

HSC	Controls Assurance Standard	Medical Devices And Equipment Management
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MEDICAL DEVICES AND EQUIPMENT MANAGEMENT

STANDARD

There is a system in place which ensures that all risks associated with acquisition, use and disposal of Medical Devices and Equipment are minimised.

TERMINOLOGY

Medical Device: The term ‘medical device’ covers a broad range of products including those used every day in most health and social care settings and is defined as:

Any device, instrument, apparatus, implement, material substance, or other article (used singly or in combination), together with any accessory thereto, which is intended by the manufacturer for:

- a. diagnosis, prevention, monitoring, treatment of alleviation of human disease or injury;
- b. investigation or modification of human anatomy or of human physiological process; which does not achieve it’s principle intended action by pharmaceutical means, but which may be assisted in it’s functioning by such means

A more extensive list of products which fall within the definition of medical device is provided on the Northern Ireland Adverse Incident Centre (NIAIC) website at www.dhsspsni.gov.uk/niaic

Equipment: Products that are not medical devices but are used in Health and Social Care settings by clients or users (e.g. chair lifts, blood tissue storage systems, fluid warming cabinets and some disinfecting and sterilizing equipment). These products fall under the term “equipment” in this standard.

Adverse Incident: Adverse Incidents involving medical devices and equipment can produce, or have the potential to produce, unexpected or unwanted outcomes that affect the safety of patients, service users or other people e.g.

- A patient, client, user, carer or professional is injured as a result of a medical device or equipment failure or its misuse.
- A patient’s or client’s treatment is interrupted or compromised by a medical device or equipment failure
- Misdiagnosis due to medical device or equipment failure leads to inappropriate treatment
- A patient’s or client’s health deteriorates due to a medical device or equipment failure.

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Carer: Throughout this standard Carers is used to mean informal carers (i.e. family members or friends who are unpaid) and paid care givers such as home helps, care assistants etc. who provide help and support.

Client: Someone who enters the community health or social care system and is provided with medical device(s) or equipment (e.g. bath hoists, walking aids, chair lifts etc.)

Clinical Supervisor: A clinically trained person responsible for the safe use of a medical device or equipment (e.g. ward manager)

Duty of Care: All employers are subject to legal and statutory requirements relating to ‘the duty of care’ that require employers to provide competent and safe staff employees, safe equipment and places of work, and a safe system of work.

End – User: An employee, carer, patient or client who uses a medical device or item of equipment in a healthcare facility or at home (e.g. wheelchair, chair lift etc.)

Medical Device and Equipment Management Procedure: A document including policies and responsibilities for purchase, acceptance, issue/recall, decontamination, maintenance, repair, tracking, monitoring and replacement of medical devices and equipment, training and actions needed in case of breakdown or adverse event. The aim is to ensure that whenever a medical device or equipment is used, it should be:

- Suitable for its intended purpose – “buy it right”;
- Properly understood by the professional and end-user – “use it right”;
- Maintained in a safe and reliable condition – “keep it right”.

Professional user and end-user knowledge and skills have major implications for safety. Instructions must be clear, concise and readily available. Training should be timely and effective, and include procedures for the routine maintenance of medical devices and equipment by Professional and end-users.

Planned preventative maintenance, carried out following manufacturers guidance by properly trained technicians, is the other key element in ensuring medical devices and equipment are safe and reliable. Professional users and technicians need to understand the basic principles on which medical devices and equipment work (generic training) as well as how to use a particular model (specific training).

End-users generally need to understand how to use a particular model (specific training). Training programmes should where possible include input from manufacturers. All medical devices and equipment should be cleaned, disinfected and/or sterilised in accordance with the latest decontamination guidance.

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Newly Delivered: The term “Newly Delivered” used throughout this standard refers to any medical device/equipment used by the organisation whether it is purchased, leased, rented, on loan, on trial, or donated.

Prescriber: A person who decides which is an appropriate medical device or item of equipment for a given patient or client (e.g. nurse, occupational therapist etc.)

Professional User: The professional users are trained staff who operate a medical device or equipment for the benefit of a patient or client. (e.g. doctor, dentist, surgeon, nurse etc.)

Technical Supervisor: People with technical or managerial roles in device/equipment management. They can be in charge of acceptance testing, installation, repair and maintenance or decontamination (e.g. estates officers, biomedical engineering staff, CSSD managers, Managers of Endoscopy Units, etc.).

User organisation: A medical device purchaser (either buys, leases, has on loan, has on trial, or is donated the device or equipment) that either uses the medical device or equipment, issues them to end-users or loans them to end-users (e.g. HSC Trust)

Medicines and Healthcare products Regulatory Agency (MHRA): An Executive Agency of the Department of Health (England) was created on 1 April 2003 from the merger of the Medicines Control Agency and the Medical Devices Agency. The MHRA 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. As the UK Competent Authority, MHRA has statutory responsibilities and powers under the UK Regulations for medical devices that it exercises across the whole of the UK.

Northern Ireland Adverse Incident Centre (NIAIC): Part of the Department of Health, Social Services and Public Safety (DHSSPS). On behalf of the DHSSPS, NIAIC is the focal point for the reporting of adverse incidents involving medical devices, non-medical equipment, plant and buildings in Northern Ireland. NIAIC works closely with the MHRA concerning medical device safety and with DoH Estates and Facilities for issues concerning estates systems.

NOTES

The Criterion in this standard list links to other controls assurance standards that have been developed for use by HSC. These are included to illustrate that controls assurance should be approached as a holistic concept based on best governance practice designed to protect patients, staff, the public and other stakeholders against **risks of all kind**.

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Assessment Guidance

HSC organisations vary significantly in size and in the nature of the services they deliver. It follows that not all controls assurance standards will apply to each organisation. This is implicit in the current Departmental guidance, eg. *The Reference Table on Applicability and Expected Levels of Compliance* which should be referred to before commencing the self-assessment exercise.

Even where a standard is generally applicable to the work of an organisation it is quite possible that not all of the criteria will be materially applicable. Before self-assessing against a standard, an organisation should consider the relevance of each criterion to its own business and conduct its assessment accordingly. Thus, where a criterion is clearly relevant to an organisation, the score should be based on the **totality of the action taken to address the requirement**. Where there is little or no relevance, the criterion should be considered “not applicable” and ignored for scoring purposes as explained in the guidance on *Reporting Compliance* issued by the Department.

This approach will ensure that the assessment has no unfairly detrimental effect on the organisation’s overall score but reflects a proper evaluation of the key areas of risks identified and the actual levels of controls put in place to manage those risks.

Likewise, the *Examples of Verification* set out in the standard are just that – examples, for guidance only. It is the nature of each organisation’s business that determines the type of evidence needed to prove that appropriate controls are in place. In effect, this may mean that only some of the examples listed are relevant to a particular HSC organisation or, indeed, that there are other more relevant examples which can be adduced as evidence of compliance. It is also the case that some evidence can be deployed to demonstrate compliance with more than one criterion or standard.

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KEY REFERENCES

Statutes

The Medical Devices Regulations and current amendments

Guidance and Codes

British Standards Institution BS EN ISO 14155 : 2009 parts 1 & 2 London,BSI

British Standards Institution BS EN ISO 14971 : 2009 London, BSI

British Standards Institution BS EN ISO 19011 : 2002 London, BSI

British Standards Institution BS EN ISO 13485 : 2003 London, BSI

Medicines and Healthcare products Regulatory Agency (MHRA) *Managing Medical Devices* DB 2006 (05) ,

Health Estates Investment Group, Northern Ireland Adverse Incident Centre (NIAIC), *Reporting Adverse Incidents and Disseminating Alerts DB2010(NI)-01.*

This is available on the NIAIC web site at www.dhsspsni.gov.uk/niaic. A full list of NIAIC guidance is available on the website.

Medicines and Healthcare products Regulatory Agency (MHRA), *Single use medical devices: Implications and Consequences of Reuse.* DB2006 (04)

Health Estates Investment Group, Northern Ireland Adverse Incident Centre (NIAIC), *Decontamination of Endoscopes* DB(NI)2002/05, December 2002

Health Estates Investment Group, Professional Estates Letter PEL(00)14, *The National Audit Report, The Management of Medical Equipment in NHS Acute Trusts in England*, August 2000

Health Estates Investment Group, Professional Estates Letter PEL(07)21, *Safety Alert Broadcast System*, December 2007

Circulars

DHSS Circular HSS(MD)16/99, *Controls assurance in infection control: decontamination of medical devices.*

DHSS Circular HSS(MD)15/99, *Variant Creutzfeldt-Jakob Disease (vCJD): Minimising the risk of transmission*

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HSS(MD)4/01 Decontamination of reusable medical devices and Addendum 3 of HSS(MD)4/01, Protocol for Local Decontamination of Surgical Instruments.

