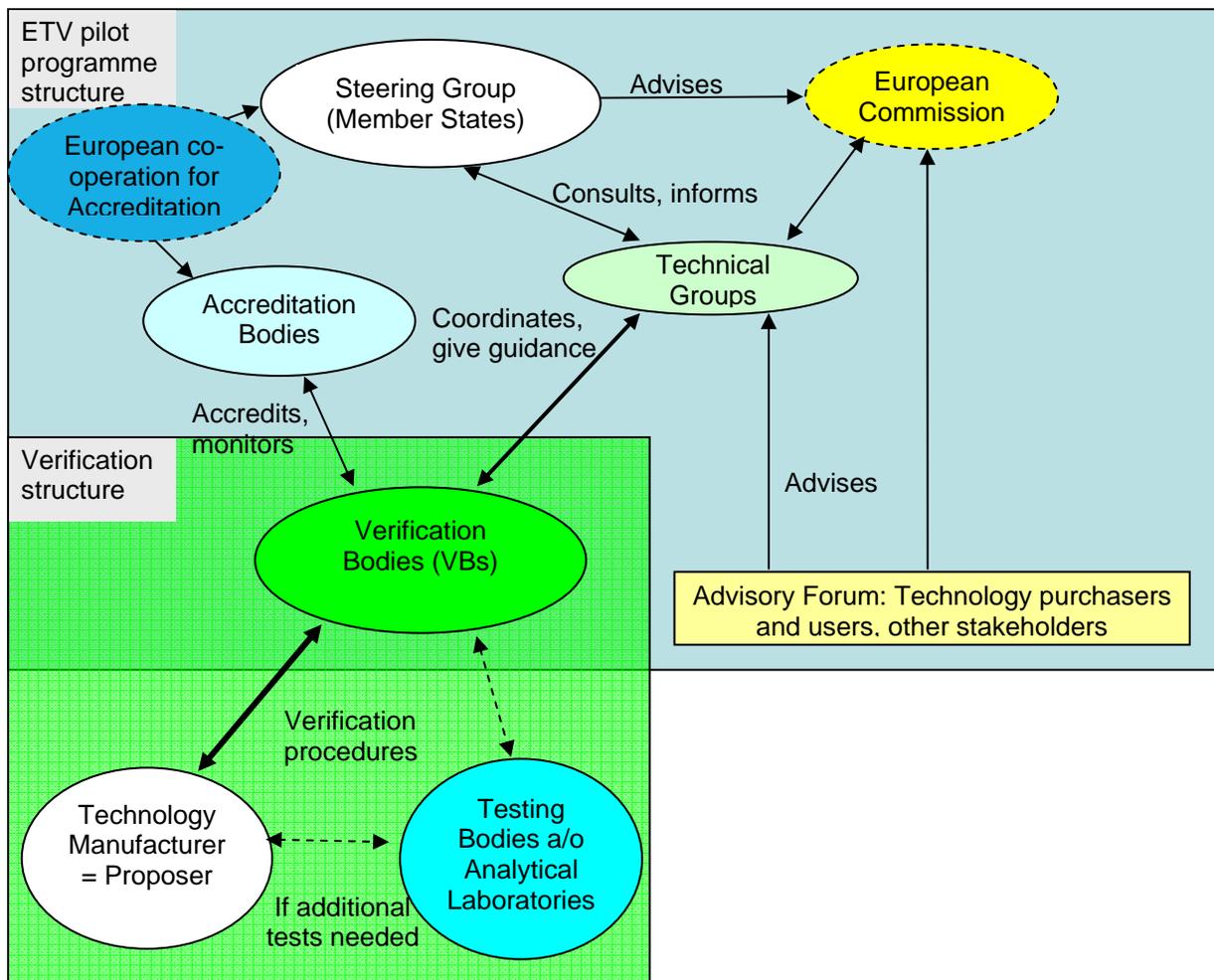
- It is likely to correspond to the definition of an innovative environmental technology provided under Appendix 1 'Glossary of terms and definitions' with a potential to contribute to the efficient use of natural resources and a high level of environmental protection;
- It belongs to one of the technology areas contained in the list of technology areas referred to under Appendix 2 'List of technology areas in the EU ETV pilot programme';
- It is ready for commercialisation or is already commercially available; exceptions to this criterion may be accepted under conditions described in part B *Verification procedure* – Entry to the EU ETV pilot programme.

It should be noted that ETV will not substitute the actual testing of a new technology, but will review test results in order to assess the veracity of a given performance claim.

A.II Entities in the EU ETV pilot programme

The EU ETV pilot programme consists of two groupings of bodies. The first one is the main organisational framework for the management of the EU-ETV pilot programme outlined as “EU ETV pilot programme structure” in the figure below. The second grouping is for bodies involved in the individual verifications, outlined as “Verification structure” in the figure below.

Main roles and responsibilities are described subsequently.



A.II.1 European Commission

A.II.1.1 Roles and responsibilities

The Commission services will ensure the overall co-ordination and supervision of the EU ETV pilot programme. In consultation with the Steering Group, it defines the rules governing ETV General Verification Protocol 1.0

the ETV pilot programme, including this GVP and the technology areas covered by the EU ETV pilot programme.

The Commission services will register and publish all Statements of Verification issued by accredited Verification Bodies, or delegate the registration to another body.

Where appropriate the Commission services will consult with the European cooperation for Accreditation on matters relating to the harmonisation of accreditation procedures, consistency of verification procedures across EA member bodies and mutual recognition of Statements of Verification.

A.II.1.2 Chair(s)

The Commission services will convene and chair the Steering Group and the Technical working groups.

A.II.2 Steering Group

A.II.2.1 Qualification and nomination

For the implementation of the EU ETV pilot programme, the Commission services will be assisted by a Steering Group composed of representatives of the participating EU Member States.

European Free Trade Association (EFTA) countries which are members of the European Economic Area (EEA) and third countries having signed an Association Agreement with the European Community are eligible to participate in the ETV pilot programme and in the Steering Group.

The Steering Group may accept representatives of non-participating countries and international organisations as observers, as appropriate.

A.II.2.2 Roles and responsibilities

The Steering Group will advise the Commission services on the implementation of the EU ETV pilot programme, in particular on:

- Ensuring the due recognition of Verification Bodies in all ETV participating countries and the acceptance of ETV 'Statements of Verification' in all relevant markets.
- The technology areas to be covered by the EU ETV pilot programme;
- Keeping technical reference documents such as the GVP up to date;
- The activities of technical working groups, in particular on technical documents and guidance having an important impact on the implementation of the EU ETV pilot programme;
- The evaluation of the EU ETV pilot programme;

- Any other subject, such as monitoring the participation of small and medium-sized enterprises, relevant for management of the EU ETV pilot programme.

A.II.3 Verification bodies

A.II.3.1 Qualification

A Verification Body shall:

1. be established under national law and have legal personality.
2. be accredited to comply with the requirements of ISO 17020. The Verification Body shall be considered an inspection body with the meaning of ISO 17020. This GVP shall be part of the documentation describing the functions of the Verification Body and the technical scope of activity under ETV for which it is accredited shall be a subset of the technology areas defined in Appendix 2. The technical scope shall be described as a list of technology groups or applications like the examples in Appendix 2.

The maintenance of accreditation under ISO 17020 shall include annual surveillance of compliance to the requirements of this GVP.

3. be a third-party body independent of the proposers (developers, vendors, purchasers and users of environmental technologies) submitting technologies to this body for verification. The Verification Body should meet the criteria of the normative Annex A of ISO 17020.

A body belonging to a business association or professional federation representing undertakings involved in the development, manufacturing, provision, use or maintenance of environmental technologies, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4. not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of the specific environmental technologies submitted to this body for verification, or represent the parties engaged in those activities. This pertains to the Verification Body, its top level management and the personnel responsible for carrying out verification tasks. This shall not preclude the use of environmental technologies that are necessary for the operations of the Verification Body or the use of environmental technologies for personal purposes.
5. not engage in any activity that may conflict with their independence of judgment or integrity in relation to verification activities for which they are selected. This pertains to the Verification Body, its top level management and the personnel responsible for carrying out verification tasks and shall apply to consultancy services.
6. ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their verification activities.

7. carry out the verification activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the result of their verification activities, especially as regards persons or groups of persons with an interest in the results of those activities.
8. be capable of carrying out all the tasks assigned to it under Verification Bodies / *Role and responsibilities*, in the technology groups for which it is accredited, whether those tasks are carried out by the Verification Body itself or on its behalf and under its responsibility.
9. have in place a system of Quality Management and Quality Assurance documenting, coordinating and monitoring the measures taken to ensure that verification activities are implemented in conformity with the requirements of part C of this General Protocol of the EU ETV pilot programme. In particular, at all times and for each verification procedure and each technology group for which it has been accredited, a Verification Body shall have at its disposal the necessary:
 - Personnel with technical knowledge and sufficient and appropriate experience to perform the verification tasks;
 - If the personnel referred to in the previous point includes external experts, the necessary agreements or conventions ensuring the availability of the personnel concerned by ETV procedures;
 - Description of procedures in accordance with which verification is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place to distinguish between tasks it carries out as a Verification Body and other activities;
 - Appropriate reviewing and recording procedures of the products of verification activities ensuring their high level of quality and reliability.

Documents referred to above shall be made available on request to the relevant services of the European Commission and of national administrations.

10. ensure that the personnel responsible for carrying out verification activities shall have the following qualifications:
 - sound technical and vocational training covering all the verification activities in relation to which the Verification Body has been selected;
 - satisfactory knowledge of the requirements of the verification procedures they carry out and adequate authority to carry out these procedures;
 - appropriate knowledge and understanding of the potential environmental impacts associated with the use of technologies in relation to which the Verification Body is accredited, throughout the life cycle of related products, of key environmental aspects of these technologies and of the main technical factors influencing environmental impacts;

- expertise in test methods and measurements (analyses) needed for the test methods;
 - appropriate knowledge of the market aspects of the technology groups for which it is accredited, including users' needs and usual practices in the sector, main actors, regulatory framework;
 - the ability to draw up reports, records and Statements of Verification demonstrating that verification procedures have been carried out and ETV requirements have been satisfied.
11. guarantee the impartiality for carrying out verification activities. This pertains to the Verification Body, its top level management and the personnel responsible for carrying out verification tasks.

The remuneration of the top level management of Verification Bodies and personnel responsible for carrying out verification activities shall not depend on the number of verifications carried out or on the results of those verifications.

12. take out liability insurance for verification activities.
13. observe professional secrecy with regard to all information obtained in carrying out their tasks during verification activities according to part B of this protocol, except in relation to the Commission, to the European Court of Auditors and to the competent authorities of the Member States in which its activities are carried out. Proprietary rights shall be protected.
14. Where a Verification Body subcontracts specific tasks connected with verification or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in items 3 to 13 and shall inform the Accreditation Body accordingly. Activities may be subcontracted or carried out by a subsidiary only with agreement of the proposer.
15. take full responsibility for the tasks performed by subcontractors or subsidiaries wherever they are established. Verification Bodies shall keep at the disposal of the Commission services, the competent authorities of the Member States in which its activities are carried out and the Accreditation Body the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under *Roles and responsibilities of Verification Bodies*.

Where a Verification Body demonstrates its conformity with the criteria laid down in the harmonised standards relevant for conformity assessment bodies or part thereof the references of which have been published in the *Official Journal of the European Union*, it shall be presumed to comply with the requirements set out in items 1 to 15 in so far as the applicable harmonised standards cover those requirements.

