Health Finance Directorate
Capital Planning and Asset Management Division

The Scottish Government

CEL 43 (2009)

30 October 2009

Dear Colleague

Safety Of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities

Summary

1. This CEL builds on and strengthens existing arrangements in relation to the above and sets out the responsibilities of Chief Executives for ensuring that procedures exist for the reporting of adverse incidents, the dissemination of safety advice and the control of risks relating to health, social care, estates and facilities equipment.

Action

2. Chief Executives must ensure that all senior managers and relevant staff within their organisation are aware of the information contained in this CEL and that procedures are in place to promote its effective and accurate implementation (for further information see **Annex A**).

3. Chief Executives should also ensure that these procedures are extended to all contractors and private or independent service providers who provide care, staff, equipment, buildings or other services or facilities for the direct care of patients or clients.

4. A single point of contact within each organisation shall be nominated as 'Equipment Co-ordinator' (in the case of NHS Boards preferably a Risk Manager). Their role will include the following duties plus any others which may be specified from time to time:

   - ensuring managers and staff are aware of the procedures for reporting adverse incidents and for implementing safety advice;
   - monitoring all adverse incidents reports from within own organisation;
   - receiving emails from Health Facilities Scotland (HFS) notifying of alerts and bulletins, and cascading within own organisation;
   - monitoring relevant websites for information on equipment safety and management issues;
   - discussing equipment safety issues with Health Facilities Scotland (HFS);

Addresses

For action
Chief Executive,
NHS Boards
Chief Executive,
Local Authorities

For information
Chief Executive, NHS
NSS
COSLA
Care Commission

Enquiries to:

Andrew Wong
Incident Reporting & Investigation Centre (IRIC)
Health Facilities Scotland
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
EDINBURGH
EH12 9EB

Tel: 0131-275 7575
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Email : Andrew.Wong@nhs.net

- promoting equipment safety by staff education and training in conjunction with HFS.
- building and maintaining communication links with HFS;
- attending Equipment Co-ordinators' conferences and seminars; and
- monitoring internal cascade systems to ensure alerts are received, assessed and acted upon.

5. The name, designation and contact details (including email address) of the appointed Equipment Co-ordinator should be notified by email to HFS. It is important that the contact email account can be accessed by other team members in the absence of the Equipment Co-ordinator to allow prompt response to all incoming safety information. The contact email address should be current at all times and HFS advised immediately of any change. HFS is contactable using the email address iric.nss@nhs.net.

6. Clear written policy and procedures must exist for:

   6.1. the **prompt reporting** of all adverse incidents involving health, social care, estates and facilities equipment to HFS (see **Annex B**), including:

      6.1.1. preserving evidence and keeping records (see **Annex B**),
      6.1.2. informing the organisational Equipment Co-ordinator, and
      6.1.3. maintaining a central register for equipment incidents in each organisation.

   6.2. the **receipt, assessment and implementation of all alerts and bulletins**, including:

      6.2.1. cascading safety information to appropriate managers, staff, users and, where appropriate, to community services, joint stores, contractors, agencies and private or independent service providers such as optometrists, ophthalmic practitioners, community pharmacists, general medical or dental practitioners, private hospitals etc, indicating whether for information or action and giving time scales for commencement and completion;
      6.2.2. confirming to the local Equipment Co-ordinator the receipt, applicability and actions started or completed;
      6.2.3. an audit system to monitor and demonstrate completion of the above.

Timescales

7. Appointment of an Equipment Co-ordinator and notification of that appointment to HFS should be completed within 3 weeks of the date of this CEL. Full implementation of the remaining actions should be undertaken as soon as possible thereafter.

Yours sincerely

JOHN MATHESON
Director Of Health Finance

Safety of Health, Social Care, Estates and Facilities Equipment: NHS Boards and Local Authorities Responsibilities

Background

1. Under health and safety legislation, all organisations have a duty of care for their staff, patients, service users and all persons accessing premises and services. Their responsibilities continue under corporate and clinical governance. This CEL relates specifically to the safety of health, social care, estates and facilities equipment.

2. When an adverse incident occurs, there is value in determining the root cause(s) and sharing lessons with others so that the risk of repeat incidents may be minimised. A central body therefore exists in Scotland to collect incident reports and to co-ordinate investigations and remedial actions.

3. Manufacturers and suppliers also require information so that they can address safety issues and meet their legal responsibilities under the Medical Device Regulations etc.

