# Project no.: 226824

# AdvanceETV

**"Coordination action on Environmental Technology Verification ETV - Building a framework for international cooperation"**

Coordination action

Area 6.3.3.3
Environmental technologies verification and testing

# Final co-verification roadmap

02.09.2011

Organisation name of lead contractor for this report: DHI

Revision: [final]

| **Project co-funded by the European Commission within the Seventh Framework Programme (2007-2013)** | | |
|---|---|---|
| **Dissemination Level** | | |
| **PU** | Public | X |
| **PP** | Restricted to other programme participants (including Commission Services) | |
| **RE** | Restricted to a group specified by the consortium (including Commission Services) | |
| **CO** | Confidential, only for members of the consortium (including the Commission Services) | |

# Contents

# Preamble

This roadmap is a working document supporting the consensus process towards a set of international procedures in environmental technology verification, ETV.

This roadmap is building upon the 1st draft combined roadmap (AdvanceETV deliverable D 3.3) produced after compilation of minimum joint and co-verification requirements (D 3.2) and preparation of a procedure for development of acceptable joint and co-verification performance parameters (D 3.1). The 1st draft was closely examined during the 2nd AdvanceETV cross cutting workshop on joint and co-verification held in Bilbao, Spain, October 18th to 20th 2010. Comments and suggestions were collected during the Bilbao workshop, and the 1st draft combined roadmap was split into two "2nd draft" roadmaps: this document for co-verification and a separate document for joint verification.

These two 2nd draft roadmaps for joint and co-verification have been further reviewed by ETV programmes, after invitation through the International Working Group for environmental technology verification (IWG-ETV), during a desk review. Furthermore, they were discussed at the 2nd AdvanceETV Conference in spring 2011, and subsequently published as an AdvanceETV report. The timing of the process has been:

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Event** | Roadmap drafting | Cross cutting workshop | Roadmap spilt and revision | Desk review | Discussion on ETV conference | Finalisation | Publication |
| **Doc** | Draft combined roadmap | | 2nd draft roadmaps | | 3rd draft roadmaps | | Final roadmaps |
| **Time** | April-October 2011 | October 2011 | February 2011 | March 2011 | May 2011 | June-August 2011 | September 2011 |

The following organisations have been contributed to development of the two roadmaps:

| **ETV programmes** | **ETV operators** | **Other organisations** |
|---|---|---|
| EU ETV pre-programme | DHI (Denmark) | European Committee for Standardization |
| DANETV (Denmark) | IVL (Sweden) | Institute for Prospective Technological Studies (EU) |
| US EPA ETV | Tecnalia (Spain) | Environment Agency (United Kingdom) |
| Canadian ETV program | Battelle (US) | HACH-LANGE (Germany) |
| ETV Korea | OCETA (ETV Canada) | DECHEMA (Germany) |
| ETV Japan | | Deltares (Netherlands) |
| ETV Philippines | | Institute for Ecology of Industrial Areas (Poland) |
| | | et environment and technology (Germany) |

The contributing organisations have not with their contributions endorsed the roadmaps in any way.

It should be noted that the IWG-ETV is at this writing completing definitions and documents for use in ETV and the reader is advised to consult these at they are completed, for any required adjustments of this roadmap.

# Rationale for and methods of the roadmap construction

This document is a description of how co-verification may be done in order to achieve the specific objectives of two or more environmental technology verification (ETV) programmes. The roadmap facilitates comparison of common elements and differences.

The roadmap describes all major steps of verification one by one. The chapters are organized approximately in the sequence of completion during the verification process; however, some of the chapters overlap so the sequence should not be interpreted as prescriptive. It is also not intended that the verification process will unfold exactly in the order of the chapters as they are presented, as there could be variations on the sequence. Although the roadmaps are based upon an analysis of the verification practices and requirements in different ETV programmes, they constitute an aggregation, leaving room for adaptations and additions. A one-to-one correspondence with identified requirements should therefore not be expected.

Each chapter begins with a clarification of the objectives for the step described in that chapter. Subsequently, each method that can be used to achieve the objectives may be further explained, if needed, with prerequisites, benefits and drawbacks. Recommended combinations are provided. The intent is not to apply all methods presented for achieving an objective, but rather for the cooperating programmes to agree in advance on the methods best suited for the purpose of achieving the objectives.

In order to provide useful guidance, the document uses unambiguous wording (i.e., one word for one meaning), and avoids justifications and background information. It is intended to be short and to the point (i.e., what, when and how). The word “must” is used for something that has to be done (objectives achieved), the word “should” is for something that is recommended (suitable combinations of methods) and the word “may” is for something that is permitted.

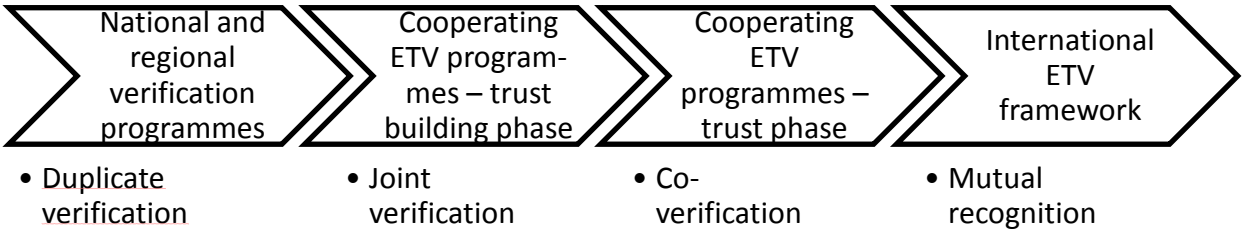
Emphasis is upon on how to achieve objectives rather than how verifications are done by different ETV programmes (i.e., the requirements legitimated by the current practices of one specific ETV programme are not followed).

