

Pharmaceutical
Research Centre

STANDARD OPERATING PROCEDURE

6 STANDARD OPERATING PROCEDURES

VERSION 3

REASON FOR REVISION: TO INCLUDE PROCEDURE FOR ELECTRONIC
COPIES

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1 INTRODUCTION

This Standard Operating Procedure defines the procedures to be used in the writing, issue, review, revision and control of Standard Operating Procedures. Managers or Heads of Department are responsible for the production of documents which define the procedures in their area of expertise. Adherence to this standard will ensure that documents are consistently formatted and controlled.

2 RESPONSIBILITIES

- 2.1 The Management Group are responsible for the implementation of this procedure.
- 2.2 The Documentation Officer has specific responsibilities for control of SOPs.

3 PROCEDURE

3.1 NEW STANDARD OPERATING PROCEDURES

- 3.1.1 When the necessity for a new standard operating procedure is recognised by Management, Staff or QA, the Manager or Head of Department in question will nominate an individual to produce a draft standard operating procedure, ideally staff with actual knowledge of the procedure.
- 3.1.2 The level of detail should be that the procedure can be followed by a scientifically aware person but not an expert, a good guide is to consider that the document could be used as a training aid.
- 3.1.3 The SOPs should be in line with the relevant legal & regulatory requirements and with current practice. If it is necessary, the content of the SOP and/or procedure should be amended.
- 3.1.4 Standard operating procedures should be written to minimise the potential for deviation and the need for frequent revision so that it accurately encompass acceptable practice, but not so closely define a situation that it is frequently deviated from or often needs revision. Thus, in defining acceptable limits the widest, scientifically -

acceptable range should be considered, rather than what is normally achievable or what seems impressive. It may be useful to quote "target limits" as well as "acceptable limits". Note: no deviation occurs if a target is aimed for, even though it may be missed.

- 3.1.5 Standard operating procedures may refer to other SOPs or published manuals.
- 3.1.6 SOPs for use of equipment should define the procedure for detecting malfunctions, and action to be taken in such a case and acceptable limits and frequency of calibration should be included.

3.2 FORMAT OF STANDARD OPERATING PROCEDURES

All standard operating procedures should adhere to the format of this SOP.

3.3 APPROVAL OF STANDARD OPERATING PROCEDURES

The SOP should be discussed between the Author and the Managers or Heads of Department and amended if necessary. The final version will be signed by the Author and Approved by the Managers or Heads of Department. The date of approval will be the date effective without delay unless there is a defined period between the approval and effective date to permit training to take place in order that qualified personnel can implement the procedure at the effective date. Where the Author is also the Managers or Heads of Department only one signature is required to approve the document. After approval the document will be processed without delay to ensure that controlled copies are available in the relevant working areas in a timely manner.

3.4 ISSUE OF STANDARD OPERATING PROCEDURES

- 3.4.1 The Documentation Officer will ensure that the document is properly approved, and then prepare sufficient copies from the master to meet the distribution list. Copies of all controlled documents are issued to the Archive and Quality Assurance Department. The master will be retained by the Documentation Officer.

- 3.4.2 Electronics copies of all standard operating procedures are available for viewing on-screen as uncontrolled copies. These electronic copies are updated as new versions are released and may be referenced for information. However, all areas and individuals requiring the documents for USE will have access to controlled paper copies.

3.5 REVIEW OF STANDARD OPERATING PROCEDURES

All standard operating procedures should be reviewed at least annually, to ensure that contents remain accurate and up to date. It is the responsibility of the Managers or Heads of Department to ensure that this is done. The review should be done by the original Author, or other staff familiar with the procedure.

3.6 REVISION OF STANDARD OPERATING PROCEDURES

- 3.6.1 Standard operating procedures may be revised following routine review or immediately if necessary to take account of changes in procedure, methods, etc. The process of drafting, agreeing and approving a revision of existing standard operating procedures is identical to that for writing a new document. The original standard operating procedure is "VERSION 1" and revisions are "VERSION 2" etc. The Reason for Revision should be briefly stated on the title page. The Documentation Officer will retrieve all official copies of the old version (except from QAU and archives), issue the new copies, ensure the destruction of the old copies, and record the action. Any controlled document which cannot be produced by the operating department must be officially recorded as "lost", and the Documentation Officer notified in writing by the relevant Head of Department. The old document will remain in force until the new version is approved, if the new procedure is already in practice it may be necessary to document it in file notes until approval of the new document. For this reason, the revision process should be as rapid as possible.
- 3.6.2 The revised standard operating procedures need not state which earlier document it replaces if it is simply the next version in the series. However, if the revision replaces other SOP titles, this should

be explained and the superseded standard operating procedures referenced in the Introduction.

- 3.6.3 The Head of Department is responsible for ensuring that all staff are aware of the content of revisions.