A.II.3.2 Nomination

Verification bodies are considered nominated under the ETV pilot programme as soon as they are accredited by national accreditation bodies to perform verification activities for specified groups of technologies.

A.II.3.3 Roles and responsibilities

Verification bodies are responsible for managing the EU ETV pilot programme for specified groups of technologies. This includes in particular:

- Implementation of the GVP of the EU ETV pilot programme for the technology groups for which they are accredited, following any guidance provided by the technical working groups responsible for these technology groups;
- Assess, approve and report test data performed by the proposer in-house for compliance with the requirements set by the Verification Body, in case this is not done by a test body;
- Ensure compliance with the quality management requirements of this GVP of any test bodies involved in their verifications, taking account of the possible accreditation or certification of the test bodies as provided under A.II.6.1;
- Assess and approve test methods and test data provided by a test body for compliance with the requirements set in this GVP and the specific verification protocol;
- Participation in the technical working groups relevant for the technology groups for which they are accredited, including active and loyal contribution to their activities and products and sharing of specific verification protocols developed under ETV;
- Receipt and processing of proposals for verification in their technical scope, in conformity with the GVP of the EU ETV pilot programme;
- Technical advice to the proposers, in particular to the small and medium-sized enterprises applying to the EU ETV pilot programme, in the context of ETV procedures and in particular as regards the definition of the performance claim, choice of test bodies and use of the Statement of Verification, within the limits acceptable under A.II.3.1, Paragraph 4;
- Annual reporting to the Commission services and the national accreditation body on the activities implemented in the framework of the ETV pilot programme, including on post-verification as provided under A.IV.

A.II.4 Technical working groups

A.II.4.1 Qualification

Technical working groups, one per technology area or sub-area, will be established in order to harmonise the implementation of ETV procedures by Verification Bodies in the different technology areas and in the different participating countries, and ensure the same level of quality of verification results, in particular Statements of Verification.

The members of the technical working groups shall meet the requirements of independence, absence of conflicts of interest, professional impartiality and professional secrecy, as required

from the personnel of Verification Bodies under Section A.II.3.1 'Qualification', paragraphs 4, 5, 7, 11 and 13. Those members of the technical working groups which are not employed by Verification Bodies shall provide a statement on honour covering these requirements.

A.II.4.2 Nomination

The technical working groups altogether shall include at least one representative of each Verification Body and a similar number of other experts, the list of which shall be approved by the Commission services after consultation of the Steering Group. The composition of the technical working groups shall be balanced from the point of view of technical, scientific and market expertise and from the point of view of representing the various parties interested in ETV, as far as possible.

A.II.4.3 Roles and responsibilities

The role of technical working groups is to provide:

- Guidance on the application of ETV procedures in relevant technology areas, including the preparation and responsibility of specific guidance documents where appropriate, and contribution to related pre-standardisation or standardisation activities where appropriate;
- Screening of potential environmental impacts associated with the use of technologies, throughout the life cycle of related technologies; identification of relevant key environmental aspects and of the main technical factors influencing environmental impacts, and drafting of reference documents summarising the information resulting from this paragraph for use by the proposers and Verification Bodies;
- Detailing the technology areas of ETV into technology groups or applications and possible subdivisions into sub-groups in order to allow for the screening of potential environmental impacts and identification of key environmental aspects. Keeping the resulting list of technology groups or applications updated;
- Exchange of good practices concerning the implementation of ETV, sharing of information on relevant market aspects for the technology area and dialogue with relevant stakeholders, including technology users.

The technical working groups will inform regularly the Steering Group of their activities and outputs, and consult the Steering Group on the documents having an important impact on the implementation of the ETV pilot programme.

In case of disagreement between a verification body and a proposer, another verification body or another stakeholder, the relevant technical working group shall give an opinion on specific cases or procedures, at the request of the Commission services or one of the parties concerned.

A.II.5 Accreditation bodies

A.II.5.1 Qualification

A national accreditation body, under the meaning of Regulation (EC) No765/2008, appointed for this purpose and complying with ISO/IEC 17011, must accredit a Verification Body to applying ISO 17020 to Environmental Technology Verification as described in this GVP.

A.II.5.2 Nomination

National accreditation bodies are established under law in each of the Member States. The participation of national accreditation bodies in the EU ETV pilot programme is co-ordinated by the European cooperation for Accreditation.

A.II.5.3 Roles and responsibilities

The role of national accreditation bodies is:

- to ensure the technical competence and capacity of verification bodies to implement ETV procedures for specified technology groups;
- to ensure that an adequate quality management system is in place, in order to guarantee the required level of quality and reliability for ETV deliverables;
- to ensure the due recognition of verification bodies in the European Union, in order to ensure the acceptance of ETV 'Statements of Verification' in all relevant markets.

A.II.6 Test bodies

Where tests are considered necessary by the Verification Body, test bodies are designated.

A.II.6.1 Qualification

Test bodies shall fulfil the relevant requirements of the GVP of the EU ETV pilot programme as set out in part C *Quality management of test bodies*.

Where a test body demonstrates its conformity by way of accreditation with the criteria laid down in:

- ISO 17025 - General requirements for the competence of testing and calibration laboratories, for the methods of testing and calibration relevant for ETV,

it shall be presumed to comply with the relevant requirements of the GVP of the EU ETV pilot programme for quality management and general test requirements.

Where a test body demonstrates its conformity by way of certification with the criteria laid down in:

- EN ISO 9001 - Quality management systems – Requirements, with the inclusion of ETV in the scope of certified quality management system,

it shall be presumed to comply with the relevant requirements of the GVP of the EU ETV pilot programme for quality management.

The staff of the test body shall not be the same as those responsible for the evaluation of the test results in the verification body and they shall not be dependent upon these.

Where analysis of test samples is required, the organisations performing these analyses (referred to as 'analytical laboratories') shall:

- be accredited to applying ISO 17025 for methods within the relevant area of analysis.

This provision applies also in case of in-house testing by the proposer.

The staff doing analysis of test samples shall not be the same as those responsible for the evaluation of the analytical results in the test body and they shall not be dependent upon these.

A.II.6.2 Nomination

Test bodies are designated by the proposer to perform tests if required, in consultation with the Verification Body. The consultation of the Verification Body is intended to facilitate the control of the qualification of designated test bodies. The designation of test bodies is up to the proposer, even when the Verification Body has itself the qualification to act also as a test body. The proposer is responsible for contracting with test bodies and for payment of the services provided by test bodies.

A.II.6.3 Roles and responsibilities - tests

Test bodies are responsible for:

- drafting the test plans, in accordance with the relevant procedures of this GVP, the specific verification protocol and in agreement with the Verification Body;
- performing the tests, ensuring the level of quality required in the specific verification protocol;
- ensuring quality of analysis used in the test and, when applicable, the compliance of analytical laboratories with the requirements of this GVP;
- drafting the report on the tests performed, for transmission to the proposer and to the Verification Body.

In the case when the proposer performs the necessary tests in-house, it may contract a test body to:

- draft the test plans, in accordance with the relevant procedures or protocols and in agreement with the Verification Body;
- review the testing plans elaborated by the proposer, in accordance with the relevant procedures or protocols and in agreement with the Verification Body;
- witness testing done by the proposer, if appropriate;
- approve test reports if drafted by the proposer and if not done by the Verification Body.

A.II.6.4 Roles and responsibilities – analyses of test samples

The analytical laboratories are responsible for:

- planning analysis and selecting analytical methods in accordance with the requirements of the test body;
- performing the analysis, ensuring the level of quality assurance required by ISO 17025;
- reporting the analytical data to the test body in agreed format and with methods applied and obtained analytical uncertainty stated.

A.II.7 European co-operation for Accreditation

A.II.7.1 Roles and responsibilities

To ensure EU wide recognition of the procedure for the accreditation of Verification Bodies.

A.II.8 Proposer

A.II.8.1 Qualification

The proposer can be any legal entity or natural person, which can be the technology manufacturer or an authorised representative of the technology manufacturer. If the technologies manufacturers concerned agree, the proposer can be another stakeholder undertaking a specific verification programme involving several technologies (e.g. as part of pre-procurement procedures).

A.II.8.2 Roles and responsibilities

The proposer is initiating and supporting the technology verification, in particular through:

- applying for verification
- contracting with a Verification Body and paying for the service provided under ETV
- liaising on plans and reports
- making technology available

The proposer is responsible for:

- reviewing and approving plans and reports before their validation by the test and Verification Bodies
- providing timely access to technology, accessories, user manuals and training for the Verification Body

- contracting and paying test bodies and for the services provided by Analytical laboratories where appropriate (e.g. in the case of in-house testing);
- complying with the rules for using the Statement of Verification

If further tests are needed after assessment of existing test data, the proposer may perform the necessary tests in-house if the testing plans, all preparatory measures such as sampling and the tests per se are prepared and implemented in agreement with and, where appropriate, witnessed by the Verification Body or an independent test body fulfilling the requirements set out in part C *Quality management of test bodies*. The test report shall be drafted by the proposer and approved by the Verification Body or test body.

A.II.9 Advisory forum

A.II.9.1 Qualification

Stakeholders with a justified interest in the ETV pilot programme may join the advisory forum.

A.II.9.2 Nomination

The Commission services will convene the advisory forum, composed of stakeholders interested in the EU ETV pilot programme.

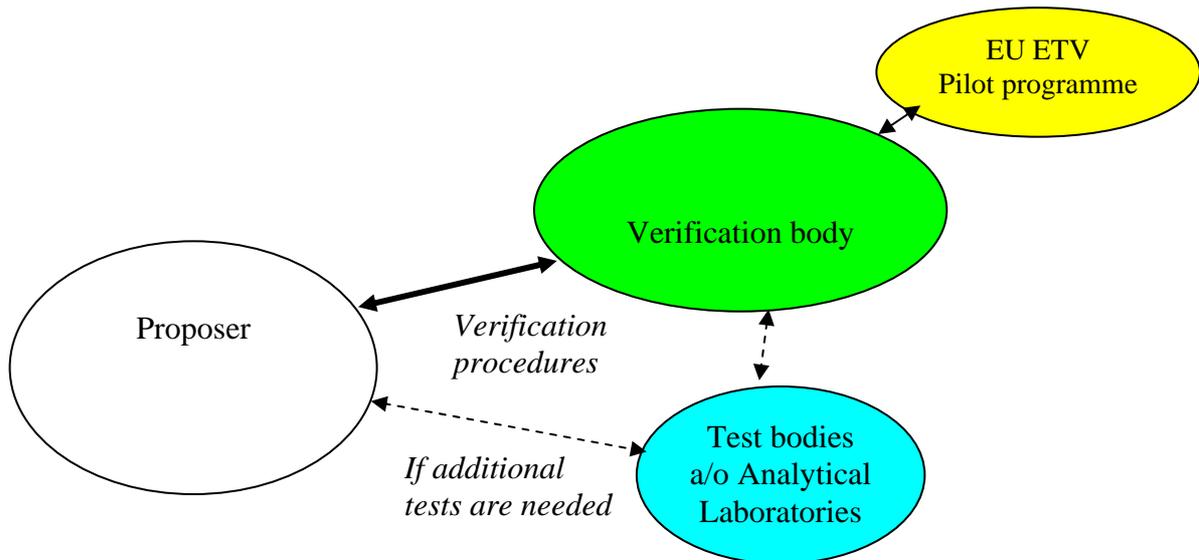
A.II.9.3 Roles and responsibilities

The advisory forum will advise on general issues relevant for the implementation of EU ETV pilot programme.

