

EQUIPPED TO CARE

BULLETIN

(Northern Ireland Version)

Equipped to Care

*The safe use of medical
devices in the 21st century*

*A guide for health care
professionals, support workers
and managers*



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

*Áisíneacht Feidhmeannach don Roinn Sláinte,
Serbhísí Sóisialta agus Sábháilteacht Phoiblí*

*DB (NI) 2000/6
DECEMBER 2000*



The Medical Devices Agency helps safeguard public health by working with users, manufacturers and lawmakers to ensure that medical devices meet appropriate standards of safety, quality and performance and that they comply with the relevant Directives of the European Union.

Our primary responsibility is to ensure that medical devices achieve their fullest potential to help healthcare professionals give patients and other users the high standard of care they have a right to expect.

The Medical Devices Agency is an Executive Agency of the Department of Health



The key aim of the Northern Ireland Adverse Incident Centre (NIAIC), part of Health Estates, is to record and investigate reported adverse incidents involving Medical Devices and equipment used in Health and Personal Social Services in Northern Ireland and to issue warning notices and guidance to help prevent recurrence and avert patient or user injury. NIAIC has direct links with MDA who co-ordinate across the adverse incident centres in England, Scotland, Wales and Northern Ireland. NIAIC also disseminates safety information in Northern Ireland, including information provided by MDA.

Health Estates is an Executive Agency of the Department of Health, Social Services and Public Safety.

INTRODUCTION

Medical Devices and equipment are used everyday by most health care professionals to support the care and treatment of patients. Professionals play a vital role in ensuring that equipment is used safely and for the purpose it was intended.

AIMS OF THIS DEVICE BULLETIN

- ◆ **help nurses, midwives, health visitors, other health care professionals and support workers understand their role in the safe use, purchase and management of medical devices.**
- ◆ **provide managers with pointers to best practice for training, purchase and maintenance of medical devices.**
- ◆ **ensure that arrangements for the purchase, use and maintenance of medical devices are firmly embedded within the local framework for clinical governance.**
- ◆ **raise awareness about the role of the Northern Ireland Adverse Incident Centre (NIAIC) and how it can provide advice and guidance to support the safe use of medical devices.**

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1. A CHANGING WORLD

1.1 Changes in Technology and Clinical Practice

Medical Devices play an increasingly important role in supporting patient care. However, they cannot replace the need for the experience of nurses, doctors and other health care professionals who assess, diagnose and deliver therapeutic care and who ensure that any device is functioning as it should.

Rapid changes in health care technology and clinical practice present particular challenges. Increased throughput of patients combined with the more complex therapies are likely to impact on the work pressures that health care professionals experience. Current trends indicate that:

- ◆ acute hospital care will continue to be intensive and complex with a sustained growth in the sophistication of medical technology to support diagnosis, treatment and care
- ◆ there will be continued growth in the capacity of the community and primary care infrastructure to provide acute and intermediate care through, for example, rapid response teams, chronic disease management and rehabilitation. Inevitably, this will lead to an increase in the use of medical devices and equipment to treat patients in the GP surgery or their own homes
- ◆ nurses and midwives will continue to need to expand their technical skills to use a growing range of medical devices, from the relatively simple to the complex
- ◆ patients will be increasingly knowledgeable about their health needs and treatment options as they access information from diverse sources, including the internet and TV
- ◆ the public will increasingly use self-screening and testing devices, for example, blood pressure, cholesterol, blood sugar testing
- ◆ patients with chronic and/or life limiting illness will wish to manage their own care and treatment regimes, for example, home intravenous therapy and dialysis. This will require appropriate individually planned education, preparation and support from health care professionals.

As medical devices become more sophisticated and frequently used, there are implications for the training of nurses, midwives, health visitors and other health care professionals.

There is an emphasis on improving the quality of care through clinical governance arrangements in HPSS organisations. Coupled with modern self-regulation there is emphasis on the accountability of both the individual and the organisation to provide a working environment that supports the provision of safe and effective care for patients. At the same time, health professionals are committed to lifelong learning and to developing their expertise.

Within a framework of clinical governance, health care professionals face challenges in risk management, clinical standard setting and clinical effectiveness.

