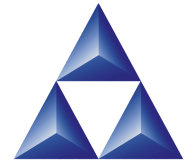


SN (NI) 2002/22

DATE: 13 June 2002

**For Attention and Action by:
Chief Executive of each HSS Trust
General Manager/Chief Executive of each HSS Board
Chief Executive of each Agency**



**HEALTH ESTATES
ESTATE POLICY**

**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

MANAGEMENT OF LOANED MEDICAL DEVICES, EQUIPMENT OR ACCESSORIES FROM MANUFACTURERS OR OTHER TRUSTS

MANUFACTURER/SUPPLIER

Various

PROBLEM

- Medical devices and equipment on loan to Trusts may not be receiving appropriate maintenance and service.
- Responsibilities for management of medical devices and equipment on loan to Trusts may not be addressed by Trust device management systems.

DISTRIBUTION

This notice should be brought to the attention of all who need to know or be aware of it, including those listed below, in accordance with local procedures. This will include:

- | | |
|-------------------------------------|--------------------------------|
| • Liaison Officers | • Device Managers |
| • Risk Managers | • Estates Managers |
| • Health & Safety Officers/Advisors | • Supplies Staff |
| • Medical Directors | • Purchasing Departments |
| • Nurse Directors | • Theatre Staff |
| • All Medical and Nursing Staff | • Catheter Laboratory Managers |
| | • Private Clinics |

Boards/Trusts should ensure that if appropriate, this information is passed to all persons having the responsibility for the premises registered under "THE REGISTERED HOMES (NI) ORDER 1992.

ACTION

The following actions should be taken:

1. Managers should ensure that Trust device and equipment management systems and procedures include requirements for:
 - liaison with purchasing departments when the acquisition of loaned equipment is anticipated including the signing of indemnity agreements (NHS Form of Indemnity) and definition of hospital's liability in the event of loss or damage to the device;
 - registration of loaned equipment, including ownership, service history, current location, service responsibility and instructions for use;
 - initial acceptance checking of loaned equipment prior to putting into service, in accordance with manufacturers' instructions;
 - provision of instructions for use (and updates) to end users;
 - periodic checking of loaned equipment for functionality and safety and repair in accordance with manufacturers' instructions, whether by the Trust, owner/manufacturer or a third party;
 - clear definition of responsibilities for the maintenance, repair and regular safety checks of loaned equipment (including identifying the person(s) responsible for

S A F E T Y

NOTICE

initiating the testing of the equipment and those responsible for performing the testing);

- adequate instructions regarding decontamination/sterilisation of re-usable equipment and availability of appropriate equipment/facilities to carry out the process by the hospital (see Annex NIAIC Safety Notice SAN(NI)2000/31;
- identification and withdrawal or return of unwanted or obsolete loaned equipment.

2. Purchasing departments should:

- advise equipment management departments (e.g. Electronic Biomedical & Medical Engineering Department (EBME) or Estates Department) whenever purchasing contracts include the loan of equipment and/or accessories from a third party;
- ensure that signed indemnity agreements are obtained for rented, loaned or borrowed equipment (including equipment on trial) before being put into service.

BACKGROUND

NIAIC has become aware of an incident in which a loaned pacing system analyser (PSA) ceased to function during temporary pacing. This caused a hypoxic episode and requiring patient resuscitation. The cause of the event was identified as damaged battery contacts, which resulted in power supply disconnection. Investigation established that the responsibilities for checking loaned equipment were unclear and that the recommended annual manufacturer's check had not taken place within the previous 5 years. The device was on permanent loan from a manufacturer and the incident could have been prevented if the equipment had been checked and serviced regularly.

Other examples of equipment that may be loaned to hospitals are programmers used with active implantable devices (pacemakers, defibrillators, neurostimulators etc), biopsy guns, ultrasound scanners, X-ray film processors, computed radiography (CR) equipment, syringe drivers, ablation equipment, some surgical instruments and specialist beds.

Where devices are on loan (e.g. borrowed from a manufacturer or another hospital) it is important to be clear about where responsibility lies for any problems which may arise. Borrowed devices must go through an acceptance procedure. The central purchasing department should handle administration of the loan. The purchasing department should ensure indemnity agreements are signed for rented, loaned or borrowed equipment including equipment on trial.

Additionally, maintenance issues have been addressed by NIAIC in Device Bulletins DB 9904(NI) (Medical Device and Equipment Management for Hospital and Community-based Organisations) and DB (NI) 2000/02 (Medical Devices and Equipment Management: Repair and Maintenance Provision) and in Safety Notice SAN(NI) 2000/31 (Handling of Surgical Instruments on Loan from another Organisation).

ENQUIRIES

Enquires to the NIAIC should quote the reference number SN(NI) 2002/22 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC), Health Estates, Estate Policy Directorate, Stoney Road, Dundonald, Belfast BT16 1US.

