Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

# Northern Ireland Adverse Incident Centre (NIAIC)

## Reporting Adverse Incidents and disseminating Safety Information

Apr 2021

## Version Control

This document is owned and controlled by the Head of Medical Device and Estates Safety Policy Branch

| Version | Details | Date | Sign off |
|---|---|---|---|
| 1.0 | Issue date – previously known as DB2010(NI)-01 | Oct 2017 | |
| 1.1 | Revised to reflect changes required to meet requirements of Internal Audit recommendations | 03/10/2018 | DW |
| 1.2 | Revised as result of requirement to review and update document to remove reference to public reporting to NIAIC | 10/3/2020 | DW |
| 1.3 | Update to take into consideration current NIAIC and MHRA practices, including the withdrawal of MDA's and introduction of NatPSA's | Mar 2021 | RS |
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# Contents

# 1. Introduction

## 1.1 The Northern Ireland Adverse Incident Centre

The Northern Ireland Adverse Incident Centre (NIAIC) operates as part of the Chief Medical Officers (CMO) Group within the Department of Health (DoH). The key aim of the NIAIC is to seek learning from investigations into reported adverse incidents involving medical devices, non-medical equipment, plant and buildings used within the healthcare environment across Northern Ireland and to issue safety information and guidance to help prevent recurrence.

The importance of open reporting of adverse incidents in the healthcare environment has been proven in many instances with additional learning and improvement being achieved. Therefore part of NIAIC's work is in encouraging a shift to a safety culture, 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. Open reporting and a balanced analysis allows for focus on the true cause of the incident and any role of the underlying systems which enables improvements, if identified, to be made.

The introduction of effective clinical governance means that there is a shared goal between the individual and the organisation to minimise risk related to the use of medical devices, equipment and plant and thereby ensure that everyone who needs to use equipment can do so safely and effectively.

The NIAIC works closely with the Medicines and Healthcare products Regulatory Agency (MHRA) - the UK Competent Authority for Medical Devices, in relation to issues concerning medical device safety. The NIAIC also liaises closely with the NHS Improvement - England, Health Facilities Scotland and NHS Wales Shared Services Partnership - Facilities Services for safety issues concerning non-medical equipment, plant and building items.

Localised learning can be fed back to individuals and reporting organisations through investigation outcome closure letters. Wider generic learning is distributed to the healthcare environment through safety information released via the Northern Ireland Central Alerting Systems (NICAS). The NICAS is a web based application to notify users about new or updated safety information and can provide an assurance pathway to the DoH that the appropriate safety actions have been implemented by the HSC and other large acute service providers.

# 2. Reportable Events

## 2.1 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 staff, patients or other persons.

For example:

- a patient, user, carer or professional is harmed while using a medical device;
- a patient, user, carer or professional is harmed, or has the potential to be harmed, due to insufficient information contained in the Instruction for Use (IfU) or decontamination guidance;
- a medical device failure causes a misdiagnosis or leads to inappropriate treatment;
- a patient's health deteriorates, treatment is interrupted or compromised due to medical device failure;
- a reduction in service due to an unexpected failure of a device or part of the estate.

The following are not considered as an adverse incident, although they can be reported for regional trending in order to understand ongoing issues:

- The incident occurred due lack of training, use off label or failure to adhere to the Instruction for Use (IfU), FSN's or Alert;
- The device or equipment was not maintained in accordance with the manufacturer's guidance;
- The failure occurred due to normal wear and tear, general maintenance issues or the device or equipment exceeds the manufacture's stated end of life; and
- Where the user or organisation has failed to implement adequate control measures to manage a known or accepted risk.

## 2.2 What is a medical device?

A medical device is any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,

- control of conception,
- disinfection of medical devices,
- providing information for medical purposes by means of in vitro examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

General workshop equipment such as power or machine tools, general purpose laboratory equipment or aids for daily living are not considered as medical devices. A list of examples of Medical Devices is provided in Appendix 1.

**Note:** **An accessory is not considered to be a medical device. However, where an accessory is intended specifically by its manufacturer to be used together with the 'parent' medical device to enable the medical device to achieve its intended purpose, it should be considered as a medical device in its own right.**

**Note:** **Software and Applications (apps) on standalone computers and mobile devices are now classified as medical devices if the app is intended to carry out a medical function.**

## 2.3 What are Estates equipment, plant and building items?

Estates equipment, plant and buildings are items directly managed and controlled by an Estates and Facilities Department. This does **not** include general IT systems, except where they are classified as a medical device (see above). Examples of non-medical equipment, plant and building items are provided in Appendix 2.

## 2.4 What should be reported to the NIAIC?

Any adverse incident (as defined in section 2.1) involving a medical device and estates, plant, equipment or buildings should be reported to the NIAIC. It is important to recognise that relatively minor incidents and near misses can have a greater significance if aggregated with other similar reports.

## 2.5 Why report?

The information from adverse incident reports can help identify safety issues with medical devices or equipment. It can prevent similar incidents happening again through analysis to provide new learning, which can then be disseminated, either locally or wider. It is important that users report all adverse issues with devices, although not all incidents reported will produce or require an outcome from the MHRA, NIAIC or the manufacturers, but will add to a body of evidence pertaining to the safety of the device. Lower level information may be recorded to assist in future investigation, general discussion or to establish if any trend in failures is developing or there is a need for additional action.

## 2.6 Who should report?

Any healthcare worker, in the public or private sector, may submit an adverse incident report directly to the NIAIC. Reporters from the Health and Social Care sector should copy their report to or submit it via their Medical Device Liaison Officers and follow the incident reporting procedures of their organisation.

Submitting a report of an adverse incident to the NIAIC does not negate the need for the user to take immediate action to protect safety or the need to report to other systems/ bodies including local incident registers, statutory bodies, etc. including the PSNI, Coroner, PHA or Health and Safety Executive (under RIDDOR).

Patients and members of the public are encouraged to report Medical Devices adverse incidents via the Yellow Card Reporting Scheme, operated by MHRA. Anonymised copies of these reports that originate from within Northern Ireland, will be provided to NIAIC for action if deemed necessary. Section 7.2 below provides information on the MHRA Yellow Card Scheme.

## 2.7 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. Although further information may be requested or needed at a later date to assist the investigation. It is essential that the reporter provides an email address to initiate communications and enough information to identify the manufacturer and the model of the device/equipment in question

## 2.8 How do I report an incident?

Complete the appropriate NIAIC AI Form and return it via email or hard copy by post. AI Report forms may be downloaded/printed from the NIAIC pages of the DoH website.

Postal Address: Northern Ireland Adverse Incident Centre
Medical Device and Estates Safety Policy Branch
Safety Strategy Unit, CMO Group
Department of Health
Room D1
Castle Buildings
Stormont Estate
Belfast, BT4 3SQ

Telephone: +44 (028) 90523868
Email: niaic@health-ni.gov.uk
Website: https://www.health-ni.gov.uk/niaic

## 2.9 What do I do with devices or equipment that has been involved in an adverse incident?

When a device has been involved or implicated in an adverse incident it is necessary to ensure that the device or equipment is clearly identified, its location is recorded and any history (event logs, settings, accessories, etc.) are maintained for investigation.

The following non exhaustive information is provided for guidance only:

- If the adverse incident is likely to be the subject of a legal enquiry or corporate investigation you should quarantine any devices associated with the incident, including all accessories. The quarantined equipment should not be released until you are provided with confirmation, from the investigating body that the devices are no longer required and may be released.
- If there is no likelihood of a legal enquiry or corporate investigation the device can be made available to the manufacturer or their service agent for analysis and repair. In doing so they should be advised that the device was implicated in a reportable adverse incident and they may be asked to provide a full report of their findings to the MHRA or the NIAIC.
- If the failure to return the device to operational use would affect service delivery and or the immediate safety of individuals, the device may be checked/repaired as quickly as possible, verified safe by a competent person and returned to service. All work carried out on the device including service records should be documented and maintained as continuity of evidence for future investigation.
- Where decontamination/cleaning would destroy vital evidence, the item should be placed in protective containment, labelled and placed in quarantine. The manufacturer/supplier should be contacted for advice prior to any further action being taken. The MHRA publication ‘Managing Medical Devices’ contains advice on decontaminating healthcare equipment. For additional information contact your local Infection Control Specialist, particularly if the item requires examination prior to any decontamination.

**Important:** **If you are in any doubt about what to do with a device, contact your local medical device liaison officer or the NIAIC.**

**Do not send medical devices to the NIAIC unless specifically requested by the NIAIC. Please note that it is illegal to send contaminated items through the post**

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

When an adverse incident report is received the details are recorded on the NIAIC Adverse Incident Register. The NIAIC team will assess the report to see if it meets the reporting criteria before undertaking any action. For medical device related incidents the MHRA will be notified and if necessary the details will be forwarded to the device manufacturer for inclusion on their post market surveillance register and

consideration for investigation or action. For estates reports the basic details maybe shared with other Devolved Administrations to assist with incident identification.

The NIAIC will monitor and review the manufacturer's response and any actions they propose to take. If it is felt necessary, the NIAIC may request additional information or highlight the issue to the MHRA or other Regulatory Bodies for consideration. If thought necessary, the NIAIC may visit site to gather further information to assist in the identification of new learning.

All reports are acknowledged and reporters advised of the nature and outcome of any investigation.

## 2.11 Reporting multiple occurrences of an incident

Although single reports have on occasion (by themselves) enabled the NIAIC, the MHRA or a manufacturer to bring about changes to the design or instructions for use of a device, multiple reports give increased leverage when assessing the need to initiate change. Hence we would recommend that you report each occurrence of an incident and do not assume that because a similar event was previously reported that there is no further need for additional reporting.

## 2.12 How long do reports remain open?

Incidents will remain open until the manufacturer completes their investigation or no further action is deemed necessary. On average, 70% of incidents are concluded within 10 weeks. Investigations maybe delayed by the lack of availability of the device or the need for a longer post market evaluation to gauge the scale of the problem.

For general enquiries about adverse incidents involving medical devices contact our Adverse Incident Centre: niaic@health-ni.gov.uk or 028 90523868.

## 2.13 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 provided as we consider appropriate in the interest of safeguarding public health. Please see the NIAIC Privacy Notice (NIAIC Privacy Notice)

The NIAIC does not require patient names or other identifying information in order to carry its functions. Healthcare staff when reporting incidents should ensure that all patient details that may identify an individual are deleted or redacted from the report or any accompanying attachments.

The details that we do require are clearly detailed on the NIAIC Adverse Incident report forms. The reporter's full contact details (name, email address, post held etc.) are essential, as this allows the NIAIC or the manufacturer to contact the reporter to acknowledge receipt of the report, to request any further information or request the return of the device and provide the outcome of the investigation.

Technical and scientific information relevant to our investigations may be sought or shared with bodies such as the MHRA and/or the Department of Health as well as with the supplier or manufacturer.

# 3. Safety Information

## 3.1 NIAIC Safety Information

Safety information from the NIAIC will be distributed by the Northern Ireland Central Alerting System (NICAS), for information on this system see section 5.1.

## 3.2 National Medical Device Safety Information

The MHRA, as the UK Competent Authority for Medical Devices, is responsible for producing safety information in respect of medical devices. This information which will be distributed, in Northern Ireland, by the NIAIC if it is deemed appropriate.

Currently the MHRA issues three types of safety information.

### 3.2.1 National Patient Safety Alert – Medical Devices

The Medicines and Healthcare products Regulatory Agency (MHRA) is now an accredited issuer of National Patient Safety Alerts, a format devised by NHS England. National Patient Safety Alerts are alerts that require local executive management level action to reduce the risk of death or serious harm. These alerts follow the criteria and template agreed by the National Patient Safety Alerting Committee (NaPSAC) and are not be limited to medical device issues. Therefore, MHRA medical device alerts will be interleaved with other Patient Safety Alerts and the reference numbers for medical device alerts may not hold a consecutive reference number. The NIAIC will continue to require assurance on this type of alert via the NICAS.

### 3.2.2 Targeted Letters

Where a safety issue is limited to a number of known sites a Targeted Letter may be used to provide guidance on the action required. Depending on the severity of the issue they may require similar assurance to that of NatPSA's at executive level.

### 3.2.3 General Medical Device Safety Information

The MHRA will continue to provide a range of other medical device safety guidance under a number of different formats. These do no not require local executive management assurance. Currently these take the form of; Medical Device Safety Bulletins and general safety information (found on their website), although the MHRA may introduce new categories to meet specific needs. The NIAIC will be releasing all these under the title Medical Device Safety Information (MDSI) until further advised.

### 3.2.4 Guidance Reports (formally Device Bulletins)

The MHRA continue to provide and update guidance reports (formally Device Bulletins).

Medical Device Alerts (MDAs) are no longer being generated and issued, although the Department and the NICAS websites will continue to display a list of those alerts that are still in force, with links to the original documents. If a MDA is not listed on these sites, it may have been either superseded or withdrawn.

## 3.3 Estates and Facilities Alerts (EFAs)

Estates and Facilities Alerts (EFAs) are produced nationally and distributed by the NIAIC to the Northern Ireland healthcare community. They contain safety information on estates issues to provide new learning or reinforce safety information.

EFAs were introduced at the start of 2010 as a national alerting system and are simultaneously published in England, Wales, Scotland and Northern Ireland. The alert in each of the Devolved Administrations will carry the same reference number.

EFAs replaced safety advice on estates, plant and buildings previously provided under the Medical Device/Equipment Alert (MDEAs) numbering system. The NIAIC website provides lists of all current EFA's. Please note that EFA's and MDEA's over 10 years old are not maintained by NIAIC, although may contain relevant information.

## 3.4 Northern Ireland Alerts (NIAs)

Northern Ireland Alerts (NIAs) are the NIAIC's means of communicating safety information for either medical devices or estate and facilities which is primarily focused on an issue applicable to Northern Ireland.

NIAs were introduced at 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 national investigation i.e. they may be superseded by national advice at some point in the future.

# 4. Field Safety Corrective Actions and Field Safety Notices

## 4.1 What is a FSCA?

Under the terms of the Medical Devices Regulations, the manufacturer is responsible for the safe functionality of the devices they manufacture. If they find an issue related to the safe functionality or use of their device which could potentially cause serious harm or death they must report this to the MHRA (the UK Competent Authority for medical devices) along with an action plan on how they propose to managing the risk. The problem and their proposed action is detailed in a document called a Field Safety Corrective Action (FSCA). If this action plan requires the end user to take action on devices in their possession, the manufacturer will distribute a Field Safety Notice (FSN).

## 4.2 What is a FSN?

A Field Safety Notice (FSN) is a safety communication issued by a medical device manufacturer, or their representatives, to all of their known customers and users of the device. A FSN details; the immediate actions being taken by the manufacturer; what they proposes to do to reduce the risk of patient harm associated with the known issue; the action the user needs to take; the time scale for the action; and most importantly, a reply slip for the customer/user to acknowledge they have received the FSN.

## 4.3 What should an organisation do if it receives an FSN?

It is essential that organisations undertake the actions detailed in the FSN and reply to the manufacturer, acknowledging receipt and providing any information requested on the FSN. An organisation's reply to the manufacturer is the evidence that the manufacturer requires to provide assurance to the MHRA that the problem is being addressed in accordance with the FSCA. Without adequate assurance, from the manufacturer, that appropriate action has been taken on devices in service, the MHRA may take additional action where it is deemed necessary

In accordance with medical device alert (MDA-2014-037) organisations should ensure that they have systems and procedures in place for the appropriate collection and dissemination of FSNs. This information should then be distributed to all relevant personnel within their organisation and to ensure that the appropriate action has been taken. The above suggests that organisations should centrally record all FSNs sent to them and monitor the required action.

The MHRA currently place manufacturers' FSNs on its website for information only and do not distribute them, unless individual organisations sign up for the appropriate safety information on their website.

# 5. Northern Ireland Central Alerting System (NICAS)

## 5.1 The Northern Ireland Central Alerting System (NICAS)

The Northern Ireland Central Alerting System is a web based application utilised by the NIAIC for the issue of relevant safety information, including links to alerts applicable to the Northern Ireland healthcare environment. The application provides an assurance loop to the DoH from relevant HSC organisations. This requires those organisations to acknowledge they have received and taken the appropriate action.

The NICAS has four user access levels:

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| Actioner: | Actioners are generally persons working within HSC Organisations. The actioner is typically the MDLO or a person designated by the executive management team for medical devices, to carry out the assurance function on behalf of their organisation. This type of user receives an email to notify them that a new safety communication has been published on NICAS. This email also contains a copy of the published safety communication. Actioners will have a secure login, which provides full access to all the information on the NICAS website. They are required to acknowledge they have received the information and to provide assurance that the actions contained within the communication have been completed within their organisation. All users are responsible for ensuring that they keep their own contact details up to date. |
| Secure User: | This type of user receives an email to notify them that a new safety communication has been published on NICAS. This email also contains a copy of the published safety communication. The Secure user will have a secure login, which provides full access to all information on the NICAS website, however they cannot update assurance information for their organisation. |
| Registered User: | This type of user receives an email to notify them that a new safety communication has been published on NICAS. This email also contains a copy of the published safety communication. Registered users have web access to public facing information on the NICAS. |
| Public: | The public can viewed non secure information on the public facing web pages. |

For general enquiries about NICAS contact our Adverse Incident Centre by email at niaic@health-ni.gov.uk or by telephone on 028 90523868.