Practitioners have a personal accountability for self-regulation, built on maintaining and improving professional knowledge and competence throughout their careers. HPSS organisations have a responsibility to ensure that local structures support professional self-regulation and that health care professionals have access to appropriate training and development.

1.2 A Shift to a “Safety Culture”

The report of the expert working group on learning from adverse events in the NHS, *An Organisation with a Memory* (DoH 2000), stated that a blame culture has existed in the NHS, which encourages people to cover up errors for fear of retribution and act against the identification of the true causes of failure, because **they focus heavily on individual actions and largely ignore the role of the underlying systems**. A shift is needed to a “safety culture”, where open reporting and balanced analysis are encouraged in principle and by example.

If adverse incidents are reported and if the chain of events leading up to and contributing to an adverse incident are analysed, it will allow the individuals involved and the organisation to identify where things went wrong. It is then possible to learn from the incident and to develop strategies which prevent the same thing happening again.

Effective clinical governance means that there is a shared goal between the individual and the organisation to minimise hazards related to the use of medical devices and to ensure that everyone who needs to, is able to use medical devices safely and effectively.

2. WHAT IS A MEDICAL DEVICE

The term “medical device” may conjure up visions of complex, highly technical equipment used in acute hospital care. However, “medical device” covers a broad range of products including products used everyday in most health care settings such as needles, syringes, infusion pumps, endoscopes, examination gloves, non-medicated dressings and blood glucose meters. A medical device can be defined as any instrument, apparatus, appliance, material or health care product, excluding drugs, used for a patient or client for the purpose of:

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

3. PERSONAL AND PROFESSIONAL ACCOUNTABILITY

All health care professionals and support workers employed in the public and private sector are accountable for ensuring that they use medical devices safely. The NHS Confederation (1999) defines accountability as “*one of the three foundations of public service. Everything done by those who work in the NHS must be able to stand the test of parliamentary scrutiny, public judgements on propriety and professional codes of conduct*”.

Nurses, midwives and health visitors will be well aware of the United Kingdom Central Council (UKCC) Code of Professional Conduct (1992) which identifies their personal accountability. Occupational therapists, physiotherapists and their professional groups have professional standards with similar principals to guide their practice. Health Care professionals should make sure they are familiar with the particular clauses in their own code.

4. ENVIRONMENT IN WHICH MEDICAL DEVICES ARE USED

A medical device that is easy for one person to use safely and effectively may present problems for someone else with different skills and experience. It is important to be aware of the characteristics of the environment within which the equipment will be used and the people who will be using it as well as the patient's needs.

What might be considered a highly complex piece of equipment in one environment, might be considered routine "bread and butter" equipment in another. For example, staff working in a nursing home would not be expected to operate a life support machine for an acutely ill patient, and intensive care nurses would not be expected to know how to fit a patient limb prosthesis without specialist training. However, under the right circumstances and with appropriate, individually tailored training, patients, and clients can be supported using complex medical devices such as a ventilator for long term or palliative care in the home setting.

Health care professionals and managers should consider the following issues in managing the use of medical devices:

- ◆ knowledge of the individual's medical condition and likely responses to treatment.
- ◆ assessment of need for particular medical devices and their availability.
- ◆ documentation of device used and monitoring undertaken (checking at specified intervals that the device is functioning as it should, for example, delivering a drug at the correct infusion rate).
- ◆ ability of the health care professional to interpret information provided by the device, for example, ECG trace, and identification of training needs.
- ◆ environment of care, for example, high tech, low tech or home setting.
- ◆ skill mix and staffing levels, for example, the ratios of qualified to unqualified nurses, of nurse to patient and single patient.
- ◆ nurse/health care professional workload and ability to monitor patient and equipment within the care environment.
- ◆ previous training and experience using similar type of devices, for example, infusion pumps, ventilators, patient hoists and prosthesis fitting.

When a health care professional selects medical devices that will be operated by patients and/or carers, a number of considerations must be taken into account:

- ◆ sensory capabilities: vision, hearing touch.
- ◆ co-ordination: manual dexterity.
- ◆ cognitive ability and memory.
- ◆ previous experience with medical devices.
- ◆ patient/carer expectations about how the device will operate.
- ◆ physical environment in which the medical device will be used and others who might have access to it, for example, children.
- ◆ patient and carer awareness of their responsibility to look after and monitor the equipment issued to them and to return HPSS-owned devices on completion of treatment.
- ◆ personal responsibility of patients and carers for maintenance of equipment where devices have been purchased privately, for example, apnoea alarms, nebulisers, TENS machines.

5. WRITTEN GUIDANCE FOR PATIENTS AND CARERS

Before a medical device is issued to a patient or carer they should receive training in how to use the device. This should be supported by written guidance. The manufacturer's instructions should provide some information but this should be tailored to the needs of the individual patient or carer. Written guidance should cover the following:

- ◆ the name of the device.
- ◆ the operation and control of the device.
- ◆ checking of the device while in use.
- ◆ recognition of a device failure or fault.
- ◆ action to be taken in the event of a device failure or fault.
- ◆ individuals to be contacted in an emergency.

6. PEOPLE MAKE ERRORS

6.1 Infusion Pump Devices

The Northern Ireland Adverse Incident Centre (NIAIC) receives many reports of adverse incidents involving infusion pumps which lead to serious injury or death. In any hundred reports involving pumps, nearly half are of over-infusions, with 80% due to user error rather than a fault with the device. In addition to the burden of knowledge that a death or serious injury

Case Studies

A report was received from the coroner of user error resulting in a fatality. An infusion rate of 20mm per hour was set instead of 2mm per hour. The practitioner who had set up the pump had not been trained in the use of the pump.

An over-infusion of diamorphine occurred because one model of a syringe driver was mistaken for another. The nurse involved was not trained to perform the procedure and other staff on the ward were only familiar with one model.

A volumetric pump set to deliver 1000ml over 8 hours delivered it in 2 hours. No fault was found with the pump nor was there any data in its memory to indicate a cause of the reported over-infusion. The possibility of user error in setting up the pump has been strongly suggested.

could have been avoided by the correct use of a device, increasingly the coroner refers such fatalities to the police authorities for investigation. In nearly all cases, nurses and midwives are responsible for setting up and calibrating infusion pumps and so it is they who find themselves most often at the centre of a police investigation and giving evidence to inquest enquiries.

It is essential to ensure that users can use devices safely if errors are to be avoided. Although adverse incidents do occur as a result of device malfunctions, more commonly, problems are due to user error.

6.2 User Error

Errors in the use of medical devices may lead to adverse incidents which harm the patient. Adverse incidents due to user error occur for a variety of reasons. These include:

- ◆ **Devices used by those who have not been properly trained in their use.**

Several incidents have been reported where ultrasound foetal monitors have apparently shown a healthy foetal heart beat but the infant was stillborn. It appears that the monitor locked onto the maternal heart beat and this passed unnoticed, despite warnings in the instructions. The 4th *Annual Report of the Confidential Enquiry into Stillbirths and Deaths in Infancy* (DoH) 1997 identified evidence of inadequacies in the knowledge base and training of midwives and medical staff in interpretation of cardiotocograph (CTG) recordings.

◆ **Devices used for a purpose other than that for which they were designed.**

Wooden tongue depressors used as limb splints in a neonatal unit were found to be contaminated with *Rhizopus microsporus* which caused potentially fatal fungal infections in four babies. NIAIC issued Hazard Notice HN (NI) 96/06 as a result.

◆ **Devices modified locally to address a clinical need.**

There have been reported incidents of infants found to have hypodermic needles embedded internally due to modification of the needle, by removal of the hub cap, to enable blood sampling by what has become known as the “broken needle technique”. This has been the most common method of blood sampling from babies and infants as health care professionals argue that the difficulty of extracting blood from small babies, because of the risk of vein collapse and trauma using conventional methods of blood sampling, justifies this technique. Manufacturers have now responded to the problem by developing needles specifically designed for blood sampling from neonates.

◆ **Device is too complex for the user’s perceptual or physical capabilities.**

A patient fell from a two-piece sling and died two days later. Most suppliers of band slings advise that they are not suitable for certain people: those with extensor spasm, flaccid hemiplegia, confusion or those with painful shoulders. NIAIC issued Hazard Circular HC (NI) 94/14 pointing out that such slings should be used carefully and selectively in accordance with the manufacturer’s instructions and that carers and users should receive full instruction in their use.

7. CHECKLIST: HOW SAFE IS YOUR PRACTICE?

Before using a medical device, ask yourself the following questions:

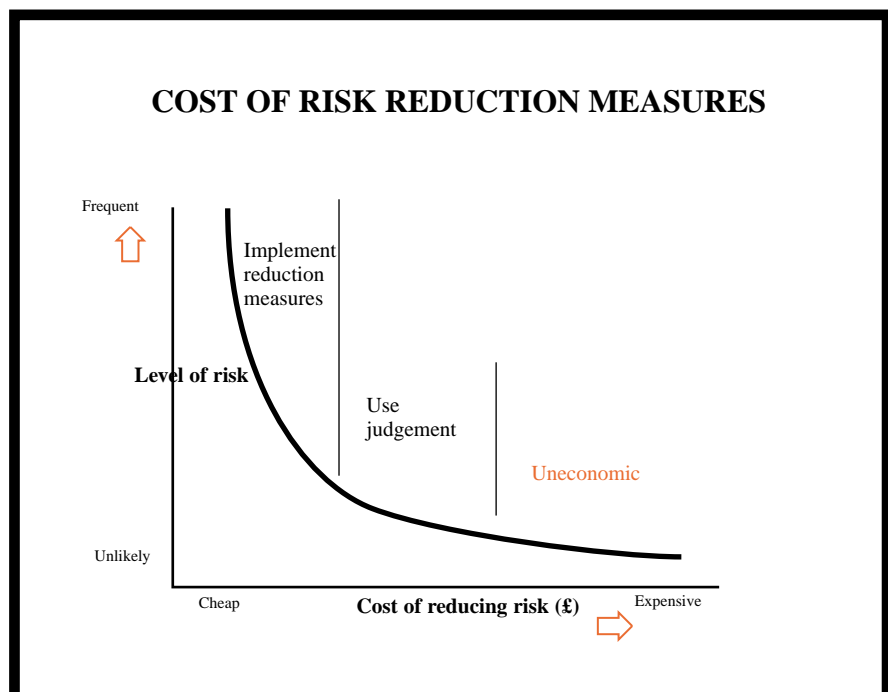
- Do I know how to handle the medical devices in my unit?
- What preparation have I been given in how to use a particular medical device, for example, an infusion pump? Was the preparation formalised and recorded or did I just pick it up as I went along?
- How was my competency to use this equipment safely assessed?
- Am I familiar with the instructions on how to use this piece of equipment and any warning labels?
- When was this equipment last serviced?
- Do my junior staff colleagues know how to use equipment?
- What is the cleaning and/or decontamination procedure for this device and what are my responsibilities in this process?
- Do I know who is responsible for risk management in my organisation?
- Do I know how to report an adverse incident?
- Do I know who my NIAIC Liaison Officer is?
- Do I have access to NIAIC Device Bulletins of relevance to my area of practice and do I read and take notice of Hazard, Advice and Safety Notices?

8. POINTERS TO BEST PRACTICE IN ORGANISATIONAL RISK MANAGEMENT

Risk management is a systematic process of risk identification, analysis, evaluation and correction of potential and actual risks to patient, client, carer, visitor, member of staff, or property. In the specific context of the use of medical devices, it can help identify potential risk and avoid adverse incidents. Organisations should operate risk management procedures which involve a systematic application of policies, procedures and practices to the analysis, evaluation and control of risks. It involves an understanding of adverse incidents and how they could occur; their expected consequences and an assessment of the likelihood of their occurrence.

In the risk management process several steps are necessary:

- ◆ identify likely and expected hazards related to use.
- ◆ identify situations and circumstances where these are most likely to occur.
- ◆ develop strategies to minimise user-related adverse incidents.
- ◆ demonstrate safe and effective device use.



Using the level of risk/cost of reducing risk curve as illustrated, decisions can be made concerning what risk reduction measures can be adopted that are reasonably practical. An example of risk management is infusion pump risk. Considering underinfusion, the likely result is a short interruption of treatment to the patient and the likely cause is poor battery management. There are two options for managing this risk:

- ◆ Regularly inspect the pumps for a diagnostic battery service - this would have a high cost implication, or;
- ◆ Include the need for charging batteries in first line maintenance training and instructions - this has a low cost implication.

Comparing the risks associated with overinfusion, the outcome of overinfusion is that it might lead to the death of the patient, possibly resulting in criminal charges being brought and action by the Health and Safety Executive. The usual causes of overinfusion are user error, therefore possible risk control measures are (in order of cost):

- ◆ Implement training in principles and use of actual pumps;
- ◆ Introduce a “permit to work” scheme.
- ◆ Introduce safe working methods such as double checks by other staff;
- ◆ Implement a full scale risk assessment of operations with benchmark scores for training and practice with frequent retests and management changes if scores do not improve, or;
- ◆ Reduce the models of pumps available.

Effective risk management is based on a partnership between the organisation and individual health care professionals. Formalised systems for procurement, training, documentation, communication of warning notices, reports of malfunctions and audit will help minimise the incidence of device-related adverse incidents.

9. TRAINING

Organisations must ensure that there are adequate arrangements for training. Equally, all health care professionals have a personal responsibility to ensure that they are properly trained in the safe use of the medical devices that they encounter.

Training in relation to medical devices should be addressed jointly by those responsible for practice and education. The theory of the principles of device management and use should be included in pre-registration and undergraduate programmes for health care professionals. Excellent examples of how this can be achieved exist where partnership arrangements have been established between provider organisations and universities to facilitate training in “clinical skill laboratories”.

Practical “on-the-job” training from an experienced mentor should be a prerequisite for all staff involved in the direct care of patients where medical devices are used to support patient care. Learning outcomes for students and practitioners should be formally agreed and documented through arrangements for mentorship, preceptorship and clinical supervision.

Practical instruction on the use of medical devices commonly in use within the unit, for example, infusion pumps, should be incorporated into induction programmes and delivered to all potential users, whatever their grade. It is essential that new staff (including locums) should only operate devices after they have received appropriate training.

Agencies providing staff to the care sector should make arrangements with local providers to ensure that induction training covers the use of medical devices commonly used in areas to which they will be allocated. The use of computerised skills inventories will assist in the allocation of bank and agency staff to practice settings appropriate to their experience and skills.

Each individual using complex medical devices such as infusion systems should keep a training log. Similar logs detailing the training of patients and/or carers receive should also be kept.

Training manuals should be produced by trainers to cover the needs of both staff and patient/carer groups. The training process in each unit should be audited.

10. MAINTENANCE AND REPAIR

Medical devices are used in a variety of settings, including hospitals, surgeries, nursing homes, residential care homes and patients' homes. Arrangements must be in place for access to appropriate servicing facilities to maintain, service and repair devices and to ensure that manufacturer's recalls, updates and modifications are carried out. This requires accurate record keeping.

Unauthorised modification of devices is dangerous. Any modifications should only be authorised by the person with overall responsibility for technical servicing, in conjunction with manufacturers, to ensure that device safety is not compromised.

A clear system for verbal and written notification of any damage to, or malfunction of, devices while in use, should be established to ensure prompt repair.

Any faulty device should be labelled and withdrawn from use until repaired. In these circumstances, provision will be needed for alternative patient care by leasing/hiring or maintaining spare equipment.

11. ADVERSE INCIDENT REPORTS AND WARNING NOTICES

HSS Boards, Trusts, GPs, Dentists and other health care professionals should identify individuals with responsibility for medical devices. These individuals should ensure that systems are in place for:

- ◆ the prompt reporting of adverse incidents through agreed channels.
- ◆ the rapid dissemination of Hazard, Advice or Safety Notices for equipment.
- ◆ maintenance of clear and concise records in a Device Register of adverse incidents and subsequent action taken.
- ◆ auditing adverse incidents and feeding back outcomes from investigations and audits to the organisation through the clinical governance framework.

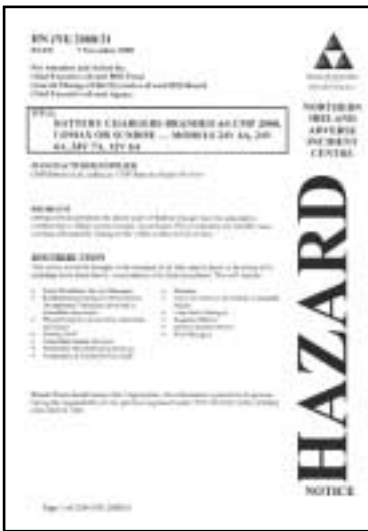
Managers should identify an individual with responsibility for ensuring that all device users are aware of local procedures for reporting adverse incidents. They must also ensure that NIAIC warning notices and Device Bulletins are disseminated throughout the organisation. NIAIC has directed HPSS organisations to appoint Liaison Officers to undertake this role.

