

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

PS14

1) Purpose

1.1) A growing number of applicant and accredited organisations are storing and transmitting their quality system documentation and data in electronic format. This can involve portions of the quality system or the entire system. 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) Please note 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 must exist that describes:

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, e.g. Virus protection, backup, agreements with IT suppliers etc. must be documented.

- 2.1.2) Electronic documents must 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 must be documented.
- 2.1.4) Training in the use of the electronic system must be provided if deemed necessary.
- 2.1.5) Archiving requirements must be defined and must meet the INAB Terms and Conditions.
- 2.1.6) The status of the electronic documentation must be clearly identified (e.g. controlled, uncontrolled, draft etc.).
- 2.1.7) Necessary documentation such as work instructions/test methods etc. must be available at all times regardless of whether the electronic system is operational or not. The capability to provide these irrespective of the functioning of the electronic system must be demonstrated.
- 2.1.8) Assessment of electronic quality system documentation will be an integral part of INAB's normal assessment/surveillance/re-assessment process for all applicant and accredited organisations.

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.**

- 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 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, competence records, responsibilities/authorisations etc.

Plans for the main activities in terms of timelines/responsibilities including:

- Installation
- Testing/validation
- 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

Agreements with external IT suppliers, if applicable
Procedures to be used for validation of the system
Procedures to be used for checking data
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 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 3 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) 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 procedures 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.

4) Contact

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

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