

SAFETY ACTION NOTICE



By arrangement with Scottish Executive Health Department & NHSScotland Property and Environment Forum

REPORTING OF ADVERSE INCIDENTS IN NHSSCOTLAND

SAN(SC)06/01
12 JAN 2006
Medical & Facilities
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Summary

All adverse incidents in NHSScotland involving medical, laboratory and estates/facilities equipment should be reported to Scottish Healthcare Supplies (SHS) who will investigate and issue advice. Healthcare facilities should ensure that effective procedures are in place for the reporting of incidents and the dissemination of safety warnings. The SHOW website provides advice on the reporting of adverse incidents by mail, fax, e-mail and on-line.

Distribution

This notice should be brought to the attention of all senior and other relevant staff in NHSScotland as well as agency staff, contractors, community pharmacists, optometrists, ophthalmic practitioners and general medical / dental practitioners.

The User Reporting System

NHS MEL(1995)74 *Reporting of Adverse Incidents and Defective Equipment* was issued by the National Health Service in Scotland, Management Executive in November 1995. It reminded Chief Executives of their responsibilities to ensure that robust management arrangements existed for the reporting of hazardous and potentially hazardous equipment to the **Incident Reporting & Investigation Centre (IRIC)** at Scottish Healthcare Supplies, as well as dissemination of safety warnings. The [MEL](#) can be viewed on the SHS website.

Adverse incidents

An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of patients, users or other persons. Local incidents may have implications for other healthcare services and it is essential that all adverse incidents are reported, especially if an incident has led to, or were it to happen again, could lead to:

- death, life-threatening illness or injury,
- deterioration in health,
- the need for medical or surgical intervention,
- unreliable test results leading to inappropriate diagnosis or therapy.

Reports of adverse incidents that appear to be caused by human error should also be reported as they might indicate deficiencies in the design of the device/equipment, instructions for use or local procedures and may help prevent repetition of mistakes through promulgation of advice or improvements in design. The User Reporting System is concerned with preventing the occurrence of adverse incidents, not with assigning blame.



SCOTTISH HEALTHCARE SUPPLIES
Gyle Square Edinburgh EH12 9EB
A Division of National Services Scotland for NHSScotland



Emergency
0131 334 1638
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0131 275 7575

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Responsibilities

Chief Executives should ensure that adequate procedures exist for the effective reporting and dissemination of information about adverse incidents involving medical, laboratory and estates/facilities equipment. Where relevant, agency staff and contractors should also be made aware of these procedures.

Where appropriate, NHS Boards should forward safety information to operational units, general medical / dental / ophthalmic practitioners, community pharmacists, optometrists and contractors.

It is recommended that NHS Boards identify an individual who will have managerial responsibility for ensuring that the arrangements detailed in MEL(1995)74 are carried out.

Reporting

IRIC receives reports on adverse incidents in NHSScotland and is responsible for co-ordinating the investigation of these reports. Adverse incidents involving medical, laboratory or estates/facilities equipment should be reported to IRIC in writing (mail, fax, e-mail or on-line) giving as much detail of the problem as possible. Details identifying individual patients should not be provided.

Reports should be submitted using one of the three available adverse incident report forms: paper **ADV/REP/1**, on-line **ADV/REP/E1** or electronic **ADV/REP/F1**, all of which are available on the [SHOW](#) webpage [How to report adverse incidents](#) together with advice on confidentiality and keeping a copy of reports. (See page 6 for other useful NHSnet and Internet links.) Examples of relevant devices and equipment are provided with each form. As all the forms were revised towards the end of 2005, previous issues should be scrapped.

Where the issue is serious or urgent, reporting should not be delayed by the lack of a detailed written report. Such incidents may be reported or advice obtained during office hours using the **IRIC helpline 0131 275 7575**. The **emergency number 0131 334 1638** will automatically divert to the on-call Hazard Co-ordinator and should be used only for urgent matters out-of-hours.

Separate procedures exist for the reporting of problems relating to food and drugs as well as blood and blood components for transfusion.

Confidentiality and data protection

IRIC does not normally require patient or staff personal details (i.e. name or other identification) to carry out investigations. Such details should be retained locally and divulged on a strictly 'need to know' basis. They should be deleted from any reports and documents accompanying the report form.

Information relevant to the investigation is likely to be shared with appropriate authorities such as Department of Health and possibly with Health & Safety Executive. It is also likely to be shared with the relevant supplier/manufacturer. Existing legislation may also require disclosure of information to others.

Unless notified to the contrary, the submission of a report gives SHS the authority to use the information appropriately and in the interests of the NHS.



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SHS safety warnings

There have been no changes to the system of Hazard Notices and Safety Action Notices in the past year. Where required, a safety warning is issued in one of the following formats:

Hazard Notice is a high priority warning where:

- there is a potential for death, serious injury or deterioration in health,
- danger would not be anticipated or recognised during normal use,
- immediate action is required.

