THE SCOTTISH OFFICE

National Health Service in Scotland
Management Executive

NHS
MEL(1995)74

St. Andrew's House
Edinburgh EH1 3DG

23 November 1995

Dear Colleague

REPORTING OF ADVERSE INCIDENTS AND DEFECTIVE EQUIPMENT

Summary

1. This letter updates the advice given in NHS Circular 1991(GEN)24 issued in September 1991, which is now cancelled. It reminds General Managers and Chief Executives of their responsibilities to ensure the reporting of, and dissemination of information about hazardous and potentially hazardous medical, scientific and estates equipment. The Annexes to this letter give details of the reporting system.

Action

2. General Managers and Chief Executives should ensure, in relation to adverse incidents and defective equipment which occur or come to notice within their areas of responsibility, that

2.1 clear written procedures exist for:

- the prompt reporting of all adverse incidents and defective systems or products to the Scottish Healthcare Supplies;

- Hazard Notices, Safety Action Notices and other safety warnings to be brought promptly to the attention of appropriate managers, staff and users of equipment.

2.2 the procedures make clear

- the actions required of staff at all levels, including those in the contracted sector

- the need not to prejudice investigation of the incident or product by altering or removing equipment or products, other than to make them safe.

NHS Circular No
1991(GEN)24 is cancelled.

GEN(1995)4 APPENDIX A - Delete reference to 1991(GEN)24
Insert ref to this MEL

Addressees

For action
General Managers,
Health Boards

General Manager,
Common Services Agency

Chief Executives,
NHS Trusts

For information
General Manager,
State Hospitals Board for Scotland

General Manager,
Health Education Board for Scotland

Executive Director,
Scottish Council for Postgraduate Medical and Dental Education

Enquiries to:

Miss K Glancy
Provider Policy Development Division
NHS Management Executive
Room 277
St Andrew's House
EDINBURGH EH1 3DG

Tel: 0131-244 2428
Fax: 0131-244 3487

2.3 the procedures are made known to all staff, including new staff, and details of the procedures are always available.

2.4 robust management arrangements exist (including clear statements of the chain of managerial responsibility to the General Managers or Chief Executives) for ensuring that:

2.4.1 adverse incidents and defective equipment are reported to Scottish Healthcare Supplies, who act on behalf of the Management Executive;

2.4.2 Hazard Notices, Safety Action Notices and other safety warnings are made known to staff;

2.4.3 any necessary action is taken promptly, and documented.

2.4.4 adequate procedures are in place and are periodically reviewed;

2.4.5 those procedures are followed.

2.5 Chief Executives are responsible for the activities within their respective Trusts. They should be aware in particular that any internal investigative procedures which exist in a Trust should **not replace reports to Scottish Healthcare Supplies**. General Managers' area of responsibility for the purposes of this MEL includes General Medical and Dental Practitioners, Pharmacists, Ophthalmic Opticians, Ophthalmic Medical Practitioners, Ophthalmologists, Chiropodists and private hospitals and nursing homes registered with the Board, as well as the remaining directly managed units (DMUs).

3. It is recommended strongly that Health Boards and Trusts identify an individual who will have managerial responsibility for ensuring that the arrangements detailed above are carried out.

Other Information

4. The issue of this letter was necessary because of changes in the reporting system. In addition, there have been some recent incidents which make a reminder of the importance of the system desirable. Cases have occurred where possible equipment failures resulting in injury to patients were not reported. A fatal accident inquiry gave publicity to a very serious case, involving the death of a patient, where a relevant Safety Action Notice was declared by the Sheriff to have been inadequately distributed. (The hospitals concerned have of course reviewed their procedures since these incidents took place.) These incidents, however, highlight the importance of making reports and ensuring that warning notices are drawn to the attention of all staff concerned.

9. As far as "estates and associated equipment" incidents are concerned as set out in Annex C, the SHS will oversee any necessary investigations (using private contractors as necessary) and liaise with the NHS in Scotland Estates Environment Forum whose Healthcare Engineering and Environment Unit will provide the professional lead.

