

AgroTech DANETV Test Centre

Test Centre Quality Manual





Document information

Title	AgroTech DANETV Test Centre. Test Centre Quality Manual.
Project	Danish Centre for Verification of Climate and Environmental technologies.
Responsible	Thorkild Q. Frandsen
Distribution	DANETV project partners
Version	3-1
Date	13-12-2013
Status	Approved for application

Document Log

Version no.	Description of changes made	Changes made by	Checked and approved by	Date
1-0	First draft version	TQF	LBK	27-08-2009
2-0	Second version approved for application	TQF	LBK	09-12-2009
3-0	Third version adapted to AgroTech's role as test body only	TQF	GUM	11-11-2013
3-1	Minor clarifications and updates made to version 3-1.	TQF	GUM	13-12-2013

CONTENTS

1	TEST CENTRE QUALITY MANUAL	1
1.1	Principles and organisation of the manual	1
1.1.1	Scope.....	1
1.1.2	References.....	1
1.1.3	Terms and definitions	1
1.2	Organisation.....	5
1.2.1	Duties and responsibilities of the test body.....	5
1.2.2	Staff	7
1.3	AgroTech DANETV test centre quality management.....	7
2	QUALITY MANAGEMENT PROCESSES	8
2.1	Quality assurance steps	8
2.2	Document and record control	9
2.3	Internal audits	9
2.4	Complaint management	10
2.5	Subcontractor management	10
2.6	Staff competence management.....	10
2.7	Facility management	11
2.8	Management review	11
3	TEST BODY ACTIVITIES DURING VERIFICATION PROCESSES	11
3.1	Contract	11
3.2	Test plan preparation	12
3.2.1	Specific verification protocol.....	12
3.2.2	Test plan requirements from specific verification protocol	12
3.2.3	Test plan	13
3.3	Testing	14
3.4	Test report.....	15
4	REFERENCES	15



APPENDIX 1	16
AgroTech DANETV Test Contract Template	16
APPENDIX 2	21
Test plan template	21
APPENDIX 3	23
Test report template.....	23
APPENDIX 4	25
Review report template	25
APPENDIX 5	27
List of lists.....	27
APPENDIX 6	29
Test plan amendment report template	29
APPENDIX 7	31
Test plan deviation report template.....	31
APPENDIX 8	33
Internal test system audit report template	33

1 TEST CENTRE QUALITY MANUAL

1.1 Principles and organisation of the manual

This quality manual is the framework for organisation, operation and quality management of the AgroTech DANETV test centre, which is one of five test bodies under DANETV, Danish Centre for Verification of Climate and Environmental Technologies.

The AgroTech DANETV test centre is established in compliance with the EU ETV pilot programme and this quality manual has been elaborated. The test centre quality manual has the form of a conventional quality manual with scope of the quality management system, documented procedures and description of interactions. The quality manual is prepared to comply with the requirements from the EU ETV pilot programme and the international standard for inspection, ISO/IEC 17020. The quality manual is integrated into the overall AgroTech quality management system where processes of work, responsibilities, rules and methods are described.

The quality manual has 3 main sections: Principles (Section 1.1), organisation (Section 1.2) and quality management processes (Section 1.3).

1.1.1 Scope

Where tests of a new technology are considered necessary by the verification body, test bodies are designated. The AgroTech DANETV test centre operates as a test body according to the EU ETV pilot programme and carries out testing for environment, energy and climate related technologies within the technology areas:

- Environmental technologies in agricultural production
- Air pollution abatement technologies
- Energy technologies
- Materials, waste and resources

1.1.2 References

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

The normative reference of the operation of the AgroTech DANETV test centre is the EU Environmental Technology Verification pilot programme, General Verification Protocol [1] and ISO 17020: General criteria for the operation of various types of bodies performing inspection [2].

With regard to quality assurance the AgroTech quality management system is based on EN ISO 9001: Quality management systems – Requirements [3] and is in operation.

1.1.3 Terms and definitions

This test centre quality manual is using a set of definitions derived from the EU GVP [1], ISO 9001 [3] and, ISO 17020 [2], see Table 1.

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

Term	Definition	Comments
Accreditation	Meaning as assigned to it by Regulation (EC) No 765/2008	EC No 765/2008 is on setting out the requirements for accreditation and market surveillance relating to the marketing of products
Additional parameter	Other effects that will be described but are considered secondary	None
Amendment	A change to a specific verification protocol or a test plan done before the verification or test step is performed	None
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 technology specified with respect to matrix, purpose (target and effect) and limitations	The application must be defined with a precision that allows the user of a technology verification to judge whether his needs are comparable to the verification conditions
DANETV	Danish centre for verification of environmental technologies	None
Deviation	A change to a specific verification protocol or a test plan done during the verification or test step performance	None
Environmental technologies	Environmental technologies are all technologies whose use is less environmentally harmful than relevant alternatives	The term technology covers a variety of products, processes, systems and services
Evaluation	Evaluation of test data for a technology for performance and data quality	None
General verification protocol (GVP)	Description of the principles and general procedure to be followed by the ETV pilot programme when verifying an individual environmental technology.	None
Innovative environmental technologies	Environmental technologies presenting a novelty in terms of design, raw materials involved, production process, use, recyclability or final disposal, when compared with relevant alternatives.	None
Matrix	The type of material that the technology is intended for	Matrices could be soil, drinking water, ground water, degreasing bath, exhaust gas condensate etc.

