ETV Test Centre and Test Organization

Centre Quality Manual – DTI Water and Chemistry Technology

Version 1

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CONTENTS

1 TEST CENTRE QUALITY MANUAL

1.1 Principles and organization of the manual

This quality manual is the framework for organization, operation and quality management of the DANETV test centre on Biomass Conversion Technology, Danish Technological Institute test centre Water and Chemistry Technology. The Biomass Conversion Test Centre is established in compliance with the emerging EU ETV system. The quality manual has the form of a conventional quality manual with 3 levels: quality manual (Chapter 1), processes (Chapters 2 and 3) and instructions/descriptions (appendices), and is prepared to comply with the requirements expected from the emerging EU ETV system, see Figure 1.

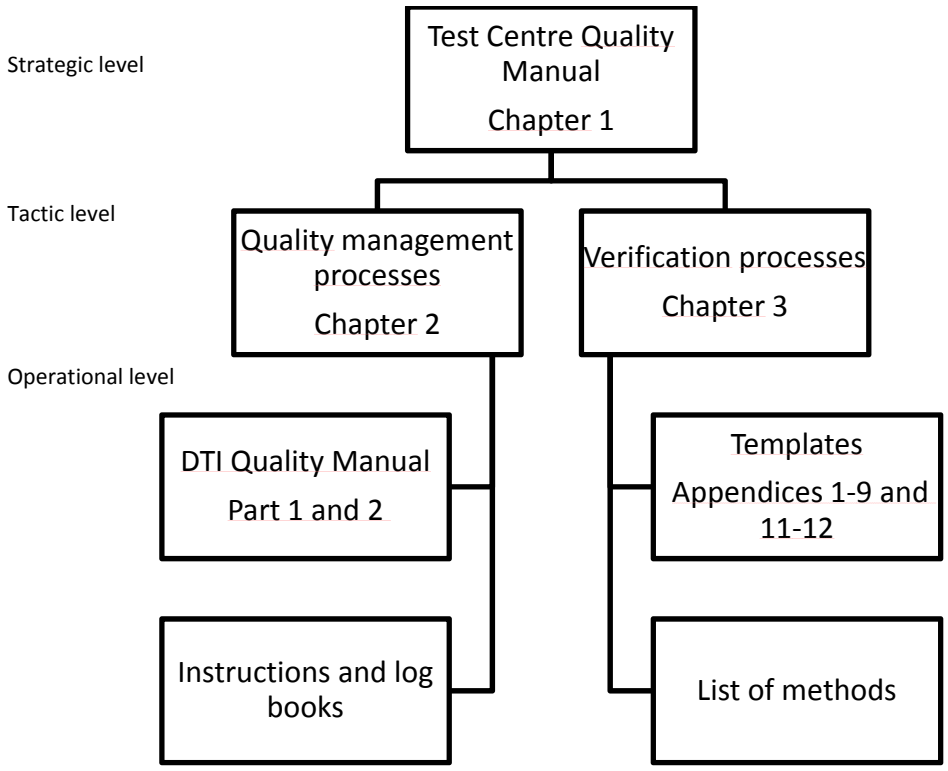

Figure 1 Organization of the DANETV test centre quality manual.

The quality manual has 3 main sections: principles (Section 1.1), organization and quality management (Section 1.2 and 1.3) and operation (Section 1.4 and 1.5).

1.1.1 Scope

Verification statements (verificates) are granted to environment, energy and climate related technology products within the technology areas:

- Biomass conversion technology

The verificates provide independent, third party documentation for performance for a specified application under defined conditions and adequate quality assurance as described in this manual.

1.1.2 Background

The emerging EU ETV system has not yet found its final form. Therefore, the requirements have been anticipated as described in /2;3/ with the emphasis upon the first descriptions of the EU ETV system /4;5/, upon the ETV system described for water treatment and water monitoring technologies, TESTNET /6/, and supported by the framework being established in other EU ETV development projects: PROMOTE /7;8/ and AIRTV /9/. Furthermore, to the extent possible, the requirements of US EPA system /10/ and the international standard for product certification /11/ are considered.

1.1.3 References

For undated references, the latest edition of the publication referred to applies.

This quality manual is the normative references for the operation of the DANETV test centres. The method of verification described here will be endorsed as a Nordtest Method as part of the NOWATECH project and will take over as normative document, when approved by Nordtest. When a final document describing the EU ETV system is available, this will be the normative reference for operation of the centres.

Informative references include:

ISO 9000: Quality management systems – fundamentals and vocabulary /12/

ISO 17000: Conformity assessment – vocabulary and general principles /13/

EN 45020: Standardization and related activities – general vocabulary /14/

ISO VIM: International vocabulary of basic and general terms in metrology /15/

ISO/IEC Guide 7. Guidelines for drafting standards suitable for use for conformity assessment /16/

CEN: Rules for the structure and drafting of CEN/CENELEC publications. ISO/IEC Directives - Part 2 /1/

EN 45011. General requirements for bodies operating product certification systems /11/

ISO/IEC Guide 65:1996. General requirements for bodies operating product certification systems /17/

ISO/IEC 17011. Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies /18/

US EPA. Environmental Technology Verification Program. Quality Management Plan /10/

EN ISO 9001. Quality management systems – Requirements /19/

ANSI/ASQ E4. Quality systems for environmental data and technology programs – Requirements with guidance for use /20/.

1.1.4 Legal status

The legal status of the centre will be established when adapted to a final EU ETV normative document. An interim legal status as a Nordic Council of Ministers/Nordic Innovation Centre system will be established by adaptation of the NOWATECH based Nordtest method.

1.1.5 Terms and definitions

This handbook is using a set of definitions derived from ISO 9000, ISO 17000, ISO 45020, ISO VIM, EN 45011 and the emerging EU ETV system as described in /2;21;22/, see Table 1.

Table 1 Terms and definitions used by the DANETV test centres.

