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Guidance for Preparing Standard Operating Procedures

1 Introduction

1.1 Overview

A Standard Operating Procedure (SOP) is a set of written instructions that document a procedure or activity followed by a department (OCDEM in this document) or an organisation. The development and use of SOPs are an integral part of a successful and well run department or organisation as they provide individuals with the information to perform a job properly, and facilitate the consistency, quality and integrity of the end-result. The term 'SOP' may not always be appropriate and terms such as protocols, instructions, worksheets, laboratory operating procedures and code of practice may also be used. For this document 'SOP' will be used.

1.2 Purpose

SOPs detail the regularly recurring work processes that are to be conducted or followed within a department or an organisation. They document the way activities are to be performed to facilitate consistent conformance to technical and quality system requirements and to support data quality. They may describe, for example: how to report faults in a laboratory or office; instructions for running an assay in the laboratory; processes for maintaining, calibrating, and using equipment. SOPs are intended to be specific to the department, organisation or facility whose activities are described

If not written correctly, SOPs are of limited value. In addition, the best written SOPs will fail if they are not followed. Therefore, the use of SOPs needs to be reviewed and re-enforced by supervisors, preferably the line manager. Current copies of the SOPs also need to be readily accessible for reference in the work areas of those individuals actually performing the activity, either in hard copy or electronic format, otherwise SOPs serve little purpose.

1.3 Benefits

The development and use of SOPs minimises variation and promotes quality through consistent implementation of a process or procedure, even if there are temporary or permanent personnel changes. SOPs can indicate compliance with departmental requirements and can be used as a part of a personnel training program, since they should provide detailed work instructions. It minimises opportunities for miscommunication and can address safety concerns.

SOPs are needed even when published methods are being utilised. For example, if an SOP is written for a standard analytical method, the SOP should specify the procedures to be followed in greater detail than appear in the published method. It should also detail how, if at all, the SOP differs from the standard method and any options that this department follows.

1.4 Writing Styles

SOPs should be written in a concise, step-by-step, easy-to-read format. The information presented should be unambiguous and not overly complicated. The document should not be wordy, redundant, or overly lengthy; keep it simple and short. Information should be conveyed clearly and explicitly to remove any doubt as to what is required.

2 Production of an SOP

2.1 Preparation

Each Group within the department should have a means in place for determining which procedures or processes need to be documented. Those SOPs should then be written by individuals knowledgeable with the activity and the department's internal structure. These individuals are essentially subject-matter experts who actually perform the work or use the process. A team approach can be followed, especially for multi-tasked processes where the experiences of a number of individuals are critical.

SOPs should be written with sufficient detail so that someone with limited experience or knowledge of the procedure, but with a basic understanding of the field, can successfully reproduce the procedure when unsupervised.

2.2 Review and Approval

SOPs should be reviewed by one or more individuals with appropriate training and experience with the process. It is especially helpful if draft SOPs are actually tested by individuals other than the original writer before the SOPs are finalised.

The finalised SOPs should be approved as described in OCDEM SOP I5: Control of Documents. Generally the immediate supervisor would review and approve each SOP. Signature approval (on OCDEM top level SOPs) indicates that an SOP has been both reviewed and approved. Electronic signatures are acceptable. SOPs do not necessarily need signature approval.

2.3 Frequency of Revisions and Reviews

SOPs need to remain current to be useful. Therefore, whenever procedures are changed, SOPs should be updated and re-approved. The review date should be added to each SOP, and if an SOP describes a process that is no longer followed, it should be withdrawn from the current file and archived

SOPs should be reviewed as deemed appropriate to their content. It is recommended that laboratory SOPs should be reviewed no longer than every two years, to ensure that the policies and procedures remain current and appropriate, or to determine whether the SOPs are even needed. Changes in legislation; the running of a procedure by a vulnerable individual; purchase of new equipment or out of hours working are examples of when an SOP might need reviewing more frequently.

3 Format

The first page or its header of each SOP should contain the following information: a title that clearly identifies the activity or procedure; an SOP identification (ID) number; date of issue and/or revision, the group to which the SOP applies, unless it is OCDEM wide, and the signatures

and signature dates of those individuals who prepared and approved the SOP if appropriate. Electronic signatures are acceptable for SOPs maintained on a computerised database.

3.1 Text

Well-written SOPs should first briefly describe the purpose of the work or process; SOPs for laboratory procedures should start with a list of reagents, suppliers and catalogue numbers plus equipment required for the procedure. This should be followed by a risk assessment or a reference to a risk assessment and references to other relevant SOPs. If further information on safety e.g. a CoSHH assessment, is required it should be attached to the end of the SOP. Any training required before the procedure can be carried out must be listed before the main body of text giving the instructions required to run the procedure.

As noted above, SOPs should be clearly worded so as to be readily understandable by a person knowledgeable with the general concept of the procedure, and the procedures should be written in a format that clearly describes the steps in order.

A table containing the revision history should be included in the SOP, this should include: the author's ,updater's or reviewer's name; date of preparation or review, revision number; a brief description of changes plus the recommended date for the next review.

Finally the information must be disseminated to those who will be running the procedure, either on paper or electronically, and records kept of any training delivered to the individual concerned.

4 Update History

Version	Date	Reason for update	Updated/reviewed by :	Date next review due
1	August 2008	New SOP	Author: SMH	August 2011
1.1	July 2011	Change of Head of Safety	SMH	July 2013
1.2	July 2015	Added new header	SMH	July 2015
1.3	10th July 2015	Updated head of Department, no other changes	SMH	July 2017