DELIVERABLE

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D2.1: Quality Management for Interoperability Testing

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Authors:

Morten Bruun-Rasmussen, (in cooperation with MedCom)
Ib Johansen, MedCom

Review:

Catherine Chronaki, HL7 Foundation
Gerard Freriks, EN 13606 Association
Stephen Kay, CEN

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REVISION HISTORY AND STATEMENT OF ORIGINALITY

Revision History

Revision	Date	Author	Organisation	Description
0.1	06.05.13	Morten Bruun-Rasmussen	(in cooperation with MedCom)	Draft structure, inspired by ISO 17025
0.2	26.06.13	Morten Bruun-Rasmussen	(in cooperation with MedCom)	Draft structure update. To be discussed in the WP2 group.
0.3	31.08.13	Morten Bruun-Rasmussen	(in cooperation with MedCom)	Draft content for the entire document to be discussed with the SEP at the Nice meeting the 5-6. September 2013.
0.4	07.10.13	Morten Bruun-Rasmussen	(in cooperation with MedCom)	Reviewed by the Core Group and the Supporting Expert Partners (round 1). Comments implemented.
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0.9	21.11.13	Morten Bruun-Rasmussen	(in cooperation with MedCom)	Content moved to new ANTILOPE deliverable template
0.91	20.09.14	Morten Bruun-Rasmussen	(in cooperation with MedCom)	Update with comments from EC annual project review
0.99	28.11.14	Morten Bruun-Rasmussen	(in cooperation with MedCom)	Review and comments from SEP. Meeting with Core Group and SEP in Paris the 19th November 2014.
1.0	08.12.14	Karima Bourquard		Quality Review

Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

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Glossary: **Definitions and Abbreviations**

Abbreviation	Explanation
CAB	Conformance Assessment Body
HITCH	Healthcare Interoperability Testing and Conformance Harmonisation
IEEE	Institute of Electrical and Electronic Engineers
IEEE 829	Standard for Software and System Test Documentation
Interoperability	The ability of two or more systems or components to exchange information and to use the information that has been exchanged
ISO	International Standards Organisation
ISO 9000	Family of quality management systems standards, designed to help organizations ensure that they meet the needs of customers
ISO 17025	General requirements for the competence of testing and calibrating laboratories
Profile	A Profile is a selection of definitions and options from standards or other specifications. Profiling is usually done in order to achieve interoperability between different products and implementations since a profile aims at harmonizing all systems implementing it to use the same messages and contents. For example, IHE's so-called Integration Profiles selects messages and options from standards like HL7or DICOM which are then implemented by all IHE-conformant systems. This ensures that IHE systems implementing the same Integration Profile are able to "talk the same language" in practice, thus enforcing interoperability between them.
QMS	See Quality Management System
Quality Management System	A Quality Management System is a set of interrelated or interacting elements that organisations use to direct and control how quality policies are implemented and quality objectives are achieved. A process-based QMS uses a process approach to manage and control how its quality policy is implemented and quality objectives are achieved. A process-based QMS is a network of several interrelated and interconnected processes (elements). Each process uses resources to transform inputs into outputs. Since the output of one process becomes the input of another process, processes interact and are interrelated by means of such input-output relationships. These process interactions create a single process-based QMS.
Quality Manual	A Quality Manual documents an organisation's quality management system (QMS).

Executive Summary

Today, it is a common requirement that eHealth solutions can share seamlessly data (i.e. are interoperable) between products from different vendors and across organisations. Unfortunately many solutions are not tested and implemented as specified and agreed before. This costs a lot of extra resources as many failures are only discovered once they are in daily operation. Unexpected failures leave customers and end-users with negative experience in using eHealth solutions in their daily practice and may seriously affect a patient's treatment and safety.

Implementing interoperability is complex and requires special attention to improve the quality of development as well as quality in use of the eHealth solutions. From a interoperability perspective, quality is judged as if the system complies with agreed (international) requirements (eq. standards and profiles) and can exchange information with systems supporting the same standards.