Term	DANETV	Comments on the DANETV approach
Analytical laboratory	Independent analytical laboratory used to analyse test samples	The test centre may use an analytical laboratory as subcontractor
Application	The use of a product specified with respect to matrix, target, effect and limitations	The application must be defined with a precision that allows the user of a product verification to judge whether his needs are comparable to the verification conditions
DANETV	Danish centre for verification of environmental technologies	The centre comprises of 4 centres covering: • Water technologies • Energy • Air • Agricultural technology
(DANETV) test centre	Preliminary name for the verification bodies in DANETV with a verification and a test sub-body	Name will be changed, when the final nomenclature in the EU ETV has been set
Effect	The way the target is affected	The effect could be concentration reduction, decrease in treatment period, pH increase, etc.
(Environmental) product	Ready to market or prototype stage product, process, system or service based upon an environmental technology	The product is the item produced and sold and thus the item that a vendor submits for verification
Environmental technology	The practical application of knowledge in the environmental area	The term technology is covering a variety of products, processes, systems and services

Term	DANETV	Comments on the DANETV approach
Evaluation	Evaluation of test data for a technology product for performance and data quality	None
Experts	Independent persons qualified on a technology in verification	These experts may be technical experts, QA experts for other ETV systems or regulatory experts
Matrix	The type of material that the product is intended for	Matrices could be soil, drinking water, ground water, etc.
Method	Generic document that provides rules, guidelines or characteristics for tests or analysis	An in-house method may be used in the absence of a standard, if prepared in compliance with the format and contents required for standards, see e.g.: /16/
NOWATECH	Nordic Water Technology Verification Centres	
Performance claim	The effects foreseen by the vendor on the target (s) in the matrix of intended use	None
Performance parameters	Parameters that can be documented quantitatively in tests and that provide the relevant information on the performance of an environmental technology product	The performance parameters must be established considering the application(s) of the product, the requirements of society (legislative regulations), customers (needs) and vendor claims
Procedure	Detailed description of the use of a standard or a method within one body	The procedure specifies implementing a standard or a method in terms of e.g.: equipment used
Producer	The party producing the product	None
Standard	Generic document established by consensus and approved by a recognized standardization body that provides rules, guidelines or characteristics for tests or analysis	None
Target	The measurable property of the matrix that is affected by the product	Targets could be *e.g.* contaminant concentration
Test centre, test sub-body	Sub-body of the test centre that plans and performs test	None

Term	DANETV	Comments on the DANETV approach
Test centre, verification sub-body	Sub-body of the test centre that plans and performs the verification	None
Test/testing	Determination of the performance of a product for parameters defined (measured) for the application	None
Vendor	The party delivering the product to the customer	Can be the producer
Verification	Evaluation of product performance parameters for a specified application under defined conditions and adequate quality assurance	None

1.2 Organization

The test centre organization is shown in Figure 2.

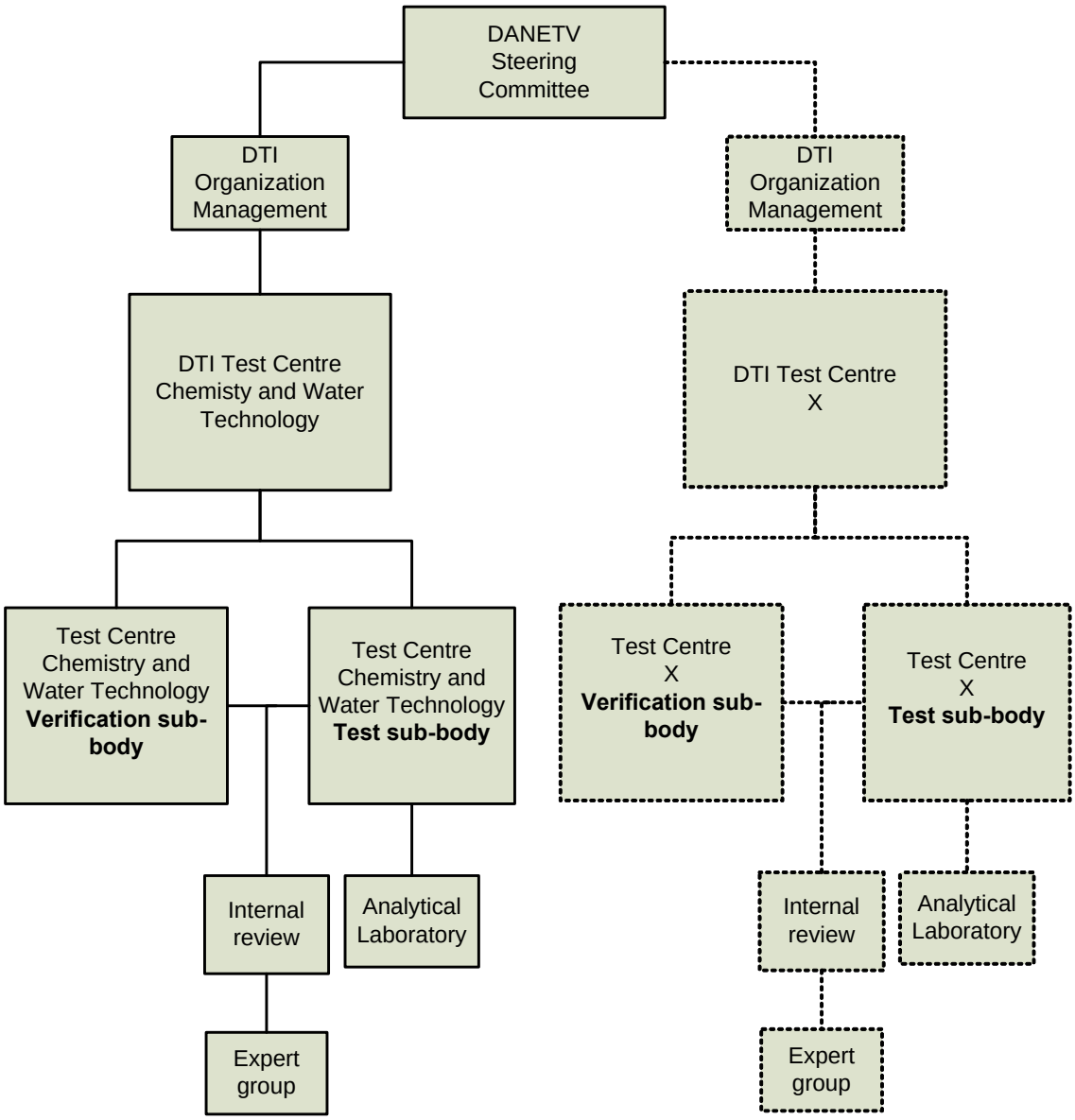

Figure 2 DANETV test centre organization.