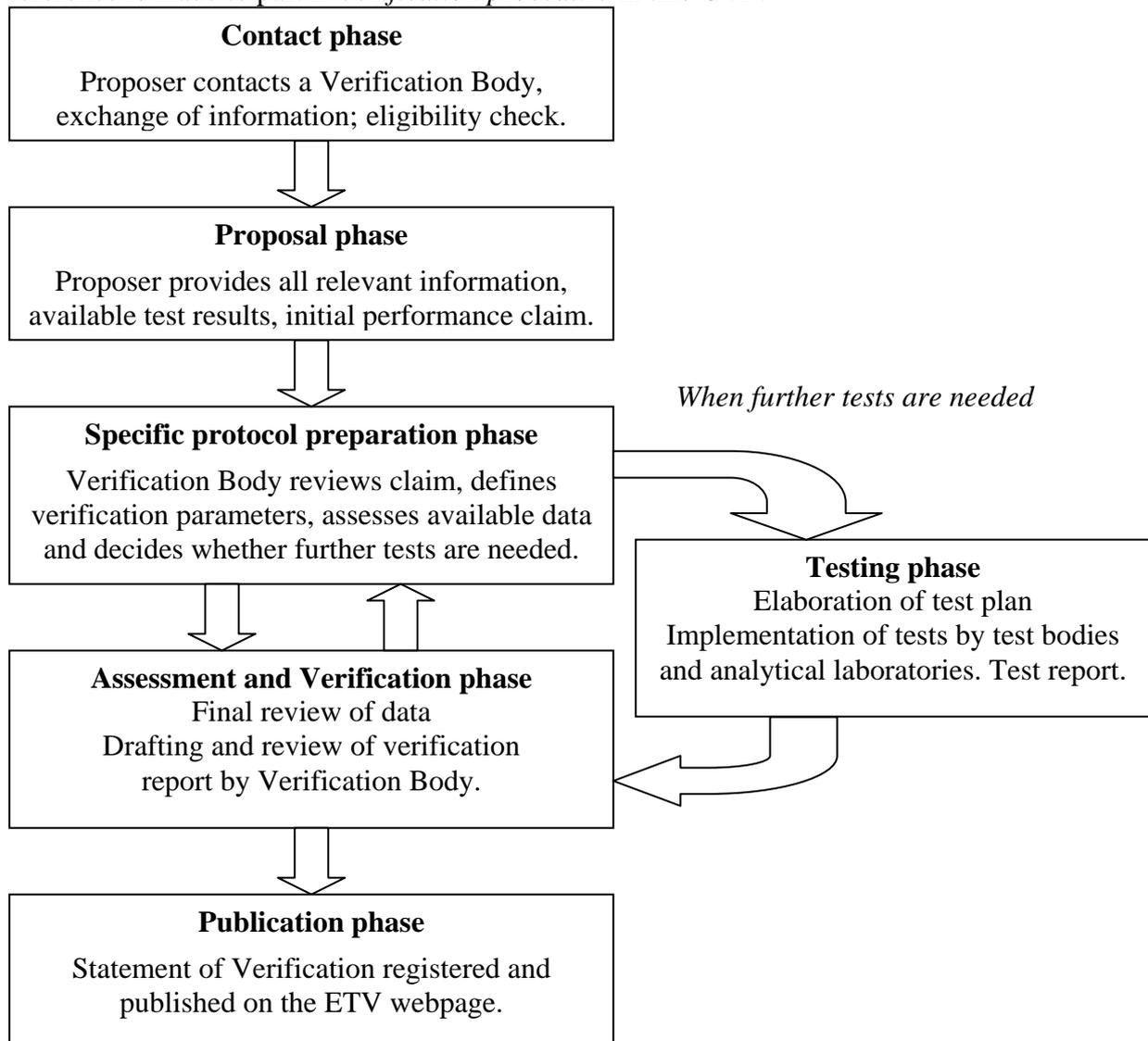
Thematic meetings or sub-groups of the advisory forum may be convened to advise on specific issues. In particular, sub-groups may give advice to the ETV technical working groups on the needs of technology users, investors and regulators in specific technology areas.

A.III Verification procedure in general

The organisations involved in individual verification procedures under the EU-ETV pilot programme can be summarised by the following chart



The verification procedure is divided in a number of (sequential) steps or phases. The figure below shows the overall procedure. For a detailed description of the verification procedure reference is made to part B *Verification procedure* in this GVP.



A.III.1 Entry to the EU-ETV pilot programme (contact and proposal phase)

Entry into the EU-ETV pilot programme is through three steps (details provided in part B):

- Contact and eligibility check
- Proposal
- Contractual agreement

In general it is expected that the proposer will be the manufacturer (as described in the previous chapter). General information about ETV can also be provided by many organisations, e.g. national authorities for development in small and medium-sized enterprises, branch organisations etc., but for a specific application the information should be checked with a Verification Body competent for the relevant technologies.

The proposer submits a proposal file to an accredited Verification body, as provided under part B of this GVP including a general description of the technology, the initial performance claim and the intended application of the technology.

The Verification body reviews the information and checks the eligibility of the proposal, based on the criteria provided for under *Scope* in this GVP.

The contractual agreement contains two steps: a first contract for the initial phase (contact, proposal and eligibility check), for which it is recommended to proceed with a fixed fee, and a contract based on the specific verification protocol development and on the differentiated activities for the following phases, including evaluation of any future changes to the technology.

A.III.2 Specific verification protocol phase

Upon successful completion of the contact phase and eligibility check the next steps in the procedure are related to the development of the specific verification protocol (details are presented in part B of this GVP).

- Performance parameter definition (revised performance claim)
- Requirements on test data and data quality
- Testing, measurement and calculation methods

The proposer and the Verification body are responsible for the development of the specific verification protocol using the provisions of part B of the GVP and any relevant document provided in the EU-ETV pilot programme through the Technical working groups or Steering group. Agreement has to be reached on the performance parameters (i.e. the revised performance claim), on requirements on test data, on testing, measurement and calculation methods.

A.III.3 Assessment of existing data

As part of the development process and market implementation activities the proposer may already have at its disposal a set of test data that are relevant to the verification procedure and may serve (or serve in part) as the basis for verification of the performance parameters defined. The data can be submitted to the Verification Body for initial assessment including the determination of the acceptability of these test data as performance data. The necessary quality control for existing data is described in part C of this GVP. In order to facilitate the acceptability of existing test data, it is recommended that tests performed before an ETV proposal are performed by organisations certified as complying with the criteria laid down in EN ISO 9001 with the inclusion of ETV in the scope of certified quality management system.

The assessment will lead to conclusions whether additional tests or measures are needed to conform to the requirements of the specific verification protocol.

A.III.4 Testing including test plan

After completion of the specific protocol preparation phase, the testing phase is entered, if required. Steps to be undertaken as part of the implementation of the verification protocol are:

- Test site selection
- Test plan
- Test report

For details one is referred to part B of this GVP.

A.III.5 Assessment of all data and verification

Upon completion of the testing phase and the collection of all relevant data, the assessment and verification phase is entered consisting of two steps.

- Assessment of data and review of test procedure
- Verification

When performance data are considered accurate and complete by the Verification body, the Verification body undertakes a final assessment of these data, reviews the procedures followed, and determines whether the performance claim can be considered verified under the EU ETV pilot programme.

A.III.6 Reporting and publication

Based on the outcome of the assessment and the verification, the next phase includes the following steps:

- Drafting the Verification report

- Drafting the Statement of Verification
- Publication of the Statement of Verification

The Verification Body draws up a full report on all the steps taken and results obtained in the implementation of the verification contract, and a draft Statement of Verification as provided under part B of the GVP. After possible revision and with the agreement of the proposer, the Statement of Verification is approved by the Verification body, registered and published by the Commission services or by a body designated by the Commission services.

The Statement of Verification shall be a short document, based on the full report referred to under part B *Verification procedure*. It shall include:

- A summary description of the technology verified, complete denomination or reference number, purpose and conditions of use;
- The verified performance parameters (claim), including the field of application, conditions and assumptions under which the specifications included in the claim are met;
- A summary of the procedures followed by the Verification Body, and by test bodies where relevant, to verify the claim, including the statistical confidence range on specifications where applicable;
- Any information necessary to understand and use the performance claim; if it is necessary to include information not verified under the ETV pilot programme, this should be clearly stated and explained.

A.IV Post verification

A.IV.1 Use of the Statement of Verification and ETV logo

The Statement of Verification may be used by the proposer in any dealings with other organisations, for marketing purposes and for official approval and may be included in the technical documentation of the verified technology. The proposer shall make the statement available in full and shall not use parts of the statement for any purpose.

The proposer may quote the Statement of Verification as follows: the XX technology has been verified for the purpose PP¹ in YY matrix² by QQ Verification Body on DD.MM.YYYY. The Statement of Verification has been registered under number NN and is accessible at the following address: <http://ec.europa.eu/environment/etv/index.htm> or on the dedicated website designated by the Commission services.

¹ The purpose shall describe the verified effect in quantitative terms, e.g. reduction of nitrate concentration in mg NO₃⁻/L

² The matrix defined for the application, e.g. effluent from domestic wastewater treatment plant

The proposer shall not use the ETV logo alone neither on products nor on published (printed, web or other) matter other than the Statement of Verification.

The proposer shall be obliged to report any information on changes in the technology to the Verification Body with the data needed to evaluate whether the conditions for verification have changed. The Verification Body shall perform this evaluation at the cost of the proposer. Substitution of one part with another with the same documented specifications is not considered a change. If, after evaluation, the Verification Body concludes that the conditions for verification have changed, a new verification procedure shall be engaged by the proposer for this technology or alternatively, the Statement of Verification shall be withdrawn. The GVP of the EU ETV pilot programme may provide for a simplified procedure to be followed in the case of the new verification of a formerly verified technology.

The verification report is considered proprietary to the proposer. However for reasons of transparency proposers are recommended to accept publication of the report, hence enabling its publication via the ETV - programme information channels. If the verification report is published, then the full report shall be published. Publication of parts of the verification report is acceptable only if the legitimate interests of the proposer in relation to the verified technology, in particular intellectual property, could suffer disproportionately great harm because of the full publication of the report. In the case of publication of parts of the verification report, the Verification Body should check, before publication and at the cost of the proposer, that the parts to be published may not lead the reader to misinterpret the meaning or results of verification under ETV.

The Statement of Verification shall be withdrawn by the Verification Body if misused by the proposer. Misuse is defined as violation of the conditions of EU ETV pilot programme verification. In the case of withdrawal, the Statement of Verification and report or parts of report shall be removed from the web.

A.IV.2 Follow-up on performed verifications

Customers' feedback on the usefulness of ETV when applying verified technologies and associated environmental benefit, and proposers' feedback on the added-value of ETV in the marketing of verified technologies and the economic benefit, are needed to contribute to the continuous evaluation and improvement of the system. Verification Bodies will seek and collect such feedback by surveying systematically proposers one year after completion of the verification process. In addition, the Commission services provide and operate the advisory forum for general exchange of experience among the community.

Complaints related to specific technology verifications under ETV should be addressed to the relevant Verification Body. In the case of a disagreement between the Verification Body and another party in relation to the ETV pilot programme, an opinion may be asked to the relevant technical working group by the Commission services, the Verification Body or the other party. In case the Verification Body decides not to follow the opinion of the technical working group, a detailed report justifying this decision should be addressed to the Commission services and to the accreditation body having accredited the Verification Body for the ETV pilot programme. The Commission services or the accreditation body may decide appropriate measures on the basis of this report.