The Quality Manual for Interoperability consists of two parts:

- Part I: Quality Management System (QMS) for Interoperability Testing.
- Part II: Interoperability Testing Processes.

The Quality Manual is a customizable description and a set of templates with customization instructions that allow a Testing Entity to create its own, specific Interoperability Testing documentation in the form of a single Quality Manual for Interoperability Testing. End users and authorities may also use it confirming or recognising the quality and competencies of an Interoperability Testing Entity.

The key potential benefits for using a Quality Managements System for interoperability testing can be expressed in the three statements below:

- it will ensure continuous improvement of interoperability
- it will improve eHealth deployment
- it will facilitate the adoption of standards

Part I of the Quality Manual describes a generic Quality Management System and requirements for the operation of Conformity Assessment Bodies (CAB) performing Interoperability Testing.

The purpose of Quality Management System for interoperability testing is to ensure the ability to provide high quality products by continuously enforcing quality policies and objectives for interoperability testing within the organization and across its borders. Thus, such a Quality Management System contributes to meet customer and applicable statutory and regulatory requirements and to enhance customer satisfaction through effective feedback processes for continual improvement of the Quality Management System processes.

The Quality Management System is constructed from three levels:

- Strategic: Policy statements which clearly state the organisational position towards

interoperability testing including clear objectives.

- Operational: Description of processes that show how the policy statements are implemented. The description normally also includes the person(s) and all parties involved.
- Administrative: Supporting documentation to be used in the QMS implementation process – this could be learning material, standards, guidelines, templates, forms, checklists etc.

The implementation of the QMS for interoperability is a continuous cycle consisting of the actions "Plan, Do, Check, Act" (PDCA) based on the main principles in ISO 9000 series.

The interoperability objectives must be measurable, since the PDCA cycle enforces frequent re-checking of the whole Quality Management process. This is, of course, only possible if the outcome of the existing interoperability objectives can be measured in order to adapt them if required.

The Interoperability Testing Entity shall establish, implement and maintain a management system appropriate to the scope of its activities. The Interoperability Testing Entity shall document its policies, systems, programmes, procedures and instructions to the extent necessary to assure the quality of the test results. They shall be communicated to, understood by, available to, and implemented by the appropriate personnel.

The Interoperability Testing Entity organisation shall ensure the competence of all who perform test, evaluate results, and sign test reports.

The Interoperability Test Entity shall use the methods and procedures for all tests as described in the Part II of the Quality Manual (ANTILOPE WP2, D2.2 Interoperability Testing Processes).

1 Introduction

Today, it is a common requirement that eHealth solutions can share and reuse data (i.e. are interoperable) seamlessly between products from different vendors and across organisations. Optimally these partners are involved in planning, either directly or via representatives.

Unfortunately many solutions are not tested and implemented as specified. This costs a lot of extra resources as many failures are discovered as recently as when the solution is already in daily operation. The unexpected failure also leaves customers and end-users with negative experience in their daily work and may seriously affect a patient's treatment.

The main benefits of a testing and certification of eHealth solutions is:

- For healthcare providers (hospitals, health insurance, national program) and healthcare professionals
    - To broaden their choice between various eHealth solutions available in the European market.
    - To have eHealth solutions that are better integrated.
    - To be able to exchange medical data at the regional, national and cross border levels.
- For the eHealth IT industry
    - To obtain a European seal across the Union and recognised by all the European countries.
    - To expand the European seal in order to address specific needs at the national /regional level.
    - To avoid redundancy (duplicative testing) among country certification or quality assurance programs.

It is evident that implementing interoperability is complex and requires special attention to improve the quality. From a technical and interoperability perspective, quality is judged as if the system complies with agreed (international) requirements (eq. profiles and standards) and can exchange information with systems supporting the same standards.

Quality management is not a concept that can be applied to one aspect of the organisation only. It is a total, encompassing strategy that affects the whole organisation, and must be developed and implemented within the greater structure of the organisation.

