Republic of Botswana

National Health Quality Standards

Standards & Guidelines for Clinics

Improving Quality & Safety of Health Services

National Health Quality Standards

Standards & Guidelines
For Clinics

Ministry of Health Headquarters
Private Bag 0038
Plot 54609
Government Enclave
Gaborone
Botswana

Tel: (00267) 363 2602
(00267) 363 2500

Fax: (00267) 397 4512

Email: mohinspectorate@gov.bw

Website: moh.gov.bw

TABLE OF CONTENTS

SE 12 FACILITY MANAGEMENT SERVICES

SE 13 SUPPORT SERVICES

Foreword

The Government of Botswana through the Ministry of Health has since independence managed to build healthcare facilities of different capacities delivering healthcare services at different levels of care. The adoption of the Primary Healthcare strategy has critically influenced the development of public healthcare facilities to be in areas within reach of every citizen. In addition over the years the private health sector has also grown significantly. This has always been a good development pertaining to access to healthcare by the people of this country.

Notwithstanding the above, there have been some major challenges faced by our health system, one which is provision of quality and safe healthcare services. People are no longer complaining of lack of hospitals and clinics but rather of the quality and safety of service they receive. The national healthcare standards represent a new approach in the way we provide healthcare and are aimed at propelling us to greater heights in meeting the needs and expectations of our patients and the public at large. They set out basic requirements that will promote delivery of services based on shared values, and also establish the basis for continuous improvement of the quality and safety of the patient care. The standards will not only provide a framework for self assessment and for external review and investigation, but would also enhance the reputation and credibility of our healthcare system. Their implementation framework provides an execution strategy or road map to realize this.

These National Health Quality Standards have been designed in such a way that they can be implemented in all types of healthcare services or settings. They provide the foundation which is applicable to the full spectrum of patient care for the various levels of care in an organization as a whole and to specific areas as appropriate.

I urge all providers to use them to strive to continuously improve the quality and safety of care. May I kindly underscore that successful implementation of the standards requires all healthcare sectors whether in Government or private sector to take account of the quality and safety of all their services. They should conduct self-assessments against the standards and manage their performance. It is envisaged that all healthcare service providers will be subjected to compliance with the standards once the legislation is put in place. I therefore urge all providers to adopt the standards in advance of the proposed legislation. Progress by healthcare sectors to achieve compliance against these standards will be assessed through independent inspections and audits.

I am confident that their implementation will build on the improvements achieved this far and will serve as a catalyst for a change to a culture of continuous improvement that puts the patients at the forefront so that we are able to provide the right care for the right person at the right time, the first time.

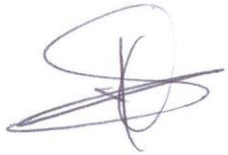
Rev. Dr. John G.N. Seakgosing
Minister of Health

Acknowledgements

The national healthcare standards are a product of various stakeholders drawn from different disciplines from both Government and private sector and other interested stakeholders. The Ministry of Health acknowledges enormous support from the Council for Health Service Accreditation of Southern Africa (COHSASA) who through their expertise and advice have made the development of the National Health Quality Standards a reality.

Our sincere thanks to the general public and various stakeholders with vested interest in healthcare for their valuable inputs and comments; and the management and staff of Kgatelopele (Block) 8 clinic for allowing us to use their facility as a pilot test site for the Clinic Services Standards.

Lastly, let me be mindful of the fact that healthcare is dynamic and assure you that the Government is committed to ensure that these standards remain relevant and the Ministry will be thankful to all stakeholders to be involved in their continuous monitoring and future reviews.



Dr. K. Seipone
Director Health Services

DEFINITION OF TERMS

Acceptability	Acknowledgement that the reasonable expectations of the patient, funders and the community have been satisfied.
Accessibility	Means that access to healthcare services is unrestricted by geographic, economic, social, cultural, organisational or linguistic barriers.
Accountability	The state of being answerable for one's decisions and actions. Accountability cannot be delegated.
Accreditation	A determination by an accrediting body that an eligible organisation is in compliance with applicable predetermined standards. (See also *certification, licensure.)*
Adverse event	An adverse event may be defined as any event or circumstance arising during a stay in a clinic/health centre that leads to unintended or unexpected physical or psychological injury, disease, suffering, disability or death not related to the natural cause of the patient's illness, underlying condition or treatment.
Advocacy	Representation of individuals who cannot act on their own behalf and/or promoting individual rights and access to the resources that will allow them to fulfil their responsibilities.
Ambulatory care	Healthcare services that do not require the hospitalisation of a patient, such as those delivered at a physician's office, clinic and casualty or outpatient facility.
Appraisal system	The evaluation of the performance of individuals or groups by colleagues using established criteria.
Appropriateness	The extent to which a particular procedure, treatment, test or service is effective, clearly indicated, not excessive, adequate in quantity, and provided in the setting best suited to the client's needs.
Assessment	Process by which the characteristics and needs of clients, groups or situations are evaluated or determined so that they can be addressed. The assessment forms the basis of a plan for services or action.
Audit	1. Systematic inspection of records or accounts by an external party to verify their accuracy and completeness. 2. Periodic in-depth review of key aspects of the organisation's operations. An audit provides management with timely information about specific topics and/or the cost-effectiveness of operations, addressing both quality and resource management issues.

3. In performance measurement, regular systematic, focused inspections by an external party of organisation records and data management processes to ensure the accuracy and completeness of performance data.

4. See also *clinical audit.*

Benchmarking	A method of improving processes by studying the processes of organisations that have achieved outstanding results and adapting these processes to fit the particular needs and capabilities of the healthcare facility concerned.
Biologicals	Medicines made from living organisms and their products including, for example, serums, vaccines, antigens and antitoxins.
Biohazard	Biohazards are infectious agents or hazardous biological materials that present a risk or potential risk to the health of humans, animals or the environment. The risk can be direct (through infection) or indirect (through damage to the environment). Biohazardous materials include certain types of recombinant DNA: organisms and viruses infectious to humans, animals or plants (e.g. parasites, viruses, bacteria, fungi, prions, rickettsia), and biologically active agents (i.e. toxins, allergens, venoms) that may cause disease in other living organisms or cause significant impact to the environment or community. Biological materials not generally considered to be biohazardous may be designated as biohazardous materials by regulations and guidelines.
Business plan	A plan of how to achieve the mission of the facility. The plan includes financial, personnel and other sub-plans, as well as service development and a quality strategy.
Cardiopulmonary resuscitation (CPR)	The administration of artificial heart and/or lung action in the event of cardiac and/or respiratory arrest. The two major components of cardiopulmonary resuscitation are artificial ventilation and closed-chest cardiac massage.
Carer	Anyone who regularly and, in an unpaid capacity, helps a relative or friend with domestic, physical or personal care required by virtue of illness or disability.
Certification	The procedure and action by which a duly authorised body evaluates and recognises (certifies) an individual, institution or programme as meeting predetermined requirements, such as standards. Certification differs from accreditation in that certification can be applied to individuals, e.g. a medical specialist, whereas accreditation is applied only to institutions or programmes, e.g. a clinic/health centre or a training programme. Certification programmes may be non-governmental or governmental and do not exclude the uncertified from practice, as do licensure programmes. While licensing is meant to establish the minimum competence

	required to protect public health, safety and welfare, certification enables the public to identify those practitioners who have met a standard of training and experience that is set above the level required for licensure.
Clinic	A defined healthcare session in a healthcare setting. 2. A defined healthcare setting.
Clinical audit	A clinically led initiative that seeks to improve the quality and outcome of patient care through structured peer review, in terms of which clinical personnel examine their practices and results against agreed standards and modify their practice where indicated.
Clinical personnel	All healthcare workers who are registered/enrolled with a professional body, and who are involved in the care of clients/patients in a particular setting. (See also *health professionals.)*
Clinical practice guideline	A generally accepted principle for patient management based on the most current scientific findings, clinical expertise and community standards of practice.
Clinical practice pathway	The optimal sequence and timing of interventions by physicians, nurses and other disciplines for a particular diagnosis or procedure, designed to minimise delays and resource utilisation and to maximise the quality of care. Clinical pathways differ from practice guidelines, protocols and algorithms as they are used by a multidisciplinary team and focus on quality and coordination of care.
Clinician	Refers to a person registered as a medical doctor.
Clinical privileges	Authorisation granted by the governing body to clinical personnel to provide specific patient care services in the organisation within defined limits, based on an individual practitioner's registration, education, training, experience, competence, health status and judgement. (See also *privileging*.)
Clinical waste	Clinical waste is waste arising from medical, dental or veterinary practice or research, which has the potential to transmit infection. Other hazardous waste, such as chemical or radioactive, may be included in clinical waste, as well as waste such as human tissues, which requires special disposal for aesthetic reasons.
Community	A collection of individuals, families, groups and organisations that interact with one another, cooperate in common activities and solve mutual concerns, usually in a geographic locality or environment.
Complementary therapist	Any practitioner who offers an alternative therapy to orthodox medical treatment. Complementary medicine does not replace

	conventional medicine.
Compliance	To act in accordance with predetermined requirements, such as standards.
Compliance survey	An external evaluation of an organisation to assess its level of compliance with standards and to make determinations regarding its compliance status. The survey includes evaluation of documentation provided by personnel as evidence of compliance verbal information concerning the implementation of standards, or examples of their implementation that will enable a determination of compliance to be made, and on-site observations by surveyors.
Confidentiality	The assurance of limits on the use and dissemination of information collected from individuals.
Contaminated blood supplies	Any blood supply that was issued to a patient after cross matching, but was not used. Any blood that was not transfused and is left in the bag. The empty bags after a blood transfusion.
Continuity	The provision of coordinated services within and across programmes and organisations, and during the transition between levels of services, across the continuum, over time, without interruption, cessation or duplication of diagnosis or treatment.
Continuum	The cycle of treatment and care incorporating access, entry, assessment, care planning, implementation of treatment and care, evaluation and community management.
Continuing education	Activities designed to extend knowledge to prepare for specialisation and career advancement and to facilitate personal development. Education beyond initial professional preparation that is relevant to the type of client service delivered by the organisation that provides current knowledge relevant to the individual's field of practice, and that is related to findings from quality improvement activities.
Contract administration	Written agreements and the administration thereof between the purchaser of the service (the healthcare facility) and the provider of the service (the external company).
Contracted service	A service that is obtained by the organisation through a contract with an agency or business. The contracted service is monitored and coordinated by the organisation's personnel and complies with national regulations and organisational policies.

Credentialing	The process of obtaining and reviewing the clinical training, experience, certification and registration of a healthcare professional to ensure that competence is maintained and consistent with privileges.
Criterion	A descriptive statement that is measurable and that reflects the intent of a standard in terms of performance, behaviour, circumstances or clinical status. A number of criteria may be developed for each standard.
Data	Unorganised facts from which information can be generated.
(a) Longitudinal data	Implies that it is for a given time span.
(b) Comparative data	When a data set is compared with like data sets or with a given time, usually of the previous month or year.
Data retention	Guidelines on how long an organisation should keep information on various media.
Delegation	Act or function for which the responsibility has been assigned to a particular person or group. The ultimate accountability for the act remains with the original delegating person or group.
Discharge note	The discharge note provides the patient and the patient's carers with written follow-up instructions, including medication, any specific dietary and medical orders and when to return for follow-up treatment, or where the patient must go to obtain further treatment.
Discharge summary	Follow-up instructions recorded in writing in the patient's record by the medical practitioner. The discharge summary includes: • the reason for admission, • significant findings, • final diagnosis, • the results of investigations that will influence further management, • all procedures performed, • medications and treatments administered, • the patient's condition at discharge, and • discharge medications and follow-up instructions.
Effectiveness	Successfully achieving or attaining results (outcomes), goals or objectives.
Efficiency	Refers to how well resources (inputs) are brought together to achieve results (outcomes) with minimal expenditure.
Element, generic	An organisational system within a service element that must achieve and maintain the stated standards and criteria in order for the service element to function optimally.

Element, service	Organisational unit of the clinic/health centre or staff with a director, manager or other designated person in charge. May be a professional service, such as nursing or surgery, a professional support service, e.g. radiology or physiotherapy, a general support system such as administration or health record system, a committee to guide aspects of the service, e.g. health and safety, or a community health service.
Ethics	Standards of conduct that is morally correct.
Evaluation	The process of determining the extent to which goals and objectives have been achieved. Actual performance or quality is compared with standards in order to provide a feedback mechanism that will facilitate continuing improvement.
Facility	The health centre, general practice or any other site providing a health service.
Food handler	Persons who in the course of their normal routine work come into contact with uncovered food not intended for their personal use. Food includes water and any other liquid intended for human consumption. A food handler is thus any person involved in the processing, production, manufacturing, packaging, preparation, sale or serving of any foodstuff, including water and beverages.
Function	A goal directed, interrelated series of processes, such as patient assessment, patient care and improving the organisation of care.
Governance	The function of determining the organisation's direction, setting objectives and developing policy to guide the organisation in achieving its mission.
Governing body	Individuals, group or agency with ultimate authority and accountability for the overall strategic directions and modes of operation of the organisation, also known as the council, board, etc.
Guidelines	Principles guiding or directing action.
Health	A state of complete physical, mental and social wellbeing, not merely the absence of disease or infirmity.
Healthcare worker	A healthcare worker/provider is an individual who provides preventive, curative, promotional or rehabilitative healthcare services in a systematic way to individuals, families or communities. An individual healthcare worker/provider may be a healthcare professional within medicine, nursing, or a field of allied health. Healthcare providers may also be a public/community health professional.

Health facility category	The category that indicates the level of care provided by the facility as defined in the accompanying Health Facility Category document.
Health professionals	Medical, nursing or allied health professional personnel who provide clinical treatment and care to clients, having membership of the appropriate professional body and, where required, having completed and maintained registration or certification from a statutory authority. (See also *clinical personnel*.)
Health promotion	Process that enables people to increase control over and to improve their health (World Health Organisation 1986).
Health record	Compilation of pertinent facts of a patient's life and health history, including past and present needs and interventions, written by team members contributing to the care and treatment of the patient.
Health summary	A 'health summary' is written by the medical practitioner assisted by the nurse in charge of the medical record. It can be read once the patient has been discharged and revisits the same clinic/health centre. The health summary will quickly and accurately inform the staff at the clinic/health centre of the condition and treatment the patient received at the previous visit.
High-risk	Refers to aspects of service delivery which, if incorrect, will place clients at risk or deprive them of substantial benefit.
High-volume	Refers to aspects of service delivery that occur frequently or affect large numbers of clients.
Human resource planning	Process designed to ensure that the personnel needs of the organisation will be constantly and appropriately met. Such planning is accomplished through the analysis of internal factors such as current and expected skill needs, vacancies, service expansions and reductions, and factors in the external environment such as the labour market.
Implementation	The delivery of planned healthcare.
Integrity of data	Relates to the completeness and accuracy of a set of data required to fulfil a particular information need. This data is protected from unauthorised additions, alterations or deletions.
Incident plan, external	A plan that defines the role of the clinic/health centre in the event of a major national or local disaster that may affect the health of many people. The plan is developed in participation with the relevant local authority, police, civil defence, fire brigade and ambulance teams.

