

---

# An approach to documentation in the medical laboratory.

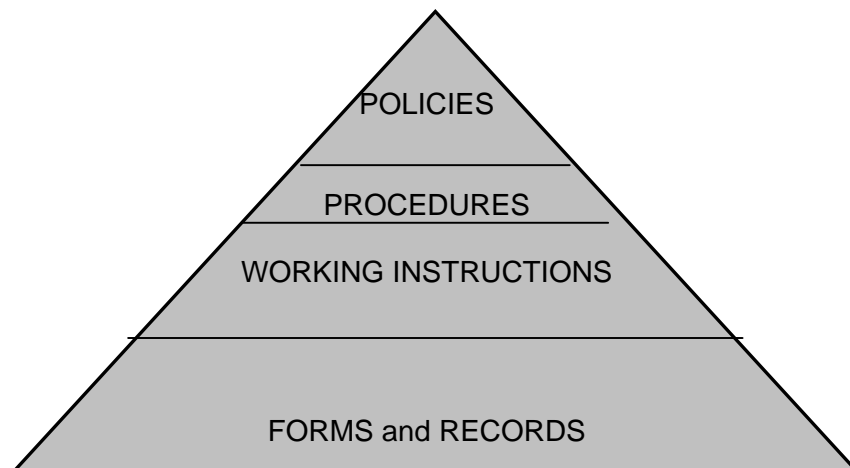
## 1 Introduction

This document and the accompanying templates are intended to be indicative of a possible approach to the management and structuring of medical laboratory documentation. There are many ways to approach this topic and in the belief that ways of doing things can always be improved it is not intended to be prescriptive.

Verification of a laboratory's compliance with accreditation standards requires evidence and documentation will form a major part of the evidence sought by external accreditation bodies. This evidence can be very broad in nature and ranges from mission statements, quality manuals and detailed laboratory procedures, to minutes of meetings and work sheets, depending upon the particular accreditation system. The preparation of this documentation is perhaps the most lengthy and time consuming part of the accreditation process for laboratories, but because of the evidential nature of many standards it is essential that it is undertaken in a systematic and structured way.

## 2 Hierarchy of documentation

Because of the wide range of documents involved in the preparation for accreditation it is useful to think in terms of a hierarchy of documentation as illustrated below



At the top of this hierarchy are the '*policies*'. Policies '**provide a statement of intent that an organisation will follow a particular course of action**'. A pathology laboratory can have one overall policy statement, usually known as the Quality Policy, which is inclusive of all aspects of the work of the laboratory or there can be a number of separate policies relating to different aspects of the laboratory intent. CPA Standard A3 requires a Quality Policy and information regarding the required

contents can be found in that Standard. The Quality Policy forms part of the Quality Manual and can be issued as a stand-alone document.

The second level in the hierarchy is '*procedures*'. Procedures are the practical way in which a policy or policies are translated into action and are often called standard operating procedures (SOP's). Procedures **'provide the information to carry out the intent'** defined by a policy. Procedures can incorporate manufacturers instructions but care must be taken that such instructions are up to date as they form part of a controlled document.

The term 'protocol' is sometimes used interchangeably with the word 'procedure', particularly when referring to clinical procedures, but for consistency in this text "procedure" will be used.

Procedures can refer to '*working instruction's*'. These are practical day to day instructions and, for example, might describe starting up or closing down a haematology analyser, a microbiology plate pouring machine, or a laboratory computer. Instructions can be embedded in a procedure or can be referred to in the procedure and published separately.

The final level in the hierarchy is represented by '*forms and records*'. Recording any information or data such as patient's results, quality control data or the result of an audit should be done in a systematic way on forms of an agreed format. Records made on forms **'provide evidence of fulfilment of intent'**. If a procedure requires something to be recorded on a form, the form must be referred to in the procedure.

The forms or records do not necessarily have to be created as 'hard copy' (a paper record) but a form can be completed, by anybody who has the correct access priority, on computer screens in the laboratory. Data entered in this way and captured in a computer file would constitute a record and requires to be readily accessible for inspection. In a pathology laboratory, request forms and test reports are an example of such documentation.

### 3 Quality manual

CPA Standard A6 sets out the requirement for and content of a Quality Manual. The Quality manual will include the Quality Policy for the laboratory. It describes the scope, purpose, organisation and management of the laboratory and its Quality Management System (Standard A4). It will describe very briefly how the requirements for each Standard are met and can act as an index to procedures.