NOTIFICATION SYSTEM

10. Where the results of investigations have implications for other users a Hazard Notice, Safety Action Notice or other safety warning may be issued. A sample *Hazard Notice* is given in Annex F and a sample *Safety Action Notice* is given in Annex G. General Managers and Chief Executives are responsible for ensuring adequate distribution systems for these publications are in place.

HANDLING OF CONTAMINATED PRODUCTS

11. Requirements for the forwarding of contaminated products for investigation are detailed in:

- SHHD letter DGM(1987)66 dated 6 November 1987 (updated guidance to be issued soon).
- Safety Action Bulletin No 63 SAB(90)61 issued September 1990.
- Hazard Notification HAZ 1991/007 issued 11 March 1991.

All products, devices and samples which have been or could have been in contact with blood, other body fluids or pathological samples must be accompanied by a *Contamination Status Certificate* when being passed to SHS or the supplier/manufacturer for examination. The Contamination Status Certificate should be presented external to the packaging which contains the potentially contaminated item in order that the certificate may be examined before opening the packaging. This requirement also applies to unused disposable items except where packaging seals are unbroken. A sample of a suitable *Contamination Status Certificate* is reproduced as *Annex E* and may be copied or adapted for local use.

12. Advice should be sought from the SHS Incident Reporting and Investigation Centre prior to the sending or transporting of contaminated products for examination by SHS or the supplier/manufacturer. Where possible, products should be decontaminated before being handled. This should be carried out using a method recommended by the manufacturer to avoid destroying vital evidence. It is illegal to send contaminated products through the post.

OTHER ACTIONS/RESPONSIBILITIES

13. This reporting system does not replace the duty of local staff to take other action as required legally, by local procedures or in line with other national requirements eg:

- Preventing further use of equipment which may be defective;
- Reporting to particular local NHS officers (eg Radiation Protection Advisers);

- Reporting notifiable incidents to the Health and Safety Executive under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1985, and the Ionising Radiations Regulations 1985;

- Reporting to the Procurator Fiscal in the case of a fatal accident;

- Informing the manufacturer of a serious adverse incident involving CE marked equipment to assist him in fulfilling his obligations under certain EC directives adopted as UK regulations.

FOOD

14. Problems with food, other than special dietary products, should be reported to:

- The Scottish Office Department of Health

- The Scottish Office Agriculture, Environment and Fisheries Department

- Scottish Healthcare Supplies, Contracts Branch for food which is on central contract to the NHS.

DRUGS

15. Guidance on reporting problems involving medicinal products (drugs alerts) is contained in NHS Circular 1991(GEN)25 issued September 1991 and Circular 1993(GEN)16 issued on 14 December 1993.

NOTES

16. Official notifications to the HSE which are copied to SHS under the terms of this circular should be clearly stated as such. Notification to SHS does not count as, or substitute for any other report.

17. If a patient dies unexpectedly, the clinician in charge of the case should report the death immediately to the Procurator Fiscal. Pending instructions from the Procurator Fiscal or his officer, any implicated product must not be interfered with in any way unless this is necessary for safety or to prevent the loss of samples or material evidence. Although the manufacturer of suspect equipment should be informed immediately, neither he nor his agent should be allowed to inspect the equipment or remove any part of it without the Procurator Fiscal's prior agreement. SHS may be required to impound implicated equipment on behalf of the Procurator Fiscal.

18. As a result of regulations implementing EC directives, manufacturers of CE marked devices will be required by law to report to the UK Competent Authority (Medical Devices Agency) any serious incident (ie death or injury) involving their products. The first directive applies to Active Implantable Medical Devices (for example, implantable cardiac pacemakers), and the UK regulations came into force on 1 January 1993. The second directive covers a much wider range of Medical Devices and the UK regulations came into

force for a transitional period commencing on 1 January 1995 and become mandatory in June 1998. An EC directive on In-vitro Diagnostic Devices is under preparation and is not expected to be in force before 1997.

ANNEX B

Reports relating to all medical equipment: including medical devices, hospital laboratory equipment, medical supplies (excluding medicinal products) and certain dietary products.

REPORTABLE CASES

1. Adverse incidents involving medical equipment may arise due to shortcomings in the equipment itself, user practice, service, maintenance, modifications or adjustments, management procedures, instructions for use or environmental conditions.