Term	Definition	Comments
Method	Action described by e.g. 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. [4]
Operational parameter	Measurable parameters that define the application and the verification and test conditions.	Operational parameters could be temperature, production capacity, concentrations of non-target compounds in matrix etc.
(Initial) performance claim	Proposer claimed technical specifications of technology. Shall state the conditions of use under which the claim is applicable and mention any relevant assumption made.	The proposer claims shall be included in the ETV proposal. The initial claims can be developed as part of the quick scan.
Performance parameters (revised performance claims)	A set of quantified technical specifications representative of the technical performance and potential environmental impacts of a technology in a specified application and under specified conditions of testing or use (operational parameters).	The performance parameters must be established considering the application(s) of the technology, the requirements of society (legislative regulations), customers (needs) and proposer initial performance claims.
Potential environmental impacts	Estimated environmental effects or pressure on the environment, resulting directly or indirectly from the use of a technology under specified conditions of testing or use.	None
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.
Product	Ready to market or prototype stage product/technology, process, system or service based upon an environmental technology.	In the EU ETV GVP [1] the term "technology" is used instead of the term "product".
Proposer	Any legal entity or natural person, which can be the technology manufacturer or an authorised representative of the technology manufacturer. If the technology manufactures concerned agree, the proposer can be another stakeholder undertaking a specific verification programme involving several technologies.	Can be vendor or producer
Purpose	The measurable property that is affected by the technology and how it is affected.	The purpose could be reduction of nitrate concentration, separation of volatile organic compounds, reduction of energy use (MW/kg) etc.
Ready to market tech-	Technology available on the market or at least available at a stage where no sub-	None

Term	Definition	Comments
nology	stantial change affecting performance will be implemented before introducing the technology on the market (e.g. full-scale or pilot scale with direct and clear scale-up instructions).	
Specific verification protocol	Protocol describing the specific verification of a technology as developed applying the principles and procedures of the EU GVP and this quality manual.	None
Standard	Generic document established by consensus and approved by a recognised standardization body that provides rules, guidelines or characteristics for tests or analysis	None
Test body	Unit that that plans and performs test	None
Verification body	Unit that plans and performs the verification	None
Test/testing	Determination of the performance of a technology for measurements / parameters defined for the application.	None
Test performance audit	Quantitative evaluation of a measurement system as used in a specific test.	E.g. evaluation of laboratory control data for relevant period (precision under repeatability conditions, trueness), evaluation of data from laboratory participation in proficiency test and control of calibration of online measurement devices.
Test system audit	Qualitative on-site evaluation of test, sampling and/or measurement systems associated with a specific test.	E.g. evaluation of the testing done against the requirements of the specific verification protocol, the test plan and the quality manual of the test body.
Test system control	Control of the test system as used in a specific test.	E.g. test of stock solutions, evaluation of stability of operational and/or on-line analytical equipment, test of blanks and reference technology tests.
Vendor	The party delivering the technology to the customer. In the EU ETV GVP and in this quality manual referred to as proposer.	Can be the producer.
Verification	Provision of objective evidence that the technical design of a given environmental technology ensures the fulfilment of a given performance claim in a specified application, taking any measurement uncertainty and relevant assumptions into	None

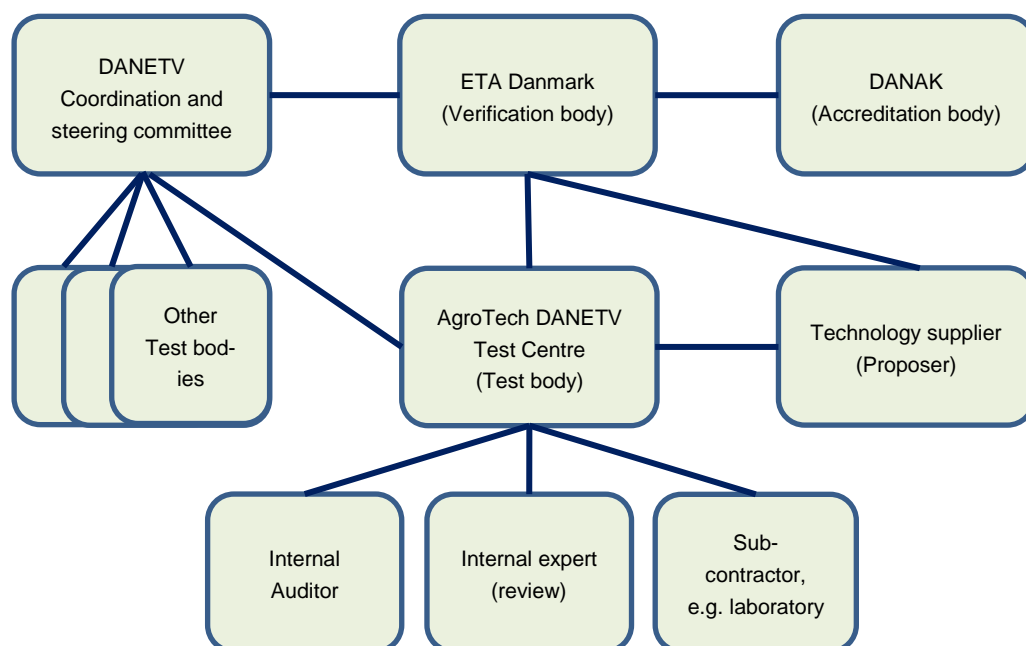
Term	Definition	Comments
	consideration.	