The Quality Manual should ideally be no longer than 20-30 pages and should be regarded as being of importance to laboratory management, laboratory personnel, users, CPA inspectors and other external bodies. CPA requires a copy to be sent with the application form. Assessors will be provided with a copy prior to the inspection visit.

## 4 Procedures

### 4.1 Types of procedure

In order to construct a logical approach to the preparation of procedures it is helpful to categorise them into management, laboratory, quality or clinical procedures.

There are no requirements for *'clinical procedures'* within CPA standards as they are normally created at the interface between the laboratory and medical practice. Examples include procedures for venepuncture or those needed for the performance of a dynamic function test.

However certain CPA Standards do require procedures to be written and these are listed in the table below. Procedures associated with standards in sections A-D can be conveniently regarded as *'management procedures'*, those associated with sections E-F as *'laboratory procedures'* and those with section H as *'quality procedures'*.

Standard F2 mandates the preparation of procedures for the conduct of all examinations (which equate to *'methods'* in common parlance) and the number of these required will depend on the range of investigations performed in a particular laboratory or department.

**Procedures required to fulfil the CPA Standards**

<p><b>Management procedures</b></p> <ul style="list-style-type: none"> <li>• <b>A8 Document control</b></li> <li>• <b>A9 Control of process and quality records</b></li> <li>• <b>A10 Control of clinical material</b></li> <li>• <b>B3 Personnel management</b></li> <li>• <b>C6 Health and safety</b></li> <li>• <b>D1 Procurement and management of equipment</b></li> <li>• <b>D2 Management of data and information</b></li> <li>• <b>D3 Management of reagents, calibration and control materials</b></li> </ul>
<p><b>Laboratory procedures</b></p> <ul style="list-style-type: none"> <li>• <b>E3 Specimen collecting and handling</b></li> <li>• <b>E4 Specimen transportation</b></li> <li>• <b>E5 Specimen reception</b></li> <li>• <b>E6 Referral to other laboratories</b></li> <li>• <b>F2 Examination procedures</b> (number depends on range of examinations performed)</li> <li>• <b>F3 Ensuring the quality of examinations</b></li> <li>• <b>G1 Reporting results</b></li> <li>• <b>G3 The telephoned result</b></li> <li>• <b>G4 The amended report</b></li> </ul>
<p><b>Quality procedures</b></p> <ul style="list-style-type: none"> <li>• <b>H1 Evaluation and improvement</b></li> </ul>

**4.2 Content of procedures**

There are any number of guidelines which suggest the content of procedures and CPA does not wish to be prescriptive in this area. The table below gives simple advice with regard to suggested headings. Following the introductory section guidance can be obtained from the particular CPA Standard as to headings of the

rest of the contents. For example, from CPA Standard B3 that requires a procedure on Personnel management, it is possible to suggest headings as follows:

- 0 Introduction
  - 0.1 Scope and purpose
  - 0.2 Responsibility
  - 0.3 References
  - 0.4 Definitions
  - 0.5 Related documents
- 1 Recruitment and selection
- 2 Personnel records
- 3 Induction
- 4 Training
- 5 Continuing education
- 6 Joint review
- 7 Meetings and communication
- 8 Disciplinary action

## 5 Document control

### 5.1 Identification

CPA Standard A8 on Document control requires a procedure for the control of all documents, including the quality manual, procedures and forms. It requires that all documents are uniquely identified and with documents produced on computer this can be by a unique file name. It is also required that date of issue, revision version, the total number of pages and authorising signatories be included in the document. Documents may be signed as a paper copy or authorised electronically.

### 5.2 Management

Standard A8 also gives advice on the management of documentation and requires that documents such as procedures be regularly reviewed. It important to note that 'review' is not the same as 'revision' and whereas documents must be regularly reviewed, that is checked for 'continuing fitness for purpose', they need only be revised when they cease to be fit for their intended purpose.

Some form of master index, that can either be hard copy or in electronic media, will aid document management. It should enable the identification of the current revision status of the documents and be able to preclude the use of invalid and/or obsolete documents. There are commercially available packages that will perform this function and other functions associated with the management of a laboratory quality system.

## Further reading

Burnett D. A Practical Guide to Accreditation in Laboratory Medicine, ACB Venture Publications (2002)