A Quality Management System (QMS) in an organisation allows an organisation to:

- Say what it does and do what it says
- Document what it does, and do what it documents
- Maintain consistency and transparency and thus the quality of interoperability testing
- Create a quality culture of a "***PDCA***" cycle (Plan, Do, Check, Act)
- Establish a clear basis from which continuous interoperability improvement can be achieved

The interoperability QMS describes the activities and information an organisation uses to better and more consistently deliver high quality services for interoperability (eq. standards, guidelines, test, quality labelling, certification) that meet and exceed the needs and expectations of its customers and beneficiaries, more cost effectively and cost efficiently, today and in the future.

Interoperability typically involves processes of multiple organisations. Interoperability QMS will in many cases therefore equally involve a group of organisations. There will be quality activities that involve all partners as well as activities within single organisations. The ideas described in this document are intended to be used by single organisations as well as by cooperating groups.

2 Scope

2.1 Quality Manual

The Quality Manual for Interoperability consists of two parts:

- Part I: Quality Management System (QMS) for Interoperability Testing (this document)
- Part II: Interoperability Testing Processes.

The Quality Manual is a customizable description and set of templates with customization instructions that allow a Testing Entity to create their own, specific Interoperability Test documentation in the form of a single Quality Manual for Interoperability Testing.

The combination of including a QMS and Interoperability Testing Processes into a single manual is the preferred approach and makes the documentation more user-friendly. The Quality Manual will ensure uniform a transparent Interoperability Testing of eHealth system across organisation and vendor systems.

A first draft of a Quality Manual for Interoperability Testing was prepared in the HITCH project[1]. The QMS was based on ISO 9000 and the Interoperability Testing Processes was based on best practice and IEEE 829.

In the ANTILOPE the Quality Manual have been extended by taking into account ISO 17000 (Conformity assessment – Vocabulary and principles), 17011 (Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies) and ISO 17025 (General requirements for the competence of testing and calibration laboratories).

2.2 Quality Management System

This document is applicable to all organisations performing Interoperability Testing of applications in the eHealth domain. The objective is for use in developing their Quality Management System (QMS) for the Interoperability Testing Processes and the general requirement for the competencies to carry out Interoperability Testing of applications in the eHealth domain.

End users and authorities may also use it confirming or recognising the quality and competencies of an Interoperability Testing Entity.

The QMS, based on ISO 9000 (chapter 5) and the general requirement for the competencies to carry out Interoperability Testing of applications in the eHealth domain is based on the ISO 17000 series (chapter 6 and 7).

The purpose of this document is to provide a guideline and a checklist for defining an interoperability QMS, which can be implemented in any organisation, who has as objective to perform interoperability testing of eHealth products.

[1] http://www.hitch-project.eu/

The immediate benefit that can be realised is the collective alignment of internal processes as well as the processes that involve partner organisations. This is finally aiming towards the enhancement of customer satisfaction, which will result in many other benefits, whether internal or external.

It should be mentioned that this document is intended to provide broad guidelines on interoperability QMS only, i.e. it is not a comprehensive guide to QMS in general.

3 QMS for Interoperability Testing

Quality Management can be used to ensure that and organisation which performs interoperability testing has consistent quality planning, quality control, quality assessment and quality improvement.

Quality Management is focused not only on the quality of the interoperability testing, but also on the means to achieve it.

3.1 Interoperability levels

The QMS for interoperability testing can be constructed from three levels as shown in Figure 1.