1.2 Organisation

The overall organisation with respect to other bodies involved in environmental technology verifications in Denmark is shown in Figure 1.

The AgroTech DANETV test centre is a test body operated under the DANETV project cooperation. The DANETV project cooperation includes the following partners: DHI, AgroTech, DELTA, FORCE Technology and Danish Technological Institute. The DANETV project is supported by the Danish Ministry of Science, Innovation and Higher Education.

Figure 1. AgroTech DANETV Test Centre organisation with respect to other bodies in environmental technology verifications in Denmark.



1.2.1 Duties and responsibilities of the test body

Where tests are considered necessary by the verification body, test bodies are designated by the proposer.

Organisation management

AgroTech is a test body and is hosting the AgroTech DANETV Test Centre. The management of AgroTech has the overall responsibility for the operation of the test centre according to this

manual. The AgroTech management provides the resources (staff and facilities) required to follow the manual and for handling any complaints over the test centre, including an organisation quality system compliant with ISO 9001 [3] for at least the test activities.

AgroTech DANETV Test Centre management

The AgroTech DANETV test centre management is responsible for the practical operation of the test centre according to this manual. The AgroTech DANETV test centre management has the responsibility for:

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

AgroTech DANETV test centre quality management

The quality manager of AgroTech is responsible for quality assurance of the test centre activities, including making internal auditors available for the centre. The quality manager has direct access to the AgroTech management.

AgroTech DANETV test centre

The AgroTech DANETV test centre has the overall responsibility for:

- Setting up and reaching of a contractual agreement with proposer on testing
- Elaboration of a test plan within the requirements set in the verification protocol with test design requirements and in agreement with the verification body
- Identification of and subcontracting with one or more analytical laboratories, if analysis of test samples is required, and ensuring that the analytical laboratories are accredited to applying ISO 17025 for methods within the relevant area of analysis
- Performance of the test according to the test plan, ensuring the level of quality required in the specific verification protocol
- Ensuring quality of analysis used in the test and, when applicable, that analytical laboratories performing the analysis are accredited to applying ISO 17025 for methods within the relevant area of analysis
- Elaboration of the test report for transmission to the proposer and the verification body.

The staff involved in testing shall not be involved in the elaboration of the verification protocol, e.g. the staff must not be assisting the verification body as external expert in the elaboration of the specific verification protocol.

If the test centre performs analysis in-house, the staff doing the analysis of test samples shall not be the same as those responsible for the evaluation of the analytical results in the test centre and they shall not be dependent upon these.

Testing performed in-house by proposer

In cases where the proposer performs the necessary tests in-house, the proposer may contract a test body to:

- Draft the test plan within the requirements set in the verification protocol with test design requirements and in agreement with the verification body.
- Review the test plans elaborated by the proposer within the requirements set in the verification protocol with test design requirements and in agreement with the verification body.
- Witness testing done by the proposer, if appropriate
- Approve test reports if drafted by the proposer and if not done by the verification body.
- Where analysis of test samples is required, the analytical laboratory shall be accredited to applying ISO 17025 for methods within the relevant area of analysis. This provision applies also in case of in-house testing by the proposer.

1.2.2 Staff

AgroTech DANETV test centre has, trains, and maintains staff that is qualified for the testing within the scope of the test body with the executive staff responsible for the units shown in table 2. Staff competence management procedures are found in section 2.6.

Table 2. Staff attached to the AgroTech DANETV Test Centre.

Organisation element	Name of responsible	Function
Centre host	Thomas B. Olsen (THO)	Chief Executive Officer, AgroTech
Test Centre	Gunnar Hald Mikkelsen (GUM)	Head of AgroTech´s department for Bio-resources and responsible for AgroTech DANETV test centre responsible
DANETV steering committee	Thorkild Qvist Frandsen (TQF)	AgroTech DANETV test centre responsible
Internal test auditor	Amparo Gomez Cortina (ACO)	Project manager

Centre host delegates responsibilities to the relevant department in charge of executing ETV testing.

Internal test auditor shall be trained as auditor and can delegate audit responsibilities to other trained auditors. Internal test auditor performs test system audits (i.e. qualitative on-site evaluation of test, sampling etc. See also section 1.1.3 (Terms and definitions) according to the EU ETV GVP [1].

1.3 AgroTech DANETV test centre quality management

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

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

The quality management processes are implemented in the AgroTech Quality Management System and are further described in section 2 of this quality manual. This description includes the principles of operation with the role of the test body and the test documents. In order to facilitate the preparation of the relevant documents, templates have been prepared and are available in appendices to the document.

