

SN (NI) 2001/01
DATE: 15 JANUARY 2001

For Attention and Action by:
Chief Executive of each HSS Trust
General Manager/Chief Executive of each HSS Board
Chief Executive of each Agency



HEALTH ESTATES
ESTATE POLICY

**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

TITLE:

**REPORTING ADVERSE INCIDENTS AND
DISSEMINATING WARNING NOTICES
RELATING TO MEDICAL DEVICES,
NON-MEDICAL EQUIPMENT, BUILDINGS,
AND PLANT**

SUMMARY

General Managers and Chief Executives are responsible for ensuring prompt reporting of adverse incidents. This Safety Notice provides information on:

- The Northern Ireland Adverse Incident Centre (NIAIC) adverse incident reporting system;
- Encourages the reporting of adverse incidents involving medical devices, non-medical equipment, buildings and plant;
- and provides information on the dissemination of NIAIC warning notices.

The text of this notice updates and replaces SN(NI)2000/NIAIC.

DISTRIBUTION

This notice should be brought to the attention of all who need to know or be aware of it, including those listed below, in accordance with local procedures. This will include:

- | | |
|-------------------------------------|----------------------------------|
| • Liaison Officers | • General Medical Practitioners |
| • Risk Managers | • General Dental Practitioners |
| • Health & Safety Officers/Advisors | • Opticians |
| • Medical Directors | • Community Pharmacists |
| • Clinical Directors | • Professions Allied to Medicine |
| • Nursing Directors | • Social Care Staff |
| • Medical, Nursing and Care Staff | • Community Care Staff |
| • Ambulance Staff and Paramedics | • Trust Pharmacists |

Boards/Trusts should ensure that if appropriate, this information is passed to all persons having the responsibility for the premises registered under "THE REGISTERED HOMES (NI) ORDER 1992.

ACTION

The following actions should be taken:

- establish and maintain procedures to ensure the prompt reporting of adverse incidents relating to medical devices, non-medical equipment, buildings and plant to NIAIC in accordance with this Notice;
- If they have not already done so, HPSS organisations should nominate a Liaison Officer to co-ordinate the reporting of incidents and the local dissemination of NIAIC warnings notices and other guidance material;

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- regularly review these procedures and update as necessary.

Further guidance is provided in the Annexes to this Notice.

BACKGROUND

The Health Estates Health & Social Services Agency (Health Estates) is an Executive Agency of the Department of Health, Social Services and Public Safety. The aim of the NIAIC, part of Health Estates, is to take all reasonable steps to protect the health of patients, staff and clients. One way in which we aim to achieve this is by investigating reports of adverse incidents involving medical devices, non-medical equipment, plant and buildings. See Annex A and B for a list of examples of medical devices, non-medical equipment, plant and buildings.

Where the results of investigations have implications for patients, staff, clients or users, NIAIC issues a Hazard Notice, Advice Notice or Safety Notice advising of hazardous products or unsafe procedures.

WHAT IS AN ADVERSE INCIDENT?

An adverse incident is an event which causes, or has the potential to cause, unexpected or unwanted effects involving the safety of patients, staff and clients. Every Health & Personal Social Services employee has a duty to see that all safety related incidents and potentially harmful products are reported, even on suspicion. For example, adverse incidents may arise due to:

- shortcomings in the medical device, non-medical equipment, plant or building item*
- inadequate instructions for use*
- inadequate servicing and maintenance*
- locally initiated modifications or adjustments*
- inappropriate user practices, (which may in turn result from inadequate training)*
- inappropriate management procedures*
- the environment in which it is used or stored*
- selection of the incorrect type of device for the patient**

Conditions of use may also give rise to adverse incidents, e.g.:

- environmental conditions (e.g. electromagnetic interference)*
- location (e.g. devices designed for hospitals may not be suitable for use in the Community or ambulances).*

* This would not apply to non-medical equipment, plant and buildings.

