Electro Diagnostics Unit

Document No.	**:**	**ED/QMS/01**
Title	**:**	**Documentation preparation and control**
Effective Date	**:**	
Review date:	**:**	
Revision History :		**First version**

Training Requirements	**A** ✓	**B**	**C**	**D**

A = New procedure requiring documented assessment of competence

B = Modified procedure requiring documented reassessment of competence

C = Familiarity with new procedure required (no assessment of competence necessary)

D = Familiarity with changes required (no assessment of competence necessary)

	Signature	**Name (print)**	**Date**
Prepared by			
Reviewed and approved by			

Document No.	**:**	**ED/QMS/01**
Version	**:**	**1.0**
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1. **INTRODUCTION**

The purpose of this SOP is to:

- To describe the procedure by which Standard Operating Procedures for all activities of the Visual Electrodiganostics Testing Service (VETS) that take place within the Electrodiagnostic Unit (EDU), University of XXXXXXX are prepared, issued, controlled and revised, to ensure ongoing compliance with Care Quality Commission Guidelines.
- To describe how other controlled documents, such as patient information leaflets, that are not included in a Standard Operating Procedure are prepared, issued, controlled and revised.
- To describe the format and context of SOPs that are submitted for inclusion in the document control system.
- To describe the procedure for allocation of specific training requirements for each SOP.

2. **SCOPE**

This SOP applies to documents that are used to control the management and processes associated with the diagnostic and screening services provided by the Electrodiagnostics Unit. They may be described as SOPs and controlled documents along with associated forms.

3. **RESPONSIBILITIES**

- Those responsible for writing or approving controlled documents must ensure that the format and content follows that outlined below. Specific responsibility for various phases of document production and control is indicated in the appropriate sections below.
- The VETS Director is responsible for the production, revision and approval of SOPs and other forms of controlled documents used within the EDU.
- The VETS Director is responsible for the definition of the training requirements included on each SOP.
- The VETS Director is responsible for managing document review, distribution of controlled documents, the distribution records and archiving of withdrawn SOPs.
- All staff have a responsibility to be familiar with the SOPs and other controlled documents which apply to their work.
- The VETS Director is responsible for ensuring that their staff are trained and comply with the requirements of the SOPs.

4. RELATED DOCUMENTS

- Care Quality Commission - Essential Standards of Quality and Safety, March 2010
- Health and Safety Policy *(UoB 007)*
- Dignity and Respect Policy *(UoB 005)*

5. PROCEDURE

- A basic SOP template can be obtained from the VETS Director. The title page format and content of this template is mandatory.
- The general format for other documents is not prescribed but all controlled documents must be prepared using the standard word processing software of the organisation.
- Each page of the document must have a header / footer which includes:
    - Document number, in four parts comprising ED/SOP or controlled document category / identification number/version number. This number will be assigned by VETS Director.
    - Document title
    - Page number and total number of pages, including any appendices or annexes attached
    - The statement '**Confidential: UNAUTHORISED COPYING PROHIBITED'** must appear on all SOPs and controlled documents for internal use only.
    - Other documents, such as patient information leaflets should carry a copyright notice in the form Copyright © Month/Year Electrodiagnostics Unit, University of Bradford.

5.1 SOP Title page format

Each SOP must have a title page which includes, in addition to the header:-

- The dated signature and printed name of the person who has prepared or modified the SOP.
- The dated signature and printed name of the person who has approved the document.

- The effective date.
- A summary of the changes in the current version compared with the previous version.
- The training requirements for the SOP as defined by the Electrodiagnostics Unit manager.

5.2 General Layout of SOPs

SOPs should be set out in numbered sections with subsections indented, as exemplified in this SOP. Additional sections may be added if required by the author. Layout (document sections) should be as follows:

- **INTRODUCTION** – A brief statement, which provides background and context for the SOP or **OBJECTIVE** – summarises the objective of the document.
- **SCOPE** – a statement of the areas to which the document applies (site, discipline, laboratory, type of study, etc) and where necessary, definition of terms.
- **RESPONSIBILITIES** – an indication of those responsible for major tasks, or the main responsibilities of particular individuals, as appropriate.
- **RELATED DOCUMENTS** – reference to other documents with major impact on the procedure, including SOPs and standard forms. Version numbers of related documents are not included.
- **PROCEDURE / USE** – a statement of specific equipment, apparatus and materials required details of the methods employed and records kept.

5.3 Other controlled documents

- Any other documents that are deemed to be controlled documents by the EDU manager must, as a minimum, include
    - a unique reference number,
    - a version number,
    - an issue date,
    - a revision date
    - the UoB logo and EDU address (as per footer in this document).
- Other content is at the discretion of the EDU manager.

5.4 Review and Approval of SOPs/controlled documents

- Draft SOPs/controlled documents may be prepared by any member of the organisation. Generally they are best written by personnel who will apply the document. The author should consult with appropriate staff to minimise revisions of the draft SOP. The draft document is then forwarded to the VETS Director.
- Draft SOPs/controlled documents will be circulated by the VETS Director to reviewers as appropriate for evaluation and comment.
- The issued drafts with any comments must be returned within two weeks of the circulation date.
- Following incorporation by the VETS Director of all comments and corrections the final version is printed on white paper for signing off.
- The author signs and dates the prepared section.
- The approval signatory checks the content of the SOP and signs and dates the SOP if satisfied. The approval signatory is designated by the Electrodiagnostics Unit manager as the most appropriate person to sign off.

5.5 Issue and Distribution

- The VETS Director is responsible for the issue and distribution of SOPs and other controlled documents.
- The VETS Director assigns an effective date and enters it on the title page or in the document header.
- The VETS Director, in consultation with users, decides which specific manuals will receive copies of the SOP and ensures the appropriate number of copies is prepared.
- The controlled documents are copied onto paper of distinctive colour reserved for the purpose.
- Manuals of controlled documents are held in designated locations and each manual has a unique number. This number is added to every document issued to that manual by the VETS Director.
- SOP manuals are located so that they are freely available to relevant staff.
- Additional copies of controlled documents which are not destined for a manual will be marked “FOR INFORMATION ONLY”. Such documents must not be used by persons undertaking the task defined by the SOP.
- Where a new version of a controlled document is issued, old versions will be collected and destroyed.

5.6 Suspending SOPs/controlled documents

- A controlled document may be suspended if the procedure that it describes is judged no longer relevant or is now described in another document.
- A request to suspend a controlled document should be made to the DC by the authoring person or equivalent together with a reason.
- The DC suspends the controlled document and removes it from the relevant manual(s). The master copy is then archived and all coloured copies of the document are destroyed.

5.7 Electronic Versions of SOPs

- An electronic version of the SOP may be held by the VETS Director but the original white, signed paper copy is the master document.
- Where electronic versions are available over an IT network access must be read only; each page of the document must be watermarked with the statement "Valid on Day of Printing Only" and include the date of printing. The DC has the responsibility for keeping the electronic versions up to date.

5.8 Document Amendment

- Any amendment, no matter how minor, requires a new version of the document to be produced. Annotation of SOPs held in manuals is not permitted.

5.9 Periodic Review of Controlled Documents

- Controlled documents will be reviewed at least every three years by designated reviewers, typically the author and users. On reviewing the controlled document the reviewer is required to complete form ED/Form/01 and attach this to the SOP.

5.10 Retention of Controlled Documents

- The master copy (white with original signatures) of superseded and suspended documents will be retained in the archives.