1.2.1 Duties and responsibilities

DANETV steering committee
The DANETV steering committee with representatives from the 4 project participants (DTI, DHI, FORCE and AgroTech) has the overall responsibility for the centres, until an EU ETV body has been established. The steering committee has the overall responsibility for the centre operation, and shall handle complaints that have not been settled in the test centres**.**

Organization management
DTI is hosting the test centre for Biomass conversion technology, and the Head of the hosting department has the overall responsibility for the operation of the test centre according to this manual. The organization management has the

overall responsibility for providing the resources (staff and facilities) required to follow the manual and for handling any complaints over the test centre, including an organization quality system compliant with Quality Manuel, Water and Chemistry technology, DTI, part 1 or ISO 9001 /19/ for at the least the verification and test activities.

Test centre management
The test centre management at DTI is responsible for practical operation of the test centre according to this manual. The test centre management has the responsibility according to procedures in DTI Quality Manual for:

- Maintaining this manual.
- Keeping records of staff training and experience.
- Keeping record of facilities and their maintenance.
- Keeping records of complaints from vendors.

Test centre, verification sub-body
The test centre verification sub-body has the overall responsibility for:

- Preliminary evaluation of applicant technology products.
- Establishment of a qualified and independent expert group for the verifications.
- Identification of suitable verification methods and test design.
- Elaboration of verification protocol in cooperation with the expert group.
- Elaboration of verification (test) report.
- Revision of verification report after quality assurance by the expert group.
- Elaboration of verification statement with logo.

The staff performing verification shall not be the same as those responsible for the test of the test centre test sub-body and they should not be dependent upon these.

Test centre, test sub-body
The test centre test sub-body has the overall responsibility for:

- Identification of and subcontracting with one or more independent analytical laboratories for analyses of test samples, if required.
- Elaboration of test plan within the requirements set in the verification with test design requirements.
- Performance of the test according to the test plan.
- Elaboration of the test report.

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

Expert group
The expert group shall have the overall responsibility for:

- Providing input on relevant applications and performance parameters of the technology to be verified.
- Elaboration of review report after quality assurance of the land document and report document, including the test report appendix.

The expert group shall be qualified and without any undue interests in the technologies verified. The experts may be technical experts, regulators or quality assurance experts from other ETV systems.

Analytical laboratories
Analytical laboratories providing analysis of any kind as part of the verification tests, within or outside the test centre body have the responsibility for:

- Maintaining an ISO 17025 accreditation with the quality management system required herein.
- Application of accredited analytical methods, where available.
- Application of other methods according to either international standard methods or in-house methods which are validated.

The selected analytical laboratory subcontractors are listed by the test centre, test sub-body (see Appendix 10).

1.2.2 Staff

The test centre has, develops and maintains staffs that are qualified for the technology verifications and tests within the scope of the centre with the executive staff responsible for the units shown in Table 2 .

Table 2 Staff attached to the DANETV Test Center, Chemistry and Water Technology

Organization element	Name	Function
DANETV Steering committee member	Lars Jøker	Head of section
DTI, Organisation manager	Bo Frølund	Head of Department
Biomass conversion Technology Test Centre manager	Kathe Tønning	Head of Projects
Verification sub-body responsible	Arne Grønkjær Hansen	Senior consultant
Test sub-body responsible	Bjørn Malmgren-Hansen	Consultant

Staff competence management procedures are found in Section 2.6.

1.2.3 Information

The test centre provides information on the verification operation and reports on the web sites www.etv-danmark.dk. and www.etv-denmark.com.

All protocols and plans (on-going verifications) and reports and verification statements (completed verifications) are published on the web site.

1.3 Test centre quality management

The quality management of the test centre has the following main points:

- Review of plans, protocols and reports.
- Document and record control.
- Internal audits with corrective and preventive actions.
- Complaint management.
- Subcontractor management.
- Staff competence management.
- Facility management.
- Annual management reviews.

The quality management processes are further described in Chapter 2.

1.4 Verification operation

The principles of operation with the role of the verification and test documents and the different sub-bodies responsible are given in Figure 3.

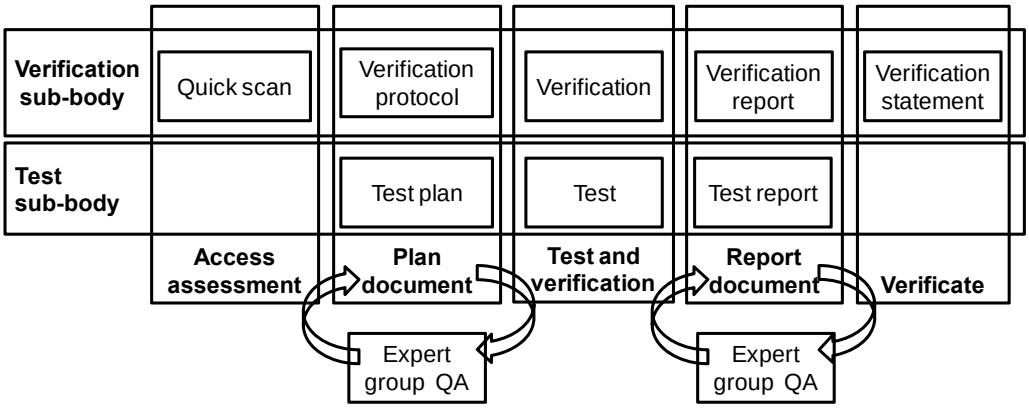

Figure 3 Principles of operation of the DANETV verification scheme.

The verification protocol and report may be prepared for one product or for a group of products aiming at the same application. Once elaborated, a verification protocol shall be used for future verifications of products aiming at the same application. The remaining documents are each prepared for one product.

A contract between the vendor and the test centre must be entered before initiating the verification. Definition of the application and of the relevant performance parameters, as well as detailed assessment of any existing test data and of the need for additional test data is done in the first phase of protocol development.

In order to facilitate the preparation of the documents, templates have been prepared and are available in appendices. Reports are in principle protocols and plans with data and evaluations inserted.

The verification processes are further detailed in Chapter 3 structured to respond to the documentation required.

1.5 Document – manager, experts, staff responsibilities

The responsibilities for preparing, reviewing and approving documents in the verification are summarized in Table 3.

Table 3 Verification document responsible summary

Document	Preparation	Review	Approval
Quick scan report	Verification staff	Verification sub-body responsible	Verification sub-body responsible
Contract	Verification staff	Test centre manager	Test centre manager
Verification protocol and report	Verification staff	Technical experts	Test centre manager
Test plan and report	Test staff	Technical experts	Verification staff
Review reports	Technical experts	None	None
Verification state-ment	Verification staff	Technical experts	Test centre manager

2 QUALITY MANAGEMENT PROCESSES

The test centre works according to Quality Manuel, Water and Chemistry technology, DTI, part 1 and 2 or ISO 9001 /19/. This is done by working according to procedures prepared for the processes listed in this chapter.

