

Policy on assessment of quality system documentation and data in an electronic environment

PS14

1) Purpose

1.1) Applicant and accredited Conformity Assessment Bodies (CAB) are increasingly using IT systems for the storage of documentation and data, transmission of results, reports etc.

The aim of this document is:

- to provide guidelines for organisations and assessors in assessing these systems with the aim of ensuring that electronic systems for quality system documentation meet the requirements of the relevant accreditation standard, including full audit trail requirements.
- to provide guidelines for organisations and assessors in assessing electronic systems that process, store and transmit data, included in the accredited activity, electronically, for example LIMS, electronic transmission of data/test results, any in-house developed software etc, again to ensure they meet the requirements of the relevant accreditation standard, including full audit trail requirements.

1.2) The requirements as stated in this document are not exhaustive, rather minimum guidelines which will enable organisations to assess the compliance of their electronic systems with the relevant accreditation standards.

2) Electronic quality system documentation

2.1) Requirements for electronic based quality system documentation:

2.1.1) A system description shall exist that describes, at minimum:

- Where documents are stored.
- Which documents are stored in electronic format.
- Access control.
- Authorisation levels for changes.
- Provisions for electronic system failure, service agreements with software providers or in house IT departments etc.
- Security and confidentiality arrangements for any documentation stored electronically, shall be documented.

- 2.1.2) Electronic documents shall always contain information on their unique identification, revision control, page numbers (where practical), approval, date of issue etc.
- 2.1.3) Provisions for control of documents after issue and prevention of inadvertent changes shall be documented.
- 2.1.4) Training in the use of the electronic system shall be provided if deemed necessary.
- 2.1.5) Archiving requirements shall be defined and must meet the INAB Terms and Conditions.
- 2.1.6) Necessary documentation such as work instructions/test methods etc. shall be available at all times regardless of whether the electronic system is operational or not. i.e. contingency arrangements shall be evident in the event of electronic system breakdown.

3) Electronic systems for the management of data, transmission of data, reporting of results and systems allowing access of third parties to a company's data, included in the accredited activity across and between all locations

3.1) If an organisation intends to implement a commercially available electronic system for the management of data included in its accredited activity, using external suppliers (for example Laboratory Information Management System (LIMS)), the organisation must submit, at least three months in advance of implementation, the following information:

- Description of the responsible team/department for implementing the system, i.e. people involved, responsibilities/authorisations etc.
- Procedure for operation of the system
- Plans for the main activities in terms of timelines/responsibilities including:
 - Installation
 - Testing/validation or verification.
 - Training and documentation
- System description – for established systems this may be a combination of the suppliers standard documentation together with company specific enhancements or changes.
- Please note commercially available IT systems can be considered sufficiently validated, if implemented without change. Verification records of its implementation in the CAB may suffice. The process shall be documented by the CAB, with justification.
- Agreements with external IT suppliers, if applicable.
- Procedures to be used for validation of the system.
- Procedures to be used for checking data traceability, including reports and re-issued report transmission.
- Availability of web based access to results/certificates/reports.
- Electronic authorisation of results and security provisions, including provision to re-issue reports and incorporation of the accreditation symbol/reference to accreditation.
- Access control procedures.
- Audit trail functionality and testing.

- Procedures for handling errors in the system.
 - Procedures for routine maintenance of the system, i.e. backup, error handling, maintenance, development etc.
 - Procedures for controlling updates and different versions of software systems .
 - Reports from any validations/verifications completed.
 - Evidence of completion of user training.
- 3.2) If a newly developed, company specific system, is being implemented, the organisation should inform INAB as soon as possible and not later than 6 months in advance of implementation of the system. Accreditation requirements should be considered at the earliest possible stage of development of such systems. The requirements in terms of documentation for these types of systems are as described in 3.1 above.
- 3.3) After review of the documentation as specified in 3.1 and as submitted by the organisation, INAB will make a decision at this stage as to whether an additional technical expert should be part of the assessment team to assess such a new system and/or an additional visit is required to the organisation for the purpose of assessment of such a system.
- 3.4) In general IT systems such as described in 3.2 will require an additional IT technical assessment. IT systems as described in 3.1 may not require a specific IT assessment if there are limited changes to the commercially available software.
- 3.5) After implementation of the electronic data management system has been completed, an organisation must also inform INAB if major upgrades to the system are being implemented. Again, three months notice must be provided to INAB for this purpose at which point the organisation must submit to INAB documentation regarding the following:
- Reason for the major upgrade to the system
 - Extent and description of the upgrade
 - Detailed description of changes to be made
 - Validation plan for the upgrade
- This documentation will be reviewed by INAB, at which point a decision will again be made as to the necessity of an additional visit/additional examination of the system in operation by a technical expert.
- During any on site assessment PS14F1 will be used by the IT technical assessor / expert to document the IT system assessment and will be used as an annex to the relevant XF116 form.
- 3.6) Accreditation standards vary in the degree to which they refer to IT systems and requirements. Assessment by INAB of IT infrastructure to support accredited activity does not in any way imply that INAB approves or endorses the IT system. The IT infrastructure, as determined necessary and fit for purpose by the CAB, is assessed by INAB as it is presented to meet management system and reporting requirements of relevant accreditation standards.

4) Implementation

From date of publication.

5) Contact

For further information about this statement please contact an INAB officer at **The Irish National Accreditation Board**.

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