# 1 Introduction

In simple terms, Environmental Technology Verification (ETV) is a way of testing, verifying and documenting how a technology can perform. Amongst other things, performance parameters are based upon a manufacturer's claims, the requirements of an environmental regulator, or the needs of a customer. Regardless of the source of the performance parameters, they all have the same aim, which is to ensure fitness-for-purpose. In other words, the environmental technology does what it is meant to do, and what the manufacturer claims the technology can do.

A growth in environmental technologies therefore creates a need for ETV programmes, as users and investors need confidence in such technologies. There are already several ETV programmes worldwide and each programme has its own ways of testing and verifying technologies. This can create problems with mutual recognition and then create trade barriers, i.e., verification in one country might not be acceptable in another. This might not be due to any problems with the quality of the verifications, but simply because of the differences between different programmes.

The intent of this roadmap is to provide guidance as to considerations to be taken when two or more organisations wish to cooperate on verification. There are at least two pathways that have been tested out through actual collaborations which are options for collaborative testing: joint and co-verification. Co-verification is covered in this roadmap; a companion document for joint verification is separately available. As shown in the figure below, joint and co-verification are interim steps between completely separated testing by two or more programmes (i.e., duplicate verification) and a single verification based on an internationally accepted framework (i.e., mutual recognition).




The definition of "joint verification", according to the International Working Group for ETV (IWG-ETV), is as follows:

***Joint Verification:*** Where a technology, product, or process undergoes a single verification process carried out collaboratively by two or more verification programmes using mutually recognized verification procedures, processes, and quality management systems. The outcome is a verification that satisfies the requirements of the respective programmes.

The term "co-verification" is currently not defined by the IWG-ETV. For the purposes of the AdvanceETV project, it has been defined as follows:

***Co-verification:*** The intent of co-verification is for the vendor to obtain equivalent verification statements from each of the participating programmes based upon the verification results obtained by a single verification organisation. This approach is different from a joint verification where two or more programmes actively participate throughout the entire verification process. In co-verification, two or more verification organisations cooperate to

determine at the outset of the verification process the acceptability of the parameters to be verified and the plan for verification; and upon completion of the ETV procedure, the acceptability of the verification process and results against what was agreed upon at the outset, and whether or not to issue a verification statement. Co-verification can also mean issuing a verification statement based on the report/verification statement produced by another organisation.

The decision as to whether the joint verification or co-verification pathway should be approached as a starting point should be discussed between the vendor and the Operating Programme (OP), i.e. the programme that is primarily responsible for conducting the verification, as to the intention of the vendor in pursuing verification. Some examples are provided for clarity:

- If the vendor has interest in primarily pursuing verification by one organisation and the involvement of a second or third organisation is considered a secondary objective, then co-verification would be a good option to pursue with the primary organisation serving as the OP.
- If the primary organisation that the vendor has interest in pursuing is not the vendor's native country, then joint verification with the primary organisation in the OP role could be pursued.
- If the vendor has completed verification by one organisation, and would like to have it recognized by another organisation, then co-verification could be pursued.

Joint and co-verification are viewed as extreme cases for collaboration; as described in this document and the joint verification roadmap, any perturbation of the two may be agreed upon between the organisations involved. The decision to pursue single, joint, or co-verification is also linked to resources, since costs will vary depending upon the approach that is taken.

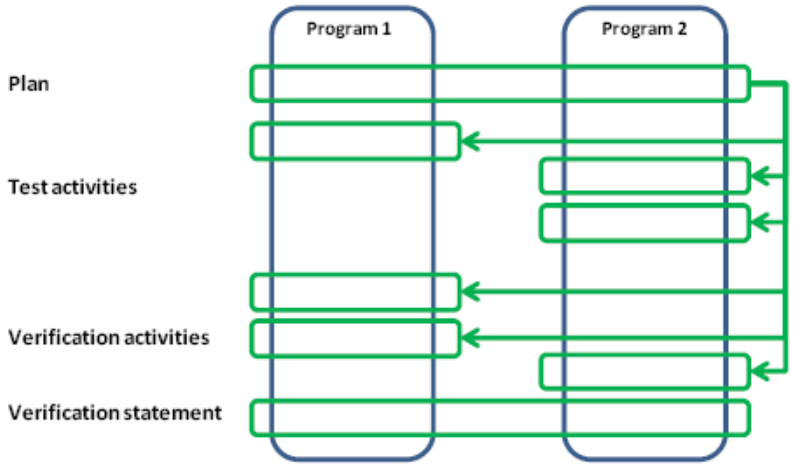



*Figure1: Illustration joint verification*

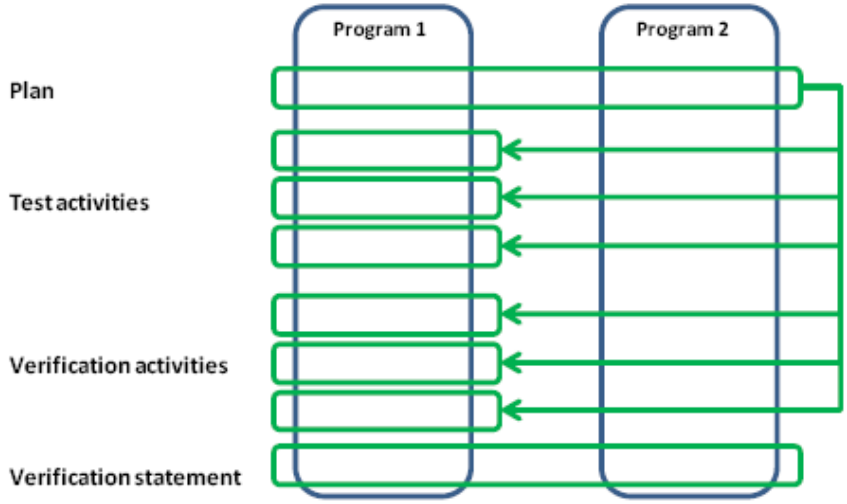



*Figure 2: Illustration co-verification*

The following table outlines the general structure used in this report for describing the steps in the verification process.

| | | |
|---|---|---|
| **Programme Responsibility** | | |
| **Objectives** | | |
| **Optional methods to be selected from** | | |

The **purple** cells (dots) state the parties responsible for the objective. This could be the OP, meaning the programme that is primarily responsible for conducting the verification, the cooperating programme (COP) that is supporting the operating programme, or both (OP + COP). It should be noted, that whereas the tasks of cooperating and operating programmes are generally clearly allocated to different programmes in co-verification, the tasks may be alternating in joint verification, with one programme providing parts of the verification or test and the other programme(s) providing other parts.

The **green** cells (solid line) list the objectives under each step of the verification process.

The **red** cells (dashed line) list methods usable for obtaining the objectives. For each objective several methods can be listed. The methods can be supplementary or complementary. As stated in the table, it should be noted that the methods are options and the requirements are mandatory.

The following sections describe the guidance provided for co-verification; the roadmap for joint verification is described in a separate document. Note that the chapters of the roadmap are not necessarily sequential as some are interrelated and may overlap. When comparing this roadmap with the roadmap for co-verification, some sections may appear identical. However, careful review is required as there are real and intended differences between the roadmaps for joint and co-verification.

# 2 Quality management, assurance and control

| **Responsible Programme** | COP | OP |
|---|---|---|
| **Objectives** | Ensure confidence in the quality of work of operating programme | Provide control of the work done |
| **Optional Methods to be Selected from** | Review of documents | Quality management systems internal audit |
| | | Performance evaluation audit |
| | | Analytical and test laboratory accreditation |
| | | Internal review of documents |
| | | External review of documents |
| | | Technical systems (internal) audit (test) |
| | | Technical systems (internal) audit (analysis) |
| | | Analytical quality control |
| | | Data quality internal audit |

## *2.1 Objectives of the step*

The overall objectives of the step are to ensure that the cooperating programme can have justified confidence in the quality of verification done by the operating programme and that the operating programme is in control of the quality of the verification done by the programme.

Appropriate selection of methods for quality management, assurance and control is the key to cooperation on ETV that is both credible and feasible. Insufficient emphasis upon quality will imply that the verification results are not trusted and thus not acknowledged, whereas an attempt to combine all methods applied by all cooperating ETV organisations will cause excessive verification times and costs.

## *2.2 Methods available for achieving the objectives*

Overall, a quality management system ensures that an organisation has the resources, competences, and procedures in place to perform the verification; quality assurance ensures that the verification process is documented and quality controlled; and quality control ensures that the quality of the actual verification is as required. Different methods of quality management, assurance and control are outlined below.

**Quality management system implementation and review:** The OP is expected to implement a quality system and document the existence and adequacy of its internal quality management system. The COP reviews this information at the outset to ensure compatibility with its own requirements.

**Technical systems audit:** This is a qualitative on-site evaluation of sampling and/or measurement systems associated with testing for a specific verification. The objective of the technical systems audit is to assess and document the acceptability of all facilities maintenance and calibration procedures; sampling and analytical activities; quality control

procedures; and reporting requirements associated with the test. Conformance with the test plan or similar document and associated methods and/or standard operating procedures is the basis for this assessment. The technical systems audit is performed by the operating programme. Technical systems audit can be performed on the test procedure and the laboratory analysis. Analytical laboratory accreditation (e.g. ISO 17025) is an external assessment of the quality management system, the procedures and the quality assurance and control performed by a laboratory. Accordingly, it can be a substitute for a technical systems audit during analysis.

**Performance evaluation audits:** This is a quantitative evaluation of the measurement system. The type and frequency of performance evaluation self-audits are specified in the test plan or similar document for test of each verification. The value or composition of reference materials must be certified or verified prior to use, and the certification or verification must be adequately documented. The performance evaluation audit is performed by the operating programme.

**Data quality audits:** This is an examination of the verification data after they have been collected and 100% verified by project personnel. Audit of at least 10% of all verification data, including equations and calculations shall be performed. 100% evaluation of all hand transcribed data should be conducted to minimize data entry errors. Data quality audits are performed by the operating programme.

**Review of documents**: This is review of planning documents, test data, and reports; as well as review of test plan amendments and deviations. Review of documents could be internal to the COP or external to the COP depending on the programme and the qualifications of its personnel. The objective of the external review (performed by such as technical experts, stakeholders, etc.) is to provide an unbiased, competent evaluation of the documents to establish credibility of the described approach. Review and comments of COP(s) and external reviewers on the draft report ensure compliance with the test plan and the adequacy of conclusions. In order to achieve a cost efficient review process, it is recommended that review procedures be agreed upon before submission to the operating organisation. This should include standard review templates and aggregation of review comments within each cooperating organisation. All reviews must be addressed by the OP in writing and the reviewer informed accordingly.

For verification programmes where verification, testing, and/or analysis are done by separate organisations, the quality assurance and control responsibilities are distributed accordingly, with the organisation receiving data from another organisation being responsible for the compliance of the delivering organisation with the data requirements including quality and documentation requirements. As an example, the technical systems audit would be done with the test organisation by the verification organisation of an operating programme, if the verification and testing were separated.

## *2.3 Minimum requirements*

Required quality measures must meet the requirements of the quality systems of each participating organisation and programme. This is considered a fundamental requirement.

The quality management systems of all organisations involved in verification must outline how documents and records are managed through documented filing and archiving procedures.

Application of more than one optional method aiming at fulfilling the same quality objective should be avoided to exclude time consumption and costs that do not provide added quality confidence. For example, if an accredited laboratory is selected, then performing an analytical technical systems audit may be a duplication of requirements.

Planning documents and reports must be assessed by the COP against the requirements of this roadmap and the process document agreed upon by the COP and the OP before starting the verification. See Chapter 10 ("Planning Documents") for more information.

For the first co-verification involving a new combination of COP(s) and OP, quality management systems audit and technical systems audit may be performed by the COP of the OP.

# 3 Technology entry into the programme

| | | | | |
|---|---|---|---|---|
| **Responsible Programme** | OP | OP | OP | OP + COP |
| **Objectives** | Inform vendor on verification process and exchange technology information with the vendor | Define application initially | Assess and communicate verification readiness | Ensure technology compliance with programme priorities |
| **Optional methods to be selected from** | Vendor application form | Vendor and OP dialogue | Assessment of technology information against application definition | Assessment of technology information against programme priorities |
| | Screening check form | Stakeholder input | Screening check form | Stakeholder concurrence |
| | | Expert input | | |

## *3.1 Objectives of the step*

The objective of the step is to ensure vendor acceptance into an ETV programme based upon an assessment of the technology's capabilities and intended application. This includes assessing initial performance parameters for inclusion in verification and evaluating whether the technology is likely to perform during performance evaluation as required for the intended application and as needed by the vendor to meet market expectations. For most programmes, it would be also an objective to ensure that the vendor is informed about the verification process and that the technology falls within the programme priorities of the participating organisations. If the technology falls outside of the current programme priorities, it will be the responsibility of each programme to determine whether or not the technology can be verified based on the scope of each programme. For some programmes, that will involve obtaining stakeholder concurrence as to whether the technology area can and should be prioritized.

This step also involves ensuring that the OP is communicating the interest of the technology vendor in co-verification to the COP, and indicating to the vendor if the COP is interested in collaborating.

The procedures for technology application and entry into an ETV Programme for co-verification are expected to be handled primarily by the operating programme. Cooperating programmes must assure themselves that the application is in compliance with their programme priorities.

## *3.2 Methods available for achieving the objectives*

Information about the candidate technology is gathered, and information about the verification process is shared with the vendor, using one or more of the following methods depending on the requirements of the verification organisation:

**Vendor application form**: This form typically provides information about the verification process and describes the information and commitments needed for preparing, conducting, and reporting the verification. Vendors provide information on the use and applications for their technology and any previous evaluations, as well as suggestions for verification parameters and test collaborators. Completion of the vendor application form provides the vendor with an understanding of the verification process. Completed vendor application forms are typically not publicly available documents.

**Screening check (quick scan):** This is an assessment partially based upon information provided by the vendor describing the properties of the candidate technology. The screening check provides the vendor with information about the probability of acquiring a verification statement after a completed test that will correspond to his/her expectations and needs. The screening check includes a first assessment of the application in terms of the matrix, effect and target of the technology product, as agreed upon with the vendor. Screening checks are typically not publicly available documents.

**Stakeholder input**: Stakeholder groups (technical groups) established by ETV organisations or programmes typically include representatives of the verification programme operator(s) and verification customers for particular technology sectors, including technology purchasers and users, technology developers and vendors, regulators and executive authorities, consulting engineers, and environmental organisations. ETV stakeholders may assist a programme by recommending technologies and technology categories and by developing performance parameters, providing input and review of verification protocols for testing, prioritizing the types of technologies to be verified, and implementing outreach activities to the customer groups they represent.

**Expert input:** Expert input is compiling technology application information through involvement of selected technical experts for a specific verification or technical area.

**Technology assessments:** Also termed pre-screening, this determines whether the technology category is appropriate for verification (market readiness, potential for environmental improvement, etc.) based on a review of readily available information (literature reviews, etc.). In addition to assessing the "verification-readiness" of a technology category before committing resources to the verification, the assessment may also assess technical or other factors to be evaluated as part of the verification.

## *3.3 Minimum requirements*

Depending on which verification organisation is the OP, the documents required may vary by name and form. Before a technology is accepted for verification, it is required that the vendor provide written information about the candidate technology and that the verification organisations make an assessment of the technology's "readiness" for verification, as well as its relevance to the objectives of the verification organisations.

It is the responsibility of the programme operators to determine if the technology is within a priority area.

A discussion on publication of verification documents must occur as part of a decision to enter a technology into a co-verification.

# 4 Contractual agreement

| **Responsible Programme** | OP | OP + COP |
|---|---|---|
| **Objectives** | Ensure contractual agreement on verification | Ensure contractual agreement on verification cooperation |
| **Optional methods to be selected from** | Contract on verification between operating programme and vendor | One or more contracts on verification cooperation between cooperating programme(s) and vendor, between operating programme and vendor and between cooperating programme(s) |
| | Contract on verification and verification cooperation between vendor, operating programme and cooperating programme(s) | Contract on verification and verification cooperation between vendor, operating programme and cooperating programme(s) |

## *4.1 Objectives of the step*

The objective of the step is to clarify and document the expectations for cooperation between the vendor, the operating programme, and the cooperating programmes in a legal contract that defines the roles and responsibilities of each party. It should be noted that the design of some programmes may impede a contract being drawn with foreign organisations and vendors.

The contractual agreement with the cooperating programme is intended to ensure resources to commit to the co-verification. The agreement also is intended to define how the resulting products (reports, verification statements, etc.) may be used by the participating organisations and if the documents will be publicly available.

The purpose of this section is to document the considerations for contractual agreements between the OP, COP(s), and vendor. The vendor needs to know what testing and verification will cost and what the additional costs will be for co-verification. All contractual agreements should specify this information. Activities described in this chapter may be done in parallel with, following, or before those activities performed in Chapter 5 (Verification Process Integrity and Cooperation).

## *4.2 Methods available for achieving the objectives*

One or more contracts can be chosen to achieve the objectives of this step. The contract should address all aspects of involvement, including cost (including maximum level of cost); liabilities; responsibility for subcontracting (i.e., who is choosing the testing organisations and analytical laboratories); timelines for responses (including the possibility of penalties if timelines are not met); logo and verification result use; access, ownership, and use of data; confidentiality; and use of protocols and test systems for additional testing. Requirements for any post verification activities, including the agreed upon approach for publication of documents, should be included.

Consideration should be given as to whether it is useful to do a two-step contract for the planning and execution phases. This allows the vendor the option to make the commitment to the verification process after the planning steps are completed. Completion of the planning phase also allows the OP to provide the most accurate assessment of verification costs to the vendor, since the exact verification procedures will be known.

**Contract on verification:** An agreement between the vendor and the operating programme includes specific information on payment for conducting verification as well as supplies, consumables, and technology related training which will be provided by the vendor for the verification.

**Contract on verification cooperation:** An agreement between the vendor, the operating programme, and the cooperating programme(s) outlining the steps, roles, and responsibilities for participating in developing plans, auditing processes, reviewing data, and reviewing reports and verification statements, as well as a clear understanding of costs; liabilities; timelines; and use of logos , verification results, data; and protocols. The option of having the process document (see Chapter 5) as an appendix to the contract should be considered, but this approach will require that the coverage of costs for elaborating the process document before a contract to be resolved.

**Contract on verification and cooperation:** An agreement that combines the above items.

## *4.3 Minimum requirements*

There must be at least one contractual agreement regulating the verification (OP and vendor) and the cooperation (OP, COP(s), and the vendor). In some cases, the contract between the vendor and the OP may precede an agreement on co-verification with a COP. This further emphasizes the need to view the sequence of Chapters 4 and 5 of this document as flexible and interchangeable.

# 5 Verification process integrity and cooperation

| | | | |
|---|---|---|---|
| **Programme Responsibility** | OP + COP | OP + COP | OP + COP |
| **Objectives** | Protect vendor against verification body requiring too extensive testing | Ensure impartial assessment of test data during verification | Describe requirements and final approval conditions for verification |
| **Optional methods to be selected from** | Independent verification and testing bodies | Independent verification and testing bodies | Co-verification process document |
| | Vendor review of planning documents | External review of documents | Co-verification roadmap |
| | External review of documents | COP review of documents | Section in contractual agreement (Chapter 4) |
| | COP review of documents | | |

## *5.1 Objectives of the step*

The objective of this step is to clearly spell out roles and responsibilities and linking the key requirements of the various involved organisations thus ensuring effective cooperation among all participating parties. This is required because different verification programmes use different terminology and because each programme may have separate programme requirements based on their own quality system. Furthermore, different programmes may have different methods of protecting vendors against impact of undue interests in the verification process.

## *5.2 Methods available for achieving the objectives*

**Roadmap**: This document outlines the general steps that need to be taken to conduct a co-verification. This is a general guidance document applicable to all types of cooperative verifications.

**Process Document**: Until there is an international standard for verification or a clearly defined approach for mutual recognition of verifications performed by different programmes, the process document is of key importance. The process document defines for a specific verification project specific roles and responsibilities and linkages among the specific organisations that are cooperating on the verification. It also lists the methods that have been agreed upon for each objective of the roadmap. It is possible that the understanding of requirements could be accomplished in the contractual agreement; however, it will usually be necessary for funding to be committed to the verification process before the process document can be written. The funding transfer will usually occur as part of the contractual agreement.

**Contractual agreements**: (see Chapter 4).

**Document review**: The document reviews are part of the quality assurance and control (see Chapter 2). Inherent in review of planning documents, is the requirement to review that the extent of the test is adequate.

## 5.3 Minimum requirements

The verification roadmap must be consulted for general guidance on defining cooperation and operation of the verification. A process document or section in contractual agreement must be prepared for each specific co-verification. All planning documents must be reviewed by the vendor.

# 6 Application definition

| | |
|---|---|
| **Programme Responsibility** | OP |
| **Objectives** | Define the intended use(s) of the product (that is, how is the technology to be applied in a real-world scenario) |
| **Optional methods to be selected from** | Application review yielding unambiguous definition such as in terms of matrix, effect, targets, or other parameters depending upon what is relevant to the product being verified |

**Explanation of specific terms mentioned in table:**

**Matrix:** The type of material for which the product is intended. Matrices could be soil, drinking water, ground water, water in a process etc.
**Targets:** The measurable property that is affected by the product. The target could be nitrate concentration, surfactant concentration, MW/kg, etc.
**Effect:** The way the target is affected. The effect could be concentration reduction, decrease in treatment period, etc.

These are three examples of parameters that could be defined as part of the application. Other parameters or terms may be applicable, depending upon the product being verified and its intended use. It is important to note that performance for a given application consideration should be specific, measureable, and defined in a quantitative manner whenever possible.

## *6.1 Objectives of the step*

The objective of the step is to provide a clear understanding of the technology and its benefits and limitations as key to designing the verification with relevant performance parameters that will provide useful performance information for the intended technology user.

## *6.2 Methods available for achieving the objectives*

**Application review and definition:** The review of the intended application typically starts with discussions with the technology vendor, and may be followed by reviews of available product literature and published literature, an evaluation of regulatory requirements, and discussions with external reviewers (stakeholder committees, technical experts, etc.) and COP(s) on how the technology can be used in the "real-world".

It should be noted that once the application is defined, it may be used to identify previously prepared generic verification protocols or equivalent, as well as completed verifications that may, should or must all be used in the further process of verification planning, depending upon the participating ETV programmes requirements. Note that more than one application may be specified in some cases.

The application definition e.g. in terms of matrix, effect, and targets by gathering additional information goes beyond that provided in the Screening check form or vendor application.

## *6.3 Minimum requirements*

The described information on the application of the technology for verification must be gathered for use in the definition of performance parameters and test data requirements.

# 7 Definition of performance parameters

| | | | |
|---|---|---|---|
| **Programme Responsibility** | OP | OP + COP | OP |
| **Objectives** | Define relevant performance parameters | Ensure compliance between performance parameters and programme requirements | Ensure vendor concurrence on performance parameters |
| **Optional methods to be selected from** | Desk study | Review performance parameter definition method in co-verification process document or section in contractual agreement | Documented vendor review and acceptance of parameters |
| | Stakeholder input | Control that agreed performance parameter definition method from co-verification process document or section in contractual agreement was used | |
| | External expert review | | |

**Explanation of specific tools mentioned in table:**

**Desk study:** This is a review based on regulatory requirements, vendor claims, application based needs including key environmental parameters, and knowledge of comparable technologies.

**Stakeholder input:** Defined in Chapter 3.

**Review of performance parameters:** This is a conventional review and may be part of review of planning documents during quality assurance and control (see Chapter 2). Inherent in review of planning documents, is the requirement to review the adequacy of performance parameters.

## *7.1 Objectives of the step*

The objective of this step is to define a set of performance parameters and their relevant ranges. A useful evaluation of the technology that also meets the programmatic and quality requirements of each participating verification programme is essential.

## *7.2 Methods available for achieving the objectives*

Irrespective of the method(s) selected to define the performance parameters, any information on or outline of performance parameters gathered in the application definition (Chapter 6) forms part of the final definition.
Definition of performance parameters must take into consideration any significant adverse effects of the technology during use or, if required by OP and/or COP, other phases of its life cycle (raw materials, production, end-of-life recycling or decommissioning).

As an example, the procedure that has been developed as part of the AdvanceETV project for deriving relevant performance parameters and their ranges can be mentioned, see Chapter 15.

## *7.3 Minimum requirements*

Performance parameters and their relevant ranges must be defined and documented in the planning documents of the verification. Performance parameters must be well-defined, agreed upon by the OP, COP, and vendor, and measureable.

# 8 Definition of test data requirements

| | |
|---|---|
| **Programme Responsibility** | OP |
| **Objectives** | Define the test design (test conditions, data extent and data quality) required for the verification |
| **Optional methods to be selected from** | Test data requirement description (extent and scale) |
| | Reference analyses and measurements requirements description |
| | Operational conditions and measurements description |
| | Identification of additional verification parameters |

**Explanation of specific items mentioned in table:**

**Test data requirement descriptions:** These will differ among technologies; examples for different technology types are given below but these are not intended to be inclusive of all possibilities.

For monitoring techniques, limit of detection, range of application, precision (repeatability and reproducibility), trueness and relevant robustness should be considered for verification, if applicable.

For treatment technologies, reference to conventional treatment methods may provide first outline of data requirements. For non-conventional methods, ensuring that relevant treatment parameters, as well as other relevant performance parameters, can be measured for verification may not be trivial.

For materials, all factors relevant to performance testing and verification, including environmental effects and life cycle aspects should be included, again if possible making reference to conventional materials.

**Reference analyses and measurements requirements description**
If measurements are required to document operational conditions of the technology being verified or if the technology is a monitoring device, reference analyses are used to enable comparison to conventional techniques. For process technologies, measurements of baseline performance of conventional technologies are used to enable this comparison. Especially for monitoring and measurement devices, the results will have to be compared to a reference method.

**Operational conditions and measurements description**
For a defined application, a technology will need to be operable under defined operational conditions, e.g. a temperature range, a concentration range, volume flow variations etc. The ranges for the different parameters have to be defined for the verification.

**Identification of additional parameters:** The identification of additional parameters to be included in evaluation (i.e., the evaluation of user manuals, sustainability, product costs or health and safety issues) for qualification of the performance of the technology.

## 8.1 Objectives of the step

The objective of this step is to define the test design (including test conditions, data extent and data quality) required for verification.

It should not be assumed based on the test data requirement description that testing must actively be performed, since most verification programmes have provisions for use of existing data (See Chapter 9).

It is essential to note that setting data requirements (this Chapter) must come before assessing if any data available may satisfy the requirements (Chapter 9).

## 8.2 Methods available for achieving the objectives

No additional guidance to the optional methods provided in the above table.

## 8.3 Minimum requirements

A precise definition of requirements for test data, which may include a description of the extent and scale, reference analyses for comparison to conventional techniques (where applicable), measurements of baseline operational conditions, and quality control measurements, must be fully described in the planning documents and subsequently documented in the verification report.

# 9 Assessment of existing data

| | |
|---|---|
| **Programme Responsibility** | OP |
| **Objectives** | Justify if existing data fulfils the test data requirements (Chapter 8), quality assurance and control requirements (Chapter 2) and integrity requirements (Chapter 5) |
| **Optional methods to be selected from** | Ensure test organisation is independent from vendor |
| | Evaluate the test plan used to generate the existing data |
| | Evaluate quality of test results and the quality control system employed |
| | Use of independent, accredited analytical, test and verification organisations |
| | Audit of test organisations |

The requirements for accepting existing data may vary from programme to programme and include such things as being generated by accredited and/or designated test organisations. In many cases, requirements of this type (e.g., quality management or preceding approval of involved organisations) may preclude existing data acceptance for verification cooperation with programmes having such requirements. This issue must be discussed and resolved for each specific verification by the OP where existing data are submitted for assessment prior to initiating the verification process.

## *9.1 Objectives of the step*

The overall objective of this step is to reduce verification time and increase cost efficiencies through accepting previously generated data (in whole or in part) as satisfying the test data requirements, while not compromising the credibility of neither the verification statement, nor the ETV programmes and processes. This step offers the opportunity for better use of resources and increased efficiency by avoiding unnecessary redundancy.

## *9.2 Methods available for achieving the objectives*

The methods suggested for quality assurance and control can in principle be used for the assessment of existing data, depending on the quality of the data and other constraints.

**Ensure testing organisation independent from vendor:** This process documents that the organisation that has done the testing is not dependent upon the vendor through joint ownership or provision of other services to the specific vendor (i.e., technology development or consulting services) other than testing the specific technology. Some programmes may not require that the testing organisation be independent from the vendor. This principle will need to be agreed upon by the OP and COP in a co-verification.

**Evaluate the test plan used to generate the existing data:** This method assesses the test plan against the test design required for the verification.

**Evaluate quality of test results and the quality control system employed:** The evaluation assesses data documentation to ensure compliance with the test data quality requirements. The evaluation is only possible if all existing data are available for review, including the test planning documents, raw data, and quality control results.

**Audit of test organisations:** An audit of the test organisation that generated the data and their quality management system by the verification organisation will show compliance with

quality management system requirements of the participating ETV programmes. If still accessible, technical systems used for the test can be audited (see Chapter 2). ISO 9001 certification or accreditation (ISO 17020 or ISO 17025) can be considered proof of existing quality management system and/or test systems.

## *9.3 Minimum requirements*

For existing data to be used in verification, they must comply with the test data requirements (Chapter 8), quality assurance and control requirements (Chapter 2) and integrity requirements (Chapter 5), and the applied methods must document that this is the case.

The assessment must clearly identify which parts of the test data requirements that can be fulfilled by which existing data.

# 10 Planning documents

| **Programme Responsibility** | OP | OP | OP + COP |
|---|---|---|---|
| **Objectives** | Define verification, test design and methods | Ensure agreement on verification and test design and methods with vendor | Ensure agreement on verification and test design and methods between ETV programmes |
| **Optional methods to be selected from** | Preparation of planning documents | Documented vendor review and acceptance of planning documents | Agree upon verification and test design and methods requirements in co-verification process document or section in contractual agreement |
| | | | Control that agreed verification and test design and methods requirements from co-verification process document or section in contractual agreement were used |

**Explanation of specific items mentioned in table:**

**Planning documents:** These will have the form of a verification protocol and a test plan, a generic verification protocol and a specific test plan or a combined test/QA plan as defined for each specific verification. The process document or a section in contractual agreement provides planning details as well. Protocols and test procedures from published verifications for similar applications should be utilized wherever possible and be expanded as required.

## *10.1 Objectives of the step*

The objective of the planning document is to compile and aggregate the requirements defined previously into plans for executing the specific technology verification and test.

## *10.2 Methods available for achieving the objectives*

No additional guidance to the optional methods provided in the above table.

## *10.3 Minimum requirements*

A planning document must be prepared that allows for assessment and execution of the test and verification. The consent of the vendor must also be ensured.

Documentation of major changes to the planning documents should be provided to the COP.

The intent of co-verification is for the vendor to obtain equivalent verification statements from each of the participating programmes based upon the verification results obtained by a single verification organisation. Therefore the required documentation must reflect this to the satisfaction of all parties.

# 11 Test and analysis

| **Programme Responsibility** | OP | OP | OP |
|---|---|---|---|
| **Objectives** | Ensure vendor confidence in test execution | Produce test data | Ensure tests performed in compliance with planning documents |
| **Optional methods to be selected from** | Vendor training of OP staff in technology operation | Execute and document test as described in planning documents | Start-up meeting with OP technical staff (verification and test organisation(s)) |
| | Regular status communication between OP and vendor | | Regular status communication between OP and vendor |
| | | | Transmission of test data to vendor for review on a regular basis. |
| | | | Documentation of plan amendments and deviations |

## *11.1 Objectives of the step*

The objective of this step is to execute and document the test for a specific verification in accordance with planning documents, ensuring vendor confidence and operating/cooperating programmes concurrence.

A key method to achieve the objectives of this step is to have frequent, timely communication and review of test progress while the test is being carried out in order to allow all test participants to actively evaluate test progress so that any necessary corrections can be made as quickly as possible.

No COP involvement is generally foreseen in this step during co-verification.

## *11.2 Methods available for achieving the objectives*

The methods applied for quality assurance and control (see Chapter 2) are to a great extent tailored to the test process. It is ideal for these activities to occur as closely to data generation as possible so that immediate feedback on conduct of the test can be provided.

**Start-up meetings**: These meetings are gatherings of test participants to go over the test details, quality assurance/quality control expectations, data delivery schedules, etc. to make sure that all participants have the same understanding of the test process. Start-up meetings are typically conducted after approval of the test plans and prior to the start of testing.

**Status communication**: The communication here includes regular communication on test progress from the test organisation to the OP (if the two are separate) and from the OP to the vendor with a frequency of updates upon and documented in the planning documents. For co-verification, once the planning documents have been established, the COP is generally not in the direct line of communication during testing.

**Regular status to vendor:** OP gives vendor a status of the testing on a regular basis.

**Transmission of generated data to vendor for review**: With this method, the vendor reviews test data as it is being generated to make sure it is as expected and that any discrepancies are detected and routed back to the test organisation (and optionally to the verification organisation if separate from the test organisation) for any required corrections to be made.

**Amendment documentation:** Documentation of an amendment, that is a change to the test as described in the planning document decided before that specific test activity, with indication of the change, the cause(s) and any consequences.

**Deviation documentation:** Documentation of a deviation, that is a change to the test as described in the planning document decided or acknowledged during execution of that specific test activity, with indication of the change, the cause(s) and any consequences.

## *11.3 Minimum requirements*

The test must be executed and documented according to the planning document(s) which take into consideration the characteristics of the national programmes.

Deviations and amendments to the planning document(s) executed by the OP must be shared with the vendor in real time.

# 12 Reporting and verification

| **Programme Responsibility** | OP | OP | COP |
|---|---|---|---|
| **Objectives** | Compile and document verification and test design and methods, data and evaluations | Ensure vendor confidence in verification results and report | Ensure verification and test design and methods, data and evaluations are in agreement with co-verification process document or section in contractual agreement |
| **Optional methods to be selected from** | Report document(s) | Vendor review of report documents and verification statement | COP review of raw data and report document(s) and statement against requirements in co-verification process document or section in contractual agreement |
| | Verification statement/ statement of verification | | |

## *12.1 Objectives of the step*

The objective of this step is to ensure that the verification and test are done as planned, that the test data requirements are fulfilled, and that the assessments done as part of the verification are reasonable and technically sound.

Requirements for verification and reporting may differ between the OP and the COP.

## *12.2 Methods available for achieving the objectives*

**Report documents:** Different types and formats of report document(s) can be applied to achieve the objectives of OP and COP(s), and may consist of documents such as the test report, verification report, QA/test report, etc. The COP should have access to all information (including raw data) for consideration of co-verification.

**Verification statement/statement of verification:** The statement summarizes the verification including a description of the technology, the application, the verification and test execution and the results. It is anticipated that separate statements will usually be prepared by the OP and COP(s) for co-verification; however, it could be preferable to the vendor for one statement to be issued, so this should be considered during initial planning for the co-verification (e.g., in the process document or contractual agreement). If separate statements are issued, the scientific content should be similar but the context (such as the application derived) could be different.

## *12.3 Minimum requirement*

One or more report document(s) describing the technology, the application, the verification and test execution and results, the existing data included in the verification and the quality assurance and control must be prepared. The potential impact of any and all deviations and amendments shall be presented.

A summary must furthermore be prepared as a statement of the verification, generally as one statement per programme although consideration should be given to a single statement for all programmes if such is desired by the vendor. If separate statements are issued, the science contents must be aligned in the OP and COP(s) statements.

# 13 Verification announcement

| | |
|---|---|
| **Programme Responsibility** | OP + COP |
| **Objectives** | Disseminate verification results and control references to verifications |
| **Optional methods to be selected from** | Web publication of planning document(s) |
| | Web publication of report document(s) |
| | Web publication of verification statement |
| | Vendor use of ETV logo, statement and results |
| | Public register of verifications |
| | Verification organisation outreach |

## *13.1 Objectives of the step*

The objective of this step is to make the results of verifications publically available and to enable technology users and other stakeholders to check the trueness of references to the ETV by technology developers.

## *13.2 Methods available for achieving the objectives*

**Web publication:** The method exploits that most verification programmes operate a web site which includes linkages to reports and/or verification statements.

It should be noted that publication of the results may be required irrespective of the vendor wishing to withdraw his technology from verification, if public resources have been spent on the verification.

**Verification logos:** ETV logos are the evidence of verification. They may be used (alone or as part of the verification statement, depending on the programme) by the vendor to communicate on the verified following the requirements of the OP and/or COP.

**Verification results:** Vendor may not use or refer the verification for any other product or application. The vendor shall make the statement available in full and shall not use parts of the statement for any purpose. If vendor chooses to present test results partly or in full in other contexts than the verification statement, this must be done without any reference to the verification, the verification body or the verification statement.

**Verification organisation outreach:** The methods verification organisations use to disseminate and highlight activities going on within the organisation including presentations of completed verifications at conferences, providing information about completed verifications and participating vendors (i.e., in newsletters), and providing updates to stakeholder committees.

## *13.3 Minimum requirements*

There needs to be agreement up front on whether the report and/or statement will be published, depending upon the programmes involved.

The operating programme publishes according to own requirements as agreed in the process document or relevant section of contractual agreement. The cooperating programme(s)

publish a verification statement based upon the process described here and according to the initial agreements between OP, COP(s) and the vendor.

# 14 Post verification

| **Programme Responsibility** | OP + COP | OP + COP |
|---|---|---|
| **Objectives** | Ensure proper vendor use of ETV logos and verification statement | Ensure validity of verification results over time if appropriate |
| **Optional methods to be selected from** | State terms of use in contractual agreement (see Chapter 4). | Apply limited validity of verification statement with possibility of prolongation |
| | Provide policy on ETV results and logo use | Require information from vendor if product is changed for assessment of continued validity |
| | Surveillance and enforcement enabled | Surveillance and enforcement enabled |
| | | Incorporate reporting of process changes in vendors ISO 9001 process, if existing. |

## *14.1 Objectives of the step*

The objective of this step is to ensure confidence in the validity of verifications, in particular to ensure that the technologies claiming to be verified have not been changed over time as part of continual improvements and upgrades to technologies, and that claims for verification are not extended to cover technologies not verified.

## *14.2 Methods available for achieving the objectives*

**ETV results and logo use policy**: This policy is describing the rules for using ETV logos, statement and verification report for all ETV programmes involved in a cooperative verification effort. Vendor consent is achieved by inclusion of ETV results use policy in the contractual agreement (see Chapter 4) and re-distribution of the results use policy to the vendor again with the signed verification statement.

**Surveillance:** Periodical review of the websites and other available information like technical documents and articles in magazines of participating vendors for references to ETV participation being in accordance to policies.

## *14.3 Minimum requirements*

The terms of use of ETV results (reports, statements and logos) must be clear for the vendor.

Verification programmes must have agreement on procedures for handling of changes to vendor information (including allowable product updates, if any), and addressing any misuse of logos and statements.

Where obligations relating to the validity (length of time that the verification statement is valid) are imposed by the OP or COP, the relevant programme (OP and/or COP) must ensure their enforcement.

# 15 References

Joint performance parameter procedure for use in joint and co-verification, AdvanceETV Deliverable 3.1, DHI, July 2010

Minimum Joint and Co-Verification Requirement Review, AdvanceETV Deliverable 3.2, DHI, October 2010

Draft joint verification and co-verification roadmaps, AdvanceETV Deliverable 3.3, DHI, October 2010