National Minimum Standards
For Private and Voluntary
Healthcare Services
A statement of national minimum standards applicable to care homes for older people made by the Minister for Health and Social Services of the Welsh Assembly Government under the powers conferred by section 23(1) of the Care Standards Act 2000

Minister for Health and Social Services
Welsh Assembly Government
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INTRODUCTION:

NATIONAL MINIMUM STANDARDS FOR PRIVATE AND VOLUNTARY HEALTHCARE

1. This document sets out National Minimum Standards for Private and Voluntary Health care issued by the Welsh Assembly Government under Section 23 of the Care Standards Act 2000 (CSA). These standards will be used by the Assembly’s Care Standards Inspectorate for Wales (CSIW) when determining whether independent health care establishments are providing adequate care, meeting the needs of patients and otherwise being carried on in accordance with relevant requirements. The National Assembly will keep the standards under review, and may publish amended standards as appropriate.

2. The relevant requirements are set out in the Private and Voluntary Health Care (Wales) Regulations 2002 (‘the Regulations’) and under the CSA. Decisions of CSIW must be justified by reference to these regulatory requirements; and when making decisions CSIW must take these standards into account. Other agencies involved in the regulatory scheme, such as the relevant Tribunal, and the Courts, must also take the standards into account when making decisions under the CSA. For example, regulation 15 of the Regulations says “the registered person shall ensure that the establishment is conducted so as to promote and make proper provision for the welfare of patients...”. When considering whether or not this requirement is met CSIW will take into account standard C.3 which relates to quality of care. In the event of deviation from the standards specified there CSIW may conclude regulation 15 is not being met and take appropriate enforcement action.

3. These are “minimum” standards, rather than “best possible” practice. Many establishments will more than meet the national minimum standards and will aspire to exceed them in many ways.

4. Minimum standards do not mean standardisation of provision. The standards are designed to be applicable to the wide variety of different types of establishment that come within the category of private and voluntary health care, and to enable rather than prevent individual establishments to develop their own particular ethos and approach to care for patients with different needs.

5. It is hoped that the standards will be used for a range of purposes, and not just as part of the regulatory process. They may be used by providers and staff in self-assessment of their establishment, provide a basis for the induction and training of staff and they can provide guidance on what is required when setting up such an establishment. They can also be used by patients as a guide to what they should expect an independent health care establishment to provide and to do. Those involved with such establishments in any way are encouraged to make full use of these standards.
6. These standards are made under section 23 of the CSA by the Minister for Health and Social Services of the Welsh Assembly Government. They will apply from 22nd April 2002, unless otherwise stated.

7. The CSA reforms the regulatory system for social care and independent health care services in England and Wales. It replaces the provisions of the Children Act 1989 about the registration and regulation of certain health care establishments, and associated regulations, which are to be repealed, subject to transitional arrangements, from 1 April 2002 and makes new provision to bring some establishments within the regulatory framework for the first time. The CSA establishes the National Assembly as the social care and independent health care registration authority for Wales. For the time being these functions are discharged through its division known as the Care Standards Inspectorate for Wales (CSIW). The CSIW will take over the registration of social and health care services previously registered with local councils and health authorities. In addition, the CSA provides for the scope of registration to be extended to other services not currently registered, such as domiciliary care agencies, fostering agencies, residential family centres and independent medical agencies.

8. The CSA confers a broad range of regulation making powers upon the National Assembly in relation to Wales covering, amongst other matters, the management, staff, premises, and conduct of social and healthcare establishments and agencies. Section 23 confers powers upon the National Assembly to publish statements of national minimum standards that the CSIW and others must take into account when making decisions (as described in paragraph 2). These standards will, where applicable, often form the basis for judgements made by the CSIW regarding applications for registration, the imposition of conditions for registration, variation of any conditions and enforcement of compliance with the CSA, including decisions about cancellation or prosecution.

9. The CSIW will therefore consider the degree to which a regulated service complies with the relevant standards when determining, for the purposes of its registration functions, if a provision of the Regulations has been breached. Any decision made by CSIW in the exercise of its registration functions may be appealed to an independent tribunal.
10. The national minimum standards for independent health care focus on ensuring that patients receive treatment and services in independent health care establishments that are safe and of an assured quality.

11. The intention is that the attached set of core standards will apply to all independent health care providers regulated by the Care Standards Inspectorate for Wales (CSIW). They are supplemented by the attached service-specific standards that will apply to the relevant individual areas of health care services to be regulated.

12. Each standard deals with a particular aspect of an independent health care establishment and is preceded by a statement of the outcome for patients intended to be achieved by the establishment. The regulations and standards have been designed to promote the achievement of that outcome.

13. The ‘standard’ dealing with a particular aspect of a hospital or other establishment is actually made up of a set of standards which are the numbered paragraphs beneath the ‘outcome’ paragraph. Each of these numbered paragraphs should, for the purposes of the CSA, be treated as a separate standard under s.23 of the CSA.

14. In order to help to distinguish and identify the standards prefixes have been added to them, as follows: C for core, A for acute hospitals, M for mental health, H for hospices, MC for maternity hospitals, TP for termination of pregnancy, P for prescribed techniques/technologies and PD for private doctors.

15. Wherever possible, all the regulations that the set of standards are linked to have been listed. However, other regulations may also be relevant and the note should be taken as a general guide rather than a comprehensive legal reference. The standards are intended to be qualitative, in that they provide a tool for judging the quality of life experienced by patients, but they are also designed to be measurable.

16. In some instances, to ease comprehension, the standards repeat the requirements of the regulations. This should not be taken to mean that the particular regulatory requirement is altered in nature – the provisions of the regulations must still all be met by the registered person.

17. Inspecting against the regulations and these standards, the CSIW will follow a consistent inspection methodology and reporting format across the country. In assessing whether or not a hospital or other establishment meets a particular regulatory requirement, the CSIW will consider if it meets each of the relevant standards.
Key Values

18. The regulations and national minimum standards for independent health care are based on certain fundamental principles. In applying these regulations and standards, CSIW will look for evidence that the policies and day-to-day operation of independent health care establishments and agencies reflect the following:

- **patient-centred services** – as the stated outcomes of the standards indicate, they are geared towards ensuring that independent health care providers put patient safety and quality assurance at the centre of what they do;

- **patient information** – linked to this, the standards aim to ensure that patients and prospective patients have clear and accurate information about independent health care providers, and that providers listen to, and publish, feedback from patients;

- **accountability** – registered persons must take the appropriate steps to fulfil their responsibility for ensuring that the regulations and standards are met, so that patients receive treatment and services that are safe and quality-assured;

- **safety and quality assurance** – the common aim of the standards, from human resources procedures to risk management arrangements to surgical and pathology arrangements to procedures for laser treatment, is to address how safety and quality assurance can be best achieved;

- **consistency** – the standards are based on the key principle that they need to be compatible with standards in the NHS.

CONTEXT AND PURPOSE

19. These national minimum standards, and the regulatory framework within which they operate, are part of a broader National Assembly policy to improve the quality of care to ensure that patients receive treatment and services that are safe and of an assured quality.

20. The standards have been prepared following an extensive consultation programme. Specialist advice was provided. All comments were carefully considered and discussions were held with key representatives. These standards incorporate the views expressed and advice provided.
Core Standards
Core Standards – Contents

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Information Provision

Introduction to Standard C1

Information provision relates to the information that the regulated body produces for external consumption. This covers, for instance:

- advertisements and other promotional material aimed at prospective patients;
- information that the CSIW may wish to collect for its own purposes. The CSIW will require information for regulation purposes, but it may also want to gather other information, for example the number of patients who have to be transferred to NHS hospitals from a particular provider.

An information provision policy must ensure that information published by the establishment about its services is accurate. Concern has been expressed about misleading information given by some independent health care providers to patients and prospective patients as to what the treatment on offer will be likely to achieve. We wish to ensure that information/advertisements that regulated bodies provide about their services are accurate and not misleading.

The standards refer to a patients guide that each provider will be required, through the Private and Voluntary Health Care (Wales) 2002 Regulations (the Regulations), to produce. The Regulations will also require each provider to produce a statement of purpose of the establishment, which must be made available for patients. When preparing information to be available for patients, the provider must take into account its use by patients who have special needs. The print format and presentation of the information, advertisements and promotional materials should take account of the Disability Wales guidance on ‘Access to Information and Means of Communication’

See also, in particular, regulations 5 to 7 and 27 to 31, and Schedule 1 of, the Regulations.
Information for Patients

OUTCOME

Patients receive clear and accurate information about their treatment.

Standard C1

C1.1 The establishment makes available to prospective patients and their families a patients guide in a clear, relevant language and format.

C1.2 The patients guide is kept under review to ensure the information in it remains up to date.

C1.3 Patients are advised about how to make suggestions and comments about the patients guide.

C1.4 The registered person ensures that information on the services provided by the establishment is not misleading and information provided to patients and prospective patients and their families is:

- in a clear, relevant language and format;
- accurate; and
- that any claims made in respect of services are justified.

C1.5 Any advertisements meet the requirements of the Advertising Standards Authority.

C1.6 Patients, and where appropriate their families and carers, receive information in a strategic, sensitive and supportive way.

C1.7 Any information given to the media respects the confidentiality of the patients, their families, their carers and staff.
Quality of Treatment and Care

Introduction to standards C2 to C7

Patient safety and quality assurance are the cornerstones of the new regulatory system for independent health care. Continuous quality improvement in the NHS is underpinned by a system of Clinical Governance which can be defined as ‘A framework through which NHS organisations are accountable for continually improving the quality of their services and safeguarding high standards of care, by creating an environment in which excellence in clinical care will flourish.’ CSIW expect that independent healthcare providers will apply the principles of clinical governance to their services as a matter of good practice.

The Regulations and standards therefore seek to ensure that treatment and care is patient-centred and that effective monitoring of clinical care takes place. Towards this end, and to help demonstrate the measures they have taken, independent health care providers will be required to have written policies and procedures in place covering various aspects of their activities (see Appendix 4). They will also be required to evaluate these policies and procedures to assess their effectiveness.

We are proposing that the timescale for evaluation is set out in the individual written policies. Some policies and procedures will need to be evaluated more often than others (for example, following changes through evidence-based practice or research), but the overall principle is that they must be evaluated at least every three years. The evaluation can be carried out by the provider itself or by bringing in an external organisation.

In addition to the standards under this quality heading, Regulations and standards under the other headings in this document contain measures that contribute towards the overall ethos of patient-centred care and quality, for instance in connection with human resources, complaints management, risk management, information provision and throughout the service-specific standards.

The standards refer to the need for the patient’s written consent before treatment. The Assembly wants a strong public voice in health and health care decision-making. The NHS Plan, for instance, makes it clear that patients are the most important people in the health service. It is equally important that patients in the independent health care sector have a say about the quality of the treatment and care being provided and that their views are heard. In line with measures in the NHS, independent health care providers will be required to carry out patient surveys, the outcome of which will be made available to patients and prospective patients as part of a patients guide that each provider will be required to produce.
These core standards, and the service-specific standards that supplement them, have been drafted so as to be, where possible, compatible with standards in the NHS and consistent with frameworks for clinical governance.

See also, in particular, regulations 14 to 16 of the Regulations.
Patient-Centred Care

OUTCOME

The treatment and care provided are patient-centred.

STANDARD C2

C2.1 The registered person has policies and procedures in place to ensure that the care provided is patient-centred, as follows:

- patients receive timely, appropriate and accurate assessment and diagnosis of their health needs and of evidence based interventions for treatment and/or care;
- patients give verbal consent to all intimate examinations, and are offered a chaperone if undergoing such an examination;
- patients and relatives are consulted about the planning and delivery of services provided to them, which includes taking into account their preferences and requests;
- patients have access to their health records;
- patients’ rights are central to the resuscitation policy;
- services are provided in such a way that facilitates access by people of different cultural and ethnic backgrounds and those with disabilities;
- patients’ privacy, dignity and confidentiality are respected at all times;
- patients are addressed by their preferred name and title;
- patients are treated with courtesy and consideration.

C2.2 Clinical procedures are explained to patients so that they understand the implications of the treatment including potential risks and side effects, and any options available to them, allowing them to give informed consent or withhold consent (including discharging themselves against medical advice).

C2.3 Patients give written consent before receiving any treatment.

C2.4 There is a written policy and procedure on how to respond to advance directives.

C2.5 There are facilities for patients to have confidential discussions with clinical staff that ensure privacy.

C2.6 Staff wear identification badges showing name and position held.

C2.7 Patients who choose not to discuss personal affairs with members of the opposite sex receive consultations with health care professionals of the same sex.
Quality of Care and Management of Patient Conditions

OUTCOME

Treatment provided to patients is in line with the relevant clinical guidelines.

STANDARD C3

C3.1 The management of specific conditions takes account of evaluations by the National Institute for Clinical Excellence (NICE) and specific clinical guidelines from the relevant medical Royal Colleges and the NHS National Service Frameworks.

C3.2 The management of patient conditions not covered by the above specific evaluations and clinical guidelines, takes account of relevant evidence based practice and appropriate professional guidelines.

C3.3 All staff and personnel providing care to patients are supported by the registered provider to achieve high standards of care, by ensuring the availability of well designed induction programmes, regular training and arrangements for continual professional development.
Monitoring Quality

OUTCOME

Patients are assured that monitoring of the quality of treatment and care takes place.

STANDARD C4

C4.1 The written policy and procedures for clinical treatment and care include arrangements for monitoring the quality of care provided including:

- clinical audit;
- the presentation of performance indicators;
- the outcomes of clinical and nursing audits;
- the use of comparative information on clinical outcomes;
- evaluation against research findings and evidence based practice;
- participation in national confidential enquiries (such as the National Confidential Enquiry into Peri-Operative Deaths);
- effective information and clinical record systems;
- the identification and recording of the respective and common responsibilities of team members;
- procedures for identifying and learning from adverse health events and near misses;
- a complaints procedure.
Care of the Dying

OUTCOME

The terminal care and death of patients is handled appropriately and sensitively.

STANDARD C5

C5.1 Care and comfort are given to patients who are dying, their death is handled with dignity and propriety, and their spiritual needs, rites and functions observed.

C5.2 Clinical staffing levels are such to allow attention to the care needs of the patient and to provide pain relief as required.

C5.3 The patient’s wishes concerning terminal care and arrangements after death are discussed and carried out.

C5.4 The patient’s family and friends are involved (if that is what the patient wants) in planning for and dealing with terminal illness and death.

C5.5 The privacy and dignity of the patient who is dying are maintained at all times.

C5.6 Palliative care being a specialist branch of medicine and nursing, requires the expertise of specialist practitioners. C 5.7 Practical assistance and advice for patients receiving palliative care, and bereavement counselling for relatives are provided by trained professionals/specialist agencies.

C5.8 The body of a patient who has died is handled with dignity and time allowed for family and friends.
Patients’ Views

OUTCOME

Patients views are obtained by the establishment and used to inform the provision of treatment and care and prospective patients.

STANDARD C6

C6.1 There are regular patient surveys that seek the views of patients and their family on the quality of the treatment and care provided.

C6.2 The outcome of the patient surveys and other measures for obtaining patient views are made available to patients, prospective patients and their families, and are provided to the CSIW.

C6.3 The outcome of the surveys are used by the regulated body to assess whether it is meeting its aims, objectives and statement of purpose.
Policies and Procedures

OUTCOME

Appropriate policies and procedures are in place to help ensure the quality of treatment and services.

STANDARD C7

C7.1 All staff read the policies and procedures relevant to their area of work (including temporary staff) and sign a statement to this effect.

C7.2 There are written policies and procedures for all operational areas within the establishment and these are placed in an accessible position, available to all staff.

C7.3 A mechanism to assess the knowledge, competency and skills of personnel against the policies and procedures, to reinforce the implications for practice is developed.

C7.4 There is a central register of policies and procedures that includes the title, issue date, review date and circulation of all policy and procedure documents.

C7.5 All policies and procedures are reviewed at least every three years and the date of review is included within each written policy.

C7.6 The establishment evaluates practice against the policies and procedures to ensure their effective implementation; the evaluation is carried out at least every three years.
Management and Personnel

Introduction to Standards C8–C15

Registered Person (standard C8)

The role of every person in an independent health care establishment is important in ensuring the delivery of safe quality care, but ultimately the registered provider must be accountable for meeting the standards required for registration, and the registered manager must be accountable for the delivery of the requisite services to those standards. This is a key feature of the new regulatory system. In this respect it is essential that both are fit persons to ‘carry on’ or manage the establishment or agency and that each have clearly defined roles of responsibility.

The new regulatory regime will require the person ‘carrying on’ (registered provider) the establishment to be registered with the CSIW, and where that person is not in charge of the day to day running of the business that a manager (registered manager) is appointed and also registered with the CSIW.

Many independent health care establishments will be owned by a company or charity, which may have a number of different establishments throughout the country. In these circumstances the company or charity will be the registered provider. However, it is important that the CSIW has a contact in the organisation for the purposes of communication, and therefore the company will have to provide the CSIW with the name of the ‘responsible individual’ who is a director, manager, company secretary, or other officer of the organisation. Where the company owns a number of independent health care establishments it will have to register in respect of each one. The person in charge of the day to day running of each establishment will have to register as the manager of the establishment.

Throughout this document the regulations and standards apply to the registered person, that is both the registered provider and the registered manager, unless indicated otherwise.

See also, in particular, regulations 9 to 13 of the Regulations.
Human Resources (standards C9 to C15)

The skill, competence and attitude of those who provide independent health care services are key elements in determining the quality of health care that patients receive. We wish to ensure that responsibility is placed on those who carry-on or manage independent health care to ensure that the people who provide treatment and care in their establishments, or on their behalf, are appropriately skilled, qualified and competent to do so.

To help achieve this the regulations, underpinned by standards, require providers to have a written human resources policy in place, covering the recruitment, induction and retention of employees and their employment conditions. The regulations also set out other staffing requirements, covering assurance about the qualifications and skills of those who work in independent health care establishments and agencies. This is a good example of how the core and service-specific standards interact: the core standards cover human resources and staffing good practice generally, such as training and continuing professional development, and the service-specific standards supplement these by specifying the skills, qualifications and competencies needed for health care professionals working in the individual services regulated.

Those who work in independent health care establishments have day to day contact with patients, very often on a one-to-one basis. It is therefore essential that the registered person is aware of the ‘fitness’ of the workers in order to ensure the safety of the patients. The registered person will be required to show that all the information and documentation on workers required in relation to the matters set out in Schedule 2 to the Regulations has been provided. This includes references and details of convictions.

A new requirement for NHS bodies is that they include in their employment application forms a declaration to be completed by the applicant stating whether or not they have been or are the subject of fitness to practice proceedings by any licensing or regulatory body. Applicants are also required to make a declaration stating whether they have been or are currently the subject of any police investigation or conviction in this or any other country. The standards are intended to ensure similar practice in the independent sector.

The regulations and standards recognise that the registered person will have some common areas of responsibility both for employed staff and for those practitioners who are given practising privileges in the regulated establishment. The regulations and standards also recognise that there are differences in the registered person’s relationship with each of the two groups. These differences are indicated by the references in the standards to ‘staff ’ (ie all those employed by the regulated body) and ‘personnel’ (ie those who work in the regulated establishment/agency, including those with practising privileges.

The Assembly’s view is that these human resources standards, and the associated regulations, will be appropriate even where the independent health care establishment/agency regulated is a single-handed operation, for example a lone private GP. In those circumstances, the registered provider (the GP) will be held accountable under the Care Standards Act for ensuring that whoever provides
services in the establishment (even if only the GP himself) is skilled and competent and otherwise suitable to provide these services.

See also, in particular, regulations 17 and 18, and Schedule 2 to the Regulations.
Role and Responsibilities of the Registered Manager

OUTCOME

Patients are assured that the establishment or agency is run by a fit person/organisation and that there is a clear line of accountability for the delivery of services.

STANDARD C8

C8.1 The manager can demonstrate that he/she has undertaken periodic training to update their knowledge, skills and competence to manage the establishment. Where the manager is a registered nurse, he/she must comply with the requirements of the professional regulatory body.

C8.2 The job description of the registered manager sets out his/her responsibilities to run the establishment in accordance with the law and the national minimum standards.

C8.3 There are clear lines of accountability within the establishment and these are described in an up-to-date organisational structure document or diagram.

C8.4 The registered manager ensures that all relevant certificates and licences which are legally required are obtained, kept up to date and displayed where required.
Human Resources Policies and Procedures

OUTCOME

Patients receive care from appropriately recruited, trained and qualified staff.

STANDARD C9

C9.1 There is a written human resource policy and supporting procedures, in line with current employment legislation, which:

- defines the way in which advertising, recruitment, induction, employment and retention of staff is managed;
- ensures that the application pack contains a form where potential staff declare whether or not they:
  - have been or are the subject of fitness to practice proceedings by a UK or an overseas licensing or regulatory body;
  - have been or are currently the subject of any police investigation or conviction in this or any other country;
- ensures that all staff are interviewed before employment, and that records of interview and references are retained;
- ensures that documentary proof is maintained of the continuing registration of professional staff with their respective professional regulatory body;
- ensures job specifications, performance review, appraisal and line management arrangements are defined for all staff;
- ensures that any relevant professional registration and indemnification is checked and authenticated for all staff and intended staff;
- sets out an expectation as to the conduct of staff, and disciplinary procedures to be followed;
- prohibits personnel from accepting gifts from patients, apart from gifts and benefits of a trivial or inexpensive seasonal nature in accordance with procedural guidance;
- ensures sickness and absence is monitored;
- covers effectively the way in which volunteers are involved.

C9.2 A person who is being offered a post or given practising privileges has his/her identity confirmed through producing appropriate documentation, such as the person's current passport.
C9.3 When employment is offered to a person from outside the EU, the prospective employee must produce his/her resident's permit and/or their work permit.

C9.4 There are arrangements in place for staff training and continuing professional development.

C9.5 All staff, including agency nurses and locum medical staff, have an effective induction and are made fully aware of current policies and procedures.

C9.6 A training record of all educational and professional development activities is kept for each member of staff.

C9.7 The performance of all staff within the organisation is reviewed on an annual basis as a minimum, in a systematic way.

C9.8 There is a written policy on equality of opportunity, which ensures specific attention is paid at all levels of the organisation to the abolition of any form of less favourable treatment to any member of staff, directly or indirectly, on the grounds of race, gender, age, sexual orientation, disability, religion or trade union membership.
Registered Nurses

OUTCOME

Patients receive care from appropriately registered nurses who have the relevant skills knowledge and expertise to deliver patient care safely and effectively

STANDARD C10

C10.1 All practitioners must be registered with the nursing professional registration body, The Nursing and Midwifery Council (NMC), (formerly UKCC), and must comply with professional codes and standards of practice in all professional activity, with particular reference to assessment, planning, delivery, evaluation and supervision of patient care.

C10.2 Registered nurses comply with Post Registration Education and Practice (PREP) standards required by the NMC to ensure continued fitness for practice and continued registration.

C10.3 Patients requiring a nursing assessment or a nursing intervention are assessed by appropriately registered nurses who are, qualified, skilled and experienced to a level determined by the assessment and intervention required.

C10.4 Each patient assessed by a registered nurse receives a nursing care plan which documents nursing care and interventions to the level assessed and demonstrates professional standards evidence based, and best practice.

C10.5 Registered nurses should work as members of a multi-professional team and should participate in, and contribute professional opinion to, multi-professional team activities such as case conferences, ward rounds and inter-disciplinary team meetings.

C10.6 Nursing staff delegated to carry out procedures on behalf of a doctor are indemnified for this and trained in the techniques, and are competent to undertake these procedures.
Practising Privileges

OUTCOME

Patients receive treatment from appropriately recruited, trained and qualified practitioners.

STANDARD C11

C11.1 Where medical practitioners are granted practising privileges (ie the grant to a person who is not employed in the establishment of permission to practise in that establishment) there are written policies and procedures on allowing practising privileges.

C11.2 The following pre and post-employment checks are carried out before a medical practitioner is granted practising privileges:

- that the practitioner is registered with the appropriate professional regulatory body;
- that the practitioner is trained and is experienced in the type of treatment he/she is given practising privileges to perform;
- that the practitioner declares whether or not he/she:
  - is currently the subject of any police investigation and/or prosecution, in the UK or any other country;
  - has ever been convicted of any criminal offence required by law to be disclosed, received a police caution in the UK, or a criminal conviction in any other country;
  - is currently the subject of any investigation or proceedings by any body having regulatory functions in relation to health/social care professionals including such a regulatory body in another country;
  - has ever been disqualified from the practice of a profession or required to practise it subject to specified limitations following fitness to practise by a regulatory body, in the UK or another country.

- that the practitioner is interviewed before employment, and that records of interview and written references are retained;
- that qualifications relevant to the post applied for are verified by validation at the interview;
- that the practitioner is appropriately registered, whether that registration covers the duties to be undertaken and whether there are any restrictions in place or investigations underway; by the relevant regulatory/licensing body;
- that employment references are sought prior to making an offer of employment from the two most recent employers;
- that indemnification is checked and authenticated;
• that documentary proof is maintained of the continuing registration with the respective professional regulatory body;
• that the procedures for practitioners to follow when gifts are offered from patients and gives guidance on what may and may not be accepted are set out;
• that the practitioner who is offered practising privileges has his/her identity confirmed through the presentation of a valid birth certificate, and passport or driving licence;
• that there are arrangements in place for ensuring the validity of work permits are verified and that their status is clarified.

C11.3 There is a written agreement with the practitioner setting out:

• the details of the practising privileges, which includes a stated requirement of the practitioner’s availability to attend the establishment within a certain time limit if notified of a problem with a patient;
• that he/she will comply with the organisation’s policies and procedures including the complaints procedure, and which requires the practitioner to inform the appropriate person if a complaint is made directly to him/her in the first instance.
• that the practitioner is required to place a copy of all clinical notes relating to care or treatment at the establishment in the patient’s health record retained by the establishment.

C11.4 There are arrangements in place for continuing professional development.

C11.5 The practitioner is made aware of the current policies and procedures in the establishment and a list of the relevant policies and procedures that he or she is expected to be familiar with is provided.

C11.6 Practising privileges are reviewed for each practitioner every two years, as a minimum and may be reviewed more frequently as a result of concerns about practice or complaints received by the establishment.
Compliance with Professional Codes of Practice

OUTCOME

Patients are treated by health care professionals who comply with their professional codes of practice.

STANDARD C12

C12.1 All health care professionals are required to abide by published codes of professional practice relevant to their professional role.

C12.2 There is written information for health care professionals that explicitly states that any breach of such codes is regarded as a disciplinary offence. This may be included in the contract of employment, practising privileges agreement, or staff handbook.

C12.3 All health care professionals take part in the ongoing continuing professional development (CPD) required by their professional body and/or Specialist College, including revalidation requirements of the GMC.
Health Care Workers and Blood Borne Viruses

OUTCOME

Patients and personnel are not infected by blood borne viruses.

STANDARD C13

C13.1 All staff and practitioners with practising privileges comply with Department of Health guidelines on health care workers infected with blood borne virus (hepatitis B, hepatitis C, HIV).

C13.2 There are written instructions for health care workers and practitioners with practising privileges on the steps required by the establishment in order to ensure their compliance and notification of infection status in line with the guidelines.

C13.3 All staff, or practitioners with practising privileges, who perform exposure-prone procedures are required to provide documentary evidence of their vaccination status with regard to hepatitis B, or to be tested for, and vaccinated against, hepatitis B if there is no evidence of previous vaccination produced.

C13.4 The establishment keeps vaccination records for all health care workers employed and all practitioners with practising privileges.
Child Protection Procedures

OUTCOME

Children receiving treatment are protected effectively from abuse.

STANDARD C14

C14.1 Where children are treated there are child protection procedures in place, with which all personnel are familiar.

C14.2 Procedures for handling allegations of child abuse are consistent with the National Assembly for Wales’ guidance *Working Together to Safeguard Children* (issued in Wales in September 2000).

C14.3 Procedures for handling allegations of child abuse reflect national guidance and are in line with the procedures of the local Area Child Protection Committee.

C14.4 All staff who care for or treat children are trained to recognise the signs and symptoms of child abuse, and are aware of relevant supporting agencies involved in child protection.

C14.5 All allegations of abuse are dealt with promptly in line with the ACPC procedures.

C14.6 A child’s wish for privacy and confidentiality is handled in way that is consistent with the need to protect the child.
Adult Protection Procedures

OUTCOME

Adults-receiving-care-are-protected-effectively-from-abuse.

STANDARD C15

C15.1 Adult protection procedures are in place with which all personnel are familiar.

C15.2 Procedures for handling allegations of abuse reflect current National Assembly guidance, and are consistent with local vulnerable adult protection procedures.

C15.3 Staff are trained to understand principles governing adult protection, to recognise symptoms of adult abuse, and to deal with allegations appropriately.
Complaints Management

Introduction to Standards C16 to C18

The lack of a clear and effective process by which patients are able to complain when dissatisfied with treatment and services is often a weakness in the current system. There have been occasions where dissatisfied patients have been passed from the provider of the health care establishment to the person who undertook the treatment with neither taking responsibility for addressing the patient’s concerns. The regulations and standards address this issue by requiring the registered person to have an effective complaints system in place.

Providers will be required to have a written procedure for handling complaints about the services, care and treatment provided in, or on behalf of, their establishments/agencies and to maintain a register of complaints. They will be required to provide the CSIW with access to their records of the complaints made and the action taken in response upon request. There is also an expectation in line with clinical governance procedures, that, through the process of complaints management and review, lessons can be learnt which contribute to the continual improvement in the quality of services, patient care, and treatment provided.

In order to be fully effective a complaints procedure must ensure that a patient’s complaint has a fair hearing and result in remedial action being taken as appropriate. Patients and prospective patients, their families and carers, need to have information available on the complaints procedure at the outset of their treatment. It is also essential that all those who work in the establishment/agency where the treatment is provided are aware of the complaints procedure, and those involved in its provision or procedural elements are trained in its operation.

The CSIW has a two-fold interest in complaints about independent health care:

- that the registered person has in place a complaints system that complies with the regulations and standards on complaints; and
- that a complaint may indicate non-compliance with a particular regulation or standard.

Where patients are unhappy about how a complaint was handled by the provider or with the outcome he/she can complain to the CSIW. A patient can in fact complain direct to the CSIW, but the CSIW may decide that the complaint should be considered at local level first and return it to the provider for action. Although it will not be appropriate for the CSIW to be involved in seeking compensation for patients, if the complaints process indicates that there has been a regulatory failure by the provider the CSIW will be able to consider the position and take appropriate action, including applying sanctions if necessary.
A NHS patient who is treated under contract in an independent hospital will continue to have access to the NHS complaints procedure. Subject to the terms of the contract, the local resolution stage could be handled by the independent hospital. However, if the NHS patient continues to be unhappy he/she can take the complaint to the next stage of independent review, and if necessary through to the Health Service Ombudsman.

In setting the timescales in the standards within which a complaint should be processed, consideration was given to those in the NHS complaints procedure, the Local Authority social services procedure and the Independent Healthcare Association complaints procedure. It was decided that it would be more appropriate to align the timeframe with that in the NHS complaints procedure.

It is important that regulated providers make clear to those who work within the establishment or agency that they can raise concerns, through the appropriate channels, about their colleagues’ performances with impunity.