Management, organization and responsibilities are defined by adopting Chapter 1 of this quality manual.

2.1 Review of plans, protocols and reports

This procedure describes how the test centre plans the reviews required. An overview of responsibilities is given in Table 4.

Table 4 Responsibilities concerning reviews and audit.

	DTI Internal		Expert group external
Function	Technical expert	Trained auditor QA staff	Technical expert
Tasks			
Plan document with verification protocol and test plan	Review		Review
Test system		Audit	
Report document with test report and verification report	Review		Review

The test centre plans recruitment of external experts, competence and independence requirements for external experts and internal reviewers, payment and scheduling. (Appendix 10 and Chapter 1.2.1).

2.2 Document and record control

The Quality Manuel - DTI Water and Chemistry Technology includes a procedure (0103) which describes the process of drafting, revising and approving the documentation of the test centre manual with the aim of ensuring that all involved in the verification processes have access to and uses the latest approved version of the manual with process descriptions.

A list of documents (Appendix 10) is maintained with indication of the persons authorized to draft, revise and approve the documents.

The procedures 0111 and 0112 in the Quality Manuel - DTI Water and Chemistry Technology describes how records of verification and testing 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 verification.

2.3 Internal audits

The procedure 0104 in the Quality Manuel - DTI Water and Chemistry Technology describes the process of periodic internal auditing of the verification and test activities in the test centre including audit responsibilities and planning, auditor training and competences and audit reporting.

Procedure 0104 in the Quality Manuel - DTI Water and Chemistry Technology describes how deviations identified during auditing are corrected (corrective actions) and how future occurrence of the same deviations is prevented by improving the quality manual including the process descriptions and working methods (preventive actions).

2.4 Complaint management

The procedure 0213 in the Quality Manuel - DTI Water and Chemistry Technology describes how vendor complaints are recorded, resolved, reported. If not resolved, complains are referred to the DANETV steering committee for resolving.

2.5 Subcontractor management

The procedure 0218 in Quality Manuel - DTI Water and Chemistry Technology describes how the test centre ensures that subcontracting of tasks such as tests, sampling, measurement or analysis to other independent bodies is done while ensuring that the subcontractor follows the quality requirements, the verification protocol and the test plan for the task, see also Section 1.2.1 for the responsibilities of an analytical laboratory working for the test centre.

The procedure 0406 in the Quality Manuel - DTI Water and Chemistry Technology describes how it is ensured that purchased items for verification and testing resemble requirements, such as those that may be specified in a verification protocol, a test plan or a working method. In particular, the procedure describes how the purchased items are controlled, accepted and calibrated (see Appendix 10).

2.6 Staff competence management

The procedures 0301 and 0302 in the Quality Manuel - DTI Water and Chemistry Technology describe how the test centre ensures that verifications and tests are done by staff with adequate competences and knowledge of their responsibilities. This is done by maintaining a list of functions in the verification and test process with competence requirements and responsibilities, staff approved for the function.

2.7 Facility management

The Quality Manuel - DTI Water and Chemistry Technology, Part 2 §5 describes how the test centre ensures that the facilities and the equipment for verification and test of products belonging to the technology area covered by the centre are available and fit for the purposes (procedures 0401 and 0402).

2.8 Management review

The procedure 0105 in the Quality Manuel - DTI Water and Chemistry Technology describes how the management of the organization hosting the centre is ensuring that the test centre is working according to this quality manual through mechanisms such as e.g. an annual management review process.

3 VERIFICATION PROCESSES

Verification is done by the Biomass conversion Technology test centre verification sub-body and testing by the test centre test sub-body.

3.1 Access assessment

Access to the verification process is given after a quick scan of the properties of the technology product in question.

The purpose of the quick scan procedure is to ensure, that the vendor knows the probability of acquiring a verification certificate after completed test.

The quick scan is done by the test centre free of charge initially, but the costs are included in a subsequent verification contract, if decided for.

3.1.1 Information from the vendor

The vendor supplies the required information by partially filling in the quick scan form, see Appendix 1. The information shall be as quantitative as possible.

3.1.2 Application definition

The quick scan procedure should include a first definition of and agreement with the vendor upon the application in the terms of the matrix, effect and target of the technology product, see Table 5.

Table 5 Definition of application.

Matrix	Effect	Targets	Technologies
The type of material that the product is intended for . Matrices could be biomass, manure etc.	The way the target is affected. The effect could be concentration reduction, decrease in treatment period, etc. **Additional parameters:** Other effects that will be described but are considered secondary. The additional parameters could be product costs (including also energy consumption and chemical consumption) , environmental health and safety and user manual quality etc.	The measurable property that is affected by the product. The target could be ammonia concentration, biomass yield, MW/kg etc. **Operation parameters:** Measurable parameters that define the application and the verification/test conditions. Operational parameters could be production capacity, concentrations of non-target compounds in matrix etc.	The practical application of knowledge in the environmental area. The term technology is covering a variety of products, processes, systems and services.

The application definition should be refined during the application and performance parameter definition done as part of the protocol preparation.

3.1.3 Evaluation of quick scan

In the evaluation of the information supplied by the vendor, the emphasis is upon:

- Description of product function.
- Relevance of performance claims.
- Data supporting performance claims.

The evaluation is based upon the information supplied by the vendor and the general information on relevance of product performance available with the centre.

3.1.4 Reporting of quick scan

The quick scan shall be reported by completing the quick scan form, Appendix 1. The vendor shall be informed on the results of the quick scan, and the vendor can decide to proceed with the verification procedure irrespectively of the conclusion of the quick scan.

3.2 Verification and test planning

3.2.1 Verification contract

If the vendor decides to proceed with verification, the centre shall provide a cost estimate for the verification. Based upon the cost estimate, a verification contract is drawn and signed by the vendor and the centre and subsequently, the verification planning can start.

The verification contract shall be done applying the template found in Appendix 2. 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, detailed evaluation of existing data, test plan design). In such cases, a contract is entered for these first parts, leaving the remaining parts for a second contract.

3.2.2 Verification protocol

The verification protocol shall describe the framework for the verification of the technology product and provide the information required for the test plan. The template for the verification protocol given in Appendix 3 shall be used.

When a verification protocol has been accepted for one product aiming at one matrix/target combination, all subsequent verifications within this combination shall include the first accepted verification protocol.

The verification protocol shall be approved by the verification responsible and the internal reviewer.

