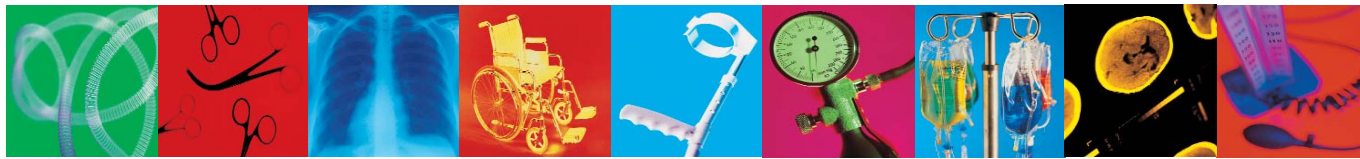


Medical Devices

Reporting Adverse Incidents



Who we are

The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency of the Department of Health.

Our aim is to enhance and safeguard the public's health by ensuring that medical devices and medicines meet the required standards of safety and effectiveness in use

The Adverse Incident Centre (AIC) is the MHRA's focal point for reporting incidents involving medical devices.

What we do

We assess all reports of adverse incidents involving medical devices.

Each incident is recorded on our database and a risk assessment is carried out to determine whether an investigation is undertaken directly by us or by the manufacturer on our behalf.

Every report is acknowledged and all reporters are advised of the nature and outcome of the investigation.

What is a medical device?

Medical devices and equipment are items used for the diagnosis and/or treatment of disease, or for monitoring patients, as well as aids for daily living.

Examples of medical devices include:

- benchtop sterilizers
- blood glucose monitors
- defibrillators, monitors and scanners
- imaging equipment
- IUDs and condoms
- surgical implants
- syringes and needles
- urine and blood test kits
- wheelchairs, walking frames and sticks

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 patients, device users or other persons.

Causes of incidents involving medical devices may include:

- design or manufacture problems
- poor user instructions and training
- inappropriate local modifications
- inadequate maintenance
- unsuitable storage and use conditions

What should be reported

Any adverse incident involving a medical device should be reported, especially if the incident has led to or, were it to occur again, could lead to:

- death or serious injury
- medical or surgical intervention (including implant revision) or hospitalisation
- unreliable test results (and risk of misdiagnosis)

Other minor safety or quality problems should also be reported as these can help demonstrate trends or highlight inadequate manufacturing or supply systems.

What happens to the device?

Devices that have been involved in an incident should be quarantined. They should not be repaired, returned to the manufacturer or discarded until we have been given the opportunity to carry out our own investigation. Further advice on this may be obtained from your local Medical Device Liaison Officer.

If sending an item for investigation, please follow published MHRA advice on decontamination.

Remember:

it is illegal to send contaminated items through the post.

How to report an incident

Adverse incidents should be reported at the earliest opportunity, following any local incident reporting policies.

We prefer you to use the online reporting system via our website: www.mhra.gov.uk

However, if necessary you may also download a form from our website and e-mail or fax it to us: e-mail: aic@mhra.gsi.gov.uk fax: 020 7084 3109

Adverse Incident hotline: 020 7084 3080