The legal regime and competent legal authorities for the relations between the Verification Body and the proposer should be indicated in the contractual agreement signed by the two parties.

Complaints related to the competence or qualification of a Verification Body under the ETV pilot programme should be addressed to the national accreditation body having accredited the Verification Body for the ETV pilot programme, following the procedure indicated in the quality manual of the Verification Body.

Complaints related to the ETV pilot programme procedures should be addressed to the services of the European Commission co-ordinating the ETV pilot programme.

A.IV.3 Outreach

The EU ETV pilot programme strives to support verified technologies, following the approach of the Environmental Technology Action Plan. Verified technologies are published by the Commission services and are included in other ETV outreach materials. The ETV pilot programme will conduct targeted outreach activities and further encourage and support the Member States and other contact points in outreach activities at national level.

On a regular basis, activities will be implemented to evaluate success and effectiveness of the programme, its bodies and procedures.

Part B: Verification procedure

B.I Entry to the EU ETV pilot programme

B.I.1 Contact and eligibility check

The starting point for verification is a contact between the proposer and a Verification Body. Before sending a full proposal for verification, the proposer provides a short quick scan document, as provided in Appendix 5 *Templates to be used during verification procedure*, with some main characteristics of the technology to be verified. The aim of the quick scan is to enable the verification body to:

- Assess the suitability of the technology for verification, e.g.
 - does it fall within the scope of the EU ETV pilot programme, as provided in Appendix 2 list of technology areas?,
 - is it ready³ for the market?,
 - does it show potential to meet user needs and to perform in line with legal requirements?,
 - does it show a sufficient level of technological innovation?
- Identify the relevant technology group
- Give a first indication about the complexity and range of costs for a full verification

The quick scan is evaluated by the contacted Verification Body. The answer from the Verification Body includes a recommendation on performing a full verification or not and a first indication of the range of costs. Furthermore, information on the eligibility of a technology and the corresponding technology area is provided. A Verification Body may exclude a technology from verification if it does not fall within the scope of ETV, if it does not fall in the scope of the Verification Body accreditation⁴, if it is not ready to market or if its performance and innovation levels are obviously too low and would harm the reputation of the ETV scheme. Apart from these cases, the decision to proceed is up to the proposer, even when the Verification Body does not recommend to perform the verification.

³ I.e. the technology is available on the market, or at least available at a stage where no substantial changes affecting performance will be implemented before introducing the technology on the market (e.g. full-scale or prototype scale with direct and clear scale-up instructions)

⁴ In this case, the Verification Body should refer the proposer to other Verification Bodies whose technical scope is likely to include the relevant technology group, where possible.

B.I.2 Proposal

The proposer with an eligible technology submits a proposal for verification to a Verification Body accredited for ETV for the relevant technology group.

The proposal shall include:

- The name and address of the technology manufacturer and, if the proposal is lodged by the authorised representatives, their name and address as well.
- The technical documentation. The technical documentation shall make it possible to understand the technology, to revise performance claim and to assess the conformity of the technology design with the performance claim. It shall contain at least the following elements:
 - a general description of the technology,
 - conceptual design and if necessary for understanding, manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.
 - descriptions and explanations necessary for the understanding of those drawings and schemes and operation of the technology,
 - where relevant, standards or technical specifications applied in full or in part,
 - results of design calculations made, examinations carried out, etc., and
 - test reports.
- The initial performance claim. The details of the initial performance claim shall relate to the technology itself, and not e.g. to the environmental management of the company, to the sources of raw material or to the information provided to users. The details shall be quantitatively verifiable. The initial performance claim shall state the conditions of use under which the claim is applicable, and mention any relevant assumption made.
- The intended application of the technology specified in terms of matrix, purpose and technical conditions, as explained below.

Matrix	Purpose	Technologies	Technical conditions
<p>The type of material that the technology is intended for.</p> <p>Matrices could be soil, drinking water, ground water, alkaline degreasing bath etc.</p>	<p>The measurable property that is affected by the technology and how it is affected.</p> <p>It is possible to define more than one purpose.</p>	<p>The practical application of the technical or scientific principles in the environmental area to achieve the purpose.</p> <p>The term technology is</p>	<p>Operational parameters:</p> <p>Measurable parameters that define the application and the verification/test conditions.</p> <p>Operational parameters may include production capacity, maximum temperature,</p>

	<p>The purpose could be reduction of nitrate concentration, separation of volatile organic compounds, reduction of energy use (MW/kg) etc.</p>	<p>covering a variety of products, processes, systems and services. The technologies could be air scrubbers, etc</p>	<p>concentrations of non-target compounds in matrix etc.</p> <p>Additional parameters:</p> <p>Other effects that will be described but are considered secondary.</p> <p>The additional parameters may include technology costs (including also energy consumption and chemical consumption), environmental health and safety and user manual quality etc.</p> <p>Also, important potential impacts on the environment along the whole life cycle (raw materials, production, use, recycling, end-of-life disposal) should be included.</p>
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- Key environmental factors (in a life-cycle perspective) identified by the related technical working group shall be taken into account.
- The supporting evidence for the adequacy of the technology design. The supporting evidence shall mention any document that has been used in or results from tests carried out by the proposer, or by another test body on his behalf and under his responsibility.
- If the technology was already evaluated or verified under an EU or non-EU environmental technology verification programme, a research or pilot project implementing all or part of the procedures provided under ETV, another evaluation or certification programme implementing the same or similar procedures, the proposer is invited to provide all related documents (including information on quality assurance and management) as supporting evidence; this will be used by the Verification Body to simplify the ETV procedure as much as possible for the technology.

The Verification Body receiving the proposal shall review the proposal and the initial performance claim on the basis of the technical documentation, implementing:

- the relevant provisions of the General Verification Protocol (GVP) of the EU ETV pilot programme,
- where relevant, the specific guidance prepared by the ETV technical working groups,

and taking due account of:

- appropriate technical standards or reference documents for the related technology group;
- key environmental factors (in a life-cycle perspective) identified by the related technical working group;
- protocols prepared for similar technologies in the EU ETV pilot programme and, where appropriate, the relevant part of protocols prepared in non-EU ETV programmes or in research and pilot projects;
- recommendations of the advisory forum where appropriate.

Based on the review, the proposal may be revised or completed by the proposer and the contract procedure for the verification is initiated, as long as the review does not cause a stop of the verification.

B.II Contractual agreement

If the proposer decides to proceed with verification, the Verification Body shall provide a detailed cost estimate for the verification together with a list of potential tests and analyses to be performed. Based upon the cost estimate, a verification contract is drafted and signed by the proposer and the Verification Body and subsequently, the verification procedure can be initiated.

When drafting the verification contract, the template found in Appendix 5 *Templates to be used during verification procedure* may be applied. It is recognised that parts of the verification contract may in some cases need to be prepared after elaborating the first parts of the verification protocol (Application and performance parameter definition, requirements on test design and data quality, assessment of existing data). In such cases, a contract is entered for these first parts, leaving the remaining parts for a second contract.

Intellectual Property Right (IPR) issues are handled in the contract.

The contract shall contain a statement on the use of the ETV report, of the Statement of Verification and ETV logo as well as a provision on reporting by the proposer for follow-up of the impact of ETV. The contract shall contain provisions on the legal regime applicable and the competent legal authorities in the case of a dispute related to the verification procedure.

B.III Specific verification protocol preparation

Based on the proposal received by the Verification Body, a specific verification protocol is set up together with the proposer using the template provided in Appendix 5 *Templates to be used during verification procedure*.

B.III.1 Technology definition and impact summary

To reach a clear understanding of the technology, its intended application and impacts, the matrices, purpose and technical conditions for the technology shall be defined, as specified in the table above in Section B.I.2 'Proposal'.

B.III.2 Performance parameter definition (revised performance claim)

The definition of the performance parameters shall be done under the lead of the Verification Body using the template given for the parameter definition table in Appendix 5 *Templates to be used during verification procedure*. The performance parameters shall be set to ensure that the technology is tested for parameters and in ranges that are relevant for the purchasers of the technology considering regulatory requirements, intended application based needs, key environmental factors and state of the art performance of similar technologies. All categories of parameters as mentioned in the parameter definition table shall be considered when setting up parameters, but categories that are not relevant for a specific verification are left out.

It shall be documented that systematic evaluation of the issues listed in the template is behind the precise definitions of application (matrix, purpose and technical conditions) and performance parameters. The required data and test principles to be followed shall be identified.

The performance parameter definition shall furthermore take into account:

- the relevant provisions of the GVP of the EU ETV pilot programme,
- where relevant, the specific protocols and guidance prepared by the ETV technical working groups,
- appropriate technical standards or reference documents for the related technology group;
- recommendations of the advisory forum where appropriate.

If a standard giving relevant performance parameters for the technology under verification and its application verified is available, reference to this standard can substitute the derivation of the performance parameter definitions.

Selection of the parameters to be defined shall be done separately for each proposal for verification in order to reflect the different requirements for different applications and technologies. If a specific protocol has been prepared under the EU ETV pilot programme for the same application and a comparable technology, and it has been published by the Commission services, the performance parameters of this protocol shall be considered for inclusion in the new protocol if relevant for the new technology.

Whenever available and relevant, standardised methods, preferably international standards, shall be recommended for the measurement of parameters.

B.III.3 Requirements on test design and data quality

The verification protocol describes the essential requirements for the test design and data quality for the technology under verification, as it shall be implemented in the test plan if required after assessment of the existing data. These requirements include the main features of the test design, e.g. continuous or batch tests, scale, test methods etc.

The requirements must reflect the performance parameters defined for the verification, but specific requirements for the test design shall be given whenever necessary in order to ensure that the tests data will enable the final data assessment and completion of the verification procedures. The requirements on test design shall be specified with respect to:

- Overall test design
- Scale (pilot and/or field)
- Performance parameters to be measured
- Methods of reference analysis if relevant, including sampling, measurement and calculation methods
- Data management
- Quality assurance
- Test report contents

Examples of requirements on the test data for different types of technology are given below and may be complemented in the guidance provided by the technical working groups:

Monitoring techniques: Ensure limit of detection, range of application, precision (repeatability and reproducibility). Trueness and relevant robustness can also be verified. If relevant, make reference to conventional methods.

Treatment technologies: Ensure relevant treatment parameters as well as other relevant parameters available for verification. If relevant, make reference to conventional methods.

Materials: Ensure to include all relevant properties, as well as environmental and health impacts, and lifetime. If relevant, make reference to conventional materials.

B.III.4 Requirements on test, measurement and calculation methods

The requirements on the choice of methods shall be defined. If available and relevant, existing standard methods (ISO, CEN) should be used. If specific requirements for analytical methods or their performance have been identified during planning, these shall be given.

The methods of processing of measurements into performance parameters including statistical methods and any required statistical levels of confidence shall be defined or referenced. Required levels of confidence shall comply with the professional practice for the technology group in question.

Where no standard methods exist, documented methods shall be used.

The requirements for the test data management with respect to the format of data storage shall be defined.

B.IV Assessment of existing data

The Verification Body undertakes an initial assessment of the supporting evidence backing the performance claim provided in the proposal, including the acceptability of submitted test data, and concludes whether additional tests or measures are needed to comply with the requirements of the verification under the EU ETV pilot programme as outlined in the specific verification protocol.

Existing data may be supplied by the proposer, i.e. data produced before approval of the specific verification protocol, with requirements on test design and test data quality specified for the technology under verification. This shall include sufficient information for assessment, i.e. in addition to the data, full address and status (independent/dependent, certifications and accreditations) of the data supplier. Data have to be supplied in a format that allows assessment against the requirements for verification outlined in the specific verification protocol.

