



TITLE:

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

MANUFACTURER/SUPPLIER

Various

PROBLEM

- This Notice replaces Safety Notice SN(NI)2002/22 "Management of Loaned Equipment or Accessories from Manufacturers or other Trusts", June 2002, which has been withdrawn.
- Medical devices and equipment on loan to organisations may not be receiving appropriate maintenance and service.
- Responsibilities for management of medical devices and equipment on loan to organisations may not be addressed by organisational device management systems.

DISTRIBUTED BY NIAIC TO:

Chief Executive of each HSS Board, Trust and Agency
NIAIC Liaison Officers

For onward distribution as appropriate to:

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:

Risk Managers	Stores Staff (Trust and RSS)
Health & Safety Officers/Advisors	Purchasing Departments
Medical Directors	Independent Health and Social Care Providers
HSS Trust Pharmacy Managers	Clinical and Social Care Governance Leads
Nursing Directors	Chairs of Local Health and Social Care Groups (LHSCGs).
All Medical, Nursing and Care Staff	Allied Health Professionals
Estates Managers	Community and Social Care Staff

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 their organisational device and equipment management systems and procedures include requirements for:
 - Appropriate liaison with RSS Purchasing Departments when the acquisition of loaned equipment (associated with the purchase or otherwise) is anticipated including the signing of indemnity agreements (NHS Form of Indemnity) and definition of the organisations liability in the event of loss or damage to the device or equipment;
 - registration of loaned devices and equipment, including ownership, service history, current location, service responsibility and instructions for use;
 - initial acceptance checking of loaned devices and equipment prior to putting into service, in accordance with manufacturers' instructions;

SAFETY

NOTICE

- provision of instructions for use (and updates) to users of the device or equipment;
- periodic checking of loaned devices and equipment for functionality and safety and repair in accordance with manufacturers' instructions, whether by the organisation, owner/manufacturer or a third party;
- clear definition of responsibilities for the maintenance, repair and regular safety checks of loaned devices and equipment (including identifying the person(s) responsible for initiating the testing of the devices and equipment and those responsible for performing the testing);
- adequate instructions regarding decontamination/sterilisation of re-usable devices and 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. Purchasers of medical devices and equipment should:

- advise the relevant Purchasing Agent (e.g. RSS) and their device and equipment management departments (e.g. Electronic Biomedical & Medical Engineering Department (EBME) or Estates Department) whenever purchasing contracts include the loan of devices or equipment and/or accessories from a third party;
- ensure that signed indemnity agreements are obtained for rented, loaned or borrowed devices and equipment (including those 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 devices and 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. Loaned devices may also include products that are on trial prior to a purchase decision such as admin/blood sets, medical gloves, electrodes, syringes etc.

Where devices and equipment are on loan (e.g. borrowed from a manufacturer or another organisation) it is important to be clear about where responsibility lies for any problems which may arise. Borrowed devices and equipment must go through an acceptance procedure. Organisations should have in place procedures that identify designated management responsibilities for administration of the loan. Designated managers should ensure indemnity agreements are signed for rented, loaned or borrowed devices and equipment including those on trial. For devices and equipment on loan between Trusts, it may be possible to address where responsibility lies through the use of an overarching loan agreement between Trusts rather than arranging individual and repetitive indemnities. However, details must be recorded for individual device or equipment on loan covered by any overarching inter-Trust agreement.

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).



HEALTH ESTATES
ESTATE POLICY

**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

SAFETY

NOTICE

ENQUIRIES

Enquires to the NIAIC should quote the reference number SN(NI) 2003/02 and be addressed to:

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

Tel: 028 9052 3714
Fax: 028 9052 3900
Email: brian.godfrey@dhsspsni.gov.uk



Brian Godfrey
NIAIC Manager



HEALTH ESTATES
ESTATE POLICY

**NORTHERN
IRELAND
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SAFETY

NOTICE

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) 2003/01. 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*



DEFECT & INVESTIGATION CENTRE

Annex to
SN(NI)2003/02

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".

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.