NHS SCOTLAND DOCUMENT
Model SOP to Meet Requirements of OIG Quality Management System

Document Reference No: NHSSIG D78_05_01

Requirements For Change Control in a Hospital Blood Bank

Document Prepared November 2005
1. Introduction

Change control is a fundamental requirement of any Quality Management System (QMS) and is a specific requirement of the EEC Guide to GMP (Orange Guide) and the QMS for hospital blood banks prepared by the NHS Operational Impact group. The purpose of change control is to provide a systematic method for assessing the impact of any change on any activity which might have an affect on the laboratories procedures, outputs and services. This policy applies to all new laboratory equipment, computer systems, analytical methods and testing kits.

2. Health and Safety

There are no specific health and safety implications involved in implementing this SOP, although part of the change control procedure will involve an assessment of whether or not there are safety implications which need to be taken into account during the approval process. Where relevant full Health and Safety risk assessments and COSHH assessments will be undertaken.

3. Materials

Not applicable

4. Staff

Staff at many levels are likely to be involved in the change control process. However the responsibility for ensuring that developments are subjected to appropriate change control procedures lies with the relevant Head of department (BMS staff). Complex developments may require the establishment of a project team in which case the responsibility then lies with the project manager. The Quality manager will be the principal source of advice on the need for change control and its management.

5. Basics of Change Control Procedure

The basic requirements of this SOP are that planned changes are subjected to effective scrutiny by all parts of the organisation which are affected. This SOP is intended to ensure that all these basic requirements are implemented.
6. Objectives

The principal objectives of Change control are as follows

- To ensure that any planned changes or modifications to processes, procedures, policies or computer hardware/software, which may impact on quality, are communicated to the relevant personnel within the organisation. This provides an opportunity for affected departments to assess any affect, to advise of any areas of concern, and time to implement any required actions.

- To plan the implementation of the change, so that minimum of disruption is caused

- To ensure that all the requirements for validation prior to implementation have been considered, addressed and where relevant an appropriate validation protocol and report have been prepared and approved.

- To ensure that all training requirements have been identified and training carried out.

- To ensure that all documentation required has been identified and is in place before the change is implemented. The minimum documentation required will vary depending on the nature of the change. Examples of documentation required to support a change would include
  - Completed validation reports
  - Completed risk analysis
  - Completed commissioning reports
  - Summarised lab test data
  - New revised SOP
  - Evidence of training

- To ensure that documented detail of organisational change is lodged so that a true and traceable record is available

- To ensure that where required effective follow up studies are carried out to demonstrate that the change has been implemented as anticipated.

7. Outline of procedure

7.1 An appropriate Departmental head or nominated deputy will be responsible for ensuring that the change control procedure is initiated (using relevant change request forms). The request will provide details of the intended change and any supporting documentation.
7.2 The change request form will be submitted to the quality manager.

7.3 The request must be carried out well in advance of implementing the change. This is important to allow sufficient time for all relevant actions to be taken and allows QA to advise of the documentation requirements which must be in place for the change to be approved.

7.4 The quality manager will liaise with relevant managers to decide on which other parts of the organisation need to be made aware of the change and more specifically which managers/consultants need to give approval. All such managers will receive a copy of the form of the change control documents and be asked to sign them. The signed forms will be stored in the change control file.

7.5 Each change control request will receive a unique reference number. A file will be opened and this will contain key documentation to support the change. The files will be held for scrutiny when required.

7.6 Copies of the completed change control documents will be issued to the relevant personnel.

8. Documentation of change control

All requests for approval of change control must be made using the specified forms. These can be completed in written form or electronically. Examples of these forms follow on the next few pages.
## Record Of Change Control

### Part 1. SUMMARY OF PROPOSED CHANGE REQUEST

<table>
<thead>
<tr>
<th>AREA PROPOSING/IMPLEMENTING CHANGE</th>
<th>LINE MANAGER/SECTION HEAD</th>
<th>PLANNED IMPLEMENTATION DATE</th>
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**DESCRIPTION OF PROPOSED CHANGE. PLEASE INCLUDE GENERAL INFO, SOPS ETC**

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**DATE:** ________________

**SIGN:** ________________

Proposing Manager
Record Of Change Control  
Part 2. Record of Consultation With Other Managers

<table>
<thead>
<tr>
<th>REF NUMBER</th>
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| SECTIONS AREAS OF LAB AFFECTED BY CHANGE |
| LIST SECTIONS/ DEPTS TO BE NOTIFIED OF PROPOSED CHANGE |

<table>
<thead>
<tr>
<th>SECTION/DEPT</th>
<th>DATE ISSUED</th>
<th>DATE RETURNED</th>
<th>RECEIVED BY/SIGN</th>
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Consultation Completed

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<th>SIGN</th>
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Record Of Change Control
Part 3. Comments From Other Managers

REFERENCE NUMBER

THIS FORM IS USED BY OTHER MANAGERS TO ADVISE OF COMMENTS ON IMPACT OF CHANGE AND SUITABILITY FOR LOCAL IMPLEMENTATION

AREA TITLE/DEPT

AREA HEAD/LINE MANAGER

SUMMARY OF CHANGE IMPACT COMMENTS:

I APPROVE/DISAPPROVE/REQUIRE MORE INFO (delete as appropriate)

Signed

Date

Please return to
Record Of Change Control
Part 4. SUMMARY OF QA ASSESSMENT

REFERENCE NUMBER

ASSESSMENT OF DOCUMENTATION REQUIREMENTS

DETAILS OF DOCUMENTATION SATISFACTORY
YES/NO

SIGNED
QUALITY MANAGER

DATE

DETAILS OF ANY FURTHER ACTION REQUIRED

SIGNED
QUALITY MANAGER

DATE
Record Of Change Control
Part 5. FINAL APPROVAL

REFERENCE NUMBER

Agreed Implementation Date: ________________

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<tr>
<th>INITIATING MANAGER</th>
<th>SIGNATURE/ DATE</th>
<th>COMMENTS</th>
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<tr>
<td>OTHER MANAGERS(SPECIFY)</td>
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<tr>
<td>QA MANAGER</td>
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