The accepted existing data are summarized in the format to be used when reporting test data. The Verification Body compares the data with the parameters, methods, target values defined for the specific verification, and test data quality requirement, and decides on acceptance and/or additional testing.

B.V Testing including test plan

If additional tests are needed, the proposer designates one or more test bodies for testing or for supporting testing done by the proposer.

The tests shall be performed according to the requirements on test design and data quality set by the verification body in the specific verification protocol.

Either the test body prepares the test plan, performs the tests and drafts a test report for the proposer and the Verification Body, or the proposer may perform the necessary tests in-house. In that case, the testing plans, all preparatory measures such as sampling and the tests per se are prepared and implemented in agreement with and, where appropriate witnessed by, an independent test body. The test report shall then be drafted by the proposer and approved by the Verification Body or test body.

B.V.1 Test site selection

The types of test sites shall be described responding to the requirements set in the specific verification protocol. The description shall allow for an understanding of the site in relation to the matrix/matrices, purpose and operation parameters defined for the verification.

The information required for the test staff to access the site shall be included.

If the technology under verification is installed and used at the field site, it shall be ensured that no commercial or other interests, influencing the test results, are associated with using the site as test site for the technology. The field site shall not be dependent upon the proposer. If a site dependent upon the proposer is the only option available, the use of that site shall be justified and decided in the specific verification protocol, and precautions such as access logging shall be applied to ensure and document that the test results were not under undue influence.

B.V.2 Test plan

The test plan is the implementation of the verification protocol in tests producing the required measurements and data. A template for the test plan is given in Appendix 5 *Templates to be used during verification procedure* and shall be followed. Reference to the verification protocol used shall be given.

The test plan is unique for each test occasion giving the exact information required by the test staff to conduct the tests as required in the specific verification protocol. The test plan shall be approved by the proposer and the Verification Body. If necessary, the verification body may involve external experts e.g. on measurement procedures in the approval.

The test method(s) used shall be given by reference, if standard or equivalent. If in-house methods are used, the method shall be referenced and outlined, or included in an appendix to the test plan.

The test schedule shall be given.

The descriptions of test operation shall allow the test staff to perform the tests as required in the specific verification protocol and to replicate operations with the least possible variation during the test. The description shall allow tracing of any errors back to sources with equipment, methods, operations or staff.

B.V.3 Test report

The format of the test report to be used is given in Appendix 5 *Templates to be used during verification procedure*. The format and location for archiving the raw data shall be defined. A summary of any amendments to and deviations from the test plan applied or recorded during tests shall be included.

The test data report shall include all analytical and calculated data as well as a reference to the staff that performed the test. The methods of calculation, test measurements and performance parameters from raw data shall be described, if not given in the analytical and test methods used. If relevant, details on equipment and software used shall be included.

If the number of amendments to and deviations from the test plan is limited, the test plan can be used for the test report by completing it with a result chapter. If not, the test plan has to be updated reflecting the deviations.

B.VI Assessment of all data and verification

B.VI.1 Assessment of data and review of test procedure

The final assessment of data is started when the performance data, including the test report data and acceptable data from the existing data prior to verification, are considered complete. They also have to satisfy data quality requirements as provided in the specific verification protocol. The Verification Body undertakes a final assessment of these data, reviews the procedures followed during testing and determines if there is a defensible and complete data set for verification and reporting.

The evaluation includes assessment of the data quality based upon the test quality assurance and compilation of the additional parameters.

The assessment is reported as part of the verification report by the Verification Body.

B.VI.2 Verification

All reports and documentation of the verification procedure are collected and evaluated by the Verification Body using the final assessment of data. All additional information to the test results, and additional parameters, e.g. information about costs, are assessed.

Additional information that was not a part of the verification procedures, provided by the proposer under its own responsibility, may be considered at this stage if it is appropriate and useful for the Statement of Verification. This includes in particular:

- Information on operating conditions that could not or were not considered for verification (e.g. limit temperatures or atmospheric moisture, maximum longevity...)
- Information on environmental impacts not directly related to the technology per se (e.g. source of raw materials, reference to complete life-cycle analysis or life cycle inventory, requirements on suppliers, instructions for re-use or recycling of materials)

The Verification Body shall assess the appropriateness and usefulness of this additional information and draft the necessary caveats to avoid confusion or misleading interpretation of this additional information.

B.VII Reporting and publication

The Verification Body draws up a full report on all the steps taken and results obtained in implementation of the verification contract, and a draft Statement of Verification. After possible revision and with the agreement of the proposer, the Statement of Verification is approved by the Verification Body, and registered and published by the Commission services or by a body designated by the Commission services.

B.VII.1 Verification report

At the end of each verification, a verification report is produced which follows the structure of the verification report, a template is provided in Appendix 5 *Templates to be used during verification procedure*. The verification report uses information from the test report and the specific verification protocol. It is produced by the Verification Body.

The verification report includes all relevant documents produced during verification as appendices:

- The quick scan
- The proposal
- The specific verification protocol
- The test plan
- The test report

B.VII.2 Statement of Verification and ETV logo

The Statement of Verification is a summary of the verification of about 4 pages. It includes:

- a summary description of the technology and purpose,
- the verified claim related to performance parameters,
- the test design,
- operation conditions,
- the test results and
- additional information.

In the Statement, the revised claim as verified is reported for the performance parameters.

The format of the statement shall follow the template in Appendix 5 *Templates to be used during verification procedure*. The overall format shall be implemented in the same form for all technologies, and should allow meaningful comparisons, to the extent possible, between technologies within the same technology group (application).

When the verification procedure is completed, the Statement of Verification with logo is prepared and is signed by the Verification Body. The Statement of Verification is registered by the Commission services or a body designated by the Commission services, and a register number is assigned to it.

B.VII.3 Publication

The verification report is considered proprietary of the proposer. However for reasons of transparency proposers are recommended to accept publicity of the report, hence enabling its publication via the EU ETV pilot programme information channels.

The verification report shall be accessible upon request by other Verification Bodies, by the Commission services, by national accreditation bodies and by members of technical working groups, under the same conditions of confidentiality applying to the verification body (see part A, *Verification bodies, Roles and responsibilities*). EU and national control authorities (including the EU Court of Auditors and Anti-Fraud Office) can request access under relevant procedures.

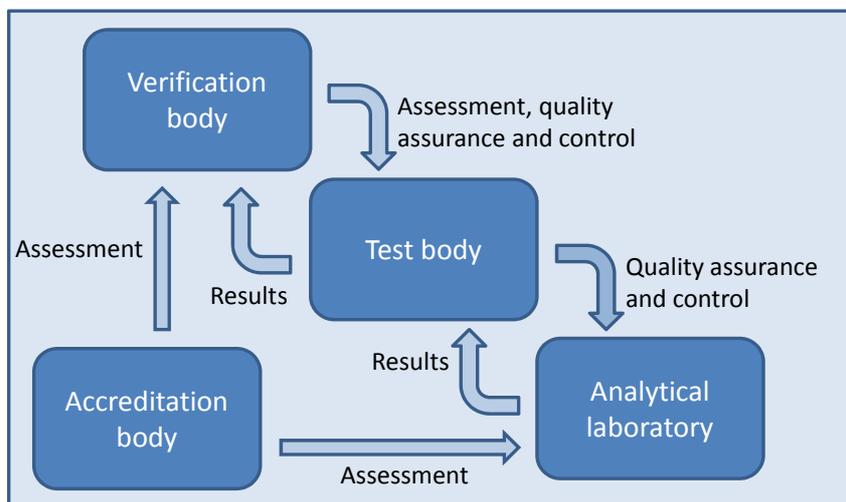
The Statement of Verification is published by the Commission services.

Part C: Quality management

In order to ensure confidence in verification results, strict quality management of the involved organizations and quality assurance of the verification process are required. All bodies involved in verification (Verification Body, test body and analytical laboratory) must have an implemented quality management system meeting the principles of ISO 9001 (Quality management systems – Requirements) or an equivalent standard and conforming to the requirements of this GVP. Verification Bodies must be accredited under ISO 17020 to applying this GVP and analytical laboratories must be accredited according to ISO 17025 (General requirements for the competence of testing and calibration laboratories) for the relevant methods of analysis.

C.I Quality assurance and control for the verification process

Principles of quality assurance in all steps of verification, test and analysis are shown in the figure below.



The accreditation body ensures that the Verification Bodies conform to the requirements of ISO 17020 and this General Verification Protocol, including the requirement for an implemented quality management system meeting the principles of ISO 9001, and that the analytical laboratories conform to the requirements of ISO 17025.

It is the responsibility of the Verification Body to ensure that test bodies meet the quality management requirements and the general test requirements of this GVP for those bodies supplying test data to the Verification Body. A test body can demonstrate meeting the quality management requirements and the general test requirements of this GVP by accreditation according to ISO 17020, for the methods of testing relevant for ETV or ISO 17025 for the methods of testing and calibration relevant for ETV, and meeting the quality management requirements by certification according to ISO 9001 with the inclusion of ETV in the scope of certified quality management system, see Section A.II.6.1.

The Verification Body in addition has the overall responsibility to ensure that the verification is done according to this General Verification Protocol. The Verification Body controls that the test body performs test planning, execution and reporting according to the procedures of this GVP and the relevant specific verification protocol.

The test body has the overall responsibility to ensure that the tests are done according to this General Verification Protocol and to the requirements on test design and data quality of the relevant specific verification protocol. The test body controls that the analytical laboratory performs planning, performance and reporting of analyses according to the requirements of this GVP and the relevant test plan.

If deviations from the above stated requirements are observed by any body involved in verification, the causes shall be investigated, the effects assessed, mitigated and reported, and measures taken to avoid repeating the deviations.

C.II Quality control for existing data

The quality of the existing data shall be evaluated by the Verification Body checking documentation, raw data and quality control data from the data production. The existing data shall meet the requirements on test design and data quality as set in the specific verification protocol. The existing data must be produced under a quality management system meeting the principles of ISO 9001 and the analytical data under quality assurance compliant with ISO 17025.

In addition to checking documentation and data, the Verification Body may undertake one or more of the following actions to evaluate the quality and acceptability of the existing data, in particular in the absence of accreditation or certification or in the case of data produced by the proposer or by bodies dependent upon the proposer:

- spot checks (test report review)
- witness checks (retrospective test performance audit)
- test system audits (in combination with one of the above)
- conditional acceptance of existing data, subject to re-testing of specific requirements or essential measurements.

C.III Quality management of test bodies

Appendix 7 *Quality management* describes the required quality management for test bodies. The areas covered are:

- Organisation
- Personnel
- Methods
- Documentation
- Complaint management
- Management supervision
- Accreditation
- Recognition

C.IV Quality assurance

C.IV.1 Verification Body

The Verification Body must include in its quality manual appropriate procedures for ensuring that the plans for, performance of and products of verification activities are of the required level of quality and reliability, i.e. how the Verification Body plans quality assurance in terms of review and audit. An overview is given in Table 1 'Quality assurance steps for verification bodies.' The procedure shall describe the process of test body audits and audit evaluation, including audit responsibilities and planning, auditor training and competences, and audit reporting.

Table 1 Quality assurance steps for verification bodies.

Location	Target task	Verification Body internal auditor	External technical expert
Verification body	Verification protocol	Review	Review
Test body	Test plan	Review	-
Test body	Test system performance and test body quality management system	Test system audit	-
Test body	Test performance	Test performance audit	-
Test body	Test report	Review	-
Verification body	Verification report	Review	Review
Verification body	Statement of verification	Review	Review

The test system audit may not be needed if the test body is accredited according to ISO 17025 as stated above.

