

## Quality Manual for Interoperability Testing.

### PART I: Quality Management System for Interoperability Testing

#### Executive Summary

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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 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.

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 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 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” based on the main principles in ISO 9000.

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. The 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 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).