DAO (DFP) 5/2001 – Corporate Governance: Statement on Internal Control
http://www.dhsspsni.gov.uk/hss/governance/documents/DAO_05_01.doc

HSS (PPM) 3/2002 – Corporate Governance: Statement on Internal Control
<http://www.dhsspsni.gov.uk/hss/governance/guidance.asp>

HSS (PPM) 4/2005 AS/NZS 4360:2004 – Risk Management
<http://www.dhsspsni.gov.uk/hss/governance/guidance.asp>

HSS (PPM) 8/2002 Risk Management in the Health and Personal Social Services
<http://www.dhsspsni.gov.uk/hss/governance/guidance.asp>

HSS (PPM) 10/2002 – Governance in the HPSS: Clinical and Social Care Governance – Guidance on Implementation
<http://www.dhsspsni.gov.uk/hss/governance/guidance.asp>

HSS (PPM) 9/2002 – Revised Public Procurement Policy for the Public Sector

HSS (PPM) 13/2002 Governance in the HPSS: Risk Management
<http://www.dhsspsni.gov.uk/hss/governance/guidance.asp>

Circular HSS (PPM) 5/2003 – Governance in the HPSS: Risk Management and Controls Assurance
<http://www.dhsspsni.gov.uk/hss/governance/guidance.asp>

Circular DAO (DFP) 25/2003 - Statement of Internal Control
<http://www.dhsspsni.gov.uk/hss/governance/guidance.asp>

Circular HSC(SQSD)19/2007 – Reporting and follow-up on serious adverse incidents:
<http://www.dhsspsni.gov.uk/hss/governance/guidance.asp>

Circular HSS (PPM) 8/2004 – Governance in the HPSS: Controls assurance standards – update
<http://www.dhsspsni.gov.uk/hss/governance/guidance.asp>

Other Publications

The National Audit Office (1999) *The Management of Medical Equipment in NHS Acute Trusts in England* The Stationary Office, London

The Audit Commission (1996) *Goods for Your Health – Improving Supplies Management in NHS Trusts* The Stationary Office, London

NHS Purchasing and Supply Agency *NHS Master Indemnity Agreements*
 NHS Purchasing and Supply Agency, London

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NHS Purchasing and Supply Agency (2001) *NHS Terms and Conditions of Contract 2001* NHS Purchasing and Supply Agency, London

NHS Supplies (1995) *Pre-purchase questionnaire* NHS Supplies, London

NHS Executive (1995) *NHS Internal Audit Manual 1995*. NHS Executive, London.

Best Practice – Best Care (2001) – A framework for setting standards, delivering services and improving monitoring and regulation in the HPSS
<http://www.dhsspsni.gov.uk/publications/archived/2001/4161finaldoc.asp>

Standards Australia (2004) *Risk Management AS/NZS 4360:2004*. Standards Association of Australia. Strathfield NSW.

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INDEX OF CRITERIA

Controls Standard Framework Category: ACCOUNTABILITY; a statement of what the standard is to achieve

Criterion 1

Board level responsibility for Medical Devices and Equipment management is clearly defined and there are clear lines of accountability throughout the organisation leading to the Board.

Controls Standard Framework Category: PROCESSES; the core processes required to produce the desired outcomes – compliance with guidance, regulations etc.

Criterion 2

There is a broad-based Medical Devices and Equipment group, established in accordance with Device Bulletin DB 2006 (05).

Criterion 3

There is a comprehensive organisation-wide implemented policy and procedure for the management of Medical Devices and Equipment.

Criterion 4

All Medical Devices and Equipment are selected and acquired in accordance with the Health Estates (NIAIC) and National Audit Office recommendations.

Criterion 5

All Medical Device developments, modifications and trials are conducted in accordance with relevant legislation and guidance.

Criterion 6

All professional users and end-users have access to manufacturer's instructions and all user organisations certify that they are current and users have received instructions on the safe use of Medical Devices or Equipment.

Criterion 7

Where Medical Device/Equipment manufacturers automatically send copies of revised instructions to a named recipient, these are appropriately dealt with.

Criterion 8

All instructions supplied by the user organisation are evaluated for their adequacy.

Criterion 9

Delivery and pre-use checks are carried out on all newly delivered Medical Devices/Equipment

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Criterion 10

All newly delivered Medical Devices and Equipment are properly stored after acceptance.

Criterion 11

Medical Devices designated for single use are not reused under any circumstances

Criterion 12

All Medical Devices and Equipment prescribing decisions are made by staff with appropriate professional qualifications and suitable experience, backed by appropriate administrative and technical support.

Criterion 13

All necessary information required to properly manage the user organisation's range of Medical Devices/Equipment is recorded on a suitable system.

Criterion 14

All Medical Devices/Equipment are properly maintained and repaired.

Criterion 15

The in-house Medical Device/Equipment maintenance department is externally accredited.

Criterion 16

All Medical devices/Equipment returned for servicing and repair are properly decontaminated.

Criterion 17

Medical Devices/Equipment are replaced in accordance with an agreed policy.

Criterion 18

All loaned, leased or on trial Medical Devices/Equipment are collected when no longer needed.

Criterion 19

All adverse incidents involving Medical Devices and Equipment are reported in accordance with NIAIC Device Bulletin DB2010(NI)-01.

Criterion 20

A complete record of guidance issued by the NIAIC is maintained; alerts and safety information are distributed to the appropriate people in the organisation; and recommendations contained in these are implemented. Organisations should have a procedure in place to manage Field Safety Notices (FSN) distributed directly from the manufacturer.

Criterion 21

The risk management process contained within the risk management system standard is applied to the management of Medical Devices and Equipment risk.

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Controls Standard Framework Category: CAPABILITY; organisations have the necessary capability – knowledge, skilled staff etc. to ensure the controls work effectively.

Criterion 22

Staff are made aware of and, where necessary, trained in adverse incident reporting and investigation requirements for Medical Devices and Equipment.

Criterion 23

All professional users are trained in the safe operation of Medical Devices and Equipment.

Criterion 24

All technical supervisors are trained in the safe operation of Medical Devices and Equipment.

Criterion 25

All end-users are given appropriate training in the safe and effective use of Medical Devices and Equipment.

Criterion 26

All staff are provided with appropriate training in the safe use of Medical Devices and Equipment.

Controls Standard Framework Category: OUTCOMES; measures of achievement.

Criterion 27

Key indicators capable of showing improvements in Medical Devices/Equipment management and/or providing early warning of risk are used at all levels of the organisation, including the Board, and the efficacy and usefulness of the indicators is reviewed regularly.

Criterion 28

The organisation participates in benchmarking its management of Medical Devices/Equipment.

Controls Standard Framework Category: MONITORING AND REVIEW; organisations management (including the board) continuously monitors and reviews the system to ensure it is working and ensure proper communication and consultation at all levels.

Criterion 29

The system in place for Medical Devices and Equipment management, including risk management arrangements, is monitored and reviewed by management and the Board in order to make improvements to the system.

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Controls Standard Framework Category: AUDIT; organisations management and the Board continuously monitors and reviews the system through audit.

Criterion 30

The Board should seek independent assurance that an appropriate and effective system of managing Medical Devices and Equipment is in place and that the necessary level of controls and monitoring are being implemented.

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CRITERION 1

Board level responsibility for Medical Devices and Equipment management is clearly defined and there are clear lines of accountability throughout the organisation leading to the board.

Source

- Medicines and Healthcare products Regulatory Agency (MHRA) *Managing Medical Devices* DB 2006 (05)
- Health Estates Investment Group, Professional Estates Letter PEL(07)21, Safety Alert Broadcast System, December 2007
- Health Estates Investment Group, Professional Estates Letter PEL(00)14, *The National Audit Office Report, The Management of Medical Equipment in NHS Acute Trusts in England*, August 2000
- The National Audit Office (1999) *The Management of Medical Equipment in NHS Acute Trusts in England* The Stationary Office, London
- Standards Australia (2004) *Risk Management AS/NZS 4360:2004*. Standards Association of Australia. Strathfield NSW.
- HSS(MD)4/01 Decontamination of reusable medical devices and Addendum 3 of HSS(MD)4/01, Protocol for Local Decontamination of Surgical Instruments.
- HSS (PPM) 10/2002 – governance in the HPSS: Clinical and Social Care Governance – Guidance on Implementation
- HSS (PPM) 3/2002 – Corporate Governance: Statement on Internal Control
- Circular HSS (PPM) 5/2003 – Governance in the HPSS: Risk Management and Controls Assurance

Guidance

Medical devices and equipment represent a substantial asset of many user organisations. Clear leadership at Board level is therefore essential if medical devices and equipment are to be managed in a strategic manner.

The Chief Executive has overall responsibility for medical device/equipment management and an Executive Director(s) should be designated as accountable officer(s) with responsibility for medical device and equipment management.

The nominated director should ensure that a Medical Device liaison officer is appointed to co-ordinate the effective reporting of adverse incidents involving medical devices/equipment to NIAIC. The nominated director should also ensure that a SABS liaison officer is appointed with responsibility for the dissemination of advice and recommendations issued by NIAIC together with providing assurance back through SABS in respect to Trust completion of recommended action. Trusts may wish to combine these liaison officer roles.

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A suitable medical device/equipment coordinator, or coordinators, should take responsibility for key device and equipment management and use matters. It may be necessary to have coordinators in relevant individual directorates/departments or geographical areas.