Incident plan, internal	A plan that provides details of preparation for action in the event of a disaster within the clinic/health centre that affects the health or safety of patients and staff, such as fire, bomb threats, explosions or loss of vital services.
Incidents	Events that are unusual, unexpected, may have an element of risk, or that may have a negative effect on clients, groups, staff or the organisation.
Indicator	A measure used to determine, over time, performance of functions, systems or processes. A statistical value that provides an indication of the condition or direction, over time, or performance of a defined process, or achievement of a defined outcome. The measurement of a specific activity that is being carried out in a healthcare setting, e.g. weight for age is a measurement of a child's nutritional status.
Induction programme	Learning activities designed to enable newly appointed staff to function effectively in a new position.
Information	Data that is organised, interpreted and used. Information may be in written, audio, video or photographic form.
Information management	Planning, organising and controlling data. Information management is an organisation-wide function that includes clinical, financial and administrative databases. The management of information applies to computer-based and manual systems.
Informed consent	Informed consent is a process whereby a patient is provided with the necessary information/education to enable him/her to evaluate a procedure with due consideration of all the relevant facts. This will enable the patient to make an appropriate decision when determining whether to consent to or refuse the proposed treatment. The patient or the guardian should be informed about the patient's condition in as much detail as possible and in simple, non-medical language. The proposed service should be described and, if an invasive procedure is envisaged, it should be clearly explained. Facility staff must confirm that the patient or guardian has understood every detail. Should the procedure or treatment have risks or side-effects, these should be described, making sure they are understood. In the same way, the benefits and possible outcomes should be discussed. Alternative treatments should be offered and discussed. If the patient/guardian should refuse the procedure/treatment, the consequences of such a decision should be made clear and, if a second opinion is sought, the patient/guardian should be apprised of the consequences of the delay and be assisted in obtaining a second opinion.

Information system	Network of steps to collect and transform data into information that supports decision making.
In-service training	Organised education designed to enhance the skills of the organisation's staff members or teach them new skills relevant to their responsibilities and disciplines. Usually provided in-house, i.e. at the place of employment.
Job description	Details of accountability, responsibility, formal lines of communication, principal duties and entitlements. It is a guide for an individual in a specific position within an organisation.
Leader	A person providing direction, guidance, regulation or control. A person followed by others.
Leadership	The ability to provide direction and cope with change. It involves establishing a vision, developing strategies for producing the changes needed to implement the vision, aligning people, and motivating and inspiring people to overcome obstacles.
Licensing	The process whereby a governmental authority grants a healthcare organisation permission to operate following an on-site inspection to determine whether minimum health and safety standards have been met.
Manager	An individual who is in charge of a certain group of tasks, or a certain section of an organisation. A manager often has a staff of people who report to him or her. Synonyms: director, executive, head, supervisor, overseer, foreman.
Management	Setting targets or goals for the future through planning and budgeting, establishing processes for achieving targets and allocating resources to accomplish plans. Ensuring that plans are achieved by the organisation, staffing, controlling and problem solving.
Mechanism	The mode of operation of a process or a system of mutually adapted parts working together.
Medical practitioner	Registered medical practitioners are medical doctors with medical degrees who are registered as medical practitioners in the country they practice in by the statutory registration authority of that country. A general practitioner (GP) is a medical practitioner who treats acute and chronic illnesses and provides preventive care and health education for all ages and all sexes. They have particular skills in treating people with multiple health issues and co-morbidities. The word physician is largely reserved for certain other types

	of medical specialists, notably in internal medicine. A physician is a healthcare provider who practices the profession of medicine, which is concerned with promoting, maintaining or restoring human health through the study, diagnosis, and treatment of disease, injury and other physical and mental impairments. They may focus their practice on certain disease categories, types of patients or methods of treatment known as specialist medical practitioners. Both the role of the physician and the meaning of the word itself vary around the world, including a wide variety of qualifications and degrees.
Mission statement	A statement that captures an organisation's purpose, customer orientation and business philosophy.
Monitoring	A process of recording observations of some form of activity.
Monitoring and evaluation	A process designed to help organisations effectively use their quality assessment and improvement resources by focusing on high-priority, quality-of-care issues. The process includes: identifying the most important aspects of the care that the organisation (or department/service) provides by using indicators to systematically monitor these aspects of care, evaluating the care at least when thresholds are approached or reached to identify opportunities for improvement or problems taking action(s) to improve care or solve problems, evaluating the effectiveness of those actions and communicating findings through established channels.
Multidisciplinary	The combination of several disciplines working towards a common goal.
Multidisciplinary team	A number of people of several disciplines with complementary skills whose functions are interdependent. They work together for a common purpose or result (outcome) on a short-term or permanent basis. Examples include project, problem-solving, quality improvement and self-managed teams. For instance, the management team and quality improvement steering committees are multidisciplinary teams.
Objective	A target that must be reached if the organisation is to achieve its goals. It is the translation of the goals into specific, concrete terms against which results can be measured.
Organisation	Comprises all sites/locations under the governance of and accountable to the governing body/owners.
Organisational chart	A graphic representation of responsibility, relationships and formal lines of communication within the facility.
Orientation programme	Activities designed to introduce new personnel to the work environment. The process by which an individual becomes familiar with all aspects of the work environment and responsibilities, or the process by which individuals, families

	and/or communities become familiar with the services and programmes offered by the organisation.
Outcome	Refers to the results of the healthcare provided, expressed in terms of the patient's health status, or physical or social function.
Peer review	The systematic, critical analysis of care, including the procedures used, treatment provided, the use of resources and the resulting outcome and quality of life for the patient, with a view to improving the quality of patient care by a group of persons of the same professional background.
Performance appraisal	The continuous process by which a manager and a staff member review the staff member's performance, set performance goals and evaluate progress towards these goals.
Performance measure	A quantitative tool or instrument that provides an indication of an organisation's performance regarding a specified process or outcome.
Planning	The determination of priorities, expected outcomes and health interventions.
Planning, operational	Determining ways in which goals and objectives can be achieved.
Planning, project	The art of directing and co-ordinating human and material resources throughout the life of a project by using modern management techniques in order to achieve predetermined objectives of scope, quality, time and cost and participant satisfaction.
Planning, strategic	Determining an organisation's mission and determining appropriate goals and objectives to implement the mission.
Policy	Written statements that act as guidelines and reflect the position and values of the organisation on a given subject.
Practice	Partners in a professional practice, employed personnel and their patients/ clients.
Primary Healthcare	The first level of contact of individuals, the family and community with the public health system, bringing healthcare as close as possible to where people live and work. Primary healthcare includes health education, promotion of proper nutrition, maternal and child healthcare (including family planning), immunisation against the major infectious diseases, appropriate treatment of common diseases and injuries and the provision of essential drugs.
Privileging	Delineation, for each member of the clinical staff, of the specific surgical or diagnostic procedures that may be performed and the types of illness that may be managed

	independently or under supervision.
Procedure	A mode of action. A procedure outlines the detailed steps required to implement a policy.
Process	A sequence of steps through which inputs (from healthcare facilities) are converted into outputs (for patients).
Professional registration	Registration in terms of current legislation pertaining to the profession concerned (e.g. The Botswana Health Professions Act 17 of 2001).
Professional staff	Staff that has a college or university level of education, and/or who may require licensure, registration or certification from a regional or state authority in order to practice, and/or personnel who exercise independent judgment in decisions affecting the service delivered to clients.
Professional team	A number of healthcare professionals whose functions are interdependent. They work together for the care and treatment of a specific patient or group of patients.
Protocol	A formal statement. May include written policies, procedures or guidelines.
Quality	Degree of excellence. The extent to which an organisation meets clients' needs and exceeds their expectations.
Quality activities	Activities that measure performance identify opportunities for improvement in the delivery of services and include action and follow-up.
Quality control	The monitoring of output to check whether it conforms to specifications or requirements and action taken to rectify the output. It ensures safety, transfer of accurate information, accuracy of procedures and reproducibility.
Quality improvement	The actions undertaken throughout the organisation to increase the effectiveness and efficiency of activities and processes, in order to bring added benefits to both the organisation and its customers.
Quality improvement programme	A planned, systematic use of selected evaluation tools designed to measure and assess the structure, process and/or outcome of practice against established standards, and to institute appropriate action to achieve and maintain quality. A systematic process for closing the gap between actual performance and desirable outcomes. Continuous quality improvement is a management method that seeks to develop the organisation in an orderly and planned fashion, using participative management, and has at its core the examination of process.

Recruitment and retention	The process used to attract, hire and retain qualified staff. Retention strategies may include reward and recognition programmes.
Rehabilitation	A dynamic process that allows disabled people to function in their environment at an optimal level. This requires comprehensively planned care and service for the total person.
Reliability	The ability of an indicator to accurately and consistently identify the events it was designed to identify across multiple healthcare settings.
Research	Critical and exhaustive investigation of a theory or contribution to an existing body of knowledge aimed at the discovery and interpretation of facts.
Responsibility	The obligation that an individual assumes when undertaking delegated functions. The individual who authorises the delegated function retains accountability.
Risk	Exposure to any event that may jeopardise the client, staff member, physician, volunteer, reputation, net income, property or liability of the organisation.
Risk management	A systematic process of identifying, assessing and taking action to prevent or manage clinical, administrative, property and occupational health and safety risks in the organisation in accordance with relevant legislation.
Safety	The degree to which potential risks and unintended results associated with healthcare are avoided or minimised.
Seamless continuum of care	In the ideal healthcare system, care is delivered in an integrated, uninterrupted or 'seamless' flow. It is defined as an integrated, client-oriented system of care composed of both services and integrating mechanisms that guides and tracks clients over time through a comprehensive array of health, mental health and social services spanning all levels of intensity of care.
Setting	The particular healthcare environment that is appropriate for the patient's needs during the continuum of care, i.e. inpatient care, outpatient attendance, rehabilitative and restorative unit or community setting.
Staff	All individuals employed by the facility – this includes part time, part time, casual or contract, clinical and non-clinical personnel.
Staff development	The formal and informal learning activities that contribute to personal and professional growth, encompassing induction,

	in-service training and continuing education.
Stakeholder	Individual, organisation or group that has an interest or share in services
Standards	The desired and achievable level of performance corresponding with a criterion, or criteria, against which actual performance is measured.
Standard development	Standards for evaluation may be developed in three stages. *Normative development* entails establishing what experts believe should happen. *Empirical standards* reflect what is achievable in practice. A *compromise* between what is professionally optimal and what can reasonably be expected to operate.
Standard, minimum	A predetermined expectation set by a competent authority that describes the minimally acceptable level of *(a)* structures in place *(b)* performance of a process and/or *(c)* measurable outcome that is practically attainable.
Standard, patient-centred	For the purposes of compliance, standards that address and are organised around what is done directly or indirectly, for or to patients (e.g. creation of patient records, patient assessment).
Standards-based evaluation	An assessment process that determines a healthcare organisation's or practitioner's compliance with pre-established standards.
Step-down facility	The Joint Commission (*Survey Protocol for Sub-acute Programmes,* 1995) defines a step-down unit as follows: "At the most complex end (of a range of sub-acute care services) are the short-stay, transitional step-down units, which are often, but not always, attached to clinic/health centres. These units provide a substitute for continued clinic/health centre stay. They serve very sick patients, for example, those in cardiac recovery, those in oncology recovery receiving chemotherapy and radiation, or others who need complex wound management or who suffer from complicated medical conditions. These sub-acute care patients require more than 5 hours of daily nursing, heavy physician involvement, and heavy pharmacy and laboratory support. The average stay is 5–30 days." (See also *sub-acute care centre*).
Structure	The physical and human resources of an organisation.
Sub-acute care centre	The Joint Commission *(Survey Protocol for Sub-acute Programmes,* 1995) defines sub-acute care as follows: "Sub-acute care is goal-oriented, comprehensive, inpatient care designed for an individual who has had an acute illness, injury or exacerbation of a disease process.

	It is rendered immediately after, or instead of, acute hospitalisation to treat one or more specific, active, complex medical conditions or to administer one or more technically complex treatments in the context of a person's underlying long-term conditions and overall situation. Generally, the condition of an individual receiving sub-acute care is such that the care does not depend heavily on high technology monitoring or complex diagnostic procedures."
Surveyor	A doctor, nurse, administrator, or any other healthcare professional who meets quality surveyor selection criteria, evaluates standard compliance and provides consultation regarding standard compliance to surveyed organisations.
System	The sum total of all the elements (including processes) that interact to produce a common goal or product.
Team	A number of people with complementary skills whose functions are interdependent. They work together for a common purpose or result (outcome) on a short-term or permanent basis. Examples include project, problem-solving, quality improvement and self-managed teams. (See also *multidisciplinary team* and *professional team*.)
Timeliness	The degree to which care is provided to the patient at the most beneficial or necessary time.
User	Someone who uses or could use the services offered by the facility.
Utilisation management	Proactive process by which an organisation works towards maintaining and improving the quality of service through the effective and efficient use of human and material resources.
Utilisation review	A method of controlling utilisation that may be: *Prospective* (pre-admission certification) – The purpose is to assess whether hospitalisation has been justified and is diagnosis-independent. *Concurrent* – Conducted to assess inpatient care at the time it is provided, the use of resources, the timeliness with which treatment is provided and the adequacy and timeliness of discharge planning. *Retrospective* – Follows a patient's discharge from the clinic/health centre or any patient who has received ambulatory care.
Validation of survey	A process whereby a facilitator assesses the completed self-assessment documents of a facility. The validation ensures that criteria have been correctly interpreted and appropriately answered, and that the technical aspects of the assessment have been correctly addressed. The facilitator uses the opportunity to provide education and consultation on standard interpretation and compliance.

Vision	A short, succinct statement of what the organisation intends to become and to achieve at some point in the future.
Waste management	Collection, treatment, storage, transportation and disposal of waste material, including biomedical, household, clinical, confidential and other waste.
Workload measurement	Manual or computerised tool for assessing and monitoring the volume of activity provided by a specific team in relation to the needs for the care, treatment and/or service they are providing.

INTRODUCTION

This manual contains the national healthcare standards for clinics and health centres, and includes guidelines for their consistent interpretation and accurate assessment.

The purpose of this manual is to serve as a guide to Botswana surveyors and facilitators, as well as clinic and health centre personnel. It provides information on certain key aspects pertaining to the layout of the standards and their interpretation, as well as core principles to be applied in assessing standard compliance.

