Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust

Medical Devices Policy Practice Guidance Note Reporting of Incidents and defects relating to Medical Devices – V05		
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1 INCIDENTS – WHAT THEY ARE

1.1 Incidents are events that produce, or have the potential to produce, unexpected or unwanted outcomes that affect the safety of patients, users or other persons

2 INCIDENTS - What should be reported?

2.1 Any incident relating to the use of medical device must be reported via the Safeguard system.

2.2 An incident that causes or has the potential to cause unexpected or unwanted effects involving the safety of the device users or other people

2.3 There is also a distinction between direct and indirect harm. Indirect harm can be caused by a device, which does not normally come into contact with patients. For example: a malfunctioning in vitro medical device (IVD) such as an automated analyser may lead to delayed or inappropriate treatment of a patient and therefore cause indirect harm. Incidents of this nature should also be reported to Medical Devices Alert (MDA). An example of a patient receiving direct harm through a Medical Device could be an intravenous (IV) drip of a medication is dosed appropriately, to the patient and within safety norms, however a single faulty valve on the IV can lead to increased medication flow and overdose, with harmful and even fatal consequence for the patient.

3 INCIDENTS – WHY SHOULD THEY BE REPORTED

3.1 Any adverse incident involving a device or its instructions for use will be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA), especially if the incident has led to or, were it to occur again could lead to:

- Death, life-threatening illness or injury
- Deterioration in health or permanent impairment of body structure or function
- The necessity for medical or surgical intervention
- Hospitalisation or prolongation of exciting hospitalisation
- Unreliable test results and associated risk of misdiagnosis or inappropriate treatment
- Ongoing faults that successive service/maintenance visits have failed to rectify

4 INCIDENTS – HOW DO THEY OCCUR

4.1 Incidents may arise due to: shortcomings in the device design or its instructions for use; poor quality control during manufacture; damage in transit; inadequate reprocessing; repair or maintenance; inadequate user training; degradation of the device due to prolonged use of inappropriate storage; user error.

5 INCIDENTS

5.1 All Adverse/Untoward Incidents and near misses should be reported by following the procedure outlined in the Trust's policy CNTW(O)05 – Incident (including the management of serious untoward incidents).

5.2 The Trust's Patient Safety Department disseminates MDA publications such as safety warnings, hazard notices and other information after correspondence with the Medical Devices Safety Officer (MDSO)and/or Medication Safety Officer (MSO)

5.3 In order to obtain as much information as possible about the incident where equipment is involved, it is necessary to leave the site as intact as possible. The following should be carried out as soon as the incident is discovered.

5.4 The Ward/Department Manager/Point of Contact as soon as possible will inform:

- Medical devices department
- Clinical Nurse Manager
- Patient Safety Department
- Others, as appropriate

The Associate Director will:

- Inform Senior Managers where appropriate
- Ensure that the correct documentation is completed and sent without delay to the appropriate person

6. Medical devices involved in an incident

Medical devices that have been involved in an incident should be quarantined and the medical devices department notified as soon as possible. The medical device should be stored securely to ensure that the machine is not used by anyone else until it has been checked by the Clinical Technologist or suitably qualified professional. All incidents involving medical devices will be discussed in the Medical Devices Safety Group, Safety, Security and Resilience (SAFE) Groups and lessons learnt disseminated.