2. A report should be sent if equipment is involved in one of the following:

- death
- injury
- deterioration in health
- unreliable test results leading to inappropriate treatment or medication
- where there is a potential for any of the above to occur

NOTE: **Single incidents, when added to other information or reports, might indicate a national or international problem.**

PRODUCT CATEGORIES

- **Imaging and Radiotherapy Equipment**: X-Ray, CT, MRI, ultrasound, nuclear medicine, image intensifiers, fluoroscopy, film processors.

- **Electromedical Equipment**: infusion pumps, fluid warmers, automatic tourniquets, physiological monitoring and measurements, and equipment used in: dialysis, cardiology, physiotherapy, ophthalmology, audiology, speech therapy, electrotherapy, endoscopy, obstetrics.

- **Life Support Equipment**: anaesthetic machines, ventilators, humidifiers, resuscitators, defibrillators, pacemakers, suction and oxygen equipment, cardiac bypass equipment, baby incubators, radiant warmers, breathing systems.

- **Operating Department Equipment**: microscopes, operating tables, trolleys, patient transfer apparatus, heating and cooling pads, blood warmers, nerve stimulators.

- **Powered Surgical Equipment**: Diathermy, drills, saws, lasers.

- **General Ward Equipment**: mobile examination lamps, powered and non-powered beds, ripple mattresses, pressure garments, thermometers, blood pressure monitors, weighing machines, diagnostic sets, patient hoists and lifting apparatus.

- **Dental and Chiropody Equipment**: instruments, chairs, curing lights, drills, water/air/suction.

- **Laboratory Equipment**: analysers, centrifuges, media preparators, safety cabinets, warming cabinets, incubators, refrigerators, test equipment.

- **Cleaning and Sterilisation Equipment**: autoclaves, sterilisers (steam, gas, chemical, dry heat), stills, disinfectors, instrument and equipment washers.

- **Aids for the Disabled**: wheelchairs, walking aids.

- **Implants**: heart valves, pacemakers, defibrillators, infusion pumps, orthopaedic prostheses.

- **Post Mortem Equipment**

- **Single Use Devices**: syringes, needles, administration sets, catheters, dressings, sutures, etc.

- **Orthotic and Prosthetic Appliances**

- **Certain Dietary Products**: enteral food preparations, ready-to-feed (RTF) preparations solely for hospital use.

- **Electrical Interference Problems**: involving any of the above.

- **Aspects of Control of Substances Hazardous to Health (COSHH)**: involving any of the above.

ANNEX C

Reports relating to estates systems and equipment: engineering systems and plant, installed services including piped medical gas and medical gas scavenging systems, buildings and building fabrics, vehicles.

REPORTABLE CASES

1. Adverse incidents in estates equipment may arise due to shortcomings in the equipment itself, user practice, service, maintenance, modifications or adjustments, management procedures, instructions for use or environmental conditions.

2. A report should be sent if equipment is involved in one of the following:

- death
- injury
- deterioration in health
- damage
- where there is a potential for any of the above to occur

NOTE: Single incidents, when added to other information or reports, might indicate a national or international problem.

PRODUCT CATEGORIES

- **Buildings and Grounds**: components, services and plant used in maintenance and construction.

- **Engineering Plant and Services of all types**: lifts, water systems, boilers and steam systems, electrical generators, heating, ventilation, air conditioning, water, drainage, electrical systems including high voltage installations and any other fixed plant (but not fixed medical equipment).

- **Fire Protection Installations and Equipment**

- **Transport**: vehicles and equipment.

- **Equipment**: in laundries, catering departments, work shops and any plant or equipment used for maintenance or cleaning.

- **Piped Medical Gas and Vacuum Installations**: oxygen, medical air etc, vacuum insulated evaporators and anaesthetic gas scavenging systems.

- **Fixed Luminaries**: including operating and examination lamps.

- **Communications Equipment**: telephones (including radio telephones), nurse call, paging, alarms, building management systems, radio and television, IT structured cabling/data, VHF/UHF communication equipment.