In some hospitals, for example, an experienced nurse takes responsibility for medical device/equipment coordination and has tasks allocated as follows: -

- Meetings - setting up and servicing the medical devices and equipment group.
- Training - running broad-based training sessions or organising participation in suitable training schemes.
- Information - identifying key workers in each division/directorate/department/facility who will keep documents up-to-date, e.g. equipment manuals, training records, NIAIC MDAs, MDEAs and Device Bulletins, text books, etc.
- Risk assessment - devise protocols, visit wards/facilities, apply protocols, repeat visits to ensure action is taken to reduce risk, etc.
- User/technical department interface - improve lines of communication between users and maintenance organisations.

It is particularly important that the medical device and equipment co-ordinator is integral to the organisation's risk management structure and as such they have clear lines of accountability. It is vital that they are given training in risk assessment techniques given their responsibility for risk assessment identified above. The co-ordinator should encourage improvements in working practice, which progressively reduce patient/client risk; communicate the outcomes of risk assessments; and stimulate continued improvement.

With the development and implementation of effective clinical and social care governance together with the integration of the co-ordinator role into organisational risk management structures, in due course these initiatives should provide organisations with the necessary skills to enable them to undertake the appropriate level of local investigation involving adverse events involving medical devices and equipment management and where appropriate take local action based on the investigation outcome.

Frequent reports including an annual report on the efficacy of the medical devices and equipment process should be submitted to the Risk Management Committee or other appropriate Committee of the Board for regular review.

Examples of Verification

- Accountability arrangements chart
- Risk Management Strategy
- Risk Management organisational chart
- Board minutes
- Risk Management Sub-Committee(s) minutes

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- Job description for SABS liaison officer
- Job description for NIAIC liaison officer
- Job description for medical device and equipment co-ordinator including risk management responsibilities.

Links with other standards

All standards

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CRITERION 2

There is a broad-based Medical Devices and Equipment group(s), established in accordance with Device Bulletin DB 2006 (05)

Source

- Medicines and Healthcare products Regulatory Agency (MHRA) *Managing Medical Devices* DB 2006 (05) ,
- Health Estates Investment Group, Professional Estates Letter PEL(00)14, The National Audit Office Report, The Management of Medical Equipment in NHS Acute Trusts in England, August 2000
- The National Audit Office (1999) *The Management of Medical Equipment in NHS Acute Trusts in England* The Stationary Office, London

Guidance

A medical devices and equipment group(s), which should contain appropriate wide ranging representation from medical, nursing, allied health professionals, infection control, engineering, purchasing staff and social care staff as appropriate, can:

- Improve communication
- Foster consent between clinical and technical supervisors in relation to any proposed changes
- Reduce confusion about who is responsible for device and equipment management tasks, training and safe medical device and equipment operation.

The remit of such a group(s) should also encompass providing advice on:

- Medical device and equipment purchasing/acquisition issues and comparisons of alternative medical devices or equipment.
- Technical specifications, regulatory compliance information and related issues
- Financial data, including consideration of full on-costs, i.e. running, maintenance and consumables costs, when preparing a medical device or equipment purchase bid, including disposable and replacement costs at the appropriate time
- Standardisation to single models where possible
- Risk management considerations
- Device/equipment evaluation reports, including user experience and preferences
- Drawing up guidelines for medical device and equipment decontamination
- Co-ordinating a medical device and equipment inventory
- Monitoring of manufacturer's instructions and training
- Medical device and equipment management and maintenance procedures.

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Examples of Verification

- Accountability arrangements chart
- Group terms of reference and membership
- Group minutes

Links with other standards

Governance

Management of Purchasing and Supply.

Decontamination

Health & Safety Management

Risk Management

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CRITERION 3

There is a comprehensive organisation-wide implemented policy and procedure for the management of Medical Devices and Equipment.

Source

- Medicines and Healthcare products Regulatory Agency (MHRA) *Managing Medical Devices* DB 2006 (05) ,
- HSS(MD)4/01 Decontamination of reusable medical devices and Addendum 3 of HSS(MD)4/01, Protocol for Local Decontamination of Surgical Instruments.

Guidance

Policy and Procedures for the deployment, monitoring and control of medical devices and equipment across the organisation should be drawn up and implemented. Policy and Procedures to be addressed include:

- The establishment, if considered desirable, of a medical device/equipment pool or library.
- The establishment of an inventory of medical devices and equipment.
- The need for safety checks prior to using medical devices and equipment.
- The training of professional users, technical supervisors, clinical supervisors, end-users, carers and staff.
- The maintenance and repair of medical devices and equipment in line with the manufacturers guidance (including decontamination, tracking, recall, replacement and disposal policies).

Examples of Verification

- Risk Management Strategy
- Policy and Procedures

Links with other standards

Governance
Risk Management
Management of Purchasing and Supply.
Decontamination
Health & Safety Management

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CRITERION 4

All Medical Devices and Equipment are selected and acquired in accordance with the Health Estates (NIAIC) and National Audit Office recommendations

Source

- The Audit Commission (1996) *Goods for Your Health – Improving Supplies Management in NHS Trusts* The Stationary Office, London.
- Medicines and Healthcare products Regulatory Agency (MHRA) *Managing Medical Devices* DB 2006 (05)
- Health Estates Investment Group, Professional Estates Letter PEL(00)14, *The National Audit Office Report, The Management of Medical Equipment in NHS Acute Trusts in England*, August 2000
- The National Audit Office (1999) *The Management of Medical Equipment in NHS Acute Trusts in England* The Stationary Office, London
- NHS Purchasing and Supply Agency *NHS Master Indemnity Agreements* NHS Purchasing and Supply Agency, London
- NHS Purchasing and Supply Agency (2001) *NHS Terms and Conditions of Contract 2001* NHS Purchasing and Supply Agency, London
- HSS (PPM) 9/2002 – Revised Public Procurement Policy for the Public Sector

Guidance

A properly planned approach to the purchase of medical devices and equipment, taking into account the needs and preferences of professionals and end-users whilst retaining consistency and control, is needed if value-for-money is to be obtained.

Planning systems should be in place for the selection and acquisition of medical devices and equipment. Acquisition covers selection and both purchase (including lease) and non-purchase acquisition of medical devices and equipment such as leasing, borrowing, in-house manufacture, modification of in-house medical devices or equipment, refurbishment and 'cannibalising'.

A supply policy should clearly demonstrate the procedure to be adopted in making decisions to purchase medical devices/equipment, including the process for prioritising allocation of equipment budget against bids received.

Where decisions are to be made on model selection, the policy should outline the procedure to be adopted. This will include establishment of criteria to be considered in model selection and ensuring that the total costs of purchase, including maintenance, training and running costs, are estimated and that the likely benefits outweigh these costs. Exemplar model selection criteria include:

- Life cycle/replacement (how long will the medical device/equipment last).

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- Fitness for intended application (must meet user organisation's performance specification, but unnecessary features may be a disadvantage e.g. complicated medical devices/equipment may break down more frequently and be harder to use).
- Guarantee/warranty (compare terms, are these negotiable?).
- Safety (which safety and performance standards have been complied with. Do NIAIC publications reveal persistent problems, have Pre-Purchase Questionnaires been completed where necessary?)
- Reliability (Have other users experienced problems or failures?).
- Service support (Are spares readily available and is service support guaranteed? For how long? Is response time guaranteed and reasonable?).
- Maintenance requirements (intervals between service, frequency and complexity of checks and calibration needed during operation).
- Technical advice (does the manufacturer give free access to technical advice, for professional users, end-users and technical staff? Is there a 24-hour helpline? Is the advice provided non-technical suitable for end-users with special needs?)
- Diversity (will this choice increase the number of types of medical device/equipment in use, and could this be to the detriment of safety)

The policy should provide for examining whether the pattern of expenditure over the financial year in procuring medical devices/equipment is conducive to ensuring good value for money.

The policy should also clearly identify the purchasing process (i.e. raising and order, financial control, tendering, contractual issues, etc.) once a decision has been made to acquire medical devices/equipment.

There should also be a policy on other methods of acquiring devices, including renting, borrowing, in-house manufacture, modification of in-house medical devices/equipment, refurbishment and 'cannibalising'. Where medical devices/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 medical devices/equipment must go through an acceptance procedure.

User Organisations should ensure indemnity agreements are signed for leased, loaned or borrowed medical devices/equipment including equipment on trial.

For in-house manufacture or modification of medical devices/equipment they might have to comply with Medical Devices Regulations at the design, manufacture and clinical evaluation stages. Adequate documentation should be produced for novel or unusual devices.

Modifying existing medical devices, or using them for purposes not intended by the manufacturer, counts as manufacture of a new medical device under

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the Regulations and may have safety implications. Where devices are subject to 'full refurbishment' by a user organisation, the user organisation may need to comply with the Medical Devices Regulations unless it already owns the device and intends to use it only for its own patients.

The policy should state that cannibalising medical devices/equipment is not a recommended acquisition option.

Examples of Verification

- Policy and Procedures
- Medical Device/Equipment Business Cases

Links with other standards

Management of Purchasing and Supply

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CRITERION 5

All Medical Device developments, modifications and trials are conducted in accordance with relevant legislation and guidance.

