



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

**SUMMARY**

This Safety Notice updates and replaces Safety Notice SN (NI) 2002/01 and: -

- Describes 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;
- Outlines proposed implications of the introduction of Controls Assurance;
- Provides information on the dissemination of NIAIC warning notices

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

**ACTION**

The following actions should be taken:

- Establish, review 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 NIAIC guidance;
- Ensure the prompt local dissemination of NIAIC warning notices and other guidance material;
- Ensure that recommended actions are implemented.

**DISTRIBUTED BY NIAIC TO:**

Chief Executive of each HSS Board, Trust and Agency	General Medical Practitioners
NIAIC Liaison Officers	General Dental Practitioners
	Community Pharmacists
	Optometrists

**For onward distribution as appropriate to:**

Risk Managers	Independent Health and Social Care Providers
Health & Safety Officers/Advisors	Children's Homes
Medical Directors	Day Care Centres
Clinical Directors	Practice Nurses
Executive Social Work Directors	Community Nurses
HSS Trust Pharmacy Managers	Practice Managers
Nursing Directors	GP Registrars
All Medical, Nursing and Care Staff	Directors of Public Health
Ambulance Staff and Paramedics	Clinical and Social Care Governance Leads
Allied Health Professionals	Chairs of Local Health and Social Care
Social Care Staff	Groups (LHSCGs).
	Community Care Staff

**SAFETY  
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. NIAIC, part of Health Estates, is the focal point for the reporting of incidents involving medical devices, non-medical equipment, plant and buildings in Northern Ireland. We work closely with our colleagues in the Medical Devices Agency (MDA) concerning medical device safety. In April 2003, a new agency called the Medicines and Healthcare products Regulatory Agency (MHRA) will replace MDA and the Medicines Control Agency (MCA). The establishment of this new Agency will not change the role and function of NIAIC.

Where the results of investigations, or other information is received, has implications for patients, clients, staff or users, NIAIC issues a warning notice, advising of hazardous products or unsafe procedures. We will be consulting in early 2003 on a proposal for a new format of warning notice to replace the existing levels of warning notice that we issue: Hazard Notice, Advice Notice and Safety Notice.

In addition, the establishment and consolidation of sound systems of risk management in HPSS bodies, supported by the introduction of Controls Assurance standards, will require HPSS bodies to review their effective control of risks associated with the use of medical devices and equipment.

## WHAT IS A MEDICAL DEVICE?

The term "medical device" covers a wide range of products used everyday in health and social care settings. Devices include items such as needles, syringes, infusion pumps, endoscopes, examination gloves, dressings, walking sticks and blood glucose meters. In other words, any instrument, apparatus, appliance material or health care product, excluding medicines, used for, or by a user for:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, or alleviation of, or compensation for, an injury or impairment.
- Investigation, replacement or modification of the anatomy or of a physiological process
- Control of Conception.

Some examples of medical devices are provided below (N.B. this is not an exhaustive list): -

### Medical devices used for the diagnosis or treatment of disease, or for monitoring of patients, such as:

*x-ray systems, ultrasound imagers and CT/MRI scanners*

*patient monitoring equipment (e.g. cardiac monitors)*

*anaesthetic equipment*

*sphygmomanometers*

*examination gloves*

*endoscopes*

*dressings*

*chiropractic equipment*

*physiotherapy equipment*

*blood warming cabinets*

*powered and unpowered surgical implants (e.g. implantable defibrillators, pacemakers, heart valves, orthopaedic prostheses, bone cements)*

