

ANNEX A

ADVERSE INCIDENT REPORTS CONCERNING MEDICAL DEVICES AND EQUIPMENT

The following list provides some examples of medical devices. It is not a comprehensive list and is provided for guidance only.

- Medical Devices and equipment for the diagnosis or treatment of disease, or monitoring of patients e.g.: non-medicated dressings; surgical instruments and equipment; IV administration sets and pumps; anaesthetic equipment; powered implants (e.g. pacemakers); implantable defibrillators; radiotherapy equipment (brachytherapy, external beam); ophthalmic equipment; sphygmomanometers; vaginal speculae; examination gloves; catheters (e.g. urinary, cardiac); endoscopes; patient monitoring equipment (e.g. cardiac monitors); surgical implants (e.g. orthopaedic prostheses, bone cements, heart valves); x-ray systems, ultrasound imagers and CT/MR scanners; dental equipment and materials; chiropody equipment; thermometers; physiotherapy equipment; syringes and needles; blood warming cabinets.
- Medical Devices and equipment for critical care, e.g.: ventilators; defibrillators.
- Medical Devices and equipment used in the care of patients, e.g.: wheelchairs and special support seating; walking aids; patient hoists; orthotic and prosthetic appliances; pressure relief equipment.
- Medical Devices and equipment used by ambulance services, e.g.: stretchers and trolleys; resuscitators
- Medical Devices and equipment for daily living, e.g.: commodes, urine drainage systems; incontinence products; hearing aids; domiciliary oxygen therapy systems; prescribable footwear; bathing and showering equipment; special chairs.

Medical devices and equipment also include the following:

- *In-vitro* diagnostic medical devices and their accessories, e.g.: devices for blood glucose measurement; pregnancy test kits; urine test strips; hepatitis and HIV test kits; blood gas analysers; specimen collection tubes.
- intra-uterine devices (IUDs); contact lenses and care products; condoms.

We are also interested in products which, whilst not themselves medical devices, are used closely in conjunction with these devices, e.g.: blood and tissue storage systems; disinfecting and sterilizing equipment e.g. bench top sterilizers; chemical and biological indicators used in sterilization processes.

Medical devices do not include general workshop equipment such as power or machine tools.

Some equipment is designed to be permanently connected to installed services, e.g. medical gas pipework, ducting or electrical supply. In these cases, the device should be regarded as comprising all parts up to and including the means of connection to the installed service.

ANNEX B

ADVERSE INCIDENT REPORTS CONCERNING NON-MEDICAL EQUIPMENT, PLANT AND BUILDINGS

The following list provides some examples of non-medical equipment, plant and building fabric that we are interested in:

- Engineering plant and services of all types e.g. boilers, generators, heating, ventilation, water, drainage, and electrical installations and any other fixed plant.
- Fire Protection installations and equipment.
- Permanently installed sterilizers, bedpan washers and disposal units.
- Equipment in laundries, catering departments, workshops and any plant or equipment used for maintenance or cleaning.
- Piped medical gas and vacuum installations, Vacuum Insulated Evaporators (VIE) and anaesthetic gas scavenging systems.
- Fixed luminaires, including operating and examination lamps
- Communications equipment e.g. telephone, nurse call, paging, alarms and radio.
- Lightning protection and anti-static precautions.
- Built environmental aspects of COSHH
- Installation aspects of fume cupboards and microbiological safety cabinets, including ductwork and their interaction with ventilation systems.
- Buildings and building components and plant used in maintenance and construction.
- Ambulances but excluding motor vehicles such as those for disabled persons and lease hire and goods vehicles.

INVESTIGATION OF ADVERSE INCIDENTS

When a report is received by NIAIC:

- It is logged on to the NIAIC database;
- an acknowledgement is sent to the reporter; and
- senior management are alerted if a fatality is involved.

The report is passed to one of NIAIC Investigation Officers to review the report and decide on the most appropriate method of investigation.

In the course of an investigation, staff may:

- talk with the user and manufacturer;
- visit the site of the incident when necessary;
- review evidence; and
- if appropriate, issue safety advice to the HPSS.
- notify the Medical Devices Agency for incidents involving medical devices and NHS Estates for incidents involving non-medical equipment, plant and buildings.

For the majority of medical device related adverse incidents reported to NIAIC, the manufacturer is alerted and provided with information about the incident, where it occurred and the equipment involved. As a result of UK Medical Device Regulations implementing the EC Medical Devices Directives concerning medical devices, manufacturers of medical devices are required by law to report to the UK Competent Authority (Medical Devices Agency) certain incidents involving their products. This system is known as the 'Vigilance System' and it covers incidents which have led to, or which might have led to, death or serious deterioration in health and/or product recall. Because of this, the manufacturer takes responsibility for resolving the incident but NIAIC monitors progress and reviews the manufacturer's response, informing the reporter of the outcome.