Source

- British Standards Institution BS EN ISO 14155 : 2009 parts 1 & 2 London,BSI
- British Standards Institution BS EN ISO 14971 : 2009 London, BSI
- British Standards Institution BS EN ISO 19011 : 2002 London, BSI
- British Standards Institution BS EN ISO 13485 : 2003 London, BSI
- Medicines and Healthcare products Regulatory Agency (MHRA) *Managing Medical Devices* DB 2006 (05)
- The Medical Devices Regulations

Guidance

There should be a policy on medical device developments, modifications and trials. It is important to be clear about where responsibilities and liabilities lie, particularly where developments might be carried out in conjunction with external partners, including universities, manufacturers, etc.

For in-house manufacture, medical devices might have to comply with the Medical Devices Regulations at the design, manufacture and clinical evaluation stages. Adequate documentation should be produced for novel or unusual medical devices. Modifying existing medical devices, or using them for purposes not intended by the manufacturer, counts as manufacture of a new medical device under the Regulations and may have safety implications.

The Medicines and Healthcare products Regulatory Agency (MHRA) guidance on application of the Medical Devices Regulations states that “If a device is made by one legal entity for use on or by the patients of that same entity, there is no placing on the market and the Regulations do not apply.” However, where any in-house manufactured medical device is supplied to another legal entity for the use on or by the patients of that entity, a CE mark will be required. In such cases, user organisations should clarify their particular position with regard to the Medical Device Regulations with the MHRA. Where medical devices are subject to 'full refurbishment' by a user organisation, the user organisation may need to comply with the Medical Devices Regulations. Again, clarification should be sought from the MHRA in such circumstances.

Whilst it might be considered for a medical device development, modification or trial to technically fall outside the scope of the Regulations, user organisations should nevertheless consider all legal and ethical issues, measured against the Regulations, as the legislative framework and benchmark.

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Risks associated with in-house developments, modifications and trials should be carefully managed. Robust and documented risk assessments should take place, in accordance with BS EN ISO 14971.

Clinical investigations of medical devices that are to be carried out on human subjects should be conducted in accordance with BS EN ISO 14155.

It is the medical device manufacturer's responsibility to ensure that a 'clinical investigation' of a medical device is conducted properly and formally registered through the MHRA.

Examples of Verification

- Policy document
- Medical Device risk assessments
- Risk Management Committee(s) minutes
- Project and technical files
- MHRA registration of Clinical Investigations
- Ethics Committee minutes

Links with other standards

Risk Management
Governance

HSC	Controls Assurance Standard	Medical Devices And Equipment Management
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CRITERION 6

All professional users and end-users have access to manufacturer's instructions and all user organisations certify that they are current and users have received instructions on the safe use of Medical Devices or Equipment.

Source

- Medicines and Healthcare products Regulatory Agency (MHRA) *Managing Medical Devices* DB 2006 (05) ,

Guidance

Good clear and up to date instructions have a crucial role in the safe and effective use of medical devices/equipment. The Medical Devices Regulations make the medical device manufacturer responsible for supplying appropriate instructions including information needed to use the medical device safely (taking account of the training and knowledge of potential users), the nature and frequency of the maintenance and calibration needed to ensure that the medical device operates properly and safely at all times, any special storage and handling conditions, and any modification or changes to the Instructions for Use which affect patient safety are supplied to the user.

Instructions issued with loaned medical devices/ equipment will often not be returned with medical device/equipment. Consequently, these may need new sets of instructions each time they are issued, and a procedure should be put in place to ensure that end-users have received instructions and are aware of their importance.

Extra care is needed in the case where the end-user is a patient or client for whom the medical device/equipment has been prescribed is not within a Trust managed environment. User organisations that provide medical devices /equipment for end-users must pass on the manufacturer's instructions about safe use of the product to minimise any legal liability in the case of an accident.

User organisations may need, in the event of litigation, to be able to call on evidence that instructions, whether written or verbal, were given to end-users in respect of certain medical devices/equipment. Aside from potential litigation, such a requirement is likely to have the beneficial effect of creating a procedure whereby medical device/equipment end-users do, as a matter of course, receive instructions and realise they are important.

The User Organisation should ensure that manufacturers' instructions are obtained and kept current. If user organisations do their own instructions, they should submit them to the manufacturer for approval. It is also worthwhile in requesting the manufacturer to supply end-user instructions in the most appropriate form.

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Examples of Verification

- Medical Devices/Equipment are issued with copies of manufacturer's instructions and/or user organisation's instructions.
- Signed statements from all users.
- Completed Pre-Purchase Questionnaires
- Terms and Conditions of Contract

Links with other standards

Management of Purchasing and Supply
Records Management

HSC	Controls Assurance Standard	Medical Devices And Equipment Management
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CRITERION 7

Where Medical Device/Equipment manufacturers automatically send copies of revised instructions to a named recipient, these are appropriately dealt with.

Source

Medicines and Healthcare products Regulatory Agency (MHRA) *Managing Medical Devices* DB 2006 (05) ,

Guidance

Manufacturers sometimes issue revised instructions, incorporating safer methods for using medical devices/equipment, and clearer guidance. It is important to make sure that manufacturers keep records of user organisations and automatically send copies of revised instructions to a named recipient. The named recipient may be the Medical Device and Equipment Coordinator, the professional user or technical user as appropriate.

User organisations should check with the manufacturer that revised instructions are actually appropriate to the products in service since there may have been product upgrades or software changes. User organisations will need to have a system in place for keeping track of all the sets of instructions in the organisation and for replacing them with the revised versions when necessary. The system should include the need to ensure that end-users received any revised manufacturers instructions in an appropriate format and any retraining if necessary. Obsolete copies of instructions for use should be disposed of or stored appropriately to ensure they do not re-enter the supply and distribution chain.

Examples of Verification

- Policy/procedure on keeping up-to-date with instructions.
- Records.
- Terms and Conditions of Contract

Links with other standards

Management of Purchasing and Supply
Records Management

HSC	Controls Assurance Standard	Medical Devices And Equipment Management
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CRITERION 8

All instructions supplied by the user organisation are evaluated for their adequacy.

Source

Medicines and Healthcare products Regulatory Agency (MHRA) *Managing Medical Devices* DB 2006 (05) ,

Guidance

Where end-users have particular problems such as disabilities or medical conditions, additional information may need to be given and, in some instances (e.g. where people are blind or confused) special training will need to be given. It may also be necessary to write instructions locally if medical devices/equipment are linked to serve a novel function, e.g. connecting a blood analyser to a computer system to permit automatic updating of patient records. In such circumstances, the user organisation may supply its own instructions. It will need to do so carefully, since this might invite legal liability. It is important, therefore, to write instructions which are adequate. A recommended topic checklist shown below is given as guidance but may not be exhaustive:

- Placement - should instructions be printed on the medical device/equipment itself, or its immediate packaging, or supplied as a leaflet?
- Content - instructions must be precise and clear, and should include commonsense advice.
- Print size - users may have visual impairment.
- Technical or difficult language – end-users may lack technical knowledge. Instructions may be incomprehensible.
- Translation from foreign language - may not be accurate.
- Translation into other languages - end-users must understand the instructions.

In some situations end-users may need a telephone advice line as well as written instructions.

If user organisations do their own instructions, they should submit them to the manufacturer for approval. It is also worthwhile in requesting the manufacturer to supply end-user instructions in the most appropriate form.

Examples of Verification

- Policy and procedure on generating instructions for end users compatible with *Managing Medical Devices* DB 2006 (05).
- Manufacturer's letter(s) of approval.
- Evidence of usage and effectiveness of telephone advice line.

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Links with other standards

Management of Purchasing and Supply
Records Management

HSC	Controls Assurance Standard	Medical Devices And Equipment Management
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CRITERION 9

Delivery and pre-use checks are carried out on all newly delivered Medical Devices/Equipment

Source

- Medicines and Healthcare products Regulatory Agency (MHRA) *Managing Medical Devices* DB 2006 (05) ,
- NHS Purchasing and Supply Agency *NHS Master Indemnity Agreements* NHS Purchasing and Supply Agency, London
- NHS Supplies (1995) *Pre-purchase questionnaire* NHS Supplies, London

Guidance

User organisations have delivery checks for newly delivered medical devices/equipment:

- Checking that the correct product, complete with manuals and accessories, has been supplied;
- Providing assurance that product items have been delivered in good condition and (where relevant) in working order;
- Ensuring that the risks associated with using a particular model for the first time have been minimised.

When a medical device/equipment is first put into service, pre-use checks should ensure that records need updating, staff may need new/refreshers training and planned preventative maintenance put in place. Professional users should be aware when they are the first person to use a new medical device. Section 4 of the DB 2006 (05) lists key topics which may need inclusion in this procedure:

- Record keeping - enter new item into inventory; attach label with local serial/control number.
- Training - organise appropriate training for users: for new models of a familiar medical device professional users need to have access to the revised operator's manual, how any controls and adjustments work, and to be aware of potential errors arising from misleading similarities to existing medical devices; for complex or novel medical devices, formal training sessions, possibly run by the manufacturer, are needed; any necessary training for technical and maintenance staff needs to be organised; and training records need updating.
- Planned preventative maintenance - inform users about day-to-day checks and operations; note which servicing organisation is to be used; work out date for first service, enter in record keeping system; file maintenance manuals.
- Labels and documentation - attach appropriate labels, possibly warning professional users that this is a new medical device and they should monitor its introduction; warning end-users to wait until they have been trained before starting to use; giving date when preventative maintenance

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will be needed; or giving basic instructions for use. Make sure copies of manuals are supplied to users with medical device/equipment. For large items (sterilising plant, x-ray, laboratory analysers) open a record (to remain with the medical device), enter acceptance test results and who to contact in case of problems.

