

Safeguarding public health

# Device Bulletin

## Reporting adverse incidents and disseminating alerts

Northern Ireland version of DB2010(01)

DB2010(NI)-01  
February 2010  
website only

## Contents

<b>1 Introduction.....</b>	<b>4</b>
1.1 The Northern Ireland Adverse Incident Centre.....	4
1.2 Medicines and Healthcare products Regulatory Agency .....	4
1.3 DH Estates and Facilities - Engineering, Technology & Environment.....	5
1.4 Guidance documents.....	5
1.5 First Medical Device Alert of the year.....	5
<b>2 What is a medical device?.....</b>	<b>7</b>
2.1 Examples of medical devices.....	7
2.2 Examples estates equipment and plant .....	8
<b>3 What is an adverse incident and when should I report it?.....</b>	<b>9</b>
3.1 Definition.....	9
3.2 Possible causes and outcomes.....	9
3.3 Who should report? .....	9
3.4 What should I report?.....	9
3.5 When should I report?.....	10
<b>4 How do I report an incident?.....</b>	<b>11</b>
4.1 Telephone reports.....	11
4.5 Reporting by email, fax or post .....	11
<b>5 What do I do with devices that have been involved in incidents?.....</b>	<b>12</b>
5.1 Quarantine, labelling and storage .....	12
5.2 Dealing with the manufacturer/supplier .....	12
5.3 Devices required for continued use.....	13
5.4 Returning devices to the manufacturer/supplier .....	13
5.5 Submitting devices to the NIAIC .....	13
5.6 Contaminated items.....	13
<b>6 What does the NIAIC do when it receives a report?.....</b>	<b>14</b>
6.1 Adverse Incident Register (AIR).....	14
6.2 Risk assessment and investigation levels .....	14
6.3 Time taken for risk assessments and investigations .....	15
6.4 Keeping in touch.....	15
6.5 Confidentiality, data protection and the provision of information to third parties .....	15

<b>7 Disseminating Medical Device Alerts and the role of the MDLO .....</b>	<b>17</b>
7.1 Medical Device Alerts (MDAs) .....	17
7.2 Estates and Facilities Alerts (EFAs) .....	17
7.3 Northern Ireland Alerts (NIAs) .....	17
7.4 Safety Alert Broadcast System (SABS) and the role of the SABS liaison officer .....	18
7.5 Role of medical device liaison officers (MDLO) in HSC trusts .....	18
7.6 MDLO annual conference .....	19
7.7 MDLO Local procedures .....	19
7.8 Targeting of MDAs, EFAs and NIAs .....	20
<b>8 Field Safety Notices and Field Safety Corrective Actions .....</b>	<b>21</b>
8.1 What are FSNs and FSCAs? .....	21
8.2 FSNs on the MHRA website .....	22
<b>9 Other reporting systems .....</b>	<b>23</b>
9.1 Local reporting and risk management systems .....	23
9.2 National Patient Safety Agency (NPSA) .....	23
9.3 Defective medicines reports and Adverse drug reactions .....	23
9.4 SABRE (reporting blood safety and quality incidents) .....	24
9.5 RIDDOR .....	24
9.6 Devolved administrations .....	25
<b>Quick reference guide .....</b>	<b>26</b>
<b>Contacts .....</b>	<b>27</b>

# 1 Introduction

## 1.1 The Northern Ireland Adverse Incident Centre

The key aim of the Northern Ireland Adverse Incident Centre (NIAIC) is to record and investigate reported adverse incidents involving medical devices, non-medical equipment, plant and building items used within the healthcare environment in Northern Ireland and to issue warning notices and guidance to help prevent recurrence and avert patient, staff, client or user injury.

The NIAIC has direct links with the Medicines and Healthcare products Regulatory Agency (MHRA) who co-ordinate across the adverse incident centres of the United Kingdom for issues concerning medical device safety. The NIAIC also has links with DH Estates and Facilities directorate, Engineering, Technology & Environment and their Scottish equivalent for safety issues concerning non-medical equipment, plant and building items.

Because of the importance in open reporting of adverse incidents, part of our work is encouraging a shift to a safety culture in the HSC, where open reporting and balanced analysis are encouraged in principle and by example. This is in contrast to a blame culture, which encourages people to cover up errors for fear of retribution and act against the identification of the true causes of failure, because they focus heavily on individual actions and largely ignore the role of the underlying systems.

With the introduction of effective clinical governance, this means that there is a shared goal between the individual and the organisation to minimise hazards related to the use of medical devices, equipment and plant ensuring that everyone who needs to, is able to use equipment safely and effectively.

One way we aim to achieve this is by investigating reports of adverse incidents and, where appropriate, instigating corrective actions to reduce the risk of recurrence.

Alerts are issued to the HSC via the SABS (Safety Alert Broadcast Systems) to manage risks relating to Medical Devices, non-medical equipment, engineering plant installed services and building fabric.

## 1.2 Medicines and Healthcare products Regulatory Agency

The Medicines and Healthcare products Regulatory Agency (MHRA) is the executive agency of the Department of Health charged with protecting and promoting public health and patient safety by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and that they are used safely.