The content of the standards has been chosen by people working in the field and familiar with current best practice. The healthcare system in a locality or in a country is the sum of the capabilities of individual organisations. Once these capabilities are catalogued, this information can be used to guide changes and improvements in service delivery. The standards provide a tool to measure capability and efficiency, but also provide a vision of what can be achieved over time through the application of quality improvement tools and training.

Although comfortable buildings with good personnel and adequate equipment is an important goal, excellent care can be provided with limited resources, proper training, personnel support and functional administrative structures. We recognise that many healthcare organisations start from a resource restricted base and that they may feel that the gap between their actual situation and the standards is too great to bridge.

The standards presented here are designed to help bridge the gap between today and a better tomorrow bringing patient care quality and patient safety to new levels. Implementing standards can be an evolutionary process taking time to do things right and better.

A: Structure/Format

This set of standards consists of several Service Elements (SE's) for the various services/departments. Each Service Element contains the relevant standards and criteria (measurable elements) to be assessed in order to ascertain the level of compliance with the standards.

The first five Service Elements, i.e. SE 1 to SE 5, are referred to as the "generic" service elements as their requirements apply across the entire clinic/health centre. The same principle applies to Service Elements 12 and 13.

Information on the compliance standards in this document has been set out in the following format and the first section of Service Element 1 - *Management and Leadership* - is used as an example to demonstrate the layout:

1 MANAGEMENT AND LEADERSHIP

OVERVIEW OF MANAGEMENT AND LEADERSHIP

Effective management of a health facility begins with understanding the various responsibilities and authorities of individuals in the health facility, and how these individuals work together.

At the governance level there is an entity .....

1.1 Governance of the health facility

1.1.1 The governing body's accountability and responsibilities are documented and are known to the health facility's managers.

Intent of 1.1.1
There is a governing body responsible for directing the operation of the organisation, which is accountable for providing quality healthcare services to its community .....

1.1.1 Criteria

1.1.1.1 Documents describe governance, accountability and responsibilities.

Guideline: This Governance structure refers to the authority(ies) above the level of the Facility Manager and may include National/Regional/District levels in the Public Sector together with the Hospital Board, or Corporate structures in the Private Sector.

With reference to the example of Service Element 1 above, the table below explains the hierarchical layout and purpose of each section:

HEADINGS IN EXAMPLE ABOVE	**EXPLANATION**
1. MANAGEMENT AND LEADERSHIP:	Number and name of the service element
Overview of Management and Leadership	General description of the service element and context of the standards in the service element.
1.1 Governance of the organisation	The first "performance indicator" (or main section) for this service element.
1.1.1 The governing body's accountability and responsibilities are documented and are known to the health facility managers.	The first standard in this service element.
Intent of 1.1.1 There is a governing body	A description of the context/scope of the abovementioned standard 1.1.1. Note that the information in this intent statement forms an integral part of aspects to be considered when measuring compliance of criteria.

1.1.1 Criteria	This heading indicates that what follows is the list of criteria (measurable items) that support standard 1.1.1
1.1.1.1 Documents describe governance accountability and responsibilities.	The first criterion in this section for standard 1.1.1
Guideline in a separate block in italics	*A description/explanation of what is expected and guidance on how to assess compliance with the criterion.*

B: Additional Notes on the "Guidelines" (section in italics below the criteria in the above example)

Purpose/intention of the guideline statements:
The purpose of these guidelines is to provide guidance on the scope and interpretation of the criteria statements. The information should also provide facility personnel (clients) with a clear indication of the requirements for compliance and some direction on the Botswana surveyors' expectations.

In some instances the guidelines also state the minimum requirements for compliance and provide direction on how to reach a decision on the compliance score.

Linked criteria/standards:
Where the comment "*Linked to:"* appears in the guideline text box, it refers to other criteria and standards that are linked to the criterion being assessed. For further information on how to deal with these linked criteria, refer to item 7 in section C ("Rules for scoring") of this document.

Root criterion
Where the guideline text box contains the word "root criterion", the following aspects apply.

- A "root" criterion is regarded as the central focus of a process or system which is supported by several other "sub-criteria" that describe the smaller components of such a system or process.
- The rating of a root criterion is dependent on the compliance rating of its supporting criteria, and should therefore reflect the aggregated average of the scores of such supporting criteria.
- This implies that a root criterion cannot be scored until such time that all its linked criteria have been assessed.

For more details on the scoring methodology for root criteria and their links, refer to item 7 in section C below.

C: Rules for assessment of compliance with criteria and the scoring system

The standards in this manual are written expectations of structures, processes or performance outcomes and it is assumed that, if these standards are met, better services/care can be delivered. If these standards are substantially met, a facility/organisation can be accredited. The standards in turn are defined by

objective, measurable elements referred to as "criteria". Criteria are given weighted values (severity ratings) according to how important the criterion requirement is in relation to various aspects (categories) such as legality, patient and staff safety, physical structure, operational effectiveness and efficiency.

Take note that assessing compliance with the standards and criteria includes various activities such as studying documentation, staff and patient interviews, patient record audits and observation of patient care processes, physical facilities and equipment.

Criteria are scored as follows:
In assessing the level of compliance with a criterion, one should not move beyond what that criterion intends to measure. ***Each criterion should be assessed*** individually according to the following principles:

I. ***Compliant (C)*** means the condition required is met. Evidence of compliance should be present in a tangible and/or observable form, e.g. written material, physical items, etc.

1.1 Should the standards, for example, require a **written** policy and procedure but the facility has only a verbal policy in place, then the criterion should be scored as ***non-compliant***.

1.2 Should the facility have a written policy but no evidence is found of consistent implementation thereof or if there is evidence of non-adherence, then the criterion should be scored as ***partially compliant***.

The same principle applies in all instances where either the standards or criteria contain words such as ***policies, procedures, programmes, plans, protocols, guidelines, etc.***

II. ***Partially compliant (PC)*** means the condition required is not totally met, but there is definite progress (>50%) towards compliance *and the deficiency does not seriously compromise the standard.* Other considerations for PC ratings are:

2.1 If the criterion requires a documented system as listed above, but there is no implementation or implementation is partial or if the policy document is still in draft form.

2.2 If the criterion contains more than one requirement, e.g. "There is a policy and procedure on the *safe prescribing, ordering and administration* of medicines," but not all components are compliant.

2.3 If assessment results can be quantified by means of conducting an audit, e.g. "less than 80% of the personnel have received training", or "evidence was found in less than 80% of patient records audited".

2.4 Since there are degrees of partial compliance (PC), the category PC is further subdivided into four degrees of severity: *mild (1), moderate (2), serious (3) and very serious (4)*. These can be thought of as being 80% towards compliance, 60% towards compliance, 40% towards compliance and 20% towards compliance. Obviously, the further away from compliance, the more severe the deficiency will be.

III. ***Non-compliant (NC)*** means there is no observable progress towards complying with the required condition. The degree of non-compliance is again scored in terms of severity, from mild (1) to very serious (4), as explained above.

IV. ***Not applicable (NA)*** means the criterion is not applicable because the facility either does not provide the service at all, or not at the particular level the criterion is designed to measure. Such criteria are excluded in calculating compliance scores.

V. To quantify the degree of compliance, criteria are awarded points according to their level of compliance and seriousness as follows:

Rating	**Score**
C	80-100
PC mild	75
PC moderate	65
PC serious	55
PC very serious	45
NC mild	35
NC moderate	25
NC serious	15
NC very serious	5
NA	Not scored

VI. **Critical criteria**

A standard may have one or more criteria that are marked "critical". This is where non- or partial compliance will compromise patient or staff safety, or where there are legal transgressions.

The methodology used in scoring critical criteria calls for an exception to the rule of PC ratings as described above:

Where a critical criterion is scored as PC, but it is so serious as to constitute a danger to patient and/or staff safety, is in direct contravention of an act or regulation, severely affects patient care or the efficiency of the facility, then it must be scored as NC, e.g. there is a fire alarm but it is not working. This must then be scored as NC rather than PC.

Furthermore, non-complaint critical criteria will result in the entire standard being scored as non-or partially compliant.

VII. **Scoring "linked" criteria**

Several criteria (either in the same SE or in different SEs) are linked with one another, either because they deal with the same system or process, they are duplications, or one of the criteria may be seen as the "root" with several other criteria focussing on "sub-components" of such a "root" criterion. Should such a linked criterion be scored NC or PC, this *may have* an impact

on the compliance ratings of other linked criteria. The following rules should be applied when scoring linked criteria.

- If a ***critical*** criterion scores NC or PC, then *selected* linked criteria should reflect a similar score.
- Also, if a substantial number of ***non-critical*** criteria linked to a critical criterion score NC or PC, the critical criterion should reflect a similar score.
- The same rule applies to criteria that relate to ***legal*** requirements and patient/staff ***safety*** matters.

  The decision to apply the above will depend on the local circumstances and the consideration of the following additional rules.

- If the majority of criteria that focus on the same system or process are scored either NC or PC, then the root criterion should reflect a similar score (because this would constitute a ***high-volume*** deficiency) Example: if ***most*** of the policies and procedures in the organisation have not been reviewed, then the root criterion (1.2.4.5) is scored NC.

- Example of linked criteria
  Criterion 1.1.1.5 regarding the licensing of facilities is directly linked to criterion 1.2.1.5, which relates to compliance with relevant laws and regulations. Further links in different SEs include, among others, criterion 2.3.1.1 regarding verifying credentials, criterion 5.4.1.2 regarding certification of fire safety and criterion 10.1.2.2 relating to Ionising Radiation regulations.

  In the above example, criterion 1.2.1.5 is the ***root criterion*** for the entire organisation, and cannot be scored compliant unless most of the other linked criteria are also compliant.

D: The Matrix Model

As explained above, the structure of the standards and criteria is such that many of these are "interlinked", either within the same Service Element or between the different Service Elements. "Interlinked" means that the same standard/criterion is either repeated in more than one location, or that the standard/criterion is similar to, or closely linked to another standard/criterion in terms of its meaning or in terms of the system or process that it measured.

In using the matrix (refer to the separate Matrix document), scoring rules should apply as indicated in subparagraphs 7.1 to 7.5 above.
The matrix document that is supplied has a section for each service element and should be interpreted as follows:

- The first column (to the left) lists those criteria for the particular Service Element that have associated links in other Service Elements and such links are displayed (in the rows) for the respective Service Elements.
- All critical criteria are identified by **BOLD and underlined** numbers.

E: Patient Record Audit

There are several criteria in the various clinical Service Elements related to the content of patient records. Such criteria are identified by the words ***patient record audit*** in the guideline statements. In order to assess compliance with these, a structured documentation audit needs to be conducted on a representative sample of patient records from all the clinical services/departments that are being assessed.

Health records/folders of discharged patients are audited for this purpose. Surveyors select patient folder numbers from admission registers in the various clinical departments in the health centre/clinic, including outpatient, emergency (casualty) and professional service settings. The reason for admission/diagnosis of the patient forms the basis of this selection, and surveyors attempt to include in the selection folders that may also contain information on aspects such as:

- Internal transfers/admissions
- External referrals/transfers
- Blood transfusions
- Nutrition therapy
- Informed consent
- Refusing treatment (RHT)
- Resuscitation
- Death

During a survey, the surveyors conduct this patient record audit before they have a group interview with clinical staff, during which they share these audit results with staff. These audit results can therefore not be changed when surveyors browse through active records during subsequent visits to the clinical wards. Also, these results cannot be changed post survey if the clinic/health centre presents progress reports on improvements with regard to remedial actions in this regard.

Surveyors are obliged to sign a Declaration of Confidentiality on appointment and they are expected to maintain the highest level of confidentiality in their handling of patient folders and dealing with patient health information.

F: Patient Interviews

The standards contain several criteria that relate to patient rights, patients' experiences while being attended to in a healthcare facility, the extent to which patients are informed about relevant matters, etc. For some of these criteria, evidence of compliance can only be obtained from the patients' responses and for that reason these criteria have been included in a patient questionnaire which the surveyors will administer in clinical areas of the clinic/health centre during the survey.

Responses from the patients are scored similarly to those for the patient record audit process described above and the average score of each criterion is transferred to the Standard Assessment Manual as the final compliance score for that particular criterion.

G: Additional Comments

I. Several criteria require compliance with laws and regulations. The guideline statements for these criteria indicate that "country-specific" requirements need to be considered for assessing compliance. In instances where country laws/regulations do not exist for such an item, it will be expected that the facility will develop their own internal policy in accordance with internationally accepted norms and standards.

II. Any reference to "staff/personnel" in the standards and criteria should be interpreted to read all personnel employed by the facility unless otherwise stated. The requirements also apply to all healthcare professionals who are allowed to render patient care, regardless of their employment status.

SE 1 MANAGEMENT AND LEADERSHIP

OVERVIEW OF MANAGEMENT AND LEADERSHIP

Effective management of a health facility begins with understanding the various responsibilities and authorities of individuals in the health facility, and how these individuals work together.

At the governance level there is an entity, i.e. Ministry of Health; Department of Clinical Services and its District Health Management Teams (DHMTs), responsible for directing the operation of the primary healthcare facilities and accountable for providing a quality service to the population that seeks care. The responsibilities of the governing authority lie primarily in providing systems, guidelines and resources, to enable the healthcare facility personnel to reach their objectives. It is the responsibility of the national body to define what services are required to best meet the health needs of the community.

The Ministry of Health defines how these services are to be implemented by the primary healthcare facility. Direction for the provision of services is provided from District Health Management Teams level. Managers at this level ensure that centralised expertise is provided to support the personnel of primary health facility services in all their activities. This is provided through visits, written communication, monitoring and education.

At the service level, a manager is appointed for day-to-day management of the healthcare facility. He or she ensures that the policies of the governing authority are implemented and that policies and procedures, appropriate to the specific service, are developed and implemented. The responsibilities of this manager are documented and are known to personnel.

While managers are appointed to posts in the health service, the primary health care facility also identifies persons who take leadership roles, such as senior nurses. These leaders take responsibility for forming teams, which ensure quality in all aspects of patient care. This can usually be done without additional resources, but it does lead to improved use of existing resources.

The lines of responsibility and accountability are documented, and are made easy to follow by being depicted in an organogram. The structure of the health facility depicts all established posts, and explains the lines of accountability for each post incumbent. The personnel in the service need to know how these lines of accountability work, both within the service and up to the most senior officer in the organisation.

The leaders are recognised and brought into the process of defining the health service's mission. Based on that mission, they work collaboratively to develop the plans and policies needed to fulfil the mission and to co-ordinate and integrate the health service's activities.

The lines of communication for achieving these goals are represented on a health facility structure. The health facility structure includes all members of the health service, including those persons at the governing level, to whom the managers have lines of responsibility and accountability. Documents prepared by each healthcare service define their goals and identify current
and planned services.

The managers of each healthcare service/department make their human resources and other resource requirements known to the governing authority. This helps to ensure that adequate human resources, space, equipment and other resources are available to meet patients' needs at all times. The service /department manager is accountable for the cost-effective use of resources.

Standards

1.1 Governance of the Health Facility

1.1.1 The governing body's accountability and responsibilities are documented and are known to the health facility managers.

Standard Intent

According to the Oxford Dictionary to govern is "to conduct the policy, actions and affairs of (a state, organisation or people) with authority." The same source defines governance as "the action or manner of governing a state, organisation, etc." It relates to decisions that define expectations, grant power, or verify performance. It consists of either a separate process or part of management or leadership processes.

A governing body is the group of people given the power and authority to govern an organisation. A governing body can take the form of a board, a council, a steering committee, or an assembly of elders or traditional owners. The role of a governing body is to plan strategic direction, set the organisation's goals, lead the organisation, make the policies and evaluate and support the management and personnel

There is a governing body responsible for directing the operation of the health facility, which is accountable for providing quality healthcare services to its community or to the population that seeks care. The responsibilities and accountability of this entity are described in a document that identifies how they are to be carried out, and are known to those responsible for management within the health facility. The responsibilities of governing bodies lie primarily in approving plans and documents submitted by the managers of the health facility. Those elements of management requiring approval by governance are documented.

The process and practices that will apply will vary significantly given the environment in which they are applied. Governance in the public sector, which includes ministries, boards and similar entities, takes into account legal and constitutional accountability and responsibilities.

In a business or non-profit organisation governance in addition to legal and constitutional accountability, relates to consistent management, policies, processes, guidance and decision rights for a given area of responsibility.

It is important that the health facility has clear leadership, operates efficiently, and provides quality healthcare services. The lines of communication for achieving these goals are presented in an organisational chart or other document.

1.1.1 Criteria

1.1.1.1 Documents describe governance accountability and responsibilities.

Root criterion

Please note that the criterion requires an organisational chart of both the governance structure and the local organisation. This document(s) should also illustrate the relationship between the Facility Manager and the first level of governance above him/her.

The phrase "lines of authority and accountability" requires more than merely a list of available posts or services rendered; it should be formulated in such a manner that it indicates to each staff member who his/her direct supervisor is, and also his/her span of responsibility. It is not a requirement to reflect names of individuals. It goes without saying that as with any other official document the organogram should be duly authorised (dated and signed).

1.1.1.2 There is an organisational chart or document, which describes the lines of authority and accountability from governance and within the service.

A mere organogram does not render this criterion compliant unless there is a concise description/lists of the key functions of the relevant structures as reflected in 1.1.1.1.

Note that some of this information may be contained in Acts, regulations or directives.

1.1.1.3 The responsibilities of governance include providing support to the personnel in the health facility.

1.1.1.4 The support from regional or district managers includes regular supervisory visits, monitoring, written communications and education.

1.1.1.5 The facility has a valid licence, issued by an acknowledged healthcare licensing authority, to operate as a healthcare facility.

Linked criteria:
1.1.1.6, 1.2.1.5

1.1.1.6 This licence covers all services offered by the facility.

Linked criteria:
1.1.1.5

1.1.1.7 The pharmacy is licensed by a relevant licensing body.

Linked criteria:
11.1.1.2

1.1.1.8 The laboratory is licensed by a relevant licensing body.

Linked criteria: *9.1.1.2*

1.1.1.9 The diagnostic imaging service is licensed by a relevant licensing body of radiation control council or equivalent body.

Linked criteria: *10.1.1.3, 10.1.2.1*

1.2 Management of the Health Facility

1.2.1 A senior manager is responsible for operating the health facility within applicable laws and regulations.

Standard Intent

The facility manager is appointed by the organisation to be responsible for the overall, day-to-day operation of the health facility. These responsibilities are documented and known to the personnel of the health facility. The individual appointed to carry out these functions has the required education and experience.

The facility manager is responsible for the implementation of all policies, which have been approved by the governing body.

1.2.1 Criteria

1.2.1.1 The organisation ensures that a qualified individual manages the facility.

This criterion is scored PC in the event that the position is temporarily filled (acting capacity).

1.2.1.2 The facility manager manages the day-to-day operation of the service.

1.2.1.3 The facility manager has the education and experience to carry out his or her responsibilities.

1.2.1.4 The facility manager ensures that approved policies are implemented.

Root criterion *This is an overarching (root) criterion of which the score is derived from the scores of linked criteria. However, this criterion is not assessed on all the policies in the organisation but only those that pertain to the senior management level, e.g. 1.2.1.4 to 1.2.1.6, which include e.g. corporate/national/district matters. In other words, this criterion is not scored down for deficiencies that derive from the level of individual departments. However, the final rating of this criterion should be in line with the overall level of compliance with the "generic" (SEs 2 to 5) policies and procedures.*

Linked criteria:
12.2.2.4

1.2.1.5 The facility manager ensures compliance with applicable Laws and Regulations.

It is unthinkable that this criterion can ever be non-compliant and as it is impossible to assess this criterion in full during an external survey, the criterion will therefore be scored compliant by default. However, a PC rating is given whenever there is actual evidence of non-adherence to any particular legal requirement. In these cases the transgression needs to be recorded in detail in order to motivate for the PC rating, and it should be based on accurate facts.

Common examples of legal non-conformances include the non-availability of fire clearance certificates, certificates of electrical installations and commissioning certificates, e.g. ethylene oxide (EO) sterilisers, pressure test certificates for vessels under pressure; failure to conduct internal/external financial audits; transcribing/dispensing by nurses; incorrect labelling of pharmaceutical items; the non-availability of proof of current licensing/registration of professional personnel with relevant councils, etc.

Linked criteria:
1.1.1.5
2.3.1.1, 2.3.1.2
3.1.1.2
4.3.1.1
5.2.1.2, 5.4.1.2, 5.6.2.1
6.2.1.7, 6.4.3.3
8.2.2.1, 8.2.5.7
9.1.1.2
10.1.2.2
11.5.1.5, 11.6.1.1, 11.6.1.2, 11.7.1.10
12.2.5.2, 12.4.1.1
13.1.4.1, 13.3.4.1

1.2.1.6 The facility manager implements processes to manage and control human, financial and other resources.

This is assessed against the organisational policy framework and evidence of implementation, and is linked to the next criterion. The criterion score is derived from the final assessment of human resource management, financial management and other criteria dealing with adequate supply and effective management of resources (equipment, medication, consumables, etc).The volume and severity of deficiencies in related sections will determine whether both criteria are penalised and to what extent.

Linked criteria:
1.2.2.6
2.1.1.1, 2.1.1.4, 2.1.1.4, 2.2.2.2
6.2.1.1, 6.2.2.9
7.2.1.1
8.2.1.1

9.3.1.1
10.2.2.1
11.4.1.1
12.2.3.8, 12.2.4.1, 12.2.5.1, 12.3.1.3, 12.4.1.3
13.3.3.1

1.2.1.7 Contracts and other arrangements are monitored to ensure that the terms of the contracts are met.

Linked criteria:
5.4.1.3
13.1.2.3, 13.3.1.1, 13.2.2.2, 13.3.1.1, 13.3.2.2

1.2.2 Budgeting, reporting and auditing processes are consistent with statutory requirements and standards.

Standard Intent

A standard method of accounting and reporting is essential for efficient delivery of quality healthcare. Efficient, cost-effective and sustainable service delivery depends upon having up-to-date and accurate financial accounts. A budgeting process results in a defined method of allocating resources.

Financial planning and management needs to be conducted by a person who is suitably qualified and experienced in all matters relating to the health facility's finances. This person must be able to identify financial constraints and possibilities and be able to respond by developing accurate policies or procedures. This person must also be able to advise on how much, what and when to invest as a result of a thorough analysis of plans. Clinical and other leaders need to be included in planning their financial requirements. They also require information relating to the funds available for managing their departments, and up-to-date statements of current expenditure. Sound accounting and auditing practices are implemented to ensure transparency.

1.2.2 Criteria

1.2.2.1 There are written policies and procedures for accounting functions.

The accounting functions describe, at all level, minimally the activities and responsibilities concerning financial administration. These also include the minimal reporting requirements for internal (financial) management and those required by law and regulation.

1.2.2.2 The accounting function is performed by an individual with appropriate training and experience.

Training on financial administrative activities as performed within the facility (and proven capability of performing these accurately) will suffice.

1.2.2.3 The qualified accounting personnel ensure that policies and procedures are available to guide all the personnel and that they are implemented.

1.2.2.4 There are written policies and procedures for maintaining internal and external financial audit systems that meet audit requirements.

1.2.2.5 There are written policies and procedures for the payment of creditors.

1.2.2.6 There is a documented budgeting process.

It is commonly accepted that there are six steps in the budgeting process, viz:
1. *set objectives*
2. *analyse available resources*
3. *estimate budget components from each sector*
4. *co-ordinate and review budget components*
5. *obtain final approval and*
6. *distribute the approved budget to relevant role players.*

Those involved in budgeting must be properly trained and guided in the objectives, benefits, steps, and procedures. The success of the budgeting process requires the co-operation of all levels within the organisation. There should be adequate supervision.

A budget committee should review budget estimates from each segment, make recommendations, revise budgeted figures as needed, and approve or disapprove of the budget.

Linked criteria:
1.2.1.6
12.2.2.1

1.2.2.7 The budgeting process is prepared in a timely manner and is used for expenditure tracking.

1.2.2.8 There is an asset register, which is routinely maintained.

1.2.2.9 There is an inventory, which is checked according to policy.

Linked criteria:
6.2.1.3

1.2.2.10 There is a mechanism for ensuring that the level of debtors is kept to the minimum.

1.2.2.11 There is an effective system for invoicing and billing patients for healthcare services rendered, which includes data quality checks.

1.2.3 The health facility's clinical and managerial leaders are identified and are collectively responsible for creating the plans and policies needed to fulfil the mission.

Standard Intent

Managers are appointed to posts and have a leadership role, leaders of a health facility may come from many sources. These leaders may represent every service in the health facility, e.g. medical, nursing, maintenance, administration, physiotherapy and radiography. Leaders may also be nominated or elected to certain committees, i.e. health and safety committees and infection control committees. Effective leadership is

essential for a health facility to be able to operate efficiently and fulfil its mission. Leadership is given to the organisation by individuals working together and separately and can be provided by any number of individuals.

Leaders may have formal titles, or be informally recognised for their seniority, stature, or contribution to the health facility. It is important that all the leaders of a health facility are recognised and brought into the process of defining the health facility's mission. The leaders work collaboratively to develop the plans and policies needed to fulfil the mission.

1.2.3 Criteria

1.2.3.1 A senior management team is responsible for operations of the facility.

1.2.3.2 The facility's clinical leaders are identified and are collectively responsible for creating plans to fulfil the organisation's mission.

1.2.3.3 The leaders are collectively responsible for ensuring that the mission statement is known to all personnel, patients, carers and the community served.

Linked criteria: *3.8.1.3*

1.2.4 The health facility manager plans for the type of services required to meet the needs of the patients served by the facility, in consultation with community members and/or stakeholders.

1.2.4 Criteria

1.2.4.1 The health facilities manager promotes networking with the leaders of other relevant organisations in the community.

Linked criteria: *3.3.1.5, 3.8.1.3*

1.2.4.2 There is evidence of meetings with representatives of the community.

1.2.4.3 Community leaders (including traditional healers where appropriate) are represented.

1.2.4.4 The management is aware of and accesses services from other provider facilities operating in the area.

Linked criteria:
3.7.1.2
6.1.1.5, 6.1.1.6, 6.1.1.8, 6.5.2.1

1.2.5 The health facility's leaders ensure that policies and procedures are implemented to support the activities of the health facility and to guide the personnel, patients and visitors.

Standard Intent

Policies and procedures are formulated at different levels of authority, e.g Acts and regulations, national health and labour departmental policies and health facility policies.

Leaders must ensure that all policies applying to the health facility are available to the personnel, and that they are implemented and monitored as they relate to various departments, services and functions. Leaders should ensure that policies and procedures are available to guide the personnel in such matters as allocation, use and care of resources, financial practices, human resource management and dealing with complaints from patients and visitors.

The availability and application of specific policies and guidelines will be assessed and measured in the relevant services, e.g. midwifery.

1.2.5 Criteria

1.2.5.1 The health facilities' manager ensures that policies and procedures guide and support the activities and management of the health facility.

Linked criteria:
3.6.1.1
4.4.1.1, 4.4.1.2, 4.5.1.3
5.2.1.4
6.3.2.1, 6.4.2.1, 6.5.1.1
7.3.1.1
8.3.1.1
9.1.1.6, 9.4.1.1, 9.4.1.7
10.1.2.1
11.3.1.1
12.2.1.4, 12.3.1.2, 12.4.1.1
13.1.1.5, 13.2.1.5, 13.3.1.5

1.2.5.2 A designated staff member is responsible for compiling and indexing policies and procedures, and ensuring their circulation, recall and review.

1.2.5.3 Policies and procedures are signed /endorsed by persons authorised to do so.

1.2.5.4 Policies and procedures are compiled into a comprehensive manual, which is indexed and easily accessible to all staff members.

1.2.5.5 All policies and procedures are reviewed at appropriate intervals, dated and signed.

1.2.5.6 There is a mechanism for ensuring that policies are known and implemented.

Linked criteria: *3.1.1.3, 3.2.1.4* *4.5.1.2* *5.1.1.2* *7.3.1.1*

1.2.6 The organisation ensures that supplies and provisions are ordered, received, safely stored and provided to departments in time to meet their needs.

1.2.6 Criteria

1.2.6.1 A suitably qualified individual is designated to control the ordering, storage, distribution and control of equipment and supplies used in the organisation.

Linked criteria: *2.1.1.1*

1.2.6.2 There is a system for ensuring that equipment and supplies are ordered, available, correctly stored and distributed.

Linked criteria: *6.4.2.2* *7.2.2.6* *8.2.3.1*

1.2.6.3 A list of approved suppliers is available.

1.2.6.4 There is a system for monitoring the quality of goods delivered.

Linked criteria: *9.3.1.10*

1.2.6.5 There is a system for monitoring the use of resources and taking corrective actions when required.

1.2.6.6 Secure adequate storage facilities are available.

Linked criteria: *9.3.1.6*

1.2.6.7 Records of goods received and goods issued are available

Linked criteria: *11.5.1.8*

1.2.6.8 The "first expired first out" principle is applied to avoid out dated stock.

1.2.6.9 There is a system for disposing of expired stock, including pharmaceuticals.

Linked criteria: *9.3.1.9* *11.5.1.7, 11.5.1.9*

1.3 Quality Leadership and Design

1.3.1 A quality improvement system is in place.

Standard Intent

If a health facility is to initiate and maintain improvement, leadership and planning are essential.

