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# National Minimum Standards for Independent Health Care Services in Wales

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A statement of national minimum standards applicable to independent hospitals, independent clinics, and independent medical agencies made by the Minister for Health and Social Services of the Welsh Assembly Government under powers conferred by section 23(1) of the Care Standards Act 2000.

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## Introduction

Independent healthcare is regulated in Wales under the Care Standards Act 2000<sup>1</sup> (“the Act”). Healthcare Inspectorate Wales (HIW) acts as the regulator of healthcare services in Wales on behalf of the Welsh Ministers who, by virtue of the Government of Wales Act 2006, are designated as the registration authority<sup>2</sup>.

HIW has responsibility for the registration and inspection of independent health care services in Wales. This includes the regulation of independent hospitals<sup>3</sup>, independent clinics, independent medical agencies, and private dentists.

Sections 22 and 23 of the Act provide Welsh Ministers with broad regulation making powers and powers to publish and keep under review, statements of National Minimum Standards (NMS). The NMS set out “minimum” standards and most providers will have no difficulty in meeting them and many will exceed them. The intention of the NMS is to ensure that patients and people who choose private healthcare are assured of safe, quality services.

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

Any decision made by HIW in the exercise of its registration functions can be appealed to the First Tier Tribunal (Care Standards)<sup>4</sup>. The standards will form the basis for judgements made by the Healthcare Inspectorate Wales (HIW) regarding registration decisions, the imposition or removal of conditions of registration, variation of any conditions and enforcement of compliance with the Care Standards Act 2000, including decisions about suspension, cancellation or prosecution.

HIW will consider the degree to which a regulated service complies with the standards when determining, for the purposes of its registration functions, if a provision of the regulations has been breached.

Wherever possible, the relevant regulation(s) that may be breached if the standard is not met is listed but this 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 framework for judging the quality of services experienced by service users, but they are also designed to be measurable.

Inspecting against the regulations and these standards, HIW will follow a consistent inspection methodology and reporting format. In assessing whether or not an

establishment or agency meets a particular regulatory requirement, the HIW will consider if it meets each of the relevant standards.

Independent healthcare services differ in their size and complexity and the way providers demonstrate that they meet the standards may vary depending on their organisational structure and systems.

Registered persons are responsible for ensuring that their services meet these standards, comply with the Act and have knowledge of whatever other legislation is relevant to the services they provide. It is anticipated that they will use these standards in their day to day monitoring of the quality of services provided. Assessment against the standards should be seen as integral to good governance and continuous improvement. The onus is on the registered provider to demonstrate they are meeting the standards on a continuous basis and that their own effective internal scrutiny arrangements identify and drive improvement.

Reference is also made to relevant supporting information to assist providers and managers.

In revising the current NMS for independent healthcare, the following principles have been applied:

These are:

- Standards will be fit for purpose in 2011 and beyond.
- The principles of good regulation are met (Better Regulation Executive (BRE)<sup>5</sup>).
- As far as possible standards are aligned and consistent with standards for the NHS.
- Unnecessary repetition of standards is avoided.
- Where relevant, they address 'service specific' variances.
- Standards are clearly articulated and easy to understand for people who use, as well as provide services.
- Standards enable registered persons to comply with the law.

### **Who these standards are for**

These standards are for registered providers and managers of services that are required to be registered by Healthcare Inspectorate Wales. The standards will assist them in ensuring that they provide the minimum standards of quality and safety that enable them to comply with legislation.

The standards might also be helpful to people who work in or use registered services, the public, Welsh Assembly Government officials and commissioners of services.

The standards will be taken into account in decisions made by HIW and in any proceedings (both civil and criminal) taken under the Act.<sup>6</sup>

### **What types of services do these standards apply to?**

Independent Healthcare services are defined in section 2 of the Care Standards Act 2000. There are three main types of services:

- Independent Hospitals;
- Independent Clinics; and
- Independent Medical Agencies.

The following services are classed as independent hospitals and these include:

- acute hospitals (who provide a wide range of services including medical and / or surgical treatment, including investigations, under general anaesthesia or intravenously administered sedation);
- mental health hospitals;
- hospices;
- dental hospitals providing treatment under general anaesthesia;
- maternity hospitals;
- hospitals providing termination of pregnancy;
- hospitals providing cosmetic surgery; and
- 'prescribed techniques' or 'prescribed technology'.

Prescribed techniques and prescribed technology are termed in this way as they are specifically prescribed within the regulations that are made under the section 2(7) of the Act. They currently include:

- Endoscopy.
- Hyperbaric oxygen treatment (HBOT).
- Circumcision of male children.
- Dialysis.
- In vitro fertilisation (IVF).
- Use of a Class 3B or 4 Laser or Intense Pulsed Light Source (IPL).

Below are examples of what the above services might provide.

## Acute hospitals

Acute hospitals generally have one or more overnight beds subject to certain exemptions but some may only provide day case procedures and patient admissions are normally planned or at short notice, rather than as an emergency. Services may be provided for both adults and children but will vary in the types and complexity of treatments that are offered. Treatment under general anaesthetic or intravenously administered sedation will be provided in these types of hospitals.

Because of the nature and complexity of the services offered, acute hospitals will have facilities to care for patients who require critical care level 1 or 2 but may, depending on the types of surgery performed, also provide critical care level 3. Where critical level 2 or 3 are not available and unexpected complications arise that necessitate patients to be transferred to a higher level of critical care, they may need to be transferred to NHS critical care facilities.

Formal transfer arrangements must be made with NHS providers before services are permitted to operate and procedures for emergency transfer clearly documented for all staff and consultants. In some circumstances, for example, where children are admitted for treatment under anaesthesia, transfer arrangements should be made in advance of their admission, even if they are not required to be implemented.

Each hospital must also have appropriate medical cover at all times. These are medical practitioners (often referred to as the resident medical officer (RMO)) who may be directly employed or contracted by the hospital and work in support of Consultants.

Many of the Consultants who operate or consult at an acute hospital are not directly employed. They are granted 'practising privileges' to consult or treat patients at the hospital. Advice about who can be granted a right to practise is usually recommended by the Medical Advisory Committee (MAC). Each actual hospital has its own MAC (usually made up of consultants from a range of specialties) who can then consider applications to practise at the hospital and advise the registered person of their views. Consultants seeking practising privileges are required to comply with a range of checks about themselves and their clinical performance, before being able to work in the hospital and will be required to adhere to the hospitals policies and procedures.

The details of what treatments and other services that each hospital provides will be set out in their Statement of Purpose which the registered provider is required to compile.

The services available may include all, some or only one of the following:

- Medical treatment which requires overnight care.
- Surgical procedures which may be under anaesthesia or intravenously administered sedation.
- IVF.
- Termination of pregnancy.



- Cosmetic surgery.
- Maternity services.
- Dental treatment.
- Cancer services.
- A prescribed technique or prescribed technology (ie Endoscopy, HBOT, Circumcision of male children, Dialysis, IVF, Class 3B / 4 laser or IPL).

Note: the above services may also trigger registration in their own right.

Those acute hospitals that offer a more complex range of treatments and procedures will usually include the following departments:

- Diagnostics.
- Pathology.
- Radiology.
- Pharmacy.
- Out Patient consultations.

A brief overview about the types of services that are frequently provided in an acute hospital are detailed under A - Z below:

## A - Z of services:

### Cancer services:

The majority of cancer services are delivered in the NHS but some patients may have part of their course of treatment in independent hospitals.

### Children's services:

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<sup>7</sup>. 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 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.

### Cosmetic surgery:

Cosmetic 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. It includes procedures such as breast augmentation, face lifts, ear correction, facial implants and fat reduction. The majority of cosmetic surgery procedures are performed in the independent sector.

### Critical care:

Some patients in independent acute hospitals may require critical care. Where the hospitals are carrying out complex operations, for example, cardiac surgery or transplantation, there must be critical care beds available for patients postoperatively in those hospitals. In other cases, post-operative complications may mean that a patient requires critical care support. The hospital has to ensure the necessary arrangements are in place so that critical care can be provided as needed, in the establishment. Alternatively, arrangements should 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 or transfers to a higher level of critical care, should be informed by the good practice contained in the Designed for Life: Quality Requirements for Adult Critical Care in Wales, Welsh Assembly Government 2006 and the Independent Healthcare Advisory Service (IHAS) Critical Care Transfer Position Paper April 2009<sup>8</sup>.

### 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.

Best practice standards and guidance for decontamination and decontamination environments to enable providers to comply with legislative requirements, are set out in Health Technical Memoranda (HTMs) and Health Building Notes (HBNs) and providers are expected to meet these standards for registration and ongoing. The MHRA<sup>9</sup> also provide advice and guidance on best practice.

### Diagnostic services: (ionising radiation)

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. As of 1 December 2009 Healthcare Inspectorate Wales (HIW) took over responsibility for inspections and enforcement in

relation to Ionising Radiation (Medical Exposure) Regulations (IR(ME)R, 2000 and its subsequent amendment regulations in November 2006. Incidents which result in a patient receiving a radiation dose much greater than intended, must be reported to HIW.

### Pharmacy services:

Existing legislation applying to drugs and medicines includes the Medicines Act 1968 and subordinate legislation, Misuse of Drugs Act 1971 and regulations made under it, 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 HIW there are other inspectorates with rights of access to pharmacies in independent sector hospitals. Home Office drugs inspectors have the authority to inspect private hospitals, which hold controlled drugs. (A licence issued by the Home Office<sup>10</sup> is also required if a registered provider wishes to produce, supply, possess, import or export controlled drugs).

Medicines and Healthcare Regulatory products Agency (MHRA) inspection and enforcement officers have a duty to investigate any breaches or suspected breaches of the Medicines Act 1968. Independent hospitals that are corporately owned, also have to have an 'Accountable Officer' to ensure arrangements and safe management of controlled drugs in the hospital.

### Pathology services:

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 37 of the Regulations.

### 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 independent hospitals mostly using a related live donor, or cadaver kidneys for which the NHS is unable to find a use.

Transplantation is legislated by the Human Organ Transplants Act 1989 and regulated by the Human Tissue Authority (HTA). The Act 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 HTA to approve all transplants from living donors, whether or not the donor is related to the recipient.

### Treatments which may trigger registration in their own right:

Below are types of treatments or procedures, that may be provided as part of the overall services of an acute hospital or may be registered as independent hospitals and solely provide these individual services and no others.

### Termination of pregnancy services:

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 Welsh Assembly Government. Abortion can be a medical or surgical procedure but 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 is now 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 the requirements of the Human Tissue Act 2004 and the guidance provided by the Human Tissue Authority.

### Endoscopy:

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.
- 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.

It is important that endoscopes are properly decontaminated before they are re-used.

### Hyperbaric oxygen treatment:

Hyperbaric oxygen treatment involves specialised equipment and experienced staff to deliver oxygen at higher than atmospheric pressures. The services are carried out by or under the supervision of, a medical practitioner.

Services provided may include treatment of the following conditions:

- air or gas embolism;
- decompression illness;
- carbon monoxide poisoning;
- gas gangrene;
- necrotising fasciitis;
- thermal burns.

Chambers regulated by the HIW will be classified as Type 1 or 2 depending on the levels of critical care management provided, as defined by the Critical Care Minimum Data Set (CCMDS):

**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.

### Dialysis:

Dialysis units provide services to people with chronic renal disease and are often located either within an NHS hospital or as a satellite unit in the community provided by the independent sector. Dialysis care provided by the independent sector is almost exclusively NHS funded care. (In some instances, because the care is 100% NHS funded care and the NHS consultant provides the medical care, services operated by private providers may not be required to be registered with HIW).

They may provide:

- Renal dialysis and / or
- Peritoneal dialysis.

The standards do not apply to dialysis which takes place in the patient's own home.

### **Class 3B or 4 Lasers or Intense Pulsed Light Source:**

Class 4 lasers and intense pulsed light sources are used in a variety of settings and for a variety of purposes. Examples of their use include:

- medical treatment in acute hospitals;
- dental treatment;
- refractive eye surgery;
- dermatological conditions;
- invasive cosmetic surgery by medical practitioners;
- minimal or non-invasive cosmetic services (which may be carried out by beauticians or healthcare professionals). Uses 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.

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 Registered<sup>11</sup> Physiotherapists and Podiatrists - who will be exempted from regulation.

The Medicines and Healthcare products Regulatory Agency (MHRA) provide advice on the use and safety of lasers - DB 2008(03) Guidance on the safe use of lasers, IPL systems and LEDs, April 2008. As a minimum, registered persons should be able to demonstrate that service users and patients are protected from adverse incidents or effects from their use, by informing their operational policies, procedures and practices through the standards set out in the MHRA guidance. Treatment protocols must be written by an expert medical or dental practitioner and a certificated Laser Protection Adviser must provide advice on the safety of the laser installation and day to day operational use.

### **In Vitro Fertilisation (IVF):**

IVF treatments are licensed by the Human Fertilisation and Embryology Authority (HFEA) and fall within regulation under the Act as a listed service. IVF treatments may also be provided within larger acute hospitals where other medical services are also provided.

## Other types of independent healthcare services:

### Maternity services:

Section 2(7)(c) of the Act brings within the definition of 'independent hospitals' establishments in which obstetric services and/or, in connection with childbirth, medical services are provided. Maternity services may be provided in a range of settings:

- Independent Clinics - for example, ante natal or post natal care by private doctors.
- Independent Hospitals - provision of more complex care, including caesarean sections. They may also have midwife led units.

It is expected that obstetricians, gynaecologists and anaesthetists who provide services in independent hospitals are current Members or Fellows of their respective medical Royal Colleges, have sufficient experience and seniority and are of good standing. They are also on the specialist register of the General Medical Council.

Midwives must be registered with the Nursing and Midwifery Council (NMC) and have notified her/his intention to practice to the Local Supervising Authority Midwifery Officer. It is expected that a Head of Midwifery is appointed in all maternity units.

### Mental health hospitals:

These types of establishments will have one or more overnight beds and offer services to adults or children with a mental illness and / or learning disability who require either short or longer term treatment and nursing care who require specialist assessment, treatment or rehabilitation. This includes patients who may be detained under the Mental Health Act 1983.

The Care Programme Approach (CPA) was introduced in Wales in 2004 and applies to people who have been detained under the Mental Health Act 1983. It provides a framework for caring for people with mental health problems and a co-ordinated care management system. This requires assessment, care planning, co-ordination and review of care. A recent review of the CPA in Wales identified a number of recommendations for improvement (Review of the Care Programme Approach in Wales 2009) and registered persons are encouraged to use these national minimum standards to help them meet the review recommendations.

Some hospitals may also offer treatment for substance misuse for treatment of withdrawal from drugs or alcohol.

The services offered may include some or all of the following support:

- Psychiatry.
- Occupational, speech and language therapy or physiotherapy.
- Art, music or drama therapy.

- Psychological therapies.
- Recreational activities.
- Services to manage physical health needs.

### Hospices:

The 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 as hospices. These are establishments with one or more overnight bed and generally provide treatment and care for either adults or children.

Services will be designed to meet the range of complex and diverse needs of both the patient and their carers by access to a multi-professional specialist palliative team. Some hospices also provide outreach services to patients in their own home. Some hospices may have their own 'in house' pharmacy services (see also section on 'pharmacy services' under Acute Hospitals above).

Children's hospices support parents with the burden of longer term care for children with life limiting conditions that often progress slowly over a number of years, (providing symptom management and respite care as well as support through death and bereavement). They need to be designed to provide environments that are appropriate for children with these conditions. The 'All Wales Palliative Care Standards for Children and Young People's Specialised Healthcare Services' (Welsh Assembly Government, 2008), builds on the National Service Framework for Children, 2005.

### Independent Clinics:

Independent clinics are establishments within which services are provided by private medical practitioners. For a service to be classed as an independent clinic, it cannot provide overnight beds or for example, a listed service (s.2(7) of the Act) such as procedures under general anaesthesia or intravenous sedation. Patient consultations are generally in premises where the doctor either has a designated consulting room or this is shared with other doctors. Appointments can be booked in advance or not required if it is a 'walk-in' service. Both general and psychiatric consultations may be provided.

Services may include:

- Basic physical or psychiatric measurements and investigations.
- Minor procedures such as curettage, cautery, cryocautery of warts, or other skin lesions.
- Longer term treatment for chronic conditions.
- Treatment for drug and alcohol misuse.
- Medicines may be prescribed.



- Discussion of diagnosis and treatment options or onward referral for other services.
- Weight management / weight loss services.
- Travel vaccination services.

In addition, establishments where no overnight beds are provided but palliative care services are provided by a medical practitioner(s) are classed as independent clinics and may include the provision of care, treatment, therapy and support services.

### Independent medical agency services:

These are often termed private 'call out' medical services. They may be provided to patients who are permanent residents or residing on a short term basis.

Services may include:

- Basic physical or psychiatric measurements and investigations.
- Minor procedures.
- Prescription of medicines.
- Discussion of diagnosis and treatment options or onward referral for other services.
- Travel vaccination services.
- Internet consultation, diagnosis or prescription.

Independent medical agencies may also provide an 'Out of Hours' call out service for independent clinics.

### Using these standards:

The standards have been written so that they are meaningful to all types of services, regardless of the setting. They have been developed to make it clear what applicants are expected to have in place at registration and ongoing, with further additional elements which they should demonstrate, once they are registered and providing the service.

Each standard includes the following sections:

- The standard number and title.
- The regulation(s) that may be breached if the standard is not met.
- The main overarching standard statement in bold.
- A section titled 'what this means', is intended to add clarity to the scope of the standard and registered persons' should also take this into account when deciding whether they meet the standard.