Technology and product description

The technology behind the product in verification shall be described in principle with respect to the mechanisms of operation and the construction.

The product in verification shall be described in detail with respect to the mechanism of the operation and the construction. The description shall allow understanding of the mode of operation within an accepted scientific and technical context.

References to any patents on the product shall be given with information on the owner of the patents and on licensing to the vendor, when the vendor is not the patent owner.

Application and performance parameter definitions

The application that the product shall be verified for shall be defined with respect to the matrices, targets and effects for the product.

The performance parameters shall be set to ensure that the product is tested for parameters and in ranges that are relevant for the buyers of the technology considering regulatory requirements, application based needs and state-of-the-art performance of similar products.

The definition of the application and the performance parameters should be done using the template given in Appendix 3 of the verification protocol template. As a minimum, it shall be documented that systematic evaluation of the issues listed in the template is behind the precise definitions of application (matrix, target and effects) and performance parameters.

If a standard giving relevant performance parameters for the applications 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 application for verification in order to reflect the different requirements for different applications.

When a set of application and performance parameter definitions has been derived, for one product aiming at one matrix/target combination, all subsequent verifications within this combination shall comply with this set.

Additional parameters
Further aspects may be included when relevant and shall then be described: user manual (Chapter 3.5.1), product costs (Chapter 3.5.2) and occupational health and environment impact (Chapter 3.5.3).

Existing data
Existing data, *i.e.* produced before approval of the verification protocol and the test plan for the product, supplied by the vendor are summarized with the name, full address and status (independent/dependent, certifications and accreditations) of the data supplier.

The data quality of the existing data is evaluated by inspection done by the verification sub-body checking documentation, raw data and quality control data from the data production. The same data quality requirements as set for the test during verification must be fulfilled by existing data. Existing data must be produced under a quality management system comparable to that of EN ISO 9001 /19/ or ANSI/ASQ E4 /20/, and analytical data under quality assurance equivalent to that of ISO 17025 /23/ or GLP /24/. Existing data produced by the vendor or by bodies dependent upon the vendor can be used for planning of the verification but not as verification data.

The accepted existing data are summarized in the format to be used reporting test data.

Test plan requirements
The verification protocol describes the requirements for the test design for the product, as it shall be implemented in the test plan.

The test plan must reflect the application and the performance parameters defined for the verification, but specific requirements for the test design shall be given in order to ensure that the tests will provide data reflecting the applica-

tion and the performance parameters required for the evaluation. The test plan requirements shall be specified with respect to:

- Overall test design.
  - Scale (laboratory, pilot and/or field).
  - Performance parameters to be measured.
- Methods of reference analysis.
- Data management.
- Quality assurance.
- Test report.

If available and relevant, test standards or methods shall be given. If specific requirements for analytical methods or their performance have been identified during planning, these shall be given.

The requirements for test data management with respect to the format of data storage shall be defined. If needed, the methods to be used for processing of raw data into measurement results shall be given.

The quality assurance requirements described for the test plan shall include requirements for reference analysis quality control, test system control, data integrity control and review/audit of test system, plans and reports.

Method evaluation
The methods of processing of measurements into performance parameters including statistical methods and any required statistical levels of confidence shall be defined or referenced.

The methods of evaluation of the test quality assurance data shall be outlined.

Verification quality assurance
The member of the verification sub-body that will review the draft verification protocol and report before submission to the external review is named. The verification protocol and report reviewer cannot be responsible for verification planning or operation.

The external expert(s) that will perform review of the verification protocol and report shall be named. A template for review reports as given in Appendix 7 may be used but in all cases, the review results and their implementation in the protocol and report shall be documented.

If the verification is done within the framework of another ETV scheme, the involvement of this scheme in quality assurance of the verification shall be given.

Verification schedule
The schedule for the verification shall be given.

3.2.3 *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 as Appendix 4 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.

The test plan shall be approved by the test responsible and the internal reviewer.

Test design

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

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

A field site shall not be dependent upon the vendor. If the product in verification is installed and used at the field site, it shall be ensured that no commercial or other interests are associated with using the site as test site for the product, besides the vendor's interest in obtaining the verification statement.

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 in the test plan shall allow the test staff to perform the tests as required in the 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.

Reference analysis

The analytical programme shall be described including agreed analytical methods and required analytical performance (detection limit, uncertainty). Contact information, requisitions and logistics should be given. The format of reporting from the laboratory (data files, accredited reports, etc.) should be described.

Data management

The methods of calculation of test measurements from raw data shall be described, if not given in the analytical and test methods used. Formats of data storage (data files, instrument prints, and report forms) shall be defined. Software other than standard spread sheets used for data collection, storage and calculations shall be indicated.

A data compilation and storage table (example in Table 6) should be used to summarize the requirements.

Table 6 Data compilation and storage summary, example

Data type	Data media	Data recorder	Data recording timing	Data storage
Test plan and report	Protected PDF files	Test responsible	When approved	Location DTI project server
Test details in laboratory and field	Log book and pre-prepared forms	Technician	During collection/test	Location DTI project server
Calculations	Excel files	Test responsible	During calculations	Location DTI project server
Analytical reports	Paper/PDF	Test responsible	When received	Location DTI project server

Quality assurance
The measures taken to ensure and quantify the test traceability and reproducibility are described. Measures such as replicate samples, replicate tests, replicate analysis, field blanks and field controls may be selected. The way reproducibility of the tests will be quantified shall be described. Reference analysis performance requirements and quality control shall be detailed.

The procedures to be applied in control of data integrity during transfer from one format to another shall be described.

The member of the test sub-body who reviewed the draft test plan and report before submission to the verification sub-body is named. The test plan and report reviewer cannot be responsible for test planning or operation. Plans for additional review and/or audits shall be given, if relevant.

Test report formats
The format of the test report shall be set, such as *e.g.* by reference to the template used in this manual (Appendix 5). The format and location for archiving of raw data shall be defined.

3.3 Test and verification

Testing shall be done according to the test plan and verification according to the verification protocol. If changes to either need to be done before doing the testing and/or verification, an amendment form is filed in and approved by the same persons that are responsible for preparation and approval of testing and verification respectively, see Table 3. Similarly, if changes are recorded during testing and/or verification, these are recorded in a deviation form and approved as for the amendment forms. Examples of amendment and deviation forms are given in Appendices 11 and 12. The amendment and deviation forms shall be retained as documentation as part of the records of testing and verification.