- **Lightning Protection and Anti-Static Precautions**
- **Incinerators and Waste Disposal Systems**
- **Fuel Supply and Storage Systems**
- **Fume Cupboards and Microbiological Safety Cabinets**: (installation aspects only), ductwork and interaction with ventilation systems.
- **Electrical Interference Problems**: involving any of the above.
- **Legionella Protection Equipment and Systems**
- **Building Environmental Aspects of Control of Substances Hazardous to Health (COSHH)**: involving any of the above.

URGENT REPORTS

are required in respect of:

- An explosion or sudden fracture of a pressure vessel, pressurised system or steam/high pressure hot water main.
- A major electrical explosion eg of power transformers or high voltage switchgear.
- A runaway and crash of a passenger lift.
- Piped medical gas system malfunction.
- Fire alarm system failure.

ANNEX D

Standard Adverse Incident Report Form

ANNEX E

Sample Contamination Certificate

ANNEX F

Sample Hazard Notice

ANNEX G

Sample Safety Action Notice

SCOTTISH HEALTHCARE SUPPLIES

By arrangement with the NHS in Scotland, Management Executive and Estates Environment Forum

ADVERSE INCIDENT REPORT FORM - ADV/REP/1

1. TO: ***Incident Reporting & Investigation Centre (IRIC)***

Scottish Healthcare Supplies
Trinity Park House
South Trinity Road
EDINBURGH EH5 3SH

Daytime help & report line: 0131 551 8333
Emergency: 0131 552 6380
Fax: 0131 552 6535

2. FROM

Hospital/Health Unit/NHS Trust: .....
Name: ..... Fax No.: .....
Title: ..... Tel No.: .....
Dept.: ..... Extension: .....

3. EQUIPMENT / DEVICE

Description: .....
Model: ..... Serial/Lot Nº .....
Manufacturer ..... Date of Manufacture: .....
Supplier: ..... CE marked: .....*YES / NO**.....
Supplier's Address: .....
..... Telephone Nº: .....

4. ADVERSE INCIDENT, PROBLEM OR CONCERN *(continue on separate sheet if necessary)*

Hospital/Unit: ..... Injury: *None / Patient / Staff / Other**.....
Dept/Ward: ..... Injury details and treatment required .....
Observed by: ....
Date(s): ....
Nature of Problem: .....
.....
.....
Possible Cause: .....
.....
Consequence: .....
.....

5. ACTION TAKEN

Device/Lot Quarantined: .....*YES / NO**..... Location: .....
Additional action / comments: .....
.....
.....
.....
.....

6. CONTAMINATED EQUIPMENT / DEVICES

Defective equipment / devices should not be modified or accessories removed before inspection has taken place.

All devices with possible contact with blood or other body fluids, or pathological samples, and all disposable devices, whether used or unused, should be accompanied by a Contamination Status Certificate.

Contaminated devices should not be sent by mail.

7. DECLARATION

Accompanying this form:

*Detailed report
*Used / unused device(s)
*Contamination Status Certificate

Signature *Date:*

....

ANNEX D

ADVERSE INCIDENT REPORTING

PRODUCT CATEGORIES

Reports relating to all medical equipment:- including medical devices, hospital laboratory equipment, medical supplies (excluding medicinal products) and certain dietary products.