Points specifically appropriate to medical devices/equipment loaned by the organisation: -

Procedures for the delivery of equipment should pay attention to safety issues in terms, for example, avoidance of cross-infection, delivery of the correct item, and commissioning. Clear procedures relating to different types of equipment are likely to contribute to greater safety.

A computerised system may help with identifying equipment in terms of whether it is simple, requires assembly, requires fixing, requires that a prescribing professional be present, requires special instructions for the end-user - and so indicate the time and personnel needed to ensure successful and safe delivery, installation and end-user training.

Examples of Verification

- Procedures for delivery and commissioning
- Delivery and commissioning records.
- Policy/procedure on acceptance checks.
- Records.
- Check storage arrangements against manufacturer's checklist

Links with other standards

Management of Purchasing and Supply
Records Management

HSC	Controls Assurance Standard	Medical Devices And Equipment Management
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CRITERION 10

All newly delivered Medical Devices and Equipment are properly stored after acceptance.

Source

Medicines and Healthcare products Regulatory Agency (MHRA) *Managing Medical Devices* DB 2006 (05) ,

Guidance

Inappropriate storage of items affects their subsequent safe use.

Manufacturer's information and instructions both on storage conditions and shelf life should be followed. Good Practice indicates: -

- Physical conditions - dirty or wet conditions; inappropriate temperature or humidity (labels on packaging should indicate appropriate storage conditions).
- Storage system - stacks too high; fragile equipment stored too far off the ground, likely to be damaged by falling from shelves.
- Separation of items needing decontamination and repair from items ready to issue - inadequate space for demarcated areas for quarantine etc.; inadequate labelling of zones; inadequate packaging and labelling of equipment.
- Shelf life and stock rotation - no stock handling procedures, so earliest deliveries are not handled first; inventory system does not identify out of date stock; excessive storage time causes rubber components to set in position (ventilators) or perish, lubricants to migrate (motor driven devices) and wood to dry out and shrink (crutches); shelf life of batteries and sterile products is exceeded; rechargeable batteries may be damaged if not subjected to regular charge/discharge cycles.

Apart from possible dangers to the end-users of the equipment, poor storage conditions also put the organisation at legal risk.

Examples of Verification

- Storage records.
- Evidence of checks of storage arrangements

Links with other standards

Management of Purchasing and Supply
Records Management

HSC	Controls Assurance Standard	Medical Devices And Equipment Management
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CRITERION 11

Medical Devices designated for single-use are not reused under any circumstances

Source

- Medicines and Healthcare products Regulatory Agency (MHRA), *Single use medical devices: Implications and Consequences of Reuse*. DB2006 (04)
- DHSS Circular HSS(MD)15/99, *Variant Creutzfeldt-Jakob Disease (vCJD): Minimising the risk of transmission*

Guidance

DB 2006 (04) draws attention to the hazards and risks associated with reprocessing and re-using a single-use medical device. It covers the legal issues and regulatory requirements of such actions, i.e. anyone who reprocesses or reuses a medical device intended by the manufacturer for use on a single occasion, bears full responsibility for its safety and effectiveness. Anyone who reprocesses a single use medical device and passes it to a separate legal entity for use has the same legal obligations under the Medical Device Regulations as the original manufacturer of the device. In this instance, if the device is not considered 'fit for its intended purpose' then the reprocessor and professional user may be committing an offence under one or more of the following Acts:

- Health and Safety at Work (Northern Ireland) Order 1978
- Part 1 of the Consumer Protection Act 1987
- The General Product Safety Regulations 1994
- The Medical Devices Regulations 2002.

In addition, reprocessing single use medical devices may affect the capabilities and/or the materials from which the medical device is made. Many problems caused by inappropriate reuse of a single-use medical device fall into one or more of the following categories:

- inadequate cleaning and decontamination;
- material alteration;
- mechanical failure;
- potential for cross infection;
- reactions to endotoxins and retain residues from chemical decontamination agents.

In order to reduce the transmission of prion proteins during surgical procedures the DHSS also issued advice on minimising the risk of transmission of variant Creutzfeldt-Jakob Disease (vCJD). DHSS Circular

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HSS(MD)15/99 mirrors advice from the NIAIC stating that '**devices designated for single episodes of use must not be reused under any circumstances whatsoever**'.

Examples of Verification

- Physical verification that single use instruments are not reused
- Training programmes demonstrating the provision and application of single use medical devices
- Clinical Waste Policy and Procedures

Links with other standards

Risk Management
Governance
Waste Management

HSC	Controls Assurance Standard	Medical Devices And Equipment Management
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CRITERION 12

All prescribing decisions concerning Medical Devices and Equipment are made by staff with appropriate professional qualifications and suitable experience, backed by appropriate administrative and technical support.

Source

Medicines and Healthcare products Regulatory Agency (MHRA) *Managing Medical Devices* DB 2006 (05) ,

Guidance

The prescription of medical devices and equipment is the responsibility of the prescribing professionals, and user organisations will need to introduce and manage procedures and policies which ensure that the prescription of different types of medical device or equipment is undertaken by suitable qualified and experienced staff. In addition, where joint working arrangements are put in place and involve the "crossing of professional boundaries" in prescribing, user organisations should clarify where professional and legal responsibility for prescription lies. User organisations will need to be clear about: -

- where professional responsibility for the issue or loan of medical devices or equipment lies
- where continuing responsibility lies to monitor the medical device or equipment and the condition of the end-user, and thus where legal liability, in case of mishap falls.

Policies can be adopted which limit which medical device or equipment certain professionals may prescribe.

Policies on safety should be based on reliable, up-to-date information and, whilst a premium must be placed on safety issues, such policies should not be allowed to lapse into rigidity which in some cases may be based more on administrative convenience than on safety.

Administrative and technical support can help prescribers avoid hazards. Computer databases, for example, can build in safeguards in relation to safety based on the information supplied by medical device and equipment suppliers. Technical support personnel can sometimes assist with prescribing decisions.

Examples of Verification

- Check policies and procedures
- Compliance with Codes of Practice
- Levels of Technical and Administration Support available to prescribers
- Medical Device and Equipment Database

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- Medical Device and Equipment Evaluation Library

Links with other standards

Risk Management
Governance
Records Management
Human Resources

HSC	Controls Assurance Standard	Medical Devices And Equipment Management
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CRITERION 13

All necessary information required to properly manage the user organisation's range of Medical Devices/Equipment is recorded on a suitable system.

Source

Medicines and Healthcare products Regulatory Agency (MHRA) *Managing Medical Devices* DB 2006 (05) ,

Guidance

Accurate and accessible records are a key factor in effective medical device and equipment management. The primary function of records includes identifying the stock of medical devices and equipment currently available for use, and ensuring prompt planned preventative maintenance and rapid repairs. Secondary functions include providing an inventory, logging service histories, and generating management information about running costs. Records may be stored manually or on a computer. Whichever approach is taken, accurate, accessible and consistent record keeping is essential. Clear records should be kept from the outset, enabling the user organisation to trace individual products (e.g. by serial number), or at least particular types or batches of medical devices throughout their whole life. Information available should include:

- the current location of a given item;
- its history - supplier, purchase date, service history; how many items are available for use (or loan/issue);
- and how many are undergoing repair or servicing.

Furthermore this will enable organisations to take appropriate action following a manufacturer's recall, and to satisfy various legal concerns (e.g. under the Consumer Protection Act 1987, civil liability which would normally be attributed to the manufacturer for a defective product transfers to the user organisation if the manufacturer cannot be identified).

Examples of Verification:

- Medical Device and Equipment Database

Links with other standards

Records Management

HSC	Controls Assurance Standard	Medical Devices And Equipment Management
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CRITERION 14

All Medical Devices/Equipment are properly maintained and repaired.

Source

- Medicines and Healthcare products Regulatory Agency (MHRA) *Managing Medical Devices* DB 2006 (05) ,
- Health Estates Investment Group, Northern Ireland Adverse Incident Centre (NIAIC), *Decontamination of Endoscopes* DB(NI)2002/05, December 2002
- Health Estates Investment Group, Professional Estates Letter PEL(00)14, *The National Audit Office Report, The Management of Medical Equipment in NHS Acute Trusts in England*, August 2000
- The National Audit Office (1999) *The Management of Medical Equipment in NHS Acute Trusts in England* The Stationary Office, London

Guidance

There should be a clear policy and procedure which underpins the process of maintenance and repair of devices/equipment in line with the guidance in Device Bulletin DB 2006 (05). This should cover:

- Repair and maintenance process
- Management and monitoring of Repair and maintenance
- Training and experience of service personnel
- Selecting a repairer
- Information on repair and maintenance
- Contract with the service provider
- Liability for medical device/equipment repair and maintenance
- Decontamination of medical devices/equipment returned into store for subsequent reuse and reissue
- Routine maintenance procedures carried out by end-users.
- Disposal

In relation to medical devices and equipment maintenance, PEL(00)14 supported the National Audit Office recommendation that HSC organisations should:

- Examine whether they can reduce maintenance costs without reducing quality through sharing maintenance with external suppliers, or by taking over some work altogether.
- Review external contracts through better contract co-ordination and monitoring of their need.
- Develop and review planned preventative schedules, in the light of experience and manufacturers' recommendations on maintenance frequencies, and sharing information and experience with other organisations, with a view to saving costs without reducing medical device/equipment safety or increasing exposure to liability.