3.4 Test and verification reporting

3.4.1 Test report

The test report uses all chapters from the test plan, see Appendix 4, except for the last chapter describing the planned report being replaced by a data report chapter such as that shown in Appendix 5.

A summary of any amendments to and deviations from the test plan recorded during tests shall be included. Templates for reporting amendments and deviations are shown in Appendix 11 and 12

The appendix from the test plan with data reporting forms shall be replaced by a test data report listing any and all deviations from the test plan with description, justification and effect evaluation, as well as all required measurements. The test data report shall include all analytical and calculated data.

The test report shall be approved by the test responsible and the internal reviewer.

3.4.2 Verification report

The verification report uses all chapters of the verification protocol, Appendix 3, with a chapter describing the evaluation of obtained data inserted as an additional chapter, see Appendix 6 for a template that shall be used.

The evaluation shall give a summary of the test results, amendments to and deviations from protocol and test plans, and performance of the product in the verification is summarized. The impact of any and all deviations from the verification protocol and test plan shall be evaluated and summarized.

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

Evaluation of required additional parameters shall be summarized.

The test report shall be given as an appendix.

The verification report shall be approved by the verification responsible and the internal reviewer.

Documentation for the verification report document review by the external expert(s) identified in the verification protocol shall be included as an appendix. Appendix 7 gives a template for review report that may be used but in all cases, the review results and their implementation in the report shall be documented.

3.4.3 Verification statement with logo

The verification statement is a maximum 4 page summary of the verification including applications, performance parameters, test design, operation conditions, test results and evaluation of additional parameters.

Statement format
The format of the statement shall be as given in Appendix 8. The overall format shall be implemented in the same form for all products, and an identical format shall be applied for all products aiming at the same application.

Statement issue
The verification statement with logo is prepared after verification and is signed by an issuing body representative (the verification sub-body of the test centre).

Statement and logo use
The verification statement with logo may be used by the vendor for marketing and approval. The vendor shall make the statement available in full and shall not use parts of the statement for any purpose.

The vendor may quote the verification statement as follows: the XX product has been verified for ZZ effect on WW target in YY matrix by QQ test centre on DD.MM.YYYY, while giving the reference for access to the full verification statement.

The vendor shall not use the logo alone neither on products nor on published (printed, web or other) matter other than the verification statement.

Surveillance
The vendor shall be obliged to report any information on changes in the product to the test centre with the data needed to evaluate whether the conditions for verification have changed. The test centre shall perform this evaluation at the cost of the vendor. Substitution of one part with another with the same documented specifications is not considered a change.

Statement validity
The verification is valid as long as the product has not been changed in such way that the conditions for verification have changed, see previous section.

Withdrawal
The verification statement shall be withdrawn by the test centre if misused by the vendor. Misuse is defined as violation of the conditions stated in this section. In case of withdrawal, this is announced on the ETV web, and reports are removed from the web.

3.5 Additional verification parameters

Additional parameters selected for evaluation in the verification protocol, see Section 3.2.2, shall be evaluated using documented procedures.

3.5.1 Evaluation of user manuals
The verification parameter for the user manual is the completeness of the description of the use of the product adequately and understandable for the typical user. This parameter is evaluated through evaluation of a number of specific points of importance. An example of a matrix that may be used for the purpose is given in Appendix 9.

A description is complete, if all essential steps are described, if they are illustrated with a figure or a photo, where relevant, and if the descriptions are understandable without reference to other guidance.

3.5.2 Evaluation of product costs

The capital investment costs and the operation and maintenance cost should be itemized based upon a determined design basis /25/. An example of a matrix that may be used for the purpose is given in Appendix 9.

The design basis should be described and the cost items relevant for the use of the product listed.

Actual costs for each cost item may be compiled and reported if found relevant for the technology area and industry praxis in question.

3.5.3 Evaluation of occupational health and environmental impact

The risks for occupational health and safety and for the environment associated with the use of the product should be compiled including a list of chemicals used during product operation and classified as toxic, T, or very toxic, Tx, for human health and/or very environmentally hazardous (N) according to /26/. The information should be given as amount used per product unit (sample). An example of a matrix that may be used for the purpose is given in Appendix 9.

Additional risks from installing, operating and maintaining the product should be evaluated, compiled and reported, if relevant. In particular, risks for human health associated with power supply and danger of infections will be considered.

If relevant, other additional verification parameters may be defined and verified using documented procedures.

4 REFERENCES

1. CEN. Rules for the structure and drafting of CEN/CENELEC publications. ISO/IEC Directives - Part 2. 2003.
2. Grøn, C. ETV Test Centre and Test Organization. Basic requirements. 13-7-2007.
3. Merkourakis, S., Calleja, I., Delgado.L., Oçafrain, A., and Laurent, S. Environmental Technologies Verification Systems. 2007. Joint Research Centre, Institute for Prospective Technological Studies.
4. Draft Scheme of the Verification Procedure. Submitted to the Commission. 2007.
5. European Commission. Consultation paper on an EU system for environmental technology verification. 2007.
6. KIWA. EU ETV - the SYSTEM. TESTNET. Draft. 2006.

7. PROMOTE. Draft of European Environmental Technology Verification System for Monitoring and Remediation Technologies. 30-6-2006.
8. CEN/WS 32. Environmental Technology Verification – Soil and Groundwater Remediation and Monitoring Technologies. CEN workshop agreement. 2008.
9. AIRTV. Testing network for verification of air emissions abatement technologies. AIRTV project flyer. 2007.
10. US EPA. Environmental Technology Verification Program. Quality Management Plan. 2008.
11. European Standard. EN 45011. General requirements for bodies operating product certification systems. 17-6-1998.
12. International Standardization Organisation. ISO 9000. Quality management systems - Fundamentals and vocabulary. 15-9-2005.
13. International Standardization Organisation. EN ISO/IEC 17000. Conformity assessment - Vocabulary and general principles. 11-1-2004.
14. European Standard. EN 45020. Standardization and related activities - General vocabulary. 2006.
15. International Standardization Organisation. ISO VIM. International vocabulary of metrology - Basic and general concepts and associated terms (VIM). 2008.
16. International Standardization Organisation. ISO/IEC Guide 7:1994. Guidelines for drafting standards suitable for use for conformity assessment. 1994.
17. ISO and IEC. ISO/IEC Guide 65:1996. General requirements for bodies operating product certification systems. 1996.
18. International Standardization Organisation. ISO/IEC 17011. Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies. 2007.
19. International Standardization Organisation. EN ISO 9001. Quality management systems - Requirements. 15-11-2008.
20. American Society for Quality. ANSI/ASQ E4-2004. Quality systems for environmental data and technology programs - Requirements with guidance for use. 4-2-2004.
21. EURODEMO, PROMOTE, and TESTNET. Common Glossary of Terms. 12-7-2006.
22. EURODEMO, PROMOTE, and TESTNET. Verification scheme definitions. 2007.
23. ISO. General requirements for the competence of testing and calibration laboratories. ISO 17025. 2005.
24. OECD. OECD Principles of Good Laboratory Practice. OECD GLP Document No. 1. 21-1-1998.