Processes of relevance for the test body during the verification are further detailed in Section 3 based upon the documentation required.

Internal system audits (i.e. audit of the ETV testing process) are implemented in the AgroTech Quality Management System and are performed by trained auditors.

2 QUALITY MANAGEMENT PROCESSES

The AgroTech DANETV test centre works according to the principles of ISO 9001 [3] and the EU ETV GVP [1]. This is done by working according to the AgroTech Quality Management System and by working using the procedures prepared for the processes listed in this section which are in compliance with the EU ETV GVP [1].

Management, organisation and responsibilities are defined in Section 1 of this quality manual.

2.1 Quality assurance steps

The process and the responsibilities for preparing, reviewing and approving documents in the verification are summarised in table 3.

Table 3. Quality assurance steps - verification document.

Document	Test body	Proposer	Verification body
Contract for testing	1. Prepare and sign	2. Approve and sign	Not involved
Verification protocol	Not involved	Not involved	3. Hand over to test body
Test plan including: <ul style="list-style-type: none"> • Test performance audit requirements^a • Test system control^b 	4. Prepare	5. Review and approve	6. Review and approve
Amendment form	7. Record and make amendments	8. Review and approve	9. Review and approve
Deviation form	10. Record and make deviations	Not involved	Not involved
Audit reports – test system audits	11. Internal test system audit ^d	Not involved	12. External test system audit
Test report, including: <ul style="list-style-type: none"> • Results for test performance audit^c • Results for test system control^c 	13. Prepare 16. Finalise and hand over to verification body	14. Review	15. Review

a) This is called "Performance control – analysis and measurements" in the test plan template.

b) This is called "Test system control" in the test plan template.

c) Headline "Test quality assurance summary, including audit result" in the test report template.

d) Performed by internal test auditor.

The test centre management recruits internal reviewers for reviewing documents (adequate project staffing).

2.2 Document and record control

This procedure describes how documents related to DANETV activities in AgroTech are drafted, revised and approved. The aim is to ensure that all persons involved in the ETV test activities have access to and uses the latest approved version of the manual with process descriptions.

All documents and records relevant to the documentation of the DANETV quality management system or the ETV test must comply with this procedure. Relevant documents include e.g. documents that contain data, changes to test plans, procedures, complaints or other subjects that affects the implementation and outcome of the test. The origin of information in documents or records can be e.g. paper, oral communication, e-mail or electronic files.

Type	Subject	Archive time	Responsibility
General	All electronic files related to DANETV activities are stored on "U:\DANETV". Access to this drive is limited to persons listed in the list "DANETV Responsibilities". The drive is backed up every day and the backup copy is kept secure for 180 days.	Not applicable	See DANETV Responsibilities
AgroTech DANETV Test Centre Quality Manual			
AgroTech DANETV Test Centre Quality Manual documents including e.g. internal review reports and complaints	Files are stored with version number and write protected. The persons responsible for revising the document are listed in DANETV Responsibilities.	> 5 years	See DANETV Responsibilities
ETV test related documents			
Contracts	Signed contracts (paper) are stored in filing cabinet in the administrative department. Scanned versions of the signed contracts are stored on U:\DANETV in a specific folder per ETV test.	3 years	AgroTech 's signee of contract
Test plans, review	Electronic files are stored with version number and write protected.	3 years	See test plan

Procedures within AgroTech 's Quality Management System describe how test data and records 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 testing.

2.3 Internal audits

Internal system audit (ETV testing process)

The procedure in AgroTech's Quality Management System "Audit" describes the process of periodic internal auditing of the test activities in the test centre including audit responsibilities and planning, auditor training and competences and audit reporting.

The procedure in AgroTech's Quality Management System "Håndtering af forbedringsforslag, kundeklager og afvigelser" describes how deviations identified during operation and 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).

Internal test audit

A template to be used during internal test system audit is found in Appendix 8. Conformities and non-conformities with respect to the test plan will be identified and noted in the audit report by the auditor. The auditor can suggest corrective actions to be carried out.

The internal test auditors appointed for the test centre conduct the audits required for the test body.

2.4 Complaint management

The procedure in AgroTech's Quality Management System "Håndtering af forbedringsforslag, kundeklager og afvigelser" describes how proposed complaints are recorded, resolved, and reported. If not resolved, complaints are referred to the DANETV steering committee for resolving.

2.5 Subcontractor management

The procedure in AgroTech's Quality Management System "Indkøb" 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 defined for the task, see also Part C: Quality Management of the EU GVP [1].

2.6 Staff competence management

This procedure describes how AgroTech DANETV test centre ensures that tests are done by staff with adequate competences and knowledge of their responsibilities.

For each group of technologies for test by AgroTech DANETV test centre the specific competences required to carry out tasks related to test are defined. This is done when the test plan has been completed.

The persons in AgroTech DANETV test centre that meet the competence requirements are listed in the document "DANETV responsibilities". Documentation (contracts, CVs) for the competences of the staff is stored in the filing cabinet in the administrative department.

When competence requirements cannot be met by AgroTech test centre staff subcontractors must be used.

