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MANAGEMENT OF CHANGES

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MANAGEMENT OF CHANGES

Note: Mandatory requirements in this guideline are defined using the terms "shall" or "must". The use of "should" indicates a recommendation. For these parts of the text other appropriately justified approaches are acceptable. The term "can" indicates a possibility or an example with non-binding character.

1. Introduction

Management of changes is defined as a systematic way to handle changes within an organisation to effectively deal with the change and to capitalise on possible opportunities. It involves adapting to the change, controlling the change and effecting new change.

In ISO/IEC 17025:2017 a specific requirement is given in clause 5.7 b) *"Laboratory management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented."*

In ISO/IEC 17025:2017, requirements for management of changes are described in several chapters, including:

- Selection and verification of methods
- Validation of methods
- Process requirements
- Technical records
- Control of data and information management
- Control of management system documents (option A)
- Corrective actions (option A)
- Internal audits

Detailed descriptions of the clauses and quotations from the text are given in Table 1 in Appendix 1.

Management of changes is also reported as an integral part of the Management Review, being part of the input and output requirements.

2. Scope

This document is a guideline intended to support OMCLs in the management of changes to the Management System (MS), including the different steps of the process.

3. Management of changes

The management of changes is a process that ensures that changes are appropriately

- identified,
- documented,
- evaluated (including the impact and consequent risks/opportunities),
- approved,
- planned,
- implemented,
- reviewed.

Management of changes is necessary when a change is considered to have a significant impact, i.e. on the volume and type of the work, on the range of laboratory activities or on the validity of

results. It should not replace the corrective action plan, validation and verification processes, or management of laboratory equipment.

Every identified change and its impact on the MS needs to be evaluated, possibly using a risk-based approach.

Typical examples of significant changes are:

- Change from a paper-based system to an electronic system (e.g. LIMS)
- Changes with impact on (performance of) testing fields, scope of batch release (e.g. systematic research on impurities/contaminations)
- Replacement of animal trials - 3Rs: Replace, Reduce, Refine
- Organisational changes, e.g. fusion of two lab units and relocation or major renovation
- Legal changes with consequences on duties or processes of an OMCL (e.g. governmental or contractual)
- Changes derived from the management review (e.g. feedback, complaints, audit results, non-conformities, risks and opportunities, opportunities for improvement, etc.).

Typical examples which would not trigger a change management process include:

- New batch of a chemical substance used in an analytical method and quality defined in the relevant SOP (change identified to be "within the design space")
- Change of typical method parameters , e.g. incubation time, temperature (already covered via validation and verification)
- Change of test equipment (already covered via PQ and verification of test method)
- Any single occurrence or non-conformity covered by the corrective action plan or elsewhere (e.g. complaint management).
- Changes/amendments to technical records

4.   Procedure

The OMCL should ensure that all the steps of a planned change are managed in a controlled and coordinated manner in order to ensure continual improvement. This can be achieved either by establishing a specific procedure for change management or by implementing these requirements in all relevant existing procedures related to change (e.g. project management, method validation, updates of QMS documents, implementation of actions addressing non-conforming work, risks and opportunities, etc.) 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.

The steps depicted in the flowchart in Figure 1 should be considered.

Need for a change identified

Define the degree of change significance to trigger a change control e.g. regulations, new equipment, key personnel, facilities, reference/control material, test methods, software etc.

Description of the change

What is the current situation?
What will be the new situation?
What is the risk if the change is not implemented?

Evaluation of the impact

- Impact of the identified risks.
- Impact on the activities of the laboratory.
- Evaluation performed by experts.
- Management system shall be included.

Definition of action plan

What/Who/When
Bear in mind the final date of change implementation.
Actions can be included in the Management system.

Go/No-Go for action plan

Personnel in charge of Management system/ expert/management
(to be defined) & resources allocation.

Action plan follow-up

Assign a person to track on regular basis:
- actions related to a specific change
- status of the on-going changes.

Implementation of the change

When all actions are closed, the change is implemented. Record the date.

Monitoring and Review

Periodic check to ensure effectiveness of implemented actions and achievement of the objectives of the change.
Applicable to stages of the process.

4.1   Identification of the change

The OMCL should define criteria to establish when changes are significant, i.e. triggering change management. Change and its status should be tracked. This may be supported by unique identification code.