The quality assurance planned for a specific verification must be described in the specific verification protocol, providing the names of experts and auditors, as well as the timing of reviews and audits. The quality assurance planned in the specific verification protocol may need amendment after completion of assessment of existing data.

The Verification Body recruits external experts for reviewing documents. The external experts shall be independent from the Verification Body and their competence shall be documented in a list of experts by the Verification Body. The Verification Body must document that the recruited external experts are free from any undue commercial, financial or other pressures that may adversely influence the independence of the experts.

The reviewing process shall be documented to ensure an adequate level of quality and reliability. Description of the method for documenting reviews shall be included in the quality manual.

C.IV.2 Test body

The test body must include in its quality manual appropriate procedures for ensuring that the plans for, performance of and products of test activities are of the required level of quality and reliability, i.e. how the test body plans quality assurance in terms of review and audit. An overview is given in Table 2 'Quality assurance steps for test bodies'. The procedure shall describe the process of an analytical laboratory performance review.

Table 2 Quality assurance steps for test bodies.

Location	Target task	Test body internal auditor	Test responsible
Test body	Test plan	Review	-
Test body	Test system performance and test body quality management system	Test system audit	-
Test body	Test performance	Test performance audit	Test system control
Analytical laboratory	Analytical performance	-	Review
Test body	Test report	Review	-

The quality assurance planned for a specific test must be described in the test plan, providing the names of experts and auditor, as well as the timing of reviews and audits. The review of analytical performance should include laboratory stated uncertainties and limits of detection, analytical quality control data and participation in proficiency tests for the analysis used and the relevant period.

The reviewing process shall be documented to ensure an adequate level of quality and reliability. Description of the method for documenting reviews shall be included in the quality manual.

Non-analytical measurement methods have to be clearly described in the test plan, including required calibration and quality control.

C.IV.3 Analytical laboratory

The analytical laboratory must include in its quality manual appropriate procedures for ensuring that the plans for, selection methods, performance of and products of analytical activities are of the required quality, i.e. how the analytical laboratory plans quality assurance in terms of review and audit. An overview is given in Table 3 'Quality assurance steps for

analytical laboratories'. The procedure shall describe the process of analytical laboratory quality assurance.

Table 3 Quality assurance steps for analytical laboratories.

Location	Target task	Laboratory staff	Laboratory internal auditor
Analytical laboratory	Method performance	Validation	-
Analytical laboratory	Laboratory analytical system and quality management	-	Test system audit
Analytical laboratory	Analytical performance	Quality control	-

The report of analytical data should include laboratory stated uncertainties and limits of detection. Routine analytical quality control data and participation in proficiency tests for the analysis used and the relevant period should be available.

C.V References to QA section

International Standardization Organisation. EN ISO 9001. Quality management systems - Requirements. 2008.

International Standardization Organisation. General criteria for the operation of various types of bodies performing inspection. ISO 17020. 1998

International Standardization Organisation. General requirements for the competence of testing and calibration laboratories. ISO 17025. 2005.

Part D: Supporting Documents (Appendices)

Appendix 1: Glossary of terms and definitions

- (1) 'Environmental technologies' are all technologies (products, processes and services) whose use is less environmentally harmful than relevant alternatives.
- (2) 'Innovative environmental technologies' are environmental technologies presenting a novelty in terms of design, raw materials involved, production process, use, recyclability or final disposal, when compared with relevant alternatives.
- (3) 'Potential environmental impacts' means estimated environmental effects or pressure on the environment, resulting directly or indirectly from the use of a technology under specified conditions of testing or use.
- (4) 'Performance claim' means a set of quantified technical specifications representative of the technical performance and potential environmental impacts of a technology in a specified application and under specified conditions of testing or use (operational parameters).
- (5) 'Verification' means the provision of objective evidence that the technical design of a given environmental technology ensures the fulfilment of a given performance claim in a specified application, taking any measurement uncertainty and relevant assumptions into consideration.
- (6) 'Operational parameters' means measurable parameters that define the application and the verification and test conditions. Operational parameters could be production capacity, concentrations of non-target compounds in matrix etc
- (7) 'Additional parameter' means other effects that will be described but are considered secondary.
- (8) 'Matrix' means the type of material that the technology is intended for. Matrices could be soil, drinking water, ground water, degreasing bath, exhaust gas condensate etc.
- (9) 'Purpose' means the measurable property that is affected by the technology and how it is affected. Purpose could be the reduction of nitrate concentration in wastewater effluent measured as mg NO₃⁻/l reduction.
- (10) 'Technology group' means a class of technologies serving the same or closely related purposes (i.e. is used in the same application).
- (11) 'Accreditation' shall have the meaning assigned to it by Regulation (EC) No 765/2008.
- (12) 'National accreditation body' shall have the meaning assigned to it by Regulation (EC) No 765/2008.
- (13) 'Harmonised standard' means a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC on the basis of a request made by the Commission in accordance with Article 6 of that Directive.

- (14) 'General verification protocol' (GVP) means the description of the principles and general procedure to be followed by the ETV pilot programme when verifying an individual environmental technology.
- (15) 'Specific verification protocol' means the protocol describing the specific verification of a technology as developed applying the principles and procedures of the General verification protocol.
- (16) 'Ready to market' means that the technology is available on the market or at least available at a stage where no substantial change affecting its performance will be implemented before introducing the technology on the market (e.g. full-scale or pilot scale with direct and clear scale-up instructions).
- (17) 'Amendment' is a change to a specific verification protocol or a test plan done before the verification or test step is performed.
- (18) 'Deviation' is a change to a specific verification protocol or a test plan done during the verification or test step performance.
- (19) 'Test performance audit' means the quantitative evaluation of a measurement system as used in a specific test, e.g. evaluation of laboratory control data for relevant period (precision under repeatability conditions, trueness), evaluation of data from laboratory participation in proficiency test and control of calibration of online measurement devices.
- (20) 'Test system audit' is the qualitative on-site evaluation of test, sampling and/or measurement systems associated with a specific test. E.g. evaluation of the testing done against the requirements of the specific verification protocol, the test plan and the quality manual of the test body.
- (21) 'Test system control' is the control of a test system as used in a specific test. E.g. test of stock solutions, evaluation of stability of operational and/or on-line analytical equipment, test of blanks and reference technology tests.

Appendix 2: List of technology areas in the EU ETV pilot programme

The technology areas covered by the ETV pilot programme are defined by the Commission services in consultation with the Steering Group where countries participating in the pilot programme are represented.

These technology areas (e.g. water treatment and monitoring) will be further detailed into specific technology groups or applications where ETV is most likely to add value (e.g. drinking water treatment), by the Technical working groups where Verification Bodies are represented.

Technical working groups will keep the list of technology groups or applications updated, creating new groups or applications as needed, and possibly dividing groups further into subgroups if needed for the screening of environmental impacts and identification of key environmental aspects, as described in the General Verification Protocol.

The establishment and revisions of the list of technology groups or applications will take into account the following aspects:

- The existence or emergence of a significant number of innovative environmental technologies potentially suited to ETV,
- The demand of technology developers and users, in particular SMEs,
- The availability of specific protocols, technical standards, scientific studies or research providing a satisfactory basis for the verification procedures,
- The availability of a significant number of test bodies having the necessary capacity and quality standards to provide accurate and reliable test data,
- The needs, in terms of technological development or quality requirements, emerging from EU and international policy developments.

Below is the initial list of technology areas (first level) and examples of technology groups or applications (second level) in the scope of ETV pilot programme.

Technology areas	Examples of technology groups/ applications with illustrative technologies
1. Water treatment and monitoring	<ul style="list-style-type: none">• Monitoring of water quality for microbial and chemical contaminants (e.g. test kits, probes, analysers)• Treatment of drinking water for microbial and chemical contaminants (e.g. filtration, chemical disinfection, advanced oxidation) and desalination of seawater

Technology areas	Examples of technology groups/ applications with illustrative technologies
	<ul style="list-style-type: none"> • Treatment of wastewater for microbial and chemical contaminants (e.g. separation techniques, biological treatment, electrochemical methods, small-scale treatment systems for sparsely populated areas)
2. Materials, waste and resources	<ul style="list-style-type: none"> • Recycling of industrial by-products and waste into secondary materials, recycling of construction waste into building materials (e.g. reworking of bricks) • Separation or sorting techniques for solid waste (e.g. reworking of plastics, mixed waste and metals), materials recovery • Recycling of batteries, accumulators and chemicals (e.g. metal reworking technologies) • Reduction of mercury contamination from solid waste (e.g. separation, waste mercury removal and safe storage technologies) • Products made of biomass (health products, fiberproducts, bioplastics, biofuels, enzymes)
3. Energy technologies	<ul style="list-style-type: none"> • Production of heat and power from renewable sources of energy (e.g. wind, sea, geothermic and biomass) • Reuse of energy from waste (e.g. 3rd generation biofuels and combustion technologies) • Energy efficiency technologies (e.g. micro-turbines, hydrogen and fuel cells, heat pumps, combined heat and power production, logistics)

The following areas may be added to the technological scope of the ETV pilot programme by the Commission services, after consultation of the ETV Steering Group, without need to update this Appendix of the General Verification Protocol.

4. Soil and groundwater monitoring and remediation	<ul style="list-style-type: none"> • Soil and groundwater monitoring (e.g. test kits, probes, analysers) • Soil pollution remediation in situ and on site (e.g. thermal treatment, air venting, chemical oxidation) • Management and de-pollution of sediments, sludge and excavated soils
---	---

5. Cleaner production and processes	<ul style="list-style-type: none"> • Savings of material resources (resource efficiency), including savings of chemicals or carbon (e.g. substitution and low-carbon technologies) • Improved energy efficiency in industry (e.g. heat exchangers, heat pumps, thermostat controls) and buildings (e.g. wall insulation, low energy loss windows, air condition controls) • Prevention and reduction of pollution and waste from industrial processes (e.g. new methods in surface coating)
6. Environmental technologies in agriculture	<ul style="list-style-type: none"> • Reduction of air contamination and odour (e.g. housing techniques, air treatment), efficient use of water • Recycling of nutrients and organic carbon from manure (e.g. separation, digestion), re-use of sewage sludge and re-use of waste water after treatment • Reduction of pesticide use and contamination (e.g. spreading equipment, precision application) , prevention of pollution from nitrates and phosphates
7. Air pollution monitoring and abatement	<ul style="list-style-type: none"> • Air emissions monitoring (e.g. sensors, analysers and monitors, including continuous emission monitors) • Abatement of pollution from stationary sources (e.g. filtration, scrubbers, stabilisation of by-products, leakage prevention)

Appendix 3: Flowsheet for verification, verification bodies

Step heading

Verification Body tasks

Contact and eligibility check

Proposer contact

- Guide to the right Verification Body
- Provide information on the first steps and the overall procedure



Proposer counseling

- Advise proposer in completing the quick scan
- Check quick scan
- Inform proposer on the likelihood of meeting the verification procedure requirements



Proposal (initial claim)

- Review the proposer's proposal and define with the proposer the use of the technology for which it is verified, including any exclusions of relevant parts of the use
- Obtain initial performance claim from the proposer



Contractual agreement

- Develop and agree with the proposer upon contractual conditions



Specific verification protocol preparation

Performance parameters definition (revised claim)

- Refine initial performance claim from the proposer to yield
- the performance parameters and the ranges of those that are relevant for verification, including any operational constraints or additional parameters for recording