2.7 Facility management

The procedure in AgroTech’s Quality Management System “Vedligehold af udstyr / systemer” describes how the test centre ensures that the facilities and the equipment for test of technologies belonging to the technology areas covered by the AgroTech DANETV Test Centre are available and fit for the purposes.

2.8 Management review

The procedure in AgroTech’s Quality Management System “Ledelse, Styring, Personale” describes how the management of the organisation hosting the AgroTech DANETV test 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.

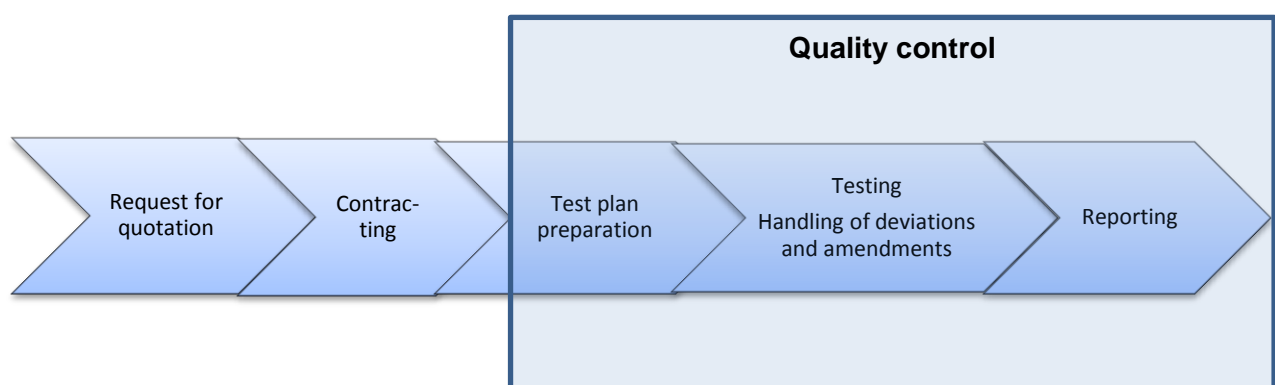
The person from the AgroTech management who is responsible for review of the AgroTech DANETV test centre is defined in the document “DANETV Responsibilities”.

3 TEST BODY ACTIVITIES DURING VERIFICATION PROCESSES

A number of activities precede the test body’s tasks and are carried out by the proposer and/or verification body. The test centre carries out testing in cases where the assessment of existing data by the verification body shows that further tests are required. Chemical analyses if required can be performed in-house or by an external analytical laboratory.

The overall processes carried out by the test body as part of verification are illustrated below.

Figure 2. Outline of processes during ETV testing.



3.1 Contract

If the proposer decides to proceed with verification, the test centre shall upon request for quotation provide a cost estimate for the planning, testing and reporting. Based upon the cost estimate, a testing contract is drawn up and signed by the proposer and the test body and when

the specific verification protocol is delivered from the verification body, the test planning can start.

The testing contract shall be done applying the template found in Appendix 1. It is recognised, that parts of the testing budget may (in some cases) need to be revised after elaboration of the first parts of the test plan (test plan design and identification of analytical laboratories). In such cases, a contract is entered with a preliminary maximum budget for these first parts, opening for later revision and negotiation.

Submission of a quotation and contracting follows the rules for review and approval described in the AgroTech Quality Management System.

3.2 Test plan preparation

3.2.1 Specific verification protocol

The specific verification protocol describes the framework for verification of technologies and provides the information required for the test plan. The verification protocol is prepared by the verification body. Some interaction with the test body during the preparation of the protocol can be foreseen. When the protocol is ready and approved by the proposer the test plan shall be derived based on the test requirements in the verification protocol.

3.2.2 Test plan requirements from specific verification protocol

The specific verification protocol describes the essential requirements for the test design and data for the technology under verification, as the test body shall implement it in the test plan. These requirements include main requirements of the test design, e.g. continuous or batch tests, test scale, test methods etc.

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

- Overall test design
 - Scale (laboratory, pilot and/or field)
 - Performance parameters to be measured (including also operational parameters and additional parameters to be covered in the testing/test reporting)
- Methods of reference analysis if relevant, including sampling, measurement and calculation methods
- Data management
- Quality assurance
- Test report contents.

The requirement on choice of methods to be used in testing will be defined. If available and relevant, existing standard methods (ISO, CEN) will be listed. If specific requirements for analytical methods or their performance have been identified during planning and elaboration of the protocol, these will be given.

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

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

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 2 and shall be followed. Reference to the specific verification protocol used shall be given in the test plan.

The test plan is unique for each test occasion giving the exact information required by the test staff to conduct the tests as required in the specific verification protocol.

The test plan shall be reviewed and approved according to AgroTech's Quality Management System. Afterwards the test plan shall be reviewed and approved by the verification responsible and the proposer.

Test design

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

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

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

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.

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

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

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 laid down. Software other than standard spread sheets used for data collection, storage and calculations shall be indicated.

A data compilation and storage table should be used to summarise the requirements (see Table 4).

Table 4. Data compilation and storage summary, an example.

