

Safeguarding public health

# Device Bulletin

Reporting adverse incidents  
and disseminating  
medical device alerts

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website only

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# 1 Introduction

## 1.1 The Northern Ireland Adverse Incident Centre

The key aim of the Northern Ireland Adverse Incident Centre (NIAIC), part of Health Estates, is to record and investigate reported adverse incidents involving medical devices, non-medical equipment, plant and building items used in Health and Personal Social Services 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 in England, Scotland, Wales and Northern Ireland for issues concerning medical device safety. The NIAIC also has links with Estates and Facilities Division - Department of Health UK and other bodies 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 HPSS, 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 and to ensure that everyone who needs to, is able to use medical devices safely and effectively.

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

Alerts are issued to the HPSS on 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 The 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 in England and Wales. They also maintain a National database of all medical device incidents across the UK. Where the result of investigations 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 DH 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 and deliver high quality patient care.

DH Estates and Facilities are committed to providing a safe environment and reducing risks to patients, staff and visitors in the NHS England & Wales. Alerts are issued to NHS on the SABS (Safety Alert Broadcast Systems) to manage risks relating to non-medical equipment, engineering plant installed services and building fabric in the NHS.

### 1.4 Guidance documents

This Device Bulletin provides guidance on the NIAIC's voluntary adverse incident reporting system; encourages users to report adverse incidents involving medical devices and provides information on the dissemination of Medical Device/Equipment Alerts.

The full text of this Device Bulletin, printable adverse incident report forms and forms for online reporting are available on the NIAIC website along with further, regularly updated, supporting information.

The MHRA have also published Device Bulletin [DB 2006\(05\)](#) 'Managing medical devices – guidance for healthcare and social services organisations'. It replaces 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 Training

Those involved in risk management (e.g. patient safety managers, local risk managers and medical device liaison officers) should give consideration to the levels and extent of training appropriate for all staff that may need to report adverse incidents involving medical devices. Such training should include the key areas covered in this Device Bulletin: what is a medical device; what is an adverse incident and when should I report it; how are reports submitted, and what should be done with the device.

## 2 What is, and is not, covered by the NIAIC?

### 2.1 Examples 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 and non-powered (e.g. implantable defibrillators, pacemakers, heart valves, orthopaedic prostheses, 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

**Medical devices and equipment also include the following in vitro diagnostic medical devices and their accessories:**

- Blood gas analysers
- Devices for blood glucose measurement
- 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
- Chemical and biological indicators used in sterilization processes
- Disinfecting and sterilizing equipment

## **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, tugs etc. excluding those vehicles that are for disabled persons, leased vehicles and goods 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 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 NIAIC is 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. Where appropriate, reporters should 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 us, 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

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 are also helpful as:

- 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?

All incidents should be reported as soon as possible, usually within 24 hours. Serious incidents should be reported to us by the fastest means available, **preferably e-mail**, or by fax and should be confirmed with a telephone call. Where the first report is by telephone, a written report (e-mail 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 Reporting by e-mail, fax or post

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

Copies of forms are also available from:

Northern Ireland Adverse Incident Centre  
Health Estates  
Stoney Road  
Dundonald  
BT16 1US  
Tel: 028 9052 3868  
Fax: 028 9052 3900  
E-mail: [niaic@dhsspsni.gov.uk](mailto:niaic@dhsspsni.gov.uk)

### 4.2 Telephone reports

Telephone reports must always be followed up by a written ( e-mail or fax) confirmation.

In cases of urgency outside normal office hours, and where it is not possible to use the online reporting facility, an answering machine at the Adverse Incident Centre carries a message giving the emergency contact telephone number for the NIAIC.

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

### 4.3 Important advice for all reporters

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. Where forms are completed centrally, the form should contain a local point of contact to allow us to progress the incident.

Your local medical device liaison officer is there to encourage and coordinate the effective reporting of medical device related adverse incidents across your organisation. It is important that your liaison officer is made aware of all reports submitted to the NIAIC.

**Reporters should ensure that local medical device liaison officers, patient safety managers and risk managers are aware of all incidents reported to the NIAIC.**

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

### 5.1 Quarantine, labelling and storage

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

Until the NIAIC has been given the opportunity to carry out an investigation, 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 material, 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. 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 you think an urgent examination of the device (and/or related items) is needed, contact the NIAIC. The Operational Manager of the NIAIC 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 in any doubt as to what to do with a device, contact the NIAIC.

### 5.2 Dealing with the manufacturer/supplier

The manufacturer or supplier should be informed promptly 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 devices 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 vigilance and extra caution.

#### 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.

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 (for address see 4.1)

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

#### 5.6 Contaminated items

Device Bulletin **DB 2003(05)** 'Management of Medical Devices Prior to Repair, Service or Investigation' (available only on the MHRA website) contains advice on procedures to be followed if healthcare equipment is contaminated and constitutes a biohazard. The NIAIC can provide additional advice where necessary, particularly where 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 staffs 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 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 350 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.

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 and data protection

The NIAIC does not normally require patient names or other identifying information in order to carry out an investigation. Healthcare staff reporting incidents should ensure that such details are deleted from their reports and 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, telephone number etc) are essential, to contact you to acknowledge receipt of your report or message and to request any further information that may be needed. In circumstances where the patient is also the reporter, contact details are required.

You are reminded that information relevant to our investigations may be shared with bodies such as 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. Existing legislation may also require disclosure of certain information to others.

Unless notified to the contrary, the submission of a report to the NIAIC provides authority for the information it contains to be used in the interest of safeguarding public health.

## 7 Disseminating Medical Device Equipment Alerts

### 7.1 Medical Device Equipment Alerts

Medical Device Equipment Alerts (MDEAs) are the NIAIC's prime means of communicating safety information to medical device users and estates and facilities issues to the health and social care. Prior to 2003, titles for these alerts included Safety Notice, Hazard Notice and Device Alert.

Each Medical Device Equipment Alert is designated for 'Immediate action' or 'Action'. MDEAs may also be used to provide updated information, or to circulate requests for information and/or feedback on specific issues.

MDEAs are reviewed on a regular basis and updated or deleted as appropriate.

### 7.2 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 MDEAs to the healthcare environment across Northern Ireland. It incorporates a feedback mechanism to record acknowledgement of receipt and action taken by trusts following the release of alerts. The SABS liaison officer ensures onward distribution of the alert as appropriate; updates and feedback on action taken is logged on the SABS website.

The NIAIC should be informed about a change of SABS contact on Tel :028 9052 3868 or E-mail: [niaic@dhsspsni.gov.uk](mailto:niaic@dhsspsni.gov.uk)

NB. A similar SABS system 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.

### 7.3 Role of medical device liaison officers in HSC trusts

HSC Trust should all have designated a medical device liaison officer (MDLO). These MDLOs encourage and train staff and users to report adverse incidents. In many organisations the MDLO and the SABS contact is the same person carrying out all functions of reporting, disseminating and feedback. In organisations where this is not the case, both contacts should work closely together.

### 7.4 Local procedures

Local procedures for all MDLOs should ensure that:

- the appointed MDLO within HSC Trusts 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
- appointed MDLO personally reports all medical device adverse incidents to the NIAIC

**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 of changes to MDLO contact details as they occur
- a deputy NIAIC Liaison Officer is appointed and can carry out all duties allocated to the MDLO
- regular reviews are undertaken to ensure that local procedures are effective and are being followed

### **7.5 Targeting of MDEAs**

Since SABS went live in Jan 2008 **all** MDEAs have been distributed to the registered SABS liaison officer in all HSC Trusts. This allows the SABS liaison officers the opportunity to decide the relevance of the alert to their organisation.

We strongly suggest that all MDEAs should be checked for relevance within your organisation before onward distribution. A suggested distribution list is included in each MDEA.

## 8 Field Safety Notices and Field Safety Corrective Actions

Each medical device manufacturer's Field Safety Notice (FSN) received is reviewed by the MHRA, placed on the MHRA's website for information and its status updated as the MHRA continues to assess the manufacturer's associated Field Safety Corrective Action (FSCA) to determine whether supplementary MHRA advice is required or the manufacturer's action is sufficient.

### 8.1 What are FSNs and FSCAs?

FSNs are used by manufacturers to inform their customers about Field Safety Corrective Actions (FSCAs) taken by them (the manufacturer) to reduce the risk of death or serious injury from adverse incidents. These are usually, but not exclusively, prompted by investigations of adverse incidents reported by medical device users, and relate particularly to those MHRA and/or manufacturer investigations which 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, etc.

The EU Medical Devices Directives legally oblige manufacturers not only to carry out such corrective actions, but also to alert the national competent authority (in the UK this is the MHRA) 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 a risk assessment on each FSCA and determines whether the manufacturer's proposed action is relevant to the UK and sufficient to protect UK public health. On most occasions it is, and the MHRA will just monitor progress to ensure that it is completed. This approach helps to minimise the need to issue Medical Device Alerts.

Medical device liaison officers and SABS liaison officers are not expected to treat FSNs in the same way as Medical Device Alerts. Additional action or direct feedback will only be required when an associated Medical Device Alert has been issued.

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 customer 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) formal risk management systems within healthcare establishments may be circumvented and 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 local 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 improve awareness of ongoing Field Safety Corrective Actions, the MHRA now place Field Safety Notices on their website. They are placed on the website for information and will not normally require further action unless you have been contacted directly by the manufacturer or if the MHRA or the NIAIC has issued supplementary advice.

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

## 9 Other reporting systems

### 9.1 Medicines

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

MHRA	Tel: 020 7084 2574
Defective Medicines Report Centre	Fax: 020 7084 2676
Market Towers	E-mail: <a href="mailto:dmrc@mhra.gsi.gov.uk">dmrc@mhra.gsi.gov.uk</a>
1 Nine Elms Lane	
London SW8 5NQ	

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)

### 9.2 RIDDOR

In addition to reporting medical device related incidents to the MHRA, 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 1997 NI (RIDDOR '97) to the relevant enforcing authority for the premises at which the incident occurred. For healthcare premises, this will usually be the local office of the Health and Safety Executive Northern Ireland (HSENI). All notifications under RIDDOR should be sent to:

HSENI	Tel: 028 9024 3249
83 Ladas Drive	Fax: 028 9054 6896
Belfast	E-mail: <a href="mailto:hseini@detini.gov.uk">hseini@detini.gov.uk</a>
BT6 9FR	<a href="http://www.hseini.gov.uk">www.hseini.gov.uk</a>

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

### 9.3 Devolved administrations

This 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 (contact details given below).

**England** Ref: MDA08/01

MHRA Adverse Incident Centre	
Market Towers	
1 Nine Elms Lane	Tel: 020 7084 3080
London	Fax: 020 7084 3109
SW8 5NQ	E-mail: <a href="mailto:aic@mhra.gsi.gov.uk">aic@mhra.gsi.gov.uk</a>

**Scotland** Ref: SAN(SC)07/01

Incident Reporting & Investigation Centre  
Scottish Healthcare Supplies  
NHS National Services Scotland  
Gyle Square  
1 South Gyle Crescent  
Edinburgh  
EH12 9EB

Tel: 0131 275 7575  
Fax: 0131 314 0722  
E-mail: [iric@shs.csa.scot.nhs.uk](mailto:iric@shs.csa.scot.nhs.uk)  
[www.show.scot.nhs.uk](http://www.show.scot.nhs.uk)

**Wales** Ref: MDA/2004/054

Welsh Assembly Government  
Office of the Chief Medical Officer  
4<sup>th</sup> Floor, East Wing  
Cathays Park  
Cardiff  
CF10 3NQ

Tel: 029 2082 3505  
Fax: 029 2082 3982  
E-mail: [haz-aic@wales.gsi.gov.uk](mailto:haz-aic@wales.gsi.gov.uk)  
[www.wales.gov.uk](http://www.wales.gov.uk)

Welsh Assembly circular MDA/2004/054 announced new arrangements whereby all hazardous medical device related incidents occurring in Wales are to be reported directly to the MHRA with a copy of the report being sent to the Surgical Materials Testing Laboratory (SMTL). The MHRA will undertake all necessary incident investigations and advise the Welsh Assembly Executive where appropriate. All non-hazardous reports/defects should be reported directly to SMTL. The Welsh Assembly Government will continue to issue its own Medical Device Alerts.

