PERSPECTIVE OF REVISED ISO/IEC 17025 ON DIGITALISATION

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April 24th 2018

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Background

Magnus Holmgren

- Quality and sustainability manager at RISE since 2000
- Eurolab Secretary 1995-2000 SP
- Technical Secretary Nordtest 1994-1995
- Research engineer (mechanics) 1987-1994 SP
- Members of different groups, committees etc. which work with Quality Assurance on the international level e.g.
  - ISO WG 44 (ISO 17025)
  - SIS TK 316 (ISO 17025)
  - Eurolab TCQA
  - EA HHC
  - EEE-PT etc.

RISE Research Industries of Sweden

- A merger of different research institutes in Sweden among them SP
- 2300 employees
- Active over all of Sweden
- 6 divisions
- Activities in a lot of areas, almost all technical fields

The new ISO 17025 in general compared to the old version

- Different structure
  - The standard ISO style (ISO 9000 with 5 main chapters) compared with the old version with two main chapters
- New items e.g.
  - Decision rules
  - PT requirements
  - A and B options
  - Etc.
- Items taken away e.g.
  - Quality manager
  - Evaluation of education
  - Requirements for digital handling
  - Etc.

Digitalisation in ISO 17025:2005 vs 17025:2017

- ISO 17025:2005 is an old standard (developed during the end of the nineteen nineties, first version 1999). That means it contains a more than twenty years old concept. The standard presumes the use of paper and pen and consider the use of computers etc. as something new that has to be handled in a specific way and special precautions must be taken when using them
- ISO 17025:2017 is neutral whether information is electronic or hard copy. In fact in some clauses it is assumed that the information is digital. In any way the new standard is considering information as information whether it is digital or hard copy, the requirements are the same.

Use of words (electronic, computer, software and digital)

ISO 17025:2005

- Electronic: 10
- Computer: 6
- Software: 14
- Digital: 2

ISO 17025:2017

- Electronic: 1
- Computer: 5
- Software. 7
- Digital: 1

4.3 Document control (17025:2005)

4.3.1 General

NOTE 1 In this context "document" could be policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, whether hard copy or electronic, and they may be digital, analog, photographic or written.

4.3.3.3 If the laboratory's document control system allows for the amendment of documents by hand pending the re-issue of the documents, the procedures and authorities for such amendments shall be defined. Amendments shall be clearly marked, initialled and dated. A revised document shall be formally re-issued as soon as practicable.

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

All these requirements assumes a handling of information is handling of physical information even though Note 1 above is mentioning electronic information and 4.3.3.4 is introducing extra requirements for electronic information.

4.13 Control of records (17025:2005)

4.13.1.2 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 of records shall be established.

NOTE Records may be in any media, such as hard copy or electronic media.

4.13.1.4 The laboratory shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.

4.13.2.3 When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialled by the person making the correction. In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data.

All these requirements assumes handling information is handling of physical information. There are special requirements for electronic information.

5.4.7 Control of data (17025:2005)

5.4.7.1 Calculations and data transfers shall be subject to appropriate checks in a systematic manner.

5.4.7.2 When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that:

a) computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;

b) procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;

c) computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.

NOTE Commercial off-the-shelf software (e.g. word-processing, database and statistical programmes) in general use within their designed application range may be considered to be sufficiently validated. However, laboratory software configuration/modifications should be validated as in 5.4.7.2 a).

The requirements are special for electronic data.

5.5 Equipment (17025:2005)

5.5.2 Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned.

5.5.4 Each item of equipment and its software used for testing and calibration and significant to the result shall, when practicable, be uniquely identified.

5.5.5 Records shall be maintained of each item of equipment and its software significant to the tests and/or calibrations performed.

Software are handled together with equipment.

5.10 Reporting the results (17025:2005)

5.10.1 General

The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.

NOTE 2 The test reports or calibration certificates may be issued as hard copy or by electronic data transfer provided that the requirements of this International Standard are met.

Allows electronic reports.