NIAIC should be informed of any device-related serious adverse incidents or minor discrepancies and faults. What may seem to be a minor problem can take on greater significance when aggregated with other similar events in demonstrating trends or may be indicative of inadequate quality assurance on the part of the manufacturer.

An adverse incident is an event which can produce, or has the potential to produce, unwanted effects involving the safety of patients, users or other persons. Adverse incidents may arise from shortcomings in the device, its operating instructions, user practices, servicing and maintenance or conditions of use.

Adverse incidents may result in, or have the potential to cause, death, a serious deterioration in health, the necessity for medical or surgical intervention or unreliable test results which could lead to an inappropriate diagnosis. The importance of an incident is not always obvious, and types of incidents vary from the extremely serious to the apparently minor.

All incidents are investigated and, depending on the outcome, may result in issuing advice to the health service through a Hazard, Advice or Safety Notice, or in some instances recall of the device.



12. REPORTING ADVERSE INCIDENTS TO NIAIC

HOW TO REPORT ADVERSE INCIDENTS TO NIAIC

Adverse Incidents relating to medical devices should be reported to NIAIC as soon as possible. Advice on how to report is given in Safety Notice SN (NI) 2001/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact the NIAIC at:

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

Tel: 02890 523714 or 523704 Fax: 02890 523900
Email: NIAIC@dhsspsni.gov.uk

Adverse incidents should be reported to NIAIC as soon as possible by completing an Adverse Incident Report Form A1. Serious cases should be reported to NIAIC by the fastest means available e.g. telephone fax or e-mail. The initial report of an incident should contain as much relevant detail including information about any device or equipment involved such as the manufacturer and supplier names, addresses and telephone numbers, product names and serial numbers etc. Having this information available allows us to begin the investigation immediately. Names and contact details of persons who may be contacted for further information should be included.

FOR NURSING ENQUIRIES RELATED TO DEVICES

Tel: 02890 523828 Fax: 02890 523900
Email: elizabeth.qua@dhsspsni.gov.uk

FOR MEDICAL ENQUIRIES RELATED TO DEVICES

Tel: 02890 520710 Fax: 02890 520718
Email: glenda.mock@dhsspsni.gov.uk

FOR EVALUATIONS AND PUBLICATIONS

Tel: 02890 523704 Fax: 02890 523900
Email: NIAIC@dhsspsni.gov.uk

13. REFERENCES

This bibliography contains documents referred to in the bulletin, together with other documents, which provide background information relevant to the subject under discussion.

13.1 Legislation

Medical Devices Regulations

Active Implantable Medical Devices Regulations 1992 (SI 1992 No 3146) as amended by SI 1995 No 1671

Medical Devices Regulations 1994 (SI 1994 No 3017)

The *In Vitro* Diagnostic Medical Device Regulations 2000 SI No. 1315.

13.2 MDA/Health Estates Publications

Device Bulletin DB 9904(NI), July 1999, *Medical Device and Equipment Management for Hospital and Community-based Organisations*.

Device Bulletin DB 2000/4 (NI), November 2000. *Single-use Medical Devices: Implications and Consequences of Reuse*

Device Bulletin DB 9902 (NI) , July 1999. *The Safe and Effective Use of Batteries for Medical Devices*

Safety Action Notice SAN (NI) 95/24, July 1995. *Decontamination of Medical Devices and Equipment prior to investigation, inspection service or repair*

Safety Notice SN (NI) 2001/01, January 2001. *Reporting Adverse Incidents and Disseminating Warning Notices relating to Medical Devices, Non-Medical Equipment, Buildings and Plant*.

13.3 Health Estates/DHSSPS Publications

Professional Estates Letter PEL (94) 34, July 1994. *Decontamination of equipment prior to inspection, service or repair*.

Professional Estates Letter PEL (98) 4, February 1998, *Medical Devices Directive – CE Marking*.