*radiotherapy equipment (brachytherapy, external beam)*

*ophthalmic equipment*

*vaginal speculae*

*catheters (e.g. urinary, cardiac)*

*iv administration sets and pumps*

*dental equipment and materials*

*Thermometers*

*syringes and needles*

*surgical instruments and equipment*

### Medical devices used for critical care, such as:

*ventilators*

*defibrillators*

### Medical devices used for the care of disabled people, such as:

*wheelchairs and special support seating*

*walking aids*

*patient hoists*

*orthotic and prosthetic appliances*

*pressure relief equipment*

**Medical devices used by ambulance services, such as:**

*stretchers and trolleys*

*resuscitators*

**Medical devices used for daily living, such as:**

*commodes*

*urine drainage systems*

*incontinence products*

*hearing aids*

*prescribable footwear*

*bathing and showering equipment*

*special chairs*

**Medical devices also include in-vitro diagnostic medical devices and their accessories, such as:**

*devices for blood glucose measurement*

*pregnancy test kits*

*urine test strips*

*hepatitis and HIV test kits*

*blood gas analysers*

*specimen collection tubes*

**Medical devices also include:**

*intra-uterine devices (IUDs)*

*condoms*

*contact lenses and care products*

**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*

*bench top sterilizers*

**What is *not* a medical device?**

Medical devices do 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*

*Permanently installed sterilizers, benchtop sterilizers, washer-disinfectors, bedpan washers and disposal units.*

*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*

*Lightning protection and anti-static precautions*

*Ambulances but excluding motor vehicles such as those for disabled persons and lease hire and goods vehicles*

*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.*

## 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, clients, staff, or other persons. 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 design or manufacture of 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,*
- *inadequate training/induction,*
- *inappropriate management procedures;*
- *the environment in which it is used or stored;*
- *selection of the incorrect type of device for the purpose\**

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 SHOULD BE REPORTED TO NIAIC?

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 or wellbeing;*
- *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.

Reports of adverse incidents that appear to be caused by human error are also helpful 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 and building items.*

Please remember that NIAIC is concerned with preventing the occurrence of adverse incidents, not with assigning blame or liability.

## **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. These forms are available in MS Word, Rich Text Format and PDF format.

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, if a case is less serious it should be reported on the next working day.

**IMPORTANT:** Full contact details (name, post held, telephone numbers etc) should always be included on your forms and in your telephone messages. This will allow us to contact you to acknowledge receipt of your report or message and to request any further information that may be needed.

## **WHAT DO I DO WITH 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 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.

If devices are required for use, defective parts may be removed so that the equipment can be repaired. Any parts removed in such circumstances must be quarantined and securely stored pending investigation. NIAIC 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 (currently under revision) 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.

### **IMPORTANT: *IT IS ILLEGAL TO SEND CONTAMINATED ITEMS THROUGH THE POST***

#### **EVIDENCE:**

All material evidence should be labeled and kept secure. 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.

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.

### **WHAT DO WE DO WHEN WE RECEIVE A REPORT?**

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
- If the report concerned a Medical Device, the Medical Devices Agency (MDA) are informed for logging on the National Incident database to determine if similar incidents have been reported.

The report is then assessed for the level of risk to determine the most appropriate method of investigation.

- If the adverse incident involved death or serious deterioration in health or wellbeing, a high potential for this if the incident should occur again, or issues of significant public health concern, NIAIC may ask MDA to take the lead on the investigation. The investigation is pursued either by a Investigation Officer from NIAIC or a device specialist from MDA and will involve more contact with the manufacturer and the reporter, and possibly contact with other agencies, third party testing facilities, coroners' courts etc. depending on the type of incident and the device. The length of the investigation varies considerably depending upon the complexity of the incident and the other parties involved in the investigation. It is usually this type of investigation that might require a warning notice to be issued.
- For the majority of adverse incidents reported to NIAIC, the manufacturer is provided with information about the incident, where it occurred and the device involved. The manufacturer may liaise with the reporter as necessary to obtain the device and/or more information if required. The manufacturer takes responsibility for resolving the incident but NIAIC monitors progress and reviews the manufacturer's response. The length of the investigation depends upon the level of co-operation we receive from the manufacturer, where the device was manufactured and any other parties involved in the investigation.
- Some of the reports that we receive do not require any NIAIC action but they are logged on the database and used for trend analysis. Subsequently in the light of further information some of them may be reclassified for further investigation.
- Some reports concern issues that are not NIAIC's remit (i.e. medicines, food, consumer issues or Health and Safety issues). We either refer these incidents to Pharmaceutical Branch in DHSSPS, or advise the reporter to contact the Food Standards Agency, the local Trading Standards or HSE

office.

