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MEDICINES MANAGEMENT STANDARD (SAFE AND SECURE HANDLING OF MEDICINES)

Standard

The organisation handles medicines safely and securely, in accordance with legislative requirements and best practice.

Overview

The Audit Commission (2001) defined medicines management as encompassing the entire way that medicines are selected, procured, delivered, prescribed, administered and reviewed to optimise the contribution that medicines make to producing informed and desired outcomes of patient care. Medicines governance more specifically focuses upon the safety and risk management issues concerned with medicines and importantly, systems risks that can lead to error and resultant adverse incidents.

This standard, while addressing many of the components identified above is not designed to cover the more specific clinical aspects of medicines management, although there are obviously intrinsic linkages. This is not to minimise the importance of the clinical and cost effective use of medicines and organisations are expected to work to these goals in the provision of optimal patient care.

The safe and secure handling of medicines in both the hospital and primary care settings requires appropriate policies, procedures and quality assurance systems to be in place. It covers processes throughout the organisation, not just in pharmacy.

This standard outlines legislative and best practice relating to the safe handling of medicines, including controlled drugs. The main legislation addressed within this standard includes:

- The Medicines Act 1968, as amended, which regulates the manufacture, distribution, import, export, sale and supply of medicinal products
- The Misuse of Drugs Act 1971, which controls the availability of drugs liable for misuse
- The Misuse of Drugs Regulations (Northern Ireland) 2002, which enables specified health care professionals to possess, supply, prescribe and/or administer controlled drugs in the sphere of their practice.
- Health Act 2006
- The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009

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Guidance

Each HSC body (Board, Trust, and Agency as it relates to them) needs to ensure the safe and secure handling and storage of medicines. This will require a review of the different locations in which medicines are stored, dispensed and transported and consideration of the various staff groups responsible for these functions.

Within the HSC body, attention should focus on a review of the risks and control systems covering: procurement, ordering, delivery, storage, distribution, prescribing, dispensing, issue, supply, administration and disposal within and between the various locations (acute / community facilities, staff working in the community, in GP practices etc). Any such review should also consider continuing professional development as related to pharmacy and medicines management, along with other associated human resource issues (such as COSHH training, skill mix, training in the management of controlled drugs, handling and disposal of drugs in the community, adverse event reporting etc). The HSC body also needs to ensure that the organisation has effective systems in place for the reporting of adverse events involving medicinal products and can demonstrate a pro-active approach to investigating any incidents locally (as well as responding to DHSSPS or MHRA alerts).

In addition to reviewing its own internal systems in relation to medicines management, the HSC body should also request evidence from organisations with which the HSC body holds service level agreements etc. as to the effectiveness of their risk management concerning the handling and storage of medicines (eg Ambulance Trust and Out-Of-Hours Service Providers) since risks need to be considered across organisational boundaries.

If an organisation undertakes a robust risk assessment against this standard and deems a particular criterion to be non-applicable, it is essential that the rationale for any such decision is documented and evidence is available to support this assessment.

It is also important to consider the linkages between this and other standards (e.g. risk management, governance, purchasing and supply, medical equipment and devices), which seek to ensure that there are controls in place to minimise all risks across the organisation.

Controlled Drugs

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 which came into operation on 1 October 2009 requires each Designated Body to appoint an Accountable Officer (AO). The AO is responsible for ensuring their Designated Body, and any body or person providing services on behalf of, or providing services under arrangements made with their Designated Body, establishes and operates safe and effective systems relating to the management and use of controlled drugs.

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This legislation also places a duty of collaboration on Responsible Bodies to share (within certain constraints) information regarding concerns about the use of controlled drugs.

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, e.g. *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, therefore, 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. Once again, 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

Circular HSS Issued 7 September 2000 - Patient Group Directions (and as amended by legislative changes)

Circular HSS (PPM) 8/2004 – Governance in the HPSS: Controls assurance standards – update

Circular HSS (PPM) 8/2002 – Risk Management in the Health and Personal Social Services

Circular HSS (PPM) 13/02 Governance in the HPSS: Risk Management

Circular HSS(PPM) 5/2003 – Governance in the HPSS – Risk Management and Controls Assurance

Circular HSC(SQSD) 61/2008

1) National Patient Safety Agency: Rapid Response Report 4: Using Vinca Alkaloid Minibags (Adult/Adolescent Units)

(2) HSC 2008/001 Updated national guidance on the safe administration of intrathecal chemotherapy

Circular HSS (PPM) 4/05 AS/NZS 4360:2004 – Risk Management

Clinical Pharmacy Review (2001), DHSSPS

DHSSPS -An Assurance Framework: a Practical Guide for Boards of DHSSPS Arm's Length Bodies, March 2009

European Commission Council Directive Title V of 2001/83/EC Labelling and Leaflet Directive

Guidelines for the Control and Administration of Medicines Domiciliary Care Agencies - RQIA January 2009

Health Act 2006

Health Building Note 29: Pharmaceutical Services

Health Services Management. The Way Forward for Hospital Pharmaceutical Services, DHSS 1989 (HSS(GHS)2-89)

HPSS Management Executive (OP1) 2/92 Supply of Medicines and Other Pharmaceutical Products – Responsibility for Prescribing Between Hospitals and Family Practitioner Services

HSCB correspondence relating to Medicines Management Policy

Managing patients' medicines after discharge from hospital Care Quality Commission October 2009

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Medicines Act 1968 Chapter 67 (as amended) The Stationery Office, London

MHRA Guidance note 14; The supply of Unlicensed relevant Medicinal Products for Individual Patients 01/2008

MHRA Rules and guidance for Pharmaceutical Manufacturers and Distributors 2007 “Orange Guide”. The Stationery Office, London

Misuse of Drugs Act 1971 (c.38) The Stationery Office, London

NHS Estates (1994) HTM 02-01 Medical gas pipeline systems. The Stationery Office, London

NHS Executive (1999) Continuing Professional Development. Quality in the new NHS HSC 1999/154

NIAIC Medical Device Alert MDA/2011/001(NI) Reporting Adverse Incidents and Disseminating Medical Device / Equipment Alerts. Health Estates, Northern Ireland Adverse Incident Centre (NIAIC).

Northern Ireland Clinical Pharmacy Standards

Northern Ireland Medicines Management Formulary (including a compendium of prescribing guidance developed through the Pharmaceutical Clinical Effectiveness Programme) as published by HSCB

Nursing and Midwifery Council: Medicines Management Standards (2008)

Pharmaceutical Society of Northern Ireland Code of Ethics and Professional Standards and Guidance Documents

Poisons Act 1972 The Stationery Office, London

Research Governance Framework for Health and Social Care second edition (2005), Department of Health, London

Research Governance Framework for Health and Social Care, (2006) DHSSPS

Research Governance Implementation Plan (2001), Department of Health, London

Safe and Secure Handling of Medicines - A Team Approach. A revision of the Duthie Report led by the Hospital Pharmacists’ Group of the Royal Pharmaceutical Society. RPSGB March 2005

Safe Disposal of Clinical Waste. Health and Safety Commission (Health Services Advisory Committee), Second Edition 1999 ISBN 07176 2492 7

Safer Management of Controlled Drugs A guide to good practice in primary care (Northern Ireland) DHSSPS

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Safer Management of Controlled Drugs A guide to good practice in secondary care (Northern Ireland) DHSSPS

Safer Management of Controlled Drugs Guidance on Standard Operating Procedures for (Northern Ireland) DHSSPS

Safety Notice SN (NI) 2003/01: Reporting Adverse Incidents and Disseminating Warning Notices Relating to Medical Devices, Non-Medical Equipment, Buildings and Plant. Health Estates, Northern Ireland Adverse Incident Centre (NIAIC).