25. Gavaskar, A. and Cumming, L. Cost Evaluation Strategies for Technologies Tested under the Environmental Technology Verification Program. 2001. Battelle.

26. European Commission. Commission Directive on classification, packaging and labelling of dangerous substances. 2001/59/EC. 2001.

A P P E N D I X 1

Quick scan report template

QUICK SCAN REPORT	Product name:	

Test centre		Vendor	
Name:		Name:	
Contact:		Contact:	
Address:		Address:	
Telephone:		Telephone:	
E-mail		E-mail	

Quick scan		Previous quick scan					
Date:		Yes		Date:		No	

Product description							
Product ready to market				Product in last development phase			
Yes		No		Yes		No	
Performance claims							
Matrices:							
Targets:							
Effects:							

Product description clear				Performance claims clear			
Yes		No		Yes		No	

Existing test data							
Tests performed				Test body qualified			
Yes		No		Yes		No	
Test report available				Test report qualified			
Yes		No		Yes		No	
Test methods available				Test methods adequate			
Yes		No		Yes		No	
Raw data available				QA of raw data adequate			
Yes		No		Yes		No	
Performance claims sustained				Performance claims relevant			
Yes		No		Yes		No	

Conclusions quick scan

Date	Name	Signature

A P P E N D I X 2

Verification contract template

Verification contract

Product name:	

Test centre		**Vendor**	
Name:		Name:	
Contact:		Contact:	
Address:		Address:	
Telephone:		Telephone:	
E-mail		E-mail	

{Test centre name} agrees to verify the above mentioned product for the below tentatively defined application in accordance with the DANETV environmental technology verification method.

Application				
Matrices:				
Targets:				
Effects:				

Costs and payments

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

Verification steps	**Included in contract**	**Costs {currency}**
Quick scan report	√	
Verification protocol		
• Application and performance parameter definition	√	
• Assessment of existing data	√	
• Test plan design	√	
• Verification protocol		
Test plan, test and test report		
Verification and verification report		
Verification statement		
Total costs	-	

Costs are all inclusive, VAT exclusive.

The payment scheme is as follows:

Payment	**Time of payment**
10% advance payment	With signed contract
50% payment	After approval of verification protocol and test plan, before initiating testing
40% final payment	After delivery of verification report and statement

If another product is verified for the same application according to the same protocol by {Test centre}, the vendor of that product will be charged with an evenly amount of the total costs paid by {vendor} that will receive a back payment for this amount.

Deliverables

{Vendor} agrees to provide without costs and delay for {test centre}:

- Contact person for the verification.
- Existing performance data of the product.
- Technology product(s) for verification as indicated in the test plan.
- Arrangement and mounting of the product at the test site.
- User instructions, training and support as needed during testing.
- Information on technology and product details and mode of action as required for a full understanding of the product.
- Comments on documents submitted for commenting.

{Test centre} agrees to provide within the contract:

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

Information

{Test centre} and {vendor} shall both inform the other part, if changes in the conditions for the verification change.

Intellectual property rights

{Vendor} warrants that the product submitted for verification is owned or controlled fully by {vendor}.

{Vendor} will retain all rights to the product and all technical data produced during the verification.

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

Schedule

A detailed schedule will be part of the verification protocol and test plan. These will be available for commenting within 6 weeks from the date of contract signing and first payment, whatever comes latest.

Limitations

{Test centre} performs the verification as described for the application of the product 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 products.

{Vendor} agrees not to use or refer the verification for any other product or application, and not to use extracts of the verification statement for any purpose.

Confidentiality

All final versions of reports, protocols, plans and statements can be made available for public access by {Test centre} through media it finds relevant such as the DANETV web sites.

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

During verification, {vendors} allows {Test centre} to give external auditors access to all information obtained or produced during the verification, as specified in the verification protocol and/or the test plan.

Liability

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

{Test centre} assumes no liability for delays or for verification results that damage the sales of the product or the vendor.

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 case of termination, any costs endured by {Test centre} as part of the verification that cannot be averted shall be paid in full by terminating part. If termination is done by the centre due to vendor's non-fulfilment of the agreements in this

contract then the costs shall be paid in full by the vendor. Termination by {Vendor} does not prevent preparation of the verification report based upon the data available at the time of termination, and the costs for reporting will be payable by {Vendor} irrespective of the termination.

Disputes

Disputes shall be governed by {Test centre home country} law.

Signatures

Test centre		**Vendor**	
Name:		Name:	
Signature:		Signature:	
Title:		Title:	
Date:		Date:	

A P P E N D I X 3

Verification protocol template

Title page

Table of contents

1. Introduction
    1.1. Name of product
    1.2. Name and contact of vendor
    1.3. Name of centre/verification responsible
    1.4. Verification and test organization
    1.5. Expert group
    1.6. Verification process
2. Description of the technology
3. Description of the product
4. Application and performance parameter definitions
    4.1. Matrix/matrices
    4.2. Target(s)
    4.3. Effects
    4.4. Performance parameters for verification
    4.5. Additional parameters
5. Existing data
    5.1. Summary of existing data
    5.2. Quality of existing data
    5.3. Accepted existing data
6. Test plan requirements
    6.1. Test design
    6.2. Reference analysis
    6.3. Data management

6.4. Quality assurance

6.5. Test report

7. Evaluation

7.1. Calculation of performance parameters

7.2. Evaluation of test data quality

7.3. Compilation of additional parameters

7.3.1. User manual

7.3.2. Product costs

7.4. Occupational health and environment

8. Verification schedule

9. Quality assurance

Appendix 1 Terms and definitions used in the verification protocol

Appendix 2 References (verification protocols, requirement documents, standards, methods)

Appendix 3 Application and performance parameter definitions

A3.1 Applications

A3.1.1 Matrix/matrices

A3.1.2 Target(s)