Safety Action Notice is a standard priority warning where (for example):

- it is possible to improve safety by long term actions,
- it is necessary to repeat warnings on long standing problems,
- manufacturers' instructions, advice or field modifications require to be followed up,
- risks should already be anticipated or recognised in time to prevent adverse effects,
- action can be planned rather than immediate.

It is our policy, when issuing safety warnings, not to mention specific locations or healthcare organisations associated with adverse incidents in Scotland.

Distributing SHS safety warnings

In general, safety warnings will have been addressed to the NHS Board Chief Executive but responsibility for receiving and distributing these may be delegated to another person. The preference for a single contact point within each NHS Board (Nominated Person) remains. Ideally, this should be the risk manager who would be responsible for receipt of safety warnings and further dissemination to staff. SHS will continue to provide a Suggested Distribution list on each safety warning with the clear understanding that this will be indicative only and that responsibility for ensuring that the correct staff receive the safety warning will rest with the Nominated Person.

During 2005, SHS launched an email safety warning information system which runs in parallel with the paper distribution system. Following the publication of each new safety warning, an email is sent from 'Hazards' to the distribution list advising of where to find it on the SHOW website. This enables NHS Boards etc. to be aware of new safety warnings, and to locate and forward them electronically within their own organisation should they wish to do so.

Distributing manufacturers' safety advice

The SHS safety warning system is not a replacement for direct action by manufacturers and healthcare organisations. It remains the responsibility of manufacturers to address safety issues concerning their products and healthcare organisations are reminded that they should have robust systems in place to identify product safety information from manufacturers and suppliers and to ensure that it is appropriately distributed, acted upon and documented. Ideally, all safety information should be routed through a single channel (e.g. the Nominated Person).

Manufacturers may send product safety information directly to healthcare organisations but if targeted wrongly (e.g. due to out-of-date staff details and equipment locations) formal risk management systems may be circumvented and crucial information may not be acted upon nor documented.



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CONTACT EMAIL: Andrew.Wong@shs.csa.scot.nhs.uk

WEBSITE: http://www.show.scot.nhs.uk/shs/hazards_safety/adverse.html

TEL: 0131 275 6901 FAX: 0131 314 0722

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Organisations should remind staff that manufacturers and suppliers may, from time to time, send product safety information to named individuals or departments. If such information is received, individual action may be appropriate but the information should also be passed to the Nominated Person to allow wider distribution and activation of formal risk management procedures.

Under European legislation, manufacturers or their European representatives are obliged to inform all relevant Competent Authorities (i.e. Medicines and Healthcare products Regulatory Agency [MHRA] in the UK) concerning any systematic recall of devices being undertaken for technical or medical reasons connected with the characteristics or performance of a device, where death or serious injury might result.

In the near future, MHRA is planning to post manufacturers' Field Safety Corrective Action (FSCA) notices on the MHRA website where they affect the UK. This will provide access to a greater breadth of safety information about medical devices known to be on the UK market. Future users of this portion of the MHRA website may, in the future, register to receive updates. Further information will be issued to advise of developments in this area.

Where necessary (i.e. to ensure that safety issues are adequately addressed) safety warnings will be issued by MHRA in addition to manufacturers' FSCA notices, and SHS will issue Scottish equivalents for NHSScotland.

Retaining material evidence

All material evidence should be labelled and kept secure. This includes the products themselves and, where appropriate, consumables, packaging materials and other means of batch identification. The evidence should not be interfered with in any way except for safety reasons or to prevent its loss. Preferably, a record should be made of all readings, settings and positions of switches, valves, dials, gauges and indicators, together with any photographs and eyewitness reports.

Defective devices / equipment should not be discarded, modified, repaired, returned to the manufacturer or accessories removed before IRIC has been informed and opportunity given for inspection. If equipment is urgently required for use, defective parts may be replaced and retained for inspection. In the case of a fatal accident all evidence should remain unaltered and kept secure, including any disposable products, packaging and drugs.

The manufacturer or supplier should be informed promptly and allowed to inspect the device / equipment if accompanied by an appropriate person. To facilitate an investigation involving consumables, it may be helpful to provide the manufacturer with samples of unused stock. Unless agreed with IRIC (and other relevant bodies such as the police or Health and Safety Executive) the manufacturer must not be allowed to exchange, interfere with or remove any part of the implicated product in case this impedes investigation.

Handling contaminated devices

Where possible, devices should be decontaminated prior to handling, in keeping with the advice contained in MHRA Device Bulletin DB2003(05) *Management of Medical Devices Prior to Repair, Service or Investigation*. However, where this is not possible or may destroy evidence or damage the device, IRIC should be consulted and arrangements agreed for alternative action.