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Examples of Verification

- Documented policy and procedure
- Medical Device and Equipment Maintenance and Repair Contracts.
- Maintenance and Repair schedules analysis
- Business Case documentation for in-house service
- Benchmarking data on costs
- Evidence of co-operation with other HSC organisations
- Routine maintenance instructions for professional users and end-users

Links with other standards

Records Management
Management of Purchasing and Supply

HSC	Controls Assurance Standard	Medical Devices And Equipment Management
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CRITERION 15

The in-house Medical Device/Equipment maintenance department is externally accredited.

Source

- Health Estates Investment Group, Professional Estates Letter PEL(00)14, *The National Audit Report, The Management of Medical Equipment in NHS Acute Trusts in England*, August 2000
- The National Audit Office (1999) *The Management of Medical Equipment in NHS Acute Trusts in England* The Stationary Office, London

Guidance

In the NAO study, thirty percent of in-house maintenance departments had external accreditation to a recognised quality standard. Apart from the greater assurance accreditation gives to medical devices and equipment users, based on examples of best practice the NAO identified that accreditation leads to a higher quality of work and the scope for efficiency savings.

Where an organisation has no external quality accreditation, it is recommended that the benefits of accreditation be evaluated.

Examples of Verification

- Current accreditation certificate
- Benefits assessment
- Business Case Documentation

Links with other standards

Records Management

HSC	Controls Assurance Standard	Medical Devices And Equipment Management
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CRITERION 16

All Medical devices/Equipment returned for servicing and repair prior to reuse are properly decontaminated.

Source

- Medicines and Healthcare products Regulatory Agency (MHRA) *Managing Medical Devices* DB 2006 (05) ,
- Health Estates Investment Group, Northern Ireland Adverse Incident Centre (NIAIC), *Decontamination of Endoscopes* DB(NI)2002/05, December 2002
- Health Estates Investment Group, Professional Estates Letter PEL(94)34, *Decontamination of Equipment Prior to inspection service or repair*, July 1994
- DHSS Circular HSS(MD)16/99, *Controls assurance in infection control: Decontamination of medical devices.*
- HSS(MD)4/01 Decontamination of reusable medical devices and Addendum 3 of HSS(MD)4/01, Protocol for Local Decontamination of Surgical Instruments.

Guidance

The user organisation should ensure that all medical devices/equipment intended for repair or maintenance are properly decontaminated and are consequently safe to handle.

These operations are vital, as a failure to have effective procedures in place will not only put staff and the end-users of equipment at risk, but will also create a danger of legal liability being incurred, for example, if unclean and consequently unsafe medical devices/equipment is supplied to community end-users.

Examples of Verification

- Policy and procedures on decontamination of medical devices and equipment.
- Evidence of implementation of policy and procedure

Links with other standards

Risk Management
Governance
Decontamination
Infection Control
Waste Management

HSC	Controls Assurance Standard	Medical Devices And Equipment Management
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CRITERION 17

Medical Devices/Equipment are replaced in accordance with an agreed policy.

Source

- Medicines and Healthcare products Regulatory Agency (MHRA) *Managing Medical Devices* DB 2006 (05) ,
- DHSS Circular HSS(MD)16/99, *Controls assurance in infection control: Decontamination of medical devices*
- Health Estates Investment Group, Northern Ireland Adverse Incident Centre (NIAIC), *Decontamination of Endoscopes* DB(NI)2002/05, December 2002
- HSS(MD)4/01 Decontamination of reusable medical devices and Addendum 3 of HSS(MD)4/01, Protocol for Local Decontamination of Surgical Instruments.

Guidance

For all medical devices and equipment, a stage is reached at which replacement must be considered. If any of the following seven criteria apply, the medical device/equipment is no longer serviceable:

- Worn out beyond economic repair
- Damaged beyond economic repair
- Unreliable (check service history)
- Clinically or technically obsolete
- Spare parts no longer available
- More cost-effective or clinically effective medical devices/equipment have become available
- Unable to be cleaned effectively prior to disinfection and/or sterilisation.

If the medical device/equipment survives this test, a date should be set for re-testing (e.g. in a year's time).

Examples of Verification

- Documented policy on replacement of medical devices
- Records for replacement tests

Links with other standards

Risk Management
Governance
Decontamination
Infection Control

HSC	Controls Assurance Standard	Medical Devices And Equipment Management
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CRITERION 18

All loaned, leased or on trial Medical Devices/Equipment are collected when no longer needed.

Source

- Medicines and Healthcare products Regulatory Agency (MHRA) *Managing Medical Devices* DB 2006 (05) ,
- Health Estates Investment Group, Northern Ireland Adverse Incident Centre (NIAIC), *Decontamination of Endoscopes* DB(NI)2002/05, December 2002
- HSS(MD)4/01 Decontamination of reusable medical devices

Guidance

From the point of view of both economics and safety, user organisations will wish to have systems in place which ensure the appropriate collection of medical devices or equipment when end-users no longer need them.

Collection systems may involve regular or semi-regular postal communications with end-users; providing them with a contact point should they require medical device and equipment information. End-users may often not know, or remember, where to return medical devices and equipment. Clearly marked medical devices and equipment may help.

Examples of Verification

- Collection procedure.
- Collection records
- User organisation budget credit systems for collection and reuse of medical devices/equipment.

Links with other standards

Risk Management
Governance
Records Management

HSC	Controls Assurance Standard	Medical Devices And Equipment Management
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CRITERION 19

All adverse incidents involving Medical Devices and Equipment are reported in accordance with Health Estates Investment Group, Northern Ireland Adverse Incident Centre (NIAIC), Reporting Adverse Incidents and Disseminating Alerts DB2010(NI)-01.

Source

- Health Estates Investment Group, Northern Ireland Adverse Incident Centre (NIAIC), *Reporting Adverse Incidents and Disseminating Alerts DB2010(NI)-01*.
- Medicines and Healthcare products Regulatory Agency (MHRA) *Managing Medical Devices* DB 2006 (05) ,
- Health Estates Investment Group, Professional Estates Letter PEL(00)14, *The National Audit Report, The Management of Medical Equipment in NHS Acute Trusts in England*, August 2000
- The National Audit Office (1999) *The Management of Medical Equipment in NHS Acute Trusts in England* The Stationary Office, London
- HSS(PPM)06/04 - Reporting and follow-up on serious adverse incidents: Interim Guidance

Guidance

NIAIC DB2010(NI)-01 is the NIAIC published guidance on reporting of adverse incidents involving medical devices and equipment.

An adverse incident is an event which gives rise to, or has the potential to produce, unexpected or unwanted effects involving the safety of patients, clients, users or other persons.

An adverse incident reporting procedure should be in place which ensures that:

- Where appropriate, a liaison officer is appointed with the necessary authority to take responsibility for the reporting of medical device/equipment related adverse incidents to NIAIC.
or
An appropriate coordinator is appointed in each individual directorates/departments or geographical area with the necessary authority to take responsibility for the reporting of medical device/equipment related adverse incidents to NIAIC and their liaison officer.
or
All staff members are instructed that they must take responsibility for the reporting of medical device/equipment related adverse incidents to NIAIC and their liaison officer.

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- Devices/equipment involved in an adverse incident together with other material evidence (e.g. packaging of a single use device) should be clearly identified and kept in quarantine, where practicable, until NIAIC has been consulted. Where quarantine is not practicable, the state of the device(s)/equipment at the time of the incident should be recorded for use in any subsequent investigation.
- Local action is taken as necessary to ensure the safety of patients, clients, users and others.
- All staff, including contractors, at all levels, are aware of their responsibilities and of the procedures to be used to report adverse incidents and isolate and retain defective items.
- End-users are aware of adverse incident reporting procedures as part of their initial instruction in how to use the medical device/equipment with periodic reminders/checks as appropriate.

In some cases the medical device/equipment coordinator (Criterion 1 refers) will also act as NIAIC liaison officer and or the SABS liaison officer, reporting adverse incidents in accordance with NIAIC requirements and receiving copies of all NIAIC publications and making sure they reach their intended readers.

With the development and implementation of effective clinical and social care governance together with the integration of the co-ordinator role into organisational risk management structures, in due course these initiatives should provide organisations with the necessary skills to enable them to undertake the appropriate level of local investigation involving adverse events involving medical devices and equipment management and where appropriate take local action based on the investigation outcome.

DHSSPS circular HSC(SQSD)19/2007 provided interim guidance on the reporting to the DHSSPS of incidents regarded as serious enough for regional action to be required. **Such incidents, should they involve medical devices, non-medical equipment, plant or building, must also be reported to NIAIC.**

In addition, the NAO recommend that the system in place for recording and reporting incidents is effective in ensuring that adverse incidents occurring within the organisation are not repeated.

Examples of Verification

- Policy and Procedure
- Documented Incident Reporting and Investigation System
- NIAIC adverse incident reports
- NIAIC adverse incident investigation reports
- Adverse Incident Investigation outcome reports to Risk Management/Governance committee(s)
- Action and Implementation Plans following adverse incident investigation (e.g. staff training, medical device replacement etc.)

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- Staff awareness surveys

Links with other standards

- Risk Management
- Governance
- Records Management

HSC	Controls Assurance Standard	Medical Devices And Equipment Management
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CRITERION 20

A complete record of guidance issued by the NIAIC is maintained; warning notices are distributed to the appropriate people in the organisation; and recommendations contained in the notices are implemented. Organisations should have a procedure in place to manage Field Safety Notices (FSN) distributed directly from the manufacturer.

Source

- Health Estates Investment Group, Northern Ireland Adverse Incident Centre (NIAIC), *Reporting Adverse Incidents and Disseminating Alerts DB2010(NI)-01* .
- Health Estates Investment Group, Professional Estates Letter PEL(07)21, Safety Alert Broadcast System, December 2007

Guidance

The organisations SABS liaison officer is responsible for the dissemination of advice and recommendations issued by NIAIC (Criterion 1 refers).

A catalogue and library of guidance issued by the NIAIC should be maintained this can be either physical or electronic. As each MDA or MDEA is received it should be reviewed and distributed to the appropriate people in the organisation who will need to be aware of the contents of the MDA or MDEA for action or for information.

User organisations have a procedure to ensure specific action has been taken by those individuals who have been sent copies or details of any MDA or MDEA containing specific action points. The procedure should include a follow-up to ensure that any actions have been implemented.

User organisations have a procedure to ensure specific action has been taken by those individuals who have been sent copies or details of any FSN specific action points. The procedure should include a follow-up to ensure that any actions have been implemented across the organisation.

Examples of Verification

- Catalogue/Library of NIAIC MDEA and MDA's
- Catalogue/Library of manufacturer's FSN's applicable to the organisation.
- Catalogue/Library of NIAIC/MHRA Device Bulletins
- Catalogue/Library of NIAIC/MHRA Guidance Publications
- Catalogue/Library of MHRA evaluation reports.
- Distribution records for MDEAs, MDA's /Device Bulletins, including any end-user action as appropriate.
- Risk Management/Governance committee(s) minutes
- Reports demonstrating implementation of warning notice actions.

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Links with other standards

All standards

HSC	Controls Assurance Standard	Medical Devices And Equipment Management
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CRITERION 21

The risk management process contained within the risk management system standard is applied to the management of Medical Devices and Equipment risk.

Source

- Standards Australia (2004) *Risk Management AS/NZS 4360:2004*. Standards Association of Australia. Strathfield NSW.
- New DHSSPSNI Policy on Risk Management
- DAO (DFP) 5/2001 – Corporate Governance: Statement on Internal Control
- HSS (PPM) 3/2002 – Corporate Governance: Statement on Internal Control
- Circular HSS (PPM) 5/2003 – Governance in the HPSS: Risk Management and Controls Assurance

Guidance

Medical device and equipment risks can be systematically identified using a number of approaches including:

- Review of adverse incidents
- Review of NIAIC MDEAs and MDA's etc.
- Medical Device and Equipment inspections/assessments
- Review of audit reports
- Workshops with staff
- Feedback from professional users
- Feedback from patients, clients and the public

The following risk management elements should be in place:

- All identified risks should be documented as part of a 'risk register' and systematically assessed and prioritised.
- Risk treatment plans should be developed and implemented (in order of priority and alongside other risk treatments which are necessary to deal with wider risks faced by the organisation, where appropriate) in order to minimise risk.
- Risks and the effectiveness of implemented risk treatments should be monitored and reviewed on a continuous basis.
- Risk Management/Governance committee(s), senior management and the Board should be informed of any significant risks and associated risk treatment plans.
- All relevant staff, including those on fixed term contracts, and other relevant stakeholders should receive information on systems in place to minimise medical device and equipment risks.
- Where appropriate, staff training should be undertaken.

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Good records need to be maintained at all times.

Examples of Verification

- Risk Register
- Risk treatment plans
- Staff training/information log
- Correspondence with stakeholders
- Risk Management/Governance committee(s) minutes
- Audit Reports

Links with other standards

Risk Management
Governance
Records Management

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CRITERION 22

Staff are made aware of and, where necessary, trained in adverse incident reporting and investigation requirements for Medical Devices and Equipment.

Source

Health Estates Investment Group, Northern Ireland Adverse Incident Centre (NIAIC), *Reporting Adverse Incidents and Disseminating Alerts DB2010(NI)-01* .

Guidance

All staff should be regularly reminded of the procedures referred to in Criterion 19 and of their responsibilities with regard to adverse incident reporting. This information should also be conveyed to new staff as part of their induction training. Regular reviews should be undertaken to ensure that the procedures are effective and are being followed.

Examples of Verification

- Documented procedures.
- Availability of NIAIC Adverse Incident report form(s).
- Staff adverse incident reporting and investigation guidance document
- Staff Induction programmes
- Professional Codes of Practice/Conduct
- Staff training reviews and action plans
- Staff awareness of Catalogue/Library of NIAIC MDAs, MDEAs, Device Bulletins, Guidance Publications, MHRA evaluation reports, etc.
- Risk Management/Governance committee(s) minutes

Links with other standards

Risk Management
Governance
Human Resources

HSC	Controls Assurance Standard	Medical Devices And Equipment Management
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CRITERION 23

All professional users are trained in the safe operation of Medical Devices and Equipment.

Source

- Medicines and Healthcare products Regulatory Agency (MHRA) *Managing Medical Devices* DB 2006 (05) ,
- Health Estates Investment Group, Northern Ireland Adverse Incident Centre (NIAIC), *Decontamination of Endoscopes* DB(NI)2002/05, December 2002
- HSS(MD)4/01 Decontamination of reusable medical devices and Addendum 3 of HSS(MD)4/01, Protocol for Local Decontamination of Surgical Instruments.

Guidance

Professional users need to understand the normal operation of medical devices/equipment. Where relevant they should:

- Be suitably trained and competent in how to use the medical device/equipment.
- Maintain competence in how to use the medical device/equipment.
- Be aware of differences between models of a given medical device/equipment, where these affect safety or medical device/equipment function.
- Be able to assemble the medical device/equipment if it needs disassembly for cleaning, and fit relevant accessories.
- Be able to set the controls appropriately.
- Be able to link the medical device/equipment to a patient effectively, causing minimum of discomfort.
- Be able to clearly show the patient/client how to use the medical device/equipment as appropriate.

If the medical device/equipment malfunctions, they should be able to:

- Recognise the difference between user operational malfunctions and device faults and failures.
- Correct operational malfunctions
- Withdraw the medical device/equipment from service when a device is faulty or fails.
- Contact appropriate personnel

When the device is removed from service, professional users should know how to clean it, have an appreciation of decontamination requirements and to organise decontamination.

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Examples of Verification

- Staff Training plans/Logs and records including continuing professional development e.g. PREP records.
- Audit reports
- Adverse incident reports

Links with other standards

Risk Management
Governance
Human Resources

HSC	Controls Assurance Standard	Medical Devices And Equipment Management
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CRITERION 24

All technical supervisors are trained in the safe operation of Medical Devices and Equipment.

Source

- Medicines and Healthcare products Regulatory Agency (MHRA) *Managing Medical Devices* DB 2006 (05) ,
- Health Estates Investment Group, Northern Ireland Adverse Incident Centre (NIAIC), *Decontamination of Endoscopes* DB(NI)2002/05, December 2002
- HSS(MD)4/01 Decontamination of reusable medical devices and Addendum 3 of HSS(MD)4/01, Protocol for Local Decontamination of Surgical Instruments.

Guidance

Technical supervisors can as appropriate assist medical device and equipment co-ordinators in the organisation and provision of training for professional users and end-users when necessary.

Technical supervisors should ensure that their technical staff have the necessary training, competence and experience to provide safe medical devices and equipment for professional users and end-users.

Examples of Verification

- Training plan and records.
- Audit reports
- Adverse incident reports

Links with other standards

Risk Management
Governance
Human Resources

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CRITERION 25

All end-users are given appropriate training in the safe and effective use of Medical Devices and Equipment.

Source

- Medicines and Healthcare products Regulatory Agency (MHRA) *Managing Medical Devices* DB 2006 (05) ,
- Health Estates Investment Group, Professional Estates Letter PEL(00)14, *The National Audit Office Report, The Management of Medical Equipment in NHS Acute Trusts in England*, August 2000
- The National Audit Office (1999) *The Management of Medical Equipment in NHS Acute Trusts in England* The Stationary Office, London

Guidance

Professional users, clinical supervisors and prescribers need to make sure that training for end-users enables them to use a medical device/equipment safely and effectively, and to perform routine maintenance as appropriate for the safe use of the medical device/equipment.

For example, end-users of ambulatory infusion pumps should be aware of how the medical device works, including special features such as bolus delivery, and the risks of siphoning if a syringe is removed from a driver. It is also essential that end-users are provided with information contained in manufacturer's instructions and that it is explained and, where necessary, expanded upon.

Where possible, user organisations should provide the same standards of equipment and training for end-users as they do for staff.

The NAO recommends that (NHS) Trusts consider how to make best use of medical engineering department and other expertise such as technical supervisors in professional user and end-user training.

Examples of Verification

- Training policy and records.
- Audit reports
- Adverse incident reports

Links with other standards

Risk Management
Governance
Human Resources

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CRITERION 26

All staff are provided with appropriate training in the safe use of Medical Devices and Equipment.

Source

- Medicines and Healthcare products Regulatory Agency (MHRA) *Managing Medical Devices* DB 2006 (05) ,
- Health Estates Investment Group, Northern Ireland Adverse Incident Centre (NIAIC), *Decontamination of Endoscopes* DB(NI)2002/05, December 2002
- HSS(MD)4/01 Decontamination of reusable medical devices and Addendum 3 of HSS(MD)4/01, Protocol for Local Decontamination of Surgical Instruments.

Guidance

Safe use of medical devices and equipment by staff requires training. Safety training for staff is often undertaken in response to health and safety legislation, e.g.:

- Health and Safety at Work (Northern Ireland) Order 1978
- Management of Health and Safety at Work Regulations (NI) 1992
- Provision and Use of Work Equipment Regulations (NI) 1999
- Manual Handling Operations Regulations (NI) 1992

“Duty of Care” means that an employer must provide and keep adequate training records. In addition, all professionals have a duty to make sure that their knowledge is kept up to date.

Examples of Verification

- Training policy and records.
- Audit reports
- Adverse Incident Reports
- Codes of Practice for Professional Regulatory Bodies
- Clinical and Social Care Governance committee(s) minutes.

Links with other standards

Risk Management
Governance
Human Resources

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CRITERION 27

Key indicators capable of showing improvements in Medical Devices/Equipment management and/or providing early warning of risk are used at all levels of the organisation, including the board, and the efficacy and usefulness of the indicators is reviewed regularly.

Source

- Health Estates Investment Group, Professional Estates Letter PEL(00)14, *The National Audit Office Report, The Management of Medical Equipment in NHS Acute Trusts in England*, August 2000
- The National Audit Office (1999) *The Management of Medical Equipment in NHS Acute Trusts in England* The Stationary Office, London
- Standards Australia (2004) *Risk Management AS / NZS 4360:2004*. Standards Association of Australia. Strathfield NSW.
- DAO (DFP) 5/2001 – Corporate Governance: Statement on Internal Control
- HSS (PPM) 3/2002 – Corporate Governance: Statement on Internal Control
- Best Practice – Best Care
- Circular HSS (PPM) 5/2003 – Governance in the HPSS: Risk Management and Controls Assurance

Guidance

The user organisation should develop indicators which demonstrate performance in medical devices and equipment management. One indicator is degree of compliance with this standard.

Ideally the indicators should be designed to demonstrate improvement in medical devices and equipment management over time. The number of indicators devised should be sufficient to monitor key health and safety concerns. It is not necessarily the case that the Board will use all the indicators. The Board should select those which are useful for ensuring that the internal controls are working satisfactorily and objectives for medical devices management are being met.

Examples of Verification

- Indicators – e.g.
 - a) Level of compliance with this standard
 - b) Adverse Incident Reports per medical device/equipment type
 - c) Breakdowns per medical device/equipment type
 - d) Lost hours per medical device/equipment type
 - e) % of trained staff per medical device or equipment
 - f) Reduction in models per medical device or equipment
- Evidence of usage at all levels

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Links with other standards

All standards

HSC	Controls Assurance Standard	Medical Devices And Equipment Management
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CRITERION 28

The organisation participates in benchmarking its management of Medical Devices/Equipment.

Source

- Health Estates Investment Group, Professional Estates Letter PEL(00)14, *The National Audit Office Report, The Management of Medical Equipment in NHS Acute Trusts in England*, August 2000
- The National Audit Office (1999) *The Management of Medical Equipment in NHS Acute Trusts in England* The Stationary Office, London

Guidance

PEL(00)14 supported the National Audit Office recommendation that (NHS) trusts should "seek to reduce the number of different models of each type of medical equipment in use and, accordingly, introduce a replacement strategy that promotes standardisation of medical equipment, to save money and minimise the staff training burden while ensuring that all clinical needs are covered" and suggests that "benchmarking between trusts has an important part to play in facilitating this work."

The NAO further recommends that (NHS) trusts should:

- Benchmark their holdings of medical equipment against those of similar trusts to examine how cost effective they are and identify good practice; and
- Benchmark their maintenance costs against those of other trusts, in order to introduce best practice and explore the potential for financial savings.

Examples of Verification

- Evidence of participation in suitable benchmarking scheme.
- Action Plan from benchmarking activity
- Benefits Analysis

Links with other standards

Risk Management
Governance

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CRITERION 29

The system in place for Medical Devices and Equipment management, including risk management arrangements, is monitored and reviewed by management and the board in order to make improvements to the system.

Source

- Standards Australia (2004) *Risk Management AS / NZS 4360:2004*. Standards Association of Australia. Strathfield NSW.
- Best Practice – Best Care
- DAO (DFP) 5/2001- Corporate Governance: Statement on Internal Control
- HSS (PPM) 10/2002 – Governance in the HPSS: Clinical and Social Care Governance – Guidance on Implementation
- HSS (PPM) 3/2002 – Corporate Governance: Statement on Internal Control
- Circular HSS (PPM) 5/2003 – Governance in the HPSS: Risk Management and Controls Assurance

Guidance

It is the responsibility of the Chief Executive and the Board to monitor and review all aspects of the medical devices and equipment management system, including:

- accountability arrangements
- processes, including risk management arrangements
- capability
- outcomes
- internal audit findings

An annual report on the efficacy of the medical devices and equipment process should be submitted to the Risk Management Committee or other appropriate Committee of the Board for review. The Risk Management Committee or other appropriate committee of the Board will play a significant role in monitoring and reviewing all aspects of the system as a basis for establishing significant information that should be presented to, and dealt with by the Board.

Examples of Verification

- Risk Management Committee(s) minutes
- Audit Committee minutes
- Accountability arrangements chart
- Risk Management Strategy
- Risk Management organisational chart
- Board minutes
- Internal audit report(s)

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- Annual Reports

Links with other standards

All standards (generic criterion)

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CRITERION 30

The organisation's board should seek independent assurance that an appropriate and effective system of managing Medical Devices and Equipment is in place and that the necessary level of controls and monitoring are being implemented.

Source

- Standards Australia (2004) *Risk Management AS/NZS 4360:2004*. Standards Association of Australia. Strathfield NSW.
- Best Practice – Best Care
- HSS (PPM 10/2002 – Governance in the HPSS: Clinical and Social Care Governance – Guidance on Implementation
- HSS (PPM) 3/2002 – Corporate Governance: Statement on Internal Control
- HSS (PPM) 6/2002 – AS/NZS 4360: 1999 – Risk Management
- DAO (DFP) 5/2001 – Corporate Governance: Statement on Internal Control
- NHS Internal Audit Manual
- Circular HSS (PPM) 5/2003 – Governance in the HPSS: Risk Management and Controls Assurance

Guidance

Significant risks to, and controls over, the delivery of the organisation's objectives should be subjected to an independent and objective review. The results of these reviews should be communicated to the board through its sub-committees appointed for this purpose (e.g. Audit Committee, Clinical and Social Care Governance Committee, Risk Management Committee).

Where controls are found to be inadequate, or are not being complied with, there should be an action plan with dates set for corrective action and follow-up.

The frequency and depth of review will depend upon the degree of risk involved. It is important that the reviews are conducted in a manner, and to a standard, that enables the board to derive meaningful assurance from them. Although a variety of review bodies may be involved, both internal and external, reflecting the differing technical expertise required, or statutory duties, there is a need to be aware of the danger of overlap or gaps in the review process. There is also the possibility of misunderstanding arising from differing approaches to the reviews

All bodies sponsored by DHSSPS are required to have an internal audit function, and they must meet the standards set out in the NHS Internal Audit Manual. They are also required to provide the Audit Committee with an objective opinion on the effectiveness of the organisation's system of internal control.

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It may be helpful in terms of economy, efficiency, and effectiveness, to nominate one internal group to co-ordinate the assurance processes.

The Health and Personal Social Services Regulation and Quality Improvement Authority (RQIA) will have a key role in providing the public and the Minister with the assurance that the objective of improving clinical and social care quality is being implemented appropriately at every level of the HSC.

Boards should ensure that external review is used to inform and improve patient care and that the organisation learns from reports and benchmarking.

Examples of Verification

- Reports to the board from the audit committee and action taken.
- Minutes of the audit committee
- Reports from internal audit
- Reports from multi-professional audit
- Reports from external audit
- Reports from RHIA and other review bodies
- Reports from RQIA
- Schedule of planned reviews
- Action plans
- Notes of follow up of actions
- Evidence file
- Details of staff and end-users involved in any review.

Possible Links with other standards

All standards