Estates and Facilities Alert

INFORMATION

Ref: EFA/2013/003 Issued: 14th October 2013

Notice

Reporting of Defects and Failures and disseminating Estates and Facilities Alerts – Interim reminder
(ROCR Ref No: ROCR/OR/0117/FT6/002MAND)

Information

The purpose of this document is to remind NHS healthcare providers, Trusts, NHS Foundation Trusts, Clinical Commissioning Groups, Dental practices and GP surgeries of the importance of reporting defects and failures (D&F) involving plant, infrastructure and non-medical devices, and the dissemination of Estates and Facilities Alerts (EFA).

Please note this alert is an interim reminder, but from 2014 will revert to being the first issued each year. This approach has been approved by NHS England.

In the interests of patients, staff and visitors safety, all staff working in a healthcare environment have a responsibility to report to the Department of Health defect or failures that occur at work.

Defects and Failures should be reported on-line through the efm information module at http://www.efm.ic.nhs.uk/.

In the interests of safety and to enable the sharing of information across all NHS service providers, it is important to ensure that the use of local reporting and risk management systems does not result in the reporting of relevant defects and failures being overlooked. If a relevant incident report is submitted to another body (for example the Health & Safety Executive), a report should also be entered onto the efm-information system. http://www.efm.ic.nhs.uk

This document provides guidance on:

1. Actions required by all providers of NHS services.
2. What are the categories of plant, devices and building fabric for which the efm-information system should be used?
3. What is a defect or failure, when should they be reported and when must they be reported?
4. How reporting should be carried out.
5. Other actions and responsibilities.
6. What should happen to defective / failed items?
7. What actions the Department of Health will take.

1. Action required by providers of NHS services

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

information purposes.

The following actions should already be in place:

1. Ensure a designated liaison person is responsible for the receiving and disseminating of EFA's for non-medical equipment and infrastructure or service plant.
2. Review your existing arrangements, to ensure there is a person in place with responsibility for promptly reporting appropriate defects and failures.
3. Ensure personnel are aware of the on-line defects and failures reporting system available on the efm-information website http://www.efm.ic.nhs.uk/

   For a user login and password please contact the NHS Information Centre on 0845 3006016.
4. Ensure relevant personnel are familiar with the Central Alerting System website where EFAs are posted www.cas.dh.gov.uk. Advising the Central Alerting System (CAS) helpdesk on Tel 020 7972 1500 or email safetyalerts@dh.gsi.gov.uk of changes to CAS liaison officer contact details.

2. What are the categories of plant, devices and building fabric for which the efm-information system should be used?

The NHS Estates and Facilities Policy Division deals with D&F relating to non-medical devices and infrastructure or service plant in the following categories:

1. Building and building components (e.g. windows, doors, ceilings etc) and lifts.
2. Engineering plant and services of all types (e.g. boilers, pressure systems, generators, heating and ventilation systems, specialised ventilation systems (e.g. theatres and isolation rooms), hot and cold water systems, drainage systems, electrical installations) and any other fixed plant equipment, but not medical devices.
3. Demolitions and construction carried out under CDM regulations, including plant. E.g.failures of protocols, such as hosing down to prevent spread of Aspergillus etc.
4. Fire protection installations and equipment.
5. Permanently installed sterilizers, bedpan washers and disposal units.
6. Equipment in laundries, catering departments, workshops and any other plant or equipment used for maintenance or cleaning.
7. Piped medical gas and vacuum systems, cryogenic liquid systems (CLS) including vacuum insulated evaporators (VIE's) and anaesthetic gas scavenging systems.
8. Fixed luminaires including examination lamps.
9. Communications equipment (e.g. telephone and bed head services, nurse call systems, paging systems, alarm and audio equipment).
10. Lightning protection and electrostatic discharge systems.
11. Incinerators and other clinical waste treatment equipment.
12. Environmental aspects (buildings) of the Control of Substances Hazardous to Health (COSHH) Regulations.
13. Installation aspects of fume cupboards and microbiological safety cabinets, including ductwork and their interaction with ventilation systems.
14. Ambulances and similar vehicles, tugs etc. excluding those vehicles that are for disabled persons, leased vehicles and goods vehicles.

3. What is a defect or failure and when should they be reported?

3.1 What amounts to a defect or failure can be classed as:

a) Any event, which gives rise to or has the potential for unexpected or unwanted effects involving the safety of patients, staff or others, arising out of the defect or failure of the equipment.

b) Incidents that arise through incorrect use, the role for which it is intended, inappropriate modifications or adjustments, or inadequate servicing and maintenance procedures, which result in a defect or failure of equipment.

c) Deficiencies in the technical or economical performance of equipment.

d) Any defects in product or product instructions, identified by Health and Safety Inspectors or Local Authority Inspectors.

e) Any failure in critical services (electricity, water, steam, gas, communications etc).

3.2 Healthcare providers **must** report defects or failures relating to section 2 categories where:

a) there has been a fatal accident or serious injury.

b) a RIDDOR 95 incident relating to equipment that contributed to an accident.

c) there was an explosion or sudden fracture of any pressure vessel, pressurised system or steam / high pressure water main.

d) there has been a major electrical discharge or explosion (e.g. transformers or switchgear).

e) there has been a runaway passenger lift or a crash.

4. How to report a Defects and failures

The D&F reporting system is an online reporting system, using a single web-based reporting portal managed by the NHS and Social Care Information Centre on behalf of the Department of Health.

Defects or failures should be reported through the this on-line reporting system at http://www.efm.ic.nhs.uk/

As reporting Defects and Failures is necessarily 'by exception', it is not necessary to obtain a login name and password in advance.

Further information is available from the efm-information Helpdesk. Tel 0845 3006016.

5. 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, because of a defect and failure. Additional actions may be required as follows:

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

6. What should happen to defective/failed items?

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

b) All material evidence shall be identified and kept secure under the charge of a responsible officer (see notes below).

c) If possible photographs (ideally digital) should be taken of the incident scene and / or the damage.

d) Defective / failed items should not be interfered with in any way except for safety reasons or to prevent injury, damage or loss.

e) Where appropriate a record should be kept of all readings, settings and position of switches, valves, dials, gauges and indicators etc.

f) A detailed incident report shall be complied and if necessary eyewitness reports should also be obtained.

g) In serious cases, these reports should be signed in front of witnesses.

h) The manufacturer/supplier should be promptly notified directly by the healthcare provider 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 by other official bodies.

i) The equipment should not be handed over to the supplier, repaired or discarded before there has been an opportunity to investigate and a course of action agreed.

j) 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 staff.

k) If equipment is contaminated and constitutes a bio hazard, advice contained in Device Bulletin, MHRA DB 2003(050) "Management of Medical Devices Prior to Repair, Service of 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 samples of any equipment, material or article, make examinations, take measurements, photographs, order dismantling, question personnel and take copies of documents.

3) Health and Safety Inspectors may also act or investigate on behalf of HM Coroner.

7. What action will the originator or Department of Health take?

When the Department receives a Defect and Failure report, the following action(s) are taken:

a) If DH is notified via a different route the originator is prompted to report the Defect or Failure onto the Defect and Failure reporting system.

b) An acknowledgement letter will be sent by DH to the originator with a unique Defect and Failure number that should be quoted in all correspondence.

c) The manufacturer / supplier should be informed by the originator and a copy of the incident report sent to them with a request to contact the originator of the defects and failure report.

d) The Department or their representative may contact the healthcare provider, to discuss the incident with healthcare provider, the manufacturer and liaise with Health and Safety Executive.

e) The report is evaluated by Department of Health to identify the appropriate action.

f) Based on historical data within the Defect and Failure system, the nature of the incident, the manufacturer's report and the healthcare providers own investigations, the Department of Health may issue an EFA to healthcare providers through the CAS, or alternatively place an item in the news section of the CAS website.

g) Types of EFAs that may be issued through the CAS system by Department of Health 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 NOTICE/REQUEST	Used to alert users about a specific issue and/or where the Department is requesting feedback.

The Department will continue to monitor all reported Defects and Failures and if necessary issue / modify appropriate guidance or research where it is felt appropriate.

Suggested Onward Distribution

Chief Executives
CAS Liaison Officer
Directors of Estates & Facilities
Risk Management Leads
Health & Safety Manager's
PFI/PPP staff

Additional information for England

The above sections of this Alert were compiled by Department of Health for circulation in England only.

Action required by this alert should be **underway by: 21st October 2013**

Action required by this alert should be **completed by: 25th November 2013**

Enquires should quote reference number EFA/2013/003 and be addressed to:

Defects & Failures
Department of Health
NHS Estates & Facilities Policy Division, 1N14
Quarry House,
Quarry Hill,
Leeds LS2 7UE
Mb-defects&failures@dh.gsi.gov.uk

HOW TO REPORT DEFECTS & FAILURES

Defects and failures relating to non-medical equipment, plant and buildings should be reported to the Department as soon as possible. Advice on what needs to be report can be found in EFA/2013/003. Defect and failure reporting is an on-line only reporting facility, available on the NHS and Social Care Information Centre website at www.efm.ic.nhs.uk

This Alert can be found on the following websites
http://www.gov.uk and https://www.cas.dh.gov.uk