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

The MHRA Adverse Incident Centre also receives reports made under the EU Blood Safety and Traceability Directives and the **UK Blood Safety and Quality Regulations** (SI 2005 No. 50).

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 Medicines and Healthcare products Regulatory Agency (MHRA).

Reports under these regulations are submitted to the MHRA using a 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 facilitates reporting to **SHOT** (Serious Hazards Of Transfusion).

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

MHRA  
Tel: 020 7084 3336  
Fax: 020 7084 3109  
E-mail: [sabre@mhra.gsi.gov.uk](mailto:sabre@mhra.gsi.gov.uk)

SHOT  
Tel: 0161 251 4208  
Fax: 0161 251 4395  
E-mail: [shot@nbs.nhs.uk](mailto:shot@nbs.nhs.uk)



## 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 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. The NIAIC publishes specific advice for incidents involving certain types of devices. 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?**

Electronic reporting using the online form on the NIAIC website is the preferred method. Reports may, however, also be sent by e-mail, 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 MHRA 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 MHRA 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 MHRA or by the manufacturer on the Agency's 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.

### **Medical Device and Equipment Alerts (MDEAs)**

MDEAs are the NIAIC's prime means of communicating safety information to medical device users in health and social care. Each MDEA is designated as 'Immediate action' or 'Action'. MDEAs may also be used to provide updated safety information or to request feedback on specific issues.

### **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 MDEAs are issued to the healthcare environment within Northern Ireland. Each HSC trust and social services board and agency has an identified SABS liaison officer. Their key roles are to co-ordinate the effective reporting of adverse incidents involving medical devices, and the appropriate dissemination of all Medical Device and Equipment Alerts issued.

## Contacts

Enquiries concerning the content of this Device Bulletin should be addressed to:

Mr Robert Sergeant  
Operational Manger NIAIC  
Health Estates  
Stoney Road  
Dundonald  
BT16 1US

Tel: 028 9052 3744  
Fax: 028 9052 3900

E-mail: [robert.sergeant@dhsspsni.gov.uk](mailto:robert.sergeant@dhsspsni.gov.uk)

# **APPENDIX 1**

## **Northern Ireland Adverse Incident Report Form 2008**

## NIAIC ADVERSE INCIDENT REPORT FORM

<b>Details of the report:</b> Reporting Body: Address :  Post Code : Reporter : Position : Tel No : Email :  Your Reference:	<b>Location of the incident:</b>  As Reporter : <input type="checkbox"/>  Facility/Building: Ward/Dept :  Local Contact : Position : Tel No : Email :
--	---

<b>Details of device:</b>			
Product		Catalogue No	
Model		Serial No	
Manufacturer			
Supplier			
Batch No		Expiry date	
Date of mfr		Quantity defective	
Location of device now			
Is there a CE-mark? <input type="checkbox"/>		If YES, was the manufacturer or supplier contacted? <input type="checkbox"/>	

<b>Incident Details :</b>		
Date of Incident	Was there a fatality? <input type="checkbox"/>	Was an injury caused? <input type="checkbox"/>

<b>Injury details:</b>
------------------------

<b>Nature of defect / details of incident:</b>
--

<b>Action taken by staff :</b>
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PLEASE NOTE IT IS ILLEGAL TO SEND CONTAMINATED ITEMS THROUGH THE POST.  
 If you still have the incident device please retain it and await further instructions from the NIAIC.

Signed	Date
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Please send completed form to: Northern Ireland Adverse Incident Centre, Health Estates, Stoney Road, Dundonald, BT16 1US, Fax 028 90523900, Preferred method e-mail : [niaic@dhsspsni.gov.uk](mailto:niaic@dhsspsni.gov.uk) Version 2008/1