# 6. Medical Device Liaison Officer (MDLO)

## 6.1 Role of medical device liaison officers (MDLOs) in HSC Trusts

The MDLO role is integral to improving medical device incident reporting and learning from incidents within HSC organisations. One of the MDLO's key roles is to promote the safe use of medical devices across their organisation, by encouragement and training in the reporting of adverse incidents, so that learning can be identified. As well as improving the quality of reporting, the MDLO will be the essential link between the identification and implementation of (local and national) medical device safety initiatives and investigating device related incidents in order to improve the safety of medical devices.

*Roles and responsibilities should include:*

- improve reporting of and learning from medical device incidents in the organisation;
- manage medical device incident reporting in the organisation; review all medical device incident reports to ensure data quality for local and national learning; where necessary investigate and get additional information from reporters;
- make sure that medical device incidents are sent to the NIAIC as soon as possible;
- receive and respond to requests for more information from the NIAIC about medical device incident reports;
- active membership of the regional Medical Devices Safety Network (NIAIC Webex);
- support the dissemination of medical devices and estates safety communications from the NIAIC throughout the organisation;
- provide assurance on behalf of their organisation into the NICAS that their organisation has acted on the published safety communications;
- act as an additional senior point of contact for manufacturers regarding Field Safety Notices and support the local action required by the organisation in relation to a Field Safety Notice
- maintain knowledge of issues arising regarding medical device safety – e.g. participate in national Medical Device Safety Officer Webex and chat forums.

# 7. Other reporting systems

## 7.1 Serious Adverse Incidents (SAIs) Reporting

Health and Social Care (HSC) Trusts, Family Practitioner Services (FPS) and Independent Service Providers (ISP) must report Serious Adverse Incidents (SAIs) arising during the course of business of an HSC organisation/Special Agency or commissioned service, to the Health and Social Care Board (HSCB) who are working in close partnership with the Public Health Agency (PHA) and the Regulation Quality Improvement Authority (RQIA) for the recording and follow up of SAIs.

All SAIs that involve Medical Devices, non-medical devices plant or building equipment **must also** be reported to the NIAIC utilising the NIAIC adverse incident form.

## 7.2 The MHRA Yellow Card Scheme

The Yellow Card Reporting Scheme is operated by the MHRA. The scheme enables safety reporting to be made for all medicines including vaccines, blood factors and immunoglobulins, herbal medicines and homeopathic remedies, and all medical devices available on the UK market, however, in NI, medical device incidents should be reported to NIAIC in the first instance, who in turn mirror these to the MHRA.

During the period of the Covid epidemic the NIAIC supports the use of the MHRA's Yellow Card System to report failures or suspected side effects to medicines, vaccines or medical device and diagnostic adverse incidents used in coronavirus treatment. This system is open to either healthcare professionals or members of the public.

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| **NB** | **Within Northern Ireland any incident involving medical devices within the healthcare should be reported as per the guidance in this document. HSC Staff who report or are informed of any reporting via the Yellow Card scheme should ensure that their MDLO is notified and the NIAIC are copied in on the incident report.** |

## 7.3 SABRE & SHOT (reporting blood safety and quality incidents)

With the introduction of the Blood Safety and Quality Regulations 2005 No. 50 and The Blood Safety and Quality (Amendment) (No.2) Regulations 2005 No. 2898 (effective for the purposes of regulation on 8 November 2005), the MHRA became responsible for ensuring that blood products, blood establishments and blood banks are acceptably safe.

Incidents relating to blood safety and quality should not be sent to the NIAIC. 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). 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
Tel: 020 7084 3336 Fax: 020 7084 3109

**SHOT**
Email: shot@nhsbt.nhs.uk
Tel: 0161 423 4208 Fax: 0161 423 4395

### 7.4 RIDDOR

In addition to reporting medical device related incidents to the NIAIC, incidents involving an injury, occupational disease or dangerous occurrence, to an employee, whether involving medical devices or not, should also be reported under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR (NI) 97) 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: mail@hseni.gov.uk
www.hseni.gov.uk

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

## 8.0 Contacts

Enquiries concerning the content of this document should be addressed to: niaic@health-ni.gov.uk or by telephone on 028 90523868.

Annex 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
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
*It does not include devices or equipment with no medical function*

**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

Annex 2

## Examples of 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.

Lightning protection and electrostatic discharge systems.

Incinerators and other clinical waste treatment equipment.

Environmental aspects (buildings) and 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.

Fixtures and fittings which have been installed to prevent patients self-harming.

Incorrect installation.