Data type	Data media	Data recorder	Data recording timing	Data storage
Test plan and report	Protected PDF-files	Test responsible, AgroTech	When approved	Files and archives at AgroTech
Test details in laboratory and field	Log book and pre-prepared forms	Technician, AgroTech	During collection	Files and archives at AgroTech
Calculations	Excel files	Test responsible, AgroTech	During calculations	Files and archives at AgroTech
Analytical reports	Paper / PDF-files	Test responsible, AgroTech	When received	Files and archives at AgroTech

Data management should describe filing and archiving of e-mail communication, paper communication, recordings in the laboratory and in field (if relevant), data, calculations and other files.

Quality assurance

The test system control planned 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. Details on performance evaluation audit and test system audit shall be given.

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 body that reviewed the draft test plan and report before submission to the verification body is named. Plans for additional review and/or audits shall be given, if relevant.

If an analytic laboratory is used it shall be ensured that it has an ISO 17025 accreditation for the relevant analyses, if possible, and furthermore fulfil the requirement in the EU ETV GVP with regard to validation, quality control and test system audit. If a laboratory with ISO 17025 accreditation for the analyses in question is not available, this shall be documented in the test plan and the measures taken to ensure adequate analytical quality be detailed.

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 3). The format and location for archiving of raw data shall be defined.

3.3 Testing

Testing shall be done according to the test plan.

Amendments to and deviations from the test plan shall be recorded and approved in an amendment report and deviation report, respectively (see templates in Appendix 6 and Appendix 7). The amendment and deviation forms shall be retained as documentation as part of the records of testing.

3.4 Test report

The test report shall be based on the template found in Appendix 3. The test report shall refer to the test plan and a summary of any amendments to and deviations from the test plan recorded during the test shall be included. Templates for reporting amendments and deviations are included in Appendix 6 and 7 respectively.

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

A summary of any amendments to and deviations from the test plan applied or recorded during tests shall be included in the test report. If the number of amendments to and deviations from the test plan is limited, the test plan can be used for the test report by completing it with a result chapter. If not, the test plan has to be updated reflecting the deviations.

The test report shall be reviewed and approved according to AgroTech's Quality Management System. Afterwards the test report shall be reviewed by the verification body and the proposer.

4 REFERENCES

1. European Commission (2011): EU Environmental Technology Verification pilot programme. General Verification Protocol. Version 1.0. 15-12-2011.
2. International Standardization Organization (1998): ISO 17020. General criteria for the operation of various types of bodies performing inspection. 15.11.1998.
3. International Standardization Organization (2008): EN ISO 9001. Quality management systems - Requirement. 15.11.2008. 8.
4. International Standardization Organization (1994): ISO/IEC Guide 7: 1994. Guidelines for drafting standards suitable for use for conformity assessment. 1994.



A P P E N D I X 1

AgroTech DANETV Test Contract Template

CONTRACT FOR ENVIRONMENTAL TECHNOLOGY TESTING:
[Name of technology for testing]

Place, 11-22-2013

The following Parties

[Name of technology supplier company]
 CVR no. [11 22 33 44]
 Address
 Postal code, town name, Denmark
 (hereinafter called the Proposer)

and

AgroTech A/S
 CVR no. 30 58 93 35
 Agro Food Park 15
 8200 Aarhus N, Denmark
 (hereinafter called AgroTech)

(hereinafter jointly called the Parties)
 (hereinafter separately called the Party)

have entered into the following agreement (hereinafter called the Agreement) governing AgroTech's delivery of services to the Proposer on the terms and conditions stated in the task description (hereinafter called the Task Description) and on the terms and conditions stated in the appended General Conditions Governing the Delivery of Services from AgroTech A/S.

Task Description

Project name: ETV Test of [name of technology for testing]	Project No.
Organisation of the cooperation: The Proposer's representative: [Name of person] Test responsible in AgroTech: [Name of person]	
Purpose: The purpose is to undertake a test of [name of technology for testing] for the below tentatively defined application in accordance with the DANETV environmental technology verification method, which is based on the EU ETV pilot programme.	
Description of application: Matrix: Purposes:	

Task content / verification steps: This contract includes the following steps in the verification:	
Verification steps	Included? (Yes/no)
Preparation of test plan in dialogue with verification body.	
Planning of test including identification of suitable test sites and setting up relevant measurement equipment.	
Implementation of the test including measurements, sampling, sending of samples for analysis on external laboratory, internal audit.	
Data handling and evaluation, including quality assurance.	
Preparation of test report and dialogue with verification body about the results and interpretation of these.	
Other steps, describe:	
<p>Products delivered to the Proposer: Electronic versions (in pdf-format) of the following documents:</p> <ul style="list-style-type: none"> • Test plan • Test report <p>In addition, AgroTech provides one original version in hard copy of the test report.</p>	
<p>Schedule: A detailed schedule will be part of the test plan. The test plan will be available for proposer for commenting within 4 weeks from the date of contract signing.</p>	
<p>Information: AgroTech and Proposer shall inform the other part if the conditions for the ETV test change.</p>	
<p>Price: The cost of the full DANETV test as described in this contract is estimated to [111.222] DKK. Please note that the estimate is not binding for AgroTech.</p> <p>An exact budget for the ETV test is made after the preparation of the test plan. Based on the final version of the test plan a contract defining the exact price for the Proposer will be made.</p>	