HSS (MD) 16/99, November 1999, *Controls Assurance in Infection Control: Decontamination of Medical Devices*. 1997, 246-253.

Professional Estates Letter PEL (00) 14, August 2000. *The Management of Medical Equipment in NHS Acute Trust in England*. Report by the Comptroller and Auditor General. 10 June 1999. ISBN 0 10 268399 9

13.4 DoH Publications

DHSS (1998) *Valuing Diversity, a Way Forward: A Strategy for Nursing, Midwifery and Health Visiting*

Department of Health (1997) *Confidential Enquiry into Stillbirths and Deaths in Infancy*, HMSO: London.

Department of Health (2000) *An Organisation with a memory. Report of an expert group on learning from adverse events in the NHS chaired by the Chief Medical Officer*, HMSO: London

13.5 Other Publications

NHS Confederation (1999) *The Pocket Guide to the New NHS*, NHS Confederation: Birmingham.

United Kingdom Central Council for Nursing, Midwifery and Health Visiting (1992) *Code of Professional Conduct*, UKCC: London

COMMON CATEGORIES OF MEDICAL DEVICE

The list below is not comprehensive but gives a sense of the wide range of products that are considered to be medical devices.

Equipment used in the diagnosis or treatment of disease or monitoring of patients, such as:

- ◆ Syringes and needles
- ◆ Catheters e.g. urinary, cardiac
- ◆ Endoscopes
- ◆ Patient monitoring equipment e.g. cardiac monitors
- ◆ Surgical implants e.g. orthopaedic prostheses, bone cements, heart valves
- ◆ Ultrasound imagers and CT/MR scanners
- ◆ Dental equipment and materials
- ◆ Chiropody/podiatry equipment
- ◆ Thermometers
- ◆ Physiotherapy equipment
- ◆ Beds
- ◆ Dressings (non-medicated)
- ◆ Surgical instruments and equipment
- ◆ IV administration sets and pumps
- ◆ Anaesthetic equipment
- ◆ Powered implants e.g. pacemakers, implantable defibrillators
- ◆ Radiotherapy equipment (brachytherapy, external beam)
- ◆ Ophthalmic equipment
- ◆ Sphygmomanometers
- ◆ Vaginal speculae
- ◆ Mattresses and covers
- ◆ Examination gloves

Equipment used in life support, such as:

- ◆ Ventilators
- ◆ Defibrillators

In vitro diagnostic medical devices and their accessories, such as:

- ◆ Blood glucose measuring devices
- ◆ Urine test strips
- ◆ Specimen collection tubes
- ◆ Blood gas analysers
- ◆ Hepatitis and HIV test kits

- ◆ Pregnancy test kits

Equipment used in the care of disabled people, such as:

- ◆ External orthotic and prosthetic appliances
- ◆ Wheelchairs and special support seating
- ◆ Patient hoists
- ◆ Pressure relief equipment
- ◆ Walking aids

Aids to daily living, such as:

- ◆ Commodes
- ◆ Urine drainage systems
- ◆ Incontinence pads
- ◆ Hearing aids
- ◆ Domiciliary oxygen therapy systems
- ◆ Prescribable footwear

Equipment used by ambulance service, such as:

- ◆ Stretchers and trolleys
- ◆ Resuscitators

Other examples of medical devices, such as:

- ◆ Condoms
- ◆ Contact lenses and care products
- ◆ Inter-uterine devices (IUDs)

We are also interested in products which, whilst not themselves medical devices, are used close conjunction with these devices, e.g.:

- ◆ Centrifuges
- ◆ Fluid warming cabinets
- ◆ Blood tissue storage systems
- ◆ Disinfecting and sterilising equipment e.g. bench top sterilisers

DISTRIBUTION

This Device Bulletin should be brought to the attention of managers and staff in all hospitals, healthcare establishments, the community and others who use medical devices.

TECHNICAL ENQUIRIES

Enquiries regarding the content of this Device Bulletin should be addressed to:

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FURTHER COPIES

Further copies of this Device Bulletin are free to Health and Social Care providers and may be obtained on written request from:

Northern Ireland Adverse Incident Centre (NIAIC)
Room A7
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast
BT16 1US

Tel: 028 9052 3704
Fax: 028 9052 3900

e-mail: NIAIC@dhsspsni.gov.uk

Health Estates

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