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CHANGE CONTROL

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CHANGE CONTROL

1. Introduction

Management and control of changes is an integral part of a Quality Management System (QMS) following ISO 17025:2005. A formal change control system should be established to regulate changes affecting processes within the QMS. These changes should be planned, documented and approved. The impact of these changes needs to be technically and scientifically evaluated to prevent risks to the quality and safety of results.

2. Scope

This document outlines a possible approach to the process for management and control of changes related to operational and technical processes.

3. References

- ISO 17025:2005 - General requirements for the competence of testing and calibration laboratories (clauses: 4.2.7, 4.4.2, 5.4.2, 5.4.5.2, 5.4.5.3)
- ISO 9000:2015 - Quality management systems - Fundamentals and vocabulary

4. Definition

Change Control is a process that ensures that changes are appropriately identified, planned, documented, validated (where relevant), approved, verified and traceable. It is a decision of the OMCL to identify what changes are significant enough to trigger a change control in the context of their organization and the extent of control, considering the elements of their QMS: key personnel, facilities, testing, materials, methods, specifications, requirements (e.g. customer, relevant entities, legal etc.), equipment, software, core processes and support systems, etc.. A typical example of a change that needs to be controlled is the change from a paper based system to an electronic system (e.g. LIMs).

Validation is a confirmation, through the provision of objective evidence, that the requirements for specific intended use or application have been fulfilled. The objective evidence needed for a validation is the result of a test or other form of determination such as performing alternative calculations or reviewing documents. The word "validated" is used to designate the corresponding status. The use conditions for validation can be real or simulated. [Definition from ISO 9000:2015 clause 3.8.13]

5. Procedure

The OMCL should establish and describe a process which will ensure that changes are implemented in a controlled and coordinated manner. This will help to minimise any disruptions to the laboratory's work, and will ensure that staff, customers and other interested parties understand and support the change. Any person could identify the need for a change and initiate the change.

The following steps could be considered during the process of a change implementation:

5.1 Change proposal

- Describe the change and what it is attempting to achieve (objectives). Justify why the change is needed and describe the risk if the change is not implemented. There are certain types of complex changes (e.g. major change to facilities, introducing electronic laboratory management system) where it may be appropriate to set up a Project Management Team (or equivalent) responsible for implementation of such a change.

- Ensure a traceable system for the change log (e.g. an identification code or number can be assigned).
- Define the scope of the change. The OMCL should evaluate direct and indirect impact of the proposed change on all relevant areas. Risk analysis should be included in this evaluation in order to identify the benefit of the change as well as actions to mitigate potential risk when it takes place.
- Identify whether the change needs to be reviewed and approved by the management and/or Quality Management personnel and/or other relevant person before its implementation. This step will require recognising the significance of the impact of the change on the QMS. Depending on the nature of the change, Quality Management personnel or other relevant personnel/ interested parties should be notified about significant changes. This usually includes changes to test methods, reference/ control material, equipment, software, facilities or key personnel.
- Assign personnel responsible for implementation, approval and review of the specific steps of the change. It needs to be noted that a change proposal may be expanded, modified or rejected, based on the evaluation performed during the approval process.
- Identify the anticipated date of the change implementation.

5.2 Implementation plan

Define the actions that need to be carried out in order to implement the change. The following points should be considered, if relevant:

- In a situation where a validation/qualification is needed, propose a validation/qualification plan to support the control process. Where applicable, consider the relevant OMCL guidelines (e.g. Validation of computerised systems or Uncertainty of measurement);
- Identify documents which will need to be updated as a result of the change;
- Identify training requirements for staff affected by the change;
- Identify the need for additional resources;
- Develop a communication plan (appropriate people within the OMCL, competent entities, customers, suppliers, interested parties, etc., may need to be informed).

5.3 Implementation

The proposed change should be implemented as per the implementation plan (see 5.2) and any significant delays should be justified.

5.4 Review the implementation of the change

- Track the status of the change. It may be helpful to have a change control log;
- Verify whether each step of the change control process is traceable and appropriately documented;
- Verify whether each step of the implementation plan was approved, implemented and completed in a timely manner and whether significant delays were justified;
- If validation/ qualification was part of the change implementation, review the validation/ qualification plan and report;
- Verify evidence of training, if applicable;
- Verify whether relevant entities/ customers/ interested parties were notified, if applicable;
- Where relevant, the implemented change should be evaluated for its effectiveness by the top management (e.g. during a review of the QMS).