Taking into account the scope of the standard, registered providers should also consider:

- What service users can expect.
- The types of activities that staff or teams need to be doing.

If the provider is an organisation, the following aspects also need to be included:

- How establishments provide assurance to the corporate board and.
- How the corporate board assures itself that the standards are met and regulations are complied with.

The standard sets out the essentials that should be in place at registration, including (where appropriate) any service specific elements and those aspects that need to be considered once registration has been granted and the service is operating.

A final section provides links to supporting information relevant to the standard. Updated guidance to reflect areas for improvement can also be accessed via the NHS Wales Governance e-Manual at: [www.nhswalesgovernance.com](http://www.nhswalesgovernance.com)

Standard one, Governance and accountability framework, underpins the other standards by ensuring that arrangements are in place to manage and monitor compliance.

Services and teams can use the standards to:

- assess for themselves how well they currently meet them;
- benchmark with others to improve further;
- identify what they do well and should be shared;
- identify what they do less well and need to put right themselves or which may need to be addressed at a corporate level;
- map against their own professional standards and show how they complement and sit alongside them; and
- make changes which contribute to overall quality improvement within their services.

Providers, their Boards and Managers can use the standards to:

- self-assess against the standards at all levels and across all activities as a key source of assurance to enable them to determine what areas are doing well and those that may need to do better.

Using the standards in this way will help embed them into day to day activities and operational working.

## National Minimum Standards for Independent Healthcare

| Standard 1<br>Governance and accountability<br>framework  | Regulation 6, 7, 9, 19 |
|---|------------------------|
| <p>Organisations and services operate within a clear and robust framework for decision making and accountability designed to achieve successful delivery of their purpose, aims, and objectives, in a manner that:</p> <ul style="list-style-type: none"> <li>a) upholds organisational values and standards of behaviour;</li> <li>b) complies with all relevant regulatory, accreditation, licensing requirements, standards, directions and instructions;</li> <li>c) secures the efficient, effective use of resources;</li> <li>d) safeguards and protects all assets, including its people; and</li> <li>e) ensures good governance when working in partnership with others.</li> </ul> |                        |
| <p>What this means:</p> <p>Effective systems and processes are in place to assure the organisation, patients, service users, regulators and other stakeholders, that they are:</p> <ul style="list-style-type: none"> <li>• Meeting the relevant national minimum standards and complying with regulations;</li> <li>• Providing high quality, evidence based treatment and care through services that are patient / service user focussed;</li> <li>• Continually monitoring the quality of treatment and services;</li> <li>• Putting things right quickly, when they go wrong; and</li> <li>• Providing treatment and services in accordance with their Statement of Purpose.</li> </ul>   |                        |
| <p><b>Elements to be in place at registration and ongoing</b></p>   |                        |
| <p>There is a document which clearly sets out:</p> <ul style="list-style-type: none"> <li>• lines of reporting, accountability and responsibilities for all of the services provided by or to, the hospital, clinic or agency; and</li> <li>• reporting to the corporate board.</li> </ul> <p>Where responsibility is delegated from the registered provider to the responsible individual or to a registered manager, permitting them to make certain decisions, this is documented and signed by someone with the relevant authority.</p>   |                        |

Where required by legislation to have named persons for specific functions that are related to the activities of the service, their name, responsibilities and lines of reporting are documented and made known to staff and service users.

There is a Statement of Purpose and Patient Guide in place, which meets the requirements of Regulations 6 and 7.

There is a quality improvement system(s) in place to continually identify, manage and respond appropriately to risks, concerns, incidents, errors, adverse events and poor performance.

Relevant policies and procedures required under regulation 9 are in place.

#### Service specific elements to be in place at registration and ongoing

##### **In vitro fertilisation (IVF)**

- Establishments carrying out IVF treatments, will have a copy of their licence from the Human Fertilisation and Embryology Authority (HFEA)

#### Additional ongoing elements - once the service is operational

Registered persons, regularly receive information about risks, concerns / complaints, incidents, errors, adverse events and poor performance to ensure action is taken as quickly as possible, to make improvements to safeguard the health, safety and welfare of patients and service users and ensure compliance with regulations.

Registered persons can demonstrate investigation of and action from critical incidents.

Registered providers have arrangements in place to review and ratify policies and procedures before they are implemented.

Information about the quality of treatment and services or compliance with the regulations and how these are managed, is provided to the registration authority when requested.

The Statement of Purpose and Patient Guide are kept under review and where revised, HIW are notified at least 28 days prior to the revision taking effect and sent a copy of the updated document.

### Supporting information and guidance

**Note:** this list is not exhaustive. It is not intended as anything other than a useful aide memoir for providers and more up to date information may have superseded this.

The NHS Governance E Manual <http://www.nhswalesgovernance.com/display/Home.aspx?a=404&s=2&m=130&d=0&p=0>

Department of Health guidance [www.dh.gov.uk](http://www.dh.gov.uk)

Audit Commission [www.audit-commission.gov.uk](http://www.audit-commission.gov.uk)

Human Fertilisation and Embryology Authority (HFEA) [www.hfea.gov.uk](http://www.hfea.gov.uk)

| Standard 2<br>Equality, Diversity and<br>Human Rights   | Regulation 17, 18 |
|---|-------------------|
| <p>Organisations and services have equality priorities in accordance with legislation which ensure that they recognise and address the:</p> <ul style="list-style-type: none"> <li>a) needs of individuals whatever their identity and background, and uphold their human rights;</li> <li>b) rights of children in accordance with the United Nations Convention on the Rights of the Child (UNCRC); and</li> <li>c) need to challenge discrimination, promote equality and human rights.</li> </ul>   |                   |
| <p>What this means:</p> <p>Services need to be designed, developed, reviewed and implemented so that they do not compromise or limit access and service users are assured that:</p> <ul style="list-style-type: none"> <li>• Their rights and freedom to make choices will be promoted and respected;</li> <li>• Good equality practices are in place and regularly reviewed to help prevent and eliminate discrimination;</li> <li>• That reasonable adjustments will be made to services to reflect their individual needs;</li> <li>• They will not be refused a service, receive a less favourable service or a service on different terms to other patients and service users on the grounds of their age, race, nationality, gender or sexual orientation, religion or belief, disability.</li> </ul> |                   |
| <p><b>Elements to be in place at registration and ongoing</b></p>   |                   |
| <p>There is an equality and diversity policy in place which sets out the organisation's approach to service user's rights and equality, regarding the services provided.</p> <p>Service users or persons acting on their behalf, have information explaining their rights and how they can raise issues specifically relating to equality, diversity and human rights.</p> <p>Service users are assured that should their freedom to choose, need to be restricted at any time to safeguard them from harm or risk of harm, will be managed in accordance with The Mental Capacity Act 2005: Deprivation of Liberty Safeguards, or other relevant legislation (for example The Mental Health Act 1983 (as amended by the Mental Health Act 2007)).</p>  |                   |

### Service specific elements to be in place at registration and ongoing

#### Termination of pregnancy

Through written information, women who undergo termination of pregnancy are able to express their preference for the disposal of their foetal tissue.

#### Mental Health

Guidance is available to staff to the principles of the Mental Health Act 1983 (as amended) in respect of detention, restraint, leave, seclusion and behavioural techniques are subject to use only following assessment in line with the Mental Health Act 1983 (as amended) Code of Practice and best practice guidelines.

### Additional ongoing elements - once the service is operational

Equality practices are regularly reviewed to help prevent and eliminate discrimination.

### Supporting information and guidance

**Note:** this list is not exhaustive. It is not intended as anything other than a useful aide memoir for providers and more up to date information may have superseded this.

Equality and Human Rights Commission [www.equalityhumanrights.com](http://www.equalityhumanrights.com)

The Mental Capacity Act 2005: Deprivation of Liberty Safeguards Code of Practice  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_085476](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085476)

Children in Wales (UN Convention):  
[www.childreninwales.org.uk/Unconvention](http://www.childreninwales.org.uk/Unconvention)

Children's Commissioner for Wales [www.childcom.org.uk](http://www.childcom.org.uk)

NHS Centre for Equality and Human Rights Equality Impact Assessment Toolkit  
(includes a list of useful websites and additional signposting information)  
(NHS CEHR, 2009)

The NHS Governance E Manual [www.nhswalesgovernance.com](http://www.nhswalesgovernance.com)  
<http://www.nhswalesgovernance.com/display/Home.aspx?a=404&s=2&m=130&d=0&p=0>

| Standard 3<br>Health Promotion, Protection and Improvement   | Regulation 15 |
|--|---------------|
| <p>Organisations and services work in partnership with others to protect and improve the health and wellbeing of citizens by:</p> <ul style="list-style-type: none"> <li>a) having systems in place to identify and act upon significant public health issues;</li> <li>b) supporting service users to maintain and improve their health, wellbeing and independence;</li> <li>c) promoting healthy lifestyles and enabling healthy choices;</li> <li>d) promoting healthy and safe workplaces;</li> <li>e) ensuring that needs assessment and public health advice informs service planning, policies and practices;</li> <li>f) having systems and plans to prevent and control communicable diseases; and</li> <li>g) having effective systems to screen and detect disease.</li> </ul> |               |
| <p>What this means:</p> <p>Promoting health, improvement in health and healthy lifestyles is integral to individualised treatment and care whether addressing service users' immediate and short term health problems or longer term conditions.</p> <p>Health promotion information, relevant to the service user group, the range of their health problems and types of services offered [in accordance with the Statement of Purpose] should be available.</p> <p>Working practices need to be informed by public health advice, to ensure appropriate health protection for people who use, work in or visit a service, to minimise the risk of communicable diseases, healthcare associated infections or untoward exposure to radiation or a harmful substance.</p>                  |               |
| <p><b>Elements to be in place at registration and ongoing</b></p>  |               |
| <p>Appropriate health protection for people who use, work in or visit a service, to minimise the risk of communicable diseases, healthcare associated infections, violence and aggression, untoward exposure to radiation or a harmful substance is in place and includes:</p> <ul style="list-style-type: none"> <li>• Policies and procedures which take account of best practice guidance.</li> <li>• Signage and guidance for visitors raising awareness of hand hygiene to help prevent and control infection.</li> </ul>   |               |



- Appropriate warning signage within the establishment for known hazards.
- Pre employment occupational health screening, access to occupational health advice and arrangements for dealing with accidental exposure to Blood Borne Viruses (eg following a needle stick injury).

#### Service specific elements to be in place at registration and ongoing

##### Termination of pregnancy

Women are able to receive sexual health information or signposting to confidential advice before they leave the establishment.

#### Additional ongoing elements - once the service is operational

Service users are enabled to make healthy choices because:

- Information about the risks to their health and how these can be reduced are available.
- Where self referral for investigations are made, information about the risks, benefits and any alternatives are provided.
- They receive support to improve their health with regular review of their goals and progress.
- There is evidence that staff actively support health promotion activities (for example, smoking cessation).

#### Supporting information and guidance

**Note:** this list is not exhaustive. It is not intended as anything other than a useful aide memoir for providers and more up to date information may have superseded this.

Public Health Wales (PHW) <http://www.wales.nhs.uk/sites3/home.cfm?orgid=719>

Patient UK <http://www.patient.co.uk/showdoc/16>

The Impact of Personally Initiated X-ray Computed Tomography Scanning for the Health Assessment of Asymptomatic Individuals: - Recommendations Made by the Committee On the Medical Aspects of Radiation in the Environment (COMARE), 2009 <http://www.comare.org.uk/index.htm>

Department of Health

<http://www.dh.gov.uk/en/Publichealth/Healthimprovement/Sexualhealth/index.htm>

Health and Safety Executive <http://www.hse.gov.uk/guidance/topics.htm>

The NHS Governance E Manual [www.nhswalesgovernance.com](http://www.nhswalesgovernance.com)  
<http://www.nhswalesgovernance.com/display/Home.aspx?a=404&s=2&m=130&d=0&p=0>

| Standard 4<br>Emergency Planning Arrangements   | Regulation 15, 26 |
|---|-------------------|
| <p><b>Organisations and services are able to deliver a robust response and ensure business and service continuity in the event of an incident or emergency situation.</b></p>   |                   |
| <p>What this means:</p> <p>Organisations have developed appropriate plans for dealing with a range of incidents or emergencies (both clinical and non-clinical and foreseeable) that might adversely affect the health, safety and welfare of service users and / or interrupt the provision of normal services. Policies and procedures are in line with evidence based best practice guidance.</p> <p>Where necessary, the arrangements can be implemented without delay and provide for a rapid response within measurable timescales.</p>   |                   |
| <p><b>Elements to be in place at registration and ongoing</b></p>   |                   |
| <p>Organisations* can respond quickly to secure the continuous safe, appropriate treatment, care and comfort of service users because they have clear policies and procedures in place for adverse incidents and emergencies including:</p> <ul style="list-style-type: none"> <li>• Resuscitation.</li> <li>• Back up arrangements where there is a failure / interruption of a utility service.</li> <li>• Uninterruptible Power Supply (UPS) system for key areas (e.g. critical care, theatres, lighting) and, in relation to mental health, secure mental health units.</li> <li>• Emergency transfers of patients who experience unexpected complications and require a higher level of critical care (where children are treated, these arrangements are made in advance of their admission).</li> <li>• An outbreak of an infectious disease.</li> <li>• Radiological incident (where such equipment is used).</li> <li>• Maternal and neo-natal emergencies (where maternity services are provided).</li> <li>• Basic and Advanced Life Support (Adults and where appropriate, Paediatric and Newborn).</li> <li>• Piped medical gases.</li> <li>• The supply of blood / blood products.</li> <li>• Fire, flood or severe damage to the premises.</li> <li>• Major incident plan.</li> </ul> |                   |

Service users, visitors and persons who work at an establishment know how to safely evacuate premises in the event of a fire, because registered persons have in place:

- Clear procedures for summoning the assistance of emergency services and fire evacuation procedures.

#### Service specific elements to be in place at registration and ongoing

##### Maternity services

Effective arrangements are in place for the safe delivery by the mother of her baby, including that an obstetrician is readily contactable in an emergency and able to arrive within 15 minutes of being contacted.

##### Mental Health Services

Arrangements are in place to meet the guidelines set out by NICE in respect of Rapid Tranquillisation.

#### Additional ongoing elements - once the service is operational

Persons working in the establishment are able to act effectively in an emergency situation because they have opportunities to undertake simulated practice, in particular for resuscitation and fire.

#### Supporting information and guidance

**Note:** this list is not exhaustive. It is not intended as anything other than a useful aide memoir for providers and more up to date information may have superseded this.

Public Health Wales (PHW)

<http://www.hpa.org.uk/HPA/AnnualReportAndAccounts2009/2009OperatingReview/StrengtheningFrontlineSystems/>

Resuscitation Council (UK) guidelines <http://www.resus.org.uk/>

Quality Requirements for Adult Critical Care in Wales, Welsh Assembly Government 2006

<http://wales.gov.uk/topics/health/publications/health/guidance/qualityrequirementsadultrcritical?lang=en>

Department of Health Critical Care guidance

<http://www.dh.gov.uk/en/Healthcare/Emergencycare/Keyemergencycaresdocuments/index.htm>

Paediatric Intensive Care Society [www.ukpics.org](http://www.ukpics.org)

National Patient Safety Agency [www.npsa.nhs.uk](http://www.npsa.nhs.uk)

Medicines and Healthcare products regulatory Agency [www.mhra.gov.uk](http://www.mhra.gov.uk)

National Institute for Clinical Excellence (NICE)  
Clinical Guideline 25 - Quick reference guide - Violence The short-term  
management of disturbed/violent behaviour in psychiatric in-patient settings  
and emergency departments

The NHS Governance E Manual [www.nhswalesgovernance.com](http://www.nhswalesgovernance.com)  
<http://www.nhswalesgovernance.com/display/Home.aspx?a=404&s=2&m=130&d=0&p=0>

\* Unless you are a registered provider who is registered as an Independent Hospital solely using a Class 3B or 4 Laser and / or an Intense Pulsed Light Source for non-surgical cosmetic treatments, or an Independent Clinic, or an Independent Medical Agency.

| Standard 5<br>Citizen Engagement and Feedback   | Regulation 19, 28 |
|---|-------------------|
| <p>Organisations and services use a range of methods and approaches to:</p> <ul style="list-style-type: none"> <li>a) engage with partners in supporting and enabling service users to be involved in the design, planning and delivery of services;</li> <li>b) seek feedback from patients, service users and carers about their experiences; and</li> <li>c) demonstrate that they act on views and feedback in making changes to improve services.</li> </ul>   |                   |
| <p>What this means:</p> <p>That the views of people who use services, their representatives and commissioners of services, are actively sought and taken into account in the design, planning, delivery, review and improvement of services.</p> <p>Systems should be in place to support and develop effective service user involvement.</p> <p>Regular service reviews are undertaken and feedback is obtained, which then informs corporate, operational and local developments and improvements.</p>  |                   |
| <p><b>Elements to be in place at registration and ongoing</b></p>   |                   |
| <p>There is assurance that the views of service users will be sought and actively used to inform service improvement and development because systems are in place which include:</p> <ul style="list-style-type: none"> <li>• A service user / patient consultation plan.</li> <li>• Information for service users about how to make suggestions and comments about the Patient Guide.</li> <li>• Operational plans which set out annual objectives for the review of services and clinical care and reflect how registered persons will engage with and involve patients, service users and their representatives.</li> <li>• Advocacy arrangements to ensure equitable access and participation in consultation processes to obtain service user views (in particular mental health services).</li> </ul> |                   |

### Additional ongoing elements - once the service is operational

Registered persons comply with regulations because they have:

Patient survey/consultation arrangements developed and in place including;

- Patient satisfaction surveys/consultation to inform improvement and governance.
- Information leaflets developed which take account of the range of patient levels of understanding.
- Statement of Purpose and Patient Guides are kept under regular review
- Documents are available in formats and languages appropriate to the needs of patients.
- Visits by the registered provider where the views of service users and their representatives are actively sought and taken into account.

Reports of the outcome of feedback and consultations or registered provider visits, detail how service user views have been considered in the review, design, delivery and improvement of services.

Service improvements also take account of and reflect evidence based best practice guidance eg National Service Frameworks, NICE guidance.

The Patient Guide includes the results of any consultation about the services provided.

### Supporting information and guidance

**Note:** this list is not exhaustive. It is not intended as anything other than a useful aide memoir for providers and more up to date information may have superseded this.

Welsh Assembly Government

Office for Public Management/ National Assembly for Wales (2001)

Signposts: A practical guide to public and patient involvement in Wales,  
[www.wales.gov.uk/signposts](http://www.wales.gov.uk/signposts)

Welsh Assembly Government (2003) Fundamentals of Care, Guidance for Health and Social Care Staff; Improving the quality of fundamental aspects of health and social care for adults,

Welsh Assembly Government (2005) National Service Framework for Children, Young People and Maternity Services in Wales,

Welsh Assembly Government (2005) Adult Mental Health Services: The Revised Adult mental Health A National Service Framework and Action Plan for Wales

Disability Discrimination Act 1995

[http://www.opsi.gov.uk/acts/acts1995/ukpga\\_19950050\\_en\\_1](http://www.opsi.gov.uk/acts/acts1995/ukpga_19950050_en_1)

The NHS Governance E Manual [www.nhswalesgovernance.com](http://www.nhswalesgovernance.com)

<http://www.nhswalesgovernance.com/display/Home.aspx?a=404&s=2&m=130&d=0&p=0>



| Standard 6<br>Participating in Quality<br>Improvement Activities   | Regulation 9, 19, 28, 30, 31, 32, 33,<br>34, 35 |
|--|---|
| <p>Organisations and services reduce harm by:</p> <ul style="list-style-type: none"> <li>a) identifying and participating in quality improvement activities and programmes;</li> <li>b) supporting and enabling teams to identify and address local improvement priorities;</li> <li>c) using recognised quality improvement methodologies;</li> <li>d) measuring and recording progress; and</li> <li>e) spreading the learning.</li> </ul>   |   |
| <p>What this means:</p> <p>There are processes in place which can assist in improving the quality of outcomes, whether this is directly relevant to particular clinical treatment, such as clinical audit, or wider care provision and activities, for example, internal audit, risk assessment or patient satisfaction surveys.</p> <p>Service users will benefit from improvement activities where these are:</p> <ul style="list-style-type: none"> <li>• embraced as a high priority;</li> <li>• proactively planned and;</li> <li>• actively embedded into day to day practice of people who work in the service, (this includes directly employed staff as well as clinicians who have been granted practising privileges).</li> </ul> |   |
| <p><b>Elements to be in place at registration and ongoing</b></p>  |   |
| <p>Persons who use services are assured of the quality of treatment and services they will receive, because registered persons have arrangements in place to manage and continually monitor this, including:</p> <ul style="list-style-type: none"> <li>• an initial agreed programme of multidisciplinary clinical audit*;</li> <li>• corporate and local level leads for clinical audit*;</li> <li>• submitting information to National Registries (where appropriate, eg National Joint Registry);</li> <li>• processes to identify, manage and monitor risks;</li> <li>• clear communication procedures for cascading the results of improvement activities to all persons who work in the service.</li> </ul>                           |   |

### Service specific ongoing elements - once the service is operational

#### Acute hospitals

Service users benefit from safe, effective care because the MAC regularly receives information about the quality and safety of clinical care undertaken by medical practitioners who work at the hospital and makes recommendations to the registered person on:

- priorities for clinical audit (which reflect local and national priorities);
- improvements to clinical services, clinical pathways and clinical procedures;
- eligibility, review, withdrawal or restriction of practising privileges.

### Additional ongoing elements - once the service is operational

Service users are not harmed by treatments and services because the registered person ensures:

- Clinical audit programmes are:
  - multidisciplinary;
  - planned as part of the ongoing annual programme of audit;
  - informed by robust, validated data and service user views and;
  - prioritised according to data or other information gathered, which reflect that improvements are required; and
- Improvement is informed (where appropriate) by:
  - the outcome of audit / surveys / service user views / observations / untoward incidents or near misses;
  - complaints / investigations;
  - relevant expert and professional advice;
  - best practice guidance;
- Regular review and update policies and procedures as a consequence of learning but at least once every 3 years.
- Retrospective improvement activity, as a consequence of learning from adverse incidents or complaints, is actioned as quickly as possible to reduce the risk of ongoing adverse outcomes for service users and monitored to ensure improvement is sustained and effective.

- Where telemedicine diagnostic services are provided from outside of the UK, there is a written contract in place, which sets out arrangements for:
  - regular audit of clinical quality;
  - the qualifications of staff who will provide the analysis of specific tests and ensures they are professionally regulated to the same standards as within the UK.

Registered persons notify Healthcare Inspectorate Wales in line with regulations 11, 14, 28, 30, 31, 32, 33, which include:

- incidents relating to specific service users;
- incidents which might effect people who use services.

A register of all events notified to Healthcare Inspectorate Wales under regulations 30 and 31, is maintained.

Where the registered person ceases to carry on the establishment or agency, the relevant person notifies Healthcare Inspectorate Wales in line with Regulations 34 and 35.

### Supporting information and guidance

**Note:** this list is not exhaustive. It is not intended as anything other than a useful aide memoir for providers and more up to date information may have superseded this.

Public Health Wales (PHW)

<http://www.wales.nhs.uk/sites3/page.cfm?orgId=719&pid=33292>

Health Quality Improvement Partnership <http://www.hqip.org.uk/>

NHS Improvement <http://www.improvement.nhs.uk/>

1000 Lives Campaign - this will also give you access to the 'How to Guides' and 'tools for improvement'

The NHS Governance E Manual [www.nhswalesgovernance.com](http://www.nhswalesgovernance.com)

<http://www.nhswalesgovernance.com/display/Home.aspx?a=404&s=2&m=130&d=0&p=0>

<http://www.nhswalesgovernance.com/display/Home.aspx?a=404&s=2&m=130&d=0&p=0>

Centre for Maternal and Child Enquiries

National Confidential Enquiry into Patient Outcome and Death

National Confidential Inquiry into Suicide and Homicide by People with Mental Illness

National Joint Registry

\* Unless you are a registered provider who is registered as an Independent Hospital solely using a Class 3B or 4 Laser and / or an Intense Pulsed Light Source for non-surgical cosmetic treatments.

| Standard 7<br>Safe and Clinically Effective Care  | Regulation 15 |
|---|---------------|
| <p>Organisations and services will ensure that patients and service users are provided with safe, effective treatment and care:</p> <ul style="list-style-type: none"> <li>a) based on agreed best practice guidelines including those defined by National Service Frameworks, National Institute for Health and Clinical Excellence (NICE), National Patient Safety Agency (NPSA) and professional bodies;</li> <li>b) that complies with safety and clinical directives in a timely way; and</li> <li>c) which is demonstrated by procedures for recording and auditing compliance with and variance from any of the above.</li> </ul>  |               |
| <p>What this means:</p> <p>Appropriate arrangements for clinical governance are in place including:</p> <ul style="list-style-type: none"> <li>• mechanisms for agreeing, adopting and implementing new or revised clinical guidance;</li> <li>• dealing with safety and advice bulletins.</li> </ul> <p>Where appropriate, if new procedures and guidance are introduced, this is linked to a training and skills strategy to support effective implementation.</p> <p>Clinical care, treatment and decision making, should reflect evidence based and best practice guidance to ensure that the risk of inappropriate or unnecessary treatment and care is reduced to the lowest possible level.</p>  |               |
| <p><b>Elements to be in place at registration and ongoing</b></p>   |               |
| <p>Treatment, care and service improvement is in line with evidence based clinical guidelines because these take account of evaluations by the:</p> <ul style="list-style-type: none"> <li>• National Institute for Healthcare and Clinical Excellence (NICE).</li> <li>• Clinical guidelines from the relevant medical Royal Colleges.</li> <li>• NHS National Service Frameworks.</li> <li>• National Patient Safety Agency (NPSA).</li> <li>• Relevant national and professional body guidelines.</li> </ul> <p>The risk of a patient receiving treatment or care that is incorrect or not evidence based is reduced because multi-disciplinary policies and guidance for the management of all conditions / situations are available to and followed by, persons who work in the service.</p> |               |

### Service specific elements to be in place at registration and ongoing

#### Lasers and Intense Pulsed Light Sources

A treatment protocol produced by an expert medical or dental practitioner is followed which sets out:

- the necessary pre-treatment checks and tests;
- how the procedure is to be applied;
- the acceptable variations in the equipment settings used, and
- when to abort a treatment and what to do when something goes wrong.

### Additional ongoing elements - once the service is operational

Registered persons ensure treatment outcomes are within acceptable ranges because they:

- Benchmark best practice and key performance indicators (KPIs).
- Audit outcomes of the quality and safety of treatment and care against best practice and KPIs.
- Record and monitor clinical pathway variances to inform improvement.
- Ensure safety bulletins and alerts are acted on within required time scales.
- Regularly review policies, procedures and protocols.

### Supporting information and guidance

**Note:** this list is not exhaustive. It is not intended as anything other than a useful aide memoir for providers and more up to date information may have superseded this.

World Health Organisation (WHO) Guidelines for Safe Surgery, 2009  
<http://www.who.int/patientsafety/safesurgery/en/>

National Patient Safety Agency [www.npsa.nhs.uk](http://www.npsa.nhs.uk)

National Patient Safety Agency, Safe Surgery Saves Lives initiative  
<http://www.npsa.nhs.uk/corporate/news/safe-surgery-saves-lives/>

National Patient Safety Agency (2006) With safety in mind: mental health services and patient safety; Patient Safety Observatory Report 2/ July 2006

National Patient Safety Agency (2006) Building a memory: preventing harm, reducing risks and improving patient safety; The first report of the National Reporting and Learning System and the Patient Safety Observatory

NHS Evidence <http://www.evidence.nhs.uk/default.aspx>

The 'All Wales Palliative Care Standards for Children and Young People's Specialised Healthcare Services' (Welsh Assembly Government, 2008),  
<http://wales.gov.uk/topics/childrenyoungpeople/publications/palliativecarestandards/?skip=1&lang=en>

Medicines and Healthcare products regulatory Agency [www.mhra.gov.uk](http://www.mhra.gov.uk)

Medicines and Healthcare products Regulation Agency (MHRA) publications including;

- Safety guidance, warnings, alerts and recalls.
- Regulatory guidance - medicines & devices.
- Device evaluations.

The NHS Governance E Manual [www.nhswalesgovernance.com](http://www.nhswalesgovernance.com)  
<http://www.nhswalesgovernance.com/display/Home.aspx?a=404&s=2&m=130&d=0&p=0>

| Standard 8<br>Care Planning and Provision  | Regulation 9, 15, 47 |
|--|----------------------|
| <p>Organisations and services will recognise and address the needs of patients, service users and their carers by:</p> <ul style="list-style-type: none"> <li>a) providing all aspects of care including referral, assessment, diagnosis, treatment, transfer of care and discharge including care at the end of life, in a timely way consistent with any national timescales, pathways and best practice;</li> <li>b) providing support to develop competence in self-care and promote rehabilitation and re-enablement; and</li> <li>c) working in partnership with other services and organisations, including social services and the third sector.</li> </ul>  |                      |
| <p>What this means:</p> <p>Patient health and wellbeing needs are identified through appropriate levels of assessment and a plan of care developed to meet those needs.</p> <p>Patient and service user needs and preferences are central to the assessment, planning and provision of their care. Good quality care planning and provision will help ensure a positive patient experience.</p> <p>To ensure that patients receive safe, individualised treatment and care, registered persons will need to consider the following when developing plans of care:</p> <ul style="list-style-type: none"> <li>- Application of relevant legislation (for example, the requirements of the Data Protection Act 1998 or Health and Safety at Work Act 1974).</li> <li>- How evidence based and best practice guidance informs all stages of the care pathway.</li> <li>- How to ensure that the right staff perform the right tasks and roles.</li> <li>- The role of team leaders or managers in the provision of treatment and care.</li> <li>- Access to timely specialist or expert advice.</li> <li>- How to empower and support service users (and where appropriate their family or representatives) to enable them to understand what is proposed for their treatment, express preferences, make decisions and care for themselves after discharge (including decisions about resuscitation).</li> <li>- How to resolve service user preferences, where these may not be possible to meet (for legal or other reasons).</li> <li>- Consistency of the quality of care planning and provision.</li> <li>- Arrangements for liaising with external agencies and professionals.</li> </ul> |                      |

### Elements to be in place at registration and ongoing

Patient admission processes are designed to be a positive experience, have a safe outcome and are appropriately planned. These are supported by organisational policies and procedures (including patient information), which explain\*:

- the arrangements for admission or acceptance to a hospital and what patients can expect;
- why and how a transfer to another hospital may be necessary (including transfer to the NHS);
- arrangements for patient assessment, diagnosis and treatment;
- how sensitive issues will be explored, discussed and decisions documented, including decisions about resuscitation;
- arrangements for discharge;
- how treatment and care is to be assessed, documented and recorded;
- who should be involved in this;
- how and when treatment and care should be reviewed;
- who can agree and who is permitted to make changes to treatment and care plans.

Care planning and provision follows an approved care pathway or framework which:

- is evidence based;
- is in place for each patient and individual to their assessed needs and risks of harm;
- clearly describes what the assessed needs are and how they will be met;
- supports multi-disciplinary working;
- supports rehabilitation and re-enablement where appropriate;
- is regularly reviewed by all relevant staff and professionals.

### Service specific elements to be in place at registration and ongoing

#### Hospices

Staff have access to 24 hour specialist palliative care advice and expertise.

#### Hospices and other services

The quality of a persons end life care is sustained because it follows a best practice model consistent with the Last Days of Life Care Pathway.



## Mental Health

The Care Programme Approach (CPA) is implemented for all patients and is developed, implemented and reviewed in line with best practice guidance.

Service users receive an assessment of their needs which is informed by:

- a comprehensive examination of their mental and physical health;
- an evaluation of their clinical history, including identification of risks to themselves or to others, including suicidal tendencies.

### Additional ongoing elements - once the service is operational

Following treatment, each patient and, where appropriate, their carer, is provided with information about taking care of themselves, any possible complications of the procedure or medication and a contact telephone number(s) where advice can be obtained at any time of the day or night.

### Supporting information and guidance

**Note:** this list is not exhaustive. It is not intended as anything other than a useful aide memoir for providers and more up to date information may have superseded this.

National Service Frameworks

Skills for Health <http://www.skillsforhealth.org.uk/>

Palliative Care in Wales Last Days of Life Care Pathway  
<http://wales.pallcare.info/index.php?p=sections&sid=30>

End of Life Care Pathway <http://www.mcpcil.org.uk/liverpool-care-pathway/>

End of Life Care Strategy (Department of Health, 2009)

Help the Hospices [www.helpthehospices.org.uk](http://www.helpthehospices.org.uk)

National Treatment Agency [www.nta.org.uk](http://www.nta.org.uk)

NICE guidelines

National Collaborating Centre for Mental Health <http://www.nccmh.org.uk/>

The NHS Governance E Manual [www.nhswalesgovernance.com](http://www.nhswalesgovernance.com)  
<http://www.nhswalesgovernance.com/display/Home.aspx?a=404&s=2&m=130&d=0&p=0>

\* Unless you are a registered person who is solely using a Class 3B or 4 Laser and / or an Intense Pulsed Light Source for non-surgical cosmetic treatments.

| Standard 9<br>Patient Information and Consent   | Regulation 9, 17, 38, 39, 40, 44 |
|---|----------------------------------|
| <p>Organisations and services recognise and address the needs of patients, service users and their carers by:</p> <ul style="list-style-type: none"> <li>a) providing timely and accessible information on their condition, care, medication, treatment and support arrangements;</li> <li>b) providing opportunities to discuss and agree options;</li> <li>c) treating their information confidentially;</li> <li>d) obtaining informed consent, in line with best practice guidance; and</li> <li>e) assessing and caring for them in line with the Mental Capacity Act 2005 when appropriate.</li> </ul>  |                                  |
| <p>What this means:</p> <p>People who use services know that they will receive the right information, at the right time, provided by the right people, in a way and language they can understand, to make the choice that is best for them, because;</p> <p>policies, guidance and processes are in place dealing with consent, in relation to adults and where treated, children, which:</p> <ul style="list-style-type: none"> <li>• establish whether a person has capacity to give consent;</li> <li>• establish what constitutes valid consent;</li> <li>• details the form that consent might take and the duration of that consent;</li> <li>• deals with lack of capacity to consent;</li> <li>• deals with advanced decisions;</li> <li>• deals with refusal to consent;</li> <li>• deals with consent issues arising from additional procedures that may be required during treatment and are not covered by the original consent and where appropriate;</li> <li>• deals with consent relating to the subsequent use of removed tissue;</li> <li>• deals with consent to visual and audio recordings;</li> <li>• deals with requirements concerning gametes and the requirements for living donation and for research and innovative treatment.</li> </ul> |                                  |

### Elements to be in place at registration and ongoing

Service users will be assured that consent to treatment and care is an integral part of their care pathway because a policy for obtaining, documenting and reviewing consent to examination, treatment and care is in place setting out how this will be managed.

The policy on consent includes reference to:

- The circumstances in which written consent must be taken.
- The way in which written consent must be documented.
- Consent by children,( including Gillick competence).
- The circumstances in which verbal or implied consent can be taken.
- The care, treatment and support options available to the person in sufficient detail to allow a meaningful discussion.
- The fact that consent is ongoing and can be withdrawn by the person after it was initially given.
- Decision-making for people who are unable to give, or choose to withhold, consent for each individual care, treatment and support activity, including, meeting the requirements of:
  - a) the Mental Health Act 1983 and the Mental Capacity Act 2005; and
  - b) the requirements of the Mental Health Act 1983, Mental Capacity Act 2005 where applicable and the Children Act 1989, for children and young people (under the age of eighteen).
- How to respond to the decisions people make about their care, treatment and support including:
  - how to act upon these decisions;
  - respecting decisions even when they disagree;
  - understanding the cultural and social values and beliefs of the person;
  - what to do when the wishes of the person conflict with their nominated representative, family, friends and carers;
  - how to respond to advanced decisions;
  - How to respond in immediate emergency situations.

Persons who obtain consent have been appropriately trained to:

- Ensure that the risks, benefits and alternative treatments are discussed so that patients can understand and make an informed decision to agree to these.
- Assess whether a person has the capacity to give consent.
- Respect a person's decision to refuse consent.
- Where known, follow any advanced decision the person may have made about the care, treatment and support they want to receive.
- Document consent discussions and decisions.
- Carry out regular reviews of consent decisions, which take into account the person's changing needs.

Patients who are at risk of cardiac or respiratory failure, or have a terminal illness, have an opportunity to discuss and experience sensitive exploration of their wishes regarding resuscitation.

The environment in which consent is obtained provides privacy to discuss confidential treatment options.

### Service specific elements to be in place at registration and ongoing

#### **Termination of pregnancy**

Before consenting to treatment, persons undergoing a termination of pregnancy will know that:

- The hospital cannot demand or accept a fee for the service, unless two certificates of opinion have been received;
- That they cannot have a termination of a pregnancy undertaken after the 20th week of gestation, unless:
  - (a) They can be treated by a medical practitioner who is suitably qualified, skilled and experienced in the late termination of pregnancy; and
  - (b) Appropriate procedures are in place to deal with any medical emergency which occurs during or as a result of the termination.
- That the hospital cannot undertake a termination of a pregnancy after the 24th week of gestation.
- That the required certificates of opinion will be placed in their healthcare record.

#### **Mental Health**

Information is available to service users, which explains their rights to appeal against detention or withdraw consent.

#### Additional ongoing elements - once the service is operational

Service users receive sufficient information to make an informed choice and decision.

Valid consent is always obtained before any examination, treatment or care is provided.

Where a person is unable to give valid consent, this is assessed through a process that complies with the Mental Capacity Act 2005.

Where treated, clinicians speak with children and their families to ensure that children are fully aware of the treatment they are to receive.

Information is provided in language and format appropriate to the level of understanding of the service user.

The person obtaining consent ensures that sufficient time is allowed to explain the proposed procedure and allow the opportunity to ask questions.

#### Supporting information and guidance

**Note:** this list is not exhaustive. It is not intended as anything other than a useful aide memoir for providers and more up to date information may have superseded this.

Welsh Assembly Government - Patient consent

<http://www.wales.nhs.uk/sites3/page.cfm?orgid=465&pid=11930>

Department of Health - Patient consent

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_103643](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_103643)

Gillick Competency and Fraser Guidelines

United Nations Convention on the Rights of the Child (UNCRC)

<http://www.unicef.org.uk/pages.asp?page=92&nodeid=convent&section=2&gclid=CMeJpliC1aQCfeh25QodB2NbMA>

HFEA <http://www.hfea.gov.uk/consent-to-fertility-treatment.html>

Human Tissue Authority <http://www.hta.gov.uk/>

The Mental Capacity Act 2005: Deprivation of Liberty Safeguards Code of Practice

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_085476](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085476)

The Mental Health Act 1983 :

[http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/DH\\_4002034](http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/DH_4002034)

The NHS Governance E Manual [www.nhswalesgovernance.com](http://www.nhswalesgovernance.com)

<http://www.nhswalesgovernance.com/display/Home.aspx?a=404&s=2&m=130&d=0&p=0>

| Standard 10<br>Dignity and Respect  | Regulation 18 |
|---|---------------|
| <p>Organisations and services recognise and address the physical, psychological, social, cultural, linguistic, religious and spiritual needs / choices and preferences of individuals and that their right to dignity and respect will be protected and provided for.</p>   |               |
| <p>What this means:</p> <p>People who use services will know that their privacy, dignity, independence and autonomy will be respected because registered persons ensure:</p> <ul style="list-style-type: none"> <li>• facilities are available to optimise privacy and dignity;</li> <li>• staff receive training and development to be able to uphold privacy, dignity and independence;</li> <li>• the provision of information in a format and way which service users can understand;</li> <li>• that there are processes in place to ensure communication with service users and that policies and procedures are informed by service user views and experiences;</li> <li>• that they have established benchmarks for dignity and respect which are regularly audited;</li> <li>• that they encourage independence and autonomy.</li> </ul> |               |
| <p><b>Elements to be in place at registration and ongoing</b></p>   |               |
| <p>The arrangements for respecting the privacy and dignity of people who use services, is set out in the Statement of Purpose for the organisation.</p> <p>People who use services have their privacy and dignity maintained through the provision of:</p> <ul style="list-style-type: none"> <li>• single sex bedroom accommodation;</li> <li>• single sex toilet and bathing facilities (accessed via a single sex route).</li> </ul>   |               |
| <p><b>Service specific elements to be in place at registration and ongoing</b></p>  |               |
| <p><b>Mental Health</b></p> <p>The privacy and dignity of people who use services is upheld because they have the option of socialising in a mixed sex communal area or a segregated communal room ie separate rooms for men and women.</p>   |               |

#### Additional ongoing elements - once the service is operational

People who use services are enabled to:

- express their views about their treatment and care;
- self determine their preferences unless this would place themselves or others at risk of harm, or there are legal reasons why they are assessed as being unable to make these choices;

Service user care pathways are audited to ensure continuous privacy and dignity is provided to them through:

- appropriate facilities to enable confidential or private conversations;
- environments which do not compromise privacy or dignity (including recorded personal information about the patient);
- staff who understand, respect and observe the need for privacy and dignity.

#### Supporting information and guidance

**Note:** this list is not exhaustive. It is not intended as anything other than a useful aide memoir for providers and more up to date information may have superseded this.

Welsh Assembly Government All Wales NHS Violence and Aggression Training Passport and Information Scheme  
[http://howis.wales.nhs.uk/doclib/AllWales\\_viol\\_agg\\_passport-e.pdf](http://howis.wales.nhs.uk/doclib/AllWales_viol_agg_passport-e.pdf)

Disability Equality Duty <http://www.dotheduty.org>

National Patient Safety Agency [www.npsa.nhs.uk](http://www.npsa.nhs.uk)

Human Rights Act 1998  
[http://www.opsi.gov.uk/acts/acts1998/ukpga\\_19980042\\_en\\_1](http://www.opsi.gov.uk/acts/acts1998/ukpga_19980042_en_1)

Department of Health - End of Life care  
<http://www.dh.gov.uk/en/Healthcare/IntegratedCare/Endoflifecare/index.htm>

The NHS Governance E Manual  
[www.nhswalesgovernance.com](http://www.nhswalesgovernance.com)  
<http://www.nhswalesgovernance.com/display/Home.aspx?a=404&s=2&m=130&d=0&p=0>



| <p>Standard 11<br/>Safeguarding Children and<br/>Safeguarding Vulnerable Adults</p>   | <p>Regulation 16, 39, 47</p> |
|---|------------------------------|
| <p>Organisations and services promote and protect the welfare and safety of children and vulnerable adults by:</p> <ul style="list-style-type: none"> <li>a) conforming to legislation and guidance;</li> <li>b) ensuring effective multi-agency working and co-operation;</li> <li>c) training and supporting staff to recognise and act on issues and concerns, including sharing of information; and</li> <li>d) sharing good practice and learning.</li> </ul>  |                              |
| <p>What this means:</p> <p>Registered persons will ensure that robust processes are in place and do all that they can, to ensure that people who use their services are protected from abuse or the risk of abuse, neglect, harm and exploitation. Systems and procedures mirror best practice guidance for the protection of children and vulnerable adults (safeguarding).</p> <p>This includes compliance with the Mental Health Act 1983 in relation to persons liable to be detained and the Mental Capacity Act 2005 regarding Deprivation of Liberty Safeguards.</p> <p>Support, empowerment and anti discriminatory practices will also be essential components of the care provided and in dealing with any safeguarding matters.</p>  |                              |
| <p><b>Elements to be in place at registration and ongoing</b></p>   |                              |
| <p>Safeguarding policies and procedures are in line with national policy and legislation and Local Area Procedures.</p> <p>There are designated lead roles for child and adult protection at corporate level.</p> <p>There are links to the local multi-agency co-ordinators for child and adult protection.</p> <p>Service users are assured that all persons who work in the service will:</p> <ul style="list-style-type: none"> <li>• know what abuse is and how to recognise the signs of abuse;</li> <li>• have received training in safeguarding which is appropriate to their role;</li> <li>• know how to respond appropriately to suspected or actual abuse;</li> <li>• be aware of operational policies which make it clear that they cannot benefit from a service user through financial or inappropriate gain.</li> </ul> |                              |

Referral processes and information sharing protocols are in line with multi-agency procedures and include contact details (address, telephone and fax) for coordinators to whom referral should be made.

Service users know how they can raise concerns about abuse because information is available to them which explains how they can do this.

Through operational policies, those who work in the service will be supported and confident to raise concerns about abuse or potential abuse.

#### Additional ongoing elements - once the service is operational

Service users are supported in reporting abuse.

Action is taken immediately when an allegation of abuse is made and to prevent further potential abuse.

Allegations of and actual abuse, are reported to HIW and to the appropriate authority, in line with the procedures set out in policies and legislation.

Safeguarding policies and procedures are regularly reviewed in line with national policy and local guidance.

Where required, there is participation in safeguarding procedures and Boards and service providers work collaboratively with other agencies.

Advocacy and support is available for service users who want to raise concerns about abuse or participate in safeguarding procedures.

Service users are assured that they will be protected from harm and abuse because there are regular audits of recruitment practices.

#### Supporting information and guidance

Note: this list is not exhaustive. It is not intended as anything other than a useful aide memoir for providers and more up to date information may have superseded this.

All Wales Child Protection Procedures 2008  
<http://www.ssiacymru.org.uk/index.cfm?articleid=298>

In Safe Hands: Implementing Adult Protection Procedures in Wales 2000  
<http://wales.gov.uk/topics/health/publications/socialcare/reports/insafehands;jsessionid=h3TxKWYG6y3Q8Y5hfXKyjk6J0Tv1HhXPp3pjBHyX2k971XVdCCChG!442808764?lang=en>

Independent Safeguarding Authority (Vetting and Barring Scheme)  
<http://www.isa-gov.org.uk/>

Mental Capacity Act 2005: Deprivation of liberty safeguards - Code of Practice  
to supplement the main Mental Capacity Act 2005 Code of Practice  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/  
PublicationsPolicyAndGuidance/DH\\_085476](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_085476)

Department of Health  
Clinical Governance and Adult Safeguarding- An Integrated Process, 2010  
[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/  
PublicationsPolicyAndGuidance/DH\\_112361](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_112361)

Deprivation of Liberty Safeguards: A Guide for Hospitals and Care Homes  
(Department of Health, 2009)

The NHS Governance E Manual [www.nhswalesgovernance.com](http://www.nhswalesgovernance.com)  
[http://www.nhswalesgovernance.com/display/Home.  
aspx?a=404&s=2&m=130&d=0&p=0](http://www.nhswalesgovernance.com/display/Home.aspx?a=404&s=2&m=130&d=0&p=0)

| Standard 12<br>Environment  | Regulation 26, 40 |
|---|-------------------|
| <p>Organisations and services comply with legislation and guidance to provide environments that are:</p> <ul style="list-style-type: none"> <li>a) accessible;</li> <li>b) well maintained;</li> <li>c) fit for purpose;</li> <li>d) safe and secure;</li> <li>e) protect privacy; and</li> <li>f) sustainable.</li> </ul>  |                   |
| <p>What this means:</p> <p>Establishments should be designed, developed, adapted and commissioned to meet their intended purpose. Design and procurement should take account of current:</p> <ul style="list-style-type: none"> <li>• Health Technical Memorandum (HTMs);</li> <li>• Health Building Notes (HBNs);</li> <li>• Infection Control in the Built Environment (HFN 30 or guidance which supersedes this);</li> <li>• Recognised standards;</li> <li>• Other relevant best practice guidance and specialist expertise;</li> <li>• Requirements of the Disability Discrimination Act 1995, Health and Safety Act 1974, Fire Safety and other relevant legislation.</li> </ul> <p>Design and procurement should have regard to:</p> <ul style="list-style-type: none"> <li>• the range of needs of the people who will work in, visit or use the services to be provided;</li> <li>• their rights to privacy, dignity, make independent choices; and</li> <li>• the need for patients to be treated in a safe environment.</li> </ul> <p>The health, safety and wellbeing of people who will work in, visit or use the services, is not adversely affected by the design or condition of the building or its fixtures, fittings and services.</p> |                   |

### Elements to be in place at registration and ongoing

Service users receive care and treatment in environments that are safe and have regard to their individual needs for privacy because registered persons have in place:

- A policy detailing arrangements for managing urgent, routine and planned preventive maintenance for all service areas.
- Arrangements for dealing with a utility failure or other emergency.
- Communication systems for assisting service users, including those who have a disability and for alerting persons to an emergency situation.
- Premises that can be safely accessed by service users with a disability.
- Systems installed to ensure the premises are adequately heated, ventilated and lit.
- Arrangements to prevent unauthorised access to the premises.
- All areas of the premises (both internal and external) are clearly identified for service users and visitors.
- The environment is at all times suitable, clean and comfortable for the treatment being provided.

\*With the exception of service providers operating an independent clinic or providing non-surgical cosmetic treatment with a class 3 or 4b laser or IPL, services will additionally have in place:

- Space for a relative, carer or friend to be able to stay with the patient at the end of their life.
- For staff on call and who remain on the premises, adequate facilities to ensure comfort, privacy and the ability to rest properly. Staff should have access at all times to a telephone which is connected to the premises' network.
- Access to outdoor space; this could be outdoor areas, gardens or grounds that allow individuals to benefit from being outside (and where appropriate, access is restricted from unauthorised access).
- A contingency plan and back up systems for potential major incidents which could affect the registered environment (for example, fire, flood, utility failure or other emergency).
- Where persons are accommodated overnight, single bedroom accommodation is provided, ideally with en suite facilities, unless this is unsafe or inappropriate.
- Gender specific toilet, washing and bathing facilities.

### Service specific elements to be in place at registration and ongoing

#### Mental Health

- Hospitals treating both males and females with a mental illness / disorder, must have a gender specific recreational / communal area, ie one for males and a separate one for females. Access to all gender specific accommodation and facilities must be via a gender specific route.
- All environments used for seclusion comply with the Mental Health Act 1983 (as amended) Code of Practice and best practice guidance (for example, Standards for Psychiatric Intensive Care Units (PICU) and Low Secure Environments, Department of Health (DH), DH - Specification for adult medium-secure services).

#### Children

- Where children are treated, the treatment areas and accommodation are segregated from that provided for adults.
- Children are always treated in an environment that is suitable to their age and needs.

#### Acute hospitals and hospices for children

- Accommodation is available for parents and where appropriate family members, which is close to the child's room.

### Additional ongoing elements - once the service is operational

Service providers should have:

- Records available of all work requested and undertaken in response to urgent, routine and planned preventive maintenance.
- Regularly updated risk assessments of any environmental or fire safety risks in relation to the services provided, the ages of service users and their potential disabilities.
- A written action plan, with time scales, to deal with identified risks.
- An ongoing audit of building defect / hazard reporting and repair response times.

### Supporting information and guidance

**Note:** this list is not exhaustive. It is not intended as anything other than a useful aide memoir for providers and more up to date information may have superseded this.

The NHS Governance E Manual [www.nhswalesgovernance.com](http://www.nhswalesgovernance.com)  
<http://www.nhswalesgovernance.com/display/Home.aspx?a=404&s=2&m=130&d=0&p=0>

Space for Health <http://www.spaceforhealth.nhs.uk/>

Welsh Health Estates <http://www.wales.nhs.uk/sites3/home.cfm?orgid=254>

Department of Health guidance [www.dh.gov.uk](http://www.dh.gov.uk)

NPSA Safer Practice Notice - Colour coding hospital cleaning materials & testing - 10 Jan 2007

\* Is solely using a Class 3B or 4 Laser and / or an Intense Pulsed Light Source for non- surgical cosmetic treatments only.

| Standard 13<br>Infection Prevention and Control<br>(IPC) and Decontamination  | Regulation 9, 15 |
|---|------------------|
| <p>Organisations and services comply with legislation and guidance on IPC and decontamination, in order to:</p> <ul style="list-style-type: none"> <li>a) eliminate or minimise the risk of healthcare associated and community acquired infections;</li> <li>b) emphasise high standards of hygiene and reflect best practice;</li> <li>c) support, encourage and enable patients, service users, carers, visitors and staff to assist and maintain high standards of hygiene;</li> <li>d) segregate, handle, transport and dispose of waste so as to minimise risks to patients, service users, carers, staff, the public and environment; and</li> <li>e) handle human tissue and subsequently dispose of it appropriately and sensitively.</li> </ul>   |                  |
| <p>What this means:</p> <p>Establishments should be designed, developed and adapted to ensure all aspects of infection prevention and control (IPC) can be effectively and efficiently managed. Design and procurement should take account of:</p> <ul style="list-style-type: none"> <li>• Health Technical Memorandum (HTMs).</li> <li>• Health Building Notes (HBNs).</li> <li>• Infection Control in the Built Environment.</li> <li>• Recognised standards.</li> <li>• Other relevant best practice guidance and specialist expertise.</li> </ul> <p>Design and procurement should have regard to:</p> <ul style="list-style-type: none"> <li>• the range of treatments and services to be provided.</li> <li>• IPC measures for people who will work in, visit or use the services to be provided.</li> </ul> <p>Different healthcare environments will need to comply with guidelines and memoranda specific to their own areas and needs to ensure that the health, safety and wellbeing of people who use the services, is not adversely affected by inadequate IPC facilities and arrangements.</p> |                  |



### Elements to be in place at registration and ongoing

Persons who use, work in or visit services will be protected from healthcare associated infections because registered providers have in place:

- An effective infection prevention and control policy by service area with reference to national model IPC policies (which includes arrangements and procedures for minimisation of the risks from exposure prone procedures and other situations where normal defences are damaged or immunity is compromised).
- Standard infection prevention and control procedures.
- Environmental cleaning plans, schedules and specifications by service area, which include all environments and equipment within that service area based on national standards and specifications to reduce the risk of cross contamination (including control of Legionella).
- Suitable infection prevention and control education and training for all employees, volunteers and persons with practising privileges.
- Suitable information to assist and enable people who visit or use the services to observe good infection control practices.
- Infection control advice.
- Occupational health advice and appropriate pre employment screening will ensure that the risk to service users of acquiring a communicable infection or blood borne virus is minimised.
- A policy for decontamination.

With the exception of service providers operating an independent clinic or offering a single specific prescribed technique or technology only\*, services will additionally have in place:

- A corporate level lead or adviser for IPC who can provide timely and specialist advice to the organisation on all aspects of IPC.
- A multi disciplinary Infection Control Team and where appropriate, access to a Clinical Microbiologist.
- A multi disciplinary Infection Control Committee (who report quarterly issues of concern and improvements, to the registered person).
- Isolation facilities and nursing procedures and associated equipment.
- An infection surveillance policy and protocol (to include provision of surgical site infection surveillance data).
- An infection control audit policy and protocol.
- Occupational health advice and where appropriate, access to occupational health services.

### Service specific elements to be in place at registration and ongoing

#### Dialysis Units

- Will have evidence of water quality and a policy for regular testing which includes the name of the person who has overall responsibility for this.

### Additional ongoing elements - once the service is operational

#### Services should:

- Regularly carry out infection control audits.
- Regularly review and act on infection control surveillance data.
- Submit infection control data to HIW when requested.
- Report outbreaks of infection in line with legislation.

### Supporting information and guidance

**Note:** this list is not exhaustive. It is not intended as anything other than a useful aide memoir for providers and more up to date information may have superseded this.

Health Technical Memoranda (HTM) HTM 01-01 and HTM 2030

Public Health Wales Surgical Site Infection Surveillance  
<http://www.wales.nhs.uk/sites3/home.cfm?orgid=379>

Space for Health <http://www.spaceforhealth.nhs.uk/>

Society of Hospital Linen Service and Laundry Managers  
<http://www.linenmanager.co.uk/>

Good Practice Wales website <http://www.goodpracticewales.com/>

Health and Safety Executive [www.hse.gov.uk](http://www.hse.gov.uk)

The Control of Substances Hazardous to Health Regulations, 1988  
[http://www.opsi.gov.uk/si/si1988/Uksi\\_19881657\\_en\\_1.htm](http://www.opsi.gov.uk/si/si1988/Uksi_19881657_en_1.htm)

Infection Prevention Nurses Association [www.icna.co.uk](http://www.icna.co.uk)

NPSA Clean Your Hands Campaign: <http://www.npsa.nhs.uk/cleanyourhands>

Safer Practice Notice 15 (2007) Colour Coding Hospital Cleaning  
Materials and Equipment:  
<http://www.npsa.nhs.uk/patientsafety/alerts-and-directives/notices/cleaning-materials/>

National Resource for Infection Control [www.nric.org.uk](http://www.nric.org.uk)

World Health Organisation 'Five Moments for Hand Hygiene'

NPSA Patient Safety Alert Clean Hands Saves Lives - Sept 2008

WHO Clean Care is Safe Care

The NHS Governance E Manual [www.nhswalesgovernance.com](http://www.nhswalesgovernance.com)  
<http://www.nhswalesgovernance.com/display/Home.aspx?a=404&s=2&m=130&d=0&p=0>

\* Is solely using a Class 3B or 4 Laser and / or an Intense Pulsed Light Source for non-surgical cosmetic treatments only

| Standard 14<br>Nutrition  | Regulation 15 |
|---|---------------|
| <p>Organisations and services will comply with legislation and guidance to ensure that:</p> <ul style="list-style-type: none"> <li>a) patients' / service users individual nutritional and fluid needs are assessed, recorded and addressed;</li> <li>b) any necessary support with eating, drinking or feeding and swallowing is identified and provided;</li> <li>c) breastfeeding is promoted and supported wherever mothers who are breastfeeding are treated.</li> </ul> <p>Where food and drink are provided:</p> <ul style="list-style-type: none"> <li>d) a choice of food is offered, which is prepared safely and meets the nutritional, therapeutic, religious and cultural needs of all; and</li> <li>e) is accessible 24 hours a day.</li> </ul> |               |
| <p>What this means:</p> <p>Nutrition is important in preventing disease, promoting health and supporting people in day to living or during their end of life care.</p> <p>Service providers* will have procedures in place to screen and where appropriate, undertake more in depth assessment of service users nutritional status and needs, to enable them to:</p> <ul style="list-style-type: none"> <li>• maintain a healthy diet;</li> <li>• support their health or improvements in their health (where appropriate, through provision of artificial nutrition and hydration).</li> </ul>   |               |
| <p><b>Elements to be in place at registration and ongoing</b></p>   |               |
| <p>Catering and nutritional policies are available and in line with best practice guidance.</p> <p>To ensure patients receive food of an appropriate quality, policies define:</p> <ul style="list-style-type: none"> <li>• food hygiene requirements that are in line with legislation for food premises and food safety;</li> <li>• requirements that food is procured from reputable suppliers, who can demonstrate safe sourcing and handling practices throughout their business.</li> </ul> <p>Clinical staff can access specialist advice on nutrition and feeding issues.</p> <p>A menu, suitable for the patient group and which has been nutritionally evaluated, is available and offers a choice of meals.</p>                                    |               |

Contingency arrangements are in place should the provision of normal food supplies be unavailable.

Cutlery and utensils which aid people to eat independently are available to suit the range of needs of service users.

Where patients are accommodated and / or treated for obesity:

- they have their weight / BMI regularly monitored;
- staff have specialist knowledge of obesity management and nutritional needs.

#### Service specific elements to be in place at registration and ongoing

##### **Maternity Services**

Information and advice is available for patients to promote and encourage breast feeding.

Support to enable successful breast feeding is provided.

##### **Independent Clinics**

Where patients are treated for obesity staff have specialist knowledge in obesity management and nutritional needs, relevant to their role.

#### Additional ongoing elements - once the service is operational

Patient recovery and improvement is not delayed because they have been provided with an appropriate nutritional diet (including where appropriate, artificial nutrition and / or hydration), advice, support and regular review of their needs, to maintain improvements.

Service users do not suffer any unintended consequences through consuming food and drink because:

- food is handled, stored, prepared and delivered in accordance with food safety legislation.

Menu planning is integral to nutritional needs assessment and also takes account of persons needs where they:

- have a temporary reduced appetite;
- are too ill to eat normal food;
- require prescribed therapeutic diets;
- have specific medical conditions;
- have religious or cultural preferences.

It is possible to express preferences for each meal because there are menu choices available.

Where patients are required to fast (for example before having a general anaesthetic or particular diagnostic test or procedure), their post procedure management, enables them to receive fluids and food as soon as it is safe to consume them.

### Supporting information and guidance

**Note:** this list is not exhaustive. It is not intended as anything other than a useful aide memoir for providers and more up to date information may have superseded this.

Nutrition Support in Adults (NICE Clinical Guideline 2006)  
<http://www.nhs.uk/Conditions/diet/Pages/Introduction.aspx>

<http://www.nutrition.org.uk/>

Hospital Hydration Best practice Toolkit, NPSA

<http://www.cks.nhs.uk/obesity>

WHCs can be accessed from the HOWIS Welsh Health Circulars website.  
<http://howis.wales.nhs.uk/whcirculars.cfm>

Nutrition and Catering Framework, 2002  
[http://new.wales.gov.uk/topics/health/publications/health/guidance/nutrition\\_catering\\_framework\\_nhs?lang=en](http://new.wales.gov.uk/topics/health/publications/health/guidance/nutrition_catering_framework_nhs?lang=en)

British Association for Parenteral and Enteral Nutrition (BAPEN)  
<http://www.bapen.org.uk/>

Food Standards Agency  
<http://www.food.gov.uk/wales>

The NHS Governance E Manual [www.nhswalesgovernance.com](http://www.nhswalesgovernance.com)  
<http://www.nhswalesgovernance.com/display/Home.aspx?a=404&s=2&m=130&d=0&p=0>

\* Unless you are a registered provider who is solely using a Class 3B or 4 Laser and / or an Intense Pulsed Light Source for non-surgical cosmetic treatments only

| Standard 15<br>Medicines Management   | Regulation 9, 15 |
|---|------------------|
| <p>Organisations and services will ensure that:</p> <ul style="list-style-type: none"> <li>a) they comply with legislation, licensing and good practice guidance for all aspects of medicines management including controlled drugs;</li> <li>b) clinicians are qualified and trained in prescribing, dispensing and administering medicines within their individual scope of practice; and</li> <li>c) there is timely, accessible and appropriate medicines advice and information for patients, service users, their carers and staff including the reporting of drug related adverse incidents.</li> </ul>  |                  |
| <p>What this means:</p> <p>The health, safety and wellbeing of people who receive medicines, is not adversely affected by inadequate training, accountability, operational systems and arrangements, for the management of medicines.</p> <p>Patients will have been provided with information about their medicines and be able to receive:</p> <ul style="list-style-type: none"> <li>• medication that is appropriate for their condition;</li> <li>• the correct medication;</li> <li>• their prescribed medication when they need it.</li> </ul>   |                  |
| <p><b>Elements to be in place at registration and ongoing</b></p>   |                  |
| <p>Service providers who order, obtain, store, control, supply, prescribe, administer or dispose of medicines have the following in place*:</p> <ul style="list-style-type: none"> <li>• An effective medicines management policy and supporting procedures covering all aspects of medicines management in the organisation (including where used, medical gases) which is in line with legislation and best practice guidance.</li> <li>• Procedures for the self administration of medicines by patients, including a documented assessment of the risks and arrangements for regular checking that the medicines are being taken as prescribed.</li> <li>• A system for reporting medicines incidents and investigating the causes so that action is taken to prevent recurrence.</li> <li>• Where required, a named Accountable Officer in line with the Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008 whose name is notified to HIW.</li> </ul> |                  |

- Arrangements to ensure they receive prompt information of any drug alerts issued by the MHRA or recommendations from the NPSA and that these are acted on without delay.
- Up to date guidance and advice for staff who handle, prescribe or administer medicines (including where children are treated, a children's British National Formulary (BNF).
- Access to a pharmacist for advice on any aspect of medicines management relevant to the services provided.
- A policy for the management of adverse reactions which ensures reporting of all adverse drug reactions to the MHRA Yellow Card Scheme.
- Resuscitation and anaphylaxis policies appropriate for the services provided.
- Emergency drugs for the management of anaphylaxis.

Medicines required for resuscitation or other medical emergencies are available in tamper evident packaging that allows them to be accessed and administered as quickly as possible.

There is a policy to include consent to treatment and administration of medicines for service users subject to the provisions of the Mental Health Act 1983 and where appropriate, assessment in line with the Mental Capacity Act 2005.

Unlicensed medicines and medicines requiring a 'special's licence' are managed in accordance with the relevant MHRA Guidance Notes.

Medicines are stored safely and securely and continually at the required temperature.

Controlled Drugs requiring safe custody are stored in accordance with the Misuse of Drugs Safe Custody Regulations 1973 and any subsequent amendments.

### Service specific elements to be in place at registration and ongoing

#### **Services who provide surgical procedures under general anaesthesia**

Information about any drugs to be administered whilst the patient is anaesthetised are discussed in advance, with the patient.

The conduct of anaesthesia is determined, administered and monitored in line with best practice guidelines for anaesthetists working in the UK.

#### **Mental health**

NICE guidance for the requirements for rapid tranquilisation are observed.



### Additional ongoing elements - once the service is operational

Service users are provided with information about their medication and the opportunity to discuss their medication and any contra indications or concerns they have about taking the medication.

When medicines are supplied to patients to take home they are also provided with the manufacturers patient information leaflet.

Drug alerts and recalls issued by the Medicines and Healthcare products Regulatory Agency (MHRA) and which require action are acted upon within required timescales.

Accurate records of the medicines administered to patients are maintained including information about allergies or sensitivities.

Systems are in place to audit the effectiveness of procedures and compliance with the legislation;

Where imported vaccines are used, the provider or where the vaccines are purchased from an agent, can demonstrate that the MHRA have raised no objection to import or an import licence is in place.

Where medicines are dispensed, labelling complies with the labelling regulations under the Medicines Act 1968.

Patients receive the correct medication because:

- Their medication is regularly reviewed.
- Staff who prescribe, dispense or administer medicines, have the relevant knowledge, skills and experience.

### Supporting information and guidance

**Note:** this list is not exhaustive. It is not intended as anything other than a useful aide memoir for providers and more up to date information may have superseded this.

National Patient Safety Agency

<http://www.nrls.npsa.nhs.uk/resources/patient-safety-topics/medication-safety/>

MHRA Guidance Notes

<http://www.mhra.gov.uk/Publications/Regulatoryguidance/Medicines/Guidancenotes/index.htm>

Immunisation against infectious diseases (The Green Book)

<http://www.dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/Greenbook/index.htm>

National Public Health Service for Wales

<http://www.wales.nhs.uk/sites3/page.cfm?orgid=719&pid=22646>

The Royal Pharmaceutical Society [www.rpsgb.org.uk](http://www.rpsgb.org.uk) [Note: the RPSGB is due to be replaced by the General Pharmaceutical Council during 2010].

National Institute for Health and Clinical Excellence (NICE) <http://www.nice.org.uk/>

The Medicines Act 1968

The Misuse of Drugs Act 1971

The Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008

Misuse of Drugs (Safe Custody) Regulations 1973

The Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations 2007

Home Office Drugs Licence:

<http://www.homeoffice.gov.uk/drugs/licensing/domestic-licences/>

The NHS Governance E Manual [www.nhswalesgovernance.com](http://www.nhswalesgovernance.com)

<http://www.nhswalesgovernance.com/display/Home.aspx?a=404&s=2&m=130&d=0&p=0>

\* Unless you are a registered provider who is solely using a Class 3B or 4 Laser and / or an Intense Pulsed Light Source for non-surgical cosmetic treatments only and use no medicines before, during or after treatment.

| Standard 16<br>Medical Devices, Equipment and<br>Diagnostic Systems  | Regulation 15, 23 and Schedule 3 |
|--|----------------------------------|
| <p>Organisations and services ensure the safe and effective procurement , use and disposal of medical equipment, devices and diagnostic systems that:</p> <ul style="list-style-type: none"> <li>a) conform to health, safety and environmental legislation and guidance;</li> <li>b) are maintained, cleaned and calibrated in accordance with manufacturer’s guidelines;</li> <li>c) are appropriate for their intended use and for the environment in which they are used;</li> <li>d) decontaminate reusable medical devices properly;</li> <li>e) is supported by an ongoing programme of training and competence assessment for staff and users of the equipment; and</li> <li>f) there is timely reporting and management of any device, equipment or system faults.</li> </ul> |                                  |
| <p>What this means:</p> <p>Service users are not put at risk through inadequate equipment (including medical devices) because these are:</p> <ul style="list-style-type: none"> <li>• available when required;</li> <li>• suitable for its intended purpose;</li> <li>• safe to use;</li> <li>• used by staff who have been properly trained and know how to use the device safely and can carry out pre use day to day checks (and where qualified and appropriate, routine maintenance).</li> </ul>  |                                  |
| <p><b>Elements to be in place at registration and ongoing</b></p>  |                                  |
| <p>The safety and suitability of equipment is assured because the registered person has in place:</p> <p>Documented policies and procedures for re-usable medical devices which includes reference to the following processes - procurement, acquisition, cleaning, disinfection, inspection, disposal, packaging, sterilization, transportation, and storage before use</p> <p>An environment and process for decontamination of medical devices which is in line with legislation, best practice guidance and relevant HTMs, for the type of device.</p>   |                                  |

Records of the decontamination process which evidence tracking / traceability of instruments, validation and verification of the decontamination process and cycle.

Safeguards to ensure that all devices are installed, handled (including collection and transportation), stored, repaired and disposed of safely.

Documented arrangements for routine cleaning, decontamination, calibration, servicing and repair of equipment.

Arrangements to report equipment / device errors and faults where appropriate, to the MHRA.

A register of all mechanical, technical, medical, patient equipment used which includes:

- details of what the equipment / device is and where it came from;
- the device serial or batch number;
- the installation / commissioning date;
- planned preventive maintenance record / history of servicing.

[Installation, commissioning and preventive maintenance also include piped medical gases].

Services which provide diagnostic procedures ensure:

- facilities are procured and maintained in line with legislation for the safe handling of radionuclides required for scanning and treatment.

#### Service specific elements to be in place at registration and ongoing

##### Lasers and Intense Pulsed Light Sources

To ensure equipment is suitable and safe to use, there must be a nominated certificated Laser Protection Adviser (LPA) for the service, who assesses and advises in writing on:

- risk assessments before the laser or IPL is operated and confirms in writing that post testing installation is satisfactory;
- identification of the Laser Controlled Area (including advice on warning signs or the need for a door interlock);
- 'Local Rules' and working practices for each device used including protective eye ware;
- regular equipment and operator safety reviews.

Suitable arrangements to remove and manage smoke plume are in place.

A register which records each occasion the equipment was used in line with the requirements of paragraph 3 of Part II of Schedule 3 of the Independent Health Care (Wales) Regulations 2011.

#### Additional ongoing elements - once the service is operational

Single-use medical devices are used once and disposed of safely.

Regular testing of emergency equipment is undertaken and records of this maintained.

Reporting and repair of equipment is timely and only undertaken by competent persons.

#### Supporting information and guidance

**Note:** this list is not exhaustive. It is not intended as anything other than a useful aide memoir for providers and more up to date information may have superseded this.

MHRA best practice for sterilization and decontamination of medical devices  
<http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Technicalinformation/Sterilizationanddecontaminationofmedicaldevices/index.htm>

MHRA <http://www.mhra.gov.uk/Publications/Safetyguidance/Otherdevicesafetyguidance/CON007423>

The Ionising Radiation (Medical Exposure) Regulations IR(MER)

The following legislation and guidance is available:

Statutory Instrument 2000 No. 1059 - The Ionising Radiation (Medical Exposure) Regulations 2000

The Ionising Radiation (Medical Exposure) Regulations 2000 - (together with Notes on Good Practice)

Statutory Instrument 2006 No. 2523 - The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006

The Medical Devices Directive

Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995

Control of Substances Hazardous to Health Regulations 2002 (COSHH)

Health and Safety (Safety Signs and Signals) Regulations 1996

[http://www.opsi.gov.uk/si/si1996/Uksi\\_19960341\\_en\\_1.htm](http://www.opsi.gov.uk/si/si1996/Uksi_19960341_en_1.htm)

The NHS Governance E Manual [www.nhswalesgovernance.com](http://www.nhswalesgovernance.com)

<http://www.nhswalesgovernance.com/display/Home.aspx?a=404&s=2&m=130&d=0&p=0>

| Standard 17<br>Blood Management  | Regulation 15 |
|--|---------------|
| <p>Organisations and services ensure that patients have access to a safe and sufficient supply of blood, blood products and blood components, through:</p> <ul style="list-style-type: none"> <li>a) compliance with legislation and national guidance on the supply and use of blood, blood products and blood components;</li> <li>b) the use of schemes and systems to reduce wastage of blood, blood products and blood components;</li> <li>c) effective planning for blood shortages;</li> <li>d) an ongoing programme of education, training and competence assessment for all staff involved in the transfusion process; and</li> </ul> <p>the reporting of all adverse blood reactions and incidents.</p> |               |
| <p>What this means:</p> <p>Patients are assured that they will not receive the wrong blood, blood component, blood product or blood from an unsafe source because:</p> <ul style="list-style-type: none"> <li>• there is a mandatory monitoring process in place for the safety of blood transfusion (Haemovigilance).</li> <li>• persons involved in the transfusion process have the right knowledge, skills and experience.</li> </ul>  |               |
| <p><b>Elements to be in place at registration and ongoing</b></p>  |               |
| <p>To ensure the safety of blood transfusion, services have the following in place:</p> <ul style="list-style-type: none"> <li>• A mandatory monitoring process for the safety of blood transfusion meets the requirements set out in legislation.</li> <li>• A system for total traceability of each unit of blood is in place and retained for thirty years.</li> <li>• Staff involved in the transfusion process, have the knowledge to ensure compliance with traceability and serious adverse event and reaction reporting.</li> <li>• Pathology units with an effective quality system in place.</li> </ul>  |               |

#### Additional ongoing elements - once the service is operational

The hospital stocks enough blood to meet the planned needs of patients.

All serious adverse reactions (SAR) and serious adverse events (SAE) associated with blood and blood component collection, processing, distribution and testing are reported to SABRE (Serious Adverse Blood Reactions and Events).

#### Supporting information and guidance

**Note:** this list is not exhaustive. It is not intended as anything other than a useful aide memoir for providers and more up to date information may have superseded this.

The Blood Safety and Quality Regulations 2005

UK Blood Transfusion Regulations 2005

Blood transfusion guidelines [www.transfusionguidelines.org.uk](http://www.transfusionguidelines.org.uk)

Background and Guidance on Reporting Serious Adverse Events and Serious Adverse Reactions, MHRA

<http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Blood/index.htm>

The NHS Governance E Manual [www.nhswalesgovernance.com](http://www.nhswalesgovernance.com)

<http://www.nhswalesgovernance.com/display/Home.aspx?a=404&s=2&m=130&d=0&p=0>



| Standard 18<br>Communicating Effectively  | Regulation 6, 7, 9, 18 |
|---|------------------------|
| <p>Organisations and services comply with legislation and guidance to ensure effective, accessible, appropriate and timely communication and information sharing:</p> <ul style="list-style-type: none"> <li>a) internally and externally;</li> <li>b) with patients, service users, carers and staff using a range of media and formats;</li> <li>c) about patients, service users and their carers;</li> <li>d) on the full range and locations of services they provide; and</li> <li>e) addressing all language and communication needs.</li> </ul>   |                        |
| <p>What this means:</p> <p>Service users and where appropriate, their representatives, receive clear and accurate information about:</p> <ul style="list-style-type: none"> <li>• the aims, objectives, purpose and range of services provided by the organisation;</li> <li>• their treatment options, treatment received, care and any advocacy or support services;</li> <li>• the costs of any treatment and services which they are required to pay for;</li> <li>• how to raise a concern, or make a complaint;</li> <li>• how to comment on or influence the way a service is provided;</li> <li>• the outcome of any investigation, when something has gone wrong.</li> </ul> <p>Information provided is reliable, accurate, regularly reviewed and not misleading.</p> <p>Information is provided in a format that takes account of:</p> <ul style="list-style-type: none"> <li>• service users language and communication needs;</li> <li>• the complexity of the information.</li> </ul> <p>Legal obligations to protect confidential personal information are met and environments where confidential and sensitive information is discussed are appropriate.</p> <p>Regular ongoing communication with persons who work in the organisation is essential to ensure they comply with operation policies and know how to carry out their day to day activities safely.</p> |                        |

### Elements to be in place at registration and ongoing

Communications are accurate, appropriate, effective and not misleading, because registered persons have in place:

- an indexed list of all policies, procedures and approved information that are used within the organisation, including a documented, approval process for their communication, dissemination, implementation and review;
- a policy for the provision of information which sets out the philosophy and expectations of the organisation regarding the provision of information to and communication with service users, their representatives and external agencies (including the media);
- procedures for communication between staff about service users (both verbal and written communication);
- guidance regarding development of appropriate information, e.g. format, language which is sensitive to any specific needs or the condition of the patient or service user;
- approval and review mechanisms for information leaflets, their content and readability, e.g. plain English and laymans terminology, following guidelines such as those with Plain English (Crystal Mark) awards or Cymraeg Clir. This should extend to alternative sources of information, such as websites;
- information leaflets about specific treatments and procedures which are regularly reviewed to ensure they remain up to date;
- guidelines for breaking bad news / being open;
- staff/clinician to patient communication training;
- a Patients Guide and Statement of Purpose in a clear, relevant language and format which is accurate, not misleading, in accordance with regulatory requirements and is kept under review.

### Additional ongoing elements - once the service is operational

Patients receive clear and accurate information about their treatment options, treatment and care received, to take home with them, including post operative instructions.

Discussion of and decisions about resuscitation, are clearly documented in the patient records and are regularly reviewed.

No information about a service user is disclosed to the media without appropriate consent.

### Supporting information and guidance

**Note:** this list is not exhaustive. It is not intended as anything other than a useful aide memoir for providers and more up to date information may have superseded this.

Plain English Campaign [www.plainenglish.co.uk](http://www.plainenglish.co.uk)

Patient Information <http://www.patient.co.uk/>

NPSA <http://www.nrls.npsa.nhs.uk/resources/?entryid45=65077>

Welsh Language Board

<http://www.byig-wlb.org.uk/english/using/Pages/index.aspx>

The NHS Governance E Manual [www.nhswalesgovernance.com](http://www.nhswalesgovernance.com)

<http://www.nhswalesgovernance.com/display/Home.aspx?a=404&s=2&m=130&d=0&p=0>

| Standard 19<br>Information Management and<br>Communications Technology  | Regulation 9 |
|---|--------------|
| <p>Organisations and services support and facilitate patient care and service delivery by:</p> <ul style="list-style-type: none"> <li>a) developing and using safe and secure information systems in accordance with legislation and within an effective governance framework;</li> <li>b) having processes to operate and manage information and data effectively and to maintain business continuity;</li> <li>c) ensuring data quality is robust and timely;</li> <li>d) using information to review, assess and improve services; and</li> <li>e) sharing information with relevant partners using protocols when necessary.</li> </ul>   |              |
| <p>What this means:</p> <p>Information management and technology systems are increasingly being used in support of direct patient care and organisational business processes. It is essential that where used, these are developed, managed and effectively supported to ensure they are fit for purpose in the delivery of safe patient care and safeguarding personal information.</p> <p>The quality of data, and the information produced as a by-product from information management systems, must be assured if it is to be used to monitor, improve, inform or in support of, direct patient care. Where information is shared with relevant partners to assist in the seamless delivery of safe patient care across the organisational, it will be essential to ensure that relevant information sharing protocols are adhered to at all times.</p> |              |
| <p><b>Elements to be in place at registration and ongoing</b></p>   |              |
| <p>Registered persons have in place appropriate arrangements for information governance and confidentiality which demonstrate compliance with legislation and best practice guidance to include:</p> <ul style="list-style-type: none"> <li>• Caldicott Principles;</li> <li>• Encryption;</li> <li>• Back up arrangements.</li> </ul>  |              |

### Supporting information and guidance

**Note:** this list is not exhaustive. It is not intended as anything other than a useful aide memoir for providers and more up to date information may have superseded this.

National patient Safety Agency

<http://www.nrls.npsa.nhs.uk/resources/?EntryId45=61913> Risk to patient safety of not using the NHS Number as the national identifier for all patients

Data Protection Act 1998

Department of Health Caldicott

Wales Caldicott Manual and website

The NHS Governance E Manual [www.nhswalesgovernance.com](http://www.nhswalesgovernance.com)

<http://www.nhswalesgovernance.com/display/Home.aspx?a=404&s=2&m=130&d=0&p=0>

The Wales Accord for the Sharing of Personal Information (WASPI)

<http://www.wales.nhs.uk/sites3/home.cfm?orgid=702>

Encryption <http://howis.wales.nhs.uk/ihc/page.cfm?orgid=770&pid=26520>

| Standard 20<br>Records Management   | Regulation 23, 43 and Schedules 3<br>and 4 |
|---|--|
| <p>Organisations and services manage all records in accordance with legislation and guidance to ensure that they are:</p> <ul style="list-style-type: none"> <li>a) designed, prepared, reviewed and accessible to meet the required needs;</li> <li>b) stored safely, maintained securely, are retrievable in a timely manner and disposed of appropriately;</li> <li>c) accurate, complete, understandable and contemporaneous in accordance with professional standards and guidance; and</li> <li>d) shared as appropriate.</li> </ul>  |  |
| <p>What this means:</p> <p>Records are created, received, maintained, used, stored and disposed of, to standards which meet legal and regulatory compliance and professional practice recommendations. The Data Protection Act 1998 is adhered to.</p> <p>Registered persons retain any records that are required to be kept under the Independent Health Care (Wales) Regulations 2011.</p> <p>The scope of records created, should to be documented, to ensure that the registered person makes appropriate arrangements to safeguard the whole range of potential records that records management policies need to encompass.</p>  |  |
| <p><b>Elements to be in place at registration and ongoing</b></p>   |  |
| <p>Service users can be confident that their records are accurate and retained securely to ensure their confidential personal information is protected because the registered person has in place:</p> <ul style="list-style-type: none"> <li>• a records management 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;</li> <li>• clear procedures to follow for all staff and those who work in or for, the establishment or agency, to ensure that confidential information is appropriately safeguarded at all stages of the service user care pathway and following discharge and archiving;</li> <li>• a nominated person who has responsibility for records management;</li> <li>• checks to ensure that any records about service users are completed contemporaneously, are accurate, remain confidential and are appropriately handled whether in current use or archived in safe storage;</li> </ul> |  |

- induction and ongoing training for staff and persons who work in the organisation to ensure they understand their responsibilities for record completion and handling;
- protocols within and between organisations that share information;
- policies and procedures to ensure disclosure of any information is within legal requirements;
- arrangements to protect the records from use by unauthorised persons, damage or loss;
- records that are required to be kept under legislation, retained for the relevant periods prescribed in legislation;
- where electronic record systems are used, effective back-up arrangements for handling technical breakdown to avoid loss or corruption of information held;
- systems to ensure secure destruction of records in line with specified retention schedules.

#### Service specific elements to be in place at registration and ongoing

##### **Termination of pregnancy**

Certificates of opinion are retained in line with the provisions of the regulations made under The Abortion Act 1967 and all terminations carried out are notified to the Chief Medical Officer.

##### **Mental Health and other services**

Records of the use of restraint and the deprivation of liberty are retained as part of the health record.

#### Additional ongoing elements - once the service is operational

Patients are assured that all information about their treatment and care is recorded, properly protected and only made available to those with the right authority to see it because:

- Health care professionals and persons involved in patient assessment, provision of treatment and care or discharge, record all treatment and nursing care given and any recommendations, in the patient's health record.
- Professional notes are integrated into a single, multi-disciplinary record, which is retained by the registered person in line with legislation.

- A summary of the patient 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.
- When referral is not from the patients 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.
- 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.
- Members of the multi-professional team have continuous access to up-to-date records and other information about patients and where appropriate their next of kin / carers.
- Where a request is made to access any personal records, the request is handled in accordance with the Data Protection Act 1998.
- Records are maintained for the appropriate periods in line with the requirements of Schedule 3 and 4 of the Independent Health Care (Wales) Regulations 2011.
- Audit of healthcare records against best practice benchmarks takes place.
- Records are created with a unique identifier.
- Where service users (or where appropriate, their representatives) request access to their records, this is handled in line with the Data Protection Act 1998.
- Staff and persons who work in the establishment or for the agency understand their personal responsibilities and accountability, in relation to service user records because they have received training.

### Supporting information and guidance

**Note:** this list is not exhaustive. It is not intended as anything other than a useful aide memoir for providers and more up to date information may have superseded this.

Information Commissioner <http://www.ico.gov.uk/>

Data Protection Act 1998

[http://www.opsi.gov.uk/acts/acts1998/ukpga\\_19980029\\_en\\_1](http://www.opsi.gov.uk/acts/acts1998/ukpga_19980029_en_1)

Department of Health - NHS Code of Practice:

[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4131747](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4131747)



Access to Health Records Act 1990

[http://www.uk-legislation.hmso.gov.uk/acts/acts1990/ukpga\\_19900023\\_en\\_1](http://www.uk-legislation.hmso.gov.uk/acts/acts1990/ukpga_19900023_en_1)

Sheffield Assessment Instrument for Letters

<http://www.ecompendium.nhs.uk/assessment-methods.asp?section=written-communication-medical-record-keeping>

Mental Health Act Code of Practice for Wales

<http://www.wales.nhs.uk/sites3/page.cfm?orgid=816&pid=33960>

The NHS Governance E Manual [www.nhswalesgovernance.com](http://www.nhswalesgovernance.com)

<http://www.nhswalesgovernance.com/display/Home.aspx?a=404&s=2&m=130&d=0&p=0>

| Standard 21<br>Research, Development and<br>Innovation  | Regulation 9, 25 |
|---|------------------|
| <p>Organisations and services will:</p> <ul style="list-style-type: none"> <li>a) ensure that the principles and requirements of the Research Governance Framework for Health and Social Care are consistently applied;</li> <li>b) have an outcome focussed research and development strategy that benefits patients and improves service delivery; and</li> <li>c) promote research, development and innovation.</li> </ul>   |                  |
| <p>What this means:</p> <p>This standard is applicable to those who undertake or participate in research to ensure that they conduct and manage all aspects of research for which they have responsibility, in accordance with best practice guidance and relevant legislation.</p> <p>Patients are assured that those involved in the conduct and management of research, in addition to the scientific, legal, ethical and financial aspects of research projects, hold in highest regard, the health and safety of patients who have lawfully consented to participate.</p>  |                  |
| <p><b>Elements to be in place at registration and ongoing</b></p>   |                  |
| <p>If the establishment or agency does <b>not</b> carry out research, a written policy must specify this to ensure that all persons who work for the establishment or agency, including those with practising privileges, are aware that <b>no</b> form of research (funded or otherwise), is permitted.</p> <p>Registered persons are responsible for ensuring that any research involving a patient meets the standards set out in the latest best practice guidance for research governance and any other relevant legislation.</p> <p>Where it is proposed that research may be undertaken, a policy must clearly set out all the activities required for approval of the research project and have appropriate arrangements in place, including:</p> <ul style="list-style-type: none"> <li>• Ethics committee approval (via the Integrated Research Application System for research involving NHS patients, or for private patients, via a Research Ethics Committee compliant with guidance issued by the registration authority).</li> <li>• Leadership e.g. corporate level lead (Medical Advisor or Director).</li> <li>• Database within the organisation for managing and tracking research projects.</li> <li>• A Code of Practice for research management which all persons involved in the research abide by.</li> </ul> |                  |

- Detailed procedural guidance for persons undertaking research.
- Processes for obtaining consent, to ensure valid consent is obtained within legal requirements. In relation to mental health, reference will need to be made to the Mental Capacity Act.
- Ensure appropriate checks are made on persons involved in research.
- Assurance regarding the scientific quality of proposed research.
- Qualified staff with relevant skills and experience undertaking research commensurate with their role in the study e.g. research sponsor, principal investigator.
- Mechanisms to ensure research is provided in accordance with the establishments Statement of Purpose.
- Risk assessments.

#### Additional ongoing elements - once the service is operational

Persons who have consented to participate in research have been given:

- comprehensive information about any risks;
- the intended purpose of the research; and
- enough time to think about their decision.

#### Signposting for supporting information and guidance

**Note:** this list is not exhaustive. It is not intended as anything other than a useful aide memoire for providers and more up to date information may have superseded this.

Welsh Assembly Government

The NHS Governance E Manual [www.nhswalesgovernance.com](http://www.nhswalesgovernance.com)  
<http://www.nhswalesgovernance.com/display/Home.aspx?a=404&s=2&m=130&d=0&p=0>

Research Governance Framework second edition (2009)  
<http://new.wales.gov.uk/topics/health/research/word/publications/researchgovernance/?lang=en>

Governance Arrangements for Research Ethics Committees (GAfREC)  
<http://www.nres.npsa.nhs.uk/news-and-publications/news/harmonised-gafrec-consultation/>

Mental Capacity Act:

<http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/SocialCare/Deliveringadultsocialcare/MentalCapacity/MentalCapacityActDeprivationofLibertySafeguards/index.htm>

Department of Health - Research and Development site

[www.dh.gov.uk/en/Researchanddevelopment/index.htm](http://www.dh.gov.uk/en/Researchanddevelopment/index.htm)

National Patient Safety Agency (NPSA)

<http://nres.npsa.nhs.uk/news-and-publications/publications/general-publications/>

General Medical Council

[http://www.gmc-uk.org/guidance/ethical\\_guidance/5991.asp](http://www.gmc-uk.org/guidance/ethical_guidance/5991.asp)

| Standard 22<br>Managing Risk and Health<br>and Safety   | Regulation 9, 19, 26 |
|---|----------------------|
| <p>Organisations and services will have systems and processes in place which comply with legislation and guidance that:</p> <ul style="list-style-type: none"> <li>a) applies best practice in assessing, managing and mitigating risk;</li> <li>b) implements policies and arrangements for reviewing and continuously improving all aspects of their activities and environment to protect and improve the health, safety and wellbeing of their patients, service users, carers, staff and the public; and</li> <li>c) acts upon safety notices, alerts and other such communications.</li> </ul>  |                      |
| <p>What this means:</p> <p>Risk management is a careful examination and assessment of what could cause harm to patients, visitors and people who work in the organisation, so that the registered person can consider what prospective precautions need to be taken.</p> <p>Risk management should be integrated into day to day activities and actions to reduce identified risks taken promptly to prevent further risk of harm.</p> <p>A risk management policy must be developed and include appropriate safeguards.</p>  |                      |
| <p><b>Elements to be in place at registration and ongoing</b></p>   |                      |
| <p>Risks to service users are managed and minimised to the lowest possible level because registered persons have in place:</p> <ul style="list-style-type: none"> <li>• An effective risk management policy and strategy that addresses governance arrangements, the workforce, the environment, clinical care, incidents and learning.</li> <li>• Arrangements for identifying, recording, escalating, reporting, managing and monitoring risks.</li> </ul> <p>Risk assessments are available and include:</p> <ul style="list-style-type: none"> <li>• fire safety arrangements which meet the Regulatory Reform (Fire Safety) Order 2005 and other relevant legislation;</li> <li>• risk assessments of the premises to reduce the risk of harm (including building components, ligature points, layout for appropriate observation and the control and prevention of legionella) and meet the requirements of the Health and Safety at Work Act 1974 and associated regulations;</li> <li>• the Control of Substances Hazardous to Health Regulations 2002 (COSHH) as amended;</li> </ul> |                      |

- the security arrangements (this should specify arrangements for security of the building, equipment, staff and service user security);
- In relation to mental health services, the security arrangements and restrictions placed on patients should be appropriate to the risk that patients pose;
- signage, so that anyone in the establishment knows what to do to prevent risks to their health and safety, including in an emergency;
- management of staff absenteeism;
- moving and handling of patients and equipment.

#### Additional ongoing elements - once the service is operational

Risks are managed effectively to prevent harm because:

- risks, including risks to service users, are identified, assessed, managed, recorded and reviewed,
- information about risks, concerns / complaints, incidents, errors, adverse events and poor performance is analysed and,
- action is taken as quickly as possible, to ensure improvements to safeguard the health, safety and welfare of patients and service users and ensure compliance with legislation.

#### Supporting information and guidance

**Note:** this list is not exhaustive. It is not intended as anything other than a useful aide memoir for providers and more up to date information may have superseded this.

NHS Litigation Authority. (2009). Risk Management Standards for Acute Trusts, Primary Care Trusts and Independent Sector Providers of NHS Care. London: NHSLA. Available at: [www.nhsla.com](http://www.nhsla.com)

Royal College of Obstetricians and Gynaecologists. (2005). Improving Patient Safety: Risk Management for Maternity and Gynaecology. London: RCOG Press. Available at: [www.rcog.org.uk](http://www.rcog.org.uk)

Health and Safety Executive [www.hse.gov.uk](http://www.hse.gov.uk)

The Regulatory Reform (Fire Safety) Order 2005  
<http://www.opsi.gov.uk/si/si2005/20051541.htm>

The NHS Governance E Manual [www.nhswalesgovernance.com](http://www.nhswalesgovernance.com)  
<http://www.nhswalesgovernance.com/display/Home.aspx?a=404&s=2&m=130&d=0&p=0>

| Standard 23<br>Dealing with Concerns and<br>Managing Incidents   | Regulation 19, 24 |
|--|-------------------|
| <p>Organisations and services comply with legislation and guidance to deal with complaints, incidents, near misses, and claims - known collectively as 'concerns' which ensure that they:</p> <ul style="list-style-type: none"> <li>a) are reported, acted upon and responded to in an appropriate and timely manner;</li> <li>b) are handled and investigated openly, effectively and by those appropriately skilled to do so;</li> <li>c) offer patients, service users and their carers support including advocacy and where appropriate redress;</li> <li>d) provide appropriate support to staff; and</li> <li>e) learn and share lessons from local and national reviews to improve services.</li> </ul>  |                   |
| <p>What this means:</p> <p>Service users should expect to have their concerns listened to and acted on in a timely manner. When things go wrong, they or their families should receive an acknowledgement with an apology and explanation of what went wrong. They may need support in dealing with the consequences.</p> <p>Effective processes should be in place which:</p> <ul style="list-style-type: none"> <li>• set out how the concerns will be handled;</li> <li>• the timescales for responding;</li> <li>• ensure a thorough investigation as soon as possible after the incident;</li> <li>• ensure concerns will be investigated by staff who have the competency and skills to do so and which;</li> <li>• promote the rights and choices of services users so they know they will be fairly treated, their concerns handled sensitively and can be supported by an advocate; and</li> <li>• ensure that any improvements are implemented without delay.</li> </ul> |                   |

### Elements to be in place at registration and ongoing

An incident reporting procedure and management system to investigate the underlying causes and ensure assessment of the actions of persons involved in the incident and risk of recurrence.

Where a risk of harm recurring is identified, action is taken as a priority to prevent further harm.

Where harm is suspected as being intentional or criminal in nature, it is escalated to the highest level within the organisation and reported to any other appropriate authority or body, including HIW.

A clear complaints procedure which is well publicised, in suitable formats to meet the range of service users communication needs and includes reference to:

- How a concern can be reported to the registered person;
- Who they can be made to;
- Contact details for HIW (including the address and telephone number);
- All stages of the process, including any independent review or adjudication;
- What concerns or complaints fall outside of the registered person's responsibility;
- The arrangements for making complaints about medical or other practitioners who have been granted practising privileges;
- The arrangements for service users who need support or lack capacity;
- The timescales for responding.

Where care and treatment are provided to children, staff are aware of the difficulties a child faces in expressing concerns or complaints and how a child should be helped to overcome these. Children and young people will receive information in formats that are accessible and understandable to them.

Information about independent advocacy and telephone help lines is available and service users supported to use them.

Staff and persons who work in or for the establishment or agency are informed about their duty to express their concerns about questionable or poor practice in accordance with the Public Interest Disclosure Act 1998.

Staff and persons who work in or for the establishment or agency are assured that they will not be penalised at any time for complaining in good faith about poor practice.

There is a written policy and procedure for staff to follow in order to raise their concerns about questionable or poor practice.



#### Additional ongoing elements - once the service is operational

Where a patient safety incident occurs, or a complaint is made, service users and / or their families or representatives receive an apology, regular updates on the progress of any investigation undertaken and the results of the investigation.

There is a record of each concern / complaint raised, details of the investigation, the outcome and the action taken to make any improvements.

An annual return of the concerns / complaints made is provided to HIW when requested.

Systems are in place for the evaluation and review of concerns and incidents.

Improvements made as a consequence of incidents are monitored for their effectiveness.

#### Supporting information and guidance

**Note:** this list is not exhaustive. It is not intended as anything other than a useful aide memoir for providers and more up to date information may have superseded this.

Being Open - communicating patient safety incidents with patients, their families and carers (NPSA, November 2009)

<http://www.nrls.npsa.nhs.uk/resources/?entryid45=65077>

Welsh Assembly Government Putting Things Right, 2009

The Independent Healthcare Advisory Service Code of Practice

[http://www.independenthealthcare.org.uk/index.php?option=com\\_phocadownload&Itemid,98/id,1/view/category/](http://www.independenthealthcare.org.uk/index.php?option=com_phocadownload&Itemid,98/id,1/view/category/)

The NHS Governance E Manual [www.nhswalesgovernance.com](http://www.nhswalesgovernance.com)

<http://www.nhswalesgovernance.com/display/Home.aspx?a=404&s=2&m=130&d=0&p=0>

Protocol between HIW and Welsh Independent Healthcare Association

<http://www.hiw.org.uk/searchresultssql.cfm?q=WIHA&orgid=477>

Welsh Risk Pool. Technical Note 23: Apologies and Explanations.

WRP, July 2001. Updated 2009. Available online at

<http://howis.wales.nhs.uk/sites3/docmetadata.cfm?orgid=287&id=71076>

General Medical Council, Good Medical Practice, GMC, 2006

| Standard 24<br>Workforce Recruitment and<br>Employment Practices   | Regulation 9, 10, 12, 13, 20, 21<br>and Schedule 2 |
|--|--|
| <p>Organisations and services ensure that their workforce:</p> <ul style="list-style-type: none"> <li>a) have all necessary recruitment and periodic employment checks and are registered with the relevant bodies;</li> <li>b) are appropriately recruited, trained, qualified and competent for the work they undertake;</li> <li>c) act and are treated, in accordance with identified standards and codes of conduct;</li> <li>d) have access to processes which permit them to raise, in confidence and without prejudice, concerns over any aspect of service delivery, treatment or management;</li> <li>e) are supervised and supported in the delivery of their role; and</li> <li>f) are dealt with fairly and equitably when their performance causes concern.</li> </ul>   |  |
| <p>What this means:</p> <p>Registered persons need to ensure that they have safe and effective recruitment and staff performance management arrangements in place so that service users can be confident that they will receive treatment and care from persons with the appropriate knowledge, skills and experience and who do not pose a risk to their health, safety and welfare.</p> <p>To safeguard the health, safety and welfare of service users, all staff and persons granted practising privileges, are recruited in line with the requirements of legislation and pre employment procedures include those checks set out below, as a minimum.</p> <p>Arrangements are in place to enable staff to deliver treatment and care to an appropriate standard with support systems that permit them to work within their codes of professional conduct.</p> |  |
| <p><b>Elements to be in place at registration and ongoing</b></p>  |  |
| <p>There is a written human resource policy and supporting procedures, in line with current legislation, which:</p> <ul style="list-style-type: none"> <li>• Defines the way in which advertising, recruitment, induction, employment and retention of staff is managed;</li> <li>• Includes written policies and procedures on granting practising privileges;</li> <li>• Explicitly states what would be regarded as a disciplinary offence;</li> <li>• Defines the checks on and use of temporary or agency staff.</li> </ul>   |  |

Service users are protected from care by unsuitable people because, there are personnel policies which:

- set out an expectation as to the conduct of staff and disciplinary procedures to be followed;
- prohibits staff and persons who work for the establishment or agency from accepting gifts from service users;
- covers effectively the way in which volunteers are deployed;
- ensures that where persons are suspected to have caused harm or risk of harm to service users, they are referred to the ISA;
- ensures persons only work in 'controlled' or 'regulated' activity in accordance with the Safeguarding Vulnerable Groups Act 2006.

The quality of recruitment ensures that only those people who are fit to work in the service are allowed to do so. Before staff and persons granted practising privileges are allowed to work for the organisation checks are carried out which:

- Ensure that 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.
- Ensure that all staff are interviewed before employment, and that records of interview and references are retained.
- Ensure that documentary proof is maintained of the continuing registration of professional staff with their respective professional regulatory body.
- Ensure that current documentary evidence of any relevant professional indemnity insurance is available and indemnification is checked and authenticated for all staff and intended staff.
- Ensure 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.
- Ensure that when employment is offered to a person they can demonstrate that they are legally permitted to work in the UK and that this is confirmed with the appropriate authorities.

- Ensure that the person is subject to a CRB check and a check that they are registered with the Independent Safeguarding Authority (ISA) as the scheme is phased in.
- Ensure the pre employment checks include assessment of physical and mental health to ensure the individual is suitable to undertake their role (including where appropriate, occupational screening for communicable disease and blood borne viruses).
- Ensure there is a record of relevant immunisations provided (where applicable).
- Ensure pre employment checks include those set out in Regulation 21 and Schedule 2 of the Independent Health Care (Wales) Regulations 2011.

Staff are not able to work or work unsupervised in the organisation, unless they have the relevant qualifications, knowledge, competencies and experience to carry out their role.

All staff know what their role is because they have a job description which includes:

- the qualifications required for the role;
- who they are responsible / accountable to;
- their responsibilities and any person specification.

The Responsible Individual is able to supervise the management because they have the requisite knowledge, skills and experience.

#### Service specific elements to be in place at registration and ongoing

##### Children

Organisations that treat children ensure that children receive care, treatment and support from a person registered by the Nursing and Midwifery Council on the parts of their register that permit a nurse to work with children, or the advice of a nurse on this part of the register is available whenever it is required.

#### Additional ongoing elements - once the service is operational

To ensure service users receive care from appropriately recruited and competent staff, there is ongoing monitoring of recruitment practices.

### Supporting information and guidance

**Note:** this list is not exhaustive. It is not intended as anything other than a useful aide memoir for providers and more up to date information may have superseded this.

Welsh Assembly Government

The NHS Governance E Manual [www.nhswalesgovernance.com](http://www.nhswalesgovernance.com)

WHCs can be accessed from the HOWIS Welsh Health Circulars website.

<http://howis.wales.nhs.uk/whcirculars.cfm>

Independent Safeguarding Authority [www.isa-gov.org.uk](http://www.isa-gov.org.uk)

Criminal Record Bureau [www.crb.gov.uk](http://www.crb.gov.uk)

Independent Healthcare Advisory Services (IHAS) Guidance for Development of a Practising Privileges Policy for Consultant Medical and Dental Staff, October 2009

General Medical Council [www.gmc-uk.org](http://www.gmc-uk.org)

Nursing Midwifery Council [www.nmc-uk](http://www.nmc-uk)

Department for Children Skills & Families [www.dfes.gov.uk/](http://www.dfes.gov.uk/)

Equality and Human Rights Commission [www.equalityhumanrights.com](http://www.equalityhumanrights.com)

General Dental Council [www.gdc-uk.org](http://www.gdc-uk.org)

Health Professions Council [www.hpc-uk.org](http://www.hpc-uk.org)

Home Office [www.homeoffice.gov.uk](http://www.homeoffice.gov.uk)

Royal Pharmaceutical Council [www.rpsgb.org.uk](http://www.rpsgb.org.uk)

Border & Immigration Agency [www.bia.homeoffice.gov.uk](http://www.bia.homeoffice.gov.uk)

Welsh Language Board <http://www.byig-wlb.org.uk/english/using/Pages/index.aspx>

| Standard 25<br>Workforce Planning, Training and<br>Organisational Development   | Regulation 20, 21, 22 |
|---|-----------------------|
| <p>Organisations and services ensure that:</p> <p>They have an appropriately constituted and sustainable workforce, who are provided with appropriate support to enable them to:</p> <ul style="list-style-type: none"> <li>a) have effective workforce plans;</li> <li>b) maintain and develop competencies in order to be developed to their full potential;</li> <li>c) participate in induction and mandatory training programmes;</li> <li>d) have an annual personal appraisal and a personal development plan enabling them to develop their role;</li> <li>e) demonstrate continuing professional and occupational development; and</li> <li>f) access opportunities to develop collaborative practice and team working.</li> </ul>   |                       |
| <p>What this means:</p> <p>The safety and quality of services is underpinned by staff and people who work in the organisation, who have the right knowledge, skills and experience.</p> <p>Workforce plans need to be developed and regularly reviewed to ensure there is always appropriate capacity and skill mix of competent staff available, when required.</p> <p>A workforce strategy will ensure that organisations plan ahead to enable them to meet organisational objectives (which will be referenced in the Statement of Purpose)</p> <p>It is essential that staff have the necessary knowledge, skills and behaviours required to undertake their specific roles and to:</p> <ul style="list-style-type: none"> <li>• enable registered persons to meet the current and future service needs of their organisation; and</li> <li>• ensure, that high standards of treatment and care are maintained.</li> </ul> <p>Organisations need to establish a co-ordinated system of skills development and training which will ensure that they are trained, motivated and competent to deliver the services they provide.</p> <p>Competence must be regarded as a vital element for compliance, mitigation of risk and improvement in the effectiveness and efficiency of services, treatment and care.</p> |                       |

### Elements to be in place at registration and ongoing

Patients receive safe treatment and care from people who work in the service because the registered person is able to demonstrate:

- They have undertaken a staffing and skill mix analysis and,
- They have sufficient numbers of appropriately qualified and, experienced staff on duty at any one time.
- The numbers of and skill mix of staff is in line with regulatory requirements and best practice guidance for:
  - the specific patient group / specialist area;
  - stage of the care pathway;
  - number and individual needs of patients.
- They have sustainable arrangements in place to manage unplanned absenteeism, holidays, vacancies, and emergencies.
- That where there are planned service developments, these are implemented only when there is an appropriately constituted workforce in place.
- That they support staff to develop, maintain and ensure they have the right knowledge and skills.
- That staff, including medical staff and those with practising privileges:
  - participate in induction and training programmes appropriate to their role;
  - are made aware of relevant policies and procedures;
  - have role profiles which identify the required qualifications, competencies and experience required;
  - comply with statutory regulation and revalidation requirements;
  - have appropriate and adequate supervision in place until competence is achieved;
  - consultant medical practitioners provide details of all the procedures they wish to carry out;
  - know how to raise issues of concern.

### Service specific elements to be in place at registration and ongoing

#### Acute hospitals

Registered persons have carried out required checks and have been advised by the Medical Advisory Committee (MAC) that all persons granted practicing privileges are competent to undertake the clinical care they wish to provide.

#### Additional ongoing elements - once the service is operational

Patients receive safe treatment and care from people who work in the service because the registered person is able to demonstrate that:

- a) Staff, medical practitioners with practising privileges and any resident medical officer (RMO):
  - participate in ongoing training relevant to their role;
  - participate in continuing professional and occupational development;
  - keep up to date professionally with changes in practice;
  - have an annual personal appraisal and personal development plan (PDP);
  - work within their professional codes of conduct;
  - are supported to raise issues of concern without fear of recrimination.
- b) Agency nurses and locum medical staff, have an effective induction and are made fully aware of current, relevant policies and procedures.
- c) A training needs analysis is undertaken, implemented, regularly reviewed and informs workforce planning.
- d) Workforce planning is regularly reviewed and:
  - an annual workforce plan is prepared;
  - the plan is informed by risk assessment and current recruitment trend data;
  - workforce risks are escalated to the registered provider and board.
- e) They maintain a record of all educational and professional development activities provided.

Personal appraisal and training records are available for each person who works in the establishment or for the purposes of the agency.

Staff are supported to raise issues of concern but where that may affect the health and welfare of patients they are made aware of how they can also make their concerns and views known to Healthcare Inspectorate Wales.

Recruitment, staffing rotas and training records for people who work within the organisation are available for inspection by Healthcare Inspectorate Wales.



### Supporting information and guidance

**Note:** this list is not exhaustive. It is not intended as anything other than a useful aide memoir for providers and more up to date information may have superseded this.

Skills for Health <http://www.skillsforhealth.org.uk/>

National Leadership & Innovation Agency for Healthcare (links to careers, CDP pages) - <http://www.wales.nhs.uk/sitesplus/829/page/36090>

The following links to the websites of Professional Bodies which promote continuing professional development:

British Association of Art Therapists - <http://www.baat.org/>

School of Postgraduate Medical and Dental Education, Cardiff - <http://www.cardiff.ac.uk/pgmde/dental>

British Association of Occupational Therapists & College of Occupational therapists - <http://www.cot.co.uk/>

The Chartered Society of Physiotherapy - <http://www.csp.org.uk/>

The Council for Professions Supplementary to Medicine - <http://www.cpsm.org.uk/>

General Dental Council - <http://www.gdc-uk.org/>

Institute of Healthcare Management - <http://www.ihm.org.uk/>

Institute of Physics & Engineering in Medicine - <http://www.ipem.org.uk/>

Royal College of Anaesthetists - <http://www.rcoa.ac.uk/>

Institute of Biomedical Science - <http://www.ibms.org/>

Royal College of General Practitioners - <http://www.rcgp.org.uk/>

Royal College of Midwives - <http://www.rcm.org.uk/>

Royal College of Nursing - <http://www.rcn.org.uk/>

Royal College of Obstetricians & Gynaecologists - <http://www.rcog.org.uk/>

Royal College of Ophthalmologists - <http://www.rcophth.ac.uk/>

Royal College of Paediatrics & Child Health - <http://www.rcpch.ac.uk/>

Royal College of Physicians - <http://www.rcplondon.ac.uk/>

Royal College of Psychiatrists - <http://www.rcpsych.ac.uk/>

Royal College of Radiologists - <http://www.rcr.ac.uk/>

Royal College of Speech & Language Therapists - <http://www.rcslt.org.uk/>

Royal College of Surgeons of England - <http://www.rcseng.ac.uk/>

Royal Pharmaceutical Society of Great Britain - <http://www.rpsgb.org.uk/>

The Society of Radiographers - <http://www.sor.org/>

The Society of Chiropodists & Podiatrists - <http://www.scpod.org/>

The Nursing & Midwifery Council - [http://www.nmc-uk.org./](http://www.nmc-uk.org/)

## Annex A

### Glossary of terms

#### Access

The extent to which people are able to receive the information, services or the care they need.

#### Advanced Decision or Directive

An advance decision (sometimes called an advance directive) can be made by a person who has the mental capacity to do so, to indicate a wish to refuse all or some forms of medical treatment if in the future if they lose mental capacity. But an advance decision cannot be used to request treatment.

#### Adverse Event

An accident, incident or circumstances that could have, or did lead to, unintended or unexpected harm, loss or damage to a person. Also sometimes referred to as a patient safety incident, critical incident or untoward incident.

#### Audit

A measurement against standards of the effectiveness, efficiency and quality of treatment and service outcomes.

#### Benchmarks

Benchmarks are used as comparators to compare performance between similar organisations or systems.

#### Best practise guidance

Guidance which is relevant to the types of treatment and services provided in the establishment or by the agency, is up to date, reflects expert and professional knowledge / advice, evidence based research and enables registered persons to meet national minimum standards and comply with regulations.

#### Blood Borne Viruses (BBV's)

Organisms that can be transmitted through broken skin or needlestick injuries such as Hepatitis B, Hepatitis C or HIV.

#### Carer

A person who provides the physical or emotional support to enable another individual to participate in daily life. Families or friends are the biggest group providing care and are sometimes called 'informal carers' or 'family carers'.

## Citizens

Means anyone who receives, or is affected by, services. In the independent sector, patients are the obvious citizens; but there are others whom the independent sector has to consider - patients' relatives, for example. Providers of services may define this term in different ways - patient, service user, service recipients, etc.

## Clinical Audit

A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against specific criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery.

## Clinical governance

A system through which organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care, by creating an environment in which clinical excellence will flourish. It includes, audit, benchmarking, critical incident review, risk management and professional development.

## Clinicians

Professionally qualified staff providing clinical care to patients.

## Commissioner

Person or organisation who buys services from an independent hospital, clinic or agency on behalf of the public, other private or voluntary sectors.

## Corporate Board

Registered providers who are organisations that have a board of directors, who are accountable for meeting the regulatory requirements.

## Critical Care

The levels of critical care determine how much treatment is needed for patients, and how intensive it is. Critical care levels range from 0 - 3.

**Level 0** - patients can be cared for on a normal ward.

**Level 1** - patients who are at risk of their conditions deteriorating, and need a higher level of care or are stepping down from a higher level of care.

**Level 2** - patients who need extended post operative or more in-depth care and observation, such as after an operation, or those who have a single failing organ. These types of patients will usually be cared for in a high dependency unit (HDU).

**Level 3** - patients who cannot breathe without help, those who need support for at least two failing organ systems, or have multi-organ failure. These patients will usually be cared for in an intensive care unit.

## Equality and Human Rights

The basic rights and freedom to choose, that should be available to everyone, regardless of age, race, gender, ethnicity, nationality, disability or religion provided through The Human Rights Act 1998.

## Gillick Competency and Fraser Guidelines

Gillick and Fraser relate to legal cases which considered whether a doctor could give treatment to under 16 year olds without parental consent. They are now used by professionals to assess whether a child is mature enough to make their own decision about a particular treatment.

## Governance

A system of accountability to service users and other stakeholders within which organisations operate, take decisions and lead their people to achieve their objectives.

## Haemovigilance

A mandatory monitoring process for the safety of blood transfusion.

## Healthcare

Services provided for, or in connection with, the prevention, diagnosis or treatment of illness, and the promotion and protection of public health.

## Healthcare Associated and Community Infections (HCAI)

All avoidable infections acquired as a direct or indirect result of health care.

## Health Promotion

Includes the provision and information on healthier lifestyles and how to make the best use of health services, with the intention of enabling people to make rational health choices and of ensuring awareness of the factors determining the health of the community.

## Health Technical Memoranda (HTM)

Best practice standards and guidance for the planning and design of healthcare facilities for example, decontamination environments or circulation and communal spaces.

## Health Building Notes (HBN)

Specific standards for installations within healthcare facilities, for example, medical gas installation or pathology services.

**Hospital blood bank** - A hospital blood bank is defined as any unit within a hospital which stores and distributes and may perform compatibility tests on, blood and blood components exclusively for use within hospital facilities, including hospital based transfusion activities.

## Health Record

A single record with a unique identifier containing information relating to the physical or mental health of a given patient who can be identified from that information and which has been recorded by, or on behalf of, a health professional, in connection with the care of that patient. This may comprise text, sound, image and/or paper and must contain sufficient information to support the diagnosis, justify the treatment and facilitate the ongoing care of the patient to whom it refers.

## Infection Control

The process of managing the risk of inadvertently re-infecting patients, service users or the public when working with or handling infectious material.

## Key performance indicators

A set of pre-determined, quantifiable quality measures, against which performance is benchmarked.

## Laser Protection Adviser (LPA)

The LPA provides advice on the safety aspects of laser / IPL installations.

## Local Rules

A written document setting out the safe operation and day to day safe management of the laser /IPL, within the establishment.

## Medical Advisory Committee

A committee which represents the views of medical colleagues and provides advice to the registered person on:

- the introduction and safety of new procedures;
- the granting of privileges for suitably trained clinicians;
- key performance indicators of persons granted practising privileges.

## Medical Devices

All products except medicines, used in health care for diagnosis, prevention, monitoring or treatment. The range of products is very wide it includes contact lenses and condoms; heart valves and hospital beds; resuscitators and radiotherapy machines; surgical instruments and syringes; wheelchairs and walking frames.

## National Patient Safety Agency (NPSA)

The NPSA lead and contribute to improved, safe patient care by informing, supporting and influencing organisations and people working in the health sector. They aim to reduce risks to patients receiving NHS care and improve safety. Support the resolution of concerns about the performance of individual clinical practitioners to help ensure their practice is safe and valued. Protect the rights, safety, dignity and well-being of research participants that are part of clinical trials and other research within the NHS.

## National Service Frameworks (NSFs)

- set national standards and identify key interventions for a defined service or care group;
- put in place strategies to support implementation and;
- establish ways to ensure progress within an agreed timescale.

## NICE (National Institute for Health and Clinical Excellence)

The role of The National Institute for Health and Clinical Excellence is to provide patients, health professionals and the public with authoritative, robust and reliable guidance on current “best practice”. The guidance covers both individual health technologies (including medicines, medical devices, diagnostic techniques, and procedures) and the clinical management of specific conditions.

## Organisations

Independent health care providers of services that need to be registered by Healthcare Inspectorate Wales, (regardless of whether they are a company or individually registered provider).

## Patient

Those in receipt of health care provided by the independent sector. Within this document a patient may also be referred to as a service user.

## Practising Privileges

Persons, usually medical practitioners, who are granted the right to practice (provide treatment) or consult, within an independent hospital.

## Public health

Public health is concerned with improving the health of the population, rather than treating the diseases of individual patients.

## Quality Assurance

A systematic process of verifying that a product or service being provided or developed is meeting specific requirements.

## Quality Monitoring

A continuous system of monitoring to ensure that treatment or services provided are safe and effective.

## Quality Requirements

Quality requirements will be established through the National Service Frameworks. They describe the care which clinicians and others will use to guide their practice.

## Registered Manager

The person who has been registered by Healthcare Inspectorate Wales as a manager of an independent hospital, independent clinic or independent medical agency. They are locally accountable for ensuring that the service meets National Minimum Standards and complies with regulations. Any hospital, clinic or agency which is operated by a company or an individual who will not be in charge on a full time day to day basis, must have a registered manager.

## Responsible Individual

A Responsible Individual must be appointed where the hospital, clinic or agency is operated by a corporate body and is responsible for supervising the management of those services. They are usually a senior person in the organisation.

## Research Governance Frameworks

Defines the broad principles of good research governance and is key to ensuring that research is conducted to high scientific and ethical standards and applies to all research undertaken within independent sector in Wales.



## Risk Management

Managing the risk of error occurring in a service. It covers all the processes involved in identifying, assessing and judging risks, assigning ownership, taking actions to mitigate or anticipate them, and monitoring and reviewing progress.

**SABRE** - Serious Adverse Blood Reactions and Events.

## Safeguarding

Activities to ensure that children and vulnerable adults are protected from abuse and harm.

## Same Sex Accommodation

Same-sex accommodation means sleeping accommodation, bathroom and toilet facilities which patients and service users share only with people of the same sex. It applies to all areas of hospitals and mental health units - including assessment units, admissions wards and day treatment areas - except where clinical need takes priority, or where it is in the interests of a group of service users to share and socialise together (for example children, adolescents, dialysis patients and those progressing through rehabilitation as part of their care pathway).

## Service User

An individual who uses services provided by the independent sector and who may also be referred to interchangeably within this document as a patient.

## Staff

The term 'staff' used in these standards includes:

- Persons directly employed by the registered provider.
- Locum / agency staff.
- Volunteers.
- Medical practitioners or other professionals who are granted practising privileges (including any persons who assist them).
- Students on placement.

## Telemedicine

The use of communication systems such as a computer or video conferencing, to enable a remote diagnosis to be made or healthcare advice to be provided.

### **Unlicensed / Off licence drug**

A drug, which has a marketing licence, but for use in a different age group, for a different health condition or by another route of administration.

### **Workforce Planning**

Planning ahead to make sure there are enough staff resources to manage and provide current services offered or those planned for the future. This involves looking at training needs, labour market trends and recruitment issues.

### **Workforce**

Persons employed or contracted to deliver services, contractors or those with practising privileges.

## References

- 1 As amended.
- 2 Section 5 of the Act designates the National Assembly for Wales as the registration authority. These functions are transferred to Welsh Ministers by virtue of paragraph 30 of schedule 11 to the Government of Wales Act 2006 (c.32).
- 3 Independent hospitals include: establishments, the main purpose of which is to provide medical treatment for illness; psychiatric treatment for illness or mental disorder or in which treatment or nursing (or both) are provided for persons liable to be detained under the Mental Health Act 1983 (s.2(3)(a)(i) and s.2(3)(b)); or the main purpose is to provide palliative care (s.2(3)(a)(i)) (hospices), or in which (whether or not other services are provided) any of the listed services are provided (s.2(3)(a)(ii) and s.2(7)). Listed services include: medical treatment under anaesthesia or sedation, dental treatment under general anaesthesia, obstetric services and in connection with childbirth, medical services, termination of pregnancy, cosmetic surgery, prescribed techniques or prescribed technologies. Prescribed techniques or technology include: Endoscopy, In Vitro Fertilisation, Dialysis, Hyperbaric Oxygen Therapy, Class 3B or 4 Lasers or Intense Pulsed Light Sources.
- 4 <http://www.carestandardstribunal.gov.uk/>
- 5 The BRE is part of the Department for Business, Innovation and Skills (BIS) and leads the regulatory reform agenda across government.
- 6 S.23(4) of the Act refers.
- 7 Further information about children treated in independent hospitals is set out in the Independent Healthcare Advisory Services (IHAS) Guidance on the Care of Children in Receiving Care in Independent Sector Acute Hospitals, 2004.
- 8 (IHAS) [http://www.independenthealthcare.org.uk/index.php?component/  
option=com\\_phocadownload/Itemid,78/id,23/view/category/](http://www.independenthealthcare.org.uk/index.php?component?option=com_phocadownload/Itemid,78/id,23/view/category/)
- 9 Medicines and Healthcare products Regulatory Agency.
- 10 The Home Office Drugs Licensing Unit is the UK's competent authority for the purposes of the United Nations Conventions on controlled drugs.
- 11 Physiotherapists and Podiatrists are registered by the Health Professions Council (HPC).