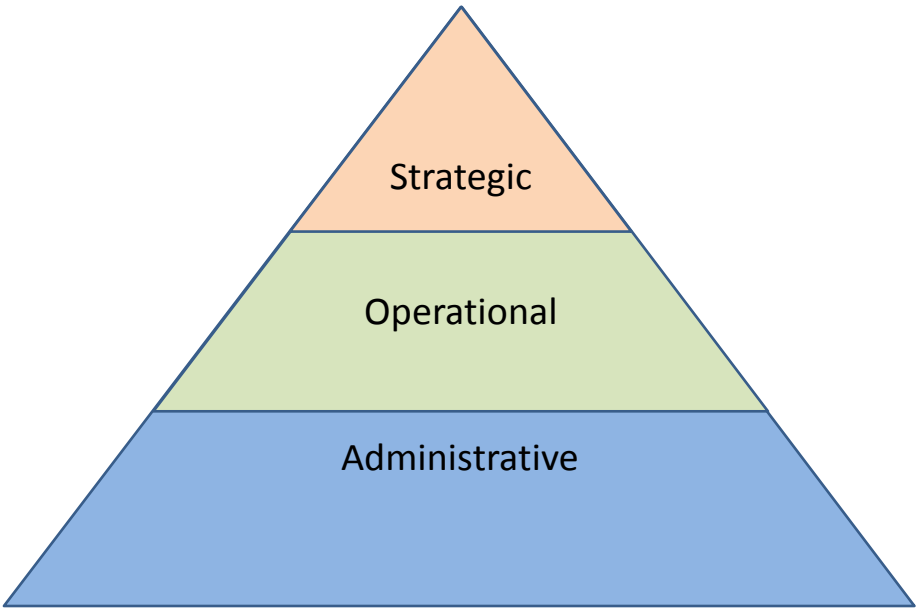

Figure 1: Levels of a QMS for interoperability testing

Strategic: Policy statements which clearly state the organisational position towards interoperability including clear objectives.

Operational: Description of processes that show how the policy statements are implemented. The description normally also includes the person(s) and all parties involved.

Administrative: Supporting documentation to be used in the QMS implementation process – this could be learning material, standards, guidelines, templates, forms, checklists etc.

3.2 The Quality Cycle

Every organisation is dynamic and always in a state of change. This includes changes to policies, objectives and procedures from time to time. Versioned documents (revisions) will reflect the changes. The updated policies, objectives and procedures should be sent to all personnel affected by the QMS for interoperability testing. The revision should have an effective date and, of course, should be distributed in advance to ensure that the changes are well known and ready for use.

The implementation of the QMS for interoperability testing is a continuous cycle consisting of the actions “Plan, Do, Check, Act” (PDCA) which are described below. The Quality Cycle broadly requires the following actions and execution orders shown in Figure 2.

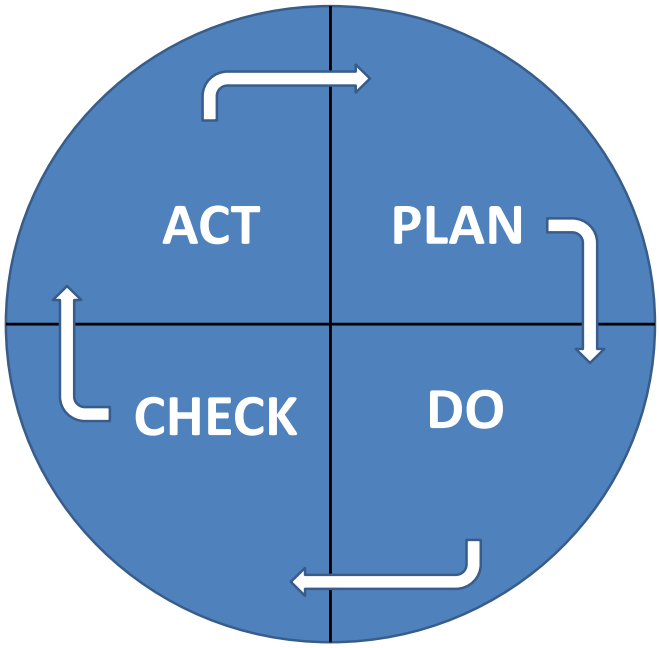

Figure 2: The PDCA cycle

- **Plan** – establish objectives and make plans (analyse organisation's situation, establish overall objectives and set interim targets, and develop plans to achieve them).
- **Do** – implement plans (do what was planned).
- **Check** – measure results (measure/monitor how far actual achievements meet the planned objectives).
- **Act** – correct and improve plans. Learn from mistakes done during practical plan implementation in order to achieve better results next time.

As interoperability testing typically involves multiple organisations, there may be multiple levels of the quality circle. An encompassing and central cycle will define the overall frame for interoperability

testing over a group of organisations. “Local” cycles within single organisations or units will also contribute to improvements.

3.3 Quality policies and objectives

Customer satisfaction in eHealth is largely driven by delivering products and services which are interoperable. Today, more than ever, there is a worldwide trend towards meeting the customer expectation regarding quality and the ability to exchange data, seamless across organisations.

This trend has been a growing realisation, that continuous quality improvement is necessary to achieve interoperability.

3.3.1 Quality Policies for Interoperability Testing

An organisation’s quality policy defines the top management’s commitment to quality. A quality policy statement should describe an organisation’s general quality orientation and clarify its basic intentions.

Quality policies for Interoperability Testing should be used to generate quality objectives and should serve as a general framework for actions.

Quality policies for Interoperability Testing can be based on the QMS principles:

- Customer focus: Conformance and interoperability testing depends on the customer’s need. Organisations should understand the current and future needs for interoperability related to health services (core health business).
- Leadership: Leaders should define clear objectives for conformance and interoperability testing. Leaders should create and maintain an environment for conformance and interoperability testing, including involving people in order to achieve the organisation’s objectives and goals.
- Involvement of people: Interoperability conformance testing shall not be presented as a constraint but rather as an ‘attitude’. People at all levels, meaning member organisation but also users of the organisation shall be involved to contribute to the organisation benefits. The organisation benefit is the benefit of all members.
- Process approach: Quality management must be an ongoing process for optimising the resources for conformance and interoperability testing.
- System approach to management: This QMS principle asks for identifying, understanding and managing interrelated processes related to conformance and interoperability testing.
- Continual improvement: Continual improvement of the organisation’s tools, plans and testing routines should be a permanent objective.
- Factual approach to decision making: Decisions on conformance and interoperability are based on analysis and comprehensible information.
- Mutually beneficial supplier relationships: An organisation and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

Quality policies for Interoperability Testing should be consistent with the organisation’s other policies, e. g. the company’s mission or vision statement.

There will be policies of the organisation itself as well as references to policies that a number of organisations have agreed upon.

3.3.2 **Quality Objectives for Interoperability Testing**

Quality objectives for interoperability testing are something the organisation aims for and tries to achieve. Quality objectives for interoperability testing are generally based on or derived from your organisation's quality policies and must be consistent with them. They are usually formulated for all relevant levels within the organisation and for all relevant functions. They should be available to all involved staff.

The purpose of a QMS for interoperability testing is to ensure its ability to provide high quality products by continuously enforcing quality policies and objectives for interoperability testing within the organization and across its borders. Thus, such a QMS contributes to meet customer and applicable statutory and regulatory requirements and enhance customer satisfaction through effective feedback processes for continual improvement of the QMS processes.

The interoperability testing objectives must be measurable, since the PDCA cycle enforces frequent re-checking of the whole Quality Management process. This is, of course, only possible if the outcome of the existing interoperability objectives can be measured in order to adapt them if required.

4 Management requirements

4.1 Organisation

The Interoperability Testing Entity shall be an entity that can be held legally responsible.

It is the responsibility of the Interoperability Testing Entity to carry out its testing activities in such a way as to meet the requirements of this document and to satisfy the needs of the customer, the regulatory authorities or organisations providing recognition.

The management system shall cover work carried out in the Interoperability Testing Entity's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.

If the Interoperability Testing Entity is a part of an organisation performing activities other than testing the responsibilities of key personnel in the organisation that have an involvement or influence the testing activities shall be defined in order to identify potential conflicts of interest.

The Interoperability Testing Entity shall:

a) have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of departures from the management system or from the procedures for performing tests, and to initiate actions to prevent or minimise such departures.

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

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

d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity

e) define the organisation and management structure of the Interoperability Testing Entity, its place in any parent organisation, and the relationships between quality management, technical operations and support services

f) specify the responsibility, authority and relationship of all personnel who manage, perform or verify work affecting the quality of the tests

g) provide adequate supervision of the testing staff, including trainees, by persons familiar with methods and procedures, purpose of each test, and with the assessment of the test

h) have technical management which has overall responsibility for the technical operations and the provision of resources needed to ensure the required quality of Interoperability Testing

i) appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are made on Interoperability Test policies or resources

j) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system

4.2 Management System

The Interoperability Testing Entity shall establish, implement and maintain a management system appropriate to the scope of its activities. The Interoperability Testing Entity shall document its policies, systems, programmes, procedures and instructions to the extent necessary to assure the quality of the test results. They shall be communicated to, understood by, available to, and implemented by the appropriate personnel

The Interoperability Test organisation's management system policies related to quality, including a quality policy statement, shall be defined. The overall objectives shall be established, and shall be reviewed during management review. The quality policy statement shall be issued under the authority of top management. It shall include at least the following:

a) the Interoperability Testing Entity's management's commitment to good professional practice and to the quality of its testing services in serving its customers

b) the managements statement of the standard of services

c) the purpose of the management system related to quality

d) a requirement that all personnel concerned with testing activities within the Interoperability Testing Entity familiarise themselves with the quality documentation and implement the policies and procedures in their work

e) the Interoperability Testing Entity management's commitment to comply with this document and to continually improve the effectiveness of the management system

4.3 Document control

4.3.1 General

The Interoperability Testing Entity shall establish and maintain a procedure to control all documents that form part of its management system, such as regulations, standards, other normative documents, test methods, as well as drawings, software, specifications, instructions and manuals.

4.3.2 Document approval and issue

All documents issued to personnel in the Interoperability Testing Entity as part of the management system shall be reviewed and approved for use by authorised personnel prior to issue. A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the management system shall be established by readily available to preclude the use or invalid and/or obsolete documents.

The procedure(s) adopted shall ensure that:

a) authorised editions of appropriate documents are available at all locations where operations essential to the effective functioning of the Interoperability Tests are performed

b) documents are periodically reviewed and, where necessary, reviewed to ensure continuing

suitability and compliance with applicable requirements

c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use

4.3.3 **Document changes**

Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval.

Where practicable, the altered or new text shall be identified in the document or the appropriate attachment.

Amendments shall be clearly marked, initialled and dated. A revised document shall be formerly re-issued as practicable.

Procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled.

4.4 **Review of requests, tenders and contracts**

The Interoperability Testing Entity shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to contract for testing shall ensure that:

a) the requirements, including the methods to be used, are adequately defined, documented and understood

b) the Interoperability Testing Entity has the capability and resources to meet the requirements

c) the appropriate test methods is selected and is capable of meeting the customers requirement

Any differences between the request or tender and the contract shall be resolved before any work commences. Each contract shall be acceptable to both the Interoperability Testing Entity and the customer.

Records of reviews, including any significant changes, shall be maintained. Records shall also be maintained of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of execution of the contract.

The review shall also cover any work that is subcontracted by the Interoperability Testing Entity.

The customer shall be informed about any deviation from the contract.

If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel.

4.5 Complaints

The Interoperability Test organisation shall have a policy and procedures for the resolution of complaints received from customers or parties. Records shall be maintained of all complaints and of the investigations and corrective action taken by the Interoperability Testing Entity.

4.6 Control of nonconforming testing work

The Interoperability Testing Entity shall have a policy and procedures that shall be implemented when any aspects of its testing work, or the result of this work, do not conform to its own procedures or the agreed requirements of the customer. The policy and procedures shall ensure that:

a) the responsible and authorities for the management of nonconforming work are designated and actions are defined and taken when nonconforming work is identified

b) an evaluation of the significance of the nonconforming work is made

c) correction is taken immediately, together with any decision about the acceptability of the nonconforming work

d) where necessary, the customer is notified and work is recalled

e) the responsibility for authorising the resumption of work is defined

4.7 Improvement

The Interoperability Testing Entity shall continuous improve the effeteness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

4.8 Corrective action

4.8.1 General

The Interoperability Testing Entity shall establish a policy and procedure and shall designate appropriate authorities for implementing corrective actions when nonconforming work or departures from the policies and procedures in the management system or technical operations have benne identified.

