



Standard Operating Procedure: Change Control

Document History

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1. Background

Change Control is the process of handling proposed alterations to items that have been previously designated as fixed. This means that an item only becomes subject to change control once it has been signed-off, stored in a baseline and placed under configuration control. The aim of change control is to ensure that if a signed-off item is changed then

- All stakeholders have an opportunity to participate in the control of any subsequent changes
- All recipients are made aware of any changes that occur
- There is an audit trail which connects a change to a configuration item to the reason for its change, and which records the participation and authorisation of those people concerned with the change.

All documents will be reviewed on a regular basis to ensure that the information is relevant and the information contained within is up to date. Regulatory or procedural changes may make it necessary to amend a document outside the normal review period but these will follow the same change control procedure.

2. Procedure

1. Once a need for change has been highlighted a change control form should be completed (section A).
2. The form should be returned to the bio repository manager who gives the form a reference number and log details of the form.
3. A review of the form will take place and a suggested course of action which will be recorded on the change control form (section B).
4. This will be reviewed by the Biorepository management group and a decision made to accept or reject the change.
5. If rejected, the reason will be recorded on the change control form (section C) and the reason fed back to the originator.
6. If accepted, this is again recorded on the change control form (section C) and the changes applied to the document and the new version stored electronically as a separate version of the document.
7. The changes should also be recorded in the document history section on the document
8. The revised document should be circulated for review before formal acceptance.
9. Once reviewed the document should be circulated to all personnel and the change control form (section D) signed to indicate the change control is completed.
10. The change control form should then be filed.

3. Associated Documents

	Document	Document Reference
1	Change Control Form	BIO:FORM:07
2		
3		
4		
5		
6		
7		