# CHANGE CONTROL

## Purpose & SCOPE

To detail the actions, responsibilities and documentation involved in changes to critical materials, equipment or procedures. Changes may include, where appropriate, risk analysis, validation studies, qualifications, training and changes to documentation and forms.

## Responsibilities

The responsibilities of the Quality Manager, Quality Coordinator and Facility Director for the Compliance Management system are documented in *Quality Management.*

Specific Change Control responsibilities:

* Any staff may initiate a proposed change to critical materials, equipment or procedures, but the change must be approved by the Facility Director and Quality Manager (or delegate), and authorised by the Quality Manager (or delegate) prior to implementation.
* The Quality Manager (or delegate) and the Facility Director are responsible for:
  + Evaluating & approving the potential impact of proposed changes prior to implementation. If the change is medically relevant, the Medical Director must also evaluate and approve the proposed change prior to implementation.
  + Determining whether *(Insert name of applicable regulatory agency)*, approval is required.
* Quality Manager (or delegate), Facility Director and/or the Scientist in Charge are responsible for:
  + Establishing acceptance criteria/specifications, qualification (design, installation, operational) and/or validation requirements, including environment re-validation if required.
  + Determining requirements for risk analysis/risk assessment.
  + Determining training requirements.

## DEFINITIONS

**Change Control:** A system of procedures through which changes are reviewed, justified, documented, approved, and implemented in conformance with regulatory and *(Insert manufacturer’s name)* requirements.

**Change:** Any addition to, deletion of, or modification to a system, process, material, product, equipment or procedure.

## Procedure

Document change control using the Compliance Management module in *(Insert name of quality software application)*, refer to *(Insert name of quality software application document)*.

If *(Insert name of quality software application)* is unavailable, use a *Compliance Management Form* to manually record the relevant information. Transfer the information to *(Insert name of quality software application)* as soon as possible.

All changes must be approved by the Quality Manger (or delegate) prior to implementation.

### Identify Proposed Change

Identify the need for a change to a material, process or equipment.

### Initiate a Change Control Report

Initiate a change control report using the Compliance Management module in *(Insert name of quality software application)*, refer to *(Insert name of quality software application document)*. Any staff member may initiate a change control report.

For equipment changes initiate an Equipment Change Control Report. For all other changes, including changes to processes and materials, initiate a standard Change Control Report.

Record the following information:

* Date
* Originator’s name
* Category (e.g. Material, Process, Equipment)
* Process (e.g. Haemopoietic)
* Description of the proposed change

### Determine Severity

The Quality Manager is to assess the severity of the change.

**Minor:** change unlikely to have a detectable impact on processes, materials, product or procedures.

**Major:** change likely to or will have a detectable impact on processes, materials, product or procedures.

### Assess Implications/Impact

The Quality Manager is to consult with the Facility Director, Scientist in-Charge and, if required, the Medical Director to determine any implications of the change.

For major changes perform a risk analysis, refer to *Risk Management*. If required, complete a *Risk Management* *Form.*

1. Regulatory Agency Notification

The Quality Manger is to conduct an evaluation of the change to determine if any regulatory agencies should be notified of the change.

For major changes to the processing of *(Insert name of applicable regulatory agency)* licensed products the Quality Manager is to notify the *(Insert name of applicable regulatory agency)*.

### Approval or Rejection

The Quality Manager is to review the request for change and approve or reject the change.

Record the date of the approval/rejection on the Change Control report. If a change requires a regulatory agency’s approval prior to implementation, do not approve the change for implementation until the approval is received from the regulatory agency.

1. Process Validation / Equipment Qualification

Changes to processes or materials are to be validated prior to implementation. Record the validation on the Change Control report.

For Equipment Change, the following actions are required and must be recorded on the Equipment Change Control Report:

* Installation Qualification
* Operational Qualification
* Performance Qualification

For new items of equipment an *Equipment Control Form* must also be completed.

1. Document Changes

The Quality Manager is to identify any documents impacted by the change and ensure they are revised, as required.

1. Training Requirements

The Quality Manager is to consult with the Facility Director and/or Scientist in Charge to determine if any staff training is required.

The Scientist in Charge is to co-ordinate staff training. Record the training on the Change Control Report and update staff training and competency records.

### Implementation

Record how and when the change is implemented.

1. Follow up Evaluation

The Quality Manger is to assess the implementation and the impact of the change. For major changes the process involved in the change may be audited to ensure effective implementation.

1. Management Review

All changes are reviewed by the *(Insert manufacturer’s name)* Management team prior to closure, refer to *Compliance Management*. Following management review further actions may be initiated.

1. Closure

The Quality Manger (or delegate) may close the non-conformance report upon completion of all of the above stages.

## Records

Maintain all change control records in accordance with *Record Management*. Retain hard copies of the Change Control reports in the CM Report files located in the office of the Scientist in Charge.

## documents

*Compliance Management* DOC148

*Quality Software Application* DOCXX

*Quality Management* DOC50

*Record Management* DOC52

*Risk Management* DOC53

## FORMS

*Compliance Management Form* FORM79

*Equipment Control Form* FORM83

*Risk Management Form* FORM133

## Procedure History

| Revision | **Date** | **Modification** | **Approved** | **Implemented** |
| --- | --- | --- | --- | --- |
| 1.0 | *(Insert date)* | Originally drafted by (*Insert name*) | (*Insert name*) | (*Insert date*) |
| 2.0 | *(Insert date)* | Revised by (*Insert name & description of changes*) | (*Insert name*) | (*Insert date)* |