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Items which have or may have been in contact with infectious material such as blood or other body fluids, or pathological samples, and all non-sterile disposable devices, whether used or unused, should be sealed in a transparent inner bag or container. Sharp objects such as needles must be protected within a rigid container to prevent injury. The item must be accompanied by a Contamination Status Certificate, accessible without opening the inner packaging. A suitable certificate [DECON/1](#) is available on the SHOW website.

Contaminated devices should not be sent by mail unless contained in special packaging which; a) is designed for the purpose, b) meets the requirements of the carrier company(ies) and c) meets the international regulations for freight if sending abroad. The supplier of the device may be able to provide appropriate packaging. If sending to SHS, agreement should be obtained from IRIC before dispatch and the package should be addressed to a named member of staff within SHS.

Other responsibilities

Reporting to SHS does not replace, and is in addition to the following:

- Preventing further use of equipment which may be unsafe;
- Local reporting procedures, e.g. to supervisors, managers, Health & Safety Advisers, Radiation Protection Advisers and Nominated Persons;
- National regulations, e.g. to Health & Safety Executive under [RIDDOR](#) (The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995);
- Reporting to the Procurator Fiscal following a sudden death or fatal accident as per NHS MEL(1998)82 - *Death and the Procurator Fiscal* issued 30 December 1998;
- Reporting serious incidents involving CE marked medical devices to the manufacturer.

SHOW (Scottish Health On the Web) websites

Hazard Notices and Safety Action Notices published by SHS are available on the SHOW website at the [INDEX SELECTION](#) page of the IRIC website. Enter the SHOW home page <http://www.show.scot.nhs.uk/> then click on the Hazard Notices & Safety Action Notices box on the right, under the NHSScotland logo.

Alternatively, enter the SHOW homepage and use the long route through the main SHS website - click on:

- NHSScotland Organisations,
- National and Support Organisations,
- [National Services Scotland - Scottish Healthcare Supplies](#),
- SHS (logo),
- [SERVICES](#),
- [Adverse Incident Reporting](#),
- [Published Hazard and Safety Action Notices](#) (menu at bottom of page) to access publication indexes.

Each index has a list of references which are hyperlinked to the complete text of each notice. These are PDF documents for which Adobe Acrobat Reader freeware is required. A word search facility is provided which will search through the text of each notice. Please note: the above is subject to change as the website is developed.

A [General complaint form](#) is available on the SHS webpage [Complaints](#) should you wish to raise any issues regarding the IRIC or any other SHS service.



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NHSnet / Internet addresses

The following NHSnet / Internet addresses (URLs) are relevant:

- **Incident Reporting & Investigation Centre e-mail address:**
IRIC@shs.csa.scot.nhs.uk
- **SHOW (Scottish Health On the Web) website homepage:**
<http://www.show.scot.nhs.uk/> (NHSnet)
<http://www.nhsscotland.com/> (Internet)
- **NHS MEL(1995)74 Reporting of Adverse Incidents and Defective Equipment:**
[http://www.show.scot.nhs.uk/shs/hazards_safety/MEL\(1995\)74.PDF](http://www.show.scot.nhs.uk/shs/hazards_safety/MEL(1995)74.PDF) (NHSnet)
[http://www.nhsscotland.com/shs/hazards_safety/MEL\(1995\)74.PDF](http://www.nhsscotland.com/shs/hazards_safety/MEL(1995)74.PDF) (Internet)
- **How to Report Adverse Incidents:**
http://www.show.scot.nhs.uk/shs/hazards_safety/hazardsp3.HTM (NHSnet)
http://www.nhsscotland.com/shs/hazards_safety/hazardsp_P_3.HTM (Internet)
- **Contamination Status Certificate DECON/1:**
http://www.show.scot.nhs.uk/shs/hazards_safety/decon1.PDF (NHSnet)
http://www.nhsscotland.com/shs/hazards_safety/decon1.PDF (Internet)
- **Safety Warnings - Index Selection:**
http://www.show.scot.nhs.uk/shs/hazards_safety/hazardsp4.HTM (NHSnet)
http://www.nhsscotland.com/shs/hazards_safety/hazardsp_P_4.HTM (Internet)
- **The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995:**
<http://www.riddor.gov.uk/>
- **General complaints:**
<http://www.show.scot.nhs.uk/shs/Complaints/complaints.htm> (NHSnet)
<http://www.nhsscotland.com/shs/Complaints/complaints.htm> (Internet)

- Notes:
- a) If you have accessed any of the above sites before, your computer may display an out of date version. To ensure that the latest version appears on screen, click 'refresh' at least twice.
 - b) Public Internet users searching for SHOW (NHSnet) pages and documents should be rerouted automatically to the public version at NHSScotland. The address for the public Internet equivalent is given below each NHSnet address in case rerouting does not occur.

THIS NOTICE SUPERSEDES SAFETY ACTION NOTICE SAN(SC)05/01 ISSUED ON 10 JANUARY 2005.



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