The Adverse Incident Centre (AIC) is the MHRA's focal point for the reporting of adverse incidents involving medical devices. Where the result of investigations of those incident reports (or any other information received) has implications for patients or

users, the Agency will issue a Medical Device Alert (MDA) advising of hazardous products, potential safety issues or unsafe procedures.

### 1.3 DH Estates and Facilities - Engineering, Technology & Environment

As part of the Department of Health(GB) the Estates and Facilities directorate, Engineering, Technology & Environment provides advice and support to help NHS organisations drive forward specialist healthcare engineering, embrace new ideas and technologies to deliver high quality patient care.

DH Estates and Facilities are committed to providing a safe environment and reducing risks to patients, staff and visitors within the NHS England & Wales. To manage risks relating to non-medical equipment, engineering plant installed services and building fabric they have signed up to a national agreement, where necessary, a common Estates & Facilities Alert will be broadcast to all regions of the United Kingdom on a similar format and numbering system. In Northern Ireland the common formatted Estates and Facilities Alerts (EFAs) will be distributed via the SABS (Safety Alert Broadcast Systems).

### 1.4 Guidance documents

This Device Bulletin provides guidance on the MHRA's and NIAIC's adverse incident reporting system for medical devices. It encourages users to report incidents to us and provides information on the dissemination of Medical Device Alerts. We update this guidance annually and distribute it to all medical device liaison officers (MDLOs). The full text of this Device Bulletin, the online reporting system and printable adverse incident report forms are available on the [NIAIC Website](#) along with further, regularly updated, supporting information.

We also draw your attention to Device Bulletin [DB 2006\(05\)](#) 'Managing medical devices'. This is an important document that provides broad-ranging advice. It replaced previous guidelines published in DB 9801, 'Medical device and equipment management for hospital and community based organisations' (including supplements 1 and 2 and also DB 2002(02) 'Medical devices and equipment management: repair and maintenance provision').

### 1.5 First Medical Device Alert of the year

Our first Medical Device Alert of the year provides an important message for all medical device users.

This year [MDA/2010/001](#) drew attention to the risks associated with the off-label use of medical devices and the modification of devices other than as directed in the instructions for use. It also highlighted concerns about the clinical use of non-CE

marked products or of CE-marked products not designed for clinical use, especially when suitable CE marked products are available.

The recurrent theme of the first MDA in recent years has been the importance of ensuring that, when a medical device related adverse incident does occur, a report is sent direct to the NIAIC. Whilst the NIAIC readily accepts that local incident reporting procedures should be followed, it is vital that those procedures do not deliberately exclude or filter out reports that would otherwise have been sent direct to us.

Entering reports onto local, HSC trust risk management systems may allow routine, automated transfer of reports to the NPSA, but those reports may not actually be forwarded on to us at the NIAIC or the MHRA for several months and, when they are, they will be in an anonymised format that can act as a further barrier to our investigation.

The MHRA has recently initiated discussions with the providers of local risk management systems, with the aim of implementing our own automated report transfer system. Until this project is completed, all medical device users throughout the health and social care sectors should ensure that all medical device-related adverse incidents within Northern Ireland are reported directly to the NIAIC.

## 2 What is a medical device?

### 2.1 Examples of medical devices

Anaesthetic equipment  
Blood warming cabinets  
Catheters (e.g. urinary, cardiac)  
Chiropody equipment  
Dental equipment and materials  
Dressings  
Endoscopes  
Examination gloves  
Hospital beds  
Implants – powered (e.g. implantable defibrillators, pacemakers) and non-powered (e.g. heart valves, orthopaedic implants, bone cements)  
Incontinence products  
IV administration sets and pumps  
Ophthalmic equipment  
Patient monitoring equipment (e.g. cardiac monitors)  
Physiotherapy equipment  
Radiotherapy equipment (brachytherapy, external beam)  
Sphygmomanometers  
Surgical instruments and equipment  
Syringes and needles  
Thermometers  
Urine drainage systems  
Vaginal specula  
X-ray systems, ultrasound imagers and CT/MR scanners

**For patient transportation or moving** (but **not** including ambulance vehicles themselves):  
Carry chairs  
Hoists and slings  
Portering chairs  
Slider boards and standing aids  
Stretchers and trolleys

**For critical care:**  
Defibrillators  
Resuscitators  
Ventilators

**For people with reduced mobility or physical impairment:**

Communication aids  
Environmental controls  
Hearing aids  
Orthotics  
Prosthetic limbs  
Pressure relief mattresses, cushions or pads  
Supportive seating  
Walking aids  
Wheelchairs (powered and non-powered)

**For daily living:**

Bathing and showering equipment  
Commodes  
Incontinence products  
Prescribable footwear  
Special chairs  
Urine drainage systems

**In vitro diagnostic medical devices and their accessories:**

Blood gas analysers  
Blood glucose meters  
Hepatitis and HIV test kits  
Pregnancy test kits  
Specimen collection tubes  
Urine test strips

**Also included are:**

Condoms  
Contact lenses and care products  
Intra-uterine devices (IUDs)

