Electro Diagnostics Unit

Document No.	**ED/QMS/03**
Title	**Adverse Events**
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			

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1. PURPOSE

The aim of this SOP is to ensure that adverse incidents /events relating to the operation of the Visual Electrodiagnostics Testing Service (VETS) that takes place within Electrodiagnostics Unit (EDU) are reported promptly and fed into the EDU quality system.

2. SCOPE

2.1 This SOP applies to any adverse incidents /events relating to service users in the operation of the VETS.

2.2 This SOP does not apply to adverse incidents / events resulting from research activities in the EDU.

3. DEFINITION OF ADVERSE EVENTS

Any event that:

- has caused harm or had the potential to cause harm to patients, staff or visitors
- led to or had the potential to lead to a breach of security of the premises and the contents contained therein
- caused harm or had the potential to cause damage to stored service user information

4. INCIDENT REPORTING TRIGGER LIST

Table 1 lists the primary areas where adverse events or near misses could occur. All such events must be reported and investigated

TABLE 1

Consent
• Failure to obtain consent before conducting diagnostic intervention • Staff member seeking consent is not appropriately trained
Governance and quality
• Wrong version of an SOP in use/ failure of change control mechanism • Breach of patient confidentiality / Data protection.
Diagnostic Testing
• Incorrect test carried out or tests carried out incorrectly • Equipment faulty or incorrectly calibrated
Tracking
• Error in labelling of data/report (e.g. report and service users details do not correspond) • Data not stored appropriately • Incomplete audit trail resulting in failure to track a service user information and data.

5. REPORTING PROCEDURES

5.1 All adverse incidents and events relating to the VETS must be reported to the VETS Director and the School of Life Sciences Quality Officer.

5.2 If the adverse event has occurred solely on the University site the VETS Director and Quality Officer will determine the necessary action to take.

5.3 If the adverse event has occurred externally, e.g. at a referring clinic, the VETS Director will report the event to the relevant individual(s) at the clinical site.

5.4 Staff members who are involved in, discover or observe an adverse event should report details to the VETS Director during the same working day, where possible, or within 24 hours at most.

5.5 As much detail as possible about the incident should be given. An adverse event form (see ED/QMS/F03 for details) must be completed.

6 HANDLING AND INVESTIGATING INCIDENTS

6.1 The underlying key causes through which events may develop into incidents should be identified by the VETS Director in conjunction with other EDU staff and the School of Life Sciences Quality Officer.

6.2 The policy of the EDU is that all adverse events or near misses must be reported and investigated so that lessons are learnt and action taken to minimise the risk of recurrence.

6.3 Subsequent investigation should highlight areas of poor performance / practice, systems failure, violation of procedures or the need for a change of practice. Table 2 summarises key pointers that should be addressed.

6.4 A final report detailing the above and any actions required will be produced and follow up on actions monitored by the Quality Officer.

Table 2 Investigation – Key Pointers

SOP	Is an SOP in place to cover the procedure?	**Yes / No**
	If yes	
	Is the SOP adequate?	
	Does it need to be revised? Did the individual know about and follow the SOP?	
Training	Was the individual appropriately trained?	Yes / No
	If not, why not?	
	Was training available?	
	Was training available but not advertised appropriately?	
	Was training available and advertised but the individual did not attend?	
	Other reasons (please explain)	
Equipment/ facilities	Was the equipment/facilities/ security fit for purpose?	Yes / No
	If not, why not?	
Previous occurrence	Have similar incidents happened before?	Yes / No
	If yes, give details	