1. Purpose

The purpose of this Guideline is to define and provide guidance on the requirements for managing and documenting changes which take place during the development, implementation or operation of a computerised system, including its supporting operating environment.

2. Scope and Applicability

The change control principles in this Guideline support the delivery and ongoing support of well-defined systems to meet user requirements. They are essential when supporting validated processes and maintaining regulatory compliance.

This Guideline applies to information/business systems, process control systems and laboratory instrumentation/systems. It applies to the following as applicable to the specified system throughout its life cycle:

- Application Software
- Operating System Software
- Embedded Software
- Computer Hardware (including microprocessors, PLCs etc)
- Networks
- System and Configuration Data
- System Documentation

This Guideline does not apply to routine changes to data, methods, reports or facilities that, in principle, are subject to predicate rules (e.g. Good Laboratory Practice, Good Manufacturing Practice and Good Clinical Practice).

3. Definitions

3.1 Computerised System

A group of hardware components assembled to perform in conjunction with a set of software programs which, collectively, are designed to perform a specific function or group of functions in a defined environment (and including peripheral devices, personnel and documentation, e.g. manuals, SOPs).

3.2 Change Control

The process of maintaining control of the status of computerised systems by the establishment of local procedures requiring the evaluation, documentation, approval and controlled implementation of all changes by qualified representatives of appropriate disciplines.

3.3 Predicate Rule

The governing national and international regulations and guidance covering Good Laboratory Practice, Good Manufacturing Practice and Good Clinical Practice.

- Any new support requirements

5.8 Change Completion and Approval

When all elements of a change have been implemented, documentation revised and appropriate testing carried out the system owner or delegate, together with QA as appropriate, should review and approve the formal change request, which should then be archived and the change history updated to include this change.

5.9 Exceptions

5.9.1 Like-for-like (i.e. functionally identical) replacements

It is not always easy to assess whether a situation is truly like-for-like and consideration should always be given to the potential impact of any subtle change. Where there is no discernible change then replacement can be by normal maintenance procedures. Like-for-like replacement should still be recorded in the system history.

5.9.2 Emergency changes

It is recognised that certain changes need to be implemented as quickly as possible. These situations will commonly arise when a user or system owner reports a fault in a critical area of use or operation and its resolution is essential to completion of a time-dependent task. What constitutes an emergency change should be clearly defined.

Even in an emergency, testing of critical elements of the change should be carried out before implementation to avoid unforeseen serious repercussions. Any necessary interim procedures should be considered and specified. The change must be subsequently reviewed, tested, documented and approved according to the appropriate procedure and in a timely manner.