4.8.2 Cause analysis

The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.

4.8.3 **Selection and implementation of corrective actions**

Where corrective action is needed, the Interoperability Testing Entity shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and prevent recurrence.

Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem.

The Interoperability Testing Entity shall document and implement any required changing resulting from corrective action investigations.

4.8.4 **Monitoring of corrective actions**

The Interoperability Testing Entity shall monitor the results to ensure that the corrective actions have been taken effective.

4.9 **Preventive action**

Needed improvements and potential sources of nonconformities, either technical or concerning the management system, shall be identified. When improvement opportunities are identified or if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.

> Procedures for preventive actions shall include the initiation of such actions and the application of controls to ensure that they are effective.

4.10 **Control of records**

4.10.1 **General**

The Interoperability Testing Entity shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.

All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times shall be established.

The Interoperability Testing Entity shall have procedures to protect and back-up records stores electronically and to prevent unauthorised access to or amendment of these records.

4.10.2 **Technical records**

The Interoperability Testing Entity shall retain records of original observations, derived data and sufficient information to establish an audit trail, staff records and a copy of each test report, for a defined period. The record for each test shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test to be repeated under

conditions as close as possible to the original. The records shall include the identity of personnel responsible for each test and checking of results.

4.11 **Internal audits**

The Interoperability Testing Entity shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and this document. The internal audit programme shall address all elements of the management system, including the testing activities. It is the responsibility of the quality manager to plan and organise audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the Interoperability Test organisation's results, the Interoperability Test organisation shall take timely corrective action, and shall notify customers in writing if investigations show that the Interoperability Testing Entity results may have been affected.

The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded.

Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.

4.12 **Management reviews**

In accordance with a predetermined schedule and procedure, the Interoperability Test organisation's top management shall periodically conduct a review of the Interoperability Testing Entity's management system and testing activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review shall take account of:

- the suitability of policies and procedures
- reports from managerial and supervisory personnel
- the outcome of recent internal audit
- corrective and preventive actions
- assessments by external bodies
- changes in the volume and type of work
- customer feedback
- complaints

- recommendations for improvement
- other relevant factors, such as quality control activities, resources and staff training

5 Personnel and test methods

5.1 General

Many factors determine the correctness and reliability of the tests performed by the Interoperability Test organisation. These factors include contribution from:

- human factors
- test and validation methods
- tools

5.2 Personnel

The Interoperability Test organisation shall ensure the competence of all who perform test, evaluate results, and sign test reports. When using staff who are undergoing training, appropriate supervision shall be provided. Personnel performing special tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.

The management of the Interoperability Test organisation shall formulate the goals with respect to the education, training and skills of the Interoperability Test organisation personnel. The Interoperability Test organisation shall have a policy and procedures for identifying training needs and provide training of personnel. The training programme shall be relevant to the present and anticipated task of the Interoperability Test organisation. The effectiveness of the training actions taken shall be evaluated.

The Interoperability Test organisation shall use personnel who are employed by, or under contract to, the Interoperability Test organisation. Where contracted and additional technical key support personnel are used, the Interoperability Test organisation shall ensure that such personnel are supervised and competent and they work in accordance with the Interoperability Test organisation's management system.

The Interoperability Test organisation shall maintain current job descriptions for managerial, technical and key support personnel involved in tests.

The management shall authorise specific personnel to perform particular types of test, to issue test reports, to give opinions and interpretations and to operate particular test tools. The Interoperability Test organisation shall maintain records of the relevant authorisation(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorisation and/or competence is confirmed.

5.3 **Test methods and validation**

The Interoperability Test organisation shall use the methods and procedures for all tests as described in the Part II of the Quality Manual (ANTILOPE WP2, D2.2 Interoperability Testing Processes).