In the course of an investigation, NIAIC may:

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

On investigation completion, NIAIC will review the information available and provide the reporter of the incident with a report.

## **NIAIC WARNING NOTICES**

We will be consulting on proposals for a new format of warning notice to replace the existing levels of warning notice that we issue. This would align NIAIC with the MDA who from 1 January 2003 are introducing a new format “Medical Device Alert”. Until this consultation has been completed and appropriate guidance has been issued concerning the introduction of any new format, the existing levels of warning notice will continue to be used. The criteria for the current levels of 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, but for fortuitous circumstances or the timely intervention of staff or a carer, and
- where the medical device, non-medical equipment, plant or building item 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, non-medical equipment, plant or building item 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.

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

## **CONTROLS ASSURANCE**

Controls assurance is the process that will enable HPSS bodies to provide evidence that they are doing their reasonable best to manage themselves so as to meet their objectives and to protect patients, clients, staff, the public and other stakeholders against risk of all kinds. It is a means by which Chief Executives as Accountable Officers can discharge their responsibilities and provide assurance to the Department, the Assembly and the public. In taking forward this agenda, the Department intends to develop controls assurance standards and Medical Devices and Equipment Management has been identified a priority area.

The draft Medical Device and Equipment Management Controls Assurance Standard (scheduled to be issued for consultation in early February 2003) proposes that HPSS bodies should designate an executive board member with specific responsibility for medical device and equipment management to ensure that it has a locus within the boardroom. The designated executive board member should in turn ensure that a medical device and equipment coordinator is designated to take responsibility for key device and equipment management in the HPSS body. The responsibilities of this coordinator role are outlined in Device Bulletin DB 9904 (NI), repeated below for information. It is proposed that the responsibilities for this role should be wider than the current responsibilities for NIAIC Liaison Officers to encompass leading and encouraging the improvement in working practices which progressively reduce patient/client risk and lead to continued improvement.

Each HPSS body has a nominated NIAIC Liaison Officer and in some cases the proposed medical device coordinator could continue to act the NIAIC Liaison Officer. However, it is important that HPSS bodies acknowledge the proposed wider responsibilities of a medical device coordinator and that they would be prepared and supported to undertake these responsibilities. It is particularly important that the medical device and equipment coordinator would be integral to the organisations risk management structure and as such they would have clear lines of accountability. It is vital that they would be given training in risk assessment techniques given their proposed responsibility for risk assessment identified below.

The proposed responsibilities of a medical device and equipment coordinator are: -

- To coordinate the effective reporting of adverse incidents involving medical devices and equipment and the dissemination of advice and recommendations issued by NIAIC (currently the NIAIC Liaison Officer responsibilities).
- To coordinate the appropriate level of local investigation involving adverse incidents involving medical devices and equipment management and where appropriate take local action based on the investigation outcome.
- Training - running broad-based training sessions or organising participation in suitable training schemes.
- Information - identifying key workers in each division/directorate/department/facility who will keep documents up-to-date, e.g. equipment manuals, training records, NIAIC notices and device bulletins, text books, etc.
- Risk assessment - devise protocols, visit wards/facilities, apply protocols, repeat visits to ensure action is taken to reduce risk, etc.
- User/technical department interface - improve lines of communication between users and maintenance organisations.

## **ROLE OF NIAIC LIAISON OFFICERS**

Until consultation is completed on the proposed Medical Device and Equipment Management Controls Assurance Standard (this proposes the role of a medical device and equipment coordinator), the current NIAIC Liaison Officer arrangements will remain in place.