- Imaging and Radiotherapy equipment; *X-Ray, CT, MRI, ultrasound, nuclear medicine, image intensifiers, fluoroscopy, film processors.*
- Electromedical equipment; *infusion pumps, fluid warmers, automatic tourniquets, physiological monitoring and measurement, dialysis, cardiology, physiotherapy, ophthalmology, audiology, speech therapy, electrotherapy, endoscopy, obstetrics.*
- Life Support equipment; *anaesthetic machines, ventilators, humidifiers, resuscitators, defibrillators, pacemakers, suction and oxygen equipment, cardiac bypass equipment, baby incubators, radiant warmers, breathing systems.*
- Operating Department equipment; *microscopes, operating tables, trolleys, patient transfer apparatus, heating and cooling pads, blood warmers, nerve stimulators.*
- Powered Surgical equipment; *diathermy, drills, saws, lasers.*
- General Ward Equipment; *mobile examination lamps, powered and non-powered beds, ripple mattresses, pressure garments, thermometers, blood pressure monitors, weighing machines, diagnostic sets, patient hoists / lifting apparatus.*
- Dental and Chiropody equipment; *instruments, chairs, curing lights, drills, water/air/suction.*
- Laboratory equipment; *analysers, centrifuges, media preparators, safety cabinets, incubators, warming cabinets, refrigerators, test equipment.*
- Cleaning and Sterilisation equipment; *autoclaves, sterilisers (steam, gas, chemical, dry heat), stills, disinfectors, instrument and equipment washers.*
- Aids for the Disabled; *wheelchairs, walking aids.*
- Implants; *pacemakers, defibrillators, infusion pumps, orthopaedic prostheses, heart valves.*
- Post Mortem equipment;
- Single Use Devices; *syringes, needles, administration sets, catheters, dressings, sutures, etc.*
- Orthotic and Prosthetic Appliances;
- Certain Dietary products; *enteral food preparations, ready-to-feed (RTF) preparations solely for hospital use.*
- Electrical interference problems; *involving any of the above.*
- Aspects of Control of Substances Hazardous to Health (COSHH); *Involving any of the above.*

Reports relating to estates systems and equipment:- engineering systems and plant, installed services including piped medical gas and medical gas scavenging systems, buildings and building fabrics, vehicles.

- Buildings and Grounds; *components, services and plant used in maintenance and construction.*
- Engineering Plant and Services of all types; *lifts, water systems, boilers and steam systems, electrical generators, heating, ventilation, air conditioning, water drainage, electrical systems including high voltage installations and any other fixed plant (but not fixed medical equipment).*
- Fire Protection installations and equipment;
- Transport; *vehicles and equipment.*
- Equipment; *in laundries, catering departments, work shops and any plant or equipment used for maintenance or cleaning.*
- Piped medical Gas and Vacuum installations; *oxygen, medical air etc., vacuum insulated evaporators, anaesthetic gas scavenging systems.*
- Fixed Luminaires; *including operating and examination lamps.*
- Communications equipment; *telephones, (including radio telephones), nurse call, paging, alarms, building management systems, radio and television, IT structured cabling/data, VHF/UHF communication equipment.*
- Lightening Protection and Anti-static precautions;
- Incinerators and waste disposal systems;
- Fuel Supply and Storage systems;
- Fume Cupboards and Microbiological Safety Cabinets (installation aspects only); *ductwork and interaction with ventilation systems.*
- Legionella Protection Equipment and Systems;
- Electrical interference problems;
- *involving any of the above.*
- Building environmental aspects of Control of Substances Hazardous to Health (COSHH); *involving any of the above.*

ANNEX E

DECON/1

SCOTTISH HEALTHCARE SUPPLIES
A Division of the Common Services Agency

CONTAMINATION STATUS CERTIFICATE

In accordance with Health Service Guidelines HSG(93)26; in Scotland DGM(87)66 (under review) "Decontamination of equipment prior to inspection, service or repair".

Equipment/Item: _____
Make: _____
Model/Code: _____
Serial/Lot No: _____
Comments: _____

Please tick appropriate box:

☐ This equipment / device has not been used in an invasive procedure or been in contact with blood, or other body fluids, or pathological samples

☐ This equipment has been cleaned and decontaminated. The method of decontamination was:

_____

☐ This equipment could not be decontaminated. The nature of risk and safety precautions to be adopted are:

_____

NB DEFECTIVE EQUIPMENT / DEVICES SHOULD NOT BE MODIFIED OR ACCESSORIES REMOVED BEFORE INSPECTION HAS TAKEN PLACE. ALL DEVICES WITH POSSIBLE CONTACT WITH BLOOD OR OTHER BODY FLUIDS, OR PATHOLOGICAL SAMPLES, AND ALL DISPOSABLE DEVICES, WHETHER USED OR UNUSED, SHOULD BE ACCOMPANIED BY A CONTAMINATION STATUS CERTIFICATE.

CONTAMINATED DEVICES SHOULD NOT BE SENT BY MAIL.