A3.1.3 Effects

A3.1.4 Exclusions

A3.2 General performance requirements

A3.2.1 Regulatory requirements

A3.2.2 Application based needs

A3.3 State of the art performance

A3.4 Performance parameter definitions

A P P E N D I X 4

Test plan template

Title page

Table of contents

1. Introduction
    1.1. Verification protocol reference
    1.2. Name and contact of vendor
    1.3. Name of centre/test responsible
    1.4. Expert group
2. Test design
    2.1. Test site
    2.2. Types
    2.3. Addresses
    2.4. Descriptions
    2.5. Tests
        2.5.1. Test methods
        2.5.2. Test staff
        2.5.3. Test schedule
        2.5.4. Test equipment
        2.5.5. Type and number of samples
        2.5.6. Operation conditions
        2.5.7. Operation measurements
        2.5.8. Product maintenance
        2.5.9. Health, safety and wastes
3. Reference analysis
    3.1. Analytical laboratory
    3.2. Analytical parameters
    3.3. Analytical methods

A P P E N D I X 5

Test report template,
parts substituted or added in test plan

7. Test results

    7.1. Test performance summary

    7.2. Test measurement summary

    7.3. Test quality assurance

    7.4. Deviations from test plan

Appendix 7 Test data report

A P P E N D I X 6

Template for verification report, parts substituted or added in verification protocol

8. Evaluation

8.1. Calculation of performance parameters (from the verification protocol)

8.2. Performance parameter summary

8.3. Evaluation of test quality

8.3.1. Control data

8.3.2. Audits

8.3.3. Deviations

8.4. Additional parameter summary

8.4.1. User manual

8.4.2. Product costs

8.4.3. Occupational health and environment

8.5. Recommendations for verification statement

Appendix 4 Test report

Appendix 5 Review reports

A5.1 Plan document

A5.2 Report document

A P P E N D I X 7

Template for review report

Review report

Document title:		Document date:	
Reviewer name:		Review date:	
Name:			
Organization:			
Address:			
Telephone:			
E-mail			

Review results					
Rate items	*Satisfactory*	*Unsatisfactory*		*Overall recommendation*	
Contents					
Scope				Acceptable as is	
Organization				Minor revisions	
Data quality				Major revisions	
Method validity				Not acceptable	
Conclusions					
Other (specify)			Reason		

Revision details				
Topic	*Report chapter, section, page*	*Revision required*	*Reason*	*Revision action(to be filled in by document owner during revision after review)*

Add additional rows, if pertinent.

A P P E N D I X 8

Template for verification statement with logo

Title page/page 1

	**Test centre logo**

Technology:		**Product:**	

Test centre		**Vendor**	
Name:		Name:	
Contact:		Contact:	
Address:		Address:	
Telephone:		Telephone:	
E-mail		E-mail	
Web		Web	

Applications and performances				
Matrices:				
Targets:				
Effects:				

Page 2

1. Technology and product description
2. Application(s)
   - 2.1. Matrices
   - 2.2. Targets
   - 2.3. Effects
   - 2.4. Exclusions

Page 3

3. Test design

3.1. Laboratory/field conditions

3.2. Matrix compositions

3.3. Target concentrations

3.4. Operation parameters

3.5. Parameters measured

4. Verification results

4.1. Performance parameters

4.2. Users manual

4.3. Product costs

4.4. Occupational health and environment

5. Quality assurance and deviations

6. Names, organizations, dates and signatures

A P P E N D I X 9

Templates for additional parameter evaluations

Parameters for user manual evaluation

Parameter	Complete description	Summary description	No descrip-tion	Not relevant
Product				
Principle of operation				
Intended use				
Performance expected				
Limitations				
Preparations				
Unpacking				
Transport				
Assembly				
Installation				
Function test				
Operation				
Steps of operation				
Points of caution				
Accessories				
Maintenance				
Trouble shooting				
Safety				
Chemicals				√
Power				√

List of capital cost items and operation and maintenance cost items per product unit

Item type	Item	Number	None
Capital			
Site preparation			
Buildings and land			
Equipment			
Utility connections			
Installation			
Start up/training			
Permits			
Operation and maintenance			
Materials, including chemicals			
Utilities, including water and energy			
Labour			
Waste management			
Permit compliance			

Compilation of classified chemicals used during product operation

Compound	CAS number	Classification	Amount used per product unit

A P P E N D I X 1 0

List of lists

List of Lists

List of external experts
The verification sub-body keeps a list of experts used during performed verifications. The list contains information about the experts name, address, e-mail, telephone number, title, work field and engagement.

List of sub-contractors
The test sub-body keeps a list of sub-contractors used during performed verifications. The list contains information about name of company, address, contact person, e-mail, telephone number and, deliveries.

List persons authorized to draft, revised and approve documents
The test centre holds a list of persons authorized to draft, revise and approve, document within the quality manual system. The list contains information about name, department, education, date of authorization and name of the person who made the authorization.

List of staff approved for functions within verification and test
The test centre keeps a list of persons working within the test centre, the verification and test sub-body. The list contains information about the person's work field and, field of responsibility.

List of methods
The test sub-body keeps a list of used in-house methods and standards.

List of protocols
The test centre keeps a list of performed verifications. The list contains information about name of product/technology and name, address, web site and e-mail of the company, technology type and application.

A P P E N D I X 1 1

Template for reports on amendment to verification protocol or test plan

AMENDMENT

PROTOCOL/PLAN DOCUMENT TITLE AND DATE:

AMENDMENT NUMBER: __

DATE OF AMENDMENT: ____ AMENDED:

AMENDMENT CONTENTS:

REASON FOR AMENDMENT:

IMPACT OF AMENDMENT:

PREVENTIATIVE ACTION:

If relevant, action to prevent that the same cause of amendment will reoccur in the future.

ORGINATED BY:

_____
Centre verification or test responsible

_____
DATE

APPROVED BY:

_____
Centre verification or test organization quality responsible

_____
DATE

A P P E N D I X 1 2

Template for reports on deviation from verification protocol or test plan

DEVIATION

PROTOCOL/PLAN DOCUMENT TITLE AND DATE:

DEVIATION NUMBER: __

DATE OF DEVIATION: ____

DESCRIPTION OF DEVIATION:

REASON FOR DEVIATION:

IMPACT OF DEVIATION:

After suggested corrective action

CORRECTIVE ACTION:

If relevant, action to prevent that the same cause of deviation will reoccur in the future.

ORGINATED BY:

_____
Centre verification or test responsible

_____
DATE

APPROVED BY:

_____
Centre verification or test organization quality responsible

_____
DATE