<p>Payment plan:</p>
<p>The Proposer's participation: Proposer agrees to provide without costs and delay for AgroTech:</p> <ul style="list-style-type: none"> • A contact person for the DANETV test • Existing performance data of the technology for testing • Units of the technology for testing as indicated in the test plan • Arrangement and mounting of the technology at the test site • User instructions, training and support as needed during testing • Information about the mode of function as required for a full understanding of the technology • Comments on documents drafted as part of the ETV test (mainly test plan and test report).
<p>Intellectual property rights: Proposer warrants that the technology for DANETV testing is controlled by proposer. Proposer will retain all rights to the technology and all technical data produced during the test.</p> <p>AgroTech will retain all rights to the test plan, methods and procedures developed by AgroTech.</p>
<p>Limitations: AgroTech performs the DANETV test as described for the application of the technology as defined in this contract. This DANETV test cannot be considered an endorsement, approval, authorisation or warranty of any kind, and the performance parameters provided cannot be extended to other applications or to other technologies. The test results reflect the performance of the technology at the time and under the conditions of the test. They cannot be understood as guaranteeing the same level of performance in the future under other conditions. Proposer agrees not to use the DANETV Test report or to refer to this for any other technology or application. Proposer agrees not to use extracts of the DANETV test report for any purpose unless an agreement about this is made with AgroTech in advance.</p>
<p>Confidentiality: All final versions of test plans and test reports can be made available for public access by AgroTech through media it finds relevant such as the DANETV web sites. All other information obtained or produced during the DANETV test is considered confidential for the part not owning the intellectual property rights. During the DANETV test the proposer allows AgroTech to give external auditors access to all information obtained or produced during the test, as specified in the test plan.</p>
<p>Liability: AgroTech assumes no liability for any damages associated with the use of test results, and proposer agrees to cover any costs that may be imposed upon AgroTech in connection with claims raised with this respect.</p> <p>AgroTech assumes no liability for delays or for test results that damage the sales of the technology or the proposer.</p>
<p>Force majeure: See general conditions governing the delivery of services from AgroTech A/S.</p>

Termination:

Either party may terminate this contract with a 15 days written notice. In case of termination, any costs endured by AgroTech as part of the DANETV test that cannot be averted shall be paid in full by the terminating part.

If termination is done by AgroTech due to proposer´s non-fulfilment of the obligations in this contract then the costs shall be paid in full by the proposer. Termination by the Proposer does not prevent preparation of the test report based upon the data available at the time of termination, and the costs for reporting will be payable by Proposer irrespective of the termination.

Disputes:

See general conditions governing the delivery of services from AgroTech A/S.

Other terms and conditions:

See the General Conditions Governing the Delivery of Services from AgroTech.

, / -

Skejby, / -

For [technology supplier company]

For AgroTech A/S



A P P E N D I X 2

Test plan template

AgroTech DANETV Test Plan Template

Title page

Table of contents

1. Introduction
 - 1.1. Verification protocol reference
 - 1.2. Name and contact of proposer
 - 1.3. Name of test body and test responsible
 2. Test design (*The test design refers to the design described in the verification protocol*)
 - 2.1. Test site
 - 2.1.1 Types (*Describe type of test: Laboratory test or on-site test*)
 - 2.1.2 Addresses
 - 2.1.3 Descriptions
 - 2.2. Tests
 - 2.2.1. Test methods (*Standardised methods, in-house methods, etc. Table with parameters and measurements methods.*)
 - 2.2.2. Test staff
 - 2.2.3. Test schedule
 - 2.2.4. Test equipment
 - 2.2.5. Type and number of samples (*performance and operational parameters*)
 - 2.2.6. Operation conditions
 - 2.2.7. Operation measurements
 - 2.2.8. Maintenance (*product/technology maintenance*)
 - 2.2.9. Health, safety and wastes
 3. Analysis and measurements (*pH, conductivity, etc.*)
 - 3.1. Analytical laboratory
 - 3.2. Analytical and measurement parameters and methods
 - 3.3. Analytical and measurement performance requirements
 - 3.4. Preservation and storage of samples
 - 3.5. Data management
 - 3.6. Data storage, transfer and control
 4. Quality assurance
 - 4.1. Test plan review
 - 4.2. Performance control – analysis and measurements (*Define test performance audit, see 1.1.3 Terms and definitions.*)
 - 4.3. Test system control (*Define, e.g. laboratory blanks, spiked samples, on-line logging.*)
 - 4.4. Data integrity check procedures
 - 4.5. Test system audits
 - 4.6. Test report review
 5. Test report (*Describe that the test report will follow the QA manual and what the test report will include.*)
 - 5.1. Amendment report
 - 5.2. Deviations report
 6. References
-
- | | |
|------------|--|
| Appendix A | Terms and definitions used in the test plan |
| Appendix B | References methods |
| Appendix C | In-house test methods |
| Appendix D | In-house analytical methods and measurements |
| Appendix E | Data reporting forms |