**We are also interested in products which, whilst not themselves medical devices, are used closely in conjunction with these devices. For example:**

Benchtop sterilizers  
Blood and tissue storage systems  
Disinfecting and sterilizing equipment  
Chemical and biological indicators used in sterilization processes

## 2.2 Examples estates equipment and plant

Building, building components and lifts

Demolitions and construction carried out under CDM regulations, including plant

Engineering plant and services of all types (e.g boilers, generators, heating, ventilation, water, drainage, electrical installations) and any other fixed plant equipment, but not medical devices

Fire protection installations and equipment  
Permanently installed sterilizers, bedpan washers and disposal units

Equipment in laundries, catering departments, workshops and any other plant or equipment used for maintenance or cleaning

Piped medical gas and vacuum systems, cryogenic liquid systems (CLS) including vacuum insulated evaporators (VIE's) and anaesthetic gas scavenging systems

Fixed luminaries including examination lamps

Communications equipment (e.g telephone and bed head services, nurse call systems, paging systems, alarm and audio equipment)

Lightning protection and electrostatic discharge systems

Incinerators and other clinical waste treatment equipment

Environmental aspects (buildings) of the Control of Substances Hazardous to Health (COSHH) Regulations

Installation aspects of fume cupboards and microbiological safety cabinets, including ductwork and their interaction with ventilation systems

Ambulances and similar vehicles,

## 3 What is an adverse incident and when should I report it?

### 3.1 Definition

An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users (including patients) or other persons.

### 3.2 Possible causes and outcomes

Causes of adverse incidents involving devices may include:

- design or manufacturing problems
- inadequate servicing and maintenance
- inappropriate local modifications
- unsuitable storage and use conditions
- selection of the incorrect device for the purpose
- inappropriate management procedures
- poor user instructions or training (which may result in incorrect user practice).

Conditions of use may also give rise to adverse incidents:

- environmental conditions (e.g. electromagnetic interference)
- location (e.g. devices designed for hospitals may not be suitable for a community or ambulance setting).

**Please remember that the MHRA and NIAIC are concerned with preventing the occurrence of adverse incidents, not with assigning blame or liability.**

### 3.3 Who should report?

Anyone may submit an adverse incident report to the NIAIC – clinicians, healthcare workers, carers, patients and members of the public.

Reporters should, however, familiarise themselves with their organisation's local incident reporting procedures and risk management systems, as these may require reports to be submitted via, or copied to, medical device liaison officers and/or patient safety managers.

### 3.4 What should I report?

Any adverse incident involving a device or its instructions for use should be reported to NIAIC, 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 (including implant revision)
- hospitalisation or prolongation of existing hospitalisation
- unreliable test results and associated risk of mis-diagnosis or inappropriate treatment
- fetal distress, fetal death, congenital abnormality or birth defect
- ongoing faults that successive service/maintenance visits have failed to rectify.

Subject to the above, specific advice on reporting incidents involving coronary stents, hip and knee joints, and breast implants should be followed. This advice is available on the MHRA website, along with a range of other product-specific information ([www.mhra.gov.uk](http://www.mhra.gov.uk) > Safety information > General safety information and advice > [Product-specific information and advice](#)).

Other minor safety or quality problems should also be reported as these can help demonstrate trends or highlight inadequate manufacturing or supply systems.

Reports of adverse incidents that appear to be caused by human error should also be reported because:

- the error may be partly (or wholly) due to deficiencies in the design of the device or instructions for use
- they may prompt promulgation of advice or device design improvements that will help prevent repetition of mistakes.

### 3.5 When should I report?

Incidents should be reported as soon as possible, usually within 24 hours. Serious incidents should be reported to us by the fastest means available either by fax or email and should be confirmed with a telephone call. Where the first report is by telephone, a written report (email or fax) should follow as soon as possible.

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.

## 4 How do I report an incident?

### 4.1 Telephone reports

Telephone reports must always be followed up by a written (online, email or fax) confirmation.

In urgent cases outside of normal office hours an answering machine at the NIAIC carries a message giving the contact telephone number for the duty officer. The duty officer is able to contact senior NIAIC staff.

Alternatively, telephone messages may be left on the answering machine for the next working day.

### 4.5 Reporting by email, fax or post

Forms for reporting incidents may be downloaded from the NIAIC website and when completed can be electronically emailed as a .doc or .pdf file. They may also be printed and sent by post or fax.

Copies of forms are also available from:

Northern Ireland Adverse Incident Centre  
Annex 6  
Castle Buildings  
Stormont Estate  
Dundonald  
BT4 3SQ

Tel: 028 90523868  
Fax: 028 90523900  
Email: [niaic@dhsspsni.gov.uk](mailto:niaic@dhsspsni.gov.uk)

## 5 What do I do with devices that have been involved in incidents?

### 5.1 Quarantine, labelling and storage

Medical devices that have been involved in an incident **should** be **quarantined**.

Until the NIAIC has been given the opportunity to carry out an investigation or give further advice, they **should not** be:

- discarded
- repaired
- returned to the manufacturer.

All material evidence, i.e. devices/parts removed, replaced or withdrawn from use following an incident, instructions for use, records of use, repair and maintenance records, packaging materials, or other means of batch identification **must** be:

- clearly identified and labelled
- stored securely.

Evidence should not be interfered with in any way except for safety reasons or to prevent its loss. Where appropriate, 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 you think an urgent examination of the device (and/or related items) is needed, contact the NIAIC directly by phone. The Operational Manager or another device specialist will decide whether to inspect the item urgently on site (or at other appropriate facilities), or may request that the device is sent to the NIAIC.

**Important: If you are in any doubt about what to do with a device, contact the NIAIC.**

### 5.2 Dealing with the manufacturer/supplier

The manufacturer or supplier should be informed promptly of incidents and, if accompanied by an appropriate person, may be allowed to inspect the items. To facilitate an investigation, it may be possible to provide the manufacturer with a sample of unused stock from a large batch. However, until advised to the contrary by the NIAIC, the manufacturer must not be allowed to exchange, interfere with, or remove any part of the product implicated in the incident as this might prejudice our investigations, or those of other official bodies.

### 5.3 Devices required for continued use

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

### 5.4 Returning devices to the manufacturer/supplier

Once the 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. The NIAIC reference number should be quoted in all circumstances.

### 5.5 Submitting devices to the NIAIC

**Important: Do not send medical devices to the NIAIC unless you have been specifically requested to do so by NIAIC.**

If responding to such a request, you must ensure that the device has been appropriately decontaminated, securely packaged, and clearly labelled (including the NIAIC reference number).

**Address the package to:**

Northern Ireland Adverse Incident Centre  
Annex 6  
Castle Buildings  
Stormont Estate  
Dundonald, BT4 3SQ

**Important: It is illegal to send contaminated items through the post**

### 5.6 Contaminated items

Device Bulletin [DB 2006\(05\)](#) 'Managing Medical Devices' contains advice on decontaminating healthcare equipment. MHRA device specialists can provide additional advice, particularly if the item requires examination prior to any decontamination.

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

## 6 What does the NIAIC do when it receives a report?

### 6.1 Adverse Incident Register (AIR)

Upon receipt, each report is acknowledged, recorded on our database (the Adverse Incident Register) and assigned a unique reference number. The NIAIC staff are available to provide an update on the progress of an investigation, or to put an incident reporter in contact with those responsible for that investigation. A copy of the incident report is sent to either the MHRA or DH Estates and Facilities (dependant on content) for inclusion on the National Database.

### 6.2 Risk assessment and investigation levels

The NIAIC Operational Manager then completes a risk assessment that helps determine whether an investigation is to be led by the NIAIC, or if we should ask the trust or the manufacturer to investigate on our behalf. Generally, if an incident involved a death or serious injury, or had a high potential to do so, the NIAIC or the MHRA will lead an '**In depth**' investigation itself. In the course of this type of investigation the NIAIC or the MHRA staff may:

- talk with the user and the manufacturer
- visit the site of the incident
- review evidence (including the device itself)
- issue safety advice (e.g. Medical Device Alert, One Liner, poster, leaflet)
- liaise with other authorities as appropriate (e.g. HSE, NPSA)

For the majority of reported incidents, the manufacturer is asked to help with the initial investigations. In these '**Standard**' investigations we provide the manufacturer with core information from the report received (the location, the device, what happened) and ask them to investigate particular aspects of the incident and to report back to us as soon as possible. At this stage we will also let you know if we are content for you to make the device (or samples from the same batch) available to the manufacturer as part of the investigation. We monitor progress of the manufacturer's investigation and assess their responses and their final report.

For other incidents, details are recorded for trend analysis and classified as '**Information only**'. In all cases the reporter is informed of our assessment and the outcome.

If at any later stage new information is brought to light, previously concluded investigations are re-appraised. Additionally, outcomes of investigations are routinely reviewed in order to identify patterns or clusters of incidents that may require further investigation.

### 6.3 Time taken for risk assessments and investigations

In most cases incident details will be recorded on the NIAIC database within one or two working days of receipt of an incident report. This is followed by a full risk assessment by the Operational Manager of the NIAIC. For the most serious incidents (e.g. those involving a death or serious injury), these processes can be completed within hours.

Of approximately 300 adverse incident reports received by the NIAIC last year, around 40% were risk assessed as requiring **Standard** investigations and around 15% as requiring **In depth** investigations. The remainder of those incidents correctly reported to the NIAIC are recorded as part of our ongoing trend analyses.

The length of time taken for completion of an investigation will vary according to a number of factors. These include:

- the complexity of the research and analysis undertaken
- the range of people that we need to contact
- the number of devices involved in the incident, and their location
- testing of the device by the manufacturer or by independent experts
- involvement of the police or a coroner

### 6.4 Keeping in touch

After initial acknowledgement, reporters are routinely kept informed of the progress of the incident investigation. At the end of an investigation we also provide the reporter with a summary of the incident investigation conclusions.

The NIAIC sends these progress updates to the person named on the report form and or the Liaison Officer. If the Liaison Officer submits the report it is important that they ensure that all NIAIC updates are passed on to the originator of the report, e.g. the healthcare worker using the device at the time of the incident.