Tel: 02890 523714, Fax: 02890 523900, Email: brian.godfrey@dhsspsni.gov.uk

Brian Godfrey
NIAIC Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in Safety Notice SN (NI) 2002/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety
Áisíneacht Feidhmeannach don Roinn Sláinte, Serbhísí Sóisialta agus Sábháilteacht Phoiblí*



HEALTH ESTATES
ESTATE POLICY

**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

SAFETY

NOTICE



DEFECT & INVESTIGATION CENTRE

Annex to
SN(NI)2002/22

FOR ACTION BY:
Chief Executive of each HSS Trust
General Manager/Chief Executive of each HSS Board
General Manager/Chief Executive of each Agency

Stoney Road Dundonald Belfast
Northern Ireland BT16 1US

Telephone 028 90 523714
Facsimile 028 90 523900GTN Code
440

SAN(NI) 2000/31
Date:9 October 2000

TITLE:
**HANDLING OF SURGICAL INSTRUMENTS ON
LOAN FROM ANOTHER ORGANISATION**

1. SUMMARY

A lack of awareness of the need to control loaned surgical instruments has led to delayed or cancelled patient treatment. Organisations have expressed concerns over the decontamination status of such instrumentation and the lack of accompanying documentation.

2. ACTION

The following information should be brought to the attention of all who need to know or be aware of it. This will include:

- | | |
|--------------------------------|---------------------------------|
| • Medical Directors | • Quality Control Pharmacists |
| • Directors of Nursing | • Chairs of Primary Care Groups |
| • Theatre Managers | • General Medical Practitioners |
| • Sterile Services Managers | • General Dental Practitioners |
| • Supplies Managers | • Practice Nurses |
| • Surgeons | • Hospices |
| • Control of Infection Doctors | • Risk Managers |
| • Infection Control Nurses | • Safety Liaison Officers |

Ensure that appropriate procedures are put in place and followed, to manage the use of loaned instrumentation.

Ensure that adequate time is allowed to carry out effective decontamination both prior to and after use.

Decontaminate all loan instrumentation both before and after use in accordance with the manufacturer's instructions. All devices should be decontaminated in a Central Sterile Services Department.

Ensure that loaned instrumentation is accompanied by relevant reprocessing instructions and a comprehensive list of contents. If these are missing or if you do not have the facilities to follow them (eg inappropriate sterilisation time/temperature relationships are quoted) the instruments should not be used.

Check that indemnity forms have been completed and that responsibilities for the instrumentation have been identified and documented.

Ensure that loaned instrumentation is included in the organisation's moving and handling policy.

Ensure that systems are in place to allow instrumentation to be tracked through the decontamination processes and to the patient upon which it is used.

Do not send contaminated items through the post.

Boards/Trusts should ensure that if appropriate, this information is passed to **ALL** persons having the responsibility for premises registered under "THE REGISTERED HOMES (NI) ORDER 1992".



An Executive Agency of the Department of Health
and Social Services and Public Safety

SAFETY ACTION NOTICE

(SAN)

3. BACKGROUND

Instrumentation may be loaned to an organisation so that a particular procedure can be performed. The instruments are loaned both from manufacturers and other hospitals and are returned after use. This practice increases the risks associated with the decontamination and reprocessing of such devices because the organisation may not be familiar with them.

General guidance on third party handling and decontamination of devices has previously been issued by the Department in the following publications:

PEL(94)34 – *Decontamination of equipment prior to inspection, service or repair.*

Device Bulletin DB9904(NI) *Medical Devices and Equipment Management for Hospital and Community Based Organisations* – Appendix A3 (Preparation of Medical Devices, Equipment and Materials to be returned to, or handled locally by, Service Departments, Manufacturers, or their representatives: Infection Hazards.)

Sterilization, Disinfection and Cleaning of Medical Equipment: Guidance on Decontaminations from the Microbiology Advisory Committee to Department of Health Medical Devices Agency. Part 2: Protocols

HSS(MD)16/99 *Controls Assurance in Infection Control: Decontamination of Medical Devices*

HSS(MD) 15/99 *Variant Creutzfeldt-Jakob Disease (vCJD): Minimising The Risk of Transmission.*

4. ENQUIRIES

Enquiries regarding this notice should be addressed as follows:

NORTHERN IRELAND DEFECT & INVESTIGATION CENTRE (NIDIC)

Health Estates

Estate Policy

Stoney Road

Dundonald

Belfast BT16 1US

marked for the attention of Mr Brian Godfrey

Tel: 028 90 523714

Fax: 028 90 523900

Email: brian.godfrey@dhsspsni.gov.uk

Yours faithfully

BRIAN GODFREY

Defect Centre Manager

HOW TO REPORT DEFECTS

Professional Estate Letter PEL(93)36 issued by Estate Services Directorate, on 27th July 1994 advises Health and Social Services Boards, HSS Trusts and Agencies how to notify HPSS about accidents with and defects in medicinal products, buildings and plant and other medical and non medical equipment and supplies.