If you need to let us know about a change in Liaison Officer details e.g. name, address, phone, fax numbers and e-mail address, please contact us at telephone number 028 9052 3704; fax: 028 9052 3900, e-mail: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk).

## **REPORTING ADVERSE INCIDENTS:**

Guidance for establishing procedures for reporting adverse incidents to NIAIC is outlined in this Notice. HPSS bodies should ensure that the appointed NIAIC Liaison Officer has the necessary authority to take responsibility for the reporting of medical device, equipment, plant or building related adverse incidents.

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 WARNING NOTICES:**

NIAIC will e-mail and fax warning notices to NIAIC Liaison Officers. One colour-coded copy (PINK for Hazard Notice, WHITE for Advice Notice and BLUE for Safety Notice) is 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 independent contractors through the Central Services Agency distribution system.

Registration and Inspection Units of HSS Boards have responsibility for distribution of NIAIC warning notices to all persons having the responsibility for the premises registered under "The Registered Homes (NI) Order 1992".

High Voltage warning notices (concerning safety issues about High Voltage electrical distribution equipment) will be distributed to HSS Trusts that have HV switchgear only.

## **WHAT SHOULD BE DONE WHEN A NIAIC WARNING NOTICE 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 notices to the appropriate people in the organisation and implement recommendations contained in the notices.

### ***HPSS bodies should:***

- identify a fax number and e-mail address for the primary receipt of NIAIC warning notices (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 warning notices indicating to whom they have been sent, including as appropriate providers of commissioned services;
- develop procedures to ensure that new staff are made aware of recent warning notices, Device Bulletins or Guidance Booklets (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 Hazard Notices and Advice Notices without delay. In acute facilities, appropriate recipients identified on each Notice should preferably receive these within 24 hours but not greater than 48 hours upon receipt from NIAIC.**
- ensure that each Hazard Notice, Advice Notice and Safety Notice is distributed individually. Do not accumulate and staple warning notices together;
- target Hazard Notices, Advice Notices and Safety Notices to the appropriate recipient identified on each

notice and is 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):
  - date issued;
  - signed assurance from recipient that required action has been taken (for example – appropriate staff have been made aware of the Notice);
- **not** cut and paste text from any NIAIC Warning Notice (this could change the context of the message).

There may be occasions when you receive a warning notice 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 warning notice received is checked and acted upon as necessary.

## **DISSEMINATION OF NIAIC DEVICE BULLETINS, GUIDANCE BOOKLETS, ONE-LINERS AND EVALUATION REPORTS**

NIAIC will issue Device Bulletins, Guidance Booklets, One-Liners and Evaluation Reports to Liaison Officers for distribution within their organisation.

NIAIC will arrange for issue to independent contractors through the Central Services Agency distribution system.

Registration and Inspection Units of HSS Boards have responsibility for distribution to all persons having the responsibility for the premises registered under "The Registered Homes (NI) Order 1992".

**Warning Notices, Device Bulletins, Guidance Booklets and One-Liners are available on the NIAIC website along with further, regularly updated, supporting information.** [www.dhsspsni.gov.uk/niaic](http://www.dhsspsni.gov.uk/niaic)

## **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 customers. 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).

## **DEFECTIVE MEDICINAL PRODUCTS**

Guidance on making reports on defective medicinal products was circulated to HSS Boards and HSS Trusts in June 2001. The guidance focused upon medicinal products which are, or may be defective. The guidance was intended to ensure that only hazardous or major defects were reported directly to the Department with other incidents dealt with using local schemes and in consultation with the Regional Pharmaceutical Laboratory Service.

## **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) 2003/01 and be addressed to:

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

Tel: 028 9052 3704

Fax: 028 9052 3900

Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

Web: [www.dhsspsni.gov.uk/niaic](http://www.dhsspsni.gov.uk/niaic)



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*