An investigation is re-appraised if new information comes to light. Outcomes of investigations are reviewed in order to identify patterns or clusters of incidents, which may require possible further investigation.

Where necessary, NIAIC will issue advice in the form of warning notices. The criteria for the various warning notices, in broad terms, are as follows:

Hazard Notices are issued: -

- in cases of **actual** death or serious injury, or when death or serious injury **would have occurred**, or in cases of illness or deterioration in health of a patient or user or other person, and
- where the medical device or estates system is **clearly** implicated, and
- where **immediate** action is necessary to **prevent** recurrence.

Advice Notices are issued: -

- in cases where there is the **potential** for death or serious injury, or there **may be implications arising from long term use**, and
- where the medical device or estate system is **likely** to be implicated, and
- where the recipient is expected to take **immediate** action on the advice.

Safety Notices are used to recommend or inform: -

- where **action** by the recipient will **improve** safety,
- where it is necessary to **repeat** warnings on long standing problems,
- to **support or follow up** manufacturers field modifications.

Professional Officer Letters are issued: -

- by the Chief Officer in any of the professional disciplines, e.g. Medical, Nursing, Pharmaceutical, Dental, etc. They are normally used when **improper use or misuse of equipment has contributed to an occurrence**.

Please note that Hazard Notices and Advice Notices specify immediate actions and it is extremely important that all personnel are instructed in the proper procedures for dealing with safety information and reporting of adverse incidents.

ANNEX D

DEFECTIVE OR CONTAMINATED ITEMS AND EVIDENCE

Defective Items

Defective items should not be repaired (either in-house or by a third party), returned to the manufacturer/supplier or discarded before an investigation has been carried out. The manufacturer or supplier should be informed promptly, and allowed to inspect the items if accompanied by an appropriate person. To facilitate an investigation, it may be possible to provide the manufacturer with a sample(s) of unused stock from a large batch. However, the manufacturer must not be allowed to exchange, interfere with, or remove any part of the product implicated in the incident if this would prejudice NIAIC investigations, or those of other official bodies.

If medical devices or other equipment are required to be kept in use, where possible remove defective parts so that the equipment may be repaired for re-use. Any parts so removed must be quarantined and securely stored pending investigation. NIAIC's advice should be sought and, in all cases, the defective parts should be clearly identified and kept secure. If it is not possible to remove defective parts or withdraw the machine from use, staff should be made aware of the need for increased vigilance and extra caution during use (see Evidence below).

Contaminated Items

Advice on procedures to be followed if healthcare equipment is contaminated and constitutes a biohazard is contained in PEL(94)34 and SAN(NI) 95/24. NIAIC can provide advice where necessary, particularly on whether arrangements should be made for the item to be examined prior to any decontamination.

Where decontamination/cleaning would destroy vital evidence, the item should be placed in protective containment, labelled and placed in quarantine. NIAIC and the manufacturer/supplier should be contacted for advice prior to any further action being taken.

IT IS ILLEGAL TO SEND CONTAMINATED ITEMS THROUGH THE POST

Evidence

All material evidence should be labelled and kept secure under the charge of a responsible officer. This includes the products themselves and, where appropriate, packaging material or other means of batch identification. The evidence should not be interfered with in any way except for safety reasons or to prevent its loss. If necessary, a record should be made of all readings, settings and positions of switches, valves, dials, gauges and indicators, together with any photographic evidence and eyewitness reports.

ROLE OF LIAISON OFFICERS

If you have not already done so please send details of your Liaison Officer (including their name, title, organisation, address, telephone, fax numbers and e-mail address) to NIAIC (tel: 02890 523704; fax: 02890 523900, e-mail: NIAIC@dhsspsni.gov.uk).

Reporting Adverse Incidents

Guidance for establishing procedures for reporting adverse incidents to NIAIC is outlined in this Notice. Local procedures for adverse incident reporting should also ensure that relevant local staff are kept informed of any adverse incidents e.g. by copying any report made to NIAIC to relevant staff or forwarding all reports to NIAIC via the Liaison Officer. This is the preferred procedure as it allows the HPSS organisation to demonstrate compliance with Health & Safety legislation by having a record of all reports of adverse incidents. A sample staff information sheet is provided at Annex H.