Wider contact is also welcome – reporters are always free to contact the Adverse Incident Centre with any general or specific enquiries and comments.

### 6.5 Confidentiality, data protection and the provision of information to third parties

Unless notified to the contrary, the submission of a report to the NIAIC provides us with the authority to use the information it contains as we consider appropriate in the interest of safeguarding public health.

The NIAIC does not normally require patient names or other identifying information in order to carry out an investigation. Healthcare staff reporting incidents should, therefore, ensure that such details are deleted or redacted from their reports, from accompanying attachments and from any subsequent correspondence.

The details that we do require are clearly specified on the NIAIC report forms. The reporter's full contact details (name, post held etc.) are essential, as this allows us to contact you to acknowledge receipt of your report or message and to request any further information that may be needed.

Where the reporter is also the patient, these contact details are still required. However, it is standard NIAIC practice to have a medical device specialist consult directly with the patient before disclosing any personal identifying information to a third party such as the device manufacturer.

Technical and scientific information relevant to our investigations may be shared with bodies such as the MHRA, the Department of Health, the Health & Safety Executive and the National Patient Safety Agency (NPSA), as well as with the supplier or manufacturer of the device concerned.

In addition, existing legislation may also require disclosure of certain information to other statutory bodies. For example, we may provide information and expert advice to the police and/or to a coroner. This may include the provision of verbal or written evidence to a coroner's inquest.

## 7 Disseminating Medical Device Alerts and the role of the MDLO

### 7.1 Medical Device Alerts (MDAs)

Medical Device Alerts (MDAs) are the MHRA's and NIAIC's prime means of communicating safety information to medical device users in health and social care. MDAs may also be used to provide updated information. Each Medical Device Alert is given one of the following categories:

- Immediate action
- Immediate action update
- Action
- Action update

MDAs are reviewed on a regular basis and updated or deleted. Our website provides lists of MDAs that are still in force. If a notice is not listed, it has been superseded or withdrawn.

### 7.2 Estates and Facilities Alerts (EFAs)

Estates and Facilities Alerts (EFAs) are the NIAIC's prime means of communicating safety information to estates users in health and social care. EFAs may also be used to provide updated information. Each Estates and Facilities Alert is given one of the following categories:

- Immediate action
- Action

EFAs have been introduced from the start of 2010, they are now published nationally with a similar format in England, Wales, Scotland and Northern Ireland, all will carry the same reference number. EFAs has replaced safety advice on estates, plant and buildings previously provided under the Medical Device/Equipment Alert (MDEAs) numbering system. Our website provides lists of EFAs that remain in force. If a notice is not listed, it has been superseded or withdrawn.

### 7.3 Northern Ireland Alerts (NIAs)

Northern Ireland Alerts (NIAs) are the NIAIC's means of communicating safety information which is only applicable in Northern Ireland. NIAs will be used where immediate safety information requires to be brought to the attention of the local healthcare environment. Often these will be superseded by national advice. Each Northern Ireland Adverse Incident Centre Alert is given one of the following categories:

- Immediate action
- Action
- Information

NIAAs have been introduced from the start of 2010, they are ONLY published in Northern Ireland and are designed to give advice on local issues or advanced notification of safety problems still under investigation. These alerts will be distributed via SABS to the healthcare community within Northern Ireland and there is no immediate plan to publish them on the internet.

#### **7.4 Safety Alert Broadcast System (SABS) and the role of the SABS liaison officer**

SABS(NI) is an electronic system developed by the Northern Ireland Adverse Incident Centre and is the primary method of distributing MDAs, EFAs and NIAAs to the healthcare environment across Northern Ireland. It incorporates a feedback mechanism for the trusts to record and acknowledge receipt, action taken and completion information for the alert. The SABS liaison officer ensures onward distribution of the alert as appropriate; updates and feedback on action taken by the trust, this is logged and monitored on the SABS website.

The NIAIC should be informed about any local changes to the SABS contacts, by Tel :028 9052 3868 or E-mail: [niaic@dhsspsni.gov.uk](mailto:niaic@dhsspsni.gov.uk)

NB. A similar alerting system, Central Alerting System (CAS), is operated by the Department Health, England to administer safety information to all NHS trusts and primary care trusts in England & Wales and should not be confused with the system which operates within Northern Ireland.

#### **7.5 Role of medical device liaison officers (MDLO) in HSC trusts**

HSC trusts in Northern Ireland should have a designated a member of staff as their medical device liaison officer (MDLO). The primary role of the MDLO is to promote effective and comprehensive adverse incident reporting through encouragement and training of healthcare, support staff and other medical device users.

In many organisations the MDLO and the SABS contact is the same person. They will encourage, promote and coordinate adverse incident reporting, manage the dissemination of medical device alerts and provide feedback. In organisations where these posts are separate, both contacts will work closely together.

A wide range of publications that may help liaison officers in fulfilling their role are available on the MHRA website under: Safety information > General safety information and advice > [Medical Device Liaison Officer information](#)

Additional support is available from the MHRA Targeting Team on 020 7084 3272 or email [dts@mhra.gsi.gov.uk](mailto:dts@mhra.gsi.gov.uk)

## 7.6 MDLO annual conference

Each year the MHRA hosts a conference for medical device liaison officers from both the healthcare and social services sectors. Details of the conference programme, venue and booking arrangements are made available on the MHRA website: [www.mhra.gov.uk](http://www.mhra.gov.uk) > [Conferences and Learning Centre](#)

## 7.7 MDLO Local procedures

Local procedures for all MDLOs should ensure that:

- the appointed MDLO has the necessary authority to take responsibility for the reporting of medical device related adverse incidents
- all medical device related incidents are reported to the NIAIC

**Note:** As highlighted in Section 1.5, this currently cannot be achieved by using local risk management systems reporting via the National Patient Safety Agency. Although the NPSA has now begun to pass medical device related reports to the MHRA, these are significantly delayed and very rarely contain sufficient detail to allow us to investigate without requests for further information.

- the appointed MDLO personally reports all medical device adverse incidents to the NIAIC (and sends on NIAIC responses to the originator of the report)

**OR**

other reporters within the trust provide the MDLO with copies of their reports to the NIAIC, and all subsequent related correspondence

- that the NIAIC is informed promptly of changes to MDLO contact details
- a deputy MDLO who can carry out all of the duties allocated to the MDLO is appointed
- regular reviews are undertaken to ensure that local procedures are effective and are being followed.

**It is important to ensure that local reporting and risk management systems are not used to filter out medical device related adverse incident reports that would otherwise have been sent directly to the Northern Ireland Adverse Incident Centre (NIAIC). If a relevant incident report is submitted to another body (such as the Health and Safety Executive or the National Patient Safety Agency), it is essential that a separate report is also sent to the NIAIC.**

## 7.8 Targeting of MDAs, EFAs and NIAs

**All** alerts are distributed electronically to the registered SABS liaison officer in HSC trusts. This provides each liaison officer with the opportunity to assess the relevance of each alert to their own organisation.

Each alert has a suggested, tailored distribution list but we strongly recommend that the MDLO checks the relevance of this list to their organisation before beginning distribution.

## 8 Field Safety Notices and Field Safety Corrective Actions

### 8.1 What are FSNs and FSCAs?

The EU Medical Devices Directives require manufacturers to monitor the safety of their products and, where necessary, carry out corrective actions on medical devices that have been distributed to customers (i.e. that are 'in the field'). Field Safety Notices (FSNs) are used by manufacturers to inform medical device users about Field Safety Corrective Actions (FSCAs) taken by them (the manufacturer) to reduce the risk of death or serious deterioration in state of health during the use of the device. FSCAs are usually, but not exclusively, prompted by investigations of adverse incidents reported by medical device users. They relate particularly to investigations made by the MHRA, NIAIC and/or manufacturer that have revealed the need to:

- change the design of the device
- remove or replace devices in the field
- make device modifications in the field or amend instructions for use.

The same Directives oblige manufacturers to alert the MHRA, as the UK Competent Authority, about any corrective actions affecting their products that have been distributed within the UK. The MHRA has monitored manufacturer's Field Safety Corrective Actions since the transposition of the European Medical Devices Directives into UK law.

The MHRA carries out an assessment of each FSCA to determine whether the manufacturer's proposed action is relevant to the UK and whether it is sufficient to protect public health. On most occasions it is, and the MHRA monitors progress to ensure that the action is completed. This approach helps to minimise the need for the MHRA to issue Medical Device Alerts.

FSNs are frequently accompanied by confirmation receipts to be completed by the medical device user and returned to the manufacturer.

**It is important that the actions advised in the FSN are taken, and that receipt of the FSN is acknowledged by your organisation. This receipt provides the manufacturer, and subsequently the MHRA, with the means to monitor the progress of Field Safety Corrective Actions. It also minimises the need for the MHRA to issue Medical Device Alerts, which otherwise place an additional burden on the health service because of the broadcast nature of the MDA and the extra administrative work required.**

Manufacturers generally send Field Safety Notices directly to healthcare organisations and these may be addressed to specific individuals or departments. Although the MHRA checks that the manufacturer's distribution lists for FSCAs are credible and likely to achieve a satisfactory result we cannot check for 100% accuracy – this is the manufacturer's responsibility. If a FSN is targeted wrongly (e.g. out-of-date information

on staff and equipment locations), crucial information may not be acted upon or documented.

All healthcare staff should be aware that if they receive a manufacturer's FSN they should notify the appropriate member of staff who can arrange for the requested action to be undertaken. This may involve wider distribution and activation of formal risk management procedures within the healthcare organisation.

## 8.2 FSNs on the MHRA website

In response to requests from some medical device liaison officers and SABS liaison officers, and in order to provide transparency concerning Field Safety Corrective Actions in the UK, the MHRA places Field Safety Notices that are relevant to the UK on their website. They are placed on the website for information and will not normally require further action unless your organisation has been contacted directly by the manufacturer or if the MHRA has issued supplementary advice.

Once reviewed and placed on the website, MHRA assesses each manufacturer's FSN the associated Field Safety Corrective Action and determines whether supplementary MHRA advice is required or if the manufacturer's action is sufficient. Regular users of these web pages may wish to register to receive email alerts for all new FSNs and status updates.

Medical device liaison officers and SABS liaison officers are not expected to treat FSNs placed on the MHRA's website in the same way as Medical Device Alerts. Additional action or direct feedback will usually only be required when a Medical Device Alert has been issued. However, in response to feedback from the liaison officer conference, the MHRA is considering with manufacturer trade associations how the medical device liaison officer network might help further in the distribution, action and receipt of FSNs. Further advice about this will be issued directly to liaison officers during the year if this proposed initiative is supported.

## 9 Other reporting systems

### 9.1 Local reporting and risk management systems

It is important to ensure that local reporting and risk management systems are not used to filter out medical device related adverse incident reports that should be sent directly to the NIAIC. If a relevant incident report is submitted to another body (such as the Health & Safety Executive or the National Patient Safety Agency), it is essential that a separate report is also sent to the NIAIC.

### 9.2 National Patient Safety Agency (NPSA)

The MHRA continues to work alongside the NPSA to ensure coordinated development of our reporting systems, with the common goal of maximising our effectiveness in preventing harm arising from the use of medical devices.

Although the NPSA alerts the MHRA about specific device issues, the confidential reporting allowed under the NPSA system can prevent the MHRA from investigating those incidents in full.

**The NPSA therefore actively encourages reporting of all medical device failures directly to the MHRA.**

### 9.3 Defective medicines reports and Adverse drug reactions

Incidents involving defective medicines should be reported to the MHRA's Defective Medicines Report Centre via our website ([www.mhra.gov.uk](http://www.mhra.gov.uk)) or by post/fax/telephone/email:

MHRA Defective Medicines Report Centre  
Market Towers  
1 Nine Elms Lane  
London SW8 5NQ

Tel: 020 7084 2574  
Fax: 020 7084 2676  
Email: [darcy@mhra.gsi.gov.uk](mailto:darcy@mhra.gsi.gov.uk)

Suspected adverse drug reactions (ADRs) not thought to be a consequence of a defective product should also be reported to the MHRA Medicines sector through the Yellow Card Scheme. For further details on how and what to report see the website at [www.mhra.gov.uk](http://www.mhra.gov.uk)

## 9.4 SABRE (reporting blood safety and quality incidents)

For incidents relating to blood safety and quality, they should be reported directly to the MHRA Adverse Incident Centre and not NIAIC. The MHRA receives reports made under the EU Blood Safety and Traceability Directives and the UK [Blood Safety and Quality Regulations](#) (SI 2005 No.50, as amended).

These regulations require the reporting of serious adverse reactions and serious adverse events relating to the collection, testing, processing, storage and distribution of blood and blood components for transfusion. Reports must be made to the designated competent authority which in the UK is the MHRA.

Reports under these regulations are submitted to the MHRA using the dedicated online reporting system, [SABRE](#) (Serious Adverse Blood Reactions & Events). SABRE is accessible via the MHRA website ([www.mhra.gov.uk](http://www.mhra.gov.uk)). The system also prompts reporting to [SHOT](#) (Serious Hazards Of Transfusion <http://www.shotuk.org/>).

Enquiries concerning the reporting of blood safety incidents should be directed to:

### **MHRA**

Email: [sabre@mhra.gsi.gov.uk](mailto:sabre@mhra.gsi.gov.uk)

Tel: 020 7084 3336

Fax: 020 7084 3109

### **SHOT**

Email: [shot@nhsbt.nhs.uk](mailto:shot@nhsbt.nhs.uk)

Tel: 0161 423 4208

Fax: 0161 423 4395

## 9.5 RIDDOR

In addition to reporting medical device related incidents to the NIAIC, incidents involving certain types of injury, occupational disease or dangerous occurrence, whether involving medical devices or not, should also be reported under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR '95) to the relevant enforcing authority for the premises at which the incident occurred. For healthcare premises, this will usually be the Health and Safety Executive Northern Ireland (HSENI). All notifications under RIDDOR should be sent to:

HSENI  
83 Ladas Drive  
Belfast  
BT6 9FR

Tel: 028 9024 3249  
Fax: 028 9054 6896  
E-mail: [hseini@detini.gov.uk](mailto:hseini@detini.gov.uk)  
[www.hseini.gov.uk](http://www.hseini.gov.uk)

Online reporting and copies of report forms are available via their website.

## 9.6 Devolved administrations

The Device Bulletin is relevant to incidents occurring in Northern Ireland only. Separate guidance is available on the reporting of incidents that have occurred within the territory of a devolved administration – see contact details below.

### England

MHRA Adverse Incident Centre  
Market Towers  
1 Nine Elms Lane  
London  
SW8 5NQ

Tel: 020 7084 3080  
Fax: 020 7084 3109  
E-mail: [aic@mhra.gsi.gov.uk](mailto:aic@mhra.gsi.gov.uk)

### Scotland Ref: CEL 43 (2009)

Incident Reporting & Investigation Centre  
Health Facilities Scotland  
NHS National Services Scotland  
Gyle Square  
1 South Gyle Crescent  
Edinburgh  
EH12 9EB

Tel: 0131 275 7575  
Fax: 0131 314 0722  
Email: [nss.irc@nhs.net](mailto:nss.irc@nhs.net)

[www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/](http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/)

### Wales Ref: MDA/2004/054

Welsh Assembly Government  
Department for Public Health & Health Professionals  
4<sup>th</sup> Floor, East Wing  
Cathays Park  
Cardiff  
CF10 3NQ

Tel: 029 2082 3922  
Fax: 029 2082 3982  
Email: [haz-aic@wales.gsi.gov.uk](mailto:haz-aic@wales.gsi.gov.uk)  
Website: [www.wales.gov.uk](http://www.wales.gov.uk)

*All hazardous medical device related incidents occurring in Wales should be reported direct to the MHRA.*

## Quick reference guide

### What is a medical device?

Medical devices and equipment are items used for the diagnosis and/or treatment of disease, for monitoring patients, and as assistive technology. This does not include general workshop equipment such as power or machine tools, or general purpose laboratory equipment.

### 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 device users (including patients) or other persons. Causes may include: design; poor user instructions or training; inappropriate modifications; inadequate maintenance; and unsuitable storage and use conditions.

### Who should report?

Anyone within Northern Ireland may submit an adverse incident report to the NIAIC – clinicians, healthcare workers, carers, patients and members of the public. Reports may also need to be submitted via or copied to medical device liaison officers and/or patient safety managers.

### What should be reported?

Any adverse incident involving a medical device should be reported to the NIAIC. Some apparently minor incidents may have greater significance when aggregated with other similar reports.

### When should an incident report be made?

All incidents should be reported to the NIAIC as soon as possible. Serious cases should be reported by the fastest means possible. Initial incident reports 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?

Reports may be sent by phone, email, fax or post. Report forms may be downloaded/printed from the website.

### What do I do with devices that have been involved in incidents?

All items should be quarantined and not repaired, returned to the manufacturer, or discarded until the NIAIC has been given the opportunity to carry out its own investigation. The NIAIC will advise you when it is necessary to submit a device for examination. If asked to send an item to the NIAIC or to the manufacturer for investigation, remember that it is illegal to send contaminated items through the post.

### What does the NIAIC do when it receives a report?

Report details are recorded on a database and risk assessments are completed by device specialists. That assessment determines whether an investigation is undertaken directly by the NIAIC or by the manufacturer on our behalf. Other incidents are recorded for information and trend analysis only. Reports are acknowledged and reporters advised of the nature and outcome of the investigation.

### How long do risk assessments and investigations take?

In most cases, a full risk assessment is completed within one or two days of receipt of an incident report. For more serious incidents, however, this can take place within hours.

### Medical Device Alerts (MDAs) and Estates & Facilities Alerts (EFAs)

MDAs and EFAs are the NIAIC's prime means of communicating safety information to in Northern Ireland healthcare environment.

### The Safety Alert Broadcast System (SABS) and the role of medical device liaison officers (MDLOs)

The Safety Alert Broadcast System is the medium through which safety information is issued to the HSC and other. Each HSC trust has an MDLO. Their key roles are to co-ordinate the effective reporting of adverse incidents involving medical devices, and the dissemination of Medical Device Alerts.

### Reporting to other organisations

Depending on the nature of the adverse incident, other central reporting bodies may also require notification.

Organisation	Telephone	website	email
NPSA	020 7927 9500	npsa.nhs.uk	enquiries@npsa.nhs.uk
MHRA Defective Medicines Report Centre	020 7084 2574	mhra.gov.uk	dmrc@mhra.gsi.gov.uk
MHRA SABRE helpdesk	020 7084 3336	mhra.gov.uk	sabre@mhra.gsi.gov.uk
RIDDOR(NI)	028 9024 3249	www.hseni.gov.uk	hseni@detini.gov.uk
England	020 7084 3080	mhra.gov.uk	aic@mhra.gsi.gov.uk
Scotland	0131 275 7575	www.hfs.scot.nhs.uk	nss.irc@nhs.net
Wales	029 2082 3922	wales.gov.uk	haz-aic@wales.gsi.gov.uk

## Contacts

Enquiries concerning the content of this Device Bulletin should be addressed to:  
Mr Robert Sergeant email: [robert.sergeant@dhsspsni.gov.uk](mailto:robert.sergeant@dhsspsni.gov.uk)

Tel: 028 9052 3744 Fax: 028 9052 3700

Enquiries about the medical device liaison officer focus group and conferences or  
about the dissemination of medical device alerts should be sent to  
email: [dts@mhra.gsi.gov.uk](mailto:dts@mhra.gsi.gov.uk)

Tel: 020 7084 3272, Fax: 020 7084 3124

The primary contents of this Device Bulletin is derived from DB2010(01)  
© Crown copyright 2010  
Medicines and Healthcare products Regulatory Agency  
An executive agency of the Department of Health  
ISBN 978-1-90-073169-X