Signed: _____ Name: _____ Date: _____

Position held: _____

Organisation: _____

HAZARD NOTICE

By arrangement with the NHS in Scotland, Management Executive

HAZ(SC)95/04
21 AUGUST 1995
Medical Device

TROPHY RADIOLOGIE (UK) LTD. INTRA-ORAL DENTAL X-RAY UNITS 70-X, IRIX 70-C AND IRIX 70-E MECHANICAL DEFECTS

SUMMARY

Mechanical defects have been reported on the Trophy Radiologie (UK) Ltd. Intra-oral Dental X-ray Units 70-X, IRIX 70-C and IRIX 70-E with potential for injury. Units manufactured between November 1990 and April 1994 require modification.

BACKGROUND

1. There are two problems associated with the scissor arm of the Trophy Radiologie (UK) Limited Intra-oral Dental X-ray Units 70-X, IRIX 70-C and IRIX 70-E, with potential to cause injury:

   a) the casting may break allowing the x-ray arm and tubehead to fall,
   b) the tubehead rotational axis may seize inside the arm resulting in the tubehead unscrewing and falling, causing the sudden rise of the scissor arm.

2. The manufacturer has advised that the implicated units will be modified free of charge through the dealer network.

ACTION

3. This Hazard Notice should be brought to the attention of all appropriate managers, staff and users.

4. All Trophy Radiologie (UK) Limited Intra-oral Dental X-ray Units 70-X, IRIX 70-C and IRIX 70-E installed/supplied since November 1990 should be identified.

5. The manufacturer or supplier should be contacted as soon as possible to ascertain what modification may be necessary.

6. Remedial action, where necessary, should be undertaken in accordance with the manufacturer's recommendations.

7. Advice should be obtained from the manufacturer (Trophy) as to whether the equipment may be safely used in the interim.

ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Mr J Mehmet, Trophy Radiologie (UK) Limited,
Unit 3, Block B, The Connaught Business Centre,
9 Malham Road, Forest Hill, LONDON SE23 1AH
Tel: 0181 291 9909

Suggested Distribution	Chief Administrative Dental Officers	Dental Surgeons	General Dental Practitioners
Maxillo facial surgeons	Medical Physics	Orthodontists	Radiation Protection Advisers
Radiation Protection Supervisors	Radiology	Safety officers	Supplies
Trust Clinical Dental Managers	Works		

SCOTTISH HEALTHCARE SUPPLIES
Trinity Park House Edinburgh EH5 3SH
A Division of the Common Services Agency for the NHS in Scotland

Emergency
0131 552 6380
Helpline
0131 551 8333

CONTACT: JOHN HARPER
TEL: 0131 551 8522
FAX: 0131 552 6535

AUTHORISING OFFICER

SAFETY ACTION NOTICE

By arrangement with the NHS in Scotland, Management Executive and the Estate Environment Forum

SAN(SC)95/25
SEPTEMBER 1995
Estates
Page 1 of 2 Pages

STEAM BOILER PLANT: ADVICE ON WATER HAMMER AND OPERATING PROCEDURES

SUMMARY

A boiler crown valve failure which resulted in a fatality has highlighted the dangers of water hammer and inappropriate procedures in the operation of steam boiler plant. Guidance is given in avoiding water hammer.

BACKGROUND

1. Following a steam boiler crown valve failure as a result of water hammer, attention is drawn to the need for safe working procedures and operative training in the operation of steam boiler plant.

2. HSE Specialist Inspector Report No.5 (1988), Avoiding Water hammer in Steam Systems is the main source of guidance. Other references are given overleaf.

3. Serious water hammer may occur as a one-off incident associated with a particular operation or sequence of operations of steam plant; for example, when a valve is opened to admit steam to a main pipeline which is cold or has been allowed to cool. The most common circumstances which cause water hammer are:

   a. Condensate driven by steam, along a steam main at high velocity, until it reaches an obstruction or a sudden change in direction such as a sharp bend, tee or a valve, which it strikes with a "hammer blow".

   b. Condensate moving into a vacuum. When steam is admitted into a cold or cooler space or if it makes contact with cooler water, it may condense rapidly. If the steam becomes trapped in a pocket, a vacuum will form as it condenses. Condensate may then be drawn into the vacuum at speeds high enough to cause water hammer.

   c. Flash steam in mains occurs when water under pressure is released to a lower pressure at a temperature above the boiling point for the lower pressure. When flash steam arises in a flooded main which is under pressure the steam expands driving the water out of the way. The flash steam then condenses, creating a vacuum in the pipe and conditions for water hammer to occur as in **b**.

4. The ways to avoid water hammer are by (A) good design, (B) adequate draining of pipework and fittings under all conditions of operation, (C) proper inspection and maintenance of the systems, (D) appropriate training of all staff in the careful operation of both manual and automatic valves. Care must be taken at the start up of steam systems to make certain that the system is effectively drained and that start up procedures minimise the rate at which the condensate forms.

ACTION

5. This Safety Action Notice should be brought to the attention of all appropriate managers, contractors, staff and boiler operatives.

6. A review of the existing installations and practices should be undertaken.

Suggested Distribution	General Managers	Estates Managers	Facilities Managers
Safety Officers & Representatives			

SCOTTISH HEALTHCARE SUPPLIES
Trinity Park House Edinburgh EH5 3SH
A Division of the Common Services Agency for the NHS in Scotland

Emergency
0131 552 6380
Helpline
0131 551 8333

CONTACT: MR B THOMPSON
UNIT DIRECTOR BABTIE GROUP
TEL: 0141 204 2511
FAX: 0141 226 3109

AUTHORISING OFFICER

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SAFETY ACTION NOTICE

By arrangement with the NHS in Scotland, Management Executive and the Estate Environment Forum

SAN(SC)95/25
SEPTEMBER 1995
Estates

STEAM BOILER PLANT: ADVICE ON WATER HAMMER AND OPERATING PROCEDURES

ENQUIRIES

Technical Enquiries regarding this Safety Action Notice should be addressed to: Mr. B. Thompson, Director, Babtie Electrical & Mechanical, 95 Bothwell Street, Glasgow G2 7HX, Tel: 0141 204 2511.

The following documents, available through HMSO and HSE Books, PO Box 1999, Sudbury, Suffolk, CO10 6FS, Tel: 01787 881165 Fax: 01787 313995.

HSC Safety of Pressure Systems - Approved Code of Practice COP37 ISBN 0-11-885514

HS(R) 30 A Guide to Pressure Systems and Transportable Gas Containers Regulations - ISBN 0 11 885516 6

PM5 HSE Guidance Note (Revised December 1989), Automatically Controlled Steam and Hot Water Boilers ISBN 0 11 883529 7

PM60 HSE Guidance Note - Steam boiler blowdown systems ISBN 0 11 883949 7

HSE Technology Division, Specialist Inspectors Report No.5 (1988), Avoiding Water hammer in Steam Systems

HSE "Introducing Competent Persons" Pressure systems and Transportable Gas Containers Regulations IND(S)29(L)

Health Guidance Note: The Pressure Systems & Transportable Gas Containers Regulations 1989 ISBN 0-11-321674-2

BS 759: Valves, gauges and other safety fittings to boilers and to piping installations for and in connection with boilers: Part 1 Specifications for valves, mountings and fittings

BS 799: Oil burning equipment

BS 2486: Recommendations for treatment of water for land boilers

BS 2790: Specification for design & manufacture of shell boilers of welded construction

BS 5410: Code of practice for oil firing

BS 5885: Automatic gas burners

BS 6759: Safety valves: Part 1, Specification for safety valves for steam & hot water

SCOTTISH HEALTHCARE SUPPLIES
Trinity Park House Edinburgh EH5 3SH
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UNIT DIRECTOR BABTIE GROUP

TEL: 0141 204 2511
FAX: 0141 226 3109

AUTHORISING OFFICER J M Monkhouse

GENERAL GUIDANCE

PURPOSE OF THE REPORTING SYSTEM

1. An adverse incident is an event which adversely affects, or has the potential to affect, the health or safety of patients, users or other persons. Local incidents may often have implications for other health care services. IT IS ESSENTIAL, THEREFORE, THAT ALL ADVERSE INCIDENTS AND DEFECTIVE EQUIPMENT ARE REPORTED PROMPTLY. Serious deficiencies in the technical performance of equipment should also be reported, as should any observation which gives cause for concern regarding safety, even when an actual incident has not occurred. The central collation of adverse incident reports is essential for the identification of trends which may result in the issue of warnings to users of potentially hazardous equipment or unsafe procedures. The term "equipment" is taken to include any items, device, supplies,service, product, system or plant as detailed in Annexes B and C.