A P P E N D I X 3

Test report template

AgroTech DANETV Test Report template

Title page

Table of contents

1. Introduction
 - 1.1 Name and contact of proposer
 - 1.2 Name of test body and test responsible
 - 1.3 Reference to test plan and specific verification protocol
 - 1.4 Summary amendment and deviations to test plan (*Summary of changes and the main effect on the testing.*)
2. Test design (*Include here only a short overview table.*)
3. Test results
 - 3.1 Test data summary (*This section shall summarise all results and shall contain calculation of all performance parameters.*)
 - 3.2 Test performance observation (*In this section is described all observations done during testing. This should be problems with equipment, unexpected things happening.*)
 - 3.3 Test quality assurance summary, including audit result (*This section shall contain the results for test performance, results for test system control and a summary from audit reports – both internal and external audits.*)
 - 3.4 Details on amendments to and deviations from test plan (*Details on amendments and deviations and the taken actions or refer to an Appendix C containing the reports.*)
4. References

Appendix A Terms and definitions used in the test report

Appendix B Test data report

Appendix C Amendment and deviation reports for test (*can be left out if chapter 3.4 is containing the main part of information.*)



A P P E N D I X 4

Review report template

Review report

Document title:		Document date:	dd.mm.yyyy
Document responsible:	Name of person and organisation	Review date:	dd.mm.yyyy
Reviewer name:	Name of person		
Organisation:	Name of organisation		
Address:			
Telephone:			
E-mail:			

Review results	
Overall recommendation	
Acceptable as it is	
Accepted with minor revisions	
Accepted with major revisions	
Not acceptable	
Describe reason for the evaluation stated above	

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 5

List of lists

AgroTech DANETV Test Centre List of lists

The following documents can be viewed in the AgroTech Quality Management System:

- Oversigt over ansvarlige personer (Overview of responsible persons)
- Oversigt over ansvarlige for indkøb (Overview of persons responsible for purchase)
- Prokura-regler i AgroTech (Rules for authorisation in AgroTech).
- Oversigt over væsentlige/kritiske leverandører (Overview of important/critical sub-contractors). This list of sub-contractors includes analytical laboratories, which are normally used during ETV tests.

In addition, the following lists are relevant for the DANETV ETV test activities:

- List of tests: AgroTech DANETV test centre keeps a list of performed ETV tests. The list contains information about the name of the product/technology and the name, address, website and e-mail of the technology supplier.
- Responsibilities related to ETV testing in AgroTech DANETV Test Centre. This document includes a list of persons working with ETV testing within AgroTech DANETV test centre and information about the person's work field and field of responsibility.



A P P E N D I X 6

Test plan amendment report template

AgroTech DANETV Test Plan Amendment Report

Test plan title:		Test plan date:	
Amendment number:		Date of amendment:	
Parts amended:	E.g. Appendix XX, section YY, table ZZ.		
Amendment contents:	What has been changed in Appendix XX, section YY, table ZZ.		
Reason for amendment:			
Impact of amendment:			
Corrective action:	If required, describe actions to be taken to prevent consequences of amendment.		
Preventative action:	If relevant, action to prevent the same cause of amendment will reoccur in the future.		

Originated by test responsible:	Approved by verification body:	Approved by proposer:
Name:	Name:	Name:
Date:	Date:	Date:
Signature:	Signature:	Signature:



A P P E N D I X 7

Test plan deviation report template

AgroTech DANETV Test Plan Deviation Report

Test plan title:		Test plan date:	
Deviation number:		Date of deviation:	
Description of deviation:	For which parts of the test plan have deviations been recorded? What has been changed?		
Reason for deviation:			
Impact of deviation:	After suggested corrective action		
Corrective action:	If required, describe actions to be taken to prevent consequences of deviation.		
Preventative action:	If relevant, actions to prevent the same cause of deviation will reoccur in the future.		

Originated by test responsible
Name:
Date:
Signature:



A P P E N D I X 8

Internal test system audit report template

AgroTech DANETV Internal Test System Audit Report

Test system audit: [technology area]

Test project: [Name of specific test going on]

	Audited person:	Auditor:	Date of audit: <i>dd.mm.yyyy</i>
Included focus areas in the audit:	Check-list that can be used for checking conformity with test plan: <ul style="list-style-type: none"> • Test method in general • Operation of technology/treatment unit • Operation conditions, and measurements for monitoring them • On-line measurements and sampling for performance parameters • Data logging and retrieval • Sampling and sample storage • Documentation of laboratory operations and sampling 		
Proposals for improvements:	<ol style="list-style-type: none"> 1. 2. 3. 4. 5. 		
Non-conformities identified:	Non-conformities noted by auditor (the attached template for non-conformity report can be used if it is appropriate): <ol style="list-style-type: none"> 1. 2. 3. 4. 5. 		
Recommended focus area for next audit:			
Other observations and comments:			
Date og auditor´s signature			

Non-conformity Report No.		Date	<i>dd.mm.yyyy</i>
Reference document			
Test method step			
Non-conformity description			
Cause			
Impact assessment			
Suggested corrective action, if any			
Date and auditor's signature			

Test responsible's assessment	Date: Signature:
Corrective action carried out	Date: Signature: