NHS England and Improvement Estates and Facilities Alert

Reporting of Defects and Failures and disseminating Estates and Facilities Alerts

Ref: NHSEI/2020/001 **Issued: 30 January 2020**

Notice

This document, previously issued in January 2018 has been updated to reflect changes to the Defects and Failures reporting system and the Central Alerting System
This Alert was compiled by NHS England and NHS Improvement for circulation in **England only.**

Information

The purpose of this document is to act as a reminder that:

- Reporting estates related incidents affecting the safety of patients and the continuity of services is part of the statutory responsibilities on NHS healthcare providers established by the Care Quality Commission (Registration) Regulations 2009: Regulation 18 http://www.cqc.org.uk/content/regulation-18-notification-other-incidents Safety incident reporting is also a requirement of Health & Safety Legislation (see Section 5, below for more detail).

- To ensure estates related safety and business continuity incidents are investigated, **all** NHS healthcare providers, Commissioners, Dental practices and GP surgeries should also report defects and failures (D&F) involving engineering plant, infrastructure and non-medical devices to NHS England and NHS Improvement's Estates Division. This will enable the sharing of information across all NHS service providers, via the Central Alerting System (CAS) or other avenues for alerts (such as the NHS Estates Collaboration Hub) depending on their nature, to help other providers learn from incidents and prevent recurrence

- Defects and Failures should be reported on-line through the ***efm*** information system's Defects & Failures module at https://efm.digital.nhs.uk/(see section 4).

- All Estates and Facilities Alerts issued via CAS need to be disseminated to the key relevant people in your organisation, to ensure senior stakeholders (at all levels) are engaged and involved thereby ensuring the appropriate action is undertaken as required.

This document provides guidance on:

1. What constitutes a defect or failure and when they should be reported.
2. The categories for which the Defect & Failure module of the ***efm***-information system should be used.
3. Action required by providers and commissioners of NHS services.
4. How reporting should be carried out.
5. Other actions and responsibilities.
6. What should happen to defective / failed items.
7. What actions NHS England and NHS Improvement will take.

1. What constitutes a defect or failure and when they should be reported

A defect or failure can be classed as:

Any adverse event involving the safety of patients, staff or others, arising from the defect or failure of equipment. These events may range from causing no actual harm (near miss) to serious harm and may include (This is not an exhaustive list, and these are just some examples):

- a fatal accident or serious injury;
- a reportable RIDDOR 2013 incident relating to equipment that contributed to an accident;
- an explosion or sudden fracture of any pressure vessel, pressurised system or steam / high pressure water main;
- a major electrical discharge or explosion (e.g. transformers or switchgear or failure of cable joints);
- any structural or component failure in a lift.

a) Incidents which result in the defect or failure of equipment that arise through (This is not an exhaustive list, and these are just some examples):
   - incorrect use of equipment;
   - inappropriate modifications or adjustments;
   - inadequate servicing and / or maintenance;
   - design or manufacturing flaw.

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

c) Failure of equipment designed to avoid patient harm (e.g. a person overcoming an anti-ligature device).

d) Any defects in a product, or product instructions, identified by Health and Safety Executive Inspectors or Local Authority Inspectors e.g. Environmental Health.

e) Any utility or infrastructure failure in critical services (electricity, water, steam, gas, communications systems etc.), including the receipt of an enforcement order from the authorising authority.

f) Serious failure of building infrastructure, i.e. collapsed ceilings/walls, window restrictor failure/ falls from windows, failure of hand-railing, etc.

g) Structural integrity of the building or associated structure is at risk. No actual failure has occurred, but there is a significant/material risk (e.g. damaged or rotting chimney, etc.).

If one or more of the above apply: we would require notification.

2. The categories for which the efm-information reporting system should be used in the event of a defect or failure

NHS England and NHS Improvement's NHS Estates Division deals with Defects & Failures relating to non-medical devices, engineering plant and infrastructure in the following categories:

1. Building and building components (e.g. general structural integrity, windows, flooring, doors, ceilings, curtain rails and tracking, showers, baths, toilets, thermostatic mixing valves etc.).
2. Engineering plant and services of all types e.g. lifts, boilers, pressure systems, generators, heating and ventilation systems, specialised ventilation systems (e.g. theatres and isolation rooms), hot and cold water systems (including water disinfection 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 detection, fire protection installations (including fire stopping, smoke dampers, fire extinguishing systems, fire doors, fire resistant glass) and portable fire-fighting equipment.