4.2   Description of the change and evaluation of the impact

A detailed description of the change to the current situation should be reported, describing the objectives of the change and therefore justifying why it is needed. The OMCL should evaluate the direct and indirect impact of the proposed change on all relevant areas/laboratory activities and on the identified risks. The risk if the change is not implemented as well as risks associated with the change should also be assessed. There are certain types of complex changes (e.g. major change to facilities, introduction of an electronic laboratory management system) where it may be appropriate to set up a Project Management Team (or equivalent) responsible for the implementation of such a change.

A risk analysis should be included in the evaluation of the impact, in order to identify the opportunities and the actions to mitigate potential risk when the change is implemented (e.g. risk for impartiality). Several methodologies can be applied to evaluate the impact, i.e. by using checklists based on, for example, activities of the laboratory, chapters/clauses of the Standard or areas of the laboratory. The list of clauses in Table 1 can be used as an example.

4.3   Definition of the action plan

Actions to be carried out in order to implement the change shall be planned and reported, as well as the expected date of effective implementation. The following points should be considered, if relevant:

- Whenever a validation/re-validation/qualification activity is needed, a plan to support the control process should be proposed. Where applicable, consider the relevant OMCL guidelines (e.g. Validation of computerised systems);
- Identification of documents which will need to be updated as a result of the change;
- Identification of training requirements for staff affected by the change;
- Identification of the need for additional resources;
- Development of a communication plan (appropriate people within the OMCL, competent entities, customers, suppliers, interested parties, etc., who may need to be informed).

It must be noticed that sometimes actions may be defined also in a post-implementation phase.

4.4   Go/no go for action plan

Approval to go ahead for the change and authorisation to rolling out the action plan.

4.5   Action plan follow-up

The following points should be considered during the follow-up/review phase of the action plan:

- Track the status of the change;
- Verify whether each step of the change management 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 informed.

4.6   Implementation of the change

The proposed change should be implemented according to the implementation plan and any significant delays should be reported and justified. When all relevant actions are closed, the change is implemented. Record the date of implementation of the change

4.7   Monitoring and review

The purpose of the ongoing monitoring and periodic review is to assure that action plan is implemented. It should take place overall the stages of the change management process. Successful implementation of the change and its effectiveness should be checked. An internal audit may be considered as tool for follow-up of major changes. The results of monitoring and review should be considered as input of the Management review.

4.8   Change Management responsibilities

In terms of responsibilities, the OMCL should define the personnel responsible for change management during the different phases, i.e. change identification, definition of the action plan, evaluation of impacts, approval, review, and implementation of the change. A person responsible for tracking actions (e.g. related to a specific change, status of ongoing changes, monitoring and review) on a regular basis should be appointed in the laboratory.

It has to be noted that a change may be expanded, modified or rejected, based on the evaluation performed during the approval process.

Relevant personnel/interested parties should be informed.

5.   References

1) ISO/IEC 17025:2017 - General requirements for the competence of testing and calibration laboratories
2) ISO 9000:2015 - Quality management systems - Fundamentals and vocabulary

APPENDIX 1

Table 1 – Chapters and quotation (full or partial) of the clauses of ISO/IEC 17025:2017 referring to management of changes.

Chapter	Clause
Structural requirements	5.7 " laboratory management shall ensure that:..b) the integrity of the management system is mantained when changes to the management system are planned and implemented"
Review of request, tenders and contract	7.1.8 "Records of reviews, including any significant changes, shall be retained."
Control of data and Information management	7.11.2 "...Whenever there are any changes...they shall be authorised, documented and validated before implementation."
Reporting results	7.8.8.1 " when an issued report needs to be changed, amended or re-issued, any change of information shall be clearly identified and, where appropriate, the reason for the change included in the report"
Control of management system documents (option A)	8.3.2. "The laboratory shall ensure that: c) changes and the current versions status of documents are identified"
Corrective actions (option A)	8.7.1 "When a non-conformity occurs, the laboratory shall f) make changes to the management system, if necessary."
Internal audit	8.8.2 "The laboratory shall: plan, establish, implement and maintain an audit programme...which shall take into consideration...changes affecting the laboratory..."
Management Review	8.9.2. "The inputs to management review shall be recorded and shall include information related to the following: a) changes in internal and external issues that are relevant to the laboratory h) changes in the volume and type of the work or in the range of laboratory activities. 8.9.3. The outputs from the management review shall record all decisions and actions related to at least: d) any need for change."