Requirements on test design and data quality

- Define essential requirements on test design and data quality required to provide the performance parameters defined, including the overall test design and any methods required



Assessment of existing data

- Assess existing data in terms of data quality and performance claim
- Decide on the need and extent of additional testing



Testing (when further tests are required)

- Advise the proposer on the selection of the test body
- Approve the test plan prepared by test body
- Supervise testing
- Assess the test report



Assessment of all data and verification

- Collect test data from the test body
- Compile and evaluate data and data quality information against requirements
- Discuss assessment results with the proposer



Quality assurance and control

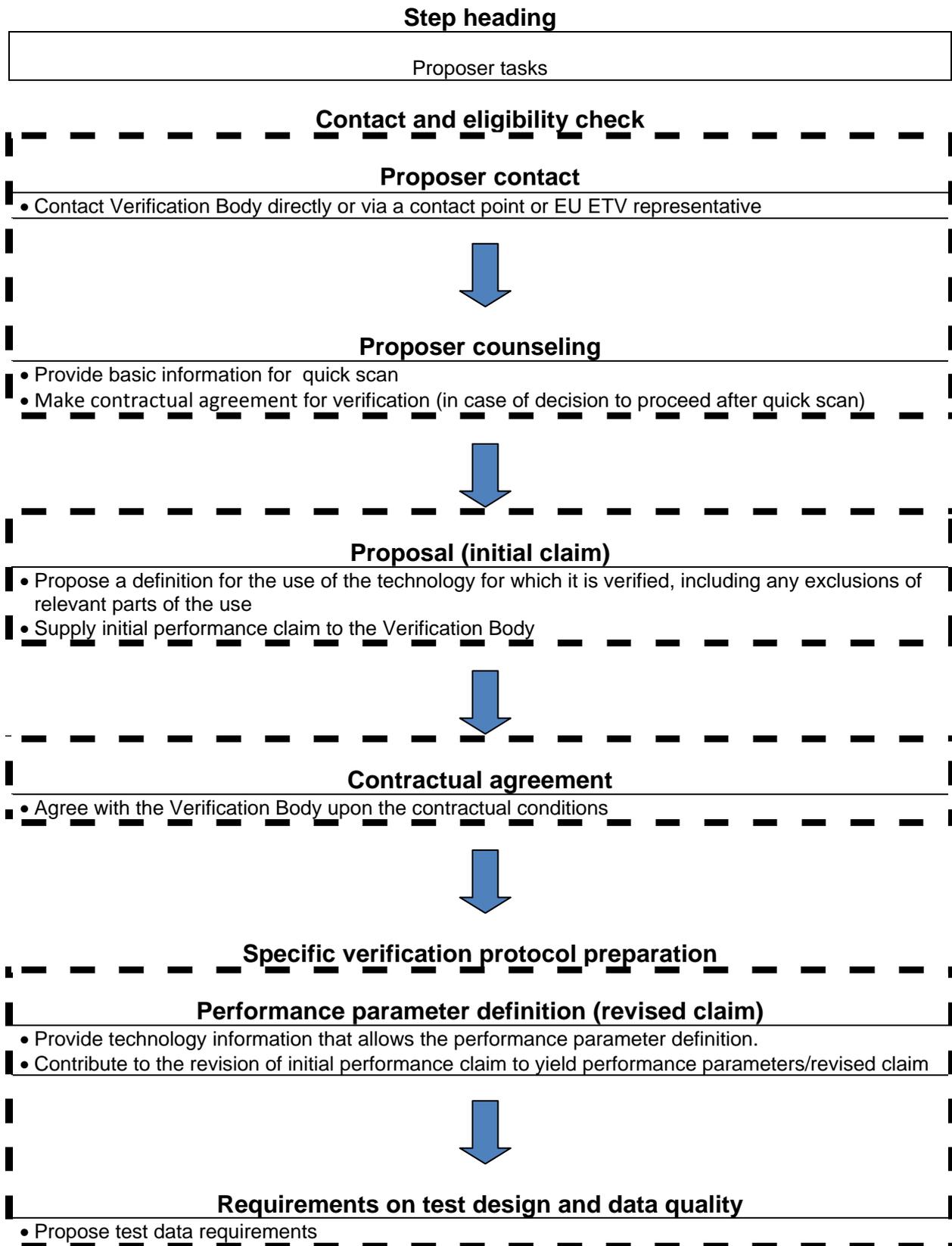
Assure and control that data are produced and documented as required, including audit



Reporting and publication (verified claim)

- Prepare the verification report and the Statement of Verification
- Report verification results to the European Commission services and obtain a registration number for the Statement of Verification

Appendix 4: Flowsheet for verification, proposers





Assessment of existing data

- Provide existing data including information on test design, execution and data quality information



Testing (when further tests are required)

- Select test body in agreement with Verification Body
- Contract the test body
- Provide all equipment and information for testing



Assessment of all data and verification

- Comment on assessment results



Quality assurance and control

Provide all information requested at that stage



Reporting and publication (verified claim)

- No tasks for proposer



Post Verification

- Make use of the published Statement of Verification in line with ETV requirements
- Provide feedback to the Verification Body on the added-value of ETV, environmental and economic benefits

Appendix 5: Templates to be used during verification procedure

Quick scan

Verification Body	Proposer
Name:	Name:
Contact:	Contact:
Address:	Address:
Telephone:	Telephone:
Telefax:	Telefax:
Email:	Email:
Date Quick Scan:	

Previous Quick Scan:

Previous Quick Scan performed: No Yes, date:

Description of the Technology, including initial, quantifiable performance claim and parameters

Description/principles clear: Yes No:

Declared performances described: Yes No:

Innovative Technology: Yes No:

Ready-to-market: Yes No:

Prototype in advanced stage of development: Yes No:

Description of tests performed and available data:

Tests performed on technology: Yes No:

Test body suitable qualified: Yes No:

Test plan available: Yes No:

Test plan suitable: Yes No:

Test methods available (Standards): Yes No:

Test methods described: Yes No:

Test methods suitable: Yes No:

Test methods reproducible: Yes No:

Test methods accuracy: Yes No:

Test results available: Yes No:

Test results in line with declaration: Yes No:

Test results ready for approval testing: Yes No:

Conclusions quick scan (incl. estimated cost range for a verification):

Verification Body:

Name:

Date:

Signature:

Verification proposal

Verification body Name: Contact: Address: Telephone: Telefax: Email: Date Quick Scan:	Proposer Name: Contact: Address: Telephone: Telefax: Email:
---	--

Previous Verification:

Previous Verification performed: No Yes, date:

Description Technology – technical documentation

- The technical documentation shall make it possible to understand the technology, to define the performance claim and to assess the conformity of the technology design with the performance claim. It shall contain at least the following elements:
 - a general description of the technology,
 - conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.
 - descriptions and explanations necessary for the understanding of those drawings and schemes and operation of the technology,
 - where relevant, standards or technical specifications applied in full or in part,
 - results of design calculations made, examinations carried out, etc., and
 - test reports.

Intended application of the technology

Matrix:

Purpose:

-The purpose should indicate the way the matrix is impacted by the technology and the quantitative parameters suggested for monitoring and documenting the effect

Initial performance claim

The specifications included in the initial performance claim shall relate to the technology itself and shall be able to be verified using quantitative test methods. The initial performance claim shall state the conditions under which the specifications are applicable, and mention any relevant assumption made.

Description/principles clear: Yes No:

Declared performances described: Yes No:

Innovative technology: Yes No:

Ready-to-market: Yes No:

Prototype in advanced stage of development: Yes No:

Remarks out of Quick Scan to be considered:

Verification body:

Name:

Date:

Signature:

Contract

Verification contract

Technology name:	
-------------------------	--

Verification body		Proposer	
Name:		Name:	
Contact:		Contact:	
Address:		Address:	
Telephone:		Telephone:	
E-mail		E-mail	

{Verification body name} agrees to verify the above mentioned technology for the below tentatively defined application in accordance with the EU-ETV environmental technology verification method.

Application

Matrices:

Purposes:

Costs and payments

The steps and the costs of the verification procedure includes {check parts and indicate costs as appropriate}:

Verification steps	Costs {currency}
Quick scan report	
Specific verification protocol	

Verification and verification report	
Statement of Verification	
Total costs	

Costs are all inclusive, VAT exclusive.

Example of the payment scheme is as follows:

Payment	Time of payment
10% advance payment	With signed contract
50% payment	After approval of specific verification protocol
40% final payment	After delivery of verification report and statement

Deliverables

{Proposer} agrees to provide without costs and delay for {Verification Body}:

- Contact person for the verification.
- Existing performance data of the technology.
- Information on technology and technology details and mode of action as required for a full understanding of the technology.
- Comments on documents submitted for commenting.

{Verification Body} agrees to provide within the contract:

- Verification of the technology as indicated in this contract.
- One original verification report and verification statement.

Information

{Verification Body} and {proposer} shall both inform the other part, if changes in the conditions for the verification change.

Intellectual property rights

{Proposer} warrants that the technology submitted for verification is owned or controlled fully by {proposer}.

{Proposer} will retain all rights to the technology and all technical data produced during the verification.

{Verification body} will retain all rights to the verification process, protocols, plans, methods and procedures developed by {Verification body}.

Schedule

A detailed schedule shall be part of the specific verification protocol. This will be available for commenting within 6 weeks from the date of signature of the contractual agreement or from the date of the first payment, whatever comes latest.

Limitations

{Verification Body} performs the verification as described for the application of the technology as defined in this contract. This verification cannot be considered an endorsement, approval, authorization or warranty of any kind, and the performance parameters provided cannot be extended to other applications or to other technologies. The verification results reflect the performance of the technology at the time and under the conditions of verification; they cannot be understood as guaranteeing the same level of performance in future or under other conditions.

{Proposer} agrees not to use the Statement of Verification or verification report, or to refer to those for any other technology or application, and not to use extracts of the Statement of Verification for any purpose.

Confidentiality

The final version of the Statement of Verification will be made available for public access by the EU ETV pilot programme through appropriate media such as the EU-ETV web site. The final versions of reports, protocols and plans may be made available for public access by the EU ETV pilot programme after agreement between {Verification Body} and {proposer}.

All other information obtained or produced during the verification is considered confidential for the part not owning the intellectual property rights.

During verification, {proposer} allows {verification Body} to give external auditors access to all information obtained or produced during the verification, as specified in the verification protocol.

Liability

{Verification Body} assumes no liability for any damages associated with the use of verification results, and {proposer} agrees to cover any costs that may be imposed upon {Verification body} in connection with claims raised with this respect.

{Verification Body} assumes no liability for delays or for verification results that damage the sales of the technology or the proposer.

Force majeure

The parties of this contract shall not be liable for failures beyond their control.

Termination

Either party may terminate this contract with a 15 days written notice. In the case of termination, any costs endured by {Verification Body} as part of the verification that cannot be averted shall be paid in full by the terminating part. If the termination is done by the {verification body} due to proposer's non-fulfilment of the obligations in this contract then the costs shall be paid in full by the proposer.

Disputes

Any dispute that may arise in relation with the verification procedure shall be governed by {Verification Body home country} law.

Signatures

Verification body		Proposer	
Name:		Name:	
Signature:		Signature:	
Title:		Title:	
Date:		Date:	

Specific verification protocol

Title page

Table of contents

1. Introduction
 - 1.1. Name of technology
 - 1.2. Name and contact of proposer
 - 1.3. Name of centre/verification responsible
 - 1.4. Verification organisation including experts
 - 1.5. Verification process
2. Description of the technology
3. Description of the technology
 - 3.1. Application and performance parameter definitions
 - 3.1.1. Matrix/matrices
 - 3.1.2. Purpose(s)
 - 3.2. Performance parameters for verification (incl. regulatory requirements, application based needs, state of the art performance,), Performance parameter definition table (see next page)
 - 3.3. Additional parameters
4. Existing data
 - 4.1. Summary of existing data
 - 4.2. Quality of existing data
 - 4.3. Accepted existing data
5. Requirements on test design and data quality
 - 5.1. Test design
 - 5.2. (if needed: Reference analysis and measurements)
 - 5.3. Data management
 - 5.4. Quality assurance
 - 5.5. Test report requirements
6. Evaluation
 - 6.1. Calculation of performance parameters
 - 6.2. Evaluation of test quality
 - 6.3. Additional parameter summary, (e.g. user manual, required resources for operation, occupational health and environment)
7. Verification schedule
8. Quality assurance
9. References

Appendix 1 Terms and definitions

Parameter definition table

Parameter (list of parameters to be considered in the specific verification protocol)	Value	Existing legal requirements	Test measurement method(s) or	Test /available data (+ performer of tests)
<p><u>Operational and benefit</u> e.g. temperature</p> <p><u>Resources</u> City water Electricity Raw materials</p> <p><u>Consumables</u></p> <p><u>Use of hazardous substances</u></p> <p><u>Waste generated</u></p> <p><u>Emissions (air, water)</u></p> <p><u>Man-power needed</u> operation maintenance</p> <p><u>Space</u></p> <p><u>Longevity</u></p> <p><u>Legal standard and/or BAT values</u></p> <p><u>Robustness/vulnerability to changing conditions of use or maintenance</u></p> <p><u>Area</u></p> <p><u>Resource use during production of equipment</u></p> <p><u>Reusability, recyclability</u> (fully or in part)</p> <p><u>End of life decommissioning and disposal</u></p>	<p>e.g. max 80° C</p> <p>600 m³/year</p>	<p>e.g. Required in France, legal reference</p>	<p>e.g. ISO.... Installed flow meter type...</p>	<p>av. data + sample (lab) e.g. Verified (2 months) (subcontractor)</p>

Test plan

Title page

Table of contents

1. Introduction
 - 1.1. Verification protocol reference
 - 1.2. Name and contact of proposer
 - 1.3. Name of test body/test responsible
2. Test design
 - 2.1. Test site
 - 2.1.1. Types of test sites
 - 2.1.2. Addresses
 - 2.1.3. Descriptions
 - 2.2. Tests
 - 2.2.1. Test methods
 - 2.2.2. Test staff
 - 2.2.3. Test schedule
 - 2.2.4. Test equipment
 - 2.2.5. Type and number of samples
 - 2.2.6. Operation conditions
 - 2.2.7. Operation measurements
 - 2.2.8. Technology maintenance
 - 2.2.9. Health, safety and wastes
3. Analysis and measurements
 - 3.1. Analytical laboratory
 - 3.2. Analytical and measurement parameters and methods
 - 3.3. Analytical and measurement performance requirements
 - 3.4. Preservation and storage of samples
 - 3.5. Data management
 - 3.6. Data storage, transfer and control
4. Quality assurance
 - 4.1. Test plan review
 - 4.2. Performance control – analysis and measurements
 - 4.3. Test system control
 - 4.4. Data integrity check procedures
 - 4.5. Test system audits
 - 4.6. Test report review
5. Test report
 - 5.1. Amendment report
 - 5.2. Deviations report

6. References

Appendix 1	Terms and definitions
Appendix 2	References methods
Appendix 3	In-house test methods
Appendix 4	In-house analytical methods and measurements
Appendix 5	Data reporting forms

Test report

Title page

Table of contents

1. Introduction
 - 1.1. Name and contact of proposer
 - 1.2. Name of centre/test responsible
 - 1.3. Reference to test plan and specific verification protocol
 - 1.4. Deviations to test plan
2. Test design
3. Test results
 - 3.1. Test data summary
 - 3.2. Test performance observation
 - 3.3. Test quality assurance summary, incl. audit result
 - 3.4. Amendments to and deviations from test plan
4. References

- | | |
|------------|--|
| Appendix 1 | Terms and definitions |
| Appendix 2 | Test data report |
| Appendix 3 | Amendment and deviation reports for test |

Verification report

Title page

Table of contents

1. Introduction
 - 1.1. Name of technology
 - 1.2. Name and contact of proposer
 - 1.3. Name of Verification Body/verification responsible
 - 1.4. Verification organisation and experts
 - 1.5. Verification process
 - 1.6. Deviations to verification protocol
2. Description of the technology
3. Description of the technology
 - 3.1. Application and performance parameter definitions
4. Existing data
 - 4.1. Accepted existing data
5. Evaluation
 - 5.1. Calculation of performance parameters
 - 5.2. Performance parameter summary
 - 5.3. Evaluation of test quality
 - 5.3.1. Control data
 - 5.3.2. Audits
 - 5.3.3. Deviations
 - 5.4. Additional parameter summary, e.g. user manual, required resources for operation, occupational health and environment
 - 5.5. Operational parameters
 - 5.6. Recommendations for verification statement
6. Quality assurance
7. References

Appendix 1 Terms and definitions

Appendix 2 Quick scan

Appendix 3 Proposal

Appendix 4 Specific verification protocol

Appendix 5 Amendment and deviation report for verification

Appendix 6 Test plan (where relevant)

Appendix 7 Test report (where relevant)

Statement of Verification

Title page/page 1



Verification Body logo

Technology:

Registration number:

Date of issuance:

Verification Body

Name:

Contact:

Address:

Telephone:

E-mail

Web

Proposer

Name:

Contact:

Address:

Telephone:

E-mail

Web

1. Technology description
2. Application(s)
 - 2.1. Matrices
 - 2.2. Purposes
 - 2.3. Exclusions
 - 2.4. Performance parameter summary
3. Test design
 - 3.1. Existing and new data
 - 3.2. Laboratory/field conditions
 - 3.3. Matrix compositions
 - 3.4. Parameter concentrations
 - 3.5. Operation parameters
 - 3.6. Parameters measured
4. Verification results
 - 4.1. Performance parameters
 - 4.2. Additional parameters
5. Additional information
6. Quality assurance and deviations
7. Names, organisations, dates and signatures

Appendix 6: Evolution of performance claim during the ETV procedure

Main steps of the ETV procedure

Example of performance claim

Contact phase

Proposer contacts a Verification Body directly or through a contact point



Proposal phase

Proposer provides all relevant information to Verification Body, including already available test results and initial claim

Initial situation

Technology T:
main purpose is A, expressed by quantifiable parameter a

Other relevant parameters to measure the performance are b and c

Operating conditions are O

Regulatory framework:
imposes that parameter b is $<$ or $=$ b_0

Initial claim:
technology T, operated under conditions O,
performs in such a way that:

$$a > \text{ or } = a_0$$

$$b < b_0$$

$$c < \text{ or } = c_0$$



Specific verification protocol phase

Verification Body checks eligibility, reviews claim, assesses available data and decides whether further tests are

After performance parameters definition phase

Key environmental aspects (in a life-cycle perspective) show that parameter d is crucial to describe the environmental aspects of technology

needed

T; in addition, parameter e is not verifiable but should be known to the user to enable an informed choice.

Knowledge of comparable technologies and users' needs shows that parameter c is better expressed in the form of parameter c', and operating conditions should be more detailed in the form of O'

Revised claim:

Technology T, operated under conditions O', performs in such a way that:

$$a > \text{ or } = a_0$$

$$b < b_0$$

$$c' < \text{ or } = c'_0$$

$$d < \text{ or } = d_0$$

for information, the proposer indicates that $e < \text{ or } = e_0$ but this is not verifiable and therefore not part of the claim to be verified.

After assessment of existing data

Third-party testing (for example, under control of the regulator) shows that $b < b_0$

In-house measurements, under third-party supervision by a qualified testing agency, provided quality test data showing that $a > \text{ or } = a_0$

Not enough information is available on parameters c' and d, requiring additional tests.



(when further tests are needed)

Testing phase

Elaboration of test plan;
Testing carried out
Test report

After testing phase

Data from test body and (if needed) analytical laboratory shows that:

$$c' < \text{ or } = c'_{1} \text{ (not } c'_0)$$

$$d < \text{ or } = d_0$$

Agreement of the proposer to include c'1 instead of c'0 in the revised claim



Assessment of all data and verification phase

Final review of data by Verification Body
Drafting and review of verification report



Publication phase

Approval and publication of the Statement of Verification

After final assessment phase

Complete numerical assessment of test data relevant for parameter a shows that the statistical range of confidence in practice in the technology area can only be obtained for

$$a > \text{ or } = a1 \text{ (not } a0)$$

Agreement of the proposer to include a1 instead of a0 in the revised claim (an alternative could be to initiate additional tests to ensure the statistical range of confidence for value a0)

Published claim (in the Statement of Verification)

Technology T, operated under conditions O', performs in such a way that:

$$a > \text{ or } = a1$$

$$b < b0$$

$$c' < \text{ or } = c'1$$

$$d < \text{ or } = d0$$

within the statistical range of confidence in practice in the technology area.

For information, the proposer adds under their responsibility that $e < \text{ or } = e0$.

Appendix 7: Quality management of test bodies

In particular, at all times and for each test procedure a test body shall have at its disposal the necessary documentation for the items given below.

Organisation

Appropriate policies, organisation and procedures shall be documented aiming at distinguishing between tasks carried out as a test body and other activities;

Personnel

A procedure on education, training and knowledge of new staff in the test body shall be included in a quality manual and shall describe how the test body ensures that tests are done by staff with adequate competences and knowledge of their responsibilities. The personnel responsible for carrying out the test activities shall have the following:

- sound technical and vocational training covering all the test activities done by the test body;
- satisfactory knowledge of the requirements of the test procedures they carry out and adequate authority to carry out those procedures;
- the ability to draw up reports and records demonstrating that test procedures have been carried out and requirements of this GVP and the ETV protocol have been satisfied.

A list of functions in the test process with competence requirements and responsibilities and staff approved for the function shall be maintained.

Methods

Descriptions of procedures (methods) of test ensuring the transparency and the ability of reproduction of those procedures shall be available.

Documentation

The test body quality management system shall include a procedure which describes the process of drafting, revising and approving documentation such as the test body quality manual with the aim of ensuring that all staff involved in the test processes have access to and uses the latest approved version of the manual with process descriptions. The description of procedures shall ensure transparency and the ability of reproduction of those procedures.

A list of documents shall be maintained with indication of the persons authorized to draft, revise and approve these documents.

The manual shall include a description of how the records of test data are stored, transferred, maintained and controlled in order to ensure data integrity for a period defined in the procedure, but not shorter than 5 years from completion of the test.

Complaint management

The test body quality manual shall describe how proposer complaints are recorded, resolved and reported. If not resolved, complaints are referred to the Verification Body for resolving.

Management supervision

The test body quality manual shall describe how the management of the organisation hosting the test body is ensuring that the test body is working according to its quality manual through mechanisms such as e.g. an annual management review process. The quality manager of the test body is designated to be responsible for maintenance and development of the quality system and for the internal auditing of all aspects of the system.

References

International Standardization Organisation. EN ISO 9001. Quality management systems - Requirements. 2008.

International Standardization Organisation. General criteria for the operation of various types of bodies performing inspection. ISO 17020. 1998

International Standardization Organisation. General requirements for the competence of testing and calibration laboratories. ISO 17025. 2005.