5.10 Reporting the results (17025:2005)

5.10.2 Test reports and calibration certificates

Each test report or calibration certificate shall include at least the following information, unless the laboratory has valid reasons for not doing so:

NOTE 1 Hard copies of test reports and calibration certificates should also include the page number and total number of pages.

5.10.7 Electronic transmission of results

In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of this International Standard shall be met (see also 5.4.7).

5.10.7 Not when ordinary mail is used?

ISO 17025:2017 (6.4 Equipment and 7.4 Handling of test and calibration items)

6.4.1 The laboratory shall have access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) that is required for the correct performance of laboratory activities and that can influence the results.

6.4.13 Records shall be retained for equipment which can influence laboratory activities. The records shall include the following, where applicable:

a) the identity of equipment, including software and firmware version;

7.4.2 The laboratory shall have a system for the unambiguous identification of test or calibration items. The identification shall be retained while the item is under the responsibility of the laboratory. The system shall ensure that items will not be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of an item or groups of items and the transfer of items.

ISO 17025:2017 (7.5 Technical records and 7.8 Reporting the results)

7.5.1 The laboratory shall ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original. The technical records shall include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. Original observations, data and calculations shall be recorded at the time they are made and shall be identifiable with the specific task.

7.8.1.1 The results shall be reviewed and authorized prior to release.

7.8.1.2 The results shall be provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. a test report or a calibration certificate or report of sampling), and shall include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. All issued reports shall be retained as technical records.

NOTE 1 For the purposes of this document, test reports and calibration certificates are sometimes referred to as test certificates and calibration reports, respectively.

NOTE 2 Reports can be issued as hard copies or by electronic means, provided that the requirements of this document are met.

ISO 17025:2017 (7.11 Control of data and information management)

7.11.1 The laboratory shall have access to the data and information needed to perform laboratory activities.

7.11.2 The laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data shall be validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction. Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they shall be authorized, documented and validated before implementation.

NOTE 1 In this document “laboratory information management system(s)” includes the management of data and information contained in both computerized and non-computerized systems. Some of the requirements can be more applicable to computerized systems than to non-computerized systems.

NOTE 2 Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated.

7.11.3 The laboratory information management system(s) shall:

a) be protected from unauthorized access;

ISO 17025:2017 (7.11 Control of data and information management) Cont.

b) be safeguarded against tampering and loss;

c) be operated in an environment that complies with provider or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;

d) be maintained in a manner that ensures the integrity of the data and information;

e) include recording system failures and the appropriate immediate and corrective actions.

7.11.4 When a laboratory information management system is managed and maintained off-site or through an external provider, the laboratory shall ensure that the provider or operator of the system complies with all applicable requirements of this document.

7.11.5 The laboratory shall ensure that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel.

7.11.6 Calculations and data transfers shall be checked in an appropriate and systematic manner.

ISO 17025:2017 (8 Management system requirements)

8.2.4 All documentation, processes, systems, records, related to the fulfilment of the requirements of this document shall be included in, referenced from, or linked to the management system.

8.3.1 The laboratory shall control the documents (internal and external) that relate to the fulfilment of this document.

NOTE In this context, “documents” can be policy statements, procedures, specifications, manufacturer’s instructions, calibration tables, charts, text books, posters,

8.4.2 The laboratory shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The laboratory shall retain records for a period consistent with its contractual obligations. Access to these records shall be consistent with the confidentiality commitments, and records shall be readily available.

Conclusion

- The requirements in the new standard are not differentiating between hardcopy and electronic information
- The laboratory shall have a laboratory information management system (LIMS)
- Calculations and data transfers shall be checked (no change compared with 2005)
- In general there are few “new” requirements in the new standard e.g. if you managed the accreditation surveillance with the old standard you will probably do it now.
- Classification of information is important
- Software seen as equipment
- No real big differences between 2005 and 2017 even though the 2005 version is considering computers and digital information as a “strange animal” and 2017 version consider electronic information and computerised systems as standard!

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Thank you!

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