HEALTH AND SAFETY EXECUTIVE

2. Under their statutory powers, the Health and Safety Executive (HSE) or Local Authority Inspectors may:-

- identify inadequacies in a product's design
- issue instructions for use or manner of use
- make observations and recommendations.

If any action by the HSE or Local Authority on NHS premises might have implications for other users and/or patients, staff, visitors or contractors, it should be reported to ***Scottish Healthcare Supplies (SHS).***

REPORTING

3. Reports should be submitted in accordance with:

Annex B: Reports relating to all *medical equipment*:- including medical devices, hospital laboratory equipment, medical supplies (excluding medicinal products) and certain dietary products;

Annex C: Reports relating to *estates equipment*:- engineering plant, installed services including piped medical gas and medical gas scavenging systems, buildings and building fabrics, vehicles;

All adverse incidents etc relating to products in Annexes B and C should be reported to Scottish Healthcare Supplies in full at the following address:-

INCIDENT REPORTING AND INVESTIGATION CENTRE (IRIC)

Scottish Healthcare Supplies
Trinity Park House
South Trinity Road
EDINBURGH
EH5 3SH

Daytime help and report line 0131 551 8333
Emergency 0131 552 6380
Fax 0131 552 6535

PROCEDURES TO BE FOLLOWED AND INFORMATION TO BE SUPPLIED

4. The initial report of an incident should contain as much essential detail as available. However, it should never be delayed on this account and serious cases should be reported by the fastest means possible. **All oral reports should be supported in writing**, preferably using the standard Adverse Incident Report Form (Annex D). Copies of this form are available from Scottish Healthcare Supplies (SHS).

5. All material evidence should be labelled and kept secure, under the charge of a responsible officer. This includes the equipment and, where appropriate, packaging or other means of batch identification. The equipment should not be interfered with in any way except for safety reasons or to prevent its loss. If necessary, a record should be made of all readings, settings and positions of switches, valves, dials, gauges and indicators, together with any photographic evidence and eye witness reports. In serious cases, this record should be witnessed, and the witness should also make a personal written record.

6. Defective items should not be allowed to be repaired or returned to the supplier or discarded before an investigation has been carried out. In addition, items should not be cleaned (but see paras 11-12 below). The manufacturer or supplier of a defective product should be informed promptly, and may be allowed to inspect the product if accompanied by an officer from the Health Board, NHS Trust or other NHS body, or SHS, with knowledge of the product so as to prevent tampering or false claims. The HSE may also wish to inspect the equipment. In the case of a large batch of consumable items it may be possible to pass samples to the manufacturer if this will aid the investigation. However, the manufacturer must not be allowed to exchange, interfere with or remove any part of the product if this would prejudice the investigations of SHS or other official bodies.

7. Where clinical need requires equipment to be kept in use, and the defective part(s) are clearly identifiable and removable, they may be removed, secured and labelled for later inspection, and the equipment repaired for re-use.

8. Where a manufacturer wishes to investigate a defective, or possibly defective, CE marked medical device, this should be reported to SHS who will seek guidance from the Medical Devices Agency (the UK Competent Authority). It should be noted that from June 1998 all medical devices must be CE marked before they can be placed on the market, in accordance with the Medical Device Regulations. Active implantable medical devices, however, must be CE marked as from 1 January 1995.

5. Although there is no statutory requirement for Health Boards, NHS Trusts and the CSA to participate in exchanging information about potentially hazardous equipment and supplies, the Management Executive takes the view that any NHS body which does not do so could be held to be failing in its duty of care to patients, staff, visitors and contractors.

Yours sincerely

PAUL WILSON
Director, NHS Trusts