WHAT TO REPORT

An adverse incident should be reported to NIAIC if the incident 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.*

NIAIC should also be informed of any other related adverse incidents or 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.

NIAIC should be informed of adverse incidents even if they appear to be caused by human error as:

- the error may be partly (or wholly) due to deficiencies in the design of the device, non-medical equipment, plant or building item or instructions for their use;*
- it will help prevent repetition of the same mistake, possibly by promulgating advice or improving the design of future devices, non-medical equipment, plant*



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and building items.

NIAIC is concerned with preventing adverse incidents occurring, not with assigning blame or liability.



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ADVERSE INCIDENT REPORTING PROCEDURES

All staff who work in Health and Personal Social Services, including contractors and those in the Private Sector, 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.

The procedures should ensure that:

- *where appropriate, a liaison officer is appointed in each HPSS organisation with the necessary authority to take responsibility for the reporting of adverse incidents to NIAIC as detailed in Annex C to this notice and that NIAIC is informed of any changes to liaison officer contact details when they occur;*
- *devices/equipment or plant involved in an adverse incident together with other material evidence (e.g. packaging of a single use device, giving sets used with infusion pumps etc.) should be clearly identified and kept in quarantine, where appropriate, until NIAIC's investigating officers have been consulted. Where quarantine is not practicable, the state of the device(s) at the time of the incident should be recorded for use in any subsequent investigation. Please refer to Annex D;*
- *local action is taken as necessary to ensure the safety of patients, staff and clients.*

Regular reviews should be undertaken to ensure that the procedures are effective and are being followed.

HOW TO REPORT AN INCIDENT

Adverse Incidents should be reported to NIAIC as soon as possible by completing an Adverse Incident Report Form A1 (Annex F). Serious cases should be reported to NIAIC by the fastest means available e.g. telephone fax or e-mail. 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 including information about any device or equipment involved such as the manufacturer and supplier names, addresses and telephone numbers, product names and serial numbers etc. Having this information available allows us to begin the investigation immediately. Names and contact details of persons who may be contacted for further information should be included. The Adverse Incident form may be photocopied for local use. It is also available in electronic format for completion and return by e-mail. Please contact the NIAIC at NIAIC@dhsspsni.gov.uk, requesting the form by return.

Outside normal office hours, the Department's Duty Officer can be contacted at Stormont House telephone 02890 520700 giving an indication that the report is for the NIAIC, Health Estates. Otherwise, if a case is less serious it should be reported on the next working day.

IMPORTANT INFORMATION

General Information on how NIAIC deals with received incident reports, the investigation process, including manufacturer's legal responsibilities and the criteria for the various levels of warning notice are given in Annex E.

REPORTING TO OTHER ORGANISATIONS INVOLVED WITH ADVERSE INCIDENTS

Please report adverse incidents to the appropriate organisation. **All those involving medical device, non-medical equipment, plant or building items should be reported to NIAIC.**

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.

RIDDOR

Incidents involving certain types of injury, occupational disease or dangerous occurrence, whether involving medical devices, non-medical equipment, buildings or plant or not, are legally notifiable to the Health & Safety Executive under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (Northern Ireland) 1997 (RIDDOR), and the Ionising Radiation Regulations (Northern Ireland) 2000.

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).

MEDICINES

Incidents involving medicines should be reported to Pharmaceutical Branch of the Department of Health, Social Services and Public Safety.

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. The EHO will also report the incident to the Food Standards Agency as necessary.

Enquires to NIAIC about this notice should quote the reference number SN (NI) 2001/01 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)

RoomA7

Health Estates

Estate Policy Directorate

Stoney Road

Dundonald

Belfast BT16 1US

Tel: 02890 523714

Fax: 02890 523900

Email: NIAIC@dhsspsni.gov.uk

Brian Godfrey
NIAIC Manager

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

Áisíneacht Feidhmeannach don Roinn Sláinte, Serbhísí Sóisialta agus Sábháilteacht Phoiblí



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