5. Permanently installed sterilizers, bedpan washers and disposal units. (Please note that endoscopy washers are deemed to be medical devices and do not therefore fall under this Defects & Failures system).
6. Equipment in laundries, catering departments, workshops and any other plant or equipment used for maintenance or cleaning.
7. Medical air compressors, 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 theatre, examination, and emergency lamps, and their associated support systems.
9. IT systems used for monitoring and controlling the site / infrastructure. Pendants and Communications equipment (e.g. telephone and bed head services, nurse call systems, paging systems, alarm and video / audio equipment).
10. Lightning protection and electrostatic discharge systems.
11. Incinerators and other clinical waste management / treatment equipment.
12. Environmental aspects (buildings) covered by the Control of Substances Hazardous to Health (COSHH) Regulations.
13. Installation aspects of fume cupboards and microbiological safety cabinets, including protection ductwork and their interaction with ventilation systems.
14. Ambulances and similar patient transport vehicles, tugs etc. excluding vehicles for disabled persons, leased vehicles and goods vehicles.
15. Fuel supply and storage systems.

3. Action required by providers and commissioners of NHS services

The provider organisation's Chief Executive / Board Member / nominated person 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 within their organisation(s) (this includes PFI, NHS LIFT, NHS Property Services and any external contractors as appropriate) for information purposes.

The following arrangements should already be in place:

1. Ensure a designated person (referred to in this document as a CAS Liaison Officer) is responsible for receiving and disseminating Estates & Facilities related alerts from the Central Alerting System (CAS).
2. Regular review of monitoring procedures to ensure there is a person in place, with backup arrangements, that always has responsibility for promptly reporting appropriate defects and failures .
3. Communication arrangements to ensure personnel are aware of the on-line defects and failures reporting system available on the ***efm***-information website **(see section 4).**
4. Ensure relevant personnel are familiar with the CAS website where alerts are posted https://www.cas.mhra.gov.uk/Home.aspx
5. Advising the CAS helpdesk by email safetyalerts@mhra.gov.uk of changes to CAS liaison officer contact details.

4. How to report Defects and failures

The web-based D&F reporting system is managed by NHS Digital on behalf of NHS England and NHS Improvement.

Defects or failures should be reported on this system: https://efm.digital.nhs.uk/ utilising the Defects & Failures module.

For all queries regarding passwords and access please contact 0300 303 5678.

For all technical queries please contact Helpdesk 0113 3973983 or 0113 2547010.

There are a huge number of organisations (including Dentists and GPs) that could theoretically raise a defect & failure report. For ease of administration, please request login details **ONLY** when you have a first incident to report.

5. Other actions and responsibilities

When an incident occurs, it should be reported to all relevant bodies (including Commissioners in respect of Significant Incidents). In the interests of safety and to enable the sharing of information across all NHS service providers and Commissioners, 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), an entry should also be made onto the ***efm***-information system: https://efm.digital.nhs.uk/

An incident which meets the criteria for being reportable via the Defects & Failures module may also require other reporting duties to be undertaken (NB this is not an exhaustive list). For example

- Reporting to the CQC,
- Entering on the National Reporting and Learning System (NRLS),
- Reporting to HSE ("Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR 2013)"),
- Reporting under "Ionising Radiation Regulations 1999";
- Reporting as a Never Event,
- Reporting as a Serious Incident,
- Informing the manufacturer/supplier

All patient safety incidents should also be reported to the NRLS https://report.nrls.nhs.uk/nrlsreporting to inform national learning, and all "serious incidents" which require investigation should be reported within STEIS (Strategic Executive Information System) and managed as defined in the Serious Incident Framework (March 2015). Information on the Serious Incident Framework can be found at https://improvement.nhs.uk/resources/serious-incident-framework/ and an update in 2018; https://improvement.nhs.uk/resources/about-new-patient-safety-incident-response-framework/

In addition reporting on the Defects & Failures module does not affect the duty of local staff to take actions as required by legislation and / or by line management, because of a defect and failure. For example additional actions (again not an exhaustive list) may be required such as:

- Preventing further use of equipment that may be defective;
- Reporting of incidents to the most appropriate NHS officer within the organisation (e.g. radiation hazards to the Radiation Protection Advisor, infection issues to Infection Control);

- The manufacturer / supplier should also be contacted by the originator of the report and supplied with a copy of the incident report, in order that the two parties can establish the reason for the D&F;
- The outcome of the investigation, either by the healthcare provider or jointly with the manufacturer, should be added to the open report on the Defect & Failure module of the ***efm*** system

NB: Any incident relating to a medical device as defined by the MHRA (e.g. endoscope washers & disinfectors) does not fall under the remit of this Defect & Failure system.

6. What should happen to defective/failed items

a) All defective equipment is potential legal evidence and should be treated as such by the most senior person on site at the time. It should not be modified, cleaned or dismantled, unless immediate repair is the only possible option.

b) All material evidence shall be identified and kept secure under the charge of a named responsible officer.

c) If possible, photographs (ideally digital and dated and timed) 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, which should be signed and dated, should be kept of all readings, settings and position of switches, valves, dials, gauges and indicators etc.

f) A detailed incident report shall be compiled and if necessary timed and signed. Eyewitness reports should also be obtained as soon as reasonably possible. In serious cases, these reports should be signed and dated in front of witnesses.

g) The manufacturer/supplier should be promptly notified directly by the NHS 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.

h) 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.

i) 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 (and where necessary inspected and re-certified) for re-use after due consultation with a named responsible officer.

j) If equipment is contaminated and constitutes a bio hazard, advice contained in the MHRA's Managing Medical Devices - Guidance for healthcare and social services organisations (April 2015) https://www.gov.uk/government/publications/managing-medical-devices should be followed.

NOTE

- It is illegal to send contaminated items through the post.
- 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.
- Health and Safety Inspectors may also act or investigate on behalf of HM Coroner.

7. What action will NHS England and Improvement take?

When NHS England and NHS Improvement's Estates Division receives a Defect and Failure report, the following action(s) are taken:

a) If NHS England and NHS Improvement's Estates Division is notified via a different route the originator will be prompted to report the Defect or Failure onto the ***efm*** reporting system. (See section 4).

b) NHS England and NHS Improvement or their representative may contact the originator, to discuss the incident and then may liaise with the manufacturer and with the Health and Safety Executive.

c) The report is evaluated by NHS England and NHS Improvement's Estates Division to identify the appropriate action.

d) Based on historical data within the Defect and Failure system, the nature of the incident, the manufacturer's report and the originator's own investigations, NHS Improvement may issue an Estates & Facilities alert to healthcare providers through the CAS or other channels.

e) Types of EFAs that may be issued through the CAS system by the NHS Estates 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 act 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.

NHS England and NHS Improvement 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 within organisations

Chief Executives
CAS Liaison Officer
Directors of Estates & Facilities
Risk Management Leads
Health & Safety Managers
PFI/PPP staff
Others as deemed appropriate

Additional information

NHS Premises Assurance Model (PAM)

The NHS Premises Assurance Model (PAM) is a tool that allows NHS organisations to better understand the efficiency, effectiveness and level of safety with which they manage their estate and how that links to patient experience. The importance of safety reporting is outlined in the PAM Safety Domain (Hard FM) where it asks "With regard to reporting and implementing estates and facilities issues within Safety-Related Systems can the organisation evidence…Clear and agreed procedures in place to report defects and failures."

For more information on NHS PAM please visit https://www.gov.uk/government/publications/nhs-premises-assurance-model-launch

NHS Estates Collaboration Hub

The NHS England and NHS Improvement Estates and Facilities team host a collaboration hub containing guidance, case studies, information about events, useful contacts and discussion forums.

http://feedback.model.nhs.uk/knowledgebase/articles/1873003-estates-and-facilities-collaboration-hub

Action required by this alert should be **underway by: 15 February 2020**

Action required by this alert should be **completed by: 22nd March 2020**

Enquires should quote reference number NHS/2020/001 and be addressed to: nhsi.mb-defects&failures@nhs.net

A copy of this Alert can be found on https://www.cas.mhra.gov.uk/Home.aspx