A comprehensive approach to quality management and improvement includes the following processes:

- planning for improvement in quality
- monitoring how well processes work through indicator data collection
- analysing the data, and
- implementing and sustaining changes that result in improvement.

These processes, when performed well, provide the framework for the health facility and its leaders to achieve the objective of providing quality patient care in a safe, well-managed environment.

The continuous monitoring, analysing and improving of clinical and managerial processes must be well organised and have clear leadership to achieve maximum benefit.

The framework presented in the compliance standards is suitable for a wide variety of structured programmes, and less formal approaches to quality management and improvement. This framework can also incorporate traditional monitoring programmes such as those related to unexpected events (risk management) and resource use (utilisation management).

Well-designed processes or services draw on a variety of information sources. Good process design:

- is consistent with the health facility's mission and plans
- meets the needs of patients, families, the personnel and others

- uses current practice guidelines, clinical standards, scientific literature, and other relevant evidence-based information on clinical practice design
- is consistent with sound business practices
- considers relevant risk management information
- uses information from related improvement activities and
- integrates and connects processes and systems.

A primary responsibility of leaders is to set priorities. Health facilities typically find more opportunities for quality monitoring and improvement than they have human and other resources to undertake. Therefore, the leaders provide focus for the organisation's quality monitoring and improvement activities. The leaders prioritise those critical, high-risk or problem-prone processes that most directly relate to the quality of care and the safety of the environment. The leaders use available data and information to identify areas that must be prioritised.

1.3.1 Criteria

1.3.1.1 There is a relevant training programme to equip the personnel with the necessary competencies for designing, implementing and evaluating a quality management and improvement programme.

Linked criteria: *2.4.2.1*

1.3.1.2 The health centre's manager and personnel collaborate to plan and carry out the quality improvement and patient safety programme.

Linked criteria: *4.2.3.1, 4.3.1.3* *5.1.1.1, 5.1.1.5, 5.3.1.2* *9.5.1.1* *10.3.1.8, 10.3.3.7*

1.3.1.3 The health centre's manager and personnel monitor the quality of data collected by the institution.

Linked criteria: *4.1.1.1, 4.2.1.1*

1.3.1.4 The health centre's manager and personnel design new and modified systems and processes according to quality improvement principles.

1.3.1.5 The quality management and improvement programme reflects the scope of service delivery in relation to managerial, clinical and support services.

1.3.1.6 The quality management and improvement programme reflects all components and quality activities in relation to standard/indicator development, monitoring/evaluation and remedial action.

Linked criteria:
5.6.1.4, 5.6.1.9
6.4.2.11
12.3.1.5, 12.2.6.2

1.3.1.7 There is a process for reviewing patient care.

Linked criteria:
4.3.2.2, 4.4.2.1, 4.4.2.16
6.3.2.5, 6.4.1.4
7.3.2.2
8.4.3.1

1.3.1.8 There is a process for reviewing medication use.

Assess rational prescribing, i.e. monitor over-prescribing and incorrect prescribing.

Linked criteria:11.7.1.6

1.3.1.9 There is a process for monitoring patient satisfaction with the care process, the care environment and the facility's personnel.

Linked criteria:
3.5.1.1
6.3.1.6

1.3.1.10 There is a relevant/appropriate system for reporting on quality management and improvement matters and communicating with all stakeholders concerned.

Linked criteria:
4.3.1.4

1.3.2 Improvement in quality is achieved and sustained.

Standard Intent

The health facility uses the information from data analysis to identify potential improvements to reduce (or prevent) adverse events. Routine monitoring data and data from intensive assessments contribute to an understanding of where improvement should be planned, and what priority should be given to the improvement. In particular, clinical and managerial leaders plan improvements to those data collection areas requiring priority.

The health facility uses appropriate resources and involves those individuals, disciplines, and departments closest to the processes or activities to be improved. Responsibility for planning and carrying out improvement is assigned to individuals or to a team. Any necessary training is provided and information management or other resources are made available.

Once a change is planned, data is collected during a test period to demonstrate that the change is actually an improvement. To ensure that the improvement is

sustained, monitoring data is then collected for ongoing analysis. Effective changes are incorporated into standard operating procedures and any necessary education of the personnel is carried out. The health facility documents those improvements achieved and sustained as part of its quality management and improvement processes.

1.3.2 Criteria

1.3.2.1 The organisation documents the improvements achieved and sustained.

1.3.2.2 This information leads to the development of processes to ensure that quality is sustained.

SE 2: HUMAN RESOURCE MANAGEMENT

OVERVIEW OF HUMAN RESOURCE MANAGEMENT

A health facility needs an appropriate number of suitably qualified people to fulfil its mission and meet patient needs.

Recruiting, evaluating and appointing personnel are best accomplished through a co-ordinated, efficient and uniform process. It is usual for this to be done at a central point. It is also essential to document an applicant's skills, knowledge, education and previous work experience. It is particularly important to review the credentials of health professionals carefully because they are involved in clinical care processes and work directly with patients.

Individual staff members have their responsibilities defined in a current job description/performance agreement. The job description is the basis for assignment, orientation to their work, and evaluation of how well they fulfil their job responsibilities. Consultant personnel have their responsibilities defined in contract agreements.

Healthcare facilities should provide their personnel with opportunities to learn and advance personally and professionally. Thus in-service education and other learning opportunities should be offered.

Standards

2.1 Personnel Planning

2.1.1 There is a plan for the provision of adequate numbers of suitably qualified personnel.

Standard Intent

Appropriate and adequate personnel are critical to patient care. The health facility's leaders define the desired education, skills, knowledge and any other requirements as part of projecting personnel complements and needs.

Personnel retention, rather than recruitment, provides greater long-term benefit. Retention is increased when leaders support personnel development. Thus, the leaders collaborate to plan and implement uniform programmes and processes related to the recruitment, retention and development of all staff members.
There is a written plan, which identifies the numbers and types of personnel required, and the skills, knowledge and other requirements needed in each department and service.

The planning process includes:

a) personnel recruitment
b) the numbers and categories of personnel required
c) the desired education, qualifications, skills and knowledge
d) assignment and reassignment of staff members
e) personal development of staff members and
f) personnel retention

2.1.1 Criteria

2.1.1.1 There are documented processes for staffing the health facility.

It is preferable that all these aspects be summarised in an executive-type summary for ease of access to relevant information. However, this does not preclude the presentation of separate documents related to various structured processes that are guided by policies, procedures, protocols or narratives and should be needs based.

The plan should be available either as part of the strategic planning process or as an operational plan. The plan should include the current personnel establishment, i.e. posts available, posts filled and posts vacant.

The personnel establishment should be based on scientific findings, e.g. analysed work-study findings, catchment area population, patient loads, bed occupancy and patient acuity levels. The study may be conducted in house or by an independent agent.

Minimum staffing levels for professional personnel should be based on accepted national or international norms/standards.
Linked criteria:
1.2.1.6, 1.2.6.1
7.1.1.1
8.1.1.1, 8.1.1.5, 8.1.1.6

9.1.3.2
10.1.2.5
11.1.1.1
12.2.1.1, 12.3.1.1, 12.4.1.2
13.1.1.2, 13.2.1.2, 13.3.1.2

2.1.1.2 The desired education, qualifications, skills and knowledge are defined for all personnel members.

The organisation complies with laws and regulations that define the desired educational levels, skills or other requirements of individual staff members, or define staffing numbers or the mix of personnel for the organisation. The organisation considers its mission and the needs of patients in addition to the requirements of laws and regulations.

Linked criteria:
6.6.3.3, 6.6.3.4
8.1.1.2
9.1.2.1, 9.1.3.1
10.3.1.1, 10.3.3.1

2.1.1.3 Details of the organisation's absenteeism, sickness rates and personnel turnover rates are recorded and analysed, to allow for informed decision making by the management of the organisation.

Linked criteria:
1.2.1.6

2.1.1.4 Details of the personnel establishment (i.e. available posts, filled and vacant posts) are recorded and analysed to allow for informed decision making by the organisation's management.

Linked criteria:
1.2.1.6

2.2 Personnel Management

2.2.1 Personnel files are maintained for all employees.

Standard Intent

Each staff member in the health facility has a record with information about his/her qualifications, results of evaluations, and work history. These records are standardised and are kept current. The confidentiality of personnel records is protected. Personnel records are safely stored, and their contents are monitored to ensure completeness.

2.2.1 Criteria

2.2.1.1 A designated staff member is responsible for the storage and retrieval of personnel records.

2.2.1.2 There is documented personnel information on each staff member.

2.2.1.3 Personnel files are kept current and reviewed annually.

2.2.1.4 Personnel files contain copies of educational certificates and/or licenses.

2.2.1.5 Personnel files contain the current job description and performance agreement.

2.2.1.6 Personnel files contain evidence of orientation to the facility.

2.2.1.7 Personnel files contain copies of records of in-service training and development received.

2.2.1.8 Personnel files contain copies of performance appraisals.

2.2.1.9 Only authorised persons have access to personnel records.

2.2.2 Each staff member's responsibilities are defined in a current job description.

Standard Intent

Individual staff members have their responsibilities defined in a current job description. The job description and performance agreement provides details of accountability, responsibility, formal lines of communication, principal duties and entitlements. It is a guide for an individual in a specific position within an organisation. Key performance areas should be included in order to evaluate the staff member's performance.

2.2.2 Criteria

2.2.2.1 Each employee has a written job description and performance agreement, which defines their responsibilities.

Linked criteria: *13.1.1.4, 13.1.2.1, 13.2.1.4, 13.2.2.1, 13.3.1.4, 13.3.2.1*

2.2.2.2 Each staff member signs their job description and performance agreement to show that that they accept it.

Linked criteria: *1.2.1.6*

2.2.2.3 Job descriptions and performance agreements are reviewed according to organisational policy.

2.2.3 The health facility uses a defined process to evaluate the knowledge and skills of the personnel to ensure that these are consistent with patient needs.

Standard Intent

The health facility defines the process for and the frequency of the ongoing evaluation of the abilities of the personnel. Ongoing evaluation ensures that training and development occurs when needed and that the staff member is able to assume new or changed responsibilities. While such evaluation is best carried out in an ongoing manner, there is at least one documented evaluation each year for each staff member.

2.2.3 Criteria

2.2.3.1 The staff member's registration, education, training and experience are used to authorise the individual to provide clinical services consistent with his/her qualifications.

2.2.3.2 There is at least one documented appraisal of each staff member each year or more frequently as defined by the health facility.

2.2.3.3 New personnel are evaluated as determined by organisational policy.

2.3 Credentialing

2.3.1 There is an effective process for gathering, verifying and evaluating the credentials (registration, education, training and experience) of those healthcare professionals who are permitted to provide patient care independently.

Standard Intent

Healthcare professionals who are registered to provide patient care without clinical supervision are primarily responsible for patient care and care outcomes. These professionals usually include doctors, dentists, nurses, radiographers, and members of other professions allied to medicine. The health facility needs to ensure that it has qualified health professionals who appropriately match its mission, resources and patient needs.

An individual's credentials consist of an appropriate current registration, completion of professional education, and any additional training and experience. There is a process for gathering this information, verifying its accuracy where possible, and evaluating it in relation to the needs of the health facility and its patients. This process can be carried out by the health facility or by an external agency. The process applies to all types and levels of employed persons (employed, honorary, contract and private practitioners).

Evaluating an individual's credentials is the basis for two decisions: whether this individual can contribute to fulfilling the organisation's mission and meeting patient needs, and, if so, what clinical services this individual is qualified to perform.

These two decisions are documented, and the latter decision is the basis for evaluating the individual's ongoing performance.

Please note that this standard applies not only to employed personnel, but to all healthcare professionals who render patient care in the organisation.

2.3.1 Criteria

2.3.1.1 There is a process for evaluating and verifying the credentials (licence, education, training and experience) of medical practitioners.

See intent statement.

This applies to all healthcare professionals who are registered as independent practitioners with their individual registration bodies. Such information is verified from the original sources, when possible.

Employed personnel are identified from the organogram, personnel establishment, personnel allocation lists and consultant practice indicator boards, etc.

Linked criteria;
1.2.1.5
2.3.1.4
8.1.1.3

2.3.1.2 There is a process for evaluating and verifying the credentials (licence, education, training and experience) of nurses and other health professionals.

This applies to all healthcare professionals who are registered as independent practitioners with their individual registration bodies.

Employed personnel are identified from the organogram, personnel establishment, personnel allocation lists and consultant practice indicator boards, etc.

Linked criteria:
1.2.1.5
2.3.1.4
6.4.3.4
10.3.1.2, 10.3.1.3, 10,3,3,2, 10.3.3.3

2.3.1.3 The registration, education, training and experience of these individuals are documented.

Copies of all the relevant original degrees/diplomas/certificates must be available, as well as evidence of registration with the relevant registration bodies.

2.3.1.4 A determination is made about the annual registration of the individual to provide patient care services.

In this context, authorisation to practice in accordance with the individual's qualification must be proven by current registration (licence) with the relevant registering body, where applicable.

Linked criteria:
2.3.1.1, 2.3.1.2

2.4 Personnel Orientation and Education

2.4.1 All staff members are orientated and inducted to the health facility and to their specific job responsibilities at the time of appointment.

Standard Intent

The decision to appoint an individual to the personnel of a health facility sets several processes in motion. To perform well, a new staff member needs to understand the operations of the entire health facility and how his/her specific responsibilities contribute to the health facility's mission. This is accomplished through a general orientation to the health facility and his/her role in the facility, and a specific orientation to the job responsibilities of his/her position. The health facility includes, as appropriate, the reporting of medical errors, infection control practices, the health facility's policies on telephonic medication orders, and so on.

It is important to orientate and induct all healthcare workers. Contract workers and volunteers are also orientated to the health facility and their specific assignment or responsibilities, such as patient safety and infection control.

2.4.1 Criteria

2.4.1.1 There are written programmes for orienting and inducting personnel to the health facility.

The organisation has a generic/macro orientation programme for all employees and evidence of participation is available in the individual's personnel record or other training and development record.

Each individual department/service has established a service-specific orientation programme and evidence of participation is available on the individual's personnel record or other training and development record.

Even if there is only one person in a department, he/she should plan and document an orientation and induction programme in the event that additional personnel should become available in the future.

Linked criteria:
13.1.2.1, 13.2.2.1, 13.3.2.1

2.4.1.2 Contract workers and volunteers are orientated to the health facility, their job responsibilities and their specific assignments.

The organisation has established both generic and service-specific orientation programmes for volunteer and contract workers and evidence of attendance is available.

2.4.2 Each staff member receives on-going in-service education, training and development to maintain or advance his/her skills and knowledge, based on identified needs.

Standard Intent

The health facility has a responsibility to ensure that the personnel are educated in matters that affect their functioning in the specific health facility. In particular, the personnel are trained in health and safety matters, infection control and cardiac life support. The health facility also collects and integrates data from several sources to understand the ongoing educational needs of the personnel. Such sources include monitoring data from the facility management programme, the introduction of new technology, skills and knowledge areas identified through the review of job performance, new clinical procedures, and future plans and strategies of the health facility.

Education is relevant to each staff member as well as to the continuing advancement of the health facility in meeting patient needs and maintaining acceptable performance, teaching new skills, and providing training on new equipment and procedures. There is documented evidence that each staff member who has attended training has gained the required competencies.

2.4.2 Criteria

2.4.2.1 The health facility has a coordinated plan for in-service education.

The organisation has a generic/macro in-service education programme for all employees and evidence of participation is available.

It is preferable that a summarised plan is provided for ease of access to relevant information. However, this does not preclude the presentation of separate documents related to various education, training and development programmes and should be needs based.

Linked criteria:
1.3.1.1
13.1.2.1, 13.2.2.1, 13.3.2.1

2.4.2.2 The health facility uses various sources of data and information to identify the in-service training and development needs of the personnel.

Examples of sources which can be used for establishing training and development needs are:
- *job observations*
- *performance reviews*
- *annual training and development' wish-lists*
- *changes in patient profile and*
- *results from clinical and document audits.*

2.4.2.3 All health facility personnel are provided with on-going in-service education, training and development.

Evidence of on-going in-service education must be submitted by means of analysed attendance data.
Refer to skills development, continuing education strategies and service-specific programmes to evaluate relevance.

Linked criteria:
5.1.1.5, 5.6.1.5
6.4.2.3
7.4.2.2
9.1.3.3, 9.1.3.4
12.2.3.5, 12.2.4.4, 12.4.1.9
13.1.2.5, 13.2.2.1, 13.3.2.1, 13.3.2.4

2.4.2.4 Personnel competencies, where relevant, are assessed and recorded before and after in-service training and development.

The organisation identifies where competencies must be tested before and after training and development. These should include the use of complex medical, technical, and electronic equipment, resuscitation techniques, fire safety, etc.

Evidence must be provided of the tests conducted to determine the individual staff member's competence.

Linked criteria:
6.6.1.2, 6.6.1.4, 6.6.2.2, 6.6.6.2

2.4.3 Staff members participate in continuing education, research, and other educational experiences to acquire new skills and knowledge and to support job advancement.

Standard Intent

The health facility has a process for informing the personnel of opportunities for continuing education and training, participation in research and investigational studies, and to acquire advanced or new skills. These opportunities may be offered by the health facility, by a staff member's professional or trade association, or through educational programmes in the community. The health facility supports such opportunities as appropriate to its mission and resources. Such support may be given through tuition support, scheduled time away from work, recognition for achievement and in other ways.

2.4.3 Criteria

2.4.3.1 The health facility supports continuing education for its professional personnel and maintains records of this in personnel files.

This refers specifically to professional personnel and the requirements for continued registration with the relevant professional bodies, where applicable. Management must have a strategy for assisting professional personnel to maintain their continued registration.

2.4.3.2 There is a development strategy for the health facility that ensures that managers receive the training and development required to fulfil their responsibilities.

This criterion refers to managers of all departments and services. Training and development could include formal management training or those specific skills required by the individual as identified by means of skills audits or performance reviews.

2.4.3.3 Personnel members are informed of opportunities to participate in advanced education, training and development, research, and other experiences.

SE 3: PATIENT AND FAMILY RIGHTS &RESPONSIBILITIES AND ACCESS TO CARE

OVERVIEW OF PATIENT AND FAMILY RIGHTS & RESPONSIBILITIES AND ACCESS TO CARE

Each patient is unique, with his or her own needs, strengths, values and beliefs. Health facilities work to establish trust and open communication with patients and to understand and protect each patient's cultural, psychosocial and spiritual values.

Patient care outcomes are improved when patients and, as appropriate, their families or those who make decisions on their behalf, are involved in care decisions and processes in a way that matches cultural expectations.

To promote patient rights in a health facility, one starts by defining those rights and responsibilities, followed by educating patients and the personnel about those rights. Patients are informed of their rights and how to act on them. The personnel are taught to understand and respect patients' beliefs and values and to provide considerate and respectful care, thus protecting the patients' dignity.

How these processes are carried out in a health facility depends on national laws, regulations and charters and any international conventions, treaties or agreements on human rights endorsed by the country.

In order to meet the community's needs for services, the health facility has to clearly define the boundaries of the community, and the level/ scope (boundaries) of the services provided by the health facility. Service managers are competent in defining these geographic areas and assessing the social and healthcare needs of their inhabitants. Equitability and availability of service provision are assisted through community participation.

Patients and their families need complete information on the care and services offered by the health facility as well as how to access those services. Providing this information is essential to building open and trusting communication between patients, their families and the health facility. Such information helps match the patient's expectations with the ability of the health facility to meet those expectations.

When the necessary care is beyond the health facility’s mission and capabilities, information on alternative sources of care and services is provided.

The service provider does the co-ordination with other services in the district/ the facility provide coordination of services with other facilities in the district, and ensures that patients are appropriately referred to the services that meet their ongoing care needs. All patients are referred to the next level of care, when their needs fall beyond the competence of the clinic personnel. Patients who need additional health or social services are referred appropriately, according the facility’s referral guidelines.

Standards

3.1 Implementation of Patient Rights and Responsibilities

3.1.1 The health facility has a patient rights and responsibilities policy.

Standard Intent

A health facility's leaders are primarily responsible for the way in which that health facility treats its patients. The leaders need to know and understand patient and family rights and their health facility's responsibilities as specified in national laws, charters and regulations. The leaders provide direction to ensure that the personnel throughout the health facility assume responsibility for protecting these rights. To effectively protect and advance patient and family rights, the leaders work collaboratively, and seek to understand their responsibilities in relation to the community served by the health facility.

Patient and family rights are a fundamental element of all contacts between the personnel of a health facility and patients and families. Thus, policies and procedures are developed and implemented to ensure that all staff members are aware of and respond to patient and family rights issues, including their role in supporting the right of patients and families to participate in the care process.

Admission to a health facility can be a frightening and confusing experience for patients, making it difficult for them to understand and act on their rights. Thus, the health facility provide information on patient and family rights, and this is given to patients when they enter the health facility for care, and is available throughout their stay, e.g. the statement may be displayed as a poster in the facility and must be appropriate to the patient's age, understanding and language. When written communication is not understood (effective or appropriate), the patient and family are informed of their rights in a manner they can understand.

3.1.1 Criteria

3.1.1.1 Organisational policy regarding patient and family rights is implemented.

Root criterion

This refers to the multidisciplinary participation and responsibility to ensure the implementation of all aspects pertaining to patient and family rights. Evidence of such collaboration can exist in the form of meetings, policies and procedures, information-sharing sessions, in-service training, relevant entries in patient records.etc.

*This is a **root criterion** that covers all operational aspects that are referred to in this Service Element. Its rating therefore needs to reflect the aggregated compliance obtained throughout all sections of this document as well as the added-on sections on patient rights in all clinical documents.*

3.1.1.2 Where applicable, relevant charters, laws and regulations are included in organisational policies regarding patient and family rights.

Patient and family rights are identified and documented in accordance with relevant and current Laws, Charters and Regulations. Where these do not apply other guidelines, e.g. WHO publications, could be consulted.

This is self explanatory and refers to national documentation on these rights (e.g. National Patient Rights Charter) as well as any additional documentation such as organisation-specific policies and procedures.

This criterion has a critical status: - if it is rated NC or PC, criterion 3.1.1.1 cannot be scored compliant.

3.1.1.3 The personnel are trained on the policies and procedures and their participation in care processes.

3.2 Protection of Privacy

3.2.1 The health facility takes measures to protect patient privacy.

Standard Intent

The health facility ensures that the patient's needs for privacy are respected, especially when the patient is providing personal information and undergoing clinical examination. Patients may desire privacy from other personnel, other patients, and even from family members.

Medical and other health information, when documented and collected in a patient record or other form, is important for understanding the patient, his/her needs, and for providing care and health facilities over time. Documented and kept/stored patient's medical and other health information in patients' records or other forms is important for understanding the patient's needs and providing care over time. The health facility respects such information as confidential, and has implemented policies and procedures that protect such information from loss or misuse. The personnel respect the confidentiality of patient information by not posting information on the patient's door or at the nursing station and by not holding patient-related discussions in public places. The misuse of patient information can result in the patient's loss of dignity, employment, and damage to personal or family relationships. Such information can be misused by the personnel of the health facility, family members or others not authorised to have access to the information.

3.2.1 Criteria

3.2.1.1 The patient's need for privacy is protected during all examinations, procedures and treatments.

The score of this criterion is derived from assessments done in all clinical areas of the facility where patients are interviewed, examined and treated.

3.2.1.2 The patient's need for privacy is protected when providing personal information.

This is the same as for 3.2.1.1 above, but note that this criterion also applies to settings where the patient provides personal information, e.g. at the main reception desk.

3.2.1.3 The patient's right to privacy is protected for all forms of counselling.

3.2.1.4 Policies and procedures to prevent the loss or misuse of patient information are implemented.

3.2.1.5 The policies include the right to confidentiality of patient records.

3.3 Right to Health Education

3.3.1 The health facility supports and protects the right of patients and families to participate in the patient care process.

Standard Intent

Every patient is offered the information and education he or she requires. Health facilities may choose to appoint education coordinators, education committees or they may work with all personnel to provide education in a coordinated manner.

3.3.1 Criteria

3.3.1.1 The health facility plans education consistent with its patient population.

3.3.1.2 There is an appropriate structure or mechanism for education throughout the health facility.

3.3.1.3 Patient and family education promotes the concept of taking responsibility for one's own healthcare.

3.3.1.4 The patient and his/her family are taught in a language and format that they can understand.

3.3.1.5 The health facility identifies and establishes relationships with community resources, which support continuing health promotion and disease prevention education.

3.3.1.6 There is a uniform process for recording patient education information.

3.4 Right to Treatment and to Refuse Treatment

3.4.1 The health facility respects the rights of patients and families to receive treatment and to refuse or discontinue treatment.

Standard Intent

Patients, or those making decisions on their behalf, may decide not to proceed with

the planned care after it has been initiated. Their ability to do so will be controlled by applicable laws and regulations. The health facility informs patients and families about their right to make these decisions, about the potential outcomes that could result from these decisions, and about their responsibilities related to such decisions. Patients and families are given information on any care and treatment alternatives. The personnel are informed of their responsibility to implement and respect the choices of patients.

3.4.1 Criteria

3.4.1.1 Patients are informed about their condition and the proposed treatment.

3.4.1.2 Patients and families are informed about their rights to refuse or discontinue treatment.

3.4.1.3 Patients are informed about the consequences of such decisions.

3.5 Right to Voice Complaints

3.5.1 The health facility informs patients and their families about the processes it has instituted to receive and act on complaints, conflicts and differences of opinion about patient care, and the patient's right to participate in those processes.

Standard Intent

Patients have a right to voice complaints about their care, and to have those complaints reviewed and, where possible, resolved. Also, decisions regarding care sometimes present questions, conflicts or other dilemmas for the health facility and the patient, family or other decision makers. These dilemmas may arise around issues of access, treatment or discharge. The health facility has established processes for seeking resolutions to such dilemmas and complaints. The health facility identifies in policies and procedures, those who need to be involved in the processes and how the patient and family participate.

3.5.1 Criteria

3.5.1.1 There is a mechanism to allow complaints to be heard and acted upon.

3.5.1.2 Patients are aware of their right to voice complaints and the processes by which to do so.

3.5.1.3 Complaints are recorded, evaluated and analysed to allow interventions to be instituted.

3.6 Informed Consent

3.6.1 The health facility has a clearly defined process for obtaining consent.

Standard Intent

One of the main ways that patients are involved in their care decisions is by

granting informed consent. The patient must be provided with all information relating to the planned care' to enable him or her to make decisions. The consent process is clearly defined by the health facility in policies and procedures. Relevant laws and regulations are incorporated into the policies and procedures.

Informed consent for care sometimes requires that people other than (or in addition to) the patient be involved in decisions about the patient's care. This is especially true when the patient does not have the mental or physical capacity to make care decisions, when culture or custom dictate that others make care decisions, or when the patient is a child or minor. When the patient cannot make decisions regarding his or her care, a surrogate decision-maker is identified. When someone other than the patient gives the consent, that individual is noted in the patient's record.

3.6.1 Criteria

3.6.1.1 Policies and procedures guide the personnel in the process of obtaining informed consent.

The consent form must include both the type of anaesthetic to be used and the procedure to be performed. If only one of the two is recorded, the criterion will be scored PC.

While anaesthetics will not be used in most of these facilities, informed consent must still be obtained for certain procedures e.g. HIV testing.

Policies and procedures should be aligned to national guidelines on obtaining verbal and written consent.

3.6.1.2 The health facility has a procedure, which is implemented, when others have to grant informed consent.

3.7 Access to Care

3.7.1 Patients have access to the health facility based on their identified healthcare needs and the health facility's mission and resources.

Standard Intent

Health facilities frequently serve communities with a diverse population. Patients may be aged, have disabilities, speak multiple languages or dialects, be culturally diverse, or present other barriers that make the process of entering the health facility and receiving care very difficult. The health facility is familiar with these barriers and has implemented processes to eliminate or reduce these barriers during the entry process. For instance, wheelchairs will be available for the physically disabled, the personnel will be trained to communicate with the hard of hearing, and translation services will be available for those who speak foreign languages. Mechanisms for meeting these needs will be documented and known to the personnel.

3.7.1 Criteria

3.7.1.1 The health facility renders services based on the needs of the population, but at least for eight hours a day, five days a week.

3.7.1.2 The health facility has access to Emergency Medical Services (EMS).

National requirements will be taken into account. It is understood that, in many cases, ambulance services may not be readily available, but there should also be evidence of negotiations to relieve such a situation. Alternative arrangements will be assessed as to suitability and effectiveness.

3.7.1.3 There are patient's appointment systems, where appropriate.

3.7.1.4 Patients who are waiting are advised of any delays that may be experienced in receiving attention.

3.7.2. *Measures are in place to ensure that patient access to the facility is facilitated by adequate infrastructural arrangements.*

3.7.2 Criteria

3.7.2.1 There is an access road to the facility.

3.7.2.2 The condition of the road does not make it difficult for patients to reach the facility (e.g. traffic, road works, safety, ambulance access).

3.7.2.3 The road is accessible throughout the year (e.g. take a situation like the rainy season into account).

3.7.2.4 Direction signs to the facility are clearly readable and up to date.

3.7.2.5 A telephone / emergency number is available.

3.7.2.6 The name of the health facility and its purpose is clearly indicated on the site.

3.7.2.7 Parking is made available close to the building entrance for patients, including the physically challenged.

3.7.2.8 There is wheelchair access to and within the building.

3.7.2.9 Ramps and stairs include safety features such as rails.

3.7.2.10 Directions to the different departments are clearly indicated.

3.8 Information for Patients about the Services Offered

3.8.1 The health facility has a process for informing patients and their families about its services and how to access those services.

Standard Intent

To improve access to its services, the health facility provides information to the community on its services and hours of operation and how to obtain care.

During the entry process, patients and their families receive sufficient information to make informed decisions about seeking care. Information is provided on proposed care, the expected results, and any expected cost to the patient or family for that care, when this is not paid for by a public or private source. Patients and families need complete information on the care and services offered by the health facility and on how to access those services. Providing this information is essential to building open and trusting communication between patients, families and the health facility. This information helps to match the patient's expectations to the ability of the health facility to meet those expectations. When the necessary care is beyond the health facility's mission and capabilities, information on alternative sources of care and services is provided

For patients and families to participate in care decisions, they need basic information regarding the medical conditions found during assessment and on the proposed care and treatment. Patients and families understand when they will be given this information and who is responsible for giving them. Patients and families understand the kinds of decisions that must be made about care and how to participate in those decisions. In addition, patients and families need to understand the health facility's process for obtaining consent and which care processes, tests, procedures and treatments require their consent.

While some patients may not wish to personally participate in the decisions regarding their care, they are, nevertheless, given the opportunity, and can choose to participate through a family member or friend or a surrogate decision-maker.

3.8.1 Criteria

3.8.1.1 Patients are given information about the care and services provided by the health facility.

This indicates some form of publicity and advertising by means of the notice boards, media, brochures, open days, website, help-desk, etc.

3.8.1.2 Information is provided in a way and in a language that is understood by those making the care decisions.

3.8.1.3 Information on services, hours of operation, and processes for obtaining care is provided to agencies and referral sources in the community, and to the population served.

SE 4: MANAGEMENT OF INFORMATION

OVERVIEW OF MANAGEMENT OF INFORMATION

Although computerisation and other technologies improve efficiency, the principles of good information management apply to all methods, whether paper-based or electronic. These standards are designed to be equally compatible with non-computerised systems and future technologies.

Each service determines its information requirements for improving managerial and clinical care. Objectives are set for each programme, and information is required to ensure that these objectives are met.

Required levels of security and confidentiality are applied. An effective process defines who has access to information, the information to which an individual has access, the user's obligation to keep information confidential and the process followed when confidentiality and/or security are violated. The service develops a policy to authorise such individuals and identifies the content and format for entries into patient records. There is a process for ensuring that only authorised individuals make entries in patient records.

The service's information management plan, once complete and approved, is implemented. The health facility provides the staff, technology and other resources necessary to implement the plan and meet the identified information needs of the healthcare providers, managers and others. The management ensures that the personnel have the necessary supplies, registers, check lists, forms, etc for data management.

Those individuals in the health facility, who generate, collect, analyse and use data and information are educated and trained to participate effectively in the management of information and to understand the need for security and confidentiality of data and information.

Aggregated data provides a profile of the service over time and allows the comparison of its performance improvement activities. In particular, aggregated data from patient visits and treatment provided (e.g. immunisations) can help the health facility understand its current performance and identify opportunities for improvement. Data is used for utilisation review and for analysing costs per patient.

By participating in external performance databases, a health facility can compare its performance to that of other similar health facilities, locally or nationally. Performance comparison is an effective tool for identifying opportunities for improvement and documenting the service's performance level.

The information management process makes it possible to combine information from various sources and generate reports to support decision-making. In particular, the combination of clinical and managerial information assists the leaders of the health facility to plan collaboratively. The information management process supports leaders with longitudinal and comparative data. Service managers and leaders use this data to improve the quality of the services offered.

The clinical record of each patient needs to contain sufficient information to support the diagnosis, justify the treatment provided, and document the care given. A standardised format and content of a patient's record will help promote the integration and continuity of care among the various providers of care to the patient, and the health facility determines the specific data and information recorded in the clinical record.

Uniform use of diagnostic and procedure codes supports data aggregation and analysis. Abbreviations and symbols are also standardised. Such standardisation is consistent with recognised national standards.

Each service has a process for assessing the quality and completeness of patient records. This is a part of the health facility's performance improvement activities and is carried out regularly. The clinical record review is based on a representative sample of the practitioners providing care and of the types of care provided. The review process is conducted by doctors, nurses and other relevant clinical professionals, who are authorised to make entries in the patient records. The focus of the review is on the quality of the records and the clinical information available during the care process. This applies to records kept on outpatient cards, as well as patient files.

Standards

4.1 Information Planning

4.1.1 The health facility meets the information needs of all those who provide clinical care, those who manage the service, and those outside the health facility who require data and information from the health facility.

Standard Intent

Information is generated and used during patient care and for safely and effectively managing an organisation. The ability to capture and provide information requires effective planning. Planning incorporates input from a variety of sources:

- the care providers
- the organisation's managers and leaders and
- those outside the organisation who need or require data or information about the organisation's operational and care processes.

The most urgent information needs of those sources influence the organisation's information management strategies and its ability to implement those strategies. The strategies are appropriate for the organisation's size, complexity of services, availability of trained personnel and other human and technical resources. The plan is comprehensive and includes all the departments and services of the organisation**.**

There is a system integrating administrative data such as numbers of patient per department, enrolment data, utilisation, bed occupancy rate where applicable and human resources data supported by IT or paper-based administration systems. The collection of data is based on the systematically investigated need for information within the organisation.

4.1.1 Criteria

4.1.1.1 The health facility uses a health information system that facilitates the collection and utilisation of data.

Root criterion

Refer to the standard intent above for guidance on the content and purpose of this plan. It is desirable that this is an integrated plan incorporating all the required components. However, such a plan may exist in different formats, e.g. separate information management manuals, or various electronic modules.

Whatever format exists, an executive summary, which reflects all data management components in the organisation, must be available. This should include finances, human resources, equipment, patient care, medication, supplies, quality management, infection control, etc. The "plan" should include all the requirements stated in this service element document.

A simple manual system that captures finances, supplies, patient numbers and basic utilisation data would be required for internal management purposes and, where applicable, external reporting.

*As this is a **root criterion**, its rating needs to reflect the aggregated scores of all criteria in this section that deal with subsections of the "plan", as well as the implementation thereof.*

Note: this includes quality management information.

4.1.1.2 The information system includes data required to measure the objectives set for each programme provided by the health facility.

The data minimally required to monitor a facility's activities needs to be captured systematically.

4.1.1.3 The requirements for the collection, collation, validation and distribution of data are clearly defined in the system.

4.1.1.4 The system identifies those permitted access to each category of data and information.

4.1.1.5 The health facility collects data in a timely and efficient manner.

4.1.1.6 Systems are in place for the storage and retrieval of patient information.

This applies to both electronic and paper-based systems. Continuity of care must be ensured by the availability of records of patient information. Whatever system is used will be assessed for accessibility and maintenance of confidentiality.

4.2 Analysis of Data

4.2.1 There is a relevant system for the analysis of data.

Standard Intent

To reach conclusions and make decisions, data must be aggregated, analysed and transformed into useful information. Data analysis involves individuals with an understanding of information management and skills in data aggregation methods, and in the use of various statistical tools. Data analysis involves the individuals responsible for the process or outcome being measured. These individuals may be clinical, managerial or a combination. Thus, data analysis provides continuous feedback of quality management information to help those individuals make decisions and continuously improve clinical and managerial processes.

The health facility determines how often data are aggregated and analysed. The frequency depends on the activity or area being measured, the frequency of measurement, and the health facility's priorities. For example, clinical data may be analysed weekly to meet national regulations, such as incidence on patient fall data may be analysed monthly if falls are infrequent. Thus aggregation of data at points in time enables the health facility to judge a particular process's stability or a particular outcome's predictability in relation to expectations.

When the health facility detects or suspects an undesirable change from what is expected, it initiates intense analysis to determine where best to

focus improvement. In particular, intense analysis is initiated when levels, patterns or trends vary significantly or undesirably from:

- what is expected
- those of other health facilities or
- recognised standards.

Certain events related to specific processes always result in intense analysis to understand the cause and prevent recurrence. When appropriate to the health facility's services, these events include:

- confirmed transfusion reactions,
- significant adverse drug reactions,
- significant medication errors,
- significant discrepancies between preoperative and postoperative diagnose, and
- significant adverse anaesthetic events.

Each health facility establishes which events are significant and the process for their intense analysis. When undesirable events can be prevented, the health facility works to carry out preventive changes.

The goal of data analysis is to be able to compare a health facility in four ways:

- with itself over time, such as month to month, or one year to the next
- with other similar health facilities, such as through reference databases
- with standards, such as those set by accrediting and professional bodies, or those set by laws or regulations and
- with desirable practices identified in the literature, such as practice guidelines.

These comparisons help the health facility to understand the source and nature of undesirable change and help to focus improvement efforts.

Understanding statistical techniques is helpful in data analysis, especially in interpreting variation and in deciding where improvement is needed. Run charts, control charts, histograms and Pareto charts are examples of statistical tools that are useful when seeking to understand trends and variations in healthcare.

4.2.1 Criteria

4.2.1.1 Data is aggregated, analysed and transformed into useful information.

Data needs to be collected and presented in a systematic manner to serve as input for internal management.

Use data for benchmarking, i.e. comparison within the health facility and with similar health facilities, when possible.

Feedback from the supervisory body, where relevant, aids the process.

4.2.1.2 The frequency of data analysis is appropriate to the process under study.

4.2.1.3 The frequency of data analysis meets the requirements of the health facility.

4.2.1.4 Intense analysis of data takes place when there are significant adverse levels, patterns or trends, as established by the health facility.

4.2.1.5 Statistical tools and techniques are used in the analysis process when suitable.

The degree of sophistication will depend on the information required, e.g. graphs, etc.

4.3 Information Usage

4.3.1 Health statistics are collected as required and reported in a timely manner to responsible officers.

4.3.1 Criteria

4.3.1.1 The health facility contributes to external reference databases when required by laws or regulations.

Data required in terms of law or regulation may be submitted directly by the health facility or via the health facilities district management office. Such data can also be used by the facility for its own benefit, where relevant. Feedback from the relevant authorities to whom the data is submitted should be readily available, to the facility in order to improve its services.

4.3.1.2 The health facility manager or delegated person checks data leaving the facility for completeness, correctness and consistency.

4.3.1.3 The performance of the facility on identified priority indicators forms part of the discussions at regular staff meetings.

4.3.1.4 The performance of the facility on identified priority indicators forms part of the discussions at meetings with community representatives.

4.3.1.5 Targets for identified priority indicators are known to the facility manager and the information co-ordinator for the facility.

4.3.1.6 The facility uses information from external data sources for benchmarking.

4.3.2 There is a programme for using information to improve practice.

4.3.2 Criteria

4.3.2.1 Data relating to the meeting of objectives for each programme are made available to the health facility personnel at least quarterly.

This is necessary to check if activities are below or above planned levels and to decide if corrective action is necessary to meet expectations.

4.3.2.2 Data is analysed and used to provide relevant information for improving the clinical service.

4.3.2.3 There is a regular scheduled meeting, at least quarterly, to review institutional mortalities and morbidities.

This must include monitoring complications and reviewing the preventive measures implemented. Both inpatients, where applicable, and outpatients need to be included, according to the patient profile of the relevant clinic.

4.4 Patient Health Records

4.4.1 The organisation has defined the type and content of patient records.

4.4.1 Criteria

4.4.1.1 There are written policies and procedures relating to the type of patient record used, e.g. carry cards or other health records.

Include the records expected at clinic level.

4.4.1.2 Policies specify the records or registers relating to the visits of each patient to be kept by the health facility.

4.4.1.3 Standardised diagnostic and procedure codes are used, if required.

The ICD 10 codes, for example.

4.4.1.4 Symbols and definitions are standardised.

4.4.1.5 Each patient has a record which is provided with a unique number.

4.4.2 Patient records contain the required information.

Standard Intent

There is a clinical record for each patient and it contains the following documented information:

- sufficient information to identify the patient
- an intake history and the findings of a physical examination that support the diagnosis and justify the treatment, and
- the course and results of treatment.

This information promotes continuity of care among healthcare providers.

4.4.2.1 The patients' records are up to date to ensure the transfer of the latest information between care providers.

Root criterion

Taking the condition of the patient into account, do the notes indicate that assessments and re-assessments by all relevant care givers have taken place at appropriate intervals and are recorded? The score of this criterion is determined by the scores of the criteria that follow. If doctors' or any other healthcare providers' notes are not available, this criterion will be scored PC.

Compliance will be verified during the ***patient record audit.***

4.4.2.2 The complete patient record containing notes by medical, nursing and other health professionals should be readily available to healthcare providers.

4.4.2.3 There is a standardised format for recording patient assessment and treatment.

Forms should be designed to guide the person recording the information. Such information should include the history, the findings on examination, diagnostic test results, diagnosis and treatment.

4.4.2.4 The signature and designation of the signatory can be identified for each patient record entry.

4.4.2.5 The date of each patient record entry can be identified.

4.4.2.6 The plan of care for each patient is noted in the patient record.

Root criterion.

The patient's plan of care is modified when the patient's needs change.
To ensure co-ordination of patient care, all members of the team should be included in the formulation of this policy framework, especially doctors and nurses. This applies to all the following criteria of this standard.

Compliance will be verified during the ***patient record audit****.*

4.4.2.7 Nursing care plans are updated after each shift.

4.4.2.8 All procedures and diagnostic tests requested are noted in the patient's record.

The term "written" here implies documented evidence. Such evidence may include nurses' and doctors' notes, as well as printed reports, which are filed in the patient record.

Compliance will be verified during the patient record audit.

4.4.2.9 There is evidence of review of the results of procedures and diagnostic tests performed.

4.4.2.10 Re-assessments are documented in the patient's record.

4.4.2.11 Medications prescribed and administered are recorded for each patient.

4.4.2.12 Adverse drug reactions are noted in the patient's record.

This is a generic policy that describes the procedure to be followed in the case of an adverse drug reaction. This includes reporting to the Drug Regulatory Unit. The prescribed form should be readily available.

If no policy is available, this criterion (as well as the next two criteria) will be scored NC. If a policy is available, but no adverse effects were reported in the files audited, this criterion is scored compliant and criterion 10.4.2.6 will be scored NA.

*Check for relevant documentation during the **patient record audit**.*
Is there evidence that the policy has been implemented? The pharmacist keeps records of events that have been reported to him/her and to the relevant authorities.

4.4.2.13 Medication errors are reported through a process and within a time frame defined by the organisation.

4.4.2.14 Patient and family education provided is noted in the patient's record.

*All education given to a patient must be recorded in the patient records. This will be verified during **record audits.** It is important that a short reference is made to what education was given. If pamphlets have been given to the patient, this should also be recorded in the patient's record.*

Some organisations record the process in the nurses' notes, while others have designed forms to record whatever education is given. Whatever method is used, it must be used uniformly throughout the organisation.

