

Estates and Facilities Division Alert

Engineering, Technology and Environment



Alert Category Immediate Action
 Action
 Update
 Information Request

DH (2007) 01

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Mandatory reporting of Defects and Failures and disseminating DH Estates and Facilities Alerts (ROCR Ref No: **ROCR/OR/0117/FT6/001**)

The purpose of this document is to remind NHS Trusts, NHS Foundation Trusts and PCTs of the importance of reporting **Defects and Failures (D&Fs)** involving non-medical devices, and the dissemination of DH Estates and Facilities Alerts.

All staff working in a healthcare environment have a responsibility to report to the Department of Health, defect or failures that occur at work. This alert replaces previous guidance.

Defects and Failures can now be reported on-line through the efm information module (<http://nww.efm.ic.nhs.uk>).

The document provides guidance on:

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HOW TO REPORT DEFECTS AND FAILURES

All staff working in a healthcare environment have a responsibility to report any defect or failure that occurs at work to the Department of Health. Guidance for reporting such incidents is contained in DH (2006) 01. If you have any queries, please seek advice from your Line Manager or the Department of Health

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1.0 Actions Required

Chief Executive / Board Member with special responsibility for health and safety should ensure that in accordance with local procedures this Alert is brought to the attention of appropriate staff for information purposes.

The following actions should already be in place:

- 1.1 Reviewing existing arrangements to ensure prompt mandatory reporting of Defects and Failures.
- 1.2 Ensure personnel are familiar with the on-line D&F reporting system available on the efm information website (<http://nww.efm.ic.nhs.uk>).
- 1.3 For a user login and password please contact the information centre on 0845 3006016 (option 1).
- 1.4 Make sure a liaison person (Director of Estates and Facilities or other person) has been appointed to coordinate the effective reporting, receiving and disseminating of non-medical equipment [Defect and Failure Alerts](#).
- 1.5 Facilitating the use of the Defect and Failure reporting system Trust wide.
- 1.6 Advising SABS helpdesk on Tel 020 7972 1500 email safetyalerts@dh.gsi.gov.uk of changes to contact details.
- 1.7 Ensure relevant personnel are familiar with the DH Estates and Facilities website on which all alerts are posted.

2.0 What Defect and Failures are reportable?

Estates and Facilities Division deals with Defects and Failure relating of non-medical devices in the following categories:

- 2.1 Building, building components and lifts.
- 2.2 Demolitions and construction carried out under CDM regulations, including plant.
- 2.3 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.
- 2.4 Fire protection installations and equipment.
- 2.5 Permanently installed sterilizers, bedpan washers and disposal units.
- 2.6 Equipment in laundries, catering departments, workshops and any other plant or equipment used for maintenance or cleaning.
- 2.7 Piped medical gas and vacuum systems, cryogenic liquid systems (CLS) including vacuum insulated evaporators (VIEs) and anaesthetic gas scavenging systems.
- 2.8 Fixed luminaries including examination lamps.
- 2.9 Communications equipment (e.g telephone and bed head services, nurse call systems, paging systems, alarm and audio equipment).
- 2.10 Lightning protection and electrostatic discharge systems.
- 2.11 Incinerators and other clinical waste treatment equipment.
- 2.12 Environmental aspects (buildings) of the Control of Substances Hazardous to Health (COSHH) Regulations.
- 2.13 Installation aspects of fume cupboards and microbiological safety cabinets, including ductwork and their interaction with ventilation systems.
- 2.14 Ambulances and similar vehicles, tugs etc. excluding those vehicles that are for disabled persons, leased vehicles and goods vehicles.

3.0 Definition of reportable Defects and Failures

3.1 A reportable Defect and Failure can be classed as:

- 3.1.1 Any event, which gives rise to or has the potential for unexpected or unwanted effects involving the safety of patients, staff or others.
- 3.1.2 Incidents that arise through incorrect use, inappropriate modifications or adjustments, or inadequate servicing and maintenance procedures.
- 3.1.3 Deficiencies in the technical or economical performance of equipment.

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- 3.1.4 Any defects in product, or product instructions, identified by Health and Safety Inspectors of Local Authority Inspectors.
- 3.1.5 Failures in critical services (electricity, water, steam, gas, communications etc).

3.2 A report is required for products listed in paragraph 2.0 above in respect of:

- 3.2.1 Any fatal accident or serious injury.
- 3.2.2 RIDDOR 95 incidents related to equipment contributed accidents.
- 3.2.3 An explosion or sudden fracture of any pressure vessel, pressurised system or steam / high pressure water main.
- 3.2.4 Any major electrical explosion (e.g transformers or switchgear).
- 3.2.5 Any runaway or crash of a passenger lift.

4.0 How reporting should be carried out

4.1 On-line reporting (preferred option)

- 4.1.1 Effective from 1st November 2004, Estates and Facilities Division have made available an on-line reporting system as part of the efm information module. See exhibit 1 – efm information module (<http://nww.efm.ic.nhs.uk>). Further information is available from the efm-information Helpdesk, Tel 0113 254 7010.
- 4.1.2 Exhibit 2 shows the layout of the on-line D&F reporting form.

4.2 Paper based reports

The form D&F 01 is available on the [DH Estates and Facilities website](#) (see exhibit 3). The form can be completed electronically and e-mailed to Estates and Facilities or printed and sent by mail or fax to:

Anne Grace	Tel: 0113 254 5694
Defect and Failure Project Officer	Fax: 0113 254 5793
Estates and Facilities Division	Email: anne.grace@dh.gsi.gov.uk
Department of Health	
3N 34A Quarry House	
Leeds LS2 7UE	

4.3 Out of hours reporting

- 4.3.1 Out of hours verbal reports can be made to the DH Estates and Facilities Division on (0113) 254 6881.
- 4.3.2 Ensure the following information is clearly stated,
 - a) Full name of the caller
 - b) Position held
 - c) Location of incident
 - d) Contact telephone number(s)
 - e) Concise details of the incident
- 4.3.3 When reports have been submitted by telephone, a written report should always follow without delay to Estates and Facilities Division.

5.0 Other actions and responsibilities

This reporting system does not affect the duty of staff locally to take actions as required legally and / or by line management, as a result of a defect and failure. Additional actions may be required as follows:

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- 5.1 Prevent further use of products that may be defective.
- 5.2 Report to particular NHS officer (e.g radiation hazards to the Radiation Protection Advisor, infection issues to Infection Control).
- 5.3 Reporting to the Health and Safety Executive (HSE) "Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR 95)".
- 5.4 To report under "Ionising Radiation Regulations 1999".

6.0 What should happen to defective / failed items?

All defective equipment is potential evidence and should be treated as such:

- 6.1 All material evidence shall be identified and kept secure under the charge of a responsible officer (see notes below).
- 6.2 If possible photographs (ideally digital) should be taken of the incident scene and / or the damage.
- 6.3 Defective / failed items should not be interfered with in any way except for safety reasons or to prevent injury or loss.
- 6.4 Where appropriate a record should be kept of all readings, settings and position of switches, valves, dials, gauges and indicators etc.
- 6.5 A detailed incident report shall be compiled and if necessary eyewitness reports should also be obtained. In serious cases, these reports should be signed in front of witnesses.
- 6.6 The manufacturer should be notified promptly and shall be allowed accompanied access with a responsible officer, to inspect the equipment. Care must be taken to ensure the manufacturer does not exchange, interfere or remove any part, as this could prejudice any subsequent investigations of the Department or other official bodies (see note below).
- 6.7 The equipment should not be handed over to the supplier, repaired or discarded before Estates and Facilities have had an option to investigate and agreed a course of action (see note below).
- 6.8 Where there is a clinical need for the equipment to be kept in use, any defective parts must be clearly identified. They can be removed, secured and identified for later inspection and the equipment can be repaired for re-use after due consultation with local risk management.
- 6.9 If equipment is contaminated and constitutes a bio hazard, advice contained in Device Bulletin, MHRA DB2003(050) "Management of Medical Devices Prior to Repair, Service or Investigation", should be followed.

NOTE:

- 1) **It is illegal to send contaminated items through the post.**
- 2) **Health and Safety Inspectors have legal powers under the Health and Safety at Work Act 1974, to enter property at a reasonable time, and take possession or sample any equipment, material or article, make examinations, take measurements, photographs, order dismantling, question personnel and take copies of documents.**
- 3) **Health and Safety Inspectors often act or investigate on behalf of the Coroner.**

7.0 What actions will Estates and Facilities take?

7.1 When Estates and Facilities receive a Defect and Failure report the following action(s) are taken:

- 7.1.1 The report is logged onto the Estates and Facilities Defect and Failure database.
- 7.1.2 An acknowledgement letter is sent to the originator with a unique D&F number that should be quoted in all correspondence.
- 7.1.3 The manufacturer / supplier is informed and a copy of the incident report sent to them.
- 7.1.4 The reports are evaluated by qualified engineers for further appropriate action(s).

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- 7.1.5 Estates and Facilities Division staff **may** visit the site, discuss the incident with Trust representatives, the manufacturer and liaise with Health and Safety Executive.
- 7.1.6 Based on the historical evidence, the seriousness of the incident, the manufacturers report and Estates and Facilities own investigations, Estates and Facilities may issue an Alert to the NHS through the Safety Alert Broadcast System (SABS).

7.2 Safety Alert Broadcast System (SABS)

SABS is a system for electronically disseminating Alerts to all NHS Trusts and Primary Care Trusts in England. The Alerts are e-mailed to SABS liaison officers. The system includes a feedback mechanism showing applicability and progress on actions taken. The DH Patient Safety Team should be informed of any changes to the SABS contact person on Tel: 020 7972 1500 or e-mail safetyalerts@dh.gsi.gov.uk

7.3 Types of Alerts issued by Estates and Facilities Division

The types of Alerts Estates and Facilities may issue are as follows:

Type	Description
IMMEDIATE ACTION	Used in cases where there is a risk of death or serious injury and where the recipient is expected to take immediate action on the advice
ACTION	Used where the recipient is expected to take action on the advice, where it is necessary to repeat warnings on long standing problems, or to support or follow-up manufacturers field modifications.
UPDATE	Used to update the recipient about previously reported incidents or series of incidents, possibly on a topical or device group basis, and where further follow-up safety information is judged to be beneficial.
INFORMATION REQUEST / NOTICE	Used to alert users about a specific issue that may become a problem and where Estates and Facilities are requesting feedback. There Alerts will be sent out with additional questions to be completed

- 7.2 Depending on the seriousness / number of previous occurrences, Estates and Facilities Division will note the incident and / or issue a briefing note in the Estates and Facilities Bulletin.
- 7.3 Estates and Facilities Division will continue to monitor all failures and if necessary issue / modify appropriate guidance.

Exhibit 1 – efm information module

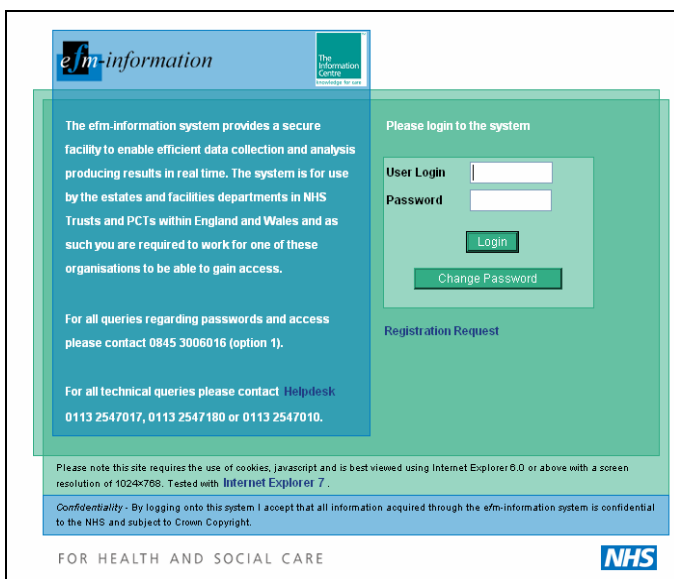
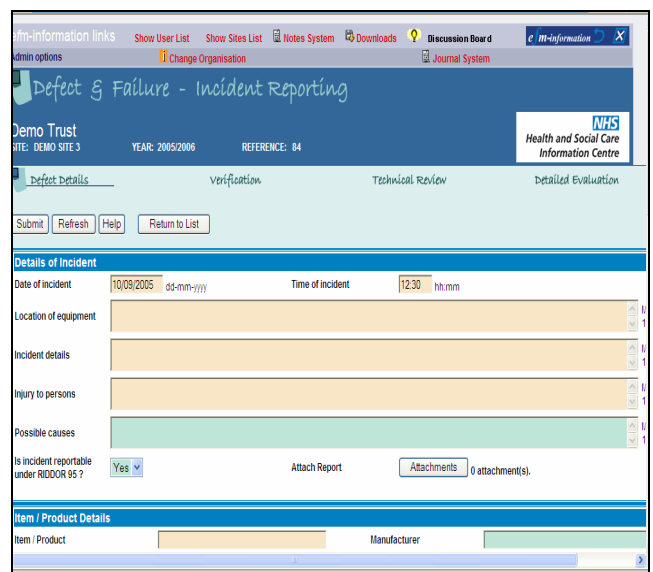


Exhibit 2 – Layout of on-line D&F reporting form



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Exhibit 3
Manual D&F report form

DH Department of Health DEFECT AND FAILURE REPORT FORM <small>(Relating to non-medical equipment, engineering plant, installed services, buildings or building fabric)</small>	
Please return to: Anne Grace Engineering, Technology & Environment Estates and Facilities Division Department of Health 3N 544 Quarry House Quarry Hill Leeds LS2 7UE Tel : (0113) 25 45694 Fax : (0113) 25 45793 Email : anne.grace@dh.gsi.gov.uk	
1) DETAILS OF PERSON REPORTING THE INCIDENT Name : _____ Position : _____ Trust / HA : _____ Site code if known : _____ Address : _____ Post Code : _____ Tel : _____ Fax : _____ E mail : _____	
2) DETAILS OF INCIDENT Date of incident : _____ Time of incident : _____ Location of incident : _____ Incident details : _____ Injury to person(s) : _____ Possible cause(s) : _____ Is the incident reportable under RIDDOR 95 <input type="checkbox"/> Yes / No <input type="checkbox"/> If Yes - Attach copy	
3) ITEM / PRODUCT DETAILS Item / Product : _____ Manufacturer : _____ Model No : _____ Serial No : _____ Date of Purchase : _____ Product Marking(s) : CE / or other (State) Manufacturer / Supplier's Address : _____ Post Code : _____ Manufacturer's Contact Name : _____ Position : _____ Tel No : _____ Fax No : _____ E-mail : _____	
4) EXTENT OF ITEM / EQUIPMENT USAGE Extent of usage _____ Previous similar incidents _____ Disruption to services <input type="checkbox"/> Yes / No <input type="checkbox"/> If Yes - state Other Equipment affected <input type="checkbox"/> Yes / No <input type="checkbox"/> If Yes - state	
5) MANUFACTURER CONTACTED Has manufacturer been contacted? <input type="checkbox"/> Yes / No <input type="checkbox"/> If Yes - Specify Has there been correspondence with manufacturer? <input type="checkbox"/> Yes / No <input type="checkbox"/> If Yes - Attach Has an internal report been generated? <input type="checkbox"/> Yes / No <input type="checkbox"/> If Yes - Attach Has photo been taken? <input type="checkbox"/> Yes / No <input type="checkbox"/> If Yes - Attach	
6) REMEDIAL ACTION What actions have already been taken to correct the problem? _____ Approx Cost (if Known) £ _____ What actions have been taken / will be taken to ensure incident does not recur? _____ Approx Cost (if Known) £ _____ Additional Comments : _____ Signed : _____ Date : _____ <small>Please attach photos, copies of manufacturer's manual, internal investigation / incident and other relevant information by email or post.</small>	

Exhibit 4
Safety Alert Broadcast System (SABS) website

About us | Site map | Help | Contact DH

DH Department of Health

DH Home **You are here: Chief Medical Officer > Safety Alert Broadcast System**

CMO Home
 Safety Alert Home
 Using this site
 Broadcasts by Date by Reference Search Alerts
 LOGIN

Welcome to the Safety Alert Broadcast System

Safety alerts issued by the Medicines and Healthcare products Regulatory Agency (Medical Device Alerts only), DH Estates & Facilities, the National Patient Safety Agency and patient safety specific guidance from the Department of Health are available on this website.

These pages are aimed at NHS staff with a particular interest in, or responsibility for, safety of equipment, buildings and patients, including Safety Alert Broadcast System liaison officers in NHS Trusts and Primary Care Trusts. The safety alerts are also likely to be of interest to other organisations which deliver patient care.

To access the latest safety alerts (also referred to as broadcasts), please use the links to the right of the screen. Older alerts can be accessed via the menu on the left or via a search. Please note that alerts issued prior to 28 April 2004 are not available on this site, but can be accessed using the links below. Refer to the "Using this site" page for further information. A file of the alert is attached to each broadcast - most in PDF format - click here to download Adobe Acrobat if necessary to read these.

Useful Links: National Patient Safety Agency | Medicines and Healthcare products Regulatory Agency | DH Estates & Facilities | Public Health Link | Healthcare Commission

NHS Trusts and Primary Care Trusts can use the log in button in the menu to access more detailed information about safety alerts which have been emailed to them, together with further guidance on the Safety Alert Broadcast System. Strategic Health Authorities can also use this function.

Click Here to access alerts issued before 1 October 2006

Latest Broadcasts

REPORTING MEDICAL DEVICE ADVERSE INCIDENTS AND DISSEMINATING MEDICAL DEVICE ALERTS (Medical Device Alert) (added 02/01/2007)

SECURITY IN MEDIUM SECURE PSYCHIATRIC UNITS (Patient Safety Alert) (added 22/12/2006)

QUATTRO CARE SPRAY CANS FOR USE IN KAVO QUATTRO CARE DENTAL HANDPIECE MAINTENANCE SYSTEM (Medical Device Alert) (added 20/12/2006)

COUNTERFEIT CONDOMS: DUREX FETTERLITE 3 PACK - LOT 21405074 DUREX PERFORMA 3 PACK - LOT T6L4142 DUREX GOSSAMER 3 PACK - LOT 21405074 (Medical Device Alert) (added 19/12/2006)

RADIAL ARTERY INTRODUCER SETS: WILLIAM COOK EUROPE FLEXIORB CHECK-FLOB MICRO PUNCTURE RADIAL ARTERY ACCESS INTRODUCER SETS WITH AOB HYDROPHILIC COATING. SEE APPENDIX FOR PART NUMBERS (Medical Device Alert) (added 18/12/2006)

Exhibit 5
DH Estates and Facilities Alerts

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DH Estates alerts

DH Estates and Facilities are committed to providing a safe environment and reducing risks to patients, staff and visitors in the NHS. 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.

An on-line reporting facility introduced in 2004 enables NHS organisations to file defects and failures reports on-line. Alternatively the form is available for download here.

>> Defect and failure reports can be submitted online via the Information Centre (opens new window)
 > Download word-processable D&F report form (RTF, 163K)

Further information can be obtained from Anne Grace, telephone: 0113 254 5694.

2006 Alerts

Please note: due to the nature and content of DH (2006) 07, it is not suitable for posting on the public internet

- > DH (2006) 09: Electrical distribution Switchgear, 160A and 200/250A FCS Switches/Fuse switches
- > DH (2006) 08: Waste compactor
- > DH (2006) 06: Steam cleaner/ vacuum cleaner
- > DH (2006) 05: Shower heads
- > DH (2006) 04: RCBO's: Merlin Gerin and Square D
- > DH (2006) 03: Infrared personal attack alarm systems
- > DH (2006) 02: Smoke detector

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