4. This CEL replaces the previous instructions contained in ***NHS MEL(1995)74 Reporting of Adverse Incidents and Defective Equipment*** issued on 23 November 1995 by the Scottish Office.

Adverse incident / user reporting system in Scotland

Arrangements for Health and Social Care equipment

5. The arrangements for reporting adverse incidents in Scotland involving health and social care equipment (medical devices/equipment and laboratory equipment) remain unchanged and cover all NHSScotland bodies and Local Authorities. A list of equipment categories is given in Annex C.

Arrangements for Estates and Facilities equipment

6. The arrangements for reporting adverse incidents involving estates and facilities equipment in Scotland remain unchanged and apply to NHSScotland bodies only.

Reporting

7. Adverse incident reports should be sent to HFS, contact details in **Annex B**. Reports should also be copied to the local Equipment Co-ordinator.

Problems not covered

8. Separate procedures exist for the reporting of problems relating to food, drugs, blood and blood components for transfusion. Serious Adverse Blood Reactions and Events (SABRE) are reportable to the Medicines and Healthcare products Regulatory Agency (MHRA).

Alerts in Scotland

Hazard Notice or Safety Action Notice

9. Hazard Notices and Safety Action Notices issued by HFS (previously Scottish Healthcare Supplies) continue to apply in Scotland unless superseded by a more recent Medical Device Alert issued by MHRA or a Scotland-only notice issued by HFS.

MHRA Medical Device Alert (MDA)

10. With effect from 25 March 2008 MDAs issued by MHRA apply in Scotland; prior to that date MDAs applied only in England and Wales.

Electronic Medical Device Alert (eMDA)

11. A new eMDA format has been used by MHRA since 1 April 2009 and applies throughout the whole of the UK. It is a web-based system with various information sections which include tabs for each devolved administration (such as contact point for enquiries and reporting adverse incidents) so that relevant information may be selected for cascading within each organisation. A PDF version of the whole MDA is also provided.

Email notification

12. As soon as a new alert is published, HFS will notify all Equipment Co-ordinators in Scotland by email. In the case of an eMDA the email will contain the summary page and link to the MHRA website. For Scottish alerts the email will contain the link to the HFS website. It is the responsibility of each Equipment Co-ordinator to determine if each alert is relevant to their organisation and to download it for onward distribution and action.

Arrangements for Estates and Facilities Alerts

13. The arrangements for issuing alerts regarding estates and facilities equipment remain unchanged and apply to NHSScotland bodies only. Local authorities will not normally receive email notification but may view these alerts on the HFS website should they wish to do so. The format is under review and further information will be issued in due course.

Other safety publications

14. From time to time, equipment safety information is published in other formats, such as MHRA Device Bulletins and ad hoc reports. Where these are relevant to Scotland, HFS will notify Equipment Co-ordinators by email.

Role of HFS

15. The Incident Reporting & Investigation Centre (IRIC), which is part of HFS, receives adverse incident reports from NHS Boards and Local Authorities. It is responsible for co-ordinating investigations so that, as far as possible, root causes can be established and remedial action taken to prevent or reduce any identified risks.

16. As the UK Competent Authority, MHRA is responsible for the regulation of medical devices throughout the UK and for issuing Medical Devices Alerts (MDAs). HFS works closely with MHRA, and will notify MHRA of each adverse incident reported in Scotland and the results of any investigation. For example, HFS may identify a need for an MDA and will liaise with MHRA in their assessment of the need for and drafting of the alert.

17. HFS also liaises with other UK Health Departments, NHS bodies and agencies on the safety of estates and facilities equipment. In particular, information is exchanged on adverse incidents reports and investigations. A UK-wide format is under consideration for estates and facilities equipment and further information may be issued in due course.

18. HFS will provide each Equipment Co-ordinator with a list of reports sent to HFS by their organisation during the previous quarter, as well as a list of all investigations still in progress.

19. HFS will be involved in raising the profile of equipment safety throughout NHSScotland through education and training programs.

20. HFS will hold a list of Equipment Co-ordinators for all NHS Boards and Local Authorities and should be notified immediately of any change. HFS will develop a network to support the work of Equipment Co-ordinators and their organisations. This will include various events to promote the management of risk and equipment safety in each organisation and generally throughout Scotland. A seminar will be arranged to launch the network and further information will be provided in due course.

ANNEX B

Safety of Health, Social Care, Estates and Facilities Equipment: NHS Boards and Local Authorities Responsibilities

Reporting Adverse Incidents

1. Reports should be submitted using one of the three adverse incident report forms: on-line, electronic or paper, all of which are available on the HFS webpage 'How to report adverse incidents' (see website address below). Advice is provided on examples of devices and equipment of interest to HFS, confidentiality, handling contaminated and potentially contaminated items, and keeping a copy of reports.

2. Reports should be forwarded to:

   Incident Reporting & Investigation Centre (IRIC)
   Health Facilities Scotland
   NHS National Services Scotland
   Gyle Square
   1 South Gyle Crescent
   EDINBURGH EH12 9EB

   IRIC Helpline: 0131 275 7575
   Fax: 0131 314 0722
   Email: iric.nss@NHS.net
   HFS Website: http://www.hfs.scot.nhs.uk (select Online Services)

3. 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.

Retaining material evidence

4. Where possible (and relevant), all material evidence relating to adverse incidents should be preserved, labelled and kept secure. This includes the product, consumables, packaging and any other means of batch identification. The evidence should not be interfered with in any way except for safety reasons or to prevent its loss.

5. Where an incident involves a machine (e.g. a ventilator) 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.

6. Defective equipment should not be discarded, modified, repaired, returned to the manufacturer or accessories removed before HFS 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 be preserved and kept secure, including any disposable products, packaging and drugs.

7. The manufacturer or supplier should be informed promptly and allowed to inspect the 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 HFS (and other relevant bodies such as the police or Health & 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 items

8. Where possible, devices or equipment should be decontaminated prior to handling, in keeping with the advice contained in MHRA Device Bulletins DB2003(05) *Management of Medical Devices Prior to Repair, Service or Investigation*, and DB2006(05) *Managing Medical Device - Guidance for healthcare and social services organisations*. However, where this is not possible or may destroy evidence or damage the device, HFS should be consulted and arrangements agreed for alternative action.

9. Items which have or may have been in contact with hazardous (e.g. cytotoxic or radioactive) chemicals or infectious material (e.g. tissue, bone, blood, other body fluids, or pathological samples) and all disposable devices, **whether used or unused**, should be sealed in a transparent inner bag or container. Sharp objects such as needles must be enclosed in a suitable rigid container to prevent injury. The item must be accompanied by a Contamination Status Certificate which is accessible without opening the inner packaging. A model certificate (DECON/1) is available on the HFS website and may be adapted and used locally.

10. 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 (e.g. a product return kit). Agreement must be obtained from the recipient before dispatch and the package addressed to a named individual.

Health & Social Care equipment, including:-

Cleaning, sterilisation and disinfection; *stills, autoclaves, sterilisers (steam, gas, chemical, dry heat), instrument washer / disinfectors.*
Daily living (assistive technology); *wheelchairs, hoists, sitting, standing & walking aids, communication & hearing aids, remote environmental controls.*
Dental, podiatry, chiropody; *instruments, chairs, curing lights, drills, water, air, suction.*
Dietary products (certain types); *enteral food preparations, ready-to-feed (RTF) preparations solely for hospital use.*
Electromedical; *infusion pumps, fluid warmers, automatic tourniquets, physiological monitoring and measurement; dialysis, cardiology, physiotherapy, audiology, speech therapy, ophthalmology, electrotherapy, endoscopy and obstetrics equipment.*
Imaging; *X-Ray, CT, MRI, ultrasound, nuclear medicine, image intensifiers, fluoroscopy.*
Implants; *cochlear*, *orthopaedic, pumps, nerve stimulators, heart valves, prostheses.*
Laboratory; *analysers, centrifuges, media preparators, safety cabinets, incubators, warming cabinets, refrigerators, test equipment.*
Life support; *anaesthetic machines, ventilators, humidifiers, resuscitators, defibrillators, pacemakers, suction and medical gas equipment, gas cylinders and regulators, cardiac bypass equipment, baby incubators, radiant warmers, breathing systems.*
Operating department; *surgical instruments, operating tables, trolleys, patient transfer, heating & cooling pads, blood warmers, nerve stimulators, diathermy, drills, saws, lasers.*
Orthotics and prosthetics; *limbs, braces, orthopaedic footwear.*
Post mortem; *tables, instruments, cutters, breathing apparatus.*
Radiotherapy; *accelerators, radioactive implants, tables, treatment planning systems.*
Single use devices; *such as syringes, needles, administration sets, catheters, dressings, sutures, swabs, sharps, staple guns.*
Ward equipment; *e.g. mobile examination lamps, hospital beds, overlay mattresses, pressure garments, thermometers, blood pressure monitors, weighing machines, diagnostic sets, patient hoists, lifting apparatus.*

Estates & Facilities equipment (NHSScotland only)**, including:-**

Buildings and grounds; *components, services, plant for maintenance, construction, cleaning.*
Communications; *two-way radios, telephones, nurse call, paging, personal alarms, building management, radio television, IT, security.*
Equipment; *in laundries, catering departments, work shops etc.*
Fire detection and protection; *smoke/fire detection, fire doors, alarms, sprinklers, extinguishers, ventilation dampers.*
Luminaires (fixed); *including operating department lamps and examination lamps.*
Fuel supply and storage; *solid fuel, petrol, oil and gas.*
Fume, laminar flow and microbiological safety cabinets (installation aspects only); *ductwork and interaction with ventilation systems*.
Gas cylinders and regulators (industrial).
Incinerators and waste disposal;
Legionella protection;
Lightning protection;
Anti-static precautions;
Living areas; *sluices, curtain rails and tracking, showers, baths, toilets, thermostatic mixing valves, doors, windows, flooring, non-specialist furniture, domestic appliances.*
Medical gas cylinders; *storage issues only.*
Operating department installations; *laminar air systems, operating lamps, microscopes.*
Pendant and bed-head services;
Piped medical gas / vacuum installations; *including regulators, pipework and wall outlets, vacuum insulated evaporators, anaesthetic gas scavenging.*
Plant and services; *lifts, automatic doors, boilers, steam generation and supply, heating, ventilation, air conditioning, water, drainage, electrical systems below 11kV, electrical generators, chills and cold storage).*
Transport; *vehicles (excluding medical equipment).*
Waste management, transport and disposal;

General (in association with any of the above);
Control of Substances Hazardous to Health (COSHH); personal protective equipment (PPE); electro-magnetic interference (EMI); data transfer, storage and retrieval systems (e.g. PACS).

Safety of Health, Social Care, Estates and Facilities Equipment: NHS Boards and Local Authorities Responsibilities

Responsibilities

Confidentiality and Data Protection

1. HFS does not normally require patient, client or staff personal details to carry out investigations. Those details should be retained locally and disclosed on a strictly 'need to know' basis. They should be deleted from any reports and documents accompanying the adverse incident report form.

2. Information relevant to the investigation of adverse incidents is likely to be shared with appropriate authorities such as the Medicines and Healthcare products Regulatory Agency, Department of Health and possibly with the Health & Safety Executive. It is also likely to be shared with the supplier or manufacturer of the product involved. Unless notified to the contrary, the submission of an adverse incident report gives HFS the authority to use the information appropriately and in the interests of the NHS and local authorities. Existing legislation may also require disclosure of information to others.

3. Published alerts do not disclose specific locations or user organisations associated with adverse incidents.

Distributing manufacturers' safety advice

4. The alert system is not a replacement for direct action by manufacturers and user organisations. **It remains the responsibility of manufacturers to address safety issues concerning their products** (Field Safety Corrective Action)**.** User organisations 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 contact point (Equipment Co-ordinator).

5. Manufacturers may send product safety information (Field Safety Notices) directly to user organisations and these may be addressed to specific individuals or departments. If targeted wrongly (e.g. out-of-date information on staff and equipment locations) formal risk management systems may be circumvented and crucial information may not be acted upon nor documented. Staff should be reminded that, although individual action may be appropriate, the information should be passed to the Equipment Co-ordinator to allow wider distribution and activation of formal risk management procedures.

6. Under European medical device legislation, manufacturers or their European representatives are obliged to inform relevant Competent Authorities concerning any Field Safety Corrective Action being undertaken for technical or medical reasons connected with the characteristics or performance of a device, where death or serious injury might result. The UK Competent Authority is the Medicines and Healthcare products Regulatory Agency (MHRA).

7. MHRA monitors all Field Safety Notices and posts those relating to medical devices known to be on the UK market on their website. Users of this website may register to receive an email alert when information is updated. Where necessary (i.e. to ensure that a safety issue is adequately addressed) a Medical Device Alert will be issued by MHRA in addition to a manufacturer's Field Safety Notice.

Other responsibilities

8. Reporting an adverse incident to HFS does not replace the following actions which should be taken at a local level:

   - **prevent** further use of equipment which may be unsafe;
   - **follow** local reporting procedures, eg to supervisors, managers, Health & Safety Advisers, Radiation Protection Advisers and the organisation's nominated Equipment Co-ordinator;
   - **comply** with statutory requirements, such as reporting incidents where appropriate, to the Health & Safety Executive under RIDDOR (The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995);
   - **report** 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; and
   - **report** serious incidents involving CE-marked medical devices to the manufacturer.

Safety of Health, Social Care, Estates and Facilities Equipment: NHS Boards and Local Authorities Responsibilities

Useful Internet links

Alerts for Scotland (Hazard Notices and Safety Action Notices published since 1995; MHRA Medical Device Alerts published since 25 March 2008) are available on the HFS website

www.hfs.scot.nhs.uk

select Online Services, then Incident Reporting and Investigation Centre (IRIC).

Reporting adverse incidents can be done by selecting How to Report Adverse Incidents. A model Decontamination Status Certificate is also available.

Please note that the website may change as it is developed.

Other relevant links

- SHOW (Scottish Health On the Web):

  www.show.scot.nhs.uk/

- MHRA Medical Device Alerts:

  www.mhra.gov.uk/Publications/Safetywarnings/index.htm

- MHRA Field Safety Notices:

  www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=967

- The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995:

  www.riddor.gov.uk/

Glossary and Definitions

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 organisations 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.

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 or equipment, instructions for use or local procedures, and may help prevent repetition of mistakes through sharing of advice or improvements in design. The Adverse Incident Reporting System is concerned with preventing the occurrence of adverse incidents, not with assigning blame.

Equipment is a generic term used in this CEL for all physical products, software, systems and services in the health and social care environment. Equipment is found in buildings such as hospitals, health centres, clinics, GP surgeries, day centres and people's homes. It includes the software, design, installation, maintenance, instructions for use and user training intrinsic to proper use. It also covers accessories. 'Equipment' covers the legally recognised term 'medical device' which is less familiar to people working in community or social care settings who are more likely to use terms such as 'daily living equipment' or 'adaptations'. It includes equipment used in the community such as wheelchairs, walking aids, hoists, bathing aids and special beds / chairs; medical implants such as hip joints and pacemakers; fixed installations such as MRI and CT scanners; movable ward equipment such as beds and drip stands; and complex electrical / electronic equipment such as monitors and defibrillators. A more detailed list is given in Annexe C. 'Equipment' also covers estates and facilities which make up and control the built environment. It covers structures such as floors, doors and windows; safety features such as fire prevention and security alarms; ambience through lighting, heating and ventilation; services such as electricity and medical gases; pressure vessels such as boilers and autoclaves; and environmental aspects of waste disposal and emissions.

Drugs and food are excluded from this definition, as is blood and blood components for transfusion.

Medical devices and accessories (taken from the Medical Devices Directive)

Medical device means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Accessory means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device.

CE marking (taken from the Medical Devices Directive)

Devices, other than devices which are custom-made or intended for clinical investigations, considered to meet the essential requirements referred to in Article 3 [of the Medical Devices Directive] must bear the CE marking of conformity when they are placed on the market. The CE marking of conformity must appear in a visible, legible and indelible form on the device or its sterile pack, where practicable and appropriate, and on the instructions for use. Where applicable, the CE marking must also appear on the sales packaging.

Alert is a generic term for formal publications providing important and urgent advice on equipment safety for the NHS and local authorities. It includes Hazard Notices and Safety Action Notices published by HFS and Medical Device Alerts published by MHRA. Other names have been used in the past (prior to 1995).

Safety Action Notice is a standard priority alert where :

- it is possible to improve safety by long term actions;
- it is necessary to repeat warnings on long standing problems;
- to support or emphasise a manufacturer's instructions or FSN;
- risks should already be anticipated or recognised in time to prevent adverse effects; or
- action can be planned rather than immediate.

Hazard Notice is a high priority alert where:

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

Medical Device Alerts are published by MHRA in the following categories:

- Action
- Action - Update
- Immediate Action
- Immediate Action - Update

Field Safety Notice (FSN) is the formal term for an alert issued by the manufacturer of a medical device to advise customers of a safety related issue regarding their product, including a recall. It normally requires the user (customer) such as a hospital to take some form of action and to confirm to the manufacturer that the FSN has been received and followed. An FSN is part of the overall Field Safety Corrective Action by which manufactures address safety issues.