4.4.2.15 Follow-up instructions are recorded in the patient's record.

4.4.2.16 A document audit process regularly reviews patient records.

The sample size needs to be defined, e.g. at least 10 records or a percentage of admissions.

4.4.2.17 Clinical information is used in clinical monitoring as part of a structured clinical audit.

The results are analysed and appropriate interventions instituted as part of the quality improvement process.

4.4.3 A discharge summary is written for each inpatient, and made available in the patient's record.

Standard Intent

The discharge summary is one of the most important documents to ensure continuity of care and facilitate correct management at subsequent visits. Information provided by the organisation may include when to resume daily

activities, preventive practices relevant to the patient's condition and, when appropriate, information on coping with disease or disability.

The summary contains at least:

a) the reason for admission,
b) the diagnosis of main and significant illnesses,
c) the results of investigations that will influence further management,
d) all procedures performed,
e) the patient's condition at discharge and
f) discharge medications and follow-up instructions.

4.4.3 Criteria

4.4.3.1 A discharge summary, which includes items a) to f) in the intent statement, is written by the medical practitioner at the discharge of each patient.

4.4.3.2 Each record contains a copy of the discharge summary.

4.5 Health Record Maintenance

4.5.1 There is an established health record storage system that ensures confidentiality and safety.

Standard Intent

Health record management must be implemented by a person with suitable training and experience. The manager controls the safe storage and retrieval of files. Files must be readily available each time the patient visits a healthcare professional, and therefore must be filed in such a way that they are easily identified. Policies and procedures, as well as managerial supervision, ensure the safety and confidentiality of files. Loss of information may be through electronic failure, fire, flood or theft. The organisation develops and implements a policy that guides the retention of patient records and other data and information. Patient records and other data and information are retained for sufficient periods to comply with law and regulation and support patient care, the management of the organisation, legal documentation, research and education. The retention policy is consistent with the confidentiality and security of such information. When the retention period is complete, patient records and other data and information are destroyed appropriately.

Facilities make more and more use of electronic systems, requiring these standards and criteria to be assessed appropriately in such instances. These electronic systems vary greatly in their application and can range from a simple spreadsheet to register all patient admissions/folders, to very sophisticated systems where the entire patient record is kept electronically.

Often, organisations do not have a single, central location from where records are managed and it is important to apply the standards and criteria to ALL areas where patient records are being handled, stored or archived. All these areas (that are under the control/management of the organisation) need to be visited during the survey, even if located off-site (e.g. across the street, on an adjacent plot, or within reasonable travelling distance). This assessment does not include warehouses of

private companies to whom the archiving of records has been contracted out, as the service agreement/contract will have to make provision for monitoring compliance with specifications.

4.5.1 Criteria

4.5.1.1 A designated individual is responsible for the storage, maintenance and retrieval of health records.

4.5.1.2 The health facility manager ensures that policies and procedures are implemented to guide the personnel.

4.5.1.3 Policies and procedures relate to the safeguarding of information in the record against loss, damage, breach of confidentiality, or use by unauthorised persons.

Although the statement is quite straightforward, it is worth noting that it covers quite a broad range of safety and security measures (e.g. poor control measures on the handling and movement of files, theft, fire, flooding, rodents, etc.) and all these aspects require assessment before a rating of compliance can be allocated.

The criterion cannot be scored unless the entire department, including archives, and its functions have been assessed.

All other departments where patient records are kept should also be assessed.

4.5.1.4 There is a system, which allows for the rapid retrieval and distribution of health records.

This refers to the manner in which the records are filed and organised in order to allow for easy retrieval of records and making them available for the required intervention. It therefore considers not only the function within the health record room or archive, but also the activities that involve the movement of files to the end-point of use.

4.5.1.5 The filing system allows for incorrectly filed records to be easily identified (e.g. through colour coding of the records).

Please note that a colour coding system is merely an option and NOT a requirement. Organisations may apply different methods as long as the system allows such misfiling to be identified. Assessors should use their own judgement as some of the colour-coding systems in use are ineffective in providing such control, e.g. when the different types of patients (maternity, paediatrics, HIV/AIDS, RTA) are allocated a specific colour, which is intended for the easy identification of files and has no bearing on the "misfiling" aspect.

4.5.1.6 The health facility has a policy on the retention of patient records and other data and information.

4.5.1.7 The retention process provides the necessary confidentiality and security.

4.5.1.8 Policies and procedures are developed for health record destruction, specifying the criteria for selection and the method of destruction.

4.5.1.9 There is provision for authorised access to patient records at all times.

This is self-explanatory, but the following needs to be noted.
The organisational policy framework needs to indicate who these "authorised" individuals are, and the arrangements should be such that there are "authorised" individuals available 24 hours per day.

There may be no "health record personnel" on duty after hours and nurses manage the administrative admission process, which allows them access to the health record section without necessarily being "authorised" in writing to have such access.

4.5.1.10 Storage space for health records is sufficient and secure against unauthorised entry.

The criterion is not specific in terms of what type of access control should be in place but it is expected that some form of access control is exercised, such as locked doors or security gates, the provision of electronic access control codes, etc. Burglar bars should be fitted to windows in the absence of intruder alarm systems. This is particularly important for the security of archives that are not manned 24 hours per day.

SE 5: RISK MANAGEMENT

OVERVIEW OF RISK MANAGEMENT

Health facilities work to provide a safe, functional and supportive facility for patients, families, personnel, volunteers and visitors. To reach this goal, facilities, equipment and medication must be effectively managed. In particular, management must strive to:

- identify, evaluate, reduce and control hazards and risks
- prevent accidents and injuries and
- maintain a safe environment.

Effective management includes the planning, education and monitoring of resources needed to safely and effectively support the clinical services provided in the in-patient, day care and home care settings. All the personnel are taught how to reduce risks, and how to monitor and report situations that pose risk. Criteria are used to monitor important systems and identify needed improvements.

Planning should consider the following areas in all settings, when appropriate to the activities of the organisation.

- Occupational health and safety programmes – the organisation complies with legislation relating to health and safety and risk management.
- Fire safety – property and occupants are protected from fire and smoke.
- Emergencies – responses to disasters and emergencies are planned and effective.
- Hazardous materials – the handling, storage and use of flammable and other materials are controlled and hazardous waste is safely disposed of.
- Security – property and occupants are protected from harm and loss.

The provision of health and safety services, emergency planning and other aspects of providing a safe environment all require personnel and volunteers to have the necessary knowledge and skills for their implementation.

Standards

5.1 Risk Management

5.1.1 *Managers and leaders work collaboratively to develop, implement and maintain effective risk management systems in the organisation.*

Standard Intent

To plan effectively, the organisation must be aware of all relevant risks. The goal is to prevent accidents and injuries, maintain safe and secure conditions for patients, families, personnel, volunteers and visitors, and reduce and control hazards and risks.

Risk management includes:

- comprehensive risk assessment of the organisation and/or facility
- planning all aspects of the risk management plan (financial, physical, environmental, medico-legal, operational, etc)
- implementation of the programme
- staff education
- testing and monitoring the programme; and
- periodic review and revision of the programme.

Monitoring of all aspects of the programme provides valuable data to make improvements in the programme and further reduce risks within the organisation.

5.1.1 Criteria

5.1.1.1 There are documented risk management processes for identifying all risks (physical, environmental, medico-legal, operational, etc) relating to organisational processes and systems, personnel, patients, visitors and physical facilities.

A formal process should be followed to identify and analyse risks in the organisation.

The risk management plan should include all relevant aspects and services of the organisation, e.g. patient, staff and visitor related risks, financial, corporate and legal risks, physical facility, security and environmental risks, etc.
This does not imply a single integrated document provided all components are dealt with in documented systems.

Take note that there are several linked criteria in each service element.
(NOTE: doing only monthly workplace inspections does not qualify for a compliance rating).

5.1.1.2 Managers and leaders ensure the development and implementation of written policies and procedures for risk management processes and activities.

5.1.1.3 On-going in-service training of all personnel in these policies, procedures and risk management principles, including reporting of adverse events, is documented.

5.1.1.4 One or more qualified and/or skilled and/or experienced individuals supervise the implementation of the risk management system.

5.1.1.5 There is a system for monitoring negative incidents/near misses/ adverse (sentinel) events and it includes the documentation of interventions and responses to recorded incidents.

5.1.1.6 Risk management systems are reviewed whenever there are changes in organisational systems and processes, or physical facilities.

5.2 Occupational Health and Safety

5.2.1 Management makes provision for occupational health services in accordance with a documented policy framework.

Standard Intent

The provision of health and safety services, emergency planning and other aspects of providing a safe environment all require staff members to have the necessary knowledge and skills for their implementation.

To plan effectively, the organisation must be aware of all the risks present in the facility and to develop a proactive plan to reduce those risks, e.g. TB screening, manual handling and needle stick injuries.

Simple first aid materials should be available for staff members to treat cuts and other minor injuries.

5.2.1 Criteria

5.2.1.1 The organisation provides its personnel with occupational health services.

The requirement of the provision of such a service will be guided by national legislation, where such exists.

It is desirable that every organisation ensures that its employees have access to an occupational health service. It is not expected that the organisation provide all components of the service itself, but some may be provided by another service provider. In the latter case, only relevant criteria will be scored.

The occupational health service here refers to the service rendered to the employees of the organisation and not, as is the practice in some organisations, pre-employment examinations and surveillance for commerce or industry in the catchment area of the health service.

This service can either be provided in-house by the organisation or as a contracted service by an outside provider, e.g. a local industrial company, private occupational health practitioners, etc.

5.2.1.2 Where applicable, legislation regarding occupational health services is implemented.

5.2.1.3 The organisation has access to the services of a knowledgeable and experienced person in the field of occupational health.

This refers to qualified occupational health practitioners in either the medical or the nursing field. The person need not be on-site at the clinic, but must be known to be available at a referral facility.

5.2.1.4 Written policies and procedures on all aspects of health and safety guide the personnel in maintaining a safe work environment.

5.2.1.5 The occupational health service provides information and training on risks specific to the health care workers.

5.2.1.6 Post exposure prophylaxis (PEP) is available to the personnel in accordance with organisational policy.

5.3 Security

5.3.1 As part of risk management, the organisation makes provision for the safety and security of personnel, volunteers, patients, visitors and buildings.

Standard Intent

The organisation has a responsibility to ensure that personnel, volunteers, patients and visitors are safe from attacks or theft by intruders. The organisation identifies areas and groups that are vulnerable and require added security.

The health facility takes responsibility for protecting patients from physical assault by outsiders, other patients and personnel. This responsibility is particularly relevant to infants and vulnerable children, the elderly, and others unable to protect themselves or signal for help. Each health facility identifies its vulnerable patient groups and establishes a process for protecting the rights of individuals in those groups. Vulnerable patient groups and the health facility's responsibility may be identified in laws, charters or regulations. Comatose patients and patients with mental or emotional disabilities are also included. Protection extends beyond preventing physical assault to other areas of safety. Verbal and other forms of abuse, negligent care, withholding health facilities and failing to provide assistance in the event of a fire or other emergency are all aspects of safety and require vigilance.

The health facility seeks to prevent assault through processes such as investigating individuals in the facility without identification, monitoring remote or isolated areas of the facility and quickly responding to those thought to be in danger of assault.

The personnel understand their responsibilities in these processes.
Plans are developed and implemented to provide protection. The loss of property belonging to the organisation must be prevented.

5.3.1 Criteria

5.3.1.1 An internal security for the health facility is provided.

The level of security must be appropriate for the type and location of the clinic. Also the assets of the clinic in terms of equipment, disposables, medications, etc. must be considered. The goal is to ensure the safety of personnel, patients and visitors, as well as property. For larger, urban clinics, forms of security may include guards and alarm systems, while a small rural clinic may be adequately protected with locked gates, doors and burglar bars.

5.3.1.2 There is effective control of access to restricted areas in the facility, e.g. laboratory, pharmacy, etc.

5.3.1.3 An external security for the facility is provided.

See the guideline for criterion 5.3.1.1.

5.3.1.4 The health facility has a process for protecting patients and personnel from assault.

5.3.1.5 A mechanism, known to the personnel, is available for summoning the assistance of security/police/protection service in the case of an emergency.

5.3.1.6 Alarm systems and signals are tested every month.

This will apply to those clinics where alarms are used as a form of security.

5.4 Fire Safety

5.4.1 As part of risk management, the organisation implements structured systems to ensure fire safety.

Standard Intent

Fire is an ever present risk in a healthcare organisation. An organisation needs to plan for:

- the prevention of fire through the reduction of risks, such as the safe storage and handling of potentially flammable materials
- safe and unobstructed means of exit in the event of fire
- clearly indicated fire escape routes
- inspection reports from the local fire departments and
- suppression mechanisms such as water hoses, chemical suppressants or sprinkler systems.

These actions, when combined, give patients, families, staff and visitors adequate time to exit the facility safely in the event of a fire or smoke. These actions are effective no matter what the age, size or construction of the facility.

The organisation's fire safety plan identifies:

- the frequency of inspection, testing and maintenance of fire protection and safety systems, consistent with requirements

- the process for testing, at least twice a year, the plan for the safe evacuation of the facility in the event of a fire or smoke
- the necessary education of personnel to protect and evacuate patients effectively when an emergency occurs
- the need for each staff member to participate in at least one emergency preparedness test per year and
- the required documentation of all inspection, testing and maintenance systems.

The organisation develops and implements a policy and plan to eliminate smoking in the organisation's facilities, or to limit smoking to designated non-patient care areas.

As the application of fire safety regulations differs vastly between countries and different authorities within the same country, it is essential that some form of fire safety certification is made by relevant authorities, either in a letter or a formal certificate. This certification documentation should state the norms/standards/regulations against which such certification of compliance was issued. In most instances, this certification remains valid until building alterations or additions take place.

5.4.1 Criteria

5.4.1.1 There are structured systems and processes in place to ensure that all occupants of the organisation's facilities are safe from fire or smoke.

Critical criterion

Root criterion

There are documented fire safety systems which include all the relevant aspects of fire safety, e.g. training, rehearsals, detection and abatement systems, servicing and storage of equipment, escape route signage, storage and handling of flammable materials, etc. This does not imply a single integrated document provided that all components of the system are dealt with.

5.4.1.2 Documented certification is available from the relevant authority to show that the facility complies with applicable laws and regulations in relation to fire safety (e.g. fire clearance certificate).

Refer to the guideline following the intent statement above.

National legislation regarding such certification will be taken into account. At the least there should be evidence that the relevant safety authorities have declared the building or patient transport vehicle/ambulance safe to perform its intended function.

5.4.1.3 Fire fