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EU Environmental Technology Verification Pilot Programme Guidance Documents

Overview of the implementation of confidentiality and no conflict of interest measures in the EU-ETV pilot programme

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Abstract

Environmental Technology Verification (ETV) is a new tool enabling the verification of the performance claims put forward by developers of innovative environmental technologies. The EU-ETV programme, launched in 2011 by DG-ENV, is supported by Technical Working Groups (TWGs), one for each technology area active under the Pilot programme. These TWGs are chaired by the JRC and composed by Commission Invited Experts and by Experts representing the Verification Bodies with the overall aim to harmonise and exchange good practices.

This document summarises the outcome of the discussion of the Technical Working Groups concerning the streamline of confidentiality and no conflict of interest covering the information that is shared amongst the members of the EU-ETV Technical Working Groups.

This document, adopted on the 31st May 2013 by the TWGs, is a guidance document, with the meaning given in the General Verification Protocol of the EU ETV Pilot Programme (version 1.1), Section A.II.4.3. It has been produced by the EU ETV Technical Working Groups, chaired by the JRC, under the auspices of DG Environment.

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History of this document

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This document is a guidance document, with the meaning given in the General Verification Protocol of the EU ETV pilot programme (version 1.1), Section A.II.4.3. It has been produced by the EU ETV Technical Working Groups, chaired by the JRC, under the auspices of DG Environment.

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1. CONTEXT

1.1. The EU ETV Pilot Programme

Environmental Technology Verification (ETV) is a new tool to help innovative environmental technologies reach the market. It consists of the validation of the performance claims put forward by technology manufacturers, on a voluntary basis, by qualified third parties. This should help manufacturers prove the reliability of their claims, and help technology purchasers identify innovations that suit their needs. As a result, technological lock-in is overcome while more effective and cheaper environmental protection measures can emerge.

The EU ETV pilot programme, run by the European Commission on an experimental basis, is implemented by Verification Bodies (VBs) specifically accredited for ETV. The technical reference defining ETV procedures and requirements is the General Verification Protocol. It ensures that all verifications made in Europe follow the same process and have the same value. VBs are coordinated by thematic Technical Working Groups, at European level, providing guidance on the implementation of ETV and ensuring the adequate harmonisation of practices.

1.2. Purpose and scope of an overview of confidentiality and no conflict of interest measures

A verification procedure relies on the sharing of technical information and specifications of a product between the manufacturer or proposer and the Verification Body who is undertaking the verification procedure. Due to the characteristics of the ETV programme, targeting essentially highly innovative technologies or products, the data and information shared could contain sensitive elements putting at risk proprietary rights and competitive advantage factors.

On the other hand, the ETV programme's goal is to become a source for reliable and credible information and therefore it is crucial to ensure that all parties involved are acting independently and impartially and have access to the information necessary for them to fulfil their roles.

In the GVP and also in the related ISO standards that govern the entities involved in the verification, such as the ISO standard 17020 for the Verification Bodies and the ISO standard 17025 for Analytical Laboratories, requirements of independence, impartiality and confidentiality are provided clearly. This ensures the handling of all information in a protected way and always with the agreement of the proposer. For Test Bodies, although no accreditation is required, equivalence to the quality management systems of ISO 9001 and to the requirements for quality management and general test requirements of ISO 17025 should be documented by the Verification Body.

This document summarises the references to independence, impartiality and confidentiality in the relevant documents and reviews how these notions are put into practice in the implementation of the ETV Programme in order to document the strong confidentiality policy established for the ETV programme. This document should be considered as a

guidance document, with the meaning given in the General Verification Protocol of the EU ETV pilot programme (version 1.1), Section A.II.4.3.

2. INDEPENDENCE, IMPARTIALITY AND CONFIDENTIALITY IN THE ETV PROGRAMME

2.1. Documents to be shared within the frame of confidentiality and no conflict of interest

The proposer is the owner, manufacturer or representative of the technology candidate for verification. The proposer is responsible for providing to the Verification Body all necessary information in order to complete the Quick Scan and, if the proposer decides to proceed with verification, the proposal and the verification contract, including existing test data. These elements are used by the Verification Body to draft the Specific Verification Protocol and, at the end of the procedure, the Verification Report and the Statement of Verification.

When further tests are needed, the services of a Test Body and/or an Analytical Laboratory may be requested who then define and prepare the Test Plan and the Test Report. When there is the need to involve a Test Body or an Analytical Laboratory, it is the responsibility of the proposer to define the contractual agreements with the relevant Test Bodies and/or Analytical Laboratories including the definition of the measures taken to ensure confidentiality and no conflict of interest, especially in the case of a contract with a Test Body that is not accredited to the ISO standard 17025.

The work of the Technical Working Groups (TWGs) foreseen in the GVP is the "*guidance on the application of ETV procedures*" and the "*screening of potential environmental impacts associated with the use of technologies in the scope of the ETV pilot programme throughout their life-cycle*". The GVP section A.II.3.3 (roles and responsibilities of the verification bodies) foresees the sharing of the Quick Scans, specific verification protocols and verification reports with the Technical Working Groups:

[...] Participating in the Technical Working Groups relevant for their technology scope, [...], and sharing relevant information required by the work of the groups, including Quick Scans, specific verification protocols and verification reports developed under ETV;"

Further, the acceptance or refusal of existent data, the decisions to publish the Verification Reports as well as the content of the Statement of Verification are also within the scope of the activities of the Technical Working Groups.

The sharing of documents with the Technical Working Groups is to be signalled to the proposer and agreed in the verification contract, as foreseen in the Quick Scan and contract templates provided respectively in annexes 3 and 5 of the GVP. The proposer can be assured that all information will be exchanged under the same confidentiality rules and no conflict of interest practices as with Verification Bodies. This is the objective of this document and of the code of conduct that regulates the experts' participation and contributions to the work of the Technical Working Groups (in Annex).

2.2. Entities involved in the verification process with access to information on specific technologies

2.2.1. Verification Body

The Verification Body is the main actor dealing with the proposer. It has been accredited for ETV under the specifications of the ISO standard 17020 and the GVP.

According to the GVP (section A.II.3), "a Verification Body shall:

[...]

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 requirements for Type A inspection bodies as defined in the normative Annex A of ISO/EIC 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. [...]*

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. [...]*

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 [GVP], 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." [...]

And according to section C.IV of the GVP, *"The Verification Body recruits external experts for reviewing documents. [They] shall not have permanent contracts or links with the Verification Body, they shall not belong to an organisation hosting or having a financial interest in the Verification Body or in the proposer, 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".*

and in the GVP, concerning confidentiality in the template of the contract between the proposer and the Verification Body (Appendix 5 - Contract):

"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 website. 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."

In version 1.1 of the GVP, the following paragraph has been added to the contract template:

"{proposer} agrees that general information on the verification process and the following documents produced during the verification may be shared in a confidential way with the ETV Technical Working Groups for the purpose of co-ordination and improvement of the EU-ETV scheme: Quick Scan without financial estimates, draft and final specific verification protocol, draft and final verification report without appendices, draft and final Statement of Verification. It is reminded that all members of the Technical Working Groups share the same confidentiality obligations as the Verification Body.

In exceptional and justified cases where the sharing of specific pieces of information or data with the Technical Working Group, in the conditions of confidentiality indicated above, would appear to put at risk the reputation or commercial interests of {proposer} or third parties, {proposer} may ask {Verification Body} not to share these pieces of information or data. The Verification Body will then inform the Technical Working Group why this information and data cannot be shared."

The contract template includes also the following paragraphs **concerning intellectual property rights** (Appendix 5 - Contract):

"{Proposer} warrants that the technology submitted for verification is owned or that intellectual property rights are controlled fully by {proposer}. [Alternatively:] Statements by the owner(s) of the technology or related intellectual property rights, consenting explicitly to the verification, are annexed to this contract.

{Proposer} will retain all rights to 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}."

The Quick Qcan template provides a box allowing the voluntary sharing of the Quick Scan prior to the signature of the contract:

"Please tick here to authorize the Verification Body to share the information provided in the Quick Scan in a confidential way with the ETV Technical Working Groups. Please note that, once a verification contract is concluded, the main process documents including the Quick Scan, Specific Verification Protocol and Verification Report, will be shared with the ETV Technical Working Groups in a confidential way."

According to the ISO 17020 standard in section 5, *"the inspection body shall ensure confidentiality of information obtained in the course of its inspection activities. Proprietary rights shall be protected."*

And in the ISO 17020 Annex A (normative), *"the inspection body [...] shall meet the following criteria:*

A.1 The inspection body shall be independent of the parties involved. The inspection body and its staff responsible for carrying out the inspection shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the items which they inspect, nor the authorized representative of any of these parties.

A.2 The inspection body and its staff shall not engage in any activities that may conflict with their independence of judgement and integrity in relation to their inspection activities. In particular they shall not become directly involved in the design, manufacture, supply, installation, use or maintenance of the items inspected, or similar competitive items."

2.2.2. Test Bodies

Test Bodies must comply with the relevant requirements of the GVP for quality management and general test requirements. This can be demonstrated through accreditation to ISO 17025 or through certification to ISO 9001 (for quality management only) or alternatively the Verification Body shall undertake the necessary checks and audits to verify that the test body meets equivalent quality and management specifications.

While the ISO standard 9001 is used as the reference criteria for quality management of the Test Body, it does not refer to confidentiality issues or conflict of interest and therefore will be left out of this document.

According to the 17025:2005 specifications, section 4.1.5, *"The laboratory shall:*

[...]

b) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;

c) have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;"

and according to section 5.4.7, "when computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that:

[...]

b) procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;"

2.2.3. Analytical Laboratories

Analytical laboratories are regulated by the ISO 17025 standard and therefore the criteria specified for them are detailed in section 2.2.2.

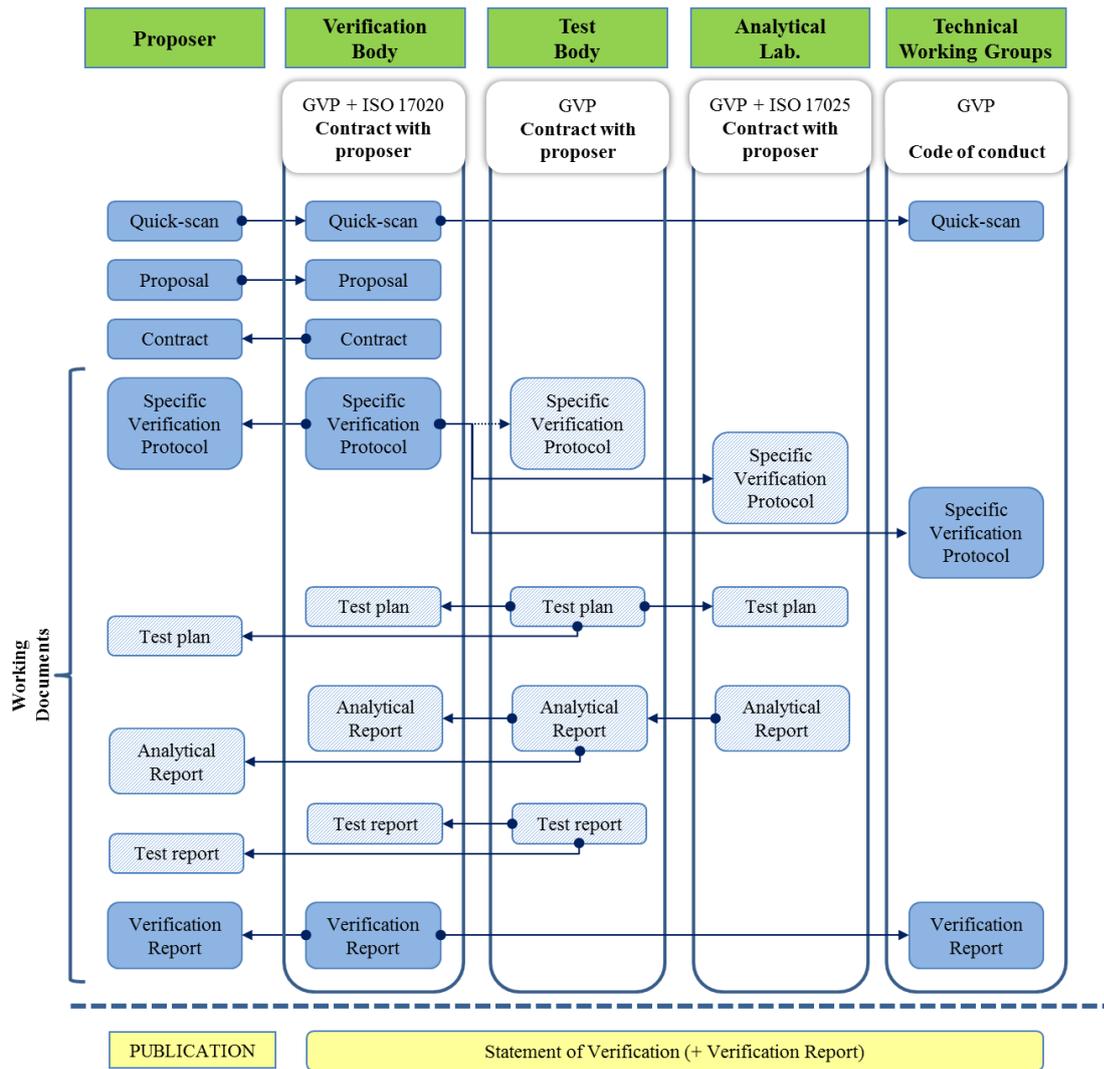
2.2.4. Technical Working Groups

According to the GVP, section A.II.4, "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."

The statement of honour includes the acceptance of a code of conduct composed by a declaration of confidentiality and a declaration of no conflict of interest (in Annex) to be signed by all members of the Technical Working Groups, including experts from Verification Bodies and Commission representatives, to ensure equality of terms and conditions.

3. SUMMARY

The diagram below summarises the main actors during the verification process, the main documents that will be shared and transmitted and the procedures in place to ensure confidentiality and no conflict of interest.



4. REFERENCES

- 1) General Verification Protocol v.1.1 (07/07/2014) - http://iet.jrc.ec.europa.eu/etv/sites/etv/files/documents/gvp_en.pdf
- 2) ISO Standard 17020
- 3) ISO Standard 17025

ANNEX

Declaration of the Experts participating
in the TWGs and its Annex

Declaration of the Expert

The undersigned constitutes the acceptance of the **Code of Conduct**, as well as the **Declaration of no conflict of interest** and the **Declaration of Confidentiality** as foreseen under the **EU-ETV Scheme**.

I undertake to abide by the Code of Conduct for experts acting as a member of an experts' group covered in Annex II (**Code of Conduct**).

I am independent of the designers, manufacturers, suppliers, installers, purchasers, owners, users and maintainers of the technologies submitted for verification to the EU ETV pilot programme and I am not the authorised representative of any of these parties.

I shall not engage in any activity that may conflict with my independence of judgement and integrity in relation of ETV activities. In particular I shall not become directly involved in the design, manufacture, supply, installation, use of maintenance of the technologies submitted to the EU ETV pilot programme for verification. This shall not preclude the use of environmental technologies for personal purposes.

I shall carry out my activities in the ETV Technical Working Groups (TWG) with the highest degree of professional integrity and impartiality and the requisite technical competence in the specific field and I shall be free from all pressures and inducement, particularly financial, which might influence my judgement or the result of TWG activities, especially as regards persons or groups of persons with an interest in the results of those activities.

I undertake to inform the Commission immediately if I discover any conflict or interest, potential or disqualifying with any task that I am asked to carry out or which is the subject of discussion in any TWG meeting in which I participate (**Declaration of no conflict of interest**).

Please tick as appropriate
 In particular, I declare that my participation in the tasks that I have to carry out could create a conflict of interest (please indicate whether this would be a "disqualifying" or "potential" conflict of interest):

<i>Short title</i>	<i>Title</i>	<i>Area</i>	<i>disqualifying (D) or potential (P)</i>
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I shall observe professional secrecy with regard to all information obtained in carrying out my tasks during TWG activities, except in relation to the Commission, to the European Court of Auditors and to the competent authorities of the Member States in which the ETV activities are carried out. Proprietary rights shall be protected.

I undertake not to reveal any detail of the technologies submitted to ETV for verification nor of the work carried out by ETV Verification Bodies or by the TWGs, including the process and outcome, without the express written approval of the Commission or the owner of the information in question. This does not apply to information already in the public domain. I understand I will be held personally responsible² for maintaining the confidentiality of any documents or electronic files sent and for returning, erasing or destroying all confidential documents or files upon completing the tasks, unless otherwise instructed by the Commission (Declaration of confidentiality).

I commit to respect the last two paragraphs even after the end of my collaboration with the Commission in the frame of the EU-ETV Pilot Programme.

For acceptance:

Name and Signature of the expert:

Place, Date:

Annexes:

Specific Conditions – Code of Conduct for Experts acting as members of the EU-ETV Technical Working Groups (1 page)

² Unless this responsibility is covered by my organisation, for example, in the framework of its accreditation to ISO 17020.

Specific Conditions – Code of Conduct for Experts acting as members of the EU-ETV Technical Working Groups

1. The task of an expert is to advise **the European Union** on the implementation of the **EU-Environmental Technology Verification Pilot Programme** in a confidential, fair and equitable manner in relation to the questions upon which he/she is asked to give advice according to the guidelines provided by the *Commission*. He/she must use his/her best endeavours to achieve this, follow any instructions given by the *Commission* to this end and deliver a constant and high quality of work.
2. The expert works as an independent person. He/she is deemed to work in a personal capacity and, in performing the work, does not represent any organisation. This paragraph does not apply to Verification Body Experts or to Commission representatives.
3. The expert must sign a *Declaration of no conflict of interest* and a *Declaration of confidentiality* before starting the work, by which he/she accepts the present *Code of Conduct*. Experts who do not sign the declaration will not be allowed to work as an expert.
4. In doing so, the expert commits him/herself to strict confidentiality and impartiality concerning his/her tasks.
5. If an expert has a conflict of interest, he/she must declare such facts to the responsible *Commission* official as soon as he/she becomes aware of this.
6. The *Commission* ensures that, where the nature of any link is such that it could threaten the impartiality of the expert, he/she does not participate in the meetings(s) of the group.
7. Where it has been decided that documents or electronic files are to be posted or made available electronically to experts, who then work from their own or other suitable premises, the expert will be held personally responsible³ for maintaining the confidentiality of any documents or electronic files sent and returning, erasing or destroying all confidential documents or files upon completing the task as instructed. In such instances, experts may seek further information (for example through the internet, specialised databases, etc.) in order to allow them to complete their advice, provided that the obtaining of such information respects the overall rules for confidentiality and impartiality. Experts may not show the contents of any material without the express written approval of the *Commission*.
8. Experts are required at all times to comply strictly with any rules defined by the *Commission* for ensuring the confidentiality of the tasks of the group of experts and its outcomes. Failure to comply with these rules may result in exclusion from the immediate and future group of experts, without prejudice to penalties that may derive from other applicable Regulations.

³ Unless this responsibility is covered by his or her organisation, for example, in the framework of its accreditation to ISO 17020.

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