See also, in particular, regulation 22 of the Regulations.
Complaints Process

OUTCOME

Patients have access to an effective complaints process.

STANDARD C16

C16.1 The registered person ensures that there is a written policy and supporting procedures for handling complaints about all aspects of service, care and treatment provided in, or on behalf of, the establishment/agency and that such a policy includes the stages and timescales for the process.

C16.2 All complainants receive a written acknowledgement within 2 working days of receipt of their complaint (unless a full reply can be sent within 5 working days). A full response should be made within 20 working days of receipt of the complaint. Where the investigation is still in progress a letter explaining the reason for the delay should be sent to the complainant and a full response made within 5 days of a conclusion being reached.

C16.3 The complaints procedure ensures that the complainant receives written confirmation of the stages of investigation and action taken.

C16.4 The complaints procedure is brought to the attention of all staff, and practitioners with practising privileges, and they receive training on:

- what constitutes a complaint;
- the procedures for dealing with a complaint.

C16.5 Those staff involved in the provision and procedural elements of the complaints procedure are trained in its operation.

C16.6 A register of complaints, including information on whether or not the complaint was upheld, the results of the investigation, the action taken and the resolution of complaints is maintained.
Information for Patients about Complaints

OUTCOME
Patients receive appropriate information about how to make a complaint.

STANDARD C17

C17.1 The complaints procedure or information based upon it is accessible to patients and their family members/carers.

C17.2 Where requested the patient and/or family members or carers are given support in using the complaints procedure.

C17.3 Where care and treatment are provided to children, staff are aware of the difficulties a child faces in expressing concerns or complaints and how the child should be helped to overcome these. The establishment should provide clear lines of access to independent advocacy and telephone help lines.
Staff Concerns

OUTCOME

Staff and personnel have a duty to express concerns about questionable or poor practice.

STANDARD C18

C18.1 Staff and personnel are informed about their duty to express their concerns about questionable or poor practice in accordance with the Public Interest Disclosure Act 1998.

C18.2 Staff are assured that they will not be penalised at any time for complaining in good faith about poor practice.

C18.3 There is a written policy and procedure for staff to follow in order to raise their concerns about questionable or poor practice.
Premises, Facilities and Equipment

Introduction to Standards C19 to C21

The design and condition of the premises where treatment takes place, and the nature of the facilities and equipment generally, have a considerable impact on the treatment, care and services that patients receive. It is essential, therefore, that the premises, facilities and equipment are suitable to meet the needs of patients safely and effectively.

To this end, the key principles of these draft standards are that:

- premises are designed and maintained with the safety of patients in mind and ensure that patients' privacy and dignity is protected;
- facilities are designed or procured using relevant skills and expertise so that they effectively deliver treatment and services;
- equipment selected and used within the establishment is wholly appropriate for the treatment provided;
- safe and regular maintenance of equipment takes place, ensuring that equipment is used in accordance with the manufacturer's instructions and is not modified or used for purposes for which it was not designed;
- all equipment is used in line with its expected 'life time' with a planned replacement programme.

See also, in particular, regulation 24 of the Regulations.
Health Care Premises

OUTCOME

Patients receive treatment in premises that are safe and appropriate for that treatment. Where children are admitted or attend for treatment, it is to a child-friendly environment.

STANDARD C19

C19.1 There is a preventive maintenance plan that covers all areas of the establishment’s buildings.

C19.2 There is fail-safe emergency lighting in place and arrangements for back up power in case the main power supply fails.

C19.3 The establishment complies with the requirements of the fire authority and the environmental health department.

C19.4 There is disabled access to all areas routinely visited by patients.

C19.5 All areas used by patients are well lit, internally and externally.

C19.6 Where patients are required to undress, changing room facilities enable privacy and dignity to be maintained.

C19.7 All in-patients have access to single sex toilet and washing facilities.

C19.8 Safe temperatures are monitored and maintained for hot water supplies and the surfaces of heating appliances (for example radiators) in all areas used by patients.

C19.9 Patient care areas are clean, hygienic and free from noxious smells.

C19.10 Waste is segregated into clinical and non-clinical items and stored in colour-coded bags and containers.

C19.11 Clinical waste stored outside the building is kept in locked containers.

C19.12 Records are kept of the thorough examination, by a competent person, of all passenger lifts and the periodic examinations, carried out under a suitable written scheme, by a competent person, of all pressure vessels.
Condition and Maintenance of Equipment and Supplies

OUTCOME

Patients receive treatment using equipment and supplies that are safe and in good condition.

STANDARD C20

C20.1 Equipment is installed, checked and serviced in compliance with the manufacturer’s instructions.

C20.2 Equipment is not modified unless the manufacturer’s advice has been sought, and no risk has been identified.

C20.3 All equipment conforms to current health and safety regulations and, where appropriate, there is a planned preventive maintenance and replacement programme.

C20.4 Records are kept of the maintenance and servicing of all equipment.

C20.5 All stock products used in the establishment are rotated to ensure that at the time of use they are in optimum condition.

C20.6 Heat sensitive and/or light sensitive items are stored in a controlled environment to keep the items in optimum condition.
**Catering Services for Patients**

**OUTCOME**

Patients receive appropriate catering services.

**STANDARD C21**

C21.1 Food is handled, stored, prepared and delivered in accordance with food safety legislation.

C21.2 All staff who handle food undertake regular training in food hygiene.

C21.3 Each in-patient is offered three full meals a day; menu choices include at least one cooked meal option per day.

C21.4 Food is nutritious, balanced and varied and meets any special needs of the patient.

C21.5 Special diets are provided on the advice of professional staff or a dietician.

C21.6 Religious or cultural needs are catered for.

C21.7 Food is presented in a manner which is attractive and appealing in terms of texture and flavour.

C21.8 A menu is prepared offering a choice of meals.
Risk Management Procedures

Introduction to Standards C22 to C30

All health care establishments, treatment and services contain elements of risk and hazards that need to be carefully identified, monitored, managed and contained. It is essential, therefore, that independent health care providers have effective safeguards in place to protect patients and those who work within, or have contact with, the establishment, treatment and services. We believe that the starting point in achieving this is to require providers to have a comprehensive written risk management policy in place to cover their services and the wide and diverse features found within their establishments.

Risk management is a careful examination of what could cause harm to patients, visitors and staff so that the provider can consider whether appropriate precautions have been taken. The risk management policy must include the safeguards that all organisations that employ staff and deliver services are required to have: a health and safety policy, arrangements to manage and learn from emergency or untoward incidents, and formal arrangements for the making and recording of contracts.

The requirement for arrangements to be in place in respect of adverse health events and near misses reflects the recommendations for the NHS contained in the Department of Health report An Organisation with a Memory (2000).

All providers will continue to have to comply with the requirements of other relevant legislation, including health and safety legislation and EU Directives.

See also, in particular, regulations 8 and 14 (5) of the Regulations.
Risk Management Policy

OUTCOME

Patients, staff and anyone visiting the registered premises are assured that all risks connected with the establishment, treatment and services are identified, assessed and managed appropriately.

STANDARD C22

C22.1 The registered person ensures that there is a comprehensive written risk management policy and supporting procedures, which covers:

- the assessment of risks throughout the establishment;
- the control of any risks identified;
- health and safety;
- infection control;
- decontamination;
- arrangements for the identification, recording, analysing and learning from adverse health events or near misses;
- arrangements for responding to emergencies;
- protection of vulnerable children and adults, including protection from abuse.

C22.2 Arrangements are in place for dealing effectively with ‘alert letters’ when these are received.

C22.3 There is a written procedure setting out the responsibilities for informing the CSIW and national professional bodies such as the GMC about staff who have been suspended on clinical or professional grounds, or practitioners whose practice privileges have been suspended, restricted or withdrawn on professional or clinical grounds.

C22.4 A named member of staff is identified to receive the information from the Medical Devices Agency. These notices are badged as Safety Action Bulletins or MDA/NHS Estates Device Alerts by the National Assembly. Relevant matters must be reported to the Agency (including failure of, and accidents in connection with, medical devices).

C22.5 A named member of staff is identified to receive information from the Medicines Control Agency. Such notices are usually badged as Hazard Notices (Pharmaceutical). Relevant matters must be reported to the Agency.
C22.6 Where in-patient care is provided there is a nurse call system installed throughout the patient care areas of the establishment including all patient bedrooms, toilet and shower/bathrooms.

C22.7 The risk management process applies to the safe and secure handling of medicines and the use of a medicine outside of its product licence.
Health and Safety Measures

OUTCOME

The appropriate health and safety measures are in place.

STANDARD C23

C23.1 There are written procedures for the classification, storage, collection, transport and disposal of all categories of waste in accordance with health and safety and environmental requirements.

C23.2 There is a written procedure for any interruption of a medical gas line to be authorised by the registered manager or by a person authorised by the registered manager.

C23.3 The registered manager ensures compliance with relevant legislation including:

- Health and Safety at Work Act 1974;
- Management of Health and Safety at Work Regulations 1999;
- Workplace (Health, Safety and Welfare) Regulations 1992;
- Provision and Use of Work Equipment Regulations 1992;
- Electricity at Work Regulations 1989;
- Health and Safety (First Aid) Regulations 1981;
- Control of Substances Hazardous to Health Regulations (COSHH) 1988;
- Manual Handling Operation Regulations 1992;
- Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 1985.

C23.4 Staff are provided with protective equipment and clothing to prevent risk of harm or injury to themselves.

C23.5 There is a written policy on the moving and handling of patients which sets out the arrangements and equipment in place to minimise the moving and handling of patients manually by staff.

C23.6 All health care staff working directly with patients have regular training in moving and handling them.

C23.7 A record is kept of accidents to patients, visitors and personnel, including the number of needle stick injuries by category and location of work of staff.
Medicines Management

OUTCOME

Measures are in place to ensure the safe management and secure handling of medicines.

STANDARD C24

C24.1 Where there is no pharmacy department on site, the responsibility for safe medicines systems for the hospital rests with a registered senior nurse or doctor.

C24.2 The establishment has access to up-to-date, relevant reference sources, for example, the British National Formulary, the Summary of Product Characteristic for every product used, and access to evaluated information about medicines.

C24.3 Where medicines are administered and supplied to patients:

- there is a written procedure for recording administration and supply of medicines to patients, including errors, to encourage an open reporting system and a non-blame culture; and
- there is a written policy for those exceptional circumstances where a medicine is administered without a written direction, for example, a life-threatening situation.

C24.4 When clinical trials take place they are undertaken in accordance with relevant legislation and best practice guidelines.

C24.5 The general principles within the National Service Frameworks and NICE guidance are applied where appropriate.
Ordering, Storage, Use and Disposal of Medicines

OUTCOME

Medicines, dressings and medical gases are handled in a safe and secure manner.

STANDARD C25

C25.1 Medicines are handled according to the requirements of the Medicines Act 1968 and the Misuse of Drugs Act 1971; nursing staff follow the UKCC Guidelines for the Administration of Medicines, October 2000, or the current published professional guidelines from the Nursing and Midwifery Council (NMC).

C25.2 There is a medicines policy and procedure, accessible to staff, covering all aspects of medicines systems and medical gases in the establishment/agency.

C25.3 Responsibility for obtaining medicines, and safe storage, handling, administration and disposal of medicines, dressings and medical gases rests with the senior pharmacist if there is a pharmacy on site, or if not with the senior nurse. Where a doctor acts as a medical director or similar the responsibilities of each should be clearly laid down in a medicines policy.

C25.4 A record is kept of ordering, receipt, supply, administration and disposal of all medicines dressings and medical gasses in order to maintain an audit trail.

C25.5 Separate lockable storage is provided for:

- controlled drugs;
- medicines for external use;
- medicines for internal use;
- medicines requiring cool storage;
- diagnostic reagents (other than test strips);
- large volume intravenous fluids;
- flammable substances.

C25.6 The keys of all cupboards used for the storage of medicines are held securely, including spare keys.

C25.7 The medicines required for resuscitation in a medical emergency are accessible and in suitable packaging.

C25.8 Medicines requiring cool storage are not kept in refrigerators used for domestic purposes but in a separate, designated refrigerator.
C25.9 There is daily monitoring of the temperature of the refrigerator, which is recorded and signed by the person monitoring the temperature and a written procedure is in place indicating the action to be taken if the temperature is outside the normal range.

C25.10 The disposal of waste is carried out by an authorised contractor who is used to complying with the arrangements for pharmaceutical waste, including cytotoxic waste where appropriate.
Controlled Drugs

OUTCOME

Controlled drugs are stored, administered and destroyed appropriately.

STANDARD C26

C26.1 Controlled drugs are handled in compliance with the requirements of the Misuse of Drugs Act and its regulations.

C26.2 A registered establishment that holds stocks of controlled drugs listed in Schedule 2 of the Misuse of Drugs Act has a Home Office licence (unless the hospital is wholly or mainly maintained by voluntary funds or by a registered charity).

C26.3 Where a pharmacist is employed, the purchase and issue of controlled drugs must be under their direct supervision (including signing orders to suppliers). Where no pharmacist is employed, a doctor or a dentist must countersign orders for supply of controlled drugs signed by the senior nurse.

C26.4 Where no pharmacist is employed, a doctor or a dentist must countersign orders signed by the senior nurse for a controlled drug.

C26.5 Controlled drugs must be stored in a locked cabinet, which complies with the Misuse of Drugs (Safe Custody) Regulations 1973.

C26.6 In the case of Schedule 2 controlled drugs (except those in Schedules 4 and 5) an appropriate record is kept of the invoices, receipt, administration and disposal of the drugs in accordance with the Misuse of Drugs Regulations 1985.

C26.7 Controlled drugs are destroyed in the presence of an authorised person (that is a police officer, an inspector of the Home Office Drugs Branch or an inspector of the Royal Pharmaceutical Society of Great Britain), Or the person to whom this function has been formally delegated, such as the registered manager or registered nurse of the hospital.
Infection Control

OUTCOME

The risk of patients, staff and visitors acquiring a hospital acquired infection is minimised

STANDARD C27

C27.1 Key infection control policies are in place, including:

- universal infection control procedures;
- hand hygiene;
- prevention of occupational exposure to blood borne viruses (BBVs) and post exposure prophylaxis;
- safe handling and disposal of clinical waste;
- housekeeping and cleaning regimes for all patient areas;
- relevant training and access to advice on infection control; and
- occupational health policies for prevention and management of communicable infections in health care workers, including those infected with blood borne viruses.

Medical Devices and Decontamination

OUTCOME

Patients are not treated with contaminated medical devices.

STANDARD C28

C28.1 Medical devices intended for single use are never reused.

C28.2 Re-usable medical devices are decontaminated in accordance with legislative and best practice requirements.
Resuscitation

OUTCOME

Patients are resuscitated appropriately and effectively.

STANDARD C29

C29.1 There is a written resuscitation policy for the establishment/agency, which has been developed in discussion with (as a minimum) the senior clinical staff.

C29.2 The resuscitation policy is brought to the attention of all personnel.

C29.3 There is a member of staff on duty at all times trained in basic resuscitation techniques with up-date training on an annual basis. Where children are cared for or treated at the establishment there should be a member of staff trained in the resuscitation of children.

C29.4 There is sensitive exploration of the wishes of competent patients regarding resuscitation and their wishes are observed.

Contracts

OUTCOME

Contracts ensure that patients receive goods and services of the appropriate quality.

STANDARD C30

C30.1 There are written, dated and signed contracts between the establishment/agency and those organisations or individuals with which it contracts for the supply of, or provision to, goods and services.

C30.2 Contracts include arrangements for the quality monitoring of the services provided under the contract and arrangements to be put in place if the service or goods provided are not of the required quality.
Records and Information Management

Introduction to Standards C31 to C33

Effective keeping and handling of records by independent health care providers across the broad range of their business contributes significantly to the efficient provision of treatment and care. It also helps to ensure that treatment and services can be effectively monitored and audited. There are also legal requirements in relation to records and confidential information that the regulations and standards reflect.

Records management relates to the physical management of a record. As such, it includes the data to be recorded, including sufficient data to permit traceability and allow effective audit, for example identifying what instruments used in a particular operation or which medical devices have been implanted. It also includes the security afforded to the records to ensure that confidentiality is safeguarded.

It is important that providers are required to have in place written policies and procedures in respect of all records, record-keeping and the control of documents. We also think it important to specify that arrangements for the storage of records must be secure. Rather than attempt to reiterate the provisions of the Data Protection Act 1998 through these regulations and standards, the standards simply require the provider to reflect in the establishment’s records management policy how it will meet the provisions of that Act.

Under the general heading of ‘records’ we have included a requirement in regulations to keep a register of patients, births, deaths and of all surgical operations. These are provisions currently in the Nursing Homes and Mental Nursing Homes Regulations 1984 (regulations 7(1) and 7(2)(a)). The requirement for the CSIW to be notified of a death in an establishment within 24 hours remains.

Information management relates to the management of the data contained within the records and includes the confidentiality of such data. We regard it as important that the regulated body has written information management policies with which all those who work within the regulated body are familiar. One of the key elements of any such information management policy is the arrangements needed to ensure the confidentiality of patients’ medical records.

See also, in particular, regulation 20 and Schedule 3 to the Regulations.
Records Management

OUTCOME

Records are created, maintained and stored to standards which meet legal and regulatory compliance and professional practice recommendations.

STANDARD C31

C31.1 The registered person ensures that there is a records policy for the creation, management, handling, storage and destruction of all records that ensures that records are managed, and stored securely, in accordance with the Data Protection Act 1998.

C31.2 Any records that are required to be kept under legislation are retained for the relevant periods prescribed in the legislation.

C31.3 Effective back-up arrangements are in place for handling technical breakdown in information systems and to avoid loss or corruption of information held.

C31.4 Destruction of records is undertaken securely.

C31.5 All health records are stored securely with arrangements in place to protect the records from use by unauthorised persons, damage or loss.

C31.6 There is written information that sets out the responsibilities of nominated post-holders for the up-dating and safekeeping of specific sets of records.
Completion of Health Records

OUTCOME

Patients are assured of appropriately completed health records.

STANDARD C32

C32.1 All entries in patients’ health records by health care professionals are dated, timed and signed, with the signature accompanied by the name and designation of the signatory.

C32.2 All entries in patients’ health records are legible.

C32.3 Any alterations or additions are dated, timed and signed, and made in such a way that the original entry can still be read.

C32.4 All health care professionals working on a patient’s case record all treatment given and recommendations in the patient’s health record.

C32.5 A summary of the patient’s health record is sent to the patient’s GP within a locally agreed timescale, but which is no more than four weeks from date of discharge.

C32.6 When referral is not from the patient’s GP or dentist, the patient is asked to formally sign a form to give or refuse consent for sending details of the treatment provided (the consultant’s discharge letter) to his/her GP.

C32.7 If the patient does not give consent for details to be sent to his/her GP, a summary of the treatment provided is given direct to the patient so that he/she has it for future reference, to pass on to the GP.
Information Management

OUTCOME

Patients are assured that all information is managed within the regulated body to ensure patient confidentiality.

STANDARD C33

C33.1 There is a written information management policy which sets out how the establishment ensures that information held by the establishment on patients, their families and staff is handled confidentially.

C33.2 The information management policy takes account of the:

- Data Protection Act 1998;
- recommendations of the Caldicot Committee report, *Report on the review of patient-identifiable information* (WHC (99)92 refers); and
- guidelines from professional bodies.

C33.3 All those who work within the establishment are familiar and comply with the information management policy.

C33.4 There is information for patients on their right to access their health records, in line with the Data Protection Act 1998.

C33.5 There is a written procedure setting out how to respond to patients’ requests for access to information in the health record.
Introduction to Standard C34

Research is a core component of quality improvement, best value in social care and clinical governance. Research itself must be undertaken within a governance framework. Such a framework has been developed by the Assembly. This framework sets out standards, delivery mechanisms and monitoring arrangements for all research.

In line with this framework, it is important that if any research is conducted by an independent health care establishment the registered person is responsible for developing and promoting a quality research culture and for ensuring that their staff and those who practice in their premises are supported in, and held to account for, the professional conduct of research.

Organisations that employ researchers, including principal investigators, have responsibility for ensuring that those researchers understand and discharge the responsibilities set out for them in the framework. They should also be prepared to take some or all of the responsibility for ensuring that a study is properly managed and for monitoring its progress. The nature of the responsibilities taken on by the organisation should be agreed with the sponsor who has ultimate responsibility for ensuring that appropriate arrangements are in place for the management and monitoring of any study they sponsor.

The registered person should ensure that agreements are in place between them, their staff, those who practice in their premises, who in turn must have agreements with funders and care organisations, about ownership, exploitation and income from any intellectual property that may arise from research conducted.

All organisations providing health care in Wales must be aware of all research being undertaken in their organisation, or drawing on patient or clients (or their data or tissue) from their organisation. In particular a research sponsor willing and able to discharge its responsibilities must be identified, and clear and documented agreements must be in place about the allocation of responsibilities between all parties involved. Accountability for this lies with the registered person. The registered person remains responsible for the quality of all aspects of the care of their patients or users, whether or not they are involved in research and whoever that research may be conducted and funded by.

See also, in particular, regulation 23 of the Regulations.
Research

OUTCOME

Any research conducted in the establishment/agency is carried out with appropriate consent and authorisation from any patients involved, in line with published guidance on the conduct of research projects.

STANDARD C34

C34.1 There is a written policy which states whether or not research is carried out in the establishment.

C34.2 Where the policy states that research is carried out within the establishment, there are written procedures that set out the requirements to be met concerning research projects.

C34.3 All clinical research projects are conducted in accordance with the Assembly research governance framework and the governance arrangements for Research Ethics Committees.

C34.4 There are documented agreements in place for the allocation of responsibilities between all parties involved.

C34.5 The lead professional for each research project is documented.

C34.6 The responsibilities of the lead professional include:

- the management of the research project;
- the monitoring of progress on the project.

C34.7 There are documented agreements in place between the establishment and their personnel and between the establishment and funders about ownership, exploitation and income from any intellectual property that may arise from research conducted on their premises.

C34.8 Records are kept of all research projects, including information about the patients involved, or patients whose data or tissue has been used in the project, for 15 years after the conclusion of the treatment.

C34.9 Informed, lawful consent or authorisation is obtained for the participation of any patient in a research project.

C34.10 The registered person is responsible for ensuring that all research projects undertaken are appropriate for the organisation to be involved in and are properly managed.
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Acute Hospitals

Introduction to Standards A1 to A47

These standards apply to:

- establishments where one or more overnight beds are provided and the main purpose of which is to provide medical treatment for illness (subject to certain exceptions, see regulation 3(2)). This includes private hospitals that provide services for NHS patients;

- other establishments the main purpose of which is to provide medical treatment under anaesthesia and sedation. Establishments where cosmetic surgery takes place.

The standards cover a variety of procedures, settings and services within acute hospitals, through which a common theme runs: there must be assurance about the quality of the treatment and services that patients receive and appropriate safeguards must be in place. To this end, the key elements throughout the standards are that all those who work within acute hospitals must be suitably qualified, training and competent, that the right skill mix of workers for particular clinical services is in place, and that safe and appropriate equipment is used.

Information Provision (standards A1 to A2)

Patients should always be given full details of the treatment they are to receive. It is the duty of the clinicians involved to ensure that all patients have an explanation of the likely outcomes of treatment. This is important in connection with cosmetic surgery, where those seeking treatment may be susceptible to unrealistic expectations of what such surgery can achieve. These standards aim to ensure that the patient is given full and clear information about the treatment being proposed before they make their decision on whether to proceed.

See also, in particular, regulation 36 of the Regulations.

Human Resources (standards A3 to A8)

The standards covering human resources aim to ensure that all those who work in the hospital are suitably qualified, trained and competent. They also address more specific issues such as ensuring that appropriate medical cover is available at all times.
See also, in particular, regulations 17 and 18 of the Regulations.

Risk Management (standards A9 to A13)

*Health and safety:* measures must be in place across the hospital to ensure a safe environment for patients, staff and visitors.

*Infection control:* prevention and control of infection is part of the overall risk management strategy within the hospital environment, and an integral part of the management of antibiotic resistance.

*Decontamination:* the decontamination of reusable medical devices is the combination of processes which, if not correctly undertaken, individually or collectively, will increase the likelihood of micro-organisms being transferred to patients or staff. The decontamination process is required to make medical devices safe for use on the patient and safe for members of staff to handle. The reusable medical device life cycle includes acquisition, cleaning, disinfecting, inspection, packaging, sterilisation, transportation, and storage before use. This cycle is used to render a reusable item safe for further use.

The Health Technical Memoranda (HTMs) and Health Building Notes (HBNs) referred to in these standards are published by NHS Estates and are available from the Stationery Office. Medical Devices Agency Device Bulletins (MDA-DB) are available from the Medical Devices Agency itself. The European Standards (ENs) are obtainable from the British Standards Institution.

*Resuscitation:* decisions concerning resuscitation are a sensitive area of medical practice. One of the basic principles of health care is that a competent patient has the right under common law to give or withhold consent to examination or treatment. Therefore, when competent patients are at risk of cardiac or respiratory failure, or have a terminal illness, there should be sensitive exploration of their wishes regarding resuscitation.

In the case of patients who are not capable of consenting to treatment, and in the absence of a valid advance refusal of treatment, it is a doctor’s duty to act in the best interests of the patient concerned. For some patients this will mean that they should not be subjected to further traumatic or non-beneficial procedures. It is important to respect a valid advance refusal of treatment made by the patient refusing resuscitation if this is applicable to the circumstances. Decisions about when to resuscitate patients are primarily a clinical matter for the doctor responsible for the treatment of the patient concerned. Before making his or her decision, an assessment is made of the patient’s best interests and this assessment should include consultation with other members of the health care team and, where appropriate, family members or others close to the patient.

A decision arrived at in the case of one patient may be inappropriate in a superficially similar case. ‘Do not resuscitate’ decisions should therefore be reached on a case by case basis. Thus a blanket ‘do not resuscitate’ policy based on a specific patient group would not be acceptable. Department of Health guidance...
Resuscitation Policy (HSC 2000/28) reinforces patients’ rights on resuscitation decisions and aims to ensure that patients are properly involved.

See also, in particular, regulations 8 and 34 of the Regulations.

Children’s Services (standards A14 to A20)

Children are treated relatively infrequently in independent acute hospitals and, apart from hospitals with dedicated paediatric units, should only be admitted for day case or overnight surgical care. Children requiring anaesthesia need specially trained staff and appropriate facilities. Children with pre-existing medical conditions requiring intervention, both acute episodes and planned (elective) intervention, require the comprehensive services of a dedicated paediatric unit, with paediatric medical and paediatric nursing staff on duty at all times, and should not be treated outside these facilities. Children who become unwell, unstable or who develop complications as a result of planned surgery, should be immediately transferred to a paediatric unit. Formal transfer arrangements should be made in advance and defined in policy.

Surgery (standards A21 to A30)

A large amount of the clinical work carried out in independent acute hospitals is surgery. The standards reflect the need for suitably qualified, trained and competent health care professionals, the appropriate equipment, and for documented procedures for operating theatres to be in place in order to ensure that surgical procedures are safe and quality-assured.

Dental surgery under general anaesthesia: in recent years there have been a number of well-publicised deaths, including of children, following general anaesthesia administered for dental treatment. Following a review led by the Chief Medical Officer and Chief Dental Officer, from 2002 all such general anaesthesia must be provided in a hospital setting with critical care facilities. The standards set out are those considered to be necessary to allow this procedure, and all other treatment under general anaesthesia, to be carried out safely to modern day standards

Cardiac surgery: some 20% of all coronary bypass surgery takes place in the independent acute sector. For this reason, and because of the specialist nature of this surgery (in respect of the skills of the operator and specialist equipment required), a specific set of standards is included for these procedures.
Cardiac surgery may involve adult, paediatric and neonatal patients and includes all forms of open and closed heart surgery. Coronary revascularisation is a major intervention with risks as well as benefits. It is never undertaken lightly and each and every patient requires careful consideration. The cardiac surgery standards therefore make reference to the standards, set out in the National Service Framework for Coronary Heart Disease, on the numbers of procedures that must be performed annually by the individual trained operator (taking account of the work the individual practitioner carries out both in NHS facilities and in independent hospitals).

**Cosmetic plastic surgery:** plastic surgery is the general term describing surgery performed to correct a problem caused by other surgery or to create a more pleasing appearance for whatever reason. Cosmetic plastic surgery is the specialisation that focuses on improved appearance for its own sake. It includes procedures such as breast augmentation, face lifts, ear correction, facial implants and fat reduction.

The majority of cosmetic plastic surgery procedures are performed in the independent sector. There is, therefore, a specific set of standards that apply to those procedures.

**Transplantation:** most transplantation is carried out in the NHS because of the constraints of organ availability, the huge expense and complexity of the procedures and the resources needed. However, some kidney transplants are undertaken in private hospitals mostly using a related live donor, or cadaver kidneys for which the NHS is unable to find a use.

The standards reflect that transplantation is regulated by the Human Organ Transplants Act 1989. This prohibits commercial dealings in human organs for transplant and restricts the transplanting of organs between people who are not genetically related. The Act also requires information about the removal and the use/disposal of transplanted organs to be sent to the Special Health Authority, UK Transplant.

See also, in particular, regulations 32 and 36–37 of the Regulations.

**Critical Care (standards A31 to A32)**

Some patients in independent acute hospitals may require critical care. Where the hospitals are carrying out complex operations, such as cardiac surgery or transplantation, there must be critical care beds available for patients post-operatively in those hospitals. In other cases, post-operative complications may mean that a patient requires critical care support. The standards provide for the hospital to have made the necessary arrangements so that critical care can be provided as needed in the establishment. Or, that arrangements must be in place with a provider of a higher level of critical care, so that patients can be transferred to appropriate facilities as necessary. Critical care provision by independent hospitals in Wales should be informed by the good practice contained in the Department of Health 'Review of Adult Critical Care Services', May 2000.
Radiology (standards A33 to A34)

The use of ionising radiation in health care is regulated through a range of legislative measures that implement Euratom Directives to protect employees, the public and patients. This legislation applies equally to the NHS and to the acute independent sector and is enforced by a number of inspectorates including those from the Health and Safety Executive and the Environment Agency. Legislation listed in these standards is that which has a primary impact on patient welfare.

Pharmacy (standards A35 to A41)

Existing legislation applying to drugs and medicines includes the Medicines Act 1968 and subordinate legislation, Misuse of Drugs Act 1971 and regulations made thereunder, the Data Protection Act 1998 and the Consumer Protection Act 1987. Hospitals need to be familiar with, and observe, the statutory requirements and make adequate arrangements concerning Controlled Drugs, Prescription Only Medicines, Pharmacy Only and General Sales List medicines held and administered in the hospital.

Apart from the CSIW there are other inspectorates with rights of access to pharmacies in independent sector hospitals. Royal Pharmaceutical Society of Great Britain inspectors have the authority to inspect all registered pharmacy premises including those in independent hospitals to ensure that they meet the basic legal requirements. Home Office drugs inspectors have the authority to inspect private hospitals, which hold controlled drugs. Medicines Control Agency inspection and enforcement officers have a duty to investigate any breaches or suspected breaches of the Medicines Act.

Pathology Services (standards A42 to A45)

The quality of pathology services is maintained in three main ways – accreditation of pathology laboratories, state registration of scientific officers and clinical scientists, and underpinning training programmes. Accreditation of pathology laboratories should be to Clinical Pathology Accreditation (UK) Ltd (CPA) standard or equivalent.

Pathology services may, in whole or in part, be carried out in the hospital, by contract with the laboratory service of a NHS hospital, by contract with another independent hospital or commercial provider or by a combination of these arrangements.

See also, in particular, regulation 33 of the Regulations.
Cancer Services (standards A46 to A47)

The majority of cancer services are delivered in the NHS but some cancer patients may have part of their course of treatment in independent hospitals. The standards reflect the need for services in the independent sector to reflect the requirements set out in the National Service Framework for cancer services where these relate to chemotherapy and radiotherapy.

Information Provision

Information for Patients

OUTCOME

Patients receive clear information about their treatment.

STANDARD A1

A1.1 Information materials for patients are written in concise, plain language and explain in non-technical language what the procedure involves.

A1.2 Published information for patients is made available for them to take away after the first consultation about the relevant surgery or treatment.

A1.3 The published information given at the consultation includes information regarding general and procedure-specific risks and complications associated with the surgery or other treatment.

A1.4 Documented post-operative instructions are given to patients to take home after the procedure/operation.

A1.5 Patient information materials are agreed by the registered person before being published and made available to patients.
Advertising

OUTCOME

Patients are not misled by adverts about the hospital and the treatments it provides.

STANDARD A2

A2.1 All advertising complies with Advertising Standards Authority standards and the BMA Guidelines for Advertising where applicable.

A2.2 Advertisements do not offer discounts linked to a deadline date for booking appointments, or other date-linked incentives.

A2.3 Promotional events such as open evenings do not include financial incentives for potential patients to book a consultation appointment at the event.

A2.4 All staff and speakers at promotional events are to be clearly identified with regard to their profession and role within the organisation.

Human Resources

Qualifications of All Medical Practitioners

OUTCOME

Patients receive treatment from appropriately trained, qualified and insured medical practitioners.

STANDARD A3

A3.1 All medical practitioners (ie including medical practitioners undertaking independent private practice whether employed, contracted or self employed providing health screening or resident medical officer services on behalf of and as part of the hospital) are registered with the General Medical Council as medical practitioners.

A3.2 All medical practitioners have annual appraisals and are revalidated in line with GMC requirements.

A3.3 All medical practitioners are covered by appropriate professional indemnity insurance either as specifically identified employees of the hospital through the policies of insurance maintained by the hospital or as members of a medical defence organisation approved by the hospital and its insurers.
A3.4 All medical practitioners provide the registered person with, and make available to the CSIW, the following clinical and performance indicators about any patient they have treated:

- any deaths at the hospital;
- unplanned re-admissions to the hospital;
- unplanned returns to theatre;
- unplanned transfers to other hospitals;
- adverse clinical incidents;
- incidence of post-operative deep vein thrombosis;
- post-operative infection rates for the hospital.

Qualifications and Experience of Medical Practitioners Undertaking Independent Private Practice (ie without supervision, commonly known as “consultants”)

OUTCOME

Medical practitioners who work independently in private practice are competent in the procedures they undertake and the treatment and services they provide

STANDARD A4

A4.1 Medical practitioners who work independently in private practice:

- Clearly demonstrate that they have the necessary qualifications, expertise and experience to undertake competently and safely the treatment and services they provide; and
- Have arrangements in place for continuing medical education relevant to the treatment and services they provide.

A4.2 Medical practitioners who work independently in private practice (except GPs):

- are on the specialist register of the General Medical Council; or
- where they were undertaking cosmetic surgery in the independent health care sector before 1 April 2002 and are not on the specialist register, satisfy the following conditions:
  - have completed recognised basic surgical or medical training;
  - have undertaken specialist training in a speciality relevant to the procedures they provide;
  - maintain a record of patients to whom they have provided treatment or services in the establishment, which is made available to the registered person and to the CSIW;
- undertake regular patient satisfaction surveys, a record of which is made available to the registered person and the CSIW at least annually.

A4.3 Medical practitioners undertaking cosmetic surgery independently in private practice for the first time from 1 April 2002 are on the specialist register of the General Medical Council.

Practising Privileges and the Medical Advisory Committee

OUTCOME

Patients receive treatment from medical consultants who have the appropriate expertise.

STANDARD A5

A5.1 Where medical practitioners are granted practising privileges there is a medical advisory committee for the hospital, which is responsible for representing the professional needs and views of consultants to the registered manager of the hospital.

A5.2 The medical advisory committee meets quarterly as a minimum and formal minutes are kept of meetings.

A5.3 The medical advisory committee makes recommendations to the registered manager on:

- eligibility criteria for practising privileges;
- each application for practising privileges;
- the review and possible restriction or withdrawal of practising privileges;
- the introduction of new clinical techniques to the hospital, including the training requirements for medical consultants to undertake the technique, the equipment required and the training/experience required by other clinical staff to support the technique(s).

A5.4 The medical advisory committee reviews twice per year as a minimum, information collated on the clinical work undertaken at the hospital by all practitioners with practising privileges by speciality, procedure and by clinical responsibility, to include as a minimum:

- any deaths at the hospital;
- unplanned re-admissions to hospital;
- unplanned returns to theatre;
- transfers to other hospitals;
• adverse clinical incidents;
• incidence of post operative deep vein thrombosis;
• post operative infection rates for the hospital.

Resident Medical Officers

OUTCOME

Patients have an appropriately skilled and trained doctor available to them at all times within the hospital.

STANDARD A6

A6.1 Where the establishment provides in-patient care there is a resident medical officer available on immediate call at all times to manage urgent patient care in the absence of the consultant under whom the patient is admitted.

A6.2 Resident medical officers have post-registration clinical experience relevant to the clinical work undertaken in the hospital.

A6.3 Resident medical officers undertake a formal induction programme, the content of which is documented.

A6.4 Resident medical officers are trained in resuscitation to Advanced Life Support level, including defibrillation and incubation skills, which is up-dated annually.

A6.5 Where the hospital admits children the resident medical officer is trained in paediatric Advanced Life Support, which is updated annually.

A6.6 There is a written job description for the resident medical officer which includes the line management arrangements for the post and the hours on-call and shift patterns.

A6.7 Resident medical officers have access to advice and support at all times from medical consultants with practising privileges and the communication arrangements are documented.

A6.8 The accommodation for resident medical officers, while on-call, is sited within easy reach of the areas in which patients are cared for.

A6.9 The resident medical officer’s on-call accommodation has a telephone connected to the hospital’s internal telephone system.
**Allied Health Professions**

**OUTCOME**

Patients receive treatment from appropriately skilled and qualified members of the allied health professions.

**STANDARD A7**

A7.1 Patients requiring consultation with, or treatment from, a member of one of the allied health professions are seen by a practitioner who is registered with the Health Professions Council (the Council for Professions Supplementary to Medicine until 2002).

A7.2 Practitioners registered with the Health Professions Council comply with their professional body’s code of practice/rules of professional conduct and standards of practice/care in consulting with and treating patients.

A7.3 There are written policies for the arrangements for out-of-hours cover for appropriate allied health professionals.

A7.4 Members of the allied health professions work as members of a multi-professional team caring for patients.

A7.5 Allied health professionals participate in multi-professional activities such as case conferences, ward rounds and individual patient care meetings.

A7.6 Each patient referred to allied health professionals has a care plan for the treatment to be delivered.

**Training, Experience and Qualifications of Staff**

**OUTCOME**

Patients receive treatment from appropriately qualified and trained staff.

**STANDARD A8**

A8.1 The registered person ensures that clinical staff are qualified and trained for the roles they undertake.

A8.2 Resuscitation training is mandatory for all clinical staff, and is in line with current Resuscitation Council (UK) publications.

A8.3 Simulation exercises are undertaken to familiarise staff with emergency care.
A8.4 Clinical staff must be subject to on-going education in the techniques and skills relevant to the clinical area in which they work and the procedures they are undertaking.

A8.5 All staff using equipment must have completed training in the safe clinical use of the equipment.

A8.6 All clinical staff are subject to continuous professional development and demonstrate that they meet the requirements for professional registration, such as revalidation.

A8.7 There is a programme of ongoing education for all staff, including update of policies, feedback of audit results and action needed to correct deficiencies.

A8.8 Education and training in infection control and decontamination is provided to all staff, including those employed in support services.

A8.9 Infection control is included in induction programmes for new staff, including support service staff.

A8.10 Medical consultants and where relevant other medical practitioners involved in prescribing, are able to demonstrate that they receive training in infection control and antimicrobial prescribing as part of their continuing professional development (CPD).

A8.11 Decontamination issues are included in induction programmes and ongoing education for all staff.

Risk Management

Health and Safety

OUTCOME

Patients, staff and anyone visiting the hospital are assured that all steps are taken to ensure the safety of the hospital environment through the ongoing assessment and management of risks, in relation to all the hospital’s activities.

STANDARD A9

A9.1 Arrangements are in place for obtaining competent health and safety advice.

A9.2 An annual health and safety report is produced in respect of the regulated setting. The report summarises the actions taken to ensure a safe, healthy environment, including, for example, training given to staff, risk assessments undertaken and action taken as a result, and an outline plan for health and safety actions to be implemented in the year ahead.
Infection Control

OUTCOME

The risk of patients, staff and visitors acquiring a health care associated infection is minimised.

STANDARD A10

A10.1 There is an appropriately functioning infection control team (ICT), either within the hospital or in another organisation to which the hospital has formal links and membership of the infection control team of that organisation.

A10.2 The membership of the ICT includes:
   • an infection control doctor (ICD);
   • an infection control nurse; and
   • a consultant medical microbiologist if the ICD is from another speciality.

A10.3 The responsibilities for infection control of each member of the ICT are included in documented job descriptions and there is a defined time commitment for infection control activities.

A10.4 Members of the ICT receive training in infection control and provide evidence of continuing professional development (CPD) in relation to the role in infection control.

A10.5 The ICT liaises closely with hospital occupational health department(s) when dealing with:
   • infection control advice relating to the health and safety of health care workers;
   • infection control advice relating to the transmission of infection from health care workers to patients or other members of the organisation’s staff and visitors.

A10.6 The ICT liaises with the local consultant in communicable disease control:
   • when dealing with outbreaks within the hospital;
   • in order to be kept informed of infection outbreaks in other local settings; and
   • in order to be kept informed of areas of work requiring the involvement of environmental health officers.

A10.7 Prevention and control of infection are considered as part of all service development activity.

A10.8 Infection control advice is provided by the ICT, particularly in relation to the following:
• the development of policies relating to engineering and building services for the hospital and to the purchase of medical devices/equipment;
• early stage planning for advice relating to engineering and building works and the purchase of medical devices/equipment;
• all stages of the contracting process for services, which have implications for infection control, for example, housekeeping, laundry, clinical waste.

A10.9 Written policies, procedures and guidance for the prevention and control of infection are implemented and reflect relevant legislation and published professional guidance.

A10.10 Each department or service has a current copy of the approved policies, procedures and guidelines pertinent to its activities.

A10.11 Key policies are in place, including:
• universal infection control precautions;
• handwashing;
• major outbreaks of communicable infections;
• isolation of patients;
• prevention of occupational exposure to blood borne viruses (BBVs) and post exposure prophylaxis;
• antimicrobial prescribing;
• control of MRSA, VRE and other antimicrobial resistant micro-organisms;
• control of tuberculosis, including multi-drug resistant tuberculosis;
• safe handling and disposal of clinical waste;
• single use and single patient use devices and other health care products;
• decontamination and reprocessing of re-usable medical devices;
• ward closure;
• collection, packaging, handling and delivery of laboratory specimens;
• occupational health policies for prevention and management of communicable infections in health care workers, including those infected with blood borne viruses;
• handling of medical devices in procedures carried out on known/suspect CJD patients and on patients in risk categories for CJD as defined in the ACDP/SEAC guidance (including disposal/quarantining procedures).

A10.12 The ICT has access to up-to-date legislation and guidance relevant to infection control.

A10.13 Timely and effective specialist microbiological support is provided for the infection control service, including the interpretation of results, either on-site or via reference centres.
A10.14 The microbiology laboratory used supports the infection control service via processing, data provision, surveillance and specialist testing.

**Decontamination**

**OUTCOME**

Patients are not infected by contaminated medical devices.

**STANDARD A11**

A11.1 Clear lines of accountability for all parts of the decontamination cycle are established, defining the relationships between all those who work in/for the establishment/agency, the ICT and senior management.

A11.2 The lines of accountability include contractors and professional liability where the organisation either buys in or sells services to other organisations.

A11.3 An annual report on the efficacy of the decontamination process is submitted through the ICT to senior management.

A11.4 Written policies and procedures define, document and control all stages of the decontamination process.

A11.5 The written policies and procedures are available for all personnel involved in any aspect of decontamination.

A11.6 All personnel involved in decontamination processes have access to up-to-date legislation and guidance.

A11.7 The following issues are addressed in the training of clinical staff:

- the correct and safe method of washing instruments manually;
- in the operation of benchtop sterilizers if in use;
- graphical symbols described in EN 980.

A11.8 All contaminated reusable medical devices are handled, collected and transported to the decontamination area in a manner that avoids the risk of contamination to patients, personnel and any area of the health care facility.

A11.9 Staff are trained to handle, collect and transport contaminated medical devices/equipment safely and wear protective clothing in accordance with local safety policies and procedures.

A11.10 Cleaning, disinfecting, storage and use of flexible or rigid endoscopes are undertaken in accordance with MDA DB 9607. A11.11 Reusable medical devices are reprocessed in a sterile service department.
A11.12 Devices are cleaned in accordance with the manufacturer’s instructions.

A11.13 Mechanical washer-disinfectors are specified, commissioned and monitored in accordance with BS 2745 and HTM 2030.

A11.14 Controlled detergents are used in accordance with material safety data sheets.

A11.15 Sterile service department sterilizers are validated, maintained and managed according to HTM 2010 and HTM 2031.


A11.17 A bench top steam sterilizer is used only in exceptional circumstances, is suitable for intended loads, and is validated, maintained and operated in accordance with the manufacturers instructions.

A11.18 There is a post sterilization drying stage if sterilized items are to be stored for future use, which includes the inspection of packages and wrapped items to ensure that they are dry when they are removed from the sterilizer.

A11.19 Manual cleaning is only undertaken in unavoidable circumstances and there is written procedure to be followed.

A11.20 Ethylene oxide sterilizer installations meet HBN 13 Supplement 1. Ethylene oxide sterilizers are validated, maintained and managed according to HTM 2010.

A11.21 Personnel are only exposed to ethylene oxide for as short a time as possible and in no circumstances exceed the maximum exposure time limits set out in Schedule 1 of the Control of Substances Hazardous to Health (COSHH) Regulations.

A11.22 All medical devices, decontamination equipment and surfaces used on a patient known to have or suspected of having CJD, or in a risk category for CJD, are dealt with in accordance with guidance published in Transmissible Spongiform Encephalopathy Agents. Safe Working and the Prevention of Infection (ACDP/SEAC) and WHC (99)158.

A11.23 Every location in which the decontamination of reusable medical devices is carried out meets the conditions defined in EN 724, HTM 2010, HTM 2030 and HBN 13, and includes the conditions defined in all relevant statutory advice including MDD registration 93/42/EEC, Health and Safety at Work Act 1974, Consumer Protection Act 1987, COSHH, Institute of Sterile Services Management, NHS Estates (2000) Coming Clean.

A11.24 Sterile service department facilities meet the requirements for the segregation of clean and dirty activities set out in HBN 13 and ISSM 2000.
A11.25 All personnel entering and leaving the clean production area:

- do so through a dedicated entrance/exit;
- thoroughly wash and dry hands on entry and exit;
- wear appropriate clothing whilst in the area.

**Resuscitation**

**OUTCOME**

Patients are resuscitated appropriately.

**STANDARD A12**

A12.1 The registered person must ensure that patients’ rights are central to decision making on resuscitation, including taking account of advance directives (living wills).

A12.2 The resuscitation policy makes specific reference to the decision-making and management of ‘do not resuscitate’ situations for critically ill patients.

A12.3 There is a written procedure for the steps to be undertaken in reaching a decision to withdraw treatment.

A12.4 All ‘do not resuscitate decisions’ are documented, with the reason and date for review in the patients health record.

A12.5 The policy includes appropriate supervision arrangements to review resuscitation decisions.

A12.6 Clinical staff with a thorough understanding of the resuscitation policy and its application are on duty at all times and available to make resuscitation decisions.

A12.7 There must be at least one person with Advanced Life Support (ALS) training, which is subject to annual updating, on duty at all times. This may be the RMO.

A12.8 Where children are admitted for treatment there must be at least one person with Paediatric Advanced Life Support (PALS) training, which is updated annually, on duty at all times. This may be the RMO. (for child in patients see A 14.11)

A12.9 Resuscitation drills are practised once every two months by members of the emergency resuscitation team.

A12.10 Induction and staff development programmes cover the resuscitation policy.
A12.11 Clinical practice in the area of resuscitation and the operation of the resuscitation policy is audited at least every three years.

### Resuscitation Equipment

**OUTCOME**

Appropriate resuscitation equipment is in place.

**STANDARD A13**

A13.1 There is resuscitation equipment readily available.

A13.2 Equipment for resuscitating patients includes:

- a defibrillator;
- portable oxygen with appropriate valves, masks, metering and delivery system;
- first line resuscitation drugs
- equipment for maintaining and securing the airway of a patient, and
- that necessary to insert and maintain intravenous infusions.

A13.3 Resuscitation equipment is checked and restocked to ensure all equipment remains in working order and suitable for use at all times, and checks are recorded with the person’s signature. Checks are to be carried out daily.

A13.4 Resuscitation equipment is cleaned and decontaminated after each usage, including practice use

A13.5 A written record is kept of the resuscitation equipment to be kept available in each area of the establishment.

A13.6 Resuscitation equipment is easily accessible and staff are aware of its location.

A13.7 During induction all staff are made aware of the location of the resuscitation equipment.
Children’s Services

Meeting the Psychological and Social Needs of Children

OUTCOME

The non-clinical needs of children are recognised and addressed.

STANDARD A14

A14.1 There is a pre-planned programme and the opportunity for a pre-admission visit to allay anxiety on the part of the child.

A14.2 There is information, specifically written for children and young people about their treatment and care in the hospital.

A14.3 The special needs of, and specific services for, children from different ethnic, cultural or religious backgrounds are reflected in local policies, as appropriate to the patient population.

A14.4 Children are kept in hospital only if their needs cannot be met at home, and they are discharged as soon as possible.

Staff Qualifications, Training and Availability to Meet the Needs of Children

OUTCOME

Children receive treatment from appropriately trained and qualified health care professionals.

STANDARD A15

A15.1 There is a written admission policy for children, which identifies the criteria for paediatric admissions for which the hospital has the relevant services, facilities and trained personnel.

A15.2 There is at least one registered nurse who holds a qualification in the care of sick children, either a Registered Sick Children’s Nurse (RSCN) or Registered Nurse (RN) Child Branch certificate, on duty at all times whenever children under the age of 16 are being treated or cared for.

A15.3 Where the hospital operates a separate children’s department or ward, there are at least two such qualified nurses on duty at all times.

A15.4 Children under three years of age are only accepted in a unit with children’s nurses, holding one of the above qualifications and paediatric medical staff on duty at all times during the admission of the child.
A15.5 Links with other children’s nurses either within the independent sector or with local NHS providers are encouraged and educational programme opportunities are developed and shared.

A15.6 The qualified children’s nurse is responsible for planning the child’s nursing care needs and completing a written record of the care plan, and for negotiating routine care with the family.

A15.7 Surgical lists to include children under the age of 12, or adolescents under the age of 16, are planned in consultation with the senior nurse to ensure that qualified children’s nurses are on-duty on the appropriate shifts.

A15.8 A lead children’s nurse is responsible for policies and protocols that are child based and family friendly, and audits paediatric care in line with the policies and protocols on a regular basis.

A15.9 Children under the age of three who carry additional surgical and anaesthesia risks are only cared for by surgeons and anaesthetists experienced in the clinical care of young children and by registered children’s nurses.

A15.10 Surgeons, anaesthetists and other staff do not undertake acute paediatric procedures only on an occasional basis, and services must comply with guidance issued by the Paediatric Forum of The Royal College of Surgeons of England Children’s Surgery – A First Class Service (May 2000).

A15.11 Every child is placed under the care of a named consultant. In addition, when children are admitted as in-patients there is a resident medical officer on duty at all times who has a minimum of six months recent paediatric experience and an accredited Paediatric Advanced Life Support certificate.

A15.12 Anaesthesia for children under the age of 12 is provided by a paediatric anaesthetist with specialist training in paediatric anaesthesia.

A15.13 There is a nominated lead consultant responsible for the oversight and organisation of all anaesthesia services for children in the hospital, including pain and resuscitation services, and for ensuring that suitable equipment, including paediatric resuscitation equipment, is purchased and maintained.

A15.14 Registered nurses and operating department practitioners with paediatric training are available at all times to assist the anaesthetist.

A15.15 Recovery staff have training and experience to ensure safe post-operative care of children.
Facilities and Equipment to Meet the Needs of Children

OUTCOME

Children’s treatment is provided with the appropriate facilities and equipment.

STANDARD A16

A16.1 Children are seen in a separate outpatient area, or where the hospital does not have a separate outpatient area for children they are seen promptly and preferably at the beginning of the session.

A16.2 The outpatient area is subject to the same environmental audit as any other area used for children to ensure that the area is safe, with any identified risks to children controlled.

A16.3 Toys and/or books suitable to the child’s age are provided.

A16.4 Children requiring anaesthesia or sedation are to be admitted to a bed and not treated in outpatients.

A16.5 All children are admitted to a single room or to one shared with other children only. An environmental risk assessment is performed to ensure the child’s safety.

A16.6 Children under the age of 12 are supervised in their rooms at all times either by hospital staff or by their parents.

A16.7 On admission children are carefully weighed with minimal clothing to allow for accurate calculation of drugs. Dual checking is recommended for the weighing of small children.

A16.8 There are segregated areas for the reception of children and adolescents into theatre and for recovery, to screen the children and adolescents from adult patients; the segregated areas contain all necessary equipment for the care of children.

A16.9 A parent is to be actively encouraged to stay at all times, with accommodation made available for the adult in the child’s room or close by.

A16.10 The child’s family is allowed to visit him/her at any time of the day, except when in individual circumstances a decision is made by the clinical team that visiting should be restricted.

A16.11 Adolescents are to have their privacy respected, and every effort is made to respect their wishes if they indicate they prefer to be seen without their parents.

A16.12 The toys provided are safe (compliant with British Safety Standards), and are age appropriate to the child.
When a child is in hospital for more than five days, play is managed and supervised by a qualified Hospital Play Specialist.

Children are required to receive education when in hospital for more than five days; the Local Education Authority has an obligation to meet this need and are to be contacted if necessary.

**Valid Consent of Children**

**OUTCOME**

Children and their families are fully aware of, and are asked to consent to, the treatment they are to receive.

**STANDARD A17**

A17.1 Clinicians speak with children and their families to ensure that children are fully aware of the treatment they are to receive.

A17.2 A parent can give permission for treatment but the child is to be told what is happening in language appropriate to his/her level of understanding.

A17.3 The doctor obtaining consent ensures that sufficient time is allowed to explain to the parent and child the proposed procedure and allow both the opportunity to ask questions.

A17.4 Older children and adolescents are able to express their wish to refuse treatment and have their concerns listened to.

A17.5 Where a child’s refusal for treatment is being overruled, it is done so on the basis that the welfare of the child is paramount and every effort is made to obtain his/her co-operation in these circumstances.

A17.6 The right of a young person over the age of 16 years to sign his/her own consent form is recognised.

A17.7 Written consent for per rectum medication has to be given when general anaesthesia is to be administered, and is recorded in the child’s health record.
Meeting Children’s Needs During Surgery

OUTCOME

Children receive appropriate treatment in connection with surgery.

STANDARD A18

A18.1 Prior to surgery children are left without food or drink for as short a time as possible, in consultation with the anaesthetist.

A18.2 Clear fluids are not withheld for more than two or three hours prior to surgery.

A18.3 The use of pre-medications, and intra-muscular injections in particular, in minor or day case surgery is exceptional and these are recorded.

A18.4 The child is subjected to the least amount of pain as possible during intravenous cannulation and blood sampling, through the use of local anaesthetic cream prior to the procedure.

A18.5 Where child exclusive lists are not used, children and adolescents are operated on at the beginning of the list to assess starvation times accurately and to avoid contact with adult patients.

A18.6 The child’s named nurse and a parent accompany the child to theatre. The parent(s) is given the option of being present until the child is asleep.

A18.7 A children’s nurse collects the child, if under the age of 12, from the recovery area. The parent(s) is given the option of accompanying the child from the recovery area.
Pain Management for Children

OUTCOME

Children receive appropriate pain relief.

STANDARD A19

A19.1 There are written procedures for the assessment of pain in children and the provision of appropriate control.

A19.2 A child's pain is assessed in partnership with the family, who know what is normal behaviour for their child, and by using a recognised pain assessment tool.

A19.3 Analgesia is given by an appropriate route, avoiding the intramuscular route.

A19.4 Provision is made for adequate analgesia on discharge of the child in discussion with the family.

Transfer of Children

OUTCOME

In emergencies, children are transferred quickly and safely to paediatric units.

STANDARD A20

A20.1 There is a documented policy for a child who becomes unwell, unstable or who develops complications as a result of planned surgery to be immediately transferred to a paediatric unit.

A20.2 Contingency emergency transfer arrangements are documented and agreed in advance with the paediatric unit.

A20.3 All staff caring for children are trained in paediatric resuscitation. Specialised paediatric resuscitation equipment is in place and the same system used for wards and theatres.

A20.4 Simulation exercises are undertaken to familiarise staff with emergency paediatric care.
Surgery (including dental treatment under general anaesthesia)

Documented Procedures for Surgery – General

OUTCOME

Patients are assured that effective procedures for surgery are in place.

STANDARD A21

A21.1 There are written policies and procedures for the carrying out of surgical operations, covering staffing arrangements, equipment, installations, facilities and theatre practice.

A21.2 There are written policies and procedures for preventing the transmission of infection for all patients and venous thromboembolism.

A21.3 A system is in place to identify a formal planned schedule of operating sessions for elective surgery, which includes a system of inter-disciplinary consultation when changes to schedules are required. In addition, the theatre manager must have the right of veto.

A21.4 There are written procedures for:

- patient identification;
- verification and site of the operation;
- checking pre-operative shaves, false teeth and crowns;
- checking pre-operative tests such as radiographs, ECGs and others as may be required.

A21.5 There are written procedures for the counting of items such as swabs, needles, operative instruments and blades, and what to do if items cannot be accounted for.

A21.6 The full details, including batch numbers and/or serial numbers, of all implanted medical devices are recorded to allow subsequent identification. The information is recorded both in the patient’s individual records and on a master list held in the operating theatre department.

A21.7 Entries in the surgical register are validated as follows:

- person is nominated to enter information in the register and signs it to confirm that the entries are accurate;
- the nurse responsible for checking swabs, needles and equipment signs the register;
• a secondary checking of swabs, needles and equipment is undertaken and the register is signed by the person carrying out those checks.

Documented Procedures for Surgery – Patient Care

OUTCOME

The procedures for surgery assure patients of safe and effective treatment.

STANDARD A22

A22.1 There are written pre-operative policies and procedures, which include unambiguous instructions to patients on:

• fasting;
• medication;
• escorts;
• transport arrangements;
• contact details for patient’s queries, such as telephone and fax numbers and e-mail address.

A22.2 There are written policies and procedures for assessing the patient’s fitness for treatment, including:

• how pre-operative medical condition(s) are brought to the attention of both the anaesthetist and surgeon;
• how the patient’s medical practitioner is consulted prior to the date of the procedure being undertaken.

A22.3 Pre-operative medical condition(s) are recorded.

A22.4 The person undertaking the surgical procedure ensures that the patient has given valid consent for the proposed surgery and/or anaesthesia and ensures relevant consent forms are signed.

A22.5 There are written pre operative procedures covering:

• the appropriate positioning of the patient on the operating table;
• the protection of the patient from diathermy burns; and
• the protection of the patient from laser and radiation risks, as appropriate.

A22.6 There are written post-operative policies and procedures, which include instructions for the patient on:

• pain relief;
• bleeding;
• care of the post-operative site;
• how the effects of general anaesthesia may impair their judgement and that they should refrain from certain activities such as driving, operating machinery or signing legal documents;
• a telephone contact number.

A22.7 There are written policies for discharge which require:
• that an appropriate medical practitioner is responsible for discharging the patient;
• procedures for assessing the patient's fitness for discharge and the criteria for that decision;
• the discharged patient to be accompanied home by a responsible adult.

A22.8 When the referral for surgery is not from the patient's GP or dentist, the patient is asked to formally sign a form to give or refuse consent for sending details of the treatment provided (the consultant's discharge letter) to his/her GP.

A22.9 Details are sent to the patient's GP within a locally agreed timescale, but which is no more than four weeks from date of discharge.

A22.10 If the patient does not give consent for details to be sent to his/her GP, a summary of the treatment provided is given direct to the patient so that he/she has it for future reference, to pass on to the GP.

A22.11 There are written procedures for staff to follow when requesting donor organs from the family of a deceased patient.

A22.12 Staff are trained in how to approach family members with regard to organ donation.
Anaesthesia and Recovery

OUTCOME

Patients receive the appropriate level of care when receiving surgical treatment.

STANDARD A23

A23.1 The anaesthetist, who is to give the anaesthetic, visits the patient before the operation and assesses the general medical fitness of the patient, reviews any medication being taken, and assesses any specific anaesthesia problems.

A23.2 The anaesthetist discusses possible plans of management with the patient and explains any options available, to enable the patient to make an informed choice.

A23.3 Information on any drugs or treatments such as blood transfusion to be given while under general anaesthesia is discussed with the patient.

A23.4 The anaesthetist develops an individualised plan of care to be received by the patient prior to, during, and following the anaesthetic which reflects the assessment of the patients condition and which includes the choice of anaesthetic technique and the post-operative management.

A23.5 The anaesthetist records the results of the pre-operative consultation.

A23.6 The person undertaking the surgical procedure ensures that the patient has given valid consent for the proposed surgery and/or anaesthesia and ensures the relevant consent forms are signed.

A23.7 The anaesthetist ensures that all the necessary equipment and drugs are present and checked before starting anaesthesia.

A23.8 The anaesthetist confirms the identity of the patient and ensures valid consent to anaesthesia and surgery before inducing anaesthesia.

A23.9 The anaesthetist is present in the operating theatre throughout the operation and is present on site until the patient has been discharged from the recovery room.

A23.10 The conduct of the anaesthesia and operation is monitored and recorded in line with the minimum monitoring standards document of the Association of Anaesthetists for Great Britain and Ireland:

- by a continuous display of the ECG;
- pulse oximetry;
- arterial pressure must be recorded, at a minimum of 5 minute intervals;
• where the patient breathes an artificial gas mixture, the inspired oxygen concentration is measured;
• a written or printed record of the anaesthetic is kept as a permanent record in the case notes.

A23.11 Until patients regain full consciousness following anaesthesia and surgery they are closely observed by appropriately trained staff on a one-to-one basis; the staff member must not double up as the person-in-charge of the operating theatre.

A23.12 During the recovery period, nursing care is provided to monitor the patient's condition, for example the respiratory state, the cardiac system, for gastroenterology and urology where catheters and drains are used, and for orthopaedics in relation to drainage and skin conditions.

A23.13 Pain is assessed in discussion with the patient and pain control provided.

A23.14 Unless patients require transfer for level 2 or level 3 critical care they are managed in a recovery room.

A23.15 Before patients are discharged from the recovery room, satisfactory control of pain and nausea is achieved.

A23.16 The recovery room is sited within the operating department and away from the admission area to the department, and conforms to Association of Anaesthetists for Great Britain and Ireland's guidelines in respect of design and levels of equipment.

A23.17 The recovery room:
• has monitoring equipment, including ECG;
• has resuscitation equipment including a defibrillator;
• is of sufficient size to accommodate a patient resting in a recumbent position;
• ensures ease of communication and access for staff in the event of an accident or emergency.

A23.18 Staff employed in the recovery room have received training in post-operative care including resuscitation and advanced life support.

A23.19 Clinical observation notes recording the patient’s progress are kept in the case notes.

A23.20 Written policies are in place to determine when patients can be safely discharged from the recovery room, making it clear that the final responsibility is always with the anaesthetist who administered the anaesthetic.
Facilities for Carrying Out Surgery (including general anaesthesia for dental treatment)

OUTCOME

Surgery is provided in safe and effective facilities.

STANDARD A24

A24.1 Facilities are accessible by wheelchair or ambulance trolley, with a patient lift available which is able to accommodate a patient trolley where facilities are above ground floor level.

A24.2 Separate waiting, treatment and recovery areas are provided which are of sufficient size to accommodate the expected throughput of patients and their carers and are organised in a way to ensure that patients are not viewed or heard by waiting patients.

A24.3 There is a designated area with a couch, which guarantees privacy to undress, for pre-operative physical examination of patients.

A24.4 The anaesthesia machines:
   • are unable to deliver an hypoxic mixture;
   • have an oxygen failure alarm;
   • have an emergency nitrous oxide shut-off system.

Operating Theatres

OUTCOME

Operating theatres have appropriate facilities, equipment, support services and staffing arrangements.

STANDARD A25

A25.1 Operating theatres have available instruments and equipment from validated Central Sterile Supply Departments.

A25.2 There is an emergency power supply for the operating theatre, in accordance with S.I.1984/1578, regulation 12(2)(b), to provide electrical power in the event of an interruption to the mains supply.

A25.3 Full equipment for endotracheal incubation is available to hand. There is immediate access to spare apparatus in the event of failure.
A25.4 There is appropriate and effective suction apparatus which is independently powered and portable.

A25.5 When artificial ventilation equipment is used, a disconnect alarm is used.

A25.6 Support services are provided, including pathology and radiology.

A25.7 Arrangements for the staffing and management of an operating suite are in line with published professional guidance for the operation taking place.

A25.8 There are written descriptions for the role of each member of professional staff in the operating theatre (including visiting staff), which include the allocation of responsibility for management and a description of the role for:

- doctors;
- registered nurses;
- care assistants;
- operating department practitioners;
- blood perfusionists and specialist technical staff.

A25.9 A registered nurse or operating department practitioner who has operating theatre experience is in charge at all times in the operating theatre.

A25.10 The operating area is of sufficient size to accommodate the patient, their escort, the anaesthetist, the surgeon and the assistants for the anaesthetist and the surgeon.

**Procedures Specific to Dental Treatment under General Anaesthesia**

**OUTCOME**
Patients are assured of safe and effective dental treatment under general anaesthesia.

**STANDARD A26**

A26.1 A comprehensive written request for dental treatment under general anaesthesia is made from a referring dental or medical practitioner.

A26.2 The request for dental treatment under general anaesthesia includes:

- the patient’s relevant dental, general medical and social history;
- a proposed treatment plan and intended outcome;
- the alternative methods of pain and anxiety relief that have been discussed with the patient.
A26.3 The patient, or their carer, is given written material on the risks associated with general anaesthesia and other forms of pain and anxiety control for dental treatment. This should be given by the referring dentist, or if they are the same person, the operating dentist.

A26.4 A named anaesthetist on the specialist register of the General Medical Council is responsible for the arrangements and quality control of general anaesthesia where dental treatment is provided.

A26.5 Staff have resuscitation training, and training in the use of drugs as in the current edition of The Dental Practitioners’ Formulary, and appropriate equipment to permit an effective response to the collapse of a patient. Staff involved in the provision of dentistry under general anaesthesia train together as a team at least once every two months to deal with emergencies.

Cardiac Surgery

OUTCOME

Cardiac surgery only takes place in hospitals that have the appropriate facilities and expertise to do so.

STANDARD A27

A27.1 Cardiac surgery must take place in operating rooms fully equipped for cardiothoracic surgery

A27.2 The registered person has regard to the facility and operator standards for angiography, PTCA and CABG in the NHS National Service Framework for Coronary Heart Disease determining the adequacy of the skills and experience of individual operators and teams engaged in this work. The experience and number of cases carried out may be combined from work in both the NHS and independent sector.

A27.3 There is a consultant anaesthetist with dedicated responsibility for cardiac anaesthesia services.

A27.4 Haematology, blood transfusion and biochemistry are rapidly accessible.

A27.5 Satellite laboratory services are in or near the operating room for the measurement of blood gases, electrolytes, haemoglobin and measurement of anticoagulation.

A27.6 Patient monitoring equipment and heart by-pass machines are maintained, repaired and calibrated by medical physicists or other suitably qualified technicians, or maintained by contractual arrangement with an external supplier, with documents available to confirm this.
A27.7 Critical care at level 2 at a minimum is provided on site where patients can be nursed immediately after the operation.

A27.8 Audit of cardiac surgery is undertaken in line with the Society of Cardiothoracic Surgeons of Great Britain and Ireland, and the British Cardiovascular Intervention Society/British Cardiac Society. This may be in conjunction with audit programmes in NHS trusts.

A27.9 Audit data is shared for peer review purposes; this may be through an associated clinical audit programme at a NHS trust.

A27.10 Agreed protocols/systems of care are in place so that, prior to discharge from hospital, people admitted suffering from coronary heart disease are invited to participate in a multi-disciplinary programme of secondary prevention and cardiac rehabilitation.

A27.11 Assessment of physical, psychological and social needs for cardiac rehabilitation is carried out before discharge.

A27.12 A written individual plan for meeting these identified needs is prepared and copied to the patient and his/her GP.

A27.13 Initial advice on lifestyle, for example smoking cessation, physical activity (including sexual activity), diet, alcohol consumption and employment is provided and recorded.

A27.14 Information about cardiac support groups is provided.

A27.15 Locally relevant information about cardiac rehabilitation is provided.
Cosmetic Surgery

OUTCOME

Patients are clear as to what cosmetic surgery entails, and are assured about the skills and experience of those carrying out those procedures.

STANDARD A28

A28.1 Surgeons performing cosmetic surgery procedures belong to a relevant professional organisation, which provides continuing medical education and adheres to the principles of the GMC’s *Good Medical Practice*.

A28.2 All surgeons maintain a comprehensive outpatient service, either at the clinic/hospital where the surgery is to be undertaken or elsewhere, ensuring that the surgeon has assessed and documented in the patient’s health record the patient’s appropriateness for receiving cosmetic surgery.

A28.3 No patient is admitted for the procedure the same day as the initial consultation.

A28.5 Referral to appropriate psychological counselling is available if clinically indicated prior to surgery.

A28.6 There are dated, documented criteria which set out the risk factors associated with the individual procedures and guide the selection of patients for different treatment options. These are held by the surgeon and discussed with the patient prior to surgery.

A28.7 There are written procedures for the safe use of all equipment used for cosmetic surgery purposes within the hospital.

A28.8 All staff using equipment must have completed training in the safe clinical use of the equipment and have demonstrated competence, which is documented to this effect.

Day Surgery

OUTCOME

Patients undergoing day surgery receive appropriate treatment and support, including pre and post-operatively.
STANDARD A29

A29.1 There are guidelines for appropriate patient selection for day case surgery. These include consideration of social factors such as whether the patient lives alone or has someone available to stay with them.

A29.2 There are written pre-operative policies and procedures in place, which include the requirement for unambiguous instructions to patients on:

- fasting;
- medication;
- escorts;
- transport arrangements;
- contact details for patient's queries, such as telephone and fax numbers and e-mail address.

A29.3 Full support services are available: radiology, pharmacy, investigative laboratories.

A29.4 Access to inpatient beds is available for post-operative complications requiring an overnight stay.

A29.5 All patients are assessed during the recovery phase for the adequacy of analgesia and fitness for discharge.

A29.6 There are written post-operative policies and procedures, which include instructions for the patient on:

- pain relief;
- bleeding;
- care of the post-operative site;
- the need to advise the patient that the effects of general anaesthesia may impair their judgement and that they should refrain from certain activities such as driving, operating machinery or signing legal documents;
- a telephone contact number at the hospital.

A29.7 There are written discharge criteria which include the requirement that discharge is recognised and handled as a medical responsibility.

A29.8 Specific instructions are available for patients, their relatives and community services if appropriate. Post-operative information must be provided for patients for each procedure undertaken in a day surgical unit, for example lens extraction, hernia, grommets.
Transplantation

OUTCOME

Transplantation takes place safely and sensitively.

STANDARD A30

A30.1 The requirements of the Human Organs Transplants Act 1989 are complied with.

A30.2 There are written policies and procedures for the conduct of transplantation operations to ensure the traceability of all donor organs that prohibit the purchase or sale of any human organs for transplant in whatever way and from whatever source.

A30.3 The procedures ensure that transplantation of organs between living people who are not genetically related is not carried out without the prior permission of the Unrelated Live Transplant Regulatory Authority.

A30.4 Information about organs removed for proposed transplants and about organs which have been transplanted into other persons is reported in accordance with the Human Organs Transplants (Supply of Information) Regulations 1989.

A30.5 In participating in the national scheme for the allocation of organs, all patients are registered on a national waiting list and follow-up information on transplanted patients is provided for inclusion on the National Transplant Database.

A30.6 There are written procedures for staff to follow when requesting donor organs from the family members of a deceased patient.

A30.7 Staff are trained in how to approach family members with regard to organ donation.

A30.8 There are written policies and procedures for xenotransplantation operations, which are in accordance with published guidance and have been scrutinised and approved by the UK Xenotransplantation Interim Regulatory Authority.

A30.9 There are documented, defined criteria and processes for the selection of suitable patients for transplantation and these are monitored.

A30.10 Critical care at level 3 is provided on site for nursing patients immediately after the operation.

A30.11 Records are kept for 11 years from the date of discharge or death of the patient.
Critical Care

Arrangements for Immediate Critical Care

OUTCOME

Appropriate post-operative and emergency arrangements are in place for patients who undergo surgery.

STANDARD A31

A31.1 There are level 1 critical care facilities available for patients who have received treatment under general anaesthetic and require:

- frequent observation by nursing staff;
- frequent or continuous cardiovascular monitoring;
- high risk intravenous infusions, for example anti-arrhythmic, vasodilators or inotropes.

A31.2 When a patient is admitted for treatment routinely requiring level 1 critical care this is noted and booked at the time of admission, ensuring that the required facilities and level of staff cover are available.

A31.3 The consultant responsible determines that level 1 critical care is required and personally hands over the patient to the responsible nurse.

A31.4 The patient is observed at regular intervals by nursing staff, the required level of observation is included in the patient’s treatment plan and adjusted in response to recovery or deterioration of condition.

A31.5 While a patient is receiving level 1 critical care, the responsible consultant visits the patient a minimum of twice daily.

A31.6 If a patient deteriorates or otherwise fulfils the criteria for a higher level of critical care, admission to the hospital's critical care facility, or transfer to another critical care facility, is immediately effected.

A31.7 The responsible consultant determines that level 2 or 3 critical care is required and personally hands over the patient to the responsible nurse.

A31.8 Patients requiring level 2 or level 3 critical care receive this level of care either within the hospital or are transferred immediately to a facility that provides it.

A31.9 Where patients need level 2 or level 3 critical care after treatment as a matter of course, due to the seriousness of the operation type, the facilities for such care must be available within the hospital.
A31.10 Where level 2 or level 3 critical care is not provided within the hospital, contingency emergency transfer arrangements are in place that are documented and agreed in advance with each of the appropriate specialised units to which patients may be transferred.

A31.11 There are written criteria for the discharge of patients from critical care.

**Level 2 or Level 3 Critical Care within the Hospital**

**OUTCOME**

Patients are assured that where level 2 or level 3 critical care is provided, as appropriate, within the hospital, it is done so effectively.

**STANDARD A32**

A32.1 Establishments with critical care facilities at level 2 or 3 have arrangements in place, in line with ‘Standards for ICU’ Intensive Care Society (1998) and the guidance contained in the ‘Comprehensive Critical Care Report’ Department of Health (May 2000) including:

- written criteria for the admission of patients to critical care beds;
- a written operational policy and protocols for post-operative management;
- staff are briefed on the policy and protocols so that they are aware of what they should do in specific circumstances;
- pathology services, including a blood bank;
- critical care beds are situated so that nursing staff are able to effectively observe the patient at all times;
- critical care beds have sufficient space on both sides to enable care to be delivered whilst all the necessary equipment is in place;
- arrangements in place for immediate back up and/or replacement in the event of equipment failure;
- records are kept of the use of each ventilator, to enable appropriate servicing arrangements in line with the manufacturer’s instructions.

A32.2 Where critical care at level 2 or above is provided staffing for critical care reflects the advice in the Department of Health Comprehensive Critical Care Report (May 2000), is based on patient dependency and ensures:

- a designated resident doctor is on duty at all times, who has adult advanced life support certification;
- a registered nurse who has training in critical care nursing is on duty in charge of the unit at all times when there are patients in it;
- all clinical staff working in critical care have up to date training in critical care techniques, at least annually.
- a resuscitation team trained in advanced life support is on duty at all times;
- a radiographer with mobile imaging equipment is available on call;
• a physiotherapist experienced in critical care available on call;
• where level 3 critical care is provided the resident medical officer is experienced to specialist registrar standard in either anaesthetics or intensive care medicine.

A32.3 The responsible consultant and the anaesthetist visit the patient twice a day, as a minimum whilst they are receiving critical care at level 2 or 3.

Radiology

Published Guidance for the Conduct of Radiology

OUTCOME

Patients and staff are assured that ionising and non-ionising radiation are undertaken in a safe and protective environment.

STANDARD A33

A33.1 The provision and use of facilities using ionising radiation are undertaken in compliance with:

• The Ionising Radiations Regulations 1999;
• The Approved Code of Practice and Guidance;
• The Ionising Radiation (Medical Exposure) Regulations 2000;
• and associated professional guidance.

A33.2 Those undertaking exposures utilising radiopharmaceuticals or sealed sources are informed by:

• The Ionising Radiations Regulations 1999;
• The Approved Code of Practice and Guidance;
• The Ionising Radiation (Medical Exposure) Regulations 2000;
• associated professional guidance.
A33.3 In addition they are informed by:

- The Medicines (Administration of Radioactive Substances) Amendment Regulations 1995;
- Notes for Guidance on the Clinical Administration of Radiopharmaceuticals and Use of Sealed Radioactive Sources.

A33.4 The provision and use of facilities using non-ionising radiation for medical exposures are undertaken in compliance with:

- Health Guidance Note – Magnetic Resonance Imaging (NHS Estates 1997);
- Health Building Note 6 Supplement 1 – Accommodation for Magnetic Resonance Imaging (NHS Estates 1994);
- Guidelines for Magnetic Resonance Diagnostic Equipment in Clinical Use (MDA 1993);
- MRI static magnetic field safety considerations (MDA DB 9803 1998);
- IPSM Report 70 Testing of Doppler Equipment;
- IPSM Report 71 Routine QA of Imaging Systems;
- Guidance Notes for Ultrasound Scanners used in the Examination of the Breast (MDA/98/52).

A33.5 There are written procedures for identifying patients with pacemakers and metallic implants.

A33.6 For MRI, special attention is given to the use of MRI compatible ancillary equipment.

A33.7 There are prominently displayed signs warning pregnant women of radiation dangers to the foetus (where appropriate to the patient profile of the hospital, these signs are multi-lingual).

Training and Qualifications of Staff Providing Radiology Services

OUTCOME

Radiological treatment is provided by appropriately trained and qualified health care professionals.

STANDARD A34

A34.1 In establishments where ionising radiation, radiopharmaceuticals or sealed sources are used a qualified and experienced person is appointed as a radiation protection adviser.

A34.2 The radiation protection adviser is involved with advising on compliance with statutory requirements and guidance, and where appropriate on the
construction, design and layout of buildings where ionising radiations are or are about to be used.

A34.3 Those interpreting a wide range of diagnostic images are clinical radiologists on the GMC’s specialist register.

A34.4 Where a wide range of examinations is provided, diagnostic examinations are performed by state registered diagnostic radiographers, trained sonographers and by medically qualified practitioners, trained in the examination techniques undertaken, in accordance with regulatory requirements.

A34.5 Diagnostic nuclear medicine examinations are only carried out and reported by qualified and experienced medical and clinical staff.

A34.6 Those interpreting a wide range of nuclear medicine images are clinical radiologists or nuclear medicine physicians on the GMC’s specialist register.

A34.7 Magnetic Resonance Imaging (MRI) and ultrasound examinations are only carried out and reported by qualified and experienced medical practitioners.

Pharmacy Services

Responsibility for Pharmaceutical Services

OUTCOME

Responsibility for obtaining, prescribing, storing, use, handling, recording and disposal of medicines is clear.

STANDARD A35

A35.1 The registered manager ensures that the safe and secure handling of medicines and medicines management is clearly defined.

A35.2 There are policies and procedures in place, which ensure that the principles of the Duthie Report (Guidelines for the Safe and Secure Handling of Medicines) are met.
A35.3 Hospitals have either:

- a pharmaceutical department; or
- suitable alternative arrangements in place for comprehensive pharmaceutical services, including out of hours arrangements.

A35.4 Where a pharmaceutical department is provided it is under the control of a pharmacist who is a registered member of the Royal Pharmaceutical Society of Great Britain, and who has hospital experience.

A35.5 The pharmacist is responsible for:

- the purchasing, quality, storage, dispensing and distribution of all medicines, as well as for ward based pharmaceutical services;
- advising on drug therapy, dosage, patient counselling and discharge medicine;
- the manufacture of various drugs.

A35.6 Out of hours access to the pharmacy is restricted to the RMO and senior nurse on duty by a dual key system, which requires both key holders to be present in order to gain access.

**Ordering, Storage, Use and Disposal of Medicines**

**OUTCOME**

Medicines, dressings and gases are handled in a safe and secure manner.

**STANDARD A36**

A36.1 All medicines, medical gases and interactive wound dressings are obtained by, and stored under the control of, a pharmacist, doctor or registered nurse.

A36.2 The pharmacist or, where there is no pharmacist employed, the registered senior nurse, signs any orders to obtain prescription-only medicines from wholesale suppliers.

A36.3 There is a written procedure for the receipt of, and responsibilities for taking action on, hazard warnings and drug recalls.

A36.4 Labelling of medicines is clearly printed (or typed), not hand written. Stock items sent to wards have batch number and expiry dates.

A36.5 Medicines within a ward, theatre or department are the responsibility of the registered nurses designated for the purpose by the registered manager.
A36.6 Medicines in current use are kept in a locked cupboard or trolley, and trolleys are fastened to a wall when not in use.

A36.7 There is a written procedure for the handover of keys at changes of shifts and for security arrangements for spare keys.

A36.8 A medication record is kept for each patient, the entries signed by the prescriber, showing:
- the name and date of birth of the patient;
- registration number and ward where appropriate;
- the name of the medicine;
- the dose;
- the route of administration;
- the frequency and time for administering each dose;
- the date of prescribing;
- any known medicines hypersensitivity or allergies;
- any special requirements.

A36.9 Records are kept for eight years from the date of discharge or death of the patient.

A36.10 Medicines brought into the hospital by individual patients, and which are not used, are kept separate from other medicines on the ward and held in a safe place until discharge of the patient when they are returned to the patient or his/her representative if still clinically appropriate.

A36.11 There is a written policy on the use of patient’s own drugs, that facilitates an audit trail for the receipt, administration and return of medicines.

A36.12 When a patient dies in the hospital any medicines dispensed specifically for the patient are kept for at least one week in case there is a need for a coroner’s inquest.
Administration of Medicines

OUTCOME

Prescription, supply and administration conform to the requirements of relevant legislation and best practice. Prescription, supply and administration of medicines are undertaken only by appropriately qualified, competent staff.

STANDARD A37

A37.1 All medicines are administered to a patient with a written prescription or, internal to the hospital, a drug administration chart that has been signed by a legally authorised prescriber.

A37.2 Where medicines are received against a prescription for a named patient, they are administered to that particular patient and under no circumstances are used for other patients.

A37.3 When medicines are no longer required by the named patient they are returned to the pharmacy.

A37.4 Medicines are administered by a registered medical practitioner, or under the supervision of, a registered nurse in accordance with the United Kingdom Central Council (UKCC) “Guidelines for the Administration of Medicines” October 2000 or when published, the equivalent guidelines of the Nursing and Midwifery Council (NMC). The administration of controlled drugs is undertaken by a medical practitioner or by a senior nurse- and is witnessed.

A37.5 All medicine doses are prepared immediately prior to their administration to patients from the container in which they are dispensed.

A37.6 A drug trolley is used where practicable.

A37.7 A drug trolley, or a lockable container, is used to transport medicines to the patient.

Self-administration of Medicines

OUTCOME

Patients are assessed, consulted and advised before they are enabled to self-administer medicines.

STANDARD A38

A38.2 There is a written policy and procedure for self-medication, which conforms to the duty of care inherent in the relationship of the hospital to the patient.
A38.3 Where the risks have been assessed and it is deemed that they cannot endanger themselves or others, patients are enabled to self-administer their medicines.

A38.4 Arrangements are only made with the agreement of the registered nurse, the patient and carer and the doctor responsible for the patient’s care.

A38.5 Medicines dispensed for patients to self-administer (or to take home) have full directions and BNF cautionary warning where appropriate.

A38.6 Regular checks are made on the quantity of medicine given to the patient to ensure the patient is taking the prescribed dose.

A38.7 The medicine is stored in a personal lockable cupboard or drawer, the keys being held by the patient.

A38.8 There is a spare key available to registered nurses or other appropriately qualified staff with entitlement to access, which is kept in a safe and secure place.

**Medicines Management**

**OUTCOME**

Senior managers are aware and involved in medicines management. Measures are in place to ensure the safe and secure handling of medicines.

**STANDARD A39**

A39.1 The organisation reports adverse incidents involving medicinal products and devices to the relevant agency (the MCA or the MDA), and appropriately manages any subsequent required action.

A39.2 There is a multi-professional, representative body, such as a Drug and Therapeutics Committee, that oversees the formulation, agreement and implementation of policies concerning medicines use.
Aseptic Dispensing

OUTCOME

Aseptic dispensing is carried out safely and appropriately.

STANDARD A40

A40.1 Arrangements for the provision of services such as parenteral nutrition, intravenous additives, and cytotoxics comply with the principles of DGM (97) 5 regarding unlicensed aseptic dispensing in hospital pharmacies.

A40.2 Non-sterile manufacturing, re-packing and extemporaneous preparation adhere to the principles outlined within the MCA’s guide to good manufacturing practice.

Storage and Supply of Medical Gases

OUTCOME

Medical gases are stored and supplied appropriately.

STANDARD A41

A41.1 There are named persons (authorised person, competent person and quality controller) as defined under HTM 2022 (WHEL (98) 1) responsible for the storage, identity, quality and purity of all gases at the terminal units, and for maintaining gas pipelines, and compliance with HTM 2022.

A41.2 The hospital has a designated suitably trained ‘Authorised Person’ for Medical Gas Pipeline Systems (MGPS).

- The person may cover a number of hospitals but must be clearly responsible for the day to day management of the MGPS. They must have knowledge of the hospital, systems and personnel. The person may be an employee or somebody external having a written service level agreement with the hospital.

- If the hospital is part of a larger group of hospitals, one person may be ‘Authorised Person’ for a number of sites, within reasonable travelling distance of each other, and able to respond to emergency situations at the hospital.

- Periods of leave must be suitably covered.

A41.3 The ‘Authorised Person MGPS’ has arrangements in place to discharge responsibility under HTM 2022. For a small private hospital the ‘Authorised Person MGPS’ may do so by arranging a contract with a suitably recognised
medical gas specialist company for a ‘Competent Person’ to maintain the system. Links in writing (contract, service agreement) would be made with a ‘Quality Controller’ to advise and perform identity and purity tests when required. The ‘Authorised Person MGPS’ must ensure that a suitable ‘permit to work’ system is in place and should receive a copy of all work carried out on the MGPS.

A41.4 The ‘Authorised Person’ has delegated a named member of staff to be his/her representative on the site, who may be the hospital engineer or another person, but they must be suitably trained and familiar with the medical gas system.

A41.5 Where the ‘Authorised Person MGPS’ is off site they must visit and perform regular audits of the hospital to ensure compliance with the management systems in place. Other matters such as safe storage of isolation valve box keys, emergency contact numbers, stock rotation of cylinders, cleanliness and security of manifold sheds should also be audited to demonstrate the MGPS are under control.

A41.6 The hospital has a designated suitably trained ‘Quality Controller (QC MGPS)’.

A41.7 Prior to use of a new system, or resumption of use of a repaired system, the QCMGPS must indicate in writing that he or she is satisfied with the identity and purity of the gases at the terminal units. This is alongside the signature of the ‘Authorised Person’ who accepts the responsibility for the correct operation of the pipeline systems.

A41.8 Any engineers (competent persons) delegated to work on the medical gas pipelines systems are properly trained and experienced, and authorised to do so by the Authorised person.

A41.9 All work is controlled by a permit to work procedure.

A41.10 Policies and procedures are produced for recording the delivery, handling and storage of full and empty medical gas cylinders, with an indication of who is in charge of this procedure at the hospital.
Pathology Services

Management of Pathology Services

OUTCOME

Pathology services are provided by appropriately qualified and trained staff.

STANDARD A42

A42.1 The provision of services is under the supervision of a medically qualified pathologist at consultant level or, in appropriate disciplines, a non-medical scientist of equivalent standing.

A42.2 The head of the service is able to assume professional, scientific, consultative, organisational and administrative responsibilities for the service.

A42.3 It is the responsibility of the head of the service to ensure that the procedures and tests performed by technical staff are within the scope of their professional training and experience.

Pathology Services Process

OUTCOME

The process by which pathology services are undertaken provides quality assurance for patients.

STANDARD A43

A43.1 The policy and procedures describe the organisation and overall scope of the laboratory services, and describe:

- the provision of diagnostic and consultancy services to clinicians including the provision of reports;
- the scientific direction of the department including any research and development programmes;
- the maintenance of performance standards including quality control;
- safety aspects of the department;
- medical and technical responsibilities which are delegated to medical or other qualified laboratory personnel;
- the arrangements for the supply, storage, distribution and return of blood and blood components.
A43.2 Written policies and procedures include arrangements for the integrated management of requests for collection of pathology specimens with documentation to ensure continuous identification of the individual from whom the specimen is collected.

A43.3 There are written policies and procedures for all arrangements for the transfer and transportation of specimens, which include:

- arrangements for the protection of those handling such items in transit;
- arrangements for the appropriate temperature controlled storage of specimens.

A43.4 There are written policies and procedures for disposal of specimens and reagents used, including the disposal of clinical and other waste arising in the laboratory.

Quality Control of Pathology Services

OUTCOME

Quality control arrangements for pathology services provide quality assurance for patients.

STANDARD A44

A44.1 Written policies and procedures are in place for internal quality control and external quality assurance and indicate sources, dates of adoption and evidence of regular review.

A44.2 A written record of all reagents, calibration and quality control material is kept.

A44.3 The written policies and procedures include a description of the range of services provided and their method, for example in house, by contract, out-of-hours.

A44.4 There are written procedures for the performance of each test, including preparation of equipment, samples and reagents, calculation of results and review of internal quality control and external quality assurance performance.
Facilities and Equipment for Pathology Services

OUTCOME

Pathology services are provided using safe and effective facilities and equipment.

STANDARD A45

A45.1 Space is available for the collection of specimens, separate from the laboratory working areas.

A45.2 There are designated storage areas for specimens, reagents and records.

A45.3 Where appropriate, mortuary and postmortem facilities are available or formal contract arrangements are made for the provision of these, together with procedures for the identification and recording of patient identity and/or of specimen material.

Cancer Services

Chemotherapy

OUTCOME

Patients receive safe chemotherapy treatment.

STANDARD A46

A46.1 There is a clinical director for the chemotherapy service who is a consultant medical oncologist, or a consultant haematologist, or other suitably qualified consultant.

A46.2 Areas where chemotherapy is administered have equipment readily available for the management of emergencies including anaphylaxis, extravasation, cardiac arrest and spillage of cytotoxics.

A46.3 Registered nurses administering chemotherapy have undertaken the N59 course, or equivalent and their competence has been assessed.

A46.4 Where children are treated by chemotherapy, nurses have undertaken the accredited course for children's chemotherapy.

A46.5 There are written procedures/protocols for the prevention and treatment of complications arising from chemotherapy.

A46.6 There is written information for patients undergoing chemotherapy, which include advice and action to be taken if the patient develops side effects or complications.
A46.7 The information for patients is available prior to starting chemotherapy.

A46.8 The responsibilities of the pharmaceutical service are documented in relation to chemotherapy.

A46.9 All cytotoxic chemotherapy prescriptions are checked and signed by a pharmacist.

A46.10 Chemotherapy treatment records are kept which include:

- treatment intention;
- route of administration;
- number of cycles intended;
- frequency of cycles and of administrations within a cycle;
- toxicities which require a dose modification;
- whether the course was completed or not.

**Radiotherapy**

**OUTCOME**

Patients receive safe radiotherapy services.

**STANDARD A47**

A47.1 Radiotherapy services are provided under the clinical direction of a consultant clinical oncologist.

A47.2 The following equipment is available for the delivery of radiotherapy services:

- two linear accelerators, or one with backup arrangements;
- treatment planning computer with 3D planning facility;
- simulator;
- superficial x-ray and electron therapy facilities;
- mould room;
- facilities for the use of unsealed isotopes, where appropriate.

A47.3 Radiotherapy physicists are directly employed or work sessionally under contract and the staffing levels for the volume comply with the recommendations of the Institute of Physics and Engineering in Medicine.
A47.4 All requests for a course of radiotherapy are documented and are classified as urgent, palliative or radical.

A47.5 There is written information for patients undergoing radiotherapy, which includes advice and action to be taken if the patient develops side effects or complications.

A47.6 The information for patients is made available prior to commencing the radiotherapy treatment.

A47.7 Records are kept of all radiotherapy given and these are stored within, or immediately accessible to the service at all times.

A47.8 The records include as a minimum:

- radiographs or other treatment planning images;
- treatment plans and dose calculation sheets.

A47.9 There is access to CT scanner facilities for planning radical treatments.

A47.10 There are documented procedures, which set out maximum and minimum doses and how the dose for each treatment is calculated.

A47.10 All patient related treatment information and individualised immobilisation aids include the patient’s name and unique identification number.

A47.11 There is a written procedure to ensure correct identification of the patient before each treatment starts.

A47.12 There is a quality management system in place, which includes radiation therapy equipment quality control.
Introduction to Standards M1 to M47

The standards for mental health establishments apply to those non-NHS establishments which, for the purposes of section 2(3) of the Care Standards Act 2000, come under the definition of ‘independent hospital’ because either:

- the main purpose of the establishment is to provide medical or psychiatric treatment for mental disorder; and/or
- treatment or nursing (or both) are provided in the establishment for persons liable to be detained under the Mental Health Act 1983.

These standards apply, therefore, to a range of premises where mental health treatment is provided, including the large mental health hospitals, smaller establishments that provide mental health treatment as their main or sole purpose, and all establishments that take people who are liable to be detained.

With the exception of standard M1 (Working with the Mental Health National Service Framework for Wales), the standards for adult mental health establishments are also applicable to establishments providing mental health services for children and adolescents. The Child and Adolescent Mental Health Services (CAMHS) strategy document ‘Everybody’s Business’ (NAW September 2001) and a Children’s National Service Framework which has been announced are also relevant.

The standards fall into two categories:

- they begin with those that apply to all mental health establishments (including for children and adolescents) that come within the definition of ‘independent hospital’ (as set out above);

- they end with those that, in addition, apply to mental health establishments that can take people liable to be detained (including for children and adolescents).

These standards do not apply to care homes, nor to establishments that mainly provide counselling or to psychiatrists’ consulting rooms.

In formulating these standards key stakeholders within the NHS, Local Authorities and independent sector were engaged in discussion and a search of the literature was conducted. In addition, 43 reports from inquiries into mental health services published between 1990 and 2000 were studied and the main recommendations...
subjected to a thematic analysis and re-written as standards. These inquiries demonstrated the tragic consequences which can follow if specific fundamental practices are not inherent within services and provided a salutary reminder of the need to have robust management systems in place if these errors are not to be repeated.

Quality of Treatment and Care (standards M1 to M4)

These standards concern the overall management of the mental health services provided by the regulated establishment, including the need for it to reflect the Adult Mental Health Services for Wales strategy document ‘Equity, Empowerment, effectiveness and efficiency’ strategy document (NAW September 2001) and, in due course, the associated National Service Framework. They recognise that services, whatever sector they operate in, do not work in isolation and require mechanisms to link with and be influenced by external agencies operating at a national, regional and local level.

Human Resources (standards M5 to M6)

These standards recognise the importance of services having the right numbers, type and skill-mix of appropriately trained staff. References are made here to ‘clinical staff’ to reflect that these services involve both health care and social care professionals.

Risk Management (standards M7 to M10)

Risk management aims to achieve the optimum balance between good quality care, treatment and rehabilitation of patients. This will be achieved through an ongoing process of identifying and assessing risks, with the objective of improved prevention, control and containment of risks.

The management of such risks is a key organisational responsibility. All managers and clinicians must accept the management of risks as one of their fundamental duties, and every member of staff must have a real sense of ownership and commitment to identifying and minimising risks.

Patient Treatment and Care (standards M11 to M35)

The Care Programme Approach (CPA) will be introduced in Wales in 2002 (in the National Service Framework for Mental Health in Wales and supplemented by detailed introductory guidance) to provide a framework for caring for people with mental health problems. The four major components will consist of:

- assessment of health and social care needs and any risks involved;
• nomination of a care co-ordinator;
• preparation of a care plan;
• regular review of the care plan.

The CPA will be aimed at providing a comprehensive service that addresses health and social care needs and gives priority within the service to those people with substantial and complex needs arising from mental disorder. It will aim to focus sensitively on the particular needs of individual patients and their carers by supporting people in their own communities where possible, and recognising their complex individual networks of care which encompass all areas of their life.

The CPA applicable to all adults of working age in contact with the secondary mental health system (health and social care) though not a requirement and the principles will also be relevant to the care and treatment of younger and older people with mental health problems.

Essential elements are the maximising of service users and carers participation in the planning and provision of care and the improvement of co-ordination and avoidance of duplication between services. The continuity of care is enhanced by the use of care co-ordinators supported by effective multi-disciplinary teams.

**Empowerment:** the involvement of patients in their individualised care, as well as in planning and implementation of services is seen as an essential component of contemporary mental health care. Without a successful range of methods to engage patients and their representative bodies, mental health services would be seen as failing to operate a service which reflected client needs or was truly inclusive. There are no quick fix solutions. It is a lengthy process of attitude and cultural change requiring personal reflection and a desire to reverse the balance of power.

**Anti-Discriminatory Practice:** it is essential that independent health care providers adopt a strong value base in applying principles of anti-discriminatory practice in their approach to patient care. Services must be proactive in addressing the needs of individual patients with due regard to race, ethnicity, religion, gender, age and sexuality and so forth.

**Least Restrictive Environment:** the principle of people having timely access to an appropriate hospital bed in the least restrictive environment, consistent with the need to protect them and the public, has been government policy for some years.

The concept of ‘least restrictive’ is not just the level of security but the mode of operation of the facility. Some residential units in secure hospitals operate a less restrictive regime than that which might be operated in a medium and even low
secure unit when measured in terms of: access to own room, numbers of possessions, access to grounds, on and off residential unit visiting etc. In promoting the principle of least restrictive environment the challenge is for services to move away from blanket policies and procedures to the justification of restrictions for individual patients on the basis of demonstrable risk.

**Additional Standards for Child and Adolescent Mental Health Services (standards M36 to M40)**

The CAHMS Document ‘Everybody’s business’ sets the strategy for Wales. These standards aim to ensure that the special needs of children and adolescents receiving mental health treatment are properly addressed. They include the need for child protection arrangements.

**Establishments for those Detained under the Mental Health Act 1983 (standards M41 to M47)**

The Mental Health Act 1983 provides the legal framework for the reception, care, treatment and discharge of mentally disordered patients, the management of their property and other related matters. It sets out the legal requirements necessary to receive people suffering from a mental disorder into hospital care for assessment and/or treatment and the systems of appeal and review open to the individual.

The Act specifies particular safeguards with respect to consent to treatment and establishes an independent body, the Mental Health Act Commission (MHAC), whose role is to protect the rights of individuals held under the Mental Health Act and to try to ensure the correct application of procedures. This is achieved through a rolling programme of visits by the MHAC to all facilities that detain patients under the Act.

The Code of Practice of the Mental Health Act 1983 provides guidance on how staff should proceed when undertaking duties under the Act and covers specific guidance on: assessment prior to possible admission under the Mental Health Act, admission under the Mental Health Act to hospital and guardianship, treatment and care in hospital, leaving hospital, and handling particular groups of patients. The Act does not impose a legal duty to comply with the Code but as it is a statutory document, failure to follow it could be referred to in evidence in legal proceedings.

In addition the Code of Practice makes a number of recommendations about other matters which hospital managers should address, including:
• ensuring that the grounds for admitting the patient are valid and reasonable, and that all detention documents are in order;
• exercising the power to transfer under the Act certain categories of detained patients to another hospital administered by the same authority, to a Special Health Authority or to a hospital in another district;
• ensuring that those formally delegated to receive documents and all those who will be required to scrutinise admission documents have a thorough knowledge of the Act;
• giving information to patients and their relatives;
• ensuring that any patient who wishes to apply to a Mental Health Review Tribunal is provided with assistance to progress and given all the necessary information;
• reviewing patient’s detention.

See also, in particular, regulations 42 to 46 of the Regulations.

Quality of Treatment and Care

Working with the National Service Framework for Mental Health in Wales (applies to adult mental health establishments only)

OUTCOME

Patients receive treatment and care that reflects the National Service Framework for Mental Health in Wales (NSFW) introduced in 2002.

STANDARD M1

M1.1 There is a written policy and there are procedures that reflect the NSFW.

M1.2 The policy demonstrates the working links and liaison channels between the establishment and NHS Trusts, Health Authorities and other commissioners of mental health services, social services, housing, primary health care, the criminal justice system and other independent organisations.

M1.3 The registered manager ensures that the establishment contributes to the work of the NSFW. If appropriate, this may involve membership of the local implementation team.
Communication Between Staff

OUTCOME

Patient treatment and care is informed by clear communication between staff.

STANDARD M2

M2.1 There are written policies and procedures to ensure effective communication between staff in relation to the treatment of a patient.

M2.2 Information is shared between all staff involved in the provision of a patient’s health and social care including the sharing of information at any handovers.

M2.3 The policy includes procedures for conducting nursing handovers between shifts.

M2.4 All involved with the patient’s care should be aware of any relevant long-term history.

M2.5 There is accurate and timely documentation in the patient’s health records (care plan) of all interventions by staff, with each entry signed and dated by the health care professional on a daily basis. Where care assistants make entries these are countersigned and evaluated by a health professional.

M2.6 When there is a change of responsible medical officer a full clinical hand-over takes place, including transfer of records.

Patient Confidentiality

OUTCOME

Patients are assured of confidentiality.

STANDARD M3

M3.1 There are written policies and procedures for maintaining the confidentiality of all details in relation to a patient’s treatment and balancing this against any risk to the patient, staff or members of the public.

M3.2 Managers ensure that staff have access to guidance and training so that they understand when it is important to share information about patient needs and difficulties, balancing the requirements of confidentiality and risk management.

M3.3 Staff are aware of the need to consider whether a breach of confidentiality can be justified where there is a potential risk to the patient, staff or members of the public.
M3.4 The limits of confidentiality between the various professionals concerned with a patient's care are carefully defined, indicating the circumstances in which others must be informed.

Clinical Audit

OUTCOME

Patients’ treatment and care is assured by clinical audit.

STANDARD M4

M4.1 Clinical audit programmes include:
- monitoring of multi-professional working in mental health care teams;
- monitoring multi-professional contributions to clinical records;
- the extent and quality of direct staff-patient contact.

M4.2 Clinical standards performance and critical incidents are audited at least annually.

M4.3 The auditing of critical incidents is led by a senior clinician external to, and not employed in another capacity by, the establishment.

M4.4 The auditing of clinical performance (including the administration of medication) and improving clinical standards is led by a senior clinician.

M4.5 The quality of implementation of the Care Programme Approach is audited, to ensure consistent and appropriate application, including:
- the quality of care plans;
- the attainment of treatment goals;
- particularly for those with multiple needs, the effectiveness of inter-agency working.

M4.6 The views of patients are routinely sought and are used as an indicator of the quality of services and included in any audit of service delivery and complaints made.
M4.7 A record is maintained of (and used in audits of service delivery):
  • emergency re-admissions;
  • number of patients applying for managers’ review of detention;
  • number of patients applying for review by Mental Health Review Tribunals
    (outside statutory review periods).

Human Resources

Staff Numbers and Skill Mix

OUTCOME

The numbers, type and skills of health care professionals ensure that patients are
appropriately treated and cared for at all times.

STANDARD M5

M5.1 The numbers and skills of health care professionals and support staff
assigned to each unit reflect the number and needs of patients on each unit.

M5.2 There is a named nurse/care co-ordinator and associate nurse system to
ensure continuity of care across all shifts.

M5.3 Nursing care co-ordinators (named nurses) are only appointed from amongst
staff who are on duty for a significant part of a patient’s stay in hospital.

M5.4 The roles and responsibilities of each member of the multi-professional team
are documented and staff members are aware of their own responsibilities
and the roles and responsibilities of the other team members.

M5.5 There are written criteria for nurse calls for medical assistance.

Staff Training

OUTCOME

Patients receive treatment and care from appropriately trained staff.

STANDARD M6

M6.1 All clinical staff receive training on the values, principles and broad standards
of the NSFW and information about how this impacts upon their own work
(e.g. the local implementation of the NSFW)
M6.2 Joint programmes of staff training are made available to optimise the working of the multi-professional teams and to establish a mutual understanding of issues and each others roles.

M6.3 All staff receive training in risk management, and understand when to refer patients for expert guidance in the context of multi-professional working. This training is tailored to individual practitioner needs, with refresher courses as appropriate.

M6.4 All clinical staff receive training in how to manage individuals who may be disturbed, aggressive, troubled, suicidal or distressed, which is updated at least annually.

M6.5 Clinical staff receive training, including annual up-dating on the prevention management of aggression and techniques to defuse situations and in physical intervention techniques according to current guidelines.

M6.6 The use of clinical policies and guideline documents are included in training programmes.

M6.7 Clinical staff are trained in appropriate resuscitation procedures (M10 refers).

M6.8 Training and education programmes include training in anti-discriminatory practice.

M6.9 Clinical staff are trained to meet the needs of disabled people including understanding the complexities of those with sensory impairment.

M6.10 Staff induction and ongoing training makes reference to professional regulation and accountability.

Risk Management

Risk Assessment and Management

OUTCOME

All potential environmental and clinical risks are assessed and managed to ensure a safe environment is maintained for patients, staff and the general public.

STANDARD M7

M7.1 There is a written risk management policy, which:

- takes account of who might be harmed and how;
- requires that the precise nature of the risks are recorded in writing;
- requires action to be taken in response to the risks identified and is documented;
• outlines a regular review system for levels of risk to be revised in the light of new information.

M7.2 An annual audit is undertaken by a senior clinician (experienced in managing challenging behaviour) and the Health and Safety Officer to review the safety, security and appropriateness of the facilities. Actions are identified and responses recorded.

M7.3 Individual clinical risk assessments are undertaken by the multidisciplinary team at least every 3 months and following a serious untoward incident or near miss involving the patient.

M7.4 The patient is involved in his or her own risk assessment and patient views recorded in the written record of the risk assessment.

M7.5 All individuals working for the service, including students and those in a voluntary capacity, are alerted to the potential risks of violence or self-harm by the patient, and have ready access to professional support.

Suicide Prevention

OUTCOME

Patients are protected from self-harm, including risk of suicide.

STANDARD M8

M8.1 There are written polices, protocols and procedures on the prevention of homicides and suicide, which take account of the recommendations of the Confidential Inquiry into Homicide and Suicides (Safer Services Department of Health 1999; Safety First Department of Health 2001).

M8.2 Where an assessment of an individual’s risk of self-harm or suicide indicates the need for special precautions, details of all interventions are recorded in the care plan including:

• the appropriate level of observation and engagement to be used (M30); and

• the recording of such observations.

M8.3 Any factors that suggest that a patient has been or might be a suicide risk (including any diagnosis of severe mental illness, previous attempts of self-harm, statements of intent, family history of suicide, or detentions under the Mental Health Act) are recorded in case summaries and discharge letters.

M8.4 All health care professionals and support staff are made aware of the risks to patients associated with periods of change and significant dates, and increase vigilance at these times.
M8.5 Arrangements are in place to regularly review the physical environment and steps are taken to reduce access to means of suicide, including the use of window restrictors.

M8.6 Local suicide/self-harm audits are undertaken to learn the lessons.

**Resuscitation Procedures**

**OUTCOME**

Patients are resuscitated appropriately and effectively.

**STANDARD M9**

M9.1 There are written resuscitation policies and procedures in place, which include guidance on when to summon an ambulance.

M9.2 Prominently labelled and easily accessible resuscitation equipment is checked and restocked weekly and a record kept, which includes a list of the equipment.

M9.3 There is a member of staff on duty at all times who is appropriately trained (and updated at least annually) in first-aid and resuscitation techniques.

**Responsibility for Pharmaceutical Services**

**OUTCOME**

Responsibility for obtaining, prescribing, storing, use, handling, recording and disposal of medicines is clear.

**STANDARD M10**

M10.1 The establishment, through an appropriate senior pharmacist, has access to up-to-date legislation and guidance relating to the safe and secure handling of medicines.
M10.2 Suitable controls are in place, which ensure that the principles of the Duthie Report are met. Appropriate and effective arrangements must be in place for the:

- storage and handling of medicines;
- the handling of controlled drugs;
- medical gases.

M10.3 Establishments that do not have a pharmacy department obtain ongoing advice from a pharmacist with the experience of mental health pharmaceutical services and the relevant legal frameworks.

M10.4 If there is a pharmacy department in the establishment it must be under the control of a pharmacist who is a registered member of the Royal Pharmaceutical Society of Great Britain, and has a knowledge of psychiatric medicine.

M10.5 The establishment should have a medicines policy covering all aspects of medicine handling. The arrangements for access to blood monitoring services should be included.

M10.6 There are clear policies and procedures for the use of medications required for any specialist services provided by the establishment.

M10.7 There are systems in place for medicines required for short-term leave from the establishment.

M10.8 When medicines are no longer required by the named patient they are returned to the pharmacy or pharmacist for disposal.

**Patient Treatment and Care**

**The Care Programme Approach**

**OUTCOME**

Patients receive treatment and care in line with the Care Programme Approach introduced in Wales in 2002 and supplemented by detailed introductory guidance.

**STANDARD M11**

M11.1 There are written policies and procedures, to systematically introduce this Care Programme Approach into establishments in accordance with guidance issued by the National Assembly for Wales, flowing from the NSFW.
Admission and Assessment

OUTCOME

Patients are admitted and assessed appropriately.

STANDARD M12

M12.1 There are written policies and procedures for voluntary admission, agreed between the relevant agencies.

M12.2 Patients receive a comprehensive assessment (including a physical health assessment) on admission or transfer from another team.

M12.3 When a patient is referred for the first time, or transferred from another team, a new clinical assessment is carried out and includes an assessment of risk of harm to self or others by the patient.

M12.4 The assessment process includes an assessment of the family employment and social circumstances of patients, and for children their educational needs. This applies especially to those with behavioural problems after admission and prior to discharge.

M12.5 All assessments include the patient’s known substance misuse including alcohol history with intake expressed in units of alcohol.

M12.6 There is a system to ensure the early identification of the patient’s needs and strengths as an individual, as well as in terms of his or her illness.

Care Programme Approach: Care Planning and Review

OUTCOME

Each patient has a care plan that addresses their needs appropriately in line with the Care Programme Approach introduced in Wales in 2002.

STANDARD M13

M13.1 There is a single detailed, multi-professional plan of care formulated for each individual patient in accordance with the guidance issued by the National Assembly for Wales.
Information for Patients on their Treatment

OUTCOME

Patients are effectively involved in decisions about their treatment.

STANDARD M14

M14.1 The patient is informed of the effect of the treatment being proposed, and his/her views are taken into account.

M14.2 The patient's ability to consent to treatment is assessed and the extent to which a patient's agreement to medication is given readily or with reservation is recorded.

M14.3 The medication regime of each patient, and the known side effects and risks, is explained fully to the patient and their carers. This information includes a publication date and is updated in response to changes in medication used and published research findings.

M14.4 Each patient receives the lowest dosage and number of medications necessary.

M14.5 Individual patients' views about their care plan and treatment, especially about the effects and side effects of drugs, are documented in the patient's health record (care plan), together with the response of the clinicians.

Patients with Developmental Disabilities

OUTCOME

The rights and needs of patients with developmental disabilities are recognised and addressed

STANDARD M15

M15.1 There are written policies and procedures for ensuring that the rights and needs of patients with developmental disabilities are recognised and addressed. These are in line with current best practice (including Welsh Mental Handicap Strategy Guidance of 1994)

M15.2 An assessment of the patient's abilities including their ability to give informed consent is recorded in their notes.

M15.3 There is evidence (recorded in the patient’s notes) that the patient is encouraged to participate in all decisions related to their care.
M15.4 Information is provided in a format designed to aid comprehension (e.g. use of Makaton).

M15.5 A multidisciplinary assessment and care plan to meet the patient’s social needs (which includes the patient’s views) is recorded in the patient’s records. This assessment and plan includes contact with family/significant others and the patient’s expressed sexual needs.

M15.6 Within the clinical team there is evidence of training and expertise in caring for patients with developmental disabilities, so that the necessary knowledge base and skills are available to develop and maximise each patient’s potential.

M15.7 All patients have received a general health check (with specific reference to sight, hearing and dental care) at least once within the last year.

M15.8 There are specialist teachers to provide tuition for adolescent patients with sight and hearing impairments.

**Electro-convulsive Therapy (ECT)**

**OUTCOME**

ECT is provided to patients safely and appropriately.

**STANDARD M16**

M16.1 There are written policies and procedures, reviewed at least every three years, on the use of electro-convulsive therapy (ECT).

M16.2 The facilities, equipment and operation of ECT meet the recommendations made in the ECT handbook (Royal College of Psychiatrists 1995).

M16.3 There is regular audit to ensure that ECT is carried out in line with the policies and procedures for its use and administration.

**Administration of Medicines**

**OUTCOME**

Appropriately trained and qualified healthcare professionals administer all medicines to patients.

**STANDARD M17**

M17.1 There is a policy to include consent to treatment and administration to patients subject to an order or liable to be detained under the Mental Health Act. A copy of the current Certificate of Consent to Treatment (form 38) or Certificate of Second Opinion (Form 39) – and if relevant s.61 Review of
Treatment/MHAC 1 – is attached to the patients medicine card and checked by the nurse each time the relevant medication is administered. The written policy on consent to treatment includes clear guidance on:

- treatment under s.57 requiring consent and a second opinion;
- implantation of hormones;
- treatment under s.58 requiring consent or a second opinion, ie electro-convulsive therapy (ECT) and medication;
- nurses and the administration of medication;
- withdrawal of consent;
- second opinion appointed doctors (SOAD);
- review of Treatment under s.61 – including provision of a copy of the MHAC1 for the patient;
- urgent treatment under s.62

M17.2 All Certificates of Consent to Treatment (Form 38) and Certificates of Second Opinion (Form 39) are audited on a regular basis.

M17.3 All medicines are administered to a patient with a written prescription or, internal to the establishment, a drug administration chart that has been signed by a legally authorised prescriber taking the provisions of Part IV of the Mental Health Act 1983 into account where appropriate.

M17.4 A medication record is kept for each patient, the entries signed by the prescriber, showing:

- the name and date of birth of the patient;
- registration number and ward where appropriate;
- the name of the medicine;
- the dose;
- the route of administration;
- the frequency and time for administering each dose;
- the date of prescribing;
- any known medicines hypersensitivity or allergies;
- any special requirements.

M 17.5 Where medicines are received against a prescription for a named patient, they are administered to that particular patient and under no circumstances are used for other patients.

M17.6 Medicines are administered by, or under the supervision of, a registered nurse in accordance with the United Kingdom Central Council (UKCC) “Guidelines for the Administration of Medicines” October 2000 or when published, the equivalent guidelines of the Nursing and Midwifery Council (NMC) The
administration of controlled drugs is undertaken by a medical practitioner or by senior nurses.

M17.7 There is a secure method of transporting medicines from the medicine cupboard to the patient.

M17.8 All medicine doses are prepared immediately prior to their administration to patients from the container in which they are dispensed.

M17.9 There are clear policies for the administration of ‘when required’ medicines.

**Self-administration of Medicines**

**OUTCOME**

Patients are assessed, consulted and advised before they are enabled to self-administer medicines.

**STANDARD M18**

M18.1 There is a written policy and procedure for self-medication, which conforms to the duty of care inherent in the relationship of the hospital to the patient.

M18.2 Where the risks have been assessed and it is deemed that they are at a minimal risk of endanger themselves or others, patients are enabled to self-administer their medicines.

M18.3 Arrangements are only made with the agreement of the registered nurse, the patient and the doctor responsible for the patient’s care.

M18.4 Medicines dispensed for patients to self-administer have full directions and BNF cautionary warning where appropriate.

M18.5 Regular checks are made on the quantity of medicine given to the patient to ensure the patient is taking the medicine as prescribed.

M18.6 The medicine is stored in a personal lockable cupboard or drawer, the keys being held by the patient.

M18.7 There is a spare key to which clinical staff have access.
Treatment for Addictions

OUTCOME

Patients with addictions receive appropriate treatment and care.

STANDARD M19

M19.1 There are written policies and procedures, reviewed at least every three years, for the management of patients who may be abusing alcohol, drugs or other substances.

M19.2 Treatment sessions are in accordance with written guidance as part of the clinical programme and include:

- individual counselling;
- group therapy;
- community group meetings; and
- education sessions.

M19.3 There are written policies and procedures, which are reviewed at least every three years, for alcohol and drug testing during treatment which details the possible consequences of a positive test result.

M19.4 Assessment of the patient should include the effect of the patient’s addiction problems on children in the family.

Transfer of Patients

OUTCOME

The transfer of patients takes place safely and effectively.

STANDARD M20

M20.1 There are written polices and procedures to ensure the safe transfer of patients.

M20.2 There is full multi-professional exchange of written information, and documented discussion when patients are transferred from one residential unit or service to another.

M20.3 There are clearly identified plans and protocols in place for meeting the needs of people moving from one service to another.

M20.4 There are standards and targets for facilitating internal transfers into and out of critical care facilities.
Patient Discharge

OUTCOME

The discharge of patients takes place appropriately and effectively.

STANDARD M21

M21.1 There are written policies and procedures, reviewed at least every three years, about patient discharge.

M21.2 The policies and procedures cover arrangements to ensure that:

- discharge planning takes place as soon as possible after admission;
- patients and carers are involved in discharge planning;
- patients are provided with a copy of their discharge care plan;
- multi-professional post-discharge plans are devised to include an assessment of the impact of the discharge on children in the family;
- GP and primary care teams are informed to include the Health Visitor when there are children in the family;

M21.3 Discharge is a systematic and planned event.

M21.4 A co-ordination meeting is held prior to discharge to assess needs and nominate a care co-ordinator, where various sources of social work and/or healthcare assistance are provided to discharged patients.

M21.5 Aftercare planning addresses the needs of the patient’s carers as part of the implementation of the Carers (Recognition and Services) Act 1995.

M21.6 A crisis or contingency plan is agreed.

M21.7 Decisions to discharge or transfer patients are based on an assessment of the circumstances leading to hospitalisation as well as assessment of changes in other aspects of behaviour.

M21.8 Discharge planning meetings are attended by all personnel, disciplines and agencies relevant to the care of the patient.

M21.9 Any referral to another agency (including a voluntary agency) for a specific service is confirmed in writing and a copy of the care plan is made available.

M21.10 Every attempt is made to ensure that, when a patient leaves hospital, the care co-ordinator enables the patient to register with a GP.

M21.11 A discharge summary is sent to the patient’s GP within 5 working days of discharge which contain details of:
• diagnosis;
• treatment;
• medication
• follow-up arrangements;
• prognosis;
• a concise explanation of the condition;
• an accurate record of any violent incident;
• aspects of social care.

M21.12 An assessment of the risk of dangerousness and self-harm is included in the discharge summary.

Patients’ Records

OUTCOME

Patients’ treatment and care is informed by accurate and comprehensive records.

STANDARD M22

M22.1 Professional notes are integrated into a single, multi-disciplinary record, which includes hospital and community records.

M22.2 The multi-disciplinary record is chronologically ordered to reflect the care given to the patient over time.

Empowerment

OUTCOME

Patients are informed about their rights, their treatment and how to obtain independent advocacy.

STANDARD M23

M23.1 Patient information leaflets (in the language(s) of the patients being cared for) are published and disseminated to patients, their family and carers about:

• patients rights;
• responsibilities;
• medication;
• therapies.
M23.2 All new patients are given written details of local organisations providing independent advocacy.

M23.3 Details of local organisations providing independent advocacy are displayed in the establishment.

Arrangements for Visiting

OUTCOME

Appropriate visiting arrangements are in place, about which patients and their visitors are clear.

STANDARD M24

M24.1 There is a written policy and information on arrangements for patients to have visits from family, friends and their carers.

M24.2 The policy and the information for patients and visitors includes:

- the circumstances when visiting may properly be restricted;
- what may not be brought into the establishment; and
- makes specific reference to the access and supervision of children.

M24.3 The policy on visiting is explained to all patients and visitors.

M24.4 Visiting should normally take place outside the times set aside for structured activities.

M24.5 Staff provide assistance to patients who need help to resist unwanted visiting and assistance to visitors to resist unreasonable demands for visiting.

M24.6 If staff believe that visiting is disruptive to a patient’s treatment programme they take responsibility for discussing this with visitors and patients.
Working with Carers and Family Members

OUTCOME

Staff involve patients’ carers and families, as appropriate, in aspects of the treatment and care provided.

STANDARD M25

M25.1 There are written policies and procedures, reviewed at least every three years, about arrangements to involve the patient’s family members, friends and carers.

M25.2 The policy includes principles and practices governing:

- relationships between staff and the patient’s family, friends and carers;
- family members’, friends’ and carers’ rights to information; and
- practical assistance and emotional support to be given to family, friends and carers.

M25.3 There are written policies and procedures for involving, with the patient’s consent, families, carers and people close to the patient in:

- taking social and family histories into account following admission;
- drawing up, agreeing and reviewing treatment and care plans;
- planning and delivering services, particularly around discharge and after-care.
- assessment of the vulnerability of children in the patient’s family during the admission, care of the patient and discharge process.

M25.4 Staff, patients, carers and families are fully informed of these procedures.

M25.5 Carers and family members are informed of opportunities to make appointments to see the care co-ordinator, responsible medical officer, consultant or other staff within a reasonable time.

M25.6 Clinical staff are encouraged to see the families and carers of patients and take account of their insights and knowledge and, where appropriate, record relevant information provided by family members and/or carers in the patient’s file.
Anti-discriminatory Practice

OUTCOME

Patients are not discriminated against.

STANDARD M26

M26.1 There is a flexible and responsive regime which enables patients to be different from each other, meet their personal, health care, religious, cultural and language needs and which does not restrict their personal rights.

M26.2 The service has written policies on patients’ rights displayed in a public area and shown to patients on admission.

M26.3 This statement includes the patient’s rights to:

- be given comprehensive information about the nature of care services available;
- be treated with privacy and dignity;
- receive impartial access to all treatment services without discrimination;
- be assured of confidential treatment and treatment records;
- be free from mental, physical and chemical abuse and mechanical restraint;
- have complaints investigated;
- refuse treatment in certain circumstances;
- have access to translation and/or translation services.

Quality of Life for Patients

OUTCOME

The care provided recognises patients’ personal needs. Quality can be compromised by inappropriate mix of patients cared for in the same area.

STANDARD M27

M27.1 Separate areas are provided for patients requiring different levels and types of nursing care, such as:

- patients on acute admission residential units;
- patients who are likely to present severe behavioural problems;
- frail elderly mentally infirm patients;
• mothers suffering from post-natal depression accompanied by their babies;
• young people; or
• vulnerable patients likely to be exploited.

M27.2 Patients are accommodated in a single bedroom unless the care plan indicates otherwise and/or the patient has made a choice to share a room. (For children see standard M37.2).

M27.3 In forensic services and locked residential units there are gender specific facilities to meet the needs of patients with severe emotional and behavioural disorders.

M27.4 Safe facilities are provided for patients which safeguard their privacy and dignity including fully segregated dressing, washing and toilet facilities for men and women.

M27.5 Within reasonable limits, patients have freedom of choice, have their own privacy, are allowed to participate in activities, and have an individual quality of life consistent with their individual care plan and the interests of other patients. In particular patients are allowed:
• choice of bedtime and rising (for children this will be personal to their age and needs);
• to dress as they choose;
• access to drinks and food outside of set meal times;
• choice of foods at meal times;
• payment for work;
• access to library, music, art, current affairs etc;
• personal belongings consistent with the space available, including plants;
• privacy in relationships;
• to maintain outside links through trips and visits;
• access to advocacy and help lines.
Patients’ Money

OUTCOME

Patients’ financial interests are safeguarded.

STANDARD M28

M28.1 The registered manager ensures that patients control their own money, except where they state that they do not wish to or they lack capacity, and that safeguards are in place to protect the interests of the patient.

M28.2 Written records of all transactions are maintained.

M28.3 Where the money of individual patients is handled, the manager ensures that the personal allowances of these patients are not pooled and that appropriate records and receipts are kept.

M28.4 The registered manager may be appointed as agent for a patient only where no other individual is available. In this case, the manager ensures that:
   - the CSIW is notified on inspection;
   - records are kept of all incoming and outgoing payments.

M28.5 If the manager is to be an appointee for social security purposes, the Benefits Agency is given appropriate notice.

M28.6 Using a risk assessment basis, those patients deemed capable have a facility to hold their own money. Secure facilities are also provided for the safe-keeping of money and valuables on behalf of patients.

Restrictions and Security for Patients

OUTCOME

Arrangements for the restriction and security of patients are clear and effective.

STANDARD M29

M29.1 There are policies and procedures that state whether the unit is to be locked or whether patients have free access in and out of the unit.

M29.2 On each occasion a residential unit which is normally open is locked, it is reported to the most senior service manager with a brief explanation of why it was locked.
Levels of Observation

OUTCOME

Appropriate arrangements are made for the observation of patients.

STANDARD M30

M30.1 There are written policies and procedures, which are reviewed at least every three years, for determining levels of observation, engagement, communication and supervision for inpatients.

M30.2 The policies are in line with guidance from the SNMAC (Standing Nursing and Midwifery Advisory Council).

M30.3 The policies state the:
- defined levels of observation determined by the senior doctor on the residential unit, or in his/her absence, the senior nurse:
- the specified levels of observation including intervals of observation;
- details of numbers and skill levels of staff and their proximity to the patient under observation;
- criteria for each level of observation;
- criteria for reviewing patients levels of observation;
- length of time staff spent on observation.

M30.4 The policies ensure that all patients on a residential unit are considered subject to general observation, which includes actively engaging and interacting with the patient.

M30.5 Clinical staff are aware of, and consistently implement, clinical policies in relation to supportive observation and engagement.

M30.6 The reasons for imposing or altering the observation level is recorded in the clinical and nursing notes.

M30.7 There are regular clinical audits of the use of supportive observation and the results are discussed with all members of the multi-professional team.
Managing Disturbed Behaviour

OUTCOME

Patients displaying aggressive and violent behaviour are managed appropriately.

STANDARD M31

M31.1 There is a specific individual treatment plan for all patients who are seriously disturbed for more than a short period, which is recorded in the multi-professional patient notes.

M31.2 The policies for dealing with disturbed behaviour includes the levels of observation to be used and the degree of restriction required.

M31.3 The level of observation is agreed by the multi-professional disciplinary team and documented in the patients care plan.

M31.4 The degree of restriction is communicated and acted upon by all staff involved in patient care.

M31.5 Where a staff member has been threatened or attacked by a patient, where possible any immediate decision about that patient’s treatment plan is taken by other members of the clinical team.

M31.6 Any major changes in the treatment of disturbed or potentially violent patients (including withdrawal of medication) are communicated to all nursing staff who have contact with the patient. Responsibility for this belongs to the nurse in charge at the start of the shift.

M31.7 Facilities are available for the separate care of seriously disturbed patients and where this is not possible they are nursed separately from other patients. If this involves the use of seclusion see M42.

M31.8 There are written policies and procedures for staff in relation to responding to patients who:

- refuse to participate in therapeutic programmes;
- verbally abuse and/or threaten physical harm to others; or
- destroy communal property.
Management of Serious/Untoward Incidents

OUTCOME

Serious/untoward incidents are handled effectively and are learnt from.

STANDARD M32

M32.1 There is a written policy for serious/untoward incidents, which sets out the procedures to be followed.

M32.2 The policy:

- requires that a named individual co-ordinates the immediate response to the incident;
- sets out alarm procedures to ensure the controlled deployment of staff in response to an incident;
- includes a procedure for any person who has been seriously injured not to be left unattended by a doctor or trained nurse for any period, however short, in any circumstances;
- sets out the process for organising any investigation and audit;
- sets out the procedures for communicating the nature of the incident at the earliest possible time to:
  - senior service staff and managers;
  - the police; and
  - the family of the patient.

M32.3 There are immediate and ongoing support systems in place for staff and patients following a serious untoward incident or near miss.

M32.4 There is a review following a serious/untoward incident, within timescales set by the organisation.

M32.5 A named individual is responsible for co-ordinating the review, who is not directly involved in the management of the part of the service concerned.

M32.6 The review of a serious incident includes the whole multi-professional care team meeting to discuss the clinical and managerial issues which led to the particular incident.

M32.7 Patients, carers and their families and any victims are involved in the review at an early stage to ascertain their views and receive information.

M32.8 The review findings and report include recommendations for changes in practice.
M32.9 All relevant parties are informed of progress and of the outcome of the review as far as is appropriate.

M32.10 Violent incidents are audited, and any necessary redeployment of resources or other action is identified.

**Unexpected Patient Death**

**OUTCOME**

The families and carers of patients who die unexpectedly, and the staff who were involved in their care, are supported sensitively.

**STANDARD M33**

M33.1 There are arrangements in place for informing the patient’s family members and carers following a patient’s death.

M33.2 Support and information is provided to family members and carers following an unexpected patient death.

M33.3 There are arrangements in place to support staff following an unexpected patient death.

M33.4 There is a procedure in place for an investigation into the death to be instigated.

M33.5 The registered person informs the Mental Health Act Commission of the death of detained patients, date of inquiry and inquest.

M33.6 Management and members of internal investigating teams are trained in the investigative process, so that they understand the stages of investigation.

**Patients Absconding**

**OUTCOME**

All attempts are made to prevent absconding. When patients do so, effective arrangements are in place to handle the absconsion.

**STANDARD M34**

M34.1 There are written policies and procedures, reviewed at least every three years, for dealing with patients absconding.

M34.2 There is information for patients requesting their co-operation in informing staff of their whereabouts at all times.
M34.3 Missing patient procedures are jointly agreed between services and the police and are regularly reviewed, and include guidance on reporting a patient’s absence and informing the CSIW.

M34.4 Services record levels of absconding and formally review them annually, and following any significant increase in the number of the absconding of a high-risk patient. Reviews explore the reasons for absconding and ways of minimizing recurrence.

### Patient Restraint and Physical Interventions

**OUTCOME**

Patients are restrained appropriately and safely.

**STANDARD M35**

M35.1 There are written policies and procedures on using restraint and physical interventions with patients; if the policy is not to use restraint or physical intervention this is documented. Restraint policies for children must be child appropriate and not derived from adult restraint policies.

M35.2 The policy includes procedures for rapid tranquillisation and emergency medication.

M35.3 Staff receive training on the prevention of violence and aggression including de-escalation techniques.

M35.4 Procedures are explicit that patients are not restrained using mechanical restraints.

M35.5 All clinical areas have resources to minimise/intervene in episodes of violence or dangerous behaviour and staff are aware of these and the procedures for use.

M35.6 Patient mix, environment and staffing levels are reviewed to minimise incidents of disturbed behaviour requiring the use of physical intervention techniques.

M35.7 Physical intervention procedures are reviewed to ensure that they are employed appropriately by the full clinical team.

M35.8 When it has been necessary for a patient to be restrained a full nursing and medical review, including a physical examination, is carried out as soon as practicable.

M35.9 There is an up-to-date register of staff who have completed courses in restraint and physical intervention.
M35.10 The number, duration and form of restraint of patients is recorded and included on documentation available to the Care Standards Inspectorate for Wales.

**Child and Adolescent Mental Health Services (additional standards)**

**Safeguarding Children**

**OUTCOME**

Child and adolescent patients are treated and cared for at all times by professionals appropriately skilled, qualified and trained, whose practice conforms to regulations and guidelines issued by the various professional bodies and is based on safeguarding the interests and rights of the patients in their care.

**STANDARD M36**

M36.1 There is a written policy to reflect the guidance set out in *Working Together to Safeguard Children* (issued in Wales in September 2000), to include staff recruitment, professional qualifications and the use of Criminal Records Bureau and police checks. This includes Protection of Children Act (POCA) checks and staff responsibility to report to the POCA list where necessary.

M36.2 A copy of the child protection policy, compiled in collaboration with the local Area Child Protection Committee (ACPC), is available. The provision of training, on induction and thereafter annually, in child protection procedures is mandatory. A designated person for child protection is identified.

M36.3 Routine reference collection before interview, and police checks prior to appointment, are required for all staff with substantial access to children.

M36.4 Staff with a professional regulatory body (eg UKCC, Council for Professions Supplementary to Medicine or the GMC) are checked for appropriate registration on recruitment and again at renewal date.

M36.5 There is a written policy for handling serious/untoward incidents and the circumstances under which reports need to be made. Those fulfilling the defined criteria, or any allegations of abuse, are reported at once to the local child protection team and to the Care Standards Inspectorate for Wales.

M36.6 There are copies of complaints procedures and helpline telephone numbers clearly visible on notice boards.
Admission and Assessment

OUTCOME

Children are appropriately admitted to, and treated in, the establishment.

STANDARD M37

M37.1 The registered person informs the Local Authority if a child remains or is likely to remain an inpatient for a period of over three months (in line with section 85 of the Children Act 1989).

Quality of Life

OUTCOME

The care provided recognises the psychological, social and personal needs of children.

STANDARD M38

M38.1 There is a pre-planned programme and a pre-admission visit to allay anxiety on the part of the child, where appropriate, and except for emergency admissions.

M38.2 All children are admitted to a single room unless there is a specific request/clinical reason to share on a companion basis.

M38.3 A structured therapeutic programme should be run during the day.

M38.4 Consideration is given to the management of mixed sex groups.

M38.5 There is a policy on restriction of liberty which is guided by the relevant criteria set out in the Mental Health Act Code of Practice 1999, and in the Children Act 1989 Guidance and Regulations, Volume 4, Chapter 8 on Secure Accommodation.

M38.6 The special needs of, and specific services for, children from different ethnic, cultural or religious backgrounds are reflected in local policies, as appropriate to the patient population.

M38.7 Children are kept in hospital only if their needs cannot be met at home, it is in their best interests, and they are discharged as soon as possible.
Facilities and Equipment to Meet the Needs of Children

OUTCOME

Appropriate facilities and equipment are used to provide treatment and care for children.

STANDARD M39

M39.1 Children are seen in a separate outpatient area or, where the establishment does not have a separate outpatient area for children, they are seen promptly and preferably at the beginning of the session.

M39.2 The outpatient area is subject to the same environmental audit as any other area used for children to ensure that the area is safe, with any identified risks to children controlled.

M39.3 Adolescents are to have their privacy respected, and every effort is made to respect their wishes if they indicate they prefer to be seen without their parents (bearing in mind that there may be clinical need for close family involvement).

M39.4 Any toys provided are safe (compliant with British Safety Standards), and are age appropriate to the child.

M39.5 Education programmes are in place for children/young people whose length of stay exceeds five days. The programmes are managed by qualified teachers and are adequate to meet the patient’s needs, although some children may be too sick to receive education.

Valid Consent of Children

OUTCOME

Children and their families are fully aware of, and are asked to consent to, the treatment they are to receive.

STANDARD M40

M40.1 Clinicians speak with children and their families to ensure that children are fully aware of the treatment they are to receive.

M40.2 A parent can give permission for treatment but the child is to be told what is happening in language appropriate to his/her level of understanding (as defined in the Mental Health Act Code of Practice 1999, section 31).
M40.3 The doctor obtaining consent ensures that sufficient time is allowed to explain to the parent and child the proposed procedure and allow both the opportunity to ask questions.

M40.4 Children and adolescents are able to refuse treatment and have their concerns listened to (as defined in the Mental Health Act Code of Practice 1999, section 31).

M40.5 Where a child’s refusal for treatment is being overruled, it is done so on the basis that the welfare of the child is paramount and every effort is made to obtain his/her co-operation in these circumstances.

M40.6 The right of a young person over the age of 16 years to sign his/her own consent form is recognised.

Establishments in which Treatment or Nursing (or both) are Provided for Persons Liable to be Detained

Information for Staff

OUTCOME

Detained patients receive treatment and care in line with the Mental Health Act 1983, and regulations made under it, and its Code of Practice together with the MHA Memorandum, and Mental Health Act Commission Practice Notes.

STANDARD M41

M41.1 There are written policies and procedures covering all the statutory functions of the hospital managers, reviewed at least every three years.

M41.2 Copies of the following documents are available in each of the clinical areas:

- Mental Health Act 1983,
- Mental Health (Hospital, Guardianship and Consent to Treatment) Regulations 1983,
- Mental Health (After Care Under Supervision) Regulations 1996,
- Mental Health (Patients in the Community) (Transfers from Scotland) Regulations,
- Mental Health Act Code of Practice,
- Mental Health (Patients in the Community) Act 1995 – Guidance on Supervised MHA 1983 Memorandum on Parts 1 to V1, VIII and X,
- Mental Health Act Commission Guidance Notes

M41.3 There are written policies and procedures for the assessment, care, treatment and discharge of detained patients, which are drafted in accordance with the most recent version of the Code of Practice, and include policies on:
• personal searches;
• patient’s correspondence;
• doctors and nurses holding powers (Section 5 of the Act);
• patients presenting with particular management problems, including the use of seclusion;
• physical restraint;
• psychological treatments, including ‘time out’;
• review of treatment (Section 61 of the Act);
• patients concerned with criminal proceedings;
• leave of absence;
• absence without leave;
• the re-taking of a detained patient in the community;
• Mental Health Review Tribunals;
• managers hearings;
• the giving of information to detained patients;
• treatment requiring the patient’s consent or a second opinion (Section 58 of the Act)
• urgent treatment (Section 62 of the Act).
(To be read in conjunction with standard M37.5 for young people under the age of 18.)

M41.4 The policies and procedures for services for detained patients are audited at least every three years.

M41.5 Guidelines for assessment of patients for admission under the Mental Health Act, which spell out the roles of all involved, are jointly developed, implemented and audited regularly.

M41.6 A form is completed by the responsible medical officer every time urgent treatment is given under Section 62 of the Mental Health Act 1983.

M41.7 The use of Section 62 is regularly monitored by managers.
The Rights of Patients under the Mental Health Act

OUTCOME

Patients and their nearest relatives are able to exercise their rights and entitlements under the Mental Health Act 1983 and its Code of Practice.

STANDARD M42

M42.1 Detained patients and their nearest relatives are made aware of their rights and entitlements under the Mental Health Act 1983 and its Code of Practice.

M42.2 Written information is produced, displayed and disseminated to all new patients and, subject to the patient’s consent, given to their nearest relative about:

- the patient’s rights and entitlements;
- the patient’s right to apply to a Mental Health Review Tribunal and request a manager’s review;
- the role and function of the Mental Health Act Commission (this may be through the availability of the Mental Health Act Commission’s leaflets for detained patients);
- The availability of solicitors recognised by the Law Society as being proficient in mental health work.

M42.3 There is a written policy and procedure, reviewed at least every three years, encompassing the requirements of Part IV of the 1983 Mental Health Act.

Seclusion of Patients

OUTCOME

Patients are secluded in accordance with the requirements of the 1983 Mental Health Act Code of Practice.

STANDARD M43

M43.1 There are written policies and procedures on seclusion which are consistent with the Mental Health Act 1983 and Code of Practice.

M43.2 The written policies include guidance on:

- minimising the use of seclusion;
- the roles of professionals in initiation and review;
- monitoring by care teams and senior management;
- the appropriate use of seclusion;
- not removing the patient’s clothing during or following an incident;
• presence of same sex staff.

M43.3 Each episode of seclusion is reviewed by professionals independent of those staff in direct contact with the patient.

M43.4 Where a patient in seclusion has been sedated a nurse remains in sight and sound of the patient and vital signs are recorded at regular intervals.

M43.5 Rooms used for seclusion:
• provide privacy from other patients;
• enable staff to observe the patient at all times;
• do not contain anything which could cause harm to the patient or others;
• are comfortably furnished and lit;
• have controllable heating and ventilation;
• are quiet but not soundproofed and includes a means for calling for attention.

M43.6 A quarterly report of episodes of seclusion is produced for senior management and the Mental Health Act Commission, with a brief explanation of each occasion.

Section 17 Leave

OUTCOME

Arrangements for Section 17 leave of absence are appropriate and clear, and in accordance with the requirements of the 1983 Mental Health Act Code of Practice and Mental Health Act Commission Guidance Note.

STANDARD M44

M44.1 There are written policies and procedures for detained patients going on Section 17 (Mental Health Act 1983) leave.

M44.2 The policies and procedures for Section 17 leave include requirements that:
• the level of the patient’s co-operation with assessment and treatment is taken into account in deciding to grant leave;
• leave is not granted until the patient has been resident for sufficient time to allow an adequate risk assessment to be undertaken;
• the named nurse/escort attends the patient reviews to report on previous leave and is party to discussion about future leave.

M44.3 All conditions pertaining to the leave are recorded on the Section 17 form, including:
• whether it is escorted, including number of escorts, or unescorted;
• level of observation;
• period of leave;
• location at which the leave will be taken;
• the purpose of the leave;
• the expected date and time of return;
• any other specific conditions.

M44.4 Careful consideration is given to the choice of venue, taking account of:
• its purpose and suitability;
• the level of risk posed to the patient in that setting;
• the patient’s reason for choosing it;
• public sensitivities.

M44.5 Leave is cancelled if an appropriate escort or appropriate transport are not available.

Absence Without Leave Under Section 18

OUTCOME

Appropriate arrangements are made for missing and dead patients.

STANDARD M45

M45.1 Procedures on dealing with the situation of when patients are absent without leave are appropriate and clear, and in accordance with the requirements of the 1983 Mental Health Act Code of Practice and Mental Health Act Commission Guidance Note.

M45.2 These procedures are reviewed regularly and made known to all staff.
Discharge of Detained Patients

OUTCOME

Arrangements for the discharge of detained patients are appropriate and clear, and in accordance with the requirements of the 1983 Mental Health Act Code of Practice.

STANDARD M46

M46.1 The registered person should not delegate his or her discharge function to persons who are either on the staff of the hospital or have a financial interest in it.

M46.2 Planning for discharge under Section 117 of the Mental Health Act 1983 commences on admission and discharge planning meetings are attended by or receive contributions from all personnel, disciplines and agencies.

M46.3 The nominated care co-ordinator under Section 117 aftercare is an experienced mental health worker, familiar with the patient, who always attends Section 117 meetings.

M46.4 When patients are discharged from medium secure units, the discharge documents include a full risk assessment which contains a description of all overt indicators of relapse and the steps to be taken in the event of a relapse.

M46.5 Discharge documents are made available to all those directly involved in providing care.

Staff Training on the Mental Health Act

OUTCOME

Patients receive treatment and care from staff trained in, and conversant with, the provisions of the Mental Health Act 1983.

STANDARD M47

M47.1 All staff receive training on their responsibilities under the 1983 Mental Health Act and its Code of Practice and receive annual updates on aspects of mental health legislation.

M47.2 There are written policies, which are reviewed at least every three years, to guide staff in explaining to patients (and their carers/family members) their legal rights and responsibilities under the mental health legislation.
M47.3 All clinical staff receive training on Section 17 (Mental Health Act 1983) leave procedures which forms part of the induction of new staff, and are updated when necessary.

M47.4 All care staff receive training and regular updating on consent to treatment matters.

M47.5 All staff receive training on responsibilities as regards Mental Health Review Tribunals and patients have full access to relevant advice.
Hospices

Introduction to Standards H1 to H15

Section 2(3)(a)(i) of the Care Standards Act brings within the definition of ‘independent hospital’ establishments the main purpose of which is to provide palliative care. For ease of reference, such establishments are described in these standards as hospices.

There are two key factors in the provision and the regulation of palliative care services. First, the need to respond to issues with a sense of urgency as time is limited for the patient nearing the end of their life. Second, the often complex and diverse needs of both the patient and their carers need to be met by access to a multi-professional specialist palliative team with a range of skills to assist with physical, psychological, social and religious and cultural needs. The attached standards reflect this.

The standards are divided into two sections. The first section covers standards that relate both to adult and children’s hospices. These standards encompass palliative care services in a range of settings: inpatient, community (ie out-reach services provided by the establishment) and day therapy. The standards have been developed by the National Council for Hospices, and will be closely linked with the development of NICE guidance on supportive and palliative care. The second section contains additional standards that apply to children’s hospices only.

The standards that relate specifically to children’s palliative care services are based on the principle that a dying child is a child first and foremost, and their needs as children should be accommodated as a priority. The environment therefore needs to be child friendly and as ‘home like’ as possible. Many of the conditions the children have progress slowly over a number of years, placing an enormous strain on family life. A children’s hospice aims to help families with this burden of care.

The standards also recognise the importance of the presence of the child’s family and the need to take account of the family’s wishes, and that a child’s needs for play, education and contact with peers of their own age are essential components of an holistic palliative care approach.

See also, in particular, regulations 34 and 35 of the Regulations.
Hospices Generally

Arrangements for Care

OUTCOME

Patients and prospective patients, their families and carers, are clear about the arrangements for palliative care.

STANDARD H1

H1.1 Written information is provided about eligibility criteria for the treatment and care being provided and how to access this, reflecting the statement of purpose.

H1.2 Information about eligibility criteria and access is made widely available to referring bodies.

H1.3 The referral process is clearly described and response times to new referrals regularly reviewed to ensure there are no delays in gaining access.

H1.4 Patients are discharged with all the identified support services in place.

H1.5 Hospices providing a community service and care at home have a lone worker safety policy.

Palliative Care Expertise and Training for Multi-professional Teams

OUTCOME

Patients are assured that their care is provided by people who have the relevant expertise.

STANDARD H2

H2.1 Staff with specialist palliative care expertise function in multi-professional teams to ensure that the palliative care needs of patients and carers are met.

H2.2 Multi-professional palliative care teams are recruited, developed, educated and trained for the services which the provider is registered to undertake.

H2.3 The multi-professional team membership is commensurate with the service being provided.
H2.4 There is a multi-professional team meeting at least weekly for patient management, with arrangements in place for ethical decision making and patient advocacy where this is indicated and required.

H2.5 Formal, multi-professional team meetings are held at least annually with other related agencies or services for audit, service operation and communication review.

H2.6 All members of the multi-professional team are trained in the assessment of palliative care needs across the dimensions of physical, psychological, social, religious and cultural needs.

H2.7 All team members are trained in the provision of general psychological care for patients and carers.

H2.8 All team members are able to communicate with patients and their carers with sensitivity, ensuring that patients and their carers receive all the information they want concerning their condition, treatment and care.

H2.9 All team members have received training and updating in communication skills and the breaking of bad news.

H2.10 There are in place systems of both professional and personal support for all those who work in the establishment.

Assessment of Patients’ and Carers’ Needs

OUTCOME

The needs of patients and carers are appropriately assessed.

STANDARD H4

H3.1 Patients’ and carers’ needs are first assessed by a member of the multi-professional team.

H3.2 The assessment covers all domains, including:

- physical;
- psychological;
- social;
• religious;
• cultural.

H3.3 Treatment and care choices are clearly explained to patients and carers with sufficient information, time and assistance to make informed decisions, and to give informed consent where appropriate.

H3.4 The patient and carer assessment is subject to review as and when changes in care are indicated.

Delivery of Palliative Care

OUTCOME

Patients receive appropriate palliative care.

STANDARD H4

H4.1 A member of the multi-professional team is designated as the principal contact for each patient and carer.

H4.2 A member of the multi-professional team is identified who will provide access to agencies or services for carer support including bereavement support.

H4.3 Information about carer support services and how they may be accessed is easily accessible in a variety of formats and places.

H4.4 There are procedures for patients and carers, and for those who work in the establishment, for accessing out-of-hours specialist advice and support.

H4.5 Care pathways are in place which delineate the care to be provided to patients and their carers and which are used as a part of clinical audit and outcomes analysis.

H4.6 The multi-professional team employ evidence-based clinical guidelines.

H4.7 Arrangements are in place for regularly and systematically obtaining patient and carer views about their experience of using palliative care services from the provider.

H4.8 There are written policies and procedures that ensure the ready availability of medicines not used routinely in the community and the availability of medicines outside normal hours (for example, parenteral medication for symptom control in the terminal phase of illness).

H4.9 The environment in which care is given affords patients and carers the privacy they require and enables them to be treated with dignity at all times.
H4.10 Care and services are delivered in such a manner as to be patient and carer centred, taking into account patient and carer preferences and requests.

H4.11 The care of the patient after death takes into account all religious and cultural requirements, and the requests of both the patient and family.

**Records of Care**

**OUTCOME**

Patient care is based upon accurate records.

**STANDARD H5**

H5.1 Members of the multi-professional team have continuous access to up-to-date records and other information about patients and their carers.

H 5.2 All team members keep patient records up to date following each patient/carer contact.

H53 There is access to an information system capable of supporting service review.

H5.4 Communications between team members and services are concise and in a language which is readily comprehensible between professionals.

**Infection Control**

**OUTCOME**

The risk of patients, staff and visitors acquiring a hospital acquired infection is minimised.

**STANDARD H6**

H6.1 There are formal links and membership of an infection control team; this may be within another organisation, such as a local acute services NHS Trust.

H6.2 There is a registered nurse with designated responsibilities for infection control that are included in a documented job description and there is a defined time commitment for infection control activities.

H6.3 The infection control link nurse has training in infection control and provides evidence of continuing professional development (CPD) in relation to the role in infection control.
H6.4 Prevention and control of infection are considered as part of all proposed service developments.

H6.5 Written policies, procedures and guidance for the prevention and control of infection are implemented and reflect relevant legislation and published professional guidance, including:

- major outbreaks of communicable infections;
- isolation of patients;
- antimicrobial prescribing;
- control of MRSA, VRE and other antimicrobial resistant micro-organisms;
- control of tuberculosis, including multi-drug resistant tuberculosis;
- collection, packaging, handling and delivery of laboratory specimens; and
- handling of medical devices in procedures carried out on known/suspect CJD patients and on patients in risk categories for CJD as defined in the ACDP/SEAC guidance (including disposal/quarantining procedures).

H6.6 Each department or service has a current copy of the approved policies, procedures and guidelines pertinent to its activities.

**Resuscitation**

**OUTCOME**

Patients rights are observed around the issue of resuscitation.

**STANDARD H7**

H7.1 Information about the hospices resuscitation policy is available for patients.

H7.2 The registered person must ensure that patients’ rights are central to decision making on resuscitation.

H7.3 The policy includes appropriate supervision arrangements to review resuscitation decisions.

H7.4 Clinical staff with a thorough understanding of the resuscitation policy and its application are on duty at all times and are available to make resuscitation decisions including those involving the resuscitation of children where relevant.

**Responsibility for Pharmaceutical Services**

**OUTCOME**

Responsibility for obtaining, prescribing, storing, use, handling, recording and disposal of medicines is clear.
STANDARD H8

H8.1 The senior nurse or medical director is responsible for safe medicines systems, unless there is a pharmacy department supplying medicines within the same body corporate as the hospice when the senior pharmacist will be responsible.

H8.2 The hospice has a ward/clinical pharmacy service from a pharmacist with experience of palliative care medicine and access to a medicines information service.

Ordering, Storage, Use and Disposal of Medicines

OUTCOME

Medicines, dressings and gases are handled in a safe and secure manner.

STANDARD H9

H9.1 All medicines, medical gases and interactive wound dressings are obtained by, and stored under, the control of a senior nurse, or medical director under the control of the senior nurse, if there is no pharmacist employed by the organisation.

H9.2 The pharmacist or, where there is no pharmacist employed, the senior nurse manager or medical director, signs any orders to obtain prescription-only medicines from wholesale suppliers.

H9.3 There is a written procedure for the receipt of, and responsibilities for taking action on, hazard warnings and drug recalls, assisted by the supplying pharmacist.

H9.4 Medicines on the unit or ward are the responsibility of the senior nurses designated for the purpose by the senior nurse manager.

H9.5 Medicines in current use are kept in a locked cupboard or trolley, and trolleys are fastened to a wall when not in use.

H9.6 There is a written procedure for the handover of keys at changes of shifts and for security arrangements for spare keys.

H9.7 A medication record is kept for each patient, the entries signed by the prescriber, showing:

- the name and date of birth of the patient;
- registration number and ward where appropriate;
- the name of the medicine;
• the dose;
• the route of administration;
• the frequency and time for administering each dose;
• the date of prescribing;
• any known medicines hypersensitivity or allergies;
• any special requirements.

H9.8 Records are kept for eight years from the date of discharge or death of the patient.

H9.9 Medicines brought into the hospice by individual patients, and which are not used, are kept separate from other medicines on the ward and held in a safe place until discharge of the patient when they are returned to the patient or his/her representative. A written policy should exist for the use of patients own drugs, including criteria to assess the suitability of medicines for continued use.

H9.10 The disposal of waste is carried out by an authorised contractor who is used to complying with the arrangements for pharmaceutical waste, including cytotoxic waste where appropriate.

H9.11 When a patient dies in the hospice the patient’s medicines are kept for at least one week in case there is a need for a coroner’s inquest.

Administration of Medicines

OUTCOME

Appropriately trained and qualified healthcare professionals administer all medicines and drugs to patients.
STANDARD H10

H10.1 All medicines are administered to a patient with a written prescription or, internal to the hospice, a drug administration chart that has been signed by a legally authorised prescriber.

H10.2 Where medicines are received against a prescription for a named patient, they are administered to that particular patient and under no circumstances are used for other patients.

H10.3 When medicines are no longer required by the named patient they are returned to the pharmacy or pharmacist for disposal.

H10.4 Medicines are administered by a medical practitioner, or under the supervision of, a registered nurse in accordance with the United Kingdom Central Council (UKCC) “Guidelines for the Administration of Medicines” or current professional guidelines published by the Nursing and Midwifery Council (NMC) and the guidance on administration in Administration Control of Medicines in Care Homes (Royal Pharmaceutical Society 2001).

H10.5 There is a secure method to transport medicines from the medicine cupboard to the patient.

Self-administration of Medicines

OUTCOME

Patients are assessed, consulted and advised before they are enabled to self-administer medicines.

STANDARD H11

H11.1 There is a written policy and procedure for self-medication, which conforms to the duty of care inherent in the relationship of the hospice to the patient.

H11.2 Where the risks have been assessed and it is deemed that they cannot endanger themselves or others, patients are enabled to self-administer their medicines.

H11.3 Arrangements are only made with the agreement of the senior nurse, the patient and the doctor responsible for the patient’s care.

H11.4 Medicines dispensed for patients to self-administer (or to take home) have full directions and BNF cautionary warning where appropriate.

H11.5 Regular checks are made on the quantity of medicine given to the patient to ensure the patient is taking the prescribed dose.
H11.6 The medicine is stored in a personal lockable cupboard or drawer, the keys being held by the patient.

H11.7 There is a spare key available to registered nurses and other appropriately qualified staff entitled to access, which is kept in a safe and secure place.

Storage and Supply of Medical Gases

OUTCOME

Medical gases are stored and supplied appropriately.

STANDARD H12

H12.1 There are named persons (authorised person, competent person and quality controller) as defined under HTM 2022 responsible for the storage, identity, quality and purity of all gases at the terminal units, and for maintaining gas pipelines, and compliance with HTM 2022.

H12.2 The hospital has a designated suitably trained ‘Authorised Person’ for Medical Gas Pipeline Systems (MGPS).

- The person may cover a number of hospitals but must be clearly responsible for the day to day management of the MGPS. They must have knowledge of the hospital, systems and personnel. The person may be an employee or somebody external having a written service level agreement with the hospital.
- If the hospital is part of a larger group of hospitals, one person may be ‘Authorised Person’ for a number of sites, within reasonable travelling distance of each other, and able to respond to emergency situations at the hospital.
- Periods of leave must be suitably covered.

H12.3 The ‘Authorised Person MGPS’ has arrangements in place to discharge responsibility under HTM 2022. For a small private hospital the ‘Authorised Person MGPS’ may do so by arranging a contract with a suitably recognised medical gas specialist company for a ‘Competent Person’ to maintain the system. Links in writing (contract, service agreement) would be made with a ‘Quality Controller’ to advise and perform identity and purity tests when required. The ‘Authorised Person MGPS’ must ensure that a suitable ‘permit to work’ system is in place and should receive a copy of all work carried out on the MGPS.

H12.4 The ‘Authorised Person’ has delegated a named member of staff to be his/her representative on the site, who may be the hospital engineer or another person, but they must be suitably trained and familiar with the medical gas system.
H12.5 Where the ‘Authorised Person MGPS’ is off site they must visit and perform regular audits of the hospital to ensure compliance with the management systems in place. Other matters such as safe storage of isolation valve box keys, emergency contact numbers, stock rotation of cylinders, cleanliness and security of manifold sheds should also be audited to demonstrate the MGPS are under control.

H12.6 The hospital has a designated suitably trained ‘Quality Controller (QC MGPS)’.

H12.7 Prior to use of a new system, or resumption of use of a repaired system, the QCMGPS must indicate in writing that he or she is satisfied with the identity and purity of the gases at the terminal units. This is alongside the signature of the ‘Authorised Person’ who accepts the responsibility for the correct operation of the pipeline systems.

H12.8 Any engineers (competent persons) delegated to work on the medical gas pipelines systems are properly trained and experienced, and authorised to do so by the Authorised person.

H12.9 All work is controlled by a permit to work procedure.

H12.10 Policies and procedures are produced for recording the delivery, handling and storage of full and empty medical gas cylinders, with an indication of who is in charge of this procedure at the hospital.

**Additional Standards for Children’s Hospices**

**Assessment and Care of Children**

**OUTCOME**

The special needs of children are addressed.

**STANDARD H13**

H13.1 The child and family’s needs are assessed (prior to admission if possible) and a care plan is developed, which is updated when required.

H13.2 The assessment process includes the child’s developmental and educational needs.

H13.3 The child and parents are included in any discussions and decisions about treatment and care, and choices are explained with sufficient information, time and assistance to make informed decisions, and to give informed consent where appropriate.
H13.4 Care staff recognise the unique wishes of each child and their family and accommodate these and the child’s daily routine in an individualised care plan which is agreed with the family and, where possible, with the child.

H13.5 The child’s care plan is reviewed on each visit to the hospice or during each episode of care in the community, but also updated as and when changes in care are indicated.

H13.6 Where children are cared for, the services provided are child and family-centred and promote a child orientated routine.

H13.7 The treatment and care provided encourages parental involvement in their child’s care.

H13.8 The treatment and care promotes a child centred routine with regard to sleeping and feeding requirements, and there is sufficient flexibility to accommodate individual children’s usual pattern of daily care.

H13.9 The child and parents are kept informed about the child’s condition.

H13.10 In partnership with parents, information is provided to the child and siblings about treatment and care which is appropriate to their age, understanding and the specific circumstances.

H13.11 Symptom control is used to promote comfort and enhance quality of life of the child. (Symptom control means the management of any/all symptoms a child may experience in order to promote comfort and enhance the quality of life. Symptom control is much more than simply pain relief, although this is an important feature of symptom control.)

H13.12 Symptom control is evaluated, at least daily, by a member of the multi-professional team.

H13.13 The evaluation of symptom control involves the family, and where necessary other agencies contributing to the care of the child and family.

H13.14 The symptom control and evaluation takes account of the particular vulnerabilities of children with sensory impairment and those who are unable to communicate.

H13.15 The care of the child both before and after death respects the wishes of both the child and family and takes into account religious and cultural requirements.

H13.16 When death occurs within the children’s hospice, there is a room with suitable facilities for the child’s body to remain until the time of the funeral if that is the parents’ wish.

H13.17 The family are offered accommodation at the hospice during this period and a designated team member should be made available to give sensitive
emotional support and information about, or practical help with, organising the funeral and any other aspects relating to the death.

H13.18 Bereavement care is offered in accordance with the wishes of the family which includes bereavement support for siblings.

H13.19 Staff work closely with other individuals or agencies who may offer support in the family’s own locality.

Qualifications and Training for Staff Caring for Children

OUTCOME
Children are cared for by appropriately qualified and trained staff.

STANDARD H14

H14.1 The multi-professional team at a children’s hospice is led by a qualified children’s nurse with a further qualification in paediatric palliative care and/or experience in the palliative care of children and young people.

H14.2 There are arrangements in place for on-call medical cover at all times (preferably by a doctor with training and expertise in paediatrics and palliative care, but, if not, access to this expertise must be available at all times).

H14.3 There is a communication policy agreed with the NHS Trusts who refer the children to include frequency of multi-professional meetings with staff inside and outside the hospice.

H14.4 Staff have training to recognise the vulnerability of ill children, including in the following areas:
- child protection;
- assessing pain and discomfort;
- how the child asserts his/her own best interests.

H14.5 Staff are trained to understand the communication needs of children according to their age and ability and any disability they may have.

H14.6 There is a minimum of one children’s nurse on duty at all times.

H14.7 There are sufficient numbers of children’s nurses employed to allow two children’s nurses to be available for each shift in 24-hours if necessary.

H14.8 There is flexibility in how children’s nurses are deployed, allowing them to be rostered according to the needs of children.

H14.9 Staff are trained in the calculation and administration of medicines to children, and those staff are the only ones allowed to check drugs for children.
H14.10 All care staff are trained in the assessment of the child across the dimensions of physical, psychological, social, developmental, educational, spiritual and cultural needs.

H14.11 All staff are trained in supporting families when there are decisions about treatment and end of life care to be made.

H14.12 All staff are aware of sources of advice and guidance regarding ethical dilemmas.

Environment for Care of Children

OUTCOME

Children’s special needs are addressed by the facilities provided.

STANDARD H15

H15.1 The establishment is furnished and equipped to meet the needs of children, with particular efforts made to minimise the clinical and institutional environment and to promote a homely and welcoming setting.

H15.2 Accommodation is provided for the child’s family, including siblings, and unrestricted parental involvement in the child’s care is promoted.

H15.3 Children are cared for alongside other children and their play and educational needs are met.

H15.4 Arrangements are made to ensure that:

- qualified play staff are employed;
- indoor and outdoor play areas are accessible to all (including children in wheelchairs);
- there is a wide variety of play equipment to meet the needs of infants and children of different ages, developmental stages and differing intellectual abilities and to help them express their feelings and prepare for experiences ahead. Access to independent advocacy and help-lines should be clear.

H15.5 There is access to teaching staff and educational facilities, and equipment for all children aged between five and 16 years, including provision for those with special educational needs.

H15.6 Children and young people should be cared for alongside children in similar peer groups and not in a facility unsuitable for their age.
H15.7 Provision is made to meet the needs of children with disabilities.

H15.8 Meals are a family occasion, centred on a communal dining area with a varied menu.

H15.9 A children’s menu is available which meets current nutritional advice and can be adapted for children of different age groups in terms of size, content and timing of meals.

H15.10 The children’s menu should cater for the tastes and preferences of children and accommodate special diets for cultural and medical purposes.

H15.11 Cutlery and utensils are available which suit the needs of children of different ages and abilities.

H15.12 Planning of the environment for children includes preventing access by a child to hot surfaces, hot water, storage of cleaning materials, and access to power points.

H15.13 All staff are made aware of their responsibility to protect children.

H15.14 Staff are alert to the presence of strangers and establish their identity immediately.

H15.15 The children’s hospice is secured at night.
Maternity Hospitals

Introduction to Standards MC1 to MC7

Section 2(7)(c) of the Care Standards Act brings within the definition of ‘independent hospitals’ establishments in which obstetric services and/or, in connection with childbirth, medical services are provided. For ease of reference, such establishments are described in these standards as maternity hospitals. For maternity hospital that are also acute hospitals these standards need to be applied alongside the acute hospital standards.

The attached standards reflect that the important factors in ensuring patients receive safe and effective maternity services (including antenatal care, delivery, post-natal care and the care of the newborn baby) are:

- recognition of the special nature of the clinical care involved;
- ensuring that those involved in providing the services are appropriately qualified and trained;
- recognition of the role of general practitioners, midwives and obstetricians;
- ensuring that urgent and emergency procedures can take place quickly and safely;
- ensuring that routine and special needs of the mother and the newborn baby are met.

See also, in particular, regulations 38 and 39 of the Regulations.
Maternity Services

Human Resources

OUTCOME

Patients receive treatment from properly qualified and trained health care professionals.

STANDARD MC1

MC1.1 Obstetricians, gynaecologists and anaesthetists are current Members or Fellows of their respective medical Royal Colleges, have sufficient experience and seniority and be in good standing. They are also on the specialist register of the General Medical Council.

MC1.2 Midwives are registered with the United Kingdom Central Council for Nursing, Midwifery and Health Visiting (UKCC) and have notified her/his intention to practice to the Local Supervisory Authority. A Head of Midwifery is appointed in all maternity units.

MC1.3 All midwives take part in a Continuing Professional Development programme which satisfies their UKCC requirements for Post Registration Education and Practice (PREP). This is checked on a three yearly basis.

MC1.4 Gynaecologists undertaking laparoscopic surgery and sterilisation have undergone accredited updated training in relevant special skills modules as developed by the Royal College of Obstetricians and Gynaecologists (RCOG). (RCOG Minimal Access Criterion Levels 1-3).

MC1.5 All midwives have access to a Supervisor of Midwives, who in turn should have access to the unit to ensure the maintenance of midwifery standards.

MC1.6 All professionals attend regular multi-disciplinary education/training sessions.

Records Management

OUTCOME

Patients treatment is informed by effective and accurate records.

STANDARD MC2

MC2.1 The type of delivery is recorded in the maternity notes.
MC2.2 Numbers of caesarean sections performed by individual consultants are kept and regularly audited.

MC2.3 There are storage facilities to keep the records traceable and secure against loss, damage or use by unauthorised persons.

**Antenatal Care**

**OUTCOME**

Patients receive safe and effective antenatal care.

**STANDARD MC3**

MC3.1 Antenatal care and antenatal screening tests and their quality standards comply with the standards detailed in the antenatal screening programme of the National Screening Committee, the Royal College of Obstetricians and Gynaecologists guidelines ‘Effective Procedures in Maternity Care suitable for Audit’ and with any guidelines from the National Institute of Clinical Excellence (NICE) concerning pregnancy and delivery.

MC3.2 Antenatal screening tests are only performed with the woman’s informed consent following a pre-test discussion with the woman, preferably together with her partner.

MC3.3 Women who choose to be screened, for whatever condition, have the results conveyed to them as soon as possible.

MC3.4 Potentially adverse results from screening tests are given in person within 48 hours of the result becoming available, enabling counselling and support to be provided. All women and their partners are offered counselling whatever their reproductive choice or the outcome.

MC3.5 Care programmes for women who are likely to refuse blood products are drawn up during pregnancy and written in the notes. Advance care directives are also obtained in these cases. Clinical guidelines in the Confidential Enquiries into Maternal Deaths (CEMD) Report are followed.

MC3.6 All women receive advice about signs and symptoms of problems such as pre-eclampsia or early labour and have a telephone contact number for a named person employed by the clinic or hospital, readily contactable at all times.

MC3.7 There are written procedures for Anti-D to be routinely used to prevent or minimise the risk of rhesus iso-immunisation for all rhesus negative pregnant women, as a minimum, following any possible sensitising event during pregnancy, and immediately after birth.
Additional Standards for Midwife-led Units – Antenatal Care

OUTCOME

Midwife-led units have effective arrangements to ensure the safety of the mother and her baby.

STANDARD MC4

MC4.1 Patients who choose to be cared for solely by a midwifery practitioner are assessed to ascertain if there are likely to be any complications at a later stage and these are explained to them.

MC 4.2 In midwife led units protocols for the identification and screening out of women at higher risk of complications, or operative delivery with subsequent transfer to a consultant unit for the remainder of their care are in place together with protocols for the emergency transfer of women with sudden or unexpected complications.

MC4.3 Women at anticipated higher risk of complications but who refuse advice to be transferred to medically led care are fully informed of the possible adverse consequences to both themselves and the foetus of this action. A written and signed record of the decision is kept.

MC4.4 There is a written evidence-based referral protocol to obstetric consultant care for women at recognised risk of possible complications.

MC4.5 In a midwife-led unit, a registered midwife who has notified her intention to practice to the Local Supervising Authority is available on-call throughout the 24-hour period, and available to attend within 15 minutes of being summoned.

MC4.6 At all times when there are women receiving care in the establishment a midwife is on duty.

MC4.7 Midwife-led units have in place agreed protocols for the management of obstetric and neonatal emergencies which include emergency access to an appropriately experienced obstetrician and/or paediatrician. At least one midwife who has undertaken the Advanced Life Support in Obstetrics (ALSO) course, or similar, is on duty at all times.
Childbirth

OUTCOME

Effective arrangements are in place for the safe delivery of the mother and her baby.

STANDARD MC5

MC5.1 There are written, referenced, evidence-based, multi-disciplinary policies for the management of all key conditions/situations on the antenatal and post-natal wards and the delivery suite. These are subject to review at intervals of not more than three years. They include written policies for all the conditions described in the latest Clinical Negligence Scheme for Trusts (CNST) Report.

MC5.2 All professional staff agree and adhere to these policies, ensuring that no confusion arises over individual deviations in practice should an emergency arise.

MC5.3 Arrangements are in place for the prompt supply of blood products in emergency situations. Regular drills take place to check the adequacy of the arrangements.

MC5.4 Arrangements are in place for the prompt transfer of women/babies requiring intensive or other specialist care. An experienced doctor, midwife or neonatal nurse accompanies the mother, baby or both.

MC5.5 A consultant obstetrician is readily contactable in an emergency and, taking into account local circumstances, is able to arrive within 15 minutes of being contacted.

MC5.6 Apart from in midwife-led units, caesarean section is undertaken rapidly and in a short enough period to eliminate unacceptable delay. When a decision is made to perform an emergency caesarean section, the person taking the decision indicates clearly the urgency with which it needs to be carried out. The time from the decision to operate until the start of operation does not normally exceed 30 minutes.

MC5.7 Each obstetric unit with a significant number of deliveries must have critical care beds where patients are cared for by an experienced midwife.

MC5.8 In the case of adverse events, including critical incidents and near miss maternal or neonatal deaths or stillbirths, a local enquiry takes place as well as a multi-disciplinary risk management assessment.

MC5.9 When an adverse incident occurs report forms are filled in by all staff involved within 24 hours.
Maternal Death or Stillbirth

OUTCOME

Maternal deaths or stillbirths are dealt with sensitively and are reported appropriately.

STANDARD MC6

MC6.1 There is a written policy in place for action following a maternal death or a stillbirth.

MC6.2 Where a maternal death, stillbirth or neonatal death takes place the following steps are taken:

- there is a local enquiry as well as the death reported to the coroner and to either the Confidential Enquiries into Maternal Deaths (CEMD) or the Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI);
- whenever possible a post-mortem is performed in light of both CEMD and CESDI recommendations for good practice;
- the relatives are fully informed about the circumstances surrounding the death and have further meetings with staff at their request;
- where the patient had a thrombosis, cardiac or other possible genetically linked problems, the possibility of an inherited defect is explored and screening of the family offered if necessary; and
- ongoing bereavement counselling is made available for the family.

MC6.3 Local leaders of religious faiths are readily contactable on request for the family of the mother or baby.

MC6.4 Staff encourage parents to see/hold their baby and there are arrangements in place for photographs to be taken.

MC6.5 Suitable facilities are provided for a mother (and her family) who has undergone still birth or who has a very ill baby so that she does not have to be cared for in close proximity to mothers with healthy babies.
Care of the Newborn Baby

OUTCOME

Mothers and newborn babies receive appropriate quality treatment and screening.

STANDARD MC7

MC7.1 There is a designated consultant paediatrician with general oversight of care protocols.

MC7.2 There is emergency access to a paediatric team for support for very ill babies and for consultations on a regular basis for other problems affecting the newborn baby.

MC7.3 Emergency transfer arrangements are agreed with a local neonatal intensive care unit.

MC7.4 Arrangements are in place for the routine examination and screening of newborn babies, these include:

- routine screening for congenital hip dysplasia and metabolic/blood disorders which are subject to national screening programme standards;
- TB screening;
- immunisation for Hepatitis B, if the need for this is identified by antenatal screening;
- a policy for prevention of vitamin K deficiency bleeding taking account of national guidance.

MC7.5 Written policies are in place for the management of common problems of newborn babies including jaundice, hypoglycaemia and infection and a unit policy for the management of group B streptococcal infection.

MC7.6 Arrangements are in place for all women and babies to be transferred to the care of their local community midwives, health visitors and GPs.

MC7.7 Parents are given information on how and where to register the birth.

MC7.8 Arrangements are in place to ensure that the allocation of an NHS number at birth is made.
Introduction to Standards TP1 to TP4

The Abortion Act 1967 as amended requires termination of pregnancy to be carried out in an NHS hospital or, in relation to Wales, in a place approved for this purpose by the National Assembly for Wales. Currently, proprietors of abortion services have to undertake to comply with the Required Standard Operating Principles as well as registration under the Registered Homes Act 1984, with respective inspections by both the Assembly and the Health Authority. The introduction of the CSIW provides an opportunity to consider streamlining the procedures for approving and monitoring abortion clinics.

The following standards apply to establishments in which terminations of pregnancy take place (defined as ‘independent hospitals’ under Section 2(7)(d) of the Care Standards Act). The standards aim to ensure that:

- services comply with the requirements of the Abortion Act;
- establishments can only accept termination of pregnancy referrals from a medical practitioner or a pregnancy advice bureau;
- appropriate information is provided to those seeking or obtaining an abortion; and
- information is provided to help facilitate the inspection of services.

Women need objective sources of information about abortion and possible alternatives and should not feel pressured into proceeding with a termination. Requiring the provision of information materials and specifying when fees can be accepted are intended to reduce these pressures.

Abortions are generally day care procedures, so women tend to leave the establishment where the procedure takes place within a couple of hours. However, they may develop complications or be in pain or be anxious about how much bleeding to expect. They should therefore be given contact telephone numbers to ring for advice. It is important that the registered person records that this information has been provided. As medical abortion becomes more frequently used (ie where a woman is given tablets to terminate the pregnancy but the actual abortion occurs some time later, sometimes when the patient has returned to her own home) it is particularly important that information and support services are available.
Respect is due to the dead foetus based on its lost potential for development into a fully formed human being. Full account should be taken of any personal wishes that have been expressed about disposal of foetal tissue. All foetal tissue should be disposed of in accordance with national guidance.

See also, in particular, regulation 40 of the Regulations.

**Termination of pregnancy**

**Information for Patients**

**OUTCOME**

Patients are aware of the measures they need to take before and after treatment.

**STANDARD TP1**

TP1.1 Patients are given information prior to attending for the procedure on:

- instructions with regard to any existing medication;
- travel directions to the establishment;
- contact telephone number for the establishment for queries prior to the procedure.

TP1.2 On leaving the establishment each patient is provided with information about:

- post procedure pain relief;
- post procedure bleeding;
- taking care of herself after the procedure;
- possible complications;
- a telephone contact number at the establishment to ring for advice;
- a 24-hour telephone number for advice elsewhere if the establishment is not open 24 hours a day.

TP1.3 A written record is maintained which notes the information given to the patient.
Privacy and Confidentiality for Patients

OUTCOME

Patients are assured of privacy and confidentiality.

STANDARD TP2

TP2.1 All records of terminations, which include patient attributable information, are stored securely and kept strictly confidential within the establishment.

TP2.2 The arrangements for the reception of patients and consultation with patients ensure that patient privacy is maintained at all times.

TP2.3 There are procedures for staff to follow to ensure that patient’s names and personal details are not heard or seen in any public area of the establishment.

Respect for Foetal Tissue

OUTCOME

Foetal tissue is handled sensitively.

STANDARD TP3

TP3.1 There are written policies and procedures for staff to follow so that foetal tissue is treated with dignity and respect, in accordance with Assembly guidance.

TP3.2 Procedures allow for any personal wishes expressed by the patient to be taken into consideration with regard to the disposal of foetal tissue.

TP3.3 Policies include a statement that foetal material may only be supplied for research purposes in accordance with the Polkinghorne Code of Practice and with express permission from the patient. The Care Standards Inspectorate for Wales should be informed about any new request to supply foetal material for research purposes.
Emergency Procedures

OUTCOME

Patients are transferred safely in cases of emergency.

STANDARD TP4

TP4.1 There are written procedures for the transfer of patients to an inpatient bed, either within the hospital or at another establishment if this is necessary due to complications from the procedure.

TP4.2 Where the transfer is to another establishment the arrangements are agreed with that establishment and documented.
Prescribed Techniques and Technologies

Introduction to Standards P1 to P16

Establishments in which treatments are provided using certain techniques and technology are regulated (until 31 March 2002) under the Registered Homes Act 1984. These are techniques or technology – such as lasers – that require expertise in delivery, the use of appropriate equipment and for the setting to have certain measures in place in order for the treatment to be delivered safely. Regulation based on these same principles will continue under the Care Standards Act.

The CSIW will maintain regulation of the techniques and technology currently regulated (although a new exemption will be introduced for Class 3B lasers where they are used by or under the supervision of registered health care professionals) and regulation will also be extended to include treatment using intense pulsed light sources and to hyperbaric oxygen treatment/therapy. The reasoning for this is set out below.

Class 3B and 4 Lasers and/or Intense Pulsed Light Sources (standards P1 to P3)

The standards cover both Class 3B and 4 lasers and intense pulsed lights, as these technologies share similar features. Intense pulsed lights are defined, in regulation 3 of the Private and Voluntary Health Care Regulations, as:

Broadband non-coherent light which is filtered to produce a specified range of wavelengths; such filtered radiation being delivered to the body with the aim of causing thermal, mechanical or chemical damage to structures such as hair follicles and skin blemishes while sparing surrounding tissues.

Class 3B lasers are concentrated energy sources used for physiotherapy, eg to relieve chronic pain and backache by ‘massaging’ the tissue by pulsing the beam through it; for acupuncture; and for wound healing, for instance pressure sores, venous and diabetic ulcers, and for softening scar tissue. The majority of users are State Registered and/or Chartered Physiotherapists and Podiatrists - who will be exempted from regulation (see above).

Class 4 lasers and intense pulsed light sources are used in a variety of settings and for a variety of purposes. For instance, they are used for medical treatment in acute hospitals; in dental treatment; and in establishments ranging from clinics providing invasive cosmetic surgery by medical practitioners, to beauty salons where operators provide minimally or non-invasive cosmetic services which do not require the operator to be medically qualified. These include the removal of hair, tattoos, birthmarks or other blemishes from the skin. Class 4 lasers and intense pulsed lights are powerful devices which, if faulty or used incorrectly, have the potential to
cause serious injury to those operating them, recipients of the treatment and other persons in the vicinity, and to ignite flammable materials.

It is essential, therefore, that all establishments that provide treatment using Class 3B lasers (except where the laser is used by or under the supervision of a health care professional), Class 4 lasers or intense pulsed light sources, whether for medical or cosmetic treatment, are effectively regulated by the CSIW so that recipients of treatment and those who work or come within the confines of the regulated establishment are protected from laser and intense pulsed light emissions.

We regard that the key elements in ensuring that lasers and intense pulsed lights sources are used safely centre around:

- clear lines of responsibility within the registered establishments on the use of lasers and intense pulsed lights, including a clear understanding by all users of the personal responsibility that using lasers and intense pulsed lights entails;
- clear policies and procedures on the use and maintenance of lasers and intense pulsed lights;
- users of laser and intense pulsed lights undergoing specialised training, and learning, maintaining and updating an effective core of knowledge about the use and impact of lasers and intense pulsed lights;
- effective record keeping;
- safe working areas; and
- protective eyewear and other risk-avoidance measures.

The attached standards reflect this.

See also, in particular, regulations 3 and 41 and Schedule 3 Part II paragraph 3 to the Regulations.

**Dialysis (standards P4 to P6)**

Haemodialysis and peritoneal dialysis are carried out in the independent sector in a range of settings. These are, typically, acute hospitals, holiday sites (for example Butlin’s and Scout Association Holiday Homes) and private satellite units where dialysis is provided under contract to the NHS. The standards do not apply to dialysis that takes place in the patient’s home.

Where the NHS uses private satellite units to provide dialysis to NHS patients, these units are required to join the Renal Registry, in association with the main unit to which they are linked. The purpose of the Renal Registry is to monitor the quantity and quality of renal care in the UK. The attached standards provide added quality assurance to that process.

See also, in particular, regulation 3 of the Regulations.
Endoscopy

Premises where endoscopy takes place are currently regulated under the Registered Homes Act. These including acute hospitals and GP’s surgeries. This position is to be carried forward under the Care Standards Act.

Endoscopes are medical devices inserted in the body for diagnostic or surgical purposes. There are two types of endoscope, flexible and rigid:

- flexible endoscopy uses natural body orifices (eg mouth, anus, nose) to introduce into the body a long flexible device. The inserted end of the device has a camera, operated remotely by the practitioner, which is used to view the internal organs. These procedures usually include upper and lower gastroscopy, bronchoscopy, laryngoscopy, cystoscopy and hysteroscopy. Most acute hospitals have an endoscopy department (sometimes known as a day surgery centre) where flexible endoscopy is undertaken, but it may also take place in other health care establishments;
- rigid endoscopy is where a rigid endoscope with a surgical instrument at the inserted end is introduced through the skin. It is also known as minimally invasive surgery or keyhole surgery and includes arthroscopy, laparoscopy, hysteroscopy and cystoscopy, among others. Rigid endoscopy usually takes place in hospital operating departments.

Endoscopes are subject to standards for medical devices and, where they are re-usable, for decontamination. Standards relating to medical devices and decontamination are to be found in both the core standards and those for acute hospitals, and are therefore not duplicated here.

See also, in particular, regulation 3 of the Regulations.

Hyperbaric Oxygen Treatment/Therapy (standards P7 to P11)

Hyperbaric oxygen therapy (HBOT) involves specialised equipment and experienced personnel to deliver oxygen at higher than atmospheric pressures. The safe and judicious use of this therapy is increasing as medical and paramedical staff become familiar with its potential benefits. It is used for a number of conditions that have been demonstrated to benefit by well-established research. The European Committee for Hyperbaric Medicine (ECHM) advocates hyperbaric oxygen for the first-line treatment of the following conditions:

- air or gas embolism;
- decompression illness;
- carbon monoxide poisoning;
- gas gangrene;
- necrotising fasciitis;
- post-radiotherapy tissue damage;
- preparation for surgery in previously irradiated tissue.
In addition, the USA Undersea and Hyperbaric Medical Society (UHMS) support the use of hyperbaric oxygen for the following additional conditions:

- crush injury;
- severe haemorrhagic anaemia;
- selected problem wounds;
- compromised skin flaps and grafts;
- refractory osteomyelitis;
- osteoradionecrosis;
- thermal burns;
- intracranial abscess.

In 1983 the New England Journal of medicine reported a controlled, double-blind study on the effect of HBOT on the symptoms of multiple sclerosis (MS). It demonstrated benefits, but the researchers recognised the need for long-term studies. A pilot study confirmed the findings, but there have been no clinical trials published in the medical literature that have satisfied the medical establishment that HBOT is of long-term benefit to MS patients. The treatment is not, therefore, among the indications for HBOT listed above. As a result, a number of HBOT chambers have been installed by charitable treatment centres throughout the UK, including 56 owned by the MS Society, and the number of HBOT units provided by commercial and charitable organisations is increasing. This is in response to increasing demand for HBOT from people whose disorders are not included on the list of those for which the NHS provides HBOT because there is sparse clinical evidence to support the use of HBOT in many of these other conditions.

HBOT poses safety risks if chambers are incorrectly operated. Excessive oxygen levels will increase the risk of fire and strict control is needed to minimise the presence of flammable materials. There have been isolated fire and explosion incidents worldwide, both in single occupancy chambers in private use and multiplace chambers under medical supervision. In addition, breathing oxygen under pressure can have ill effects. The consensus of opinion among experts is that specific regulation of the treatment is welcomed.

The CSI IW will therefore regulate hyperbaric chambers used for therapeutic purposes.

Hyperbaric facilities vary in capacity. A multiplace chamber can accommodate more than one patient with an attendant inside the chamber. A monoplace chamber accommodates one patient only, with the attendant outside the chamber.

Chambers regulated by the CSI IW will be classified as Type 1, 2 or 3 depending on the levels of critical care management provided, as defined in the Department of Health’s document Comprehensive Critical Care:

- Type 1 chambers – these are able to accept patients who need level 2 or above critical care.
- Type 2 chambers – these are unable to accept patients who need level 2 or above critical care at the time of referral, or who are thought likely to deteriorate to those levels during hyperbaric treatment.
- Type 3 chambers - those chambers used only for the treatment of patients with neurological disorders for which NHS hyperbaric treatment is not clinically indicated, eg multiple sclerosis or cerebral palsy.

Certain establishments operating hyperbaric chambers will be exempted in the regulations from registering with the CSIW. These include those run by the armed forces for the treatment of their own staff; and where the primary purpose of the chamber is pursuant to regulation 6(3)(b) of the Diving at Work Regulations 1997 or regulation 8 or 12 of the Work in Compressed Air Regulations 1996. These chambers will not be available for the general public.

See also, in particular, regulation 3 of the Regulations.

**In Vitro Fertilisation (standards P12 to P16)**

The regulations and standards reflect the particular interests the CSIW will have in regulating establishments where assisted conception services take place, as opposed to the licensing role that the Human Fertilisation and Embryology Authority (HFEA) has.

The HFEA is a non-departmental public body accountable to the Secretary of State for Health. It was set up in August 1991 under the Human Fertilisation and Embryology Act 1990. The HFEA’s creation reflected public and professional concern about the potential future of human embryo research and infertility treatments, and a widespread desire for statutory regulation of this highly sensitive area. The HFEA’s principal tasks are to licence and monitor those clinics that carry out in vitro fertilisation (IVF), donor insemination and human embryo research. HFEA also regulates the storage of gametes (sperm and eggs) and embryos.

The CSIW will supplement the work of the HFEA by concentrating on aspects of fertility treatment that are outside the remit of the HFEA.

See also, in particular, regulation 3 of the Regulations.
Class 3B and 4 Lasers and/or Intense Pulsed Light Sources

Procedures for Use of Lasers and Intense Pulsed Lights

OUTCOME

Patients receive treatment using lasers and intense pulsed lights from competent operators and in accordance with appropriate procedures.

STANDARD P1

P1.1 A protocol produced by an expert medical or dental practitioner is followed which sets out the necessary pre-treatment checks and tests, the manner in which the procedure is to be applied, the acceptable variations in the settings used, and when to abort a treatment. In particular, the protocol addresses:

- contraindications;
- technique;
- pre-treatment tests;
- post-treatment care;
- recognition of treatment-related problems;
- procedure if anything goes wrong with treatment;
- permitted variation on machine variables;
- procedure in the event of equipment failure.

P1.2 The protocol is supported by written procedures for the use of devices, including when they are being used on a trial or demonstration basis, and these cover:

- the potential hazards associated with lasers and/or intense lights;
- controlled and safe access;
- authorised users’ responsibilities;
- methods of safe working;
- safety checks;
- normal operating procedures;
- personal protective equipment;
- prevention of use by unauthorised persons; and
- adverse incident procedures.

P1.3 There is a register of persons authorised to use lasers and intense lights. Authorised users sign to indicate that they accept and understand the procedures drawn up for the use of lasers and intense lights in the registered establishment (the Local Rules).

P1.4 Laser and intense light users have access to safety advice from a certificated laser protection adviser.
P1.5 A person with overall on-site responsibility for lasers and intense lights is appointed.

P1.6 Records are maintained every time the laser or intense light is operated, including:

- the name of the person treated;
- the date;
- the operator;
- the treatment given; and
- any accidents or adverse effects.

Training for Staff using Lasers and Intense Pulsed Lights

OUTCOME

Patients receive treatment from appropriately trained operators.

STANDARD P2

P2.1 All laser and intense pulsed light users have training, which is recorded and covers the following:

- characteristic features of light from lasers and intense pulsed light sources;
- hazards from device malfunction;
- equipment management;
- effects of light on the eye, skin and body tissues;
- safety management, including Local Rules and controlled areas;
- minimising risks;
- action to be taken in the event of an adverse incident.

P2.2 All staff using lasers and intense pulsed lights have regular update training, both planned and in reaction to relevant technological and medical developments.

P2.3 All operators of lasers and intense pulsed light sources use them only for treatments for which they have been trained and, where appropriate, hold qualifications.
Safe Operation of Lasers and Intense Pulsed Lights

OUTCOME

The environment in which lasers and intense pulsed lights are used is safe.

STANDARD P3

P3.1 The area around working lasers and intense pulsed light sources is controlled to protect other persons while treatment is in progress. The controlled area is clearly defined and not used for other purposes, or as access to other areas, when treatment is being carried out.

P3.2 While the equipment is being operated, the authorised user is responsible for the safety of all persons in the controlled area. No other laser or intense pulsed light source is in use in the same controlled area at the same time.

P3.3 All lasers and intense pulsed light sources have labels identifying them, their wavelength or range of wavelengths, and maximum output power of radiation emitted.

P3.4 In establishments with class 4 lasers, warning signs as specified in EN 60825-1 are displayed on the equipment and on the outside of doors to the controlled area.

P3.5 Protective eyewear is worn by everyone within the controlled area whenever there is a risk of exposure to hazardous levels of laser or intense pulsed light radiation.

P3.6 Operators ensure patient safety by:

- checking with patients if they have any medical condition or treatment for which laser or intense pulsed light treatment would be a contraindication;
- where appropriate, covering the skin outside the area being treated;
- where appropriate, checking the skin type and pigmentation prior to treatment.

P3.7 For all lasers and intense pulsed light sources with a key switch, formal arrangements exist for the safe custody of the key, separate from the equipment. Only authorised users have access to the key. The key is not left unattended with the equipment.

P3.8 Lasers and intense pulsed light sources are regularly serviced and maintained to ensure they are operating within their design specification. A record of servicing and repairs is kept.
Dialysis

Arrangements for Dialysis

OUTCOME

Patients undergo dialysis in accordance with safe and appropriate procedures.

STANDARD P4

P4.1 There are written criteria for the selection and assessment of patients undergoing dialysis.

P4.2 The criteria and processes for the selection of suitable patients are monitored.

P4.3 Local protocols for the management of patients, including standards of care to be achieved, are developed and agreed locally by all professionals, based on national guidelines.

P4.4 Where patients are being treated outside hospital, there are explicit arrangements in place for rapid transfer to specialist hospital facilities for unforeseen complications in patients on dialysis.

P4.5 These arrangements are clearly communicated to staff and regularly audited and reviewed.

Facilities for Dialysis

OUTCOME

The environment in which dialysis is undertaken is safe and appropriate.

STANDARD P5

P5.1 There is space around each bed/chair to allow nursing practice to take place and reduce the risk of cross-infection.

P5.2 There is screening of each bed space to ensure privacy for patients.

P5.3 There is dirty utility area, separate from clean areas, for safe disposal of clinical waste.

P5.4 There is safe storage for chemical substances, all of which are fully labelled.

P5.5 There are hand washing facilities for staff in the clinical area.

P5.6 If hepatitis B infected patients are treated, isolation facilities are available and used.
P5.7 Department of Health guidelines on the prevention of blood-borne virus infection in renal dialysis units are followed.

P5.8 Where haemodialysis is given, the specific standards for water quality for haemodialysis, set out in the latest version of the Renal Association’s standards document, Treatment for adult patients with renal failure, and the appropriate test schedules therein, are complied with.

Staffing for Dialysis

OUTCOME

Patients receive dialysis from staff with the relevant expertise.

STANDARD P6

P6.1 Supervision of nursing care is undertaken by a nurse with the relevant National Board certificates.

P6.2 All staff who come into contact with patients are offered vaccination against Hepatitis B.

Hyperbaric Oxygen Treatment

Arrangements for Hyperbaric Oxygen Treatment in Type 1, 2 and 3 Chambers

OUTCOME

Patients receive hyperbaric treatment safely and in accordance with appropriate procedures.

STANDARD P7

P7.1 Recommendations in appropriate guidance, for example those of the British Hyperbaric Association, are complied with.

P7.2 The hyperbaric unit works to a set of standard operating procedures (the Local Rules), which are clearly set out, available to and complied with by all staff.

P7.3 The written operating procedures cover:

- the potential hazards associated with hyperbaric chambers;
• methods of safe working;
• safety checks;
• normal operating procedures;
• personal protective equipment;
• adverse incident procedures.

P7.4 Personnel involved with providing hyperbaric treatments are trained and assessed as being competent in the following:

• equipment management;
• safety management;
• minimising risks;
• basic resuscitation skills;
• action to be taken in the event of an adverse incident.

P7.5 All staff involved in the provision of hyperbaric treatment have regular update training on the techniques and equipment used.

P7.6 There is equipment available to initiate resuscitation outside of the chamber.

Staff Qualifications and Training for Type 1 and 2 Chambers

OUTCOME

Patients receive treatment in hyperbaric chambers from competent operators.

STANDARD P8

P8.1 The hyperbaric unit operates under the clinical responsibility of a medical director who is a registered medical practitioner and possesses clinical experience in hyperbaric and diving medicine.

P8.2 The medical director ensures that the theoretical and practical training requirements of staff are met and that regular refresher courses are undertaken.

P8.3 The nursing and technical staff should hold appropriate qualifications eg CHRN, CHT or equivalent.

P8.4 When children under 12 years old are treated, a qualified children’s nurse (registered sick children’s nurse, RSCN, or registered nurse child branch certificated) accompanies the patient at all times, with the exception of a) attendance inside the hyperbaric chamber, if not appropriate, or b) where delay of treatment until could affect outcome.

P8.5 If the unit treats children there are formal links with a paediatrician to provide advice to the unit.
Facilities for Treatment in Type 1 and 2 Chambers

OUTCOME

Patients receive hyperbaric oxygen treatment in a safe environment.

STANDARD P9

P9.1 The unit holds the range of equipment needed for establishing and maintaining an airway, including suction equipment and a defibrillator, and a range of appropriate drugs.

P9.2 Clinical equipment available for use both inside and outside of the chamber includes indirect blood pressure equipment, stethoscope, auroscope/ophthalmoscope, thermometer and equipment for neurological assessment.

P9.3 Equipment for urinary catheterisation, intravenous cannulation, and pneumothorax drainage is also available.

P9.4 Multiplace chambers must have at least two compartments (ie an airlock) to allow access and egress of medical staff and equipment while maintaining pressure.

Patient Care in Type 1 and 2 Chambers

OUTCOME

Appropriate arrangements for patient care are in place.

STANDARD P10

P10.1 The initial referral is a key point in treatment of patients, and all relevant information is recorded in a standard format.

P10.2 The clinical status of a patient is clearly established by the duty medical officer before a referral is accepted, and the means of transfer, along with an estimated time of arrival, is agreed.

P10.3 Wherever possible, the transfer arrangements after treatment, such as return to hospital, an intensive care unit or home, are agreed at the time of referral.

P10.4 The unit assesses the patient medically before treatment starts.
Critical Care in Type 1 Chambers

OUTCOME

Patients are assured that where level 2 or level 3 critical care is provided, as appropriate, within the hyperbaric chamber, it is done so effectively.

STANDARD P11

P11.1 Patients requiring level 2 or 3 critical care receive it either at the hyperbaric chamber, or are transferred immediately and quickly to the nearest facility that provides it.

P11.2 Where level 2 or 3 critical care is provided within the hyperbaric chamber:

- there is a written operational policy and protocols for critical care management in the chamber;
- staff are briefed on the policy and protocols so that they are aware of what they should do in specific circumstances;
- the duty medical officer is experienced to specialist registrar standards in either anaesthetics or intensive care medicine.

P11.3 Monitoring equipment available for both inside and outside the chamber includes ECG, pulse oximetry, capnography, invasive blood pressure equipment, mechanical ventilator (hyperbaric compatible), and syringe drivers.

P11.4 Arrangements are in place to transfer patients to critical care facilities where necessary, and are agreed in advance with the hospital most likely to receive such patients.

P11.5 The unit provides equipment to enable the safe transfer of patients to critical care facilities.

P11.6 The unit has arrangements with a local hospital for radiographic and laboratory investigations.
In Vitro Fertilisation

Qualifications and Training of Staff

OUTCOME

Fertility treatment is provided by appropriately skilled and competent staff.

STANDARD P12

P12.1 There is a lead clinician responsible for the delivery of the clinical services provided who is a member of the Royal College of Obstetricians and Gynaecologists and on the relevant specialist register of the General Medical Council.

P12.2 The person in charge of the embryology/semionology laboratory is qualified with a degree in medical or biological science, or an HND in a discipline appropriate to the work being undertaken, or a professional qualification in medical laboratory work.

P12.3 All clinical staff undertaking assisted conception techniques have undergone training and supervised practice in these techniques and have certification or a signed statement to this effect.

P12.4 All staff members of the service receive training and regular up-dates on the legal framework within which the assisted conception services are working.

P12.5 All members of staff in contact with patients are routinely tested for chicken pox and rubella.

Management of Patients

OUTCOME

Patients receive appropriate treatment.

STANDARD P13

P13.1 Local protocols for the management of patients are developed and agreed by all professionals.

P13.2 Local protocols for the prevention and management of ovarian hyperstimulation syndrome are available in all premises carrying out ovulation induction and assisted conception.
P13.3 All deaths, including from ovarian hyperstimulation, are reported to the Confidential Enquiry into Maternal Deaths (CEMD) whether or not the woman had a positive pregnancy test.

P13.4 There are protocols for health care professionals on the value of semen cryostorage in cases where men are undergoing medical treatment likely to make them infertile, so the situation is dealt with quickly and effectively.

P13.5 There are written protocols for the close monitoring of patients, in order to avoid unnecessary complications, including multiple pregnancy.

P13.6 Written protocols set out that no more than, either, three eggs or three embryos are placed in a woman in any one cycle, regardless of the procedure used, and this is recorded in clinical notes and monitored.

Patient Information and Decision Making

OUTCOME

Patients are effectively involved in making decisions about treatment.

STANDARD P14

P14.1 The appropriateness of the treatment is fully considered with all people seeking treatment, including advice on the chance of a live birth following treatment.

P14.2 In each individual case the decision to recommend treatment is based on the likelihood that a pregnancy will not occur without treatment.

P14.3 Prior to consideration of treatment for unexplained infertility consideration is given to the likelihood of treatment-independent pregnancy, depending on the woman’s age, the duration of infertility and the previous pregnancy history.

P14.4 There is written information for patients setting out the factors that will be taken into consideration before treatment can be confirmed.

P14.5 Prior to patients giving consent to treatment, they are given specific information about:
  - the risks associated with multiple pregnancy and birth; and
  - the risk of ovarian hyperstimulation syndrome.

P14.6 There is written information for people seeking treatment and those considering donation on the safeguarding of confidentiality.
P14.7 There is written information for patients on the assisted conception treatments and techniques provided by the service, which includes the possible risks and side effects of treatments and the verified live birth rate for the service.

P14.8 All publicity material conforms to the general principles in the guidelines of the GMC and the Code of Professional Conduct of the United Kingdom Central Council for Nursing, Midwifery and Health Visiting.

**Counselling for Patients**

**OUTCOME**

Patients make informed decisions about treatment and are supported during it.

**STANDARD P15**

P15.1 All patients are offered the opportunity for independent counselling on the implications of treatment before consent to treatment is given.

P15.2 Counselling is made available throughout all stages of infertility investigations and treatment, and after the treatment process is complete. Where pregnancy occurs as a result of treatment, the offer of further counselling is also considered.

P15.3 Whenever genetic tests are proposed, written and oral information is provided and counselling is offered by an appropriately trained person.

P15.4 There is information for patients on national counselling organisations which can provide ongoing therapeutic counselling services.

**Facilities for Assisted Conception Services**

**OUTCOME**

The facilities are appropriate for fertility treatment.

**STANDARD P16**

P16.1 The service facilities and layout are designed to ensure that the need for privacy of donors and people seeking treatment is met.

P16.2 The room used for egg collection for in vitro fertilisation is close to the laboratory where fertilisation is to take place.

P16.3 There is a dedicated room for the production of semen specimens.
P16.4 There is secure, atmospheric and temperature controlled storage for gametes/embryos and reagents.

P16.5 There are written procedures for the indelible labelling of material from individual patients to ensure the unique identification of a patient’s material and records at all stages of treatment.

P16.6 Gametes and embryos are stored in a secure designated area with access by authorised personnel only.
Introduction to Standards PD1 to PD8

These standards cover a variety of services that are provided by private medical practitioners. They apply to:

- private walk-in medical centres, where services are provided by a medical practitioner; and
- exclusively private medical practitioners (ie those who do no NHS work at all).

Independent Clinics

Exclusively private medical practitioners and private walk-in medical centres will be brought within regulation for the first time. Exclusively private medical practitioners include a range of doctors such as private GPs, consultants and psychiatrists who fall outside the NHS clinical governance framework. It is therefore essential that they are regulated to help ensure the delivery of quality care to their patients.

The CSIW’s interest is in independent health care services to which the general public has access. In line with this, regulation will not extend to private doctors to whom the public does not have access, for instance those doctors whose work solely comprises the provision of occupational health services for the employees of an organisation.

Many of the elements necessary to provide quality assurance in a private medical practitioner’s premises or in a private walk-in medical centre are already covered in the core standards. These additional service-specific standards build on the core standards to reflect the nature of the provision of treatment in such premises, such as consultations, health assessments, screening and vaccinations.

There has been concern about whether a person’s GP should be informed of the treatment provided in a walk-in medical centre. This is of course confidential but it is important that the patient should have the opportunity to have this information passed to his/her GP if they so wish. Therefore, the standards require the registered person to have a policy in place for seeking the person’s consent or refusal to send the details of the treatment to his/her GP, and if the person agrees the timescale in which this will be carried out.

See also, in particular, regulation 47 of the Regulations.
Independent Clinics

Arrangements for Provision of Treatment

OUTCOME

Patients are assured that appropriate arrangements for all aspects of their treatment are in place.

STANDARD PD1

PD1.1 The medical history of the patient is ascertained before any treatment is provided.

PD1.2 Patients are advised of the expected fee for the proposed treatment or consultation in advance of treatment being initiated.

PD1.3 Where potentially serious conditions or those of clinical significance are identified there are referral systems in place to guarantee appropriate clinical follow-up.

PD1.4 Private areas offering auditory privacy are provided for consultations.

Management of Patients

OUTCOME

Patients with chronic diseases receive the appropriate level of care and advice on how to control their disease.

STANDARD PD2

PD2.1 There are protocols adopted for the management of chronic diseases which are used to guide the care provided for illnesses such as:

- asthma;
- diabetes;
- hypertension;
- coronary heart disease.

PD2.2 Patients with chronic diseases are offered appropriate education and advice to enable them to be both involved in their care and to control their disease and reduce associated risk factors.
Minor Surgery

OUTCOME

Minor surgery takes place safely.

STANDARD PD3

PD3.1 Minor surgery takes place in a suitably designed and maintained room, the walls and floor of which are finished in a material that keeps it free from infection.

PD3.2 Written policies and procedures and guidance for the prevention and control of infection and decontamination of instruments are implemented and reflect relevant legislation and published professional guidance.

PD3.3 Single use surgical instruments should be used where possible and not re-used. Multiple use instruments where used must be decontaminated and re-processed for use by a validated central sterile services department.

PD3.4 A couch or theatre table is provided on which the minor surgery takes place.

PD3.5 All clinical staff are trained in basic resuscitation.

PD3.6 Resuscitation equipment is available for use and is checked at least weekly.

PD3.7 There are written procedures for dealing with emergencies, including arrangements for transfers to hospital.

Midwifery and Antenatal Care

OUTCOME

Midwifery and antenatal care are provided effectively.

STANDARD PD4

PD4.1 Patients who choose to be cared for solely by a midwifery practitioner are assessed to ascertain if there are likely to be any complications at a later stage and these are explained to them. A clear evidence-based referral protocol to obstetric consultant care for women at recognised risk of possible complications is in place.

PD4.2 Antenatal care and screening tests and quality standards comply, as a minimum, with the standards detailed in the antenatal screening programme of the National Screening Committee and with guidelines from the National Institute of Clinical Excellence (NICE) about antenatal care.
Prescribing

OUTCOME

Medication is prescribed safely and effectively.

STANDARD PD5

PD5.1 There are policies in place for the effective prescribing of medication, which are in line with published evidence.

PD5.2 When treating patients for drug misuse the Department of Health Guidelines on Drug Misuse and Dependence – guidelines on clinical management are followed.

PD5.3 Patients are given information about the medications that are prescribed to them including how to take them, the benefits and possible side effects.

PD5.4 Arrangements for repeat prescribing ensure that all patients receiving regular medications are reviewed at intervals, and at least annually.

PD5.5 The prescribing of antidepressants and benzodiazepines are monitored regularly in the light of evidence-based guidelines.

PD5.6 There is a record of the drugs stored in the establishment.

Pathology Services

OUTCOME

Patients are assured that effective pathology services are in place.

STANDARD PD6

PD6.1 There are written procedures for the accurate recording and labelling of all specimens.

PD6.2 Specimens are stored at the appropriate temperature.

PD6.3 There is a written agreement with a laboratory for the provision of pathology services.

PD6.4 There are written procedures for the transfer and transportation of specimens, including arrangements for the protection of those handling such items in transit.
Contacting Practitioners and Out-of-Hours Services

OUTCOME

Patients are able to contact private doctors.

STANDARD PD7

PD7.1 Contact information is available, including all telephone numbers and times of regular sessions worked elsewhere, to ensure that the practitioner can be contacted promptly in the case of emergency.

PD7.2 Private GPs provide an out-of-hours service that ensures:

- patients are able to contact the GP out-of-hours, normally by making no more than two telephone calls to do so;
- that a doctor deputising for the GP is properly inducted and is made aware of their responsibilities under the Care Standards Act 2000;
- that an effective system is in place for transferring and acting on information about patients seen by other doctors out-of-hours.
Information to GPs

OUTCOME

Patients are offered the opportunity to give or refuse consent for information on their treatment to be passed to their normal GP.

STANDARD PD8

PD8.1 The registered person for a private walk-in medical centre ensures that there is a policy in place for asking the patient to formally agree to give or refuse consent to inform their normal GP of any treatment or medication provided.

PD8.2 If the patient gives consent, details are sent to the patient’s GP within a locally agreed timescale, but which is no more than 4 weeks.

PD8.3 If the patient does not give consent for details to be sent to his/her GP, a summary of the treatment provided is given direct to the patient so that he/she has it for future reference, to pass on to the GP.
Appendices
Appendices

Appendix 1 - GLOSSARY OF TERMS

Accident

Any unexpected or unforeseen occurrence, especially one that results in injury or damage.

Accident report

A written report of an accident. The format of the report is laid down in health and safety legislation.

Accountability

The state of being answerable for one’s decisions and actions. Accountability cannot be delegated.

Audit

The process of setting or adopting standards and measuring performance against those standards with the aim of identifying both good and bad practice and implementing changes to achieve unmet standards.

Adolescents

Young people in the process of moving from childhood to adulthood. Adolescents may have special needs as patients/users.

Adverse clinical incident

An incident, accident or occurrence, relating to clinical systems or procedures which results in harm, or an injury, or near miss to a patient/user or member of staff.

Advocate

An individual who acts independently on behalf of, and in the interests of, patients/users who may feel unable to represent themselves in their contacts with a health care or other facility.

Aim

Overall purpose or goal of a department or service.
Annual report

A report, written annually, which details progress over the last year and plans for the following year, which includes financial and activity statements.

Care plan

A document which details the care and treatment that a patient/user receives and identifies who delivers the care and treatment. This term covers the term ‘individual plan’ (see also health record).

Care programme approach (CPA)

The individual packages of care (care programmes), developed in conjunction with social services, for all patients accepted by the specialist psychiatric services. Care programmes may range from ‘minimal’ single worker assessment and monitoring, for individuals with less severe mental health and social needs, to complex and multi-professional assessments and treatment.

Carer

A person who may be paid or unpaid, who regularly helps another person, often a relative or friend with domestic, physical, emotional or personal care as a result of illness or disability. This term incorporates spouses, partners, parents, guardians, paid carers, other relatives, and voluntary carers who are not health professionals.

Checklist

A means of recording observations relating to fixed criteria, used to check compliance with agreed procedures or standards.

Clinical governance

A framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.

Clinical responsibilities

Range of activities for which a clinician is accountable.

Continuing education

Activities which provide education and training to staff. These may be used to prepare for specialisation or career development as well as facilitating personal development.
Contract/agreement

The document agreed between providers of health care and the purchasers of health care detailing activity, financial and quality levels to be achieved.

COSHH

Acronym for the control of substances hazards to health legislation.

Criterion

A measurable component of performance. A number of criteria need to be met to achieve the desired standards.

Critical care – Level 1

Patients at risk of their condition deteriorating, or those recently relocated from higher levels of care, whose needs can be met on an acute ward without additional advice and support from the critical care team.

Critical care – Level 2

Patients requiring more detailed observation or intervention including support for a single failing organ system or post-operative care and those stepping down from higher levels of care.

Critical care – Level 3

Patients requiring advanced respiratory support alone or basic respiratory support together with support of at least two organ systems. This level includes all complex patients requiring support for multi-organ failure.

Duty of care

Duty of health care staff to put the care and safety of the patient/user first in all circumstances.

Errors

Mistakes made by staff in the performance of their duties.

Evaluation

The study of the performance of a service (or element of treatment and care) with the aim of identifying successful and problem areas of activity.
Food hygiene

Taking all measures necessary to ensure the safety and wholesomeness of foodstuffs.

Hazards

The potential to cause harm, including ill-health and injury, damage to property, plant, products or the environment, production losses or increased liabilities.

Health and safety policy

A plan of action for the health, safety and well-being of staff, patients/users, residents and visitors.

Hospital acquired infection

An infection acquired by a patient/user during their stay in hospital which is unconnected with their reason for admission.

ICD code

International classification of diseases coding system.

Incident

An event or occurrence, especially one which leads to problems. An example of this could be an attack on one person by another within a service.

Induction programme

Learning activities designed to enable newly appointed staff to function effectively in a new position.

Job description

Details of accountability, responsibility, formal lines of communication, principal duties, entitlements and performance review. A guide for an individual in a specific position within an organisation.

Keyworker

A keyworker is the person responsible for co-ordinating the care plan for each individual patient/user, for monitoring its progress and for staying in regular contact with the patient/user and everyone involved. A keyworker can come from a variety of different professional or non-professional backgrounds.
**Manual handling**

Any transportation of a load by picking up, setting down, pushing, pulling, carrying or moving thereof, by hand or bodily force.

**Monitoring**

The systematic process of collecting information on clinical and non-clinical performance. Monitoring may be intermittent or continuous. It may also be undertaken in relation to specific incidents of concern or to check key performance areas.

**Multiprofessional**

A combination of several professions working towards a common aim.

**Near miss**

An incident, or an incident avoided, which it is realised had the potential to cause harm on injury.

**Objective**

A specific and measurable statement which sets out how overall aims are to be achieved.

**Organisation**

The term used in this publication to describe the entire organisation, as opposed to the term service, which is used to describe one part of the organisation (see also service).

**Organisational chart**

A graphical representation of the structure of the organisation including areas of responsibility, relationships and formal lines of communication and accountability.

**Outcome**

The end result of care and treatment, that is the change in health, functional ability, symptoms or situation of the person, which can be used to measure the effectiveness of care and treatment.

**Patient survey**

Seeking the views of patients through responses to pre-prepared questions and carried out through interview or self-completion questionnaires.
**Personnel**

All those who work in the regulated establishment ie those with practising privileges as well as staff.

**Planning**

The process by which the service determines how it will achieve its aims and objectives. This includes identifying the resources which will be needed to meet the aims and objectives.

**Policy**

An operational statement of intent in a given situation.

**Procedure**

The steps taken to fulfil a policy.

**Professional standards**

Professionally agreed levels of performance.

**Protocol**

The adoption, by all staff, of national or local guidelines to meet local requirements in a specified way.

**Quality Assurance (QA)**

A generic term to cover the review of the quality of services provided, along with interventions designed to improve that quality through the remedying of deficiencies identified by the review process. The review may include both qualitative and quantitative measurements and may or may not relate to clearly stated standards.

**Research and development**

The searching out of knowledge and evidence about the relationship between different factors in the provision of services. Research does not require action in response to findings.

**Review**

The examination of a particular aspect of a service or care setting so that problem areas requiring corrective action can be identified.
Risk management

A systematic approach to the management of risk, to reduce loss of life, financial loss, loss of staff availability, staff and patient/client/user safety, loss of availability of buildings or equipment, or loss of reputation.

Risk management strategy

A written statement of objectives for the management of risk and a plan for meeting those objectives. The strategy should be consistent with the business plan.

Serious untoward incident

An accident or occurrence which results in significant injury to a patient/user, member of staff, carer or visitor.

Skill mix

The balance of skill, qualifications and experience of nursing and other clinical staff employed in a particular area.

Staff

Those employed by the regulated establishment.

Survey

The collection of views from a sample of people in order to obtain a representative picture of the views of the total population being studied.

Untoward incident

Any incident, accident or occurrence, relating to clinical or non clinical work which could result in an injury or near miss to a patient, member of staff or visitor.

Valid consent

The legal principle by which a patient is informed about the nature, purpose and likely effects of any treatment proposed before being asked to consent to accepting it.

Vital services

These services are essential to the normal operation of the organisation. Examples include electricity, water, medical gases and telecommunications.
Appendix 2  - POLICIES AND PROCEDURES

Independent health care providers will develop policies and procedures, appropriate to the setting, for the following:

Core Requirements

Arrangements for admission, acceptance transfer and discharge of patients Reg 8
Arrangements for assessment, diagnosis and treatment of patients Reg 8
Ensuring patients give consent to treatment Reg 8
Disclosure of patient information Reg 8
Ensuring that care is patient-centred, including: Patients consent to examinations Std C2
Patients consultation about treatment Std C2
Patients access to health records Std C2
Patients privacy, dignity, confidentiality Std C2
Responding to advance directives Std C2
Monitoring quality of clinical treatment and care Std C4
Human resources Reg 8
Equal opportunities Std C9
Granting practising privileges Std C11
Child protection Std C14
Handling complaints Reg 22
Fitness of the premises Reg 8
Monitoring the suitability of facilities and equipment Reg 8
Maintenance of the premises Std C19
Risk Management Reg 8
Informing the CSIW of staff suspensions on clinical grounds Std C22
Handling waste Std C23
Interruption of medical gas lines Std C23
Moving and handing of patients Std C23
Resuscitation Std C29
Records and information management Reg 8
Information provision Reg 8
Research Std C34

Service–Specific Requirements

Acute hospitals
Resuscitation Reg 34
Out of hours cover for allied health professionals Std A7
Infection control Std A10
Decontamination Std A11
Pain management for children S Std A19
Transfer of children Std A20
Procedures for surgery Std A21–23
Use of cosmetic surgery equipment Std A28
Day surgery Std A29
Conduct of transplantation Std A30
(including donor organs/xenotransplantation)
Critical care Std A31-32
Radiology Std A33
Responsibility for pharmaceutical services Std A35
Security of medicines and drugs (including action on hazard warnings) Std A36
Administration of medicines Std A37
Self–medication Std A38
Medicines management(anti–microbial policies) Std A39
Medical gas cylinders Std A41
Pathology services Std A42-45
Chemotherapy Std A46
Radiotherapy Std A47

Mental Health Establishments
Safety of the patient and others Reg 43
Management of disturbed behaviour Reg 44
Patients receiving visitors Reg 45
The Mental Health National Service Framework Std M1
Communication between staff re patient treatment Std M2
Patient confidentiality Std M3
Risk management Std M7
Suicide prevention Std M8
Resuscitation Std M9
Overall medicines policy Std M10
The Care Programme Approach Std M11
Voluntary admission Std M12
Electro–convulsive therapy Std M16
Administration of medicines Std M17-18
Treatment for addictions Std M19
Transfer of patients Std M20
Patient discharge Std M21
Working with carers and family members Std M25
Patients rights Std M26
Restrictions and security for patients Std M29
Levels of observation Std M30
Managing disturbed behaviour Std M31
Managing serious/untoward incidents Std M32
Patients absconding Std M34
Patient restraint and physical interventions Std M35
Safeguarding children Std M36
Freedom of movement for children Std M38
Assessment, care, treatment and discharge of detained patients Std M41
Seclusion of patients Std M43
Leave for detained patients Std M44
Staff training on the Mental Health Act Std M47
Hospices
Availability of medicines Std H4
Infection control Std H6
Resuscitation Std H7
Acting on hazard warnings and drug recalls Std H9
Medicines storage – handover of keys Std H9
Administration of medicine Std H10
Medication including self–medication Std H11
Medical gas cylinders Std H12
NHS communication policy re children in hospices Std H15
Resuscitation Reg 34

Maternity Hospitals
Use of Anti–D Std MC3
Referral to obstetric consultant care Std MC4
Antenatal and post–natal wards and the delivery suite Std MC5
Maternal deaths and still–births Std MC6
Handling common problems faced by newborn babies Std MC7

Termination of Pregnancy Establishments
Handing foetal tissue Reg 40
Transfer of patients to hospital Std TP4

Prescribed Techniques and Technologies
Use of lasers and intense lights Std P1
IVF–labelling Std P16

Private Doctors (independent clinics)
Emergency procedures re minor surgery Std PD3
Prescribing Std PD5
Pathology services Std PD6
Informing the patient’s GP Std PD8