

Medical Device/Equipment ALERT

Ref. MDEA(NI)2005/01

Issued: 4 January 2005



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	✓
INFORMATION REQUEST	

Reporting Adverse Incidents and Disseminating Medical Device/Equipment Alerts

This Alert provides information on the Northern Ireland Adverse Incident Centre (NIAIC) adverse incident reporting system, encourages users to report adverse incidents involving medical devices, non-medical equipment, buildings and plant and provides information on the dissemination of Medical Device/Equipment Alerts.

This document updates MDEA(NI)2004/01 issued in January 2004.

The full text of this Alert, printable adverse incident report forms and forms for on-line reporting are available on the NIAIC website along with further, regularly updated, supporting information: www.dhsspsni.gov.uk/niaic

Action by:

- Chief Executives of HSS Boards, Trusts and Agencies
- NIAIC Liaison Officers
- General Medical Practitioners, General Dental Practitioners, Community Pharmacists & Optometrists
- Independent Health and Social Care providers
- All users of Medical Devices

Actions:

The following actions should be taken:

- establish, review and maintain local procedures and encourage staff and users to report of adverse incidents in accordance with NIAIC guidance;
- ensure a NIAIC liaison officer has been appointed;
- ensure local dissemination of Medical Device/Equipment Alerts by the liaison officer;
- ensure that recommended actions are implemented;
- advise NIAIC of changes to liaison officer contact details;
- ensure that the NIAIC website is regularly checked for updates and further information.

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

Distributed by NIAIC to:

Chief Executive of each HSS Board
Chief Executive of each HSS Trust
Chief Executive of each Agency
NIAIC Liaison Officers

General Medical Practitioners
General Dental Practitioners
Community Pharmacists
Optometrists
Hospices
Education and Library Boards

For Onward Distribution To:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Risk Managers
- Medical Device & Equipment Co-ordinators
- Health & Safety Officers/Advisors
- Medical Directors
- Clinical Directors
- Nursing Directors
- Clinical and Social Care Governance Leads
- Device Managers
- Estates Managers
- Trust Pharmacy Managers
- Executive Social Work Directors
- All Medical, Nursing and Care Staff
- Allied Health Professionals
- Ambulance Staff and Paramedics
- Supplies Staff (RSS)
- All wards
- Intensive Care Units
- Coronary Care
- Sterile Services Departments
- Operating Theatre Staff
- Accident & Emergency Departments
- Outpatient Departments
- Day Procedure Units
- Laboratories
- Resuscitation Officers
- Infection Control Staff
- Children's Homes
- Day Care Centres
- GP Practice Managers
- GP Registrars
- Practice Nurses/Treatment Room Nurses
- Midwives
- Community Nurses and Health Visitors
- Directors of Public Health
- Social Care Staff
- Community Care Staff
- Independent Health and Social Care Providers including Private Clinics, Agencies, Residential and Nursing Homes through HSS Board R&I Units
- Chairs of Local Health and Social Care Groups

What is a medical device?

The term "medical device" covers a wide range of products used everyday in health and social care settings used for the diagnosis and/or treatment of disease, for monitoring of patients and items known as assistive technology. Devices include items such as needles, syringes, infusion pumps, endoscopes, examination gloves, dressings, walking sticks and blood glucose meters.

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

This does not include general workshop equipment such as power or machine tools, or general purpose laboratory equipment. Drug inhalers, pre-filled syringes and certain other medicine/device combinations also fall into this category.

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; Fixed luminaires including operating and examination lamps; Piped medical gas and vacuum installations; Vacuum Insulated Evaporators (VIE) and anaesthetic gas scavenging systems; equipment in

laundries, catering departments, workshops and any plant or equipment used for maintenance or cleaning; 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; communications equipment e.g. telephone, nurse call, paging, alarms and radio systems; Lightning protection and anti-static precautions.

What is an adverse incident?

An adverse incident is **an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of patients, clients, staff, or other persons.** For example, adverse incidents may arise due to:

- design or manufacture problems;
- inadequate user instructions or training;
- inadequate servicing and maintenance;
- inappropriate local modifications;
- inappropriate user practices;
- unsuitable storage or use conditions

What should be reported to NIAIC?

Any adverse incident involving a medical device, non-medical equipment, plant or building should be reported to NIAIC, especially if the incident has led to or, were it to occur again, could lead to: death or serious injury; deterioration in health or permanent impairment of body structure or function, medical or surgical intervention (including implant revision) or inpatient hospitalisation or unreliable test results leading to inappropriate diagnosis or therapy.

NIAIC should also be informed of other minor faults and discrepancies, since they may take on a greater significance when aggregated with other similar events in demonstrating trends or may be indicators of inadequate quality assurance on the part of the manufacturer or supplier.

DHSSPS circular HSS(PPM)06/04 provided interim guidance on the reporting to the DHSSPS of incidents regarded as serious enough for regional action to be required. **Such incidents, should they involve medical devices, non-medical equipment, plant or building, must also be reported to NIAIC.**

When should an incident report be made?

Adverse Incidents should be reported to NIAIC as soon as possible. Serious cases should be reported to NIAIC by the fastest means available, preferably on-line, fax, or e-mail followed up by a confirmatory telephone call. Telephone reports should be followed up as soon as possible by completing an Adverse Incident Report Form.

The initial report of an incident should contain as much relevant detail as is immediately available but should not be delayed for the sake of gathering additional information.

How do I report an incident?

On-line reporting is now available through the NIAIC website. We strongly recommend that, where possible, on-line reporting be used. Successful use of this route will provide the reporter with immediate confirmation of receipt.

Paper forms for reporting incidents may be downloaded from the NIAIC website and then either completed electronically and e-mailed or printed and sent by mail or fax.

Outside normal office hours, the Department's Duty Officer can be contacted at Stormont House telephone 028 9052 0700 giving an indication that the report is for the NIAIC, Health Estates. Otherwise, the NIAIC telephone number 028 9052 3868 has a voice message service giving contact details of the NIAIC Manager.

What do I do with Medical Devices or equipment that have been involved in incidents?

Medical Devices or Equipment:

All items that have been involved in an incident should initially be quarantined where possible and **should not be repaired** (either in-house or by a third party), **returned to the manufacturer** (unless otherwise agreed with NIAIC) **or discarded** before NIAIC has been given the opportunity to carry out an investigation themselves. 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, until advised to the contrary by NIAIC, 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 our investigations, or those of other official bodies.

Once NIAIC has indicated that an item may be returned to the manufacturer, the manufacturer should be contacted to ensure that correct forms of documentation and carriage are arranged. In particular a manufacturer's returns authorisation reference number may be required.

In exceptional circumstances, where devices cannot be removed from use because there is no alternative available, and where patient health would otherwise suffer, NIAIC should be contacted for confirmation that the device may continue to be used or repaired and put back in use. If it is not possible to remove defective parts or withdraw the device from use, users should be made aware of the need for increased vigilance and extra caution during use.

Any parts of devices removed and replaced in these circumstances, and any devices withdrawn from use, must be clearly identified, quarantined and stored securely pending investigation.

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, labeled and placed in quarantine. NIAIC and the manufacturer/supplier should be contacted for advice prior to any further action being taken.

Evidence:

All material evidence should be labelled and kept secure. This includes the products themselves, their instruction for use, records of use, repair and maintenance records 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.

If it is believed that an urgent examination of the defective item (or related items) is needed, then consideration should be given to sending the item(s) to NIAIC, or inviting us to inspect them on site.

NIAIC Medical Device/Equipment Alerts

Medical Devices/Equipment Alerts (MDEAs) are the NIAIC's prime means of communicating safety information to health and social care providers. Each MDEA is designated for Immediate Action or Action. MDEAs may also be used to provide updated information or to circulate requests for information and/or feedback on specific issues.

Role of NIAIC liaison officers in HPSS organisations

Reporting Adverse Incidents:

All HPSS organisations must ensure that a NIAIC Liaison Officer is appointed with the necessary authority to take responsibility for the reporting of medical device, equipment, plant or building related adverse incidents and the dissemination of Medical Device/Equipment Alerts.

All staff who work in Health and Personal Social Services, including contractors and independent health and social care providers, should be regularly reminded of their responsibilities with regard to adverse incident reporting and of the relevant local procedures including the need to isolate and retain defective or suspect items. This information should also be conveyed to new and agency staff as part of their induction training. Regular reviews should be undertaken to ensure that local procedures are effective and are being followed

Distribution of NIAIC MDEAs:

NIAIC will e-mail MDEAs to HPSS Chief Executives and NIAIC Liaison Officers. One hard copy of each MDEA is also sent by first class post to the HPSS body Chief Executive and the NIAIC Liaison Officer.

NIAIC will arrange for the issue of warning notices to General Medical Practitioners, General Dental Practitioners and Community Pharmacists through the Central Services Agency distribution system. Registration and Inspection Units of HSS Boards have responsibility for distribution of NIAIC MDEAs to all persons having the responsibility for the premises registered under "The Registered Homes (NI) Order 1992". To assist R&I Units in this, MDEAs will indicate in the "**Onward Distribution To**" section the registered premises that the MDEA should be sent to.

What should be done when a NIAIC MDEA is received?

HPSS bodies, independent contractors and independent health and social care providers should:

- maintain a complete record of advice and recommendations issued by NIAIC;
- distribute MDEAs to the appropriate people in the organisation and implement recommendations contained in the notices.

HPSS organisations should:

- identify a fax number and e-mail address for the primary receipt of NIAIC MDEAs (usually the NIAIC Liaison Officer);
- arrange for someone to deputise in the Liaison Officer absence;
- establish procedures to record action taken following the receipt of MDEAs indicating to whom they have been sent for action, including as appropriate providers of commissioned services;
- develop procedures to ensure that new staff are made aware of recent MDEAs (for example: organisational policies and procedures; set up a folder of warning notices; establish an electronic library of warning notices, induction programs etc.)

NIAIC Liaison Officers should:

- distribute MDEAs designated as “Immediate Action” without delay. In acute facilities, appropriate recipients identified on each MDEA should preferably receive these within 24 hours but not greater than 48 hours upon receipt from NIAIC.
- ensure that each MDEA is distributed individually. Do not accumulate and staple MDEAs together;
- target MDEAs to the **appropriate recipient identified on each notice that require to take action** and is also brought to the attention of all who need to know or be aware of it in accordance with local procedures.
- maintain records to show, for example, the date issued and signed assurance from recipient that required action has been taken (for example – appropriate staff have been made aware of the MDEA);
- **not** cut and paste text from any NIAIC MDEA (this could change the context of the message).

There may be occasions when you receive a MDEA that refers to a medical device, non-medical equipment, plant or building item that users do not use. When a safety related concern arises, NIAIC’s priority is to alert all potential users of the particular device, equipment, plant or building item, so we target the whole sector in which the product may be in use. This includes professionals who do not use the medical device or item of equipment, but have contact with members of the public that may. In the interests of patient, client and staff safety it is vital that each MDEA received is checked and acted upon as necessary.

Enquires to NIAIC about this notice should quote the reference number MDEA(NI)2005/01 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

Tel: 028 9052 3868
Fax: 028 9052 3900
Email: NIAIC@dhsspsni.gov.uk
Web: www.dhsspsni.gov.uk/niaic



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