Dissemination of NIAIC warning notices

One postal copy of Hazard Notices, Advice Notices and Safety Notices is sent to the Chief Executive/General Manager of all HPSS organisations. Hazard Notices & Advice Notices are faxed direct to Liaison Officers and a colour coded postal copy follows (PINK for Hazard Notice, WHITE for Advice Notice and BLUE for Safety Notice). Liaison Officers who have provided NIAIC with an e-mail address will also receive all warning notices by this channel of communication.

Organisations should:

- Identify a fax number and e-mail address for the primary receipt of Hazard Notices and Advice Notices;
- arrange for someone to deputise in the Liaison Officer's absence;
- distribute Hazard Notices and Advice Notices immediately. Safety Notices could take a less immediate route depending on the subject and the local situation;
- target Hazard Notices, Advice Notices and Safety Notices to the appropriate recipient;
- establish control procedures to record action taken following the receipt of Hazard Notices, Advice Notice and Safety Notices indicating to whom they have been sent;
- maintain records to show (for example):
 1. date issued;
 2. signed assurance from recipient that required action has been taken (for example – appropriate staff have been made aware of the Notice);
 3. general comments to assist equipment knowledge (for example: “Not relevant for this Unit – this type of equipment not used here”);
- establish follow up procedures to ensure that returns are received;
- assist and encourage the development of a procedure to ensure that new staff are made aware of recent Hazard Notices, Advice Notices and Safety Notices (for example: set up a folder of Hazard Notices, Advice Notices and Safety Notices for all unit staff to see).

Dissemination of NIAIC Device Bulletins and Evaluation Reports

Device Bulletins are issued when guidance and information is needed over an extended area, for example, decontaminating endoscopes. They deal effectively with problems which keep recurring and which can be solved by good training and practice, rather than by modifying or

withdrawing a particular product. It is vital that they are issued to all staff with responsibility for training, staff responsible for setting organisational policies for equipment management and any other relevant staff. Similarly, Evaluation Reports, Disability Equipment Assessments and Pressure Sore Prevention Reports should be made available to staff responsible for equipment purchasing in these specific areas.

OTHER ACTIONS AND RESPONSIBILITIES

This reporting system does not affect the statutory or other duties of staff locally to take appropriate actions as required legally and/or by line management, as a result of an adverse incident. These include:

- ◆ *to safeguard patients, staff, clients and others*
- ◆ *to prevent further use of a product which may be defective*

As part of the above actions, Regional Supplies Service may issue their own notices, which identify problems and are used to bring them to the attention of users. These Notices should not be confused with NIAIC's Hazard, Advice and Safety Notices.

- ◆ *to report to Health and Safety Executive Northern Ireland (HSENI) or Director of Public Health when legally obliged to do so*

Some incidents are legally notifiable to the HSENI under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (Northern Ireland) 1997 (RIDDOR), and the Ionising Radiation Regulations (Northern Ireland) 2000.

A copy of any such notification should be sent to NIAIC. A clear note should be attached showing that it is a copy of an official notification to HSENI related to medical devices, non-medical equipment or plant and that it is a report being made under this Safety Notice. Notification to NIAIC does not count as, or substitute for, any other report, which should be sent (e.g., in respect of an employee's industrial injury).

- ◆ *to report the findings of HSENI or local City/Borough Council Authorities to NIAIC*

Under their statutory powers, HSENI or local council inspectors may identify inadequacies in a medical device, instructions for use or manner of use. They may also make recommendations. Any such observations or recommendations which may have implications for other users should be reported to NIAIC.

- ◆ *to refer to the local Environmental Health Officer incidents or complaints relating to food*

Incidents relating to foods involving contamination or potential contamination should be reported immediately to the local environment health officer (EHO) who will decide on what, if any, further action will be taken.

- ◆ *to refer to the coroner in the case of unexpected death*

If a patient dies unexpectedly, the clinician or other officer in charge or the case should report the death immediately to the Coroner and report this to the NIAIC. Pending the instructions of the Coroner or his officer, any product implicated must not be interfered with in any way unless this is necessary for safety or to prevent loss of samples. Although the manufacturer of a suspect device should be informed immediately, neither he nor his agent should be allowed to inspect the device or remove any part of it without the Coroner's prior agreement. The Department of Health, Social Services and Public Safety has agreed with the Coroners' Society that, with the permission of the Coroner, NIAIC officers can examine suspect devices so as not to delay remedial action to protect others.

- ◆ *to inform the manufacturer of a medical device which carries the CE marking, to assist him in fulfilling his obligations under EC Directives*

As a result of UK regulations implementing the EC Medical Devices Directives concerning medical devices, manufacturers of medical devices are required by law to report to the UK Competent Authority (the Medical Devices Agency) certain incidents involving their products. This system is known as the 'Vigilance System' and it covers incidents which have led to, or which might have led to, death or serious deterioration in health and/or product recall. The regulations implementing the first EC Directive apply to active implantable medical devices (e.g. implantable pacemakers) and came into force on 1 January 1993. The second set of regulations, applying to all other medical devices (with the exception of *in vitro* diagnostic devices), came into force on 1 January 1995. A third EC Directive applying to *in vitro* diagnostic devices came into force on 7 June 2000.

Users should not rely solely upon the manufacturer making a Vigilance report to NIAIC, but should follow the recommendations of this Notice and report all adverse incidents to NIAIC. Generally, by informing NIAIC, the manufacturer is informed through the investigation process.



***NORTHERN IRELAND
ADVERSE INCIDENT CENTRE
ADVERSE INCIDENT REPORT FORM***

This form should be used for reports of adverse incidents concerning medical devices, non-medical equipment, buildings and plant. It should be completed and submitted without delay to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates, Estate Policy
Stoney Road
Dundonald, Belfast BT16 1US
Tel: 02890 523714, Fax: 02890 523900, e-mail: NIAIC@dhsspsni.gov.uk

ORIGIN OF REPORT	
Reporting Body:	
Address:	
Person making report:	
Position:	
Telephone/Fax number:	
Date and Time of Incident:	
DETAILS OF MEDICAL DEVICE, NON-MEDICAL EQUIPMENT, BUILDING ELEMENT OR PLANT	
Product:	
Brand Name:	
Model:	
Catalogue Number:	
Serial Number:	
Batch Number:	
Manufacturer:	
Supplier:	
Date of Manufacture:	
Expiry Date:	
Quantity Defective:	
Location of device/equipment:	
Is there a CE-Mark?	YES/NO/Don't Know
If YES, was the manufacturer or supplier contacted?	YES/NO

Please see over page

DESCRIPTION OF INCIDENT	
Was there a fatality?	YES/NO
Was any injury caused?	YES/NO
Nature of injury and treatment:	
Details of Incident or defect:	
Contact Name for further details:	
Telephone number:	
Signature of person making report:	
ACTION TAKEN BY STAFF/MANUFACTURER/SUPPLIER	
IMPORTANT INFORMATION	
<p>Medical Devices that are the subject of this report should not be interfered with except for reasons of safety or to prevent loss of patient related data. Dial settings, position of taps, switches etc. and other relevant information should be recorded.</p> <p>Where the devices have been used, they should be contaminated, unless this would destroy material evidence in which case the devices should be enclosed in a suitable container to reduce the risk of infection. Contaminated items should not be sent through the post. Advice on decontamination is given in PEL (94) 34.</p> <p>For single use devices or consumables all material evidence, including wrapping materials and containers, should be kept and suitably labelled.</p> <p>The manufacturer of the devices or their agents may be allowed to inspect them in the presence of a responsible officer but must not be allowed to interfere with them, or remove any part, at this stage.</p> <p>Further advice on decontamination, devices held in quarantine, manufacturer access to devices or other related matters can be obtained by contacting the NIAIC.</p> <p>If you wish to send samples to NIAIC, please sign the declaration below.</p>	
I confirm that the necessary decontamination has been completed	
Signed:	
Date:	

Please send the completed form to NIAIC at the address overleaf.

Health Estates is an Executive Agency of the Department of Health, Social Services and Public Safety

NORTHERN IRELAND ADVERSE INCIDENT CENTRE



HEALTH ESTATES
ESTATE POLICY

IF AN INCIDENT HAPPENS:

Report the incident if it has led to, or were it to occur again could lead to:

- **death, life-threatening illness or injury;**
- **deterioration in health;**
- **the necessity for medical or surgical intervention;**
- **unreliable test results leading to inappropriate diagnosis or therapy.**

Also report:

- **any other related adverse incidents or minor faults and discrepancies.**
- **adverse incidents even if they appear to be caused by human error.**

What to do:

- **Keep devices/equipment or plant involved in an adverse incident together with other material evidence (e.g. packaging, giving sets used with infusion pumps etc.) clearly identify them and keep in quarantine.**
- **If this is not practicable, record the state of the device(s) at the time of the incident.**
- **Take any local action as necessary to ensure the safety of patients, staff and clients.**

Who to Contact:

- **Liaison Officer for your organisation:**

Telephone:

- **Northern Ireland Adverse Incident Centre (NIAIC)**

Health Estates

Estate Policy Directorate

Stoney Road

Dundonald BT16 1US Telephone 02890 523714

Fax 02890 523900

e-mail NIAIC@dhsspsni.gov.uk