Standards Australia Risk Management AS/NZS 4360:2004

The Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003. SR 2003 No 34 The Stationery Office, London

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 SR 2009 No 225 The Stationery Office, London

The Health and Safety at Work (Northern Ireland) Order 1978. SI 1978 No 1039 (NI 9). The Stationery Office, London

The Ionising Radiation (Medical Exposure) Regulations 2000 SI 2000 No 1059. The Stationery Office, London

The Management of Clinical waste in the Delivery of Health and Social Care In the Community. Health Estates (2002) PEL (01)11

The Management of Health and Safety at Work Regulations 1999. SI 1999 No. 3242. The Stationery Office, London

The Medicines (Administration of Radioactive Substances) Regulations 1978 SI 1978 No 1006 The Stationery Office, London

The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 SI 2008 No. 2789 The Stationery Office, London

The Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973 SR 1973 No 179 (as amended) The Stationery Officer, London

The Misuse of Drugs Regulations (Northern Ireland) 2002 SR 2002 No 1 (as amended) The Stationery Office, London

The Prescription Only Medicines (Human Use) Order 1997 SI 1997 No 1830 (as amended) The Stationery Office, London

The Radioactive Substances Act 1993 (c. 12) The Stationery Office, London

The Segregation Primary Packaging, Secondary Packaging and Storage of Clinical Waste. Health Estates. HSS-E. PEL (99)9 dated 15 March 1999.

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Updated Guidance on Reporting Defective Medicines issued 18/02/2011

Use and Control of Medicines: Guidelines for the safe prescribing, administration, handling, storage and custody of medicinal products in the Health and Personal Social Services (6th reprint, Sept 2010), DHSSPS.

Additional Reading

Department of Health - 'Building a Safer NHS. Improving Medication Safety' (2004)

Department of Health Clinical Governance in Community Pharmacy. Guidelines on good practice for the NHS Dec 2001. Department of Health, London.

Department of Health Extending Independent Nurse Prescribing within the NHS in England. A guide for implementation. 2nd edition 2004 Department of Health, London.

Department of Health (2000) The NHS Cancer Plan: a plan for investment, a plan for reform Department of Health, London

Department of Health (2001) External inquiry into the adverse incidents that occurred at Queen's Medical Centre, Nottingham Department of Health, London

Department of Health (2001) The Prevention of Intrathecal Medication Errors Department of Health, London

Department of Health, London, Manual of Cancer Services

Developing Essential Drug Policies WHO/DAP/96.2

Ensuring Best Practice in Pharmaceutical Procurement. Pharmaceutical Contracting Executive Group September 2004

Good Practice in Prescribing and Managing Medicines and Devices [updates Good Practice in Prescribing Medicines (2008)] General Medical Council

Healthcare Commission - 'The Best Medicine, The management of medicines in acute and specialist Trusts' (2007)

Healthcare Commission - Acute Hospitals Portfolio-Medicines management 2005/2006.

Healthcare Commission - Talking about medicines: The management of medicines in trusts providing mental health services (2007)

Hospital Pharmacist (2002) One-stop dispensing, use of patients' own drugs and self-administration scheme (article March 2002 Vol 9).

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Hospital Pharmacy Practice in the UK and the Responsible Pharmacist Requirements, Royal Pharmaceutical Society of Great Britain and the Pharmaceutical Society of Northern Ireland

Institute of Physics and Engineering in Medicine Medical and Dental Guidance Notes ISBN 1903613 09 4.

National Service Frameworks (NSF) as published by Department of Health

NHS Executive (1993) Reporting Adverse Incidents and Reactions, and Defective Products Relating to Medical and Non- Medical Equipment and Supplies, Food, Buildings and Plant and Medicinal Products HSG (93) 13 1993

NHS Executive (1999) Clinical Governance in the New NHS. HSC 1999/065. 1999

NHS Executive (2000) The Employment of Operating Department Practitioners (ODPs) in the NHS Letter dated 20 March 2000.

NHS Pharmaceutical Quality Control Committee (2004) Guidance for the Purchase and Supply of Unlicensed Medicinal Products – Notes for Prescribers and Pharmacists 3rd edition June 2004.

NICE guidance endorsed by DHSSPS for implementation in the HSC

NPSA alerts cascaded by DHSSPS

Pharmacy in the Future - Implementing the NHS Plan Department of Health (2000)

The Handling of Medicines in Social Care RPSGB (2007)

The International Committee on Harmonisation (ICH) Harmonised Tripartite Guideline for Good Clinical

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INDEX OF MEDICINES MANAGEMENT

Criterion 1 (*Accountability*)

1. Board level responsibility for the safe, secure and cost effective handling of medicines is clearly defined and there are clear lines of accountability throughout the organisation, leading to the board.

Criterion 2 - 12 (*Processes*)

2. Procurement of medicines is cost effective in compliance with current legislation, professional standards and best practice and having regard for patient safety.
- 3.
4. Storage, distribution and handling of medicines is safe and secure and conducted by appropriately qualified, trained and competent staff and in compliance with all legislative requirements, professional standards and good practice guidance.
5. Manufacturing / production of medicines (sterile and non sterile) is carried out under MHRA “Specials” Licence by appropriately qualified, trained and competent staff and in compliance with all legislative requirements, professional standards and good practice guidance.
6. Prescribing of medicines is carried out by appropriately qualified, trained and competent staff and in compliance with all legislative requirements, professional standards and good practice guidance, utilising resources cost effectively and in a manner which promotes patient safety.
7. Dispensing of medicines is carried out by appropriately qualified, trained and competent staff and in compliance with all legislative requirements, professional standards and good practice guidance.
8. Supply and administration of medicines is safely, securely and cost effectively carried out by appropriately qualified, trained and competent staff and in compliance with all legislative requirements, professional standards and good practice guidance and in a manner which safeguards patients and the public.
9. Destruction or otherwise disposal of medicines no longer required is carried out by appropriately authorised, qualified, trained and competent staff and in compliance with all legislative requirements, professional standards and good practice guidance.
10. Unlicensed aseptic dispensing in hospital pharmacies complies with Circular HSSE (OCE) 1/97
11. Supply of medicines for clinical trials is undertaken in accordance with relevant legislation and best practice guidelines.

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12. The organisation has an effective system for the management of defective medicinal products / devices and reports adverse incidents involving medicinal products and devices to the relevant agency and appropriately manages any subsequent required action.
13. The risk management process contained within the risk management standard is applied to the safe and secure handling of medicines.

Criterion 13-14 (*Capability*)

14. The organisation, through the Head of Pharmacy and Medicines Management, has access to up-to-date legislation and guidance relating to the safe and secure handling of medicines.
15. Adequate resources support the processes outlined in criterion 2 – 12 to ensure the safe, secure, cost effective and appropriate use of medicines.

Criterion 15 & 16 (*Monitor, review, learn, improve*)

16. Key indicators capable of showing improvements in the safe, secure, cost effective handling and procurement of medicines and the management of associated risk are used at all levels of the organisation, including the board, and the efficacy and usefulness of the indicators is reviewed regularly.
17. The system in place for the safe, secure cost effective handling of medicines, including risk management arrangements, is monitored and reviewed by management and the board in order to make improvements to the system.

Criterion 17 (*Independent assurance & Outcomes*)

18. The board seeks independent assurance that an appropriate and effective system for the safe, secure and cost effective handling of medicines is in place and that the necessary level of controls and monitoring is being implemented.

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CRITERION 1

Board level responsibility for the safe, secure and cost effective handling of medicines is clearly defined and there are clear lines of accountability throughout the organisation, leading to the board.

Source

- Standards Australia Risk Management AS/NZS 4360:2004
- Best Practice Best Care (2001) - A framework for setting standards, delivering services and improving monitoring and regulation in the HSC.
- Audit Commission (2001) A Spoonful of Sugar. Medicines management in NHS hospitals. Audit Commission, London.
- Audit Commission (2002) Procurement and Supply. Review of National Findings, Acute Hospital Portfolio, No.5, p.20.

Guidance

The Chief Executive of the organisation has the overall statutory responsibility for the safe, secure, cost effective handling of medicines. The Chief Executive must ensure that, where applicable, in relation to the management and use of controlled drugs, an Accountable Officer (AO) is appointed within the organisation. The Head of Pharmacy and Medicines Management has responsibility for ensuring that systems are in place to appropriately address all aspects of the safe, secure and cost effective handling of medicines, including, where relevant, their AO responsibilities, and reports directly to the Chief Executive for this purpose across the whole of the organisation. The organisation's commitment to the safe and secure handling of medicines should be clearly signalled.

Clear lines of accountability for the safe, secure and cost-effective handling of medicines throughout the organisation should be established; these should define the relationships between the board, board sub-committee(s) responsible for overseeing all aspects of risk management and governance, Pharmacy Services and other relevant groups. There must be a medicines management committee / Drug and Therapeutics Committee whose responsibility it is to review, analyse and monitor medicines management processes.

Examples of Verification

- Accountability arrangements chart
- Minutes of the board sub-committee(s) responsible for overseeing risk management
- Board minutes
- A strategy for medicines use, within the organisation, has been approved by the board, reviewed and reported annually
- Terms of reference for any medicines management committee required.
- Job description of Head of Pharmacy and Medicines Management.

Links with other Standards

All Standards

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CRITERION 2

Procurement of medicines is cost effective, in compliance with current legislation, professional standards and best practice and having regard for patient safety

Source

- Guidance for the Purchase and Supply of Unlicensed Medicinal Products – Notes for prescribers and pharmacists. NHS Pharmaceutical Quality Control Committee 3rd Edition, 2004
- Circular HSS (PPM) 8/2003. Revised Public Procurement Policy for the Public Sector. DHSSPS
- Circular HSS (PPM) 7/2004. Procurement strategy for Health, Social Services and Public Safety. DHSSPS.
- The Public Contracts Regulations 2006 SI 2006 No 5
- Public contracts (Amendment) Regulations 2009 No 2992
- DHSSPS Revision of Procurement Controls Limits – Procurement Guidance Note 01/04 issued 16/09/10 (ref DH1/10/149941)
- DHSSPS best practice guidance on joint working between the HSC and Pharmaceutical Industry and other relevant commercial organisations 2010
- Quality Assurance Policy for contact procurement of licensed pharmaceuticals. NHS Pharmaceutical Quality Assurance Committee 2nd Edition April 2011

Guidance

Under the management of Heads of Pharmacy and Medicines Management, wherever possible, corporate action should be taken to ensure the efficient and effective procurement of all medicines, particularly in the context of the Regional Pharmaceutical Contracting Executive Group, established by Trust Chief Executives and aligned to public procurement policy and strategy. Any deviation from this principle of regional action should be the exception rather than the rule.

Examples of Verification

- There is a local procurement of medicines policy in place, which complies with relevant aspects of legislation
- Relevant staff are aware of, and have access to the organisation's procurement policy including unlicensed medicines
- Implementation of a 'purchasing for safety' policy for procurement of pharmaceuticals
- Quantity and value of pharmaceuticals procured by quotation or tender according to the DHSSPS Procurement Controls Limits – Procurement Guidance medicines, as a percentage of the whole, subject to regional procurement
- Procedures for ordering and stock control of medical gases are in place
- Compliance with Good Procurement Practice as defined by Audit Commission (2002)
- Procedures in place to manage supply chain failures
- SLA with Regional Pharmacy Procurement and BSO PaLS

Links with other Standards

Health and Safety

Management of Purchasing and Supply

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CRITERION 3

Storage, distribution and handling of medicines is safe and secure and conducted by appropriately qualified, trained and competent staff and in compliance with all legislative requirements, professional standards and good practice guidance.

Source

- The Control of Substances Hazardous to Health Regulations (Northern Ireland) 2000. SR 2003 No 120 The Stationery Office, London
- The Radioactive Material (Road Transport) Regulations 2002 SI 2002 No. 1093 (as amended) The Stationery Office, London
- The Radioactive Material (Road Transport) (Northern Ireland) Order 1992 SI 1992 No 234(NI 2). The Stationery Office, London
- Pressure Systems Safety Regulations 2000 SI 2000 No 128 The Stationery Office, London
- NHS Estates (1994) HTM 02-01 Medical gas pipeline system. The Stationery Office, London
- HTM 22: Hospital Technical Memorandum 22 – ‘Piped medical gases, medical compressed air and medical vacuum installations’
- The Medicines (Administration of Radioactive Substances) Regulations 1978 SI 1978 No 1006 The Stationery Office, London
- The Ionising Radiation (Medical Exposure) Regulations 2000 SI 2000 No 1059. The Stationery Office, London

Other Reading

Guidance

The revised Duthie report sets out standards for the handling, administration, storage and custody of medicinal products, in Trusts (including Trust community facilities), community clinics, residential and nursing homes, domiciliary care, supported living, community nursing or midwife units and the ambulance service. At each step where a medicine changes hands there should be clear procedures which document:

- Where responsibility lies, whether it may be delegated and how far it extends
- What should be recorded where, by whom and how long records should be kept
- How often stock reconciliation should take place and who should undertake the task
- Appropriate procedures must be in place for the ordering, stock control, storage, movement and safe handling of all medicines having particular regard to those with specialised requirements such as medical gases, controlled drugs and those of a hazardous nature. A mechanism to alert in event of supply failure or discrepancy should be in place.

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Particular attention should be paid to all medicine security issues including:

- *Storage of medicines, whether in bulk in the pharmacy or in smaller quantities elsewhere*
- *Methods of ordering medicines (electronic and paper-based)*
- *Means of delivery*
- *Receipts procedures, including full records*
- *Adequate and robust audit trails*
- *Methods of distribution both within and between hospitals*
- *Dispensing of medicines including patients own medicines, dispensing for discharge and self administration*
- *Administration of medicines*
- *Disposal of medicines*
- *Where self-administration schemes are in operation*

Physical security measures include:

- *Lockable cabinets for securing controlled drugs which meet or exceed the Misuse of Drugs (Safe Custody)(Northern Ireland) Regulations 1973*
- *Control of access to cabinets and cupboards*
- *Lockable cupboards, freezers and fridges for the storage of medicines, with temperature monitoring as appropriate conforming to British Standards where applicable*
- *Cupboards which meet the requirements as set out in the revised Duthie report for all medicines*
- *Lockable medicine trolleys which are immobilised when not in use*
- *Lockable, bedside medicine storage cupboards, which are not easily portable (where appropriate)*
- *Lockable / tamper evident security sealed containers for transporting / moving medicines*
- *Entrances to pharmacies and other controlled areas should have solid doors, fitted with security locks and intruder alarms*
- *Stationery including requisition books, order books and blank prescription forms should be kept in a locked cupboard or access controlled secure area.*
- *Audit of adherence to local medicines policies*

COSHH regulations require organisations to ensure that precautions are taken by staff handling medicinal products, which are hazardous to health by any route (inhalation, ingestion, and absorption through the skin or contact with the skin). Contact should either be prevented or, where this is not reasonably practicable, adequately controlled.

There must be a clear audit trail i.e. a secure system for recording, monitoring and reconciling medicines whether electronic or paper based.

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Examples of Verification

- There is a local policy in place, which complies with relevant aspects of legislation
- Relevant staff are aware of, and have access to the organisation's procurement of medicines policy
- Local procedures comply with the organisations' security policy and the principles of the revised Duthie report and the Use and Control of Medicines
- There is a policy in place, of which staff are aware, which states the required action to be taken when there is a breach of security
- COSHH assessments
- Procedures for storage, movement and safe handling of medical gases are in place and approved by the Medical Gas Committee
- Systems are in place, which meet the principles of the 'Use and Control of Medicines' guidelines
- The organisation audits itself against these principles, and can demonstrate, if necessary, those mechanisms have been put in place to change practice.
- Training and development plans for all staff
- Documentation of training / CPD and competency checks
- Evidence of audit and monitoring to assess and assure compliance with organisational policies and procedures
- SOPs are present, suitable, comply with all relevant legislation and are reviewed at least 2 yearly (or earlier if triggered by a near miss, an adverse incident, new guidance or legislation)

Links with other Standards

Health and Safety
Management of Purchasing and Supply
Medical Devices
Records Management
Waste Management

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CRITERION 4

Manufacturing / production of medicines (sterile and non sterile) is carried out under MHRA “Specials” Licence by appropriately qualified, trained and competent staff and in compliance with all legislative requirements, professional standards and good practice guidance.

Source

- MHRA Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2007 – Pharmaceutical Press
- MHRA Guidance Note 14 (revised January 2008), “The supply of unlicensed relevant medicinal products for individual patients”.

Other Reading

- British Pharmacopoeia monograph for unlicensed medicines

Guidance

The manufacturing / production of medicines by an organisation should be restricted to situations where a licensed product is unavailable. All manufacturing / production must be carried out under the appropriate MHRA licence. The holder of a manufacturer ‘Specials’ licence (MS) will be authorised to perform a defined range of manufacturing, quality control and / or importation activities. Licensed activities are subject to regular inspection by the MHRA Inspectors.

The over-labeling or re-packing of medicinal products is an assembly activity and is therefore licensable

Wholesaling of medicines can only take place under a full wholesale dealer licence (WL) which allows the holder to wholesale deal pharmacy (P), prescription only (POM), traditional herbal medicinal products (THMP), General Sale List (GSL) and can include dealing in unlicensed medicines. This includes procurement, holding, or wholesale distribution of medicinal products for human use (including “specials”) sourced in the UK or another EEA Member State, unless exempt. Those holding a manufacturing licence may undertake wholesaling of the products manufactured under that licence.

There should be a programme of capacity planning for equipment and staff.

Examples of Verification

- Manufacturer's licence
- Wholesale Dealer licence
- Maintenance and retention of relevant manufacturing/wholesaling records
- Policy

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- Regular internal and external audit reports with a GMP focus and progress on follow-up
- Record of rejects and delays in service provision
- Staff skill mix and competence assessed
- Records of appropriate training
- SOPs are present, suitable, comply with all relevant legislation and are reviewed in accordance with GMP guidance (or earlier if triggered by a near miss, an adverse incident, new guidance or legislation)
- Capacity plan
- Error/near miss reporting in place

Links with other Standards

Human Resources
Health and Safety
Medical Devices and Equipment

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CRITERION 5

Prescribing of medicines is carried out by appropriately qualified, trained and competent staff and in compliance with all legislative requirements, professional standards and good practice guidance. utilising resources cost effectively and in a manner which promotes patient safety.

Source

- Crest Guidance 2006: Protocol for the Inter Hospital Transfer of Patients and their Records
- GAIN Guidance June 2011 – Guidelines on Regional Immediate Discharge Documentation for Patients being Discharged from Secondary into Primary Care
- Medicines and Healthcare Products Regulatory Agency. MHRA guidelines on the Yellow Card Scheme. (www.mhra.gov.uk)
- NI Clinical Pharmacy Standard
- Priorities for Action, DHSSPS

Other Reading

- NHS Executive (2000) Patient group directions HSC 2000/026
- Medicines legislation – what it means for midwives. NMC Circular 1/2005 SAT/rc 6 January 2005
- National Confidential Enquiry into Patient Outcome and Death report 2008, ‘Systemic Anti-Cancer Therapy: for better, for worse?’

Guidance

Medical and non-medical prescribers may prescribe, administer or supply Prescription Only Medicines directly to a patient in areas where they are competent and should ensure separation of prescribing and administering or supply activities whenever possible. Supplementary prescribers may only prescribe under and in accordance with the terms of an agreed patient specific clinical management plan and the patient’s agreement.

Legislation is framed to ensure that the majority of clinical care should be provided on an individual, patient-specific basis. Where the direction of a doctor is not patient specific, the responsible organisation would need to ensure that the appropriate patient group direction meets the criteria (some of which are statutory) set out in Circular HSS Issued 7 September 2000.

There must be a clear audit trail i.e. a secure system for recording, monitoring and reconciling medicines whether electronic or paper based.

Patients should be appropriately monitored and prescribing decisions adjusted in response to the outcomes of such monitoring.

Appropriate protocols should be in place to ensure that arrangements for communication and transfer of patient information relating to medicines, prescribing and medication history support safe practice and confidentiality.

Unlicensed medicines should only be used where a licensed alternative is not available and pharmaceutical quality assurance has been demonstrated for both the

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procurement and use of such products and all such decisions are supported by a robust risk assessment.

Chemotherapy prescribing, supply, and administration should be in accordance with the policy of the local cancer network. In addition, prescribing, supply and administration of intrathecal chemotherapy must comply with HSC(SQSD)61/2008

The BNF contains guidance on how to write prescriptions to ensure clarity and safety. These principles should be adopted, and adapted for local use as appropriate. Ward/Clinical pharmacy services should be in place to ensure that prescriptions are safe, clear, legible etc, and comply with local and national guidance.

Prescribing choices should take into account the regional prescribing policies and NICE guidance and the organisation should ensure that these are observed within in-patient, out-patient and other settings.

Examples of Verification

- Staff groups are subject to regular qualification and registration checks:
- All patient group directions have been identified, located, reviewed and are in date Compliance with Manual of Cancer Services Department of Health, London
- Register of staff authorised to prescribe, administer and supply intrathecal chemotherapy
- A register maintained of all non-medical prescribers recording the scope of their prescribing authority
- Robust procedures in place for the procurement and use of unlicensed medicines
- Audit of prescriptions and treatment cards (e.g. using ward / clinical pharmacist intervention records).
- There is an internal audit process in place, including regular and periodic checks by pharmacy and nursing staff, which evaluates and documents compliance to controlled drug prescription writing
- Training and development plans for all staff and training records
- SOPs are present, suitable, comply with all relevant legislation and are reviewed at least 2 yearly (or earlier if triggered by a near miss, an adverse incident, new guidance or legislation)
- Protocol(s) for communication and transfer of patient information relating to medicines, prescribing and medication history
- Audit of adherence to the NI Formulary in addition to relevant National, and Regional prescribing policies across wards departments, outpatient settings and other sectors
- HSCB performance management and service improvement directorate (PMSID) data on clinical pharmacy services
- NI Safety Forum Medicines Collaborative data and action plans
- Policy for use of unlicensed medicines

Links with other Standards

Human Resources

Records Management

Risk Management

HSC	Controls Assurance Standard	Medicines Management
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CRITERION 6

Dispensing of medicines is carried out by appropriately qualified, trained and competent staff and in compliance with all legislative requirements, professional standards and good practice guidance.

Source

- European Commission Council Directive Title V of 2001/83/EC Labelling and Leaflet Directive
- 28 Day Dispensing on Discharge from Hospital. Letter Circular HSS SC (804) BP411/01
- MHRA Guidance Note 14 – The supply of Unlicensed Relevant Medicinal Products for Individual Patients (Revised January 2008)

Other Reading

Guidance

There must be a clear audit trail i.e. a secure system for recording, monitoring and reconciling medicines whether electronic or paper based.

Appropriate protocols should be in place to ensure that arrangements for communication and transfer of patient information relating to medicines, prescribing and medication history support safe practice and confidentiality.

Unlicensed medicines should only be used where a licensed alternative is not available and pharmaceutical quality assurance has been demonstrated for both the procurement and use of such products.

In accordance with the EU directive, patient information leaflets should be supplied each time a medicine is dispensed to a patient.

Pharmacists have a legal and professional duty to ensure the safe, accurate and clinically appropriate dispensing of medicines, including those that are extemporaneously prepared.

For inpatient medication, where pharmaceutical oversight may commence with the clinical check at ward level with subsequent delegation of dispensing tasks, the pharmacist who has responsibility for the dispensing activities must ensure that the staff involved in carrying out the delegated tasks is suitably trained and competent to undertake the tasks required

Similarly, good practice dictates that such controls should be in place for the dispensing of medicines for patients to take home, for one stop dispensing for discharge and for inpatient use. Appropriate clinical pharmacy input should also be provided.

The pharmacist who has responsibility for the dispensing activities must at all times be satisfied that suitable systems are in place to discharge their legal and professional duties of supervision. These systems must be fully documented in suitable standard operating procedures (SOPs), which adequately cover all the processes by which

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dispensing, and its associated activities are undertaken. The SOPs should be reviewed at least every 2 years or earlier if triggered by a near miss, an adverse incident, new guidance or legislation.

The SOPs should include a suitable system for reporting, recording and prompt review of known dispensing errors.

Extemporaneous preparation should be carried out in accordance with good practice and the professional guidance issued by the PSNI within the Code of Ethics & Professional Standards.

Examples of Verification

- Staffing schedules are in place to ensure adequate cover
- SOPs are present, suitable, comply with all relevant legislation and are reviewed at least 2 yearly (or earlier if triggered by a near miss, an adverse incident, new guidance or legislation)
- Maintenance records
- COSHH records
- Relevant post-basic training schemes (e.g. accredited technician checking) are suitable and are appropriately accredited
- CPD policy
- Training and development plans for all staff
- Documentation of training / CPD and competency checks
- Log of errors / near misses and procedures for dealing with errors present
- Dispensing complete with patient information leaflet
- Audit of adherence to local medicines policies and can demonstrate, if necessary, that mechanisms have been put in place to change practice.

Links with other Standards

Health and Safety
Human Resources
Medical Devices and Equipment
Records Management
Risk Management

HSC	Controls Assurance Standard	Medicines Management
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CRITERION 7

Supply and administration of medicines is safely, securely and cost effectively carried out by appropriately qualified, trained and competent staff and in compliance with all legislative requirements, professional standards and good practice guidance and in a manner which safeguards patients and the public.

Source

- Crest Guidance 2006: Protocol for the Inter Hospital Transfer of Patients and their Records
- GAIN Guidance June 2011 – Guidelines on Regional Immediate Discharge Documentation for Patients being Discharged from Secondary into Primary Care

Other Reading

- RQIA Nursing Home Minimum Standards
- RQIA Residential Care Home Minimum Standards
- RQIA Guidelines for the Control and Administration of medicines by Domiciliary Care Agencies

Guidance

Prescription Only Medicines (POM) may only be supplied to a patient against the prescription or written direction of an ‘appropriate practitioner’, as stated in section 58 of the Medicines Act and the POM Order 1997 SI 1997/1830 as amended. The sale, supply and administration of GSL, P and POM medicines are governed by legislation and best practice requirements. Practitioners must operate strictly within the legislative boundaries.

The principle supply route is through the pharmacist and pharmacy staff should be involved in replenishing, monitoring, and adjusting medicines stock control.

Medical and non-medical prescribers may prescribe, administer or supply Prescription Only Medicines directly to a patient in areas where they are competent and should ensure separation of prescribing and administering or supply activities whenever possible. Midwives may acquire and possess specified controlled drugs, under a supply order, which is signed by a Doctor or Supervisor of Midwives and any of the substances that are specified in medicines legislation under midwives’ exemption, provided it is in the course of their professional midwifery practice.

Legislation is framed to ensure that the majority of clinical care should be provided on an individual, patient-specific basis.

As with other circumstances when medicines are prescribed, supplied and administered, there must be a clear audit trail i.e. a secure system for recording, monitoring and reconciling medicines whether electronic or paper based.

HSC	Controls Assurance Standard	Medicines Management
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Appropriate protocols should be in place to ensure that arrangements for communication and transfer of patient information relating to medicines, prescribing and medication history support safe practice and confidentiality.

Unlicensed medicines should only be used where a licensed alternative is not available and pharmaceutical quality assurance has been demonstrated for both the procurement and use of such products. Evidence of consent should be obtained, where appropriate.

Chemotherapy prescribing, supply, and administration should be in accordance with the policy of the local cancer network. In addition, prescribing, supply and administration of intrathecal chemotherapy must comply with HSC(SQSD)61/2008

In accordance with the EU directive, patient information leaflets should be supplied each time a medicine is dispensed to a patient.

Controlled Drugs

Possession, supply, storage and record keeping of controlled drugs must meet the requirements of both the Medicines Act and the Misuse of Drugs Act and regulations made under the Acts. Comprehensive guidance is available in the BNF, Pharmaceutical Society of Northern Ireland's Code of Ethics, Safer Management of Controlled Drugs A guide to good practice in primary care (Northern Ireland) and Safer Management of Controlled Drugs A guide to good practice in secondary care (Northern Ireland).

Examples of Verification

- Staff groups are subject to regular qualification and registration checks.
- Training and development plans for all staff and training records
- Pharmacy technician/assistant “top-up” service
- There is a policy in place that includes an assessment checklist to support the use of patient’s own drugs (POD) if applicable
- Protocol(s) for communication and transfer of patient information relating to medicines, prescribing and medication history
- There is an agreed protocol to assess patients’ suitability for self-administration of medicines, which documents informed consent to participate if applicable.
- Robust procedures in place for the procurement and use of unlicensed medicines
- Compliance with Manual of Cancer Services Department of Health, London
- Register of staff authorised to prescribe, administer and supply intrathecal chemotherapy
- Record of verification of nurse training for drug administration
- Audit of prescriptions and treatment cards (e.g. using ward / clinical pharmacist intervention records).
- There is an internal audit process in place, including regular and periodic checks by pharmacy and nursing staff, which evaluates and documents compliance to controlled drug record keeping legislation where appropriate
- Evidence of monitoring and auditing of controlled drugs

HSC	Controls Assurance Standard	Medicines Management
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- Responsible pharmacist records for registered pharmacies
- Declaration and Self–assessment form as requested
- SOPs are present, suitable, comply with all relevant legislation and are reviewed at least 2 yearly (or earlier if triggered by a near miss, an adverse incident, new guidance or legislation)
- There is a suitable policy / procedure in place for dealing with discrepancies in reconciliation of stock:

The policy should include when to involve

- external organisations
- pharmacy destruction records where appropriate

Links with other Standards

Health and Safety

Human Resources

Medical Devices and Equipment

Records Management

Risk Management

HSC	Controls Assurance Standard	Medicines Management
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CRITERION 8

Destruction or otherwise disposal of medicines no longer required is carried out by appropriately authorised, qualified, trained and competent staff and in compliance with all legislative requirements, professional standards and good practice guidance.

Source

- Environmental Protection Act 1990 (c. 43) The Stationery Office, London
- Environmental Protection (Prescribed Processes and Substances) Regulations 1991 SI No 472 The Stationery Office, London
- The Special Waste Regulations (Northern Ireland) 1998 SR 1998 No 289
- A guide to pharmaceutical clinical waste (2002), DHSSPS

Other Reading

- The Hazardous Waste (England and Wales) Regulations 2005
- Guidelines for Drug Donations (WHO)
- Guidelines on the Handling and Disposal of Pharmacy Wastes NHS Pharmaceutical Quality Assurance Committee (September 2002, under review)

Guidance

A number of principles should be adopted when disposing of medicines:

- Witnessed accountability
- Secure transit
- Protection of personnel
- Protection of the environment
- Adequate documentation
- Legally authorised persons to carry out and, where necessary, witness the destruction
- Adherence to legislation
- Denaturing methods which adhere to professional guidance

Some clinical waste is also classified as ‘special waste’ and is subject to controls under the Special Waste Regulations 1998 Prescription-only medicines (‘Medicinal Product’ is the term used in the SR) are classed as special waste. The regulations require all movements to be tracked using consignment notes, with adequate records being kept for three years.

There must be documented systems and procedures in place for the destruction of all Controlled Drugs, including patients’ own drugs, which comply with regulations where these apply.

There must be a clear audit trail i.e. a secure system for recording, monitoring and reconciling medicines whether electronic or paper based.

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Any person required by the Misuse of Drugs Regulations (Northern Ireland) 2002 to keep records of Controlled Drugs in Schedule 1, 2 may only destroy controlled drugs within these schedules in the presence of an authorised person.

In addition, any person who is required to keep records for controlled drugs in Schedules 3 and 4 may only destroy these controlled drugs in the presence of an authorised witness. This would include any person manufacturing products containing Schedule 3 or 4 controlled drugs.

Examples of Verification

- There is a written policy relating to the safe disposal of medicines
- Staff are aware of, and have access to the organisation's policy
- Methods of destruction follow locally agreed procedures but they must take into account national guidance when appropriate
- SOPs are present, suitable, comply with all relevant legislation and are reviewed at least 2 yearly (or earlier if triggered by a near miss, an adverse incident, new guidance or legislation)

Links with other Standards

Environment Management
 Health and Safety
 Records Management
 Waste Management

HSC	Controls Assurance Standard	Medicines Management
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CRITERION 9

Unlicensed aseptic dispensing in hospital pharmacies complies with Circular HSSE(OCE)1/97,.

Source

- Ionising Radiations Regulations 1999. Approved Code of Practice and Guidance. The Stationery Office, London. ISBN 071761-7467 HSE Books
- The Medicines (Administration of Radioactive Substances) Regulations 1978 SI 1978 No 1006 The Stationery Office, London, and relevant amendments
- The Ionising Radiation (Medical Exposure) Regulations 2000 SI 2000 No 1059. The Stationery Office, London and relevant amendments
- The Radioactive Substances Act 1993 (c. 12) The Stationery Office, London
- MHRA Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2007 – Pharmaceutical Press
- Circular HSSE (OCE) 1/97 Aseptic Dispensing in HPSS Hospitals
- Pharmaceutical Isolators: A guide to their application, design and control. Pharmaceutical Press, 2004 ISBN 0 85369 5733
- Quality Assurance of Aseptic Preparation Services A.M. Beaney (4th Edition) Pharmaceutical Press, October 2005 ISBN 0 85369 6152
- HC (76) 9 Report of the working party on the additions of drugs to intravenous fluids.
- Chief Pharmaceutical Officer Letter (CPh3/03) Aseptic dispensing in HPSS hospitals. DHSSPS.
- Chief Pharmaceutical Officer Letter (CPh (1/95) Aseptic Dispensing for NHS Patients Farwell J. Aseptic dispensing for NHS patients [Farwell report]. London: Department of Health; 1995.

Other Reading

- Notes for Guidance on the Clinical Administration of Radiopharmaceuticals and Use of Sealed Radioactive Sources (March 2006). Administration of Radioactive Substances Advisory Committee (ARSAC)
- Medical and Dental Guidance Notes prepared by the Institute of Physics and Engineering in Medicine. ISBN 1903613 09 4
- Quality Assurance of Radio Pharmaceuticals: The radiopharmacy group and the NHS Quality Control Committee Nuclear Medicine Communications 2000
- Manual of Cancer Services Department of Health, London
- Pharmaceutical Resource for Oncology in Northern Ireland, Report of the RMSC working group (2003) National Occupation Standards – Chemotherapy 2011
- NCEPOD report. Systemic Anti-Cancer Therapy: For better, For worse (2008).
- NCEPOD report: Parenteral Nutrition: A Mixed Bag (2010).
- NCAG report: Chemotherapy Services in England. Ensuring quality and safety. Aug 2009.
- Guidelines for the safe prescribing, handling and administration of hazardous drugs. NICaN. February 2010.

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Guidance

The Medicines Act 1968 allows HSC hospital pharmacies to carry out aseptic preparation without a manufacturer's licence, if the activity is under the supervision of a pharmacist. HSC organisations are liable to prosecution, under the Medicines Act 1968, if medicinal products supplied are not of the nature or quality required.

Unlicensed aseptic dispensing facilities in hospital pharmacies should undergo regular inspections every 12-18 months in accordance with National Guidelines. The inspections are carried out by the Regional Pharmaceutical Service. The results of the inspections should be made known to the trust Chief Executive and those commissioning health services so that standards are maintained. There should also be a programme of regular internal audit.

There should be a programme of capacity planning for equipment and staff.

Aseptic dispensing is an increasing and demanding activity. Extant guidance indicates that it should be carried out under the control of a pharmacist in suitable facilities to avoid the additional risk of microbiological contamination and medication errors sometimes associated with the preparation of parenteral medication at ward level.

Radiopharmaceutical dispensing activities, in addition, must take into account the registration of open sources by the Environment Agency, additional training requirements for staff, the radiological implications for staff and a prospective programme for quality assurance of products.

Verification that users of radiopharmaceuticals are authorised to do so must be sought prior to use. Where products are transported to other sites, proper packaging and the services of a safety adviser must be employed. Radiopharmacies should be licensed unless operated under the direct supervision of a pharmacist.

Examples of Verification

- Policy
- Regular internal and external audit reports to Professional leads and Organisations together with progress on follow-up
- Staff skill mix and competence assessed
- Capacity plan
- Error/near miss reporting in place
- Robust systems in place for high risk procedures e.g. vinca alkaloids and intrathecal injections
- Range of products prepared linked to risk assessment of hospital usage of intravenous products
- Records of appropriate training
- SOPs are present, suitable, comply with all relevant legislation and are reviewed in accordance with GMP guidance (or earlier if triggered by a near miss, an adverse incident, new guidance or legislation)
- Copies of the Radioactive Substances Act regulations authorisation from the Environment Agency for storage and disposal of radioactive materials

HSC	Controls Assurance Standard	Medicines Management
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- COSHH assessments
- Radiation exposure monitoring of staff
- Certification of clinicians under the Medicines (Administration of Radioactive Substances) Regulations 1978 (Commonly referred to as “ARSAC” certificates)

Links with other Standards

Infection Control

Human Resources

Health and Safety

Medical Devices and Equipment

HSC	Controls Assurance Standard	Medicines Management
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CRITERION 10

The supply of medicines for clinical trials is undertaken in accordance with relevant legislation and best practice guidelines

Source

- Statutory Instrument 2004/1031 The Medicines for Human Use (Clinical Trials) Regulations 2004
- Statutory Instrument 2006/1928 The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006
- Statutory Instrument 2008/2984 The Medicines for Human Use (Clinical Trials) Amendment (No. 2) Regulations 2006
- Statutory Instrument 2008/941 The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality Amendment Regulations 2008
- EU Directive 2001/20/EC. Good Clinical Practice in Clinical Trials
- EU Directive 2005/28/EC. Good Clinical Practice
- Clinical Trials Research Governance Framework for Health and Social Care R&D Office DHSSPS Dec 2006
- Eudralex - The Rules Governing Medicinal Products in the European Union, Vol 4, EU Guidelines to Good Manufacturing Practice - Medicinal Products for Human and Veterinary Use, Annex 13 Investigational Medicinal Products
- Guidance on Good Clinical Practice and Clinical Trials (2006), Department of Health, London

Other Reading

- The International Committee on Harmonisation (ICH) Harmonised Tripartite Guideline for Good Clinical Practice 2006. www.emea.europa.eu
- Clinical Trials Toolkit - a comprehensive resource for practical help in meeting requirements of the UK Medicines for Human Use (Clinical Trials) Regulations 2004 and the EU Clinical Trial Directive. www.ct-toolkit.ac.uk
- Good Clinical Practice for Trials on Medical Products in the European Community, 111/3976/88-EN Final, Office for Official Publications of the European Community.

Guidance

All clinical trials involving medicines must comply with the Medicines for Human Use (Clinical Trials) Regulations 2004 SI 2004/1031. The regulations can be found at <http://www.mhra.gov.uk>. The key points relating to medicines are included in Parts 5, 6, and 7 of these regulations.

Pharmaceutical Society of Northern Ireland provide guidance on clinical trials which is published in General Legal Requirements – A Guide for Pharmacists in Northern Ireland and Medicines for Human Use (pt 1)

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Key points include:

- A suitably trained and competent pharmacist designated as responsible for clinical trials supplies
- Responsibility of the pharmacist to ensure that the authorisation certificate is in place before the trial starts
- Active participation in the Trust research governance processes
- Pharmaceutical input to the trial protocol
- Pharmaceutical input to the local research ethics committee
- Ordering, storage and dispensing in accordance with the requirements of 'Good Clinical Practice for Trials on Medical Products in the European Community' and the guidelines provided in the revised Duthie Report.
- The manufacture, assembly or importation of Investigational Medicinal Products (IMPs) is carried out in accordance with a manufacturing authorisation (MIA (IMP)), granted by the licensing authority.
- Each production batch of IMP is checked and certified by a Qualified Person (QP) prior to release for use in a clinical trial.
- Stock accountability
- Access to trial protocols
- Reimbursement of pharmacy costs

Examples of Verification

- Training records for designated, competent staff trained in GCP
- Drug trial policy
- Approvals obtained from Ethics Committee, MHRA and Trust R&D committee including relevant approvals for any subsequent amendments..
- Records of receipt, dispensing and study administration and waste disposal to GCP standard
- Job description for the designated pharmacist
- Appropriate records of receipt, dispensing and stock reconciliation
- Evidence of Pharmacist involvement in:
 - Protocol development
 - Documentation and designing of Standard operating procedures
 - Patient information
 - Secure Database of all the studies managed by the pharmacy department.

Links with other Standards

Health and Safety
Human Resources
Records Management
Risk Management
Waste Management

HSC	Controls Assurance Standard	Medicines Management
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CRITERION 11

The organisation has an effective system for the management of defective medicinal products / devices and reports adverse incidents involving medicinal products and devices to the relevant agency and appropriately manages any subsequent required action.

Source

- NIAIC Medical Device Alert MDA/2011/001(NI) Reporting Adverse Incidents and Disseminating Medical Device / Equipment Alerts. Health Estates, Northern Ireland Adverse Incident Centre (NIAIC).
- DB 2010(01) 9 Feb 2010 Reporting adverse incidents and disseminating alerts Health Estates, Northern Ireland Adverse Incident Centre (NIAIC).
- Updated Guidance on Reporting Defective Medicines - Letter from CPO 18 Feb 2011

Other Reading

- Department of Health 2000, An Organisation With A Memory. Report of An Expert Group on Learning From Adverse Events in the NHS. The Stationery Office, London.
- Department of Health 2001, Building a Safer NHS for Patients. Implementing An Organisation With A Memory, Department of Health, London
- A Guide to Defective Medicinal Products – Reporting, Investigating and Recalling Suspected Defective Medicinal Products. MHRA
- Learning from Adverse Incidents and Near Misses reported by HSC organisations and Family Practitioner Services HSC (SQSD) 08/2010
- Early Alert system HSC (SQSD) 10/2010
- National framework for reporting and learning from serious incidents requiring investigation. Ref: 0974. March 2010

Guidance

Organisations must identify and learn from all patient safety incidents and demonstrate improvements in practice, based on local and national experience and from the information derived from analysis of incidents.

1 Adverse Drug Reactions

HSC organisations should encourage the prompt reporting to the Medicines and Healthcare products Regulatory Agency (MHRA) of *any* suspected adverse reactions due to “black triangle” drugs and any serious or unusual suspected reactions to established products. Staff should be aware of the process for reporting an adverse drug reaction and report suspected adverse reactions via the yellow card system

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2 Defective Products

a) Defective Medicinal Products

Adverse incidents arising from any medicinal product, thought to be defective, as opposed to incidents due to error, should be reported to the MHRA and Pharmacy Advice and Services Branch, DHSSPS in accordance with Updated Guidance on Reporting Defective Medicines - letter from the Chief Pharmaceutical Officer, 18 Feb 2011 DHSSPS.

b) Defective medical devices

Procedures should be established and maintained to ensure the prompt reporting of adverse incidents relating to medical devices to the Northern Ireland Adverse Incident Centre (NIAIC) to conform with the NIAIC Medical Device Alert "Reporting Adverse Incidents and Disseminating Medical Device / Equipment Alerts" MDA/2011/001(NI).

Organisations should ensure that:

Defective medicinal products and devices

- Products are kept and, if necessary quarantined, until the option of investigating the incident has been dismissed.
- An auditable procedure is in place in primary and secondary care relating to the management of drug recalls.

3 Medication Incidents

The organisation should have a local, multidisciplinary, medication incident (prescribing, dispensing, and administration) reporting and monitoring system as part of the risk management system. Trusts should consider facilitating online reporting of medication incidents. Staff should ensure that both actual incidents and near misses are considered and that all serious incidents are subject of a root cause analysis. These incidents should be analysed and recommendations considered for regional application where appropriate. The analyses should be used to inform the priorities of the Medicines Governance Team.

The best practice policies, safety memos and learning bulletins issued by the Northern Ireland Medicines Governance Team should be evaluated and implemented.

Duty of Collaboration (controlled drugs)

Under The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 there is a legal duty placed on Responsible Bodies to share information and intelligence (within certain constraints), about controlled drugs in the healthcare sector.

HSC	Controls Assurance Standard	Medicines Management
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Examples of Verification

There are policies that outline:

- required and timely action taken in the event of a suspected defect with a medicinal product or device and staff are aware of the policies;
- response to drug alerts, including out of hours, with a named lead professional and annual audit of results from the system;
- prompt reporting and analysis of adverse medication incidents.
- A pharmacist is nominated to co-ordinate the reporting of adverse incidents arising from any medicinal product / any action(s) resulting from a 'drug alert' letter
- A Liaison Officer is nominated to co-ordinate the reporting of incidents / local dissemination of NIAIC safety warnings.
- Regular reviews are undertaken to ensure the procedures are effective and are being followed.
- Medication incidents should be promptly reported on the organisational incident reporting system and investigated appropriately
- The organisation contributes to the regional analysis of medication incidents undertaken by the Northern Ireland Medicines Governance Team
- Learning from incidents is utilised to develop and revise SOPs
- The organisation implements best practice policies/safety memos/learning bulletins/guidance from the Medicines Governance Team and DHSSPS e.g. Circular HSS(SQSD)07/08.
- Record of those incidents investigated in more detail, including resulting action plans.
- Incidents relating to controlled drugs which raise concerns about a relevant person are reported to the Chair of the LIN quarterly through Occurrence Reports.
- Participation at Local Intelligence Network meetings
- Minutes from the organisation's multi-professional management committees for medication incidents.
- Induction/training schedule and content
- Record of actions taken in response to a drug recall or alert

Links with other Standards

Health and Safety
Human Resources
Medical Devices and Equipment
Risk Management

HSC	Controls Assurance Standard	Medicines Management
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CRITERION 12

The risk management process contained within the risk management standard is applied to the safe and secure handling of medicines.

Source

- Standards Australia Risk Management AS/NZS 4360:2004

Guidance

Risks should be systematically identified and recorded on a continuous basis. Risks associated with the safe and secure handling of medicines can be systematically identified using a number of approaches including:

- Control self assessment workshops
- Use of checklists
- Judgements based on experience and records
- Flow charts
- Systems analysis
- Scenario analysis
- And systems engineering techniques

Historic data, including adverse event data, medication incident reports, complaint and claim information, staff sickness/absence details can also be a valuable source of information to identify risk.

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.
- Senior management and the board should be informed of any significant risks and associated risk treatment plans.
- Upon induction all medical, nursing and pharmacy staff including those on fixed term contracts, and other relevant stakeholders should receive information and training on systems in place to minimise risks associated with the safe and secure handling of medicines.
- Ongoing staff training in the safe and secure handling of medicines should be undertaken and records of that provided in relation to the management and use of controlled drugs
- Ongoing monitoring to ensure that safe and effective systems relating to the management and use of controlled drugs are in place which comply with legislative requirements

HSC	Controls Assurance Standard	Medicines Management
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Examples of Verification

- Risk Register
- Risk treatment plans
- Staff training/information log
- Induction schedule and content
- Correspondence with stakeholders
- Reporting mechanisms that inform risk management process
- Evidence of audit and monitoring of the management and use of controlled drugs
- Relationship with Risk Management Standard

Links with other Standards

Human Resources
Records Management
Risk management

HSC	Controls Assurance Standard	Medicines Management
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CRITERION 13

The organisation, through the Head of Pharmacy and Medicines Management, has access to up-to-date legislation and guidance relating to the safe and secure handling of medicines.

Guidance

Access to legislation and guidance is essential for the organisation to carry out the statutory duties imposed upon it by law and mandatory duties imposed by the DHSSPS.

As a minimum, the organisation should have access to the key references listed on the front page of this standard.

There should be appropriate mechanisms in place for the dissemination of information.

There are many sources of information on legislation and guidance on the safe and secure handling of medicines, including books and, through subscriptions to specialist information providers, CD-ROMs containing the full text. Up-to-date DHSSPS guidance can be accessed on the Internet on the DHSSPS website (<http://www.dhsspsni.gov.uk>). Equivalent NHS documents can be accessed via the Department of Health COIN database (<http://www.doh.gov.uk>). The Medicines and Healthcare products Regulatory Agency (<http://www.mhra.gov.uk>) contains some information. Full text copies of all legislation issued from 1 January 1997 can be downloaded from <http://www.official-documents.co.uk>, which contains information on UK official documents.

Wherever possible, the DHSSPS Governance website www.dhsspsni.gov.uk/hss/governance/index.asp contains the relevant information pertaining to the development of controls assurance standards for Northern Ireland. Further useful guidance can be obtained from the Health Care Standards (formerly CASU) website (<http://www.hcsu.org.uk>).

Examples of Verification

- Library
- CD-ROMs
- Internet access
- Cascade process chart

Links with other Standards

All standards

HSC	Controls Assurance Standard	Medicines Management
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CRITERION 14

Adequate resources support the processes outlined in criteria 2 – 12 to ensure the safe, secure, cost effective and appropriate, use of medicines.

Source

- Circular HSS (PPM) 3/2002 – Corporate Governance: Statement of Internal Control
- Circular HSS (PPM) 8/2002 - Risk Management in the Health and Personal Social Services
- Circular HSS (PPM) 10/2002 – Governance in the HPSS: Clinical and Social Care Governance - Guidance on Implementation.
- Circular HSS(PPM) 5/2003 – Governance in the HPSS – Risk Management and Controls Assurance
- NICE Technology Assessments and Clinical Guidelines endorsed by DHSSPS

Guidance

A fundamental element of the safe and secure handling of medicines is the need for all parts of the system to be adequately resourced with competent personnel and suitable facilities and equipment. In addition it is vitally important that there is strong collaboration across Primary and Secondary Care relative to the use of medicines. A range of NICE guidelines are endorsed by DHSSPS and communicated to HSC for implementation. The Pharmaceutical Clinical Effectiveness (PCE) Programme aims to achieve improvement in the quality and safety in the use of medicines and related pharmaceutical technology while delivering significant patient benefits and savings for the health service in Northern Ireland through influencing prescribing practices by both primary and secondary care medical staff. The programme has produced regional guidelines on procurement, prescribing, dispensing and monitoring, activities across HSC. Both NICE and PCE guidance have informed the contents of the NI Regional Formulary for primary and secondary care.

Examples of Verification

- Baseline data for services against standards
- Benchmarking
- CPD – Training budgets/staffing budget
- Audit – Critical incidents, facilities
- Capacity Planning
- Business Plan
- Review monitoring process to ensure that pharmacy remains adequately resourced
- Minutes of meetings of Drug and Therapeutics Committee
- Document joint initiatives, policies etc.
- Audit of adherence to the NI Formulary in addition to relevant National, and Regional prescribing policies across wards departments, outpatient settings and other sectors

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Links with other Standards

Financial management

Medical Devices and Equipment

Risk Management

HSC	Controls Assurance Standard	Medicines Management
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CRITERION 15

Key indicators capable of showing improvements in the safe, secure and cost effective handling and procurement of medicines and the management of associated risk are used at all levels of the organisation, including the board, and the efficacy and usefulness of the indicators is reviewed regularly.

Source

- Standards Australia Risk Management AS/NZS 4360:2004.
- Quality Standards for Health and Social Care – Criterion 5.3.1 (f) and Criterion 5.3.3 (f)

Guidance

The organisation should develop indicators, which demonstrate that medicines are being safely and securely handled and risks are minimised. One indicator is degree of compliance with this standard. Ideally the indicators should be designed to demonstrate improvement in the performance of pharmacy services and staff prescribing and handling medicines over time. The number of indicators devised should be sufficient to monitor all aspects of the process, including risk management. It is not necessarily the case that the organisation will use all the indicators. The organisation should select those, which are useful for ensuring that the internal controls are working satisfactorily and medicines are being safely and securely handled.

Examples of Verification

- Indicators
- Evidence of usage at all levels
- Audit of adherence to the Northern Ireland Medicines Management Formulary in addition to relevant National, and Regional prescribing policies across wards departments, outpatient settings and other sectors

Links with other Standards

All standards

HSC	Controls Assurance Standard	Medicines Management
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CRITERION 16

The system in place for the safe, secure and cost effective handling of medicines, including risk management arrangements, is monitored and reviewed by management and the board in order to make improvements to the system.

Source

- Standards Australia Risk Management AS/NZS 4360:2004.
- Quality Standards for Health and Social Care 2006 – Criterion 5.3.1 (f) and Criterion 5.3.3 (f)

Guidance

It is the responsibility of management and the board to monitor and review all aspects of the system for the safe and secure handling of medicines, including:

- Accountability arrangements
- Processes, including risk management arrangements
- Capability
- Outcomes
- Internal audit findings

The review should be carried out by individuals with the relevant knowledge and expertise of the safe and secure handling of medicines and should include review of any adverse incidents.

The committee with responsibility for risk management 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. The Audit Committee should review internal audit findings.

Controlled drugs

Under The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009, the Accountable Officer must ensure that appropriate systems are in place to ensure the safe and effective management and use of controlled drugs subject to their oversight.

Examples of Verification

- Internal audit report(s)
- Audit Committee minutes
- Minutes of the board sub-committee(s) responsible for overseeing risk management and governance
- Declarations and self assessments

Links with other Standards

All standards

HSC	Controls Assurance Standard	Medicines Management
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CRITERION 17

The board seeks independent assurance that an appropriate and effective system for the safe, secure and cost effective handling of medicines is in place and that the necessary level of controls and monitoring are being implemented.

Source

- Circular HSS (PPM) 10/2002 – Governance in the HPSS: Clinical and Social Care Governance - Guidance on Implementation.
- Circular HSS (PPM) 3/2002 - Corporate Governance: Statement on Internal Control
- Circular HSS (PPM) 8/2002 – Risk Management in the Health and Personal Social Services
- Circular HSS(PPM) 5/2003 – Governance in the HPSS – Risk Management and Controls Assurance
- Quality Standards for Health and Social Care 2006 – Criterion 5.3.1 (f) and Criterion 5.3.3 (f)

Guidance

Management should consider the range of independent internal and external assurance available, and avoid duplication and omission.

The adequacy of the independent assurance will depend upon the scope and depth of the work performed, bearing in mind its timeliness and the competency of the staff performing it. The level of reliance that can be placed upon such assurances should consider, among other things, the professional standing of the assurer, their level of independence, and whether they could reasonably expect to provide an objective opinion. It is important that any review that takes place results in a report, recommendations for action where necessary, and the retention of sufficient evidence to enable other potential reviewers to rely upon the work already undertaken. The reports should be made to the appropriate sub-committee of the board.

Management arrangements will include an internal audit function, as well as other quality control and assurance functions such as clinical audit. The internal audit function is required to give an opinion to the board on the adequacy and effectiveness of the overall system of internal control. In doing so, they will seek to work with, and rely on the work of other bodies for example RQIA.

In addition, the HSC organisation will be subject to independent inspection by the DHSSPS Medicines Regulatory Group on those areas subject to statutory authority.

Examples of Verification

- Schedule of planned reviews
- Copy of report
- Committee minutes

HSC	Controls Assurance Standard	Medicines Management
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- Action plans
- Notes of follow up of actions
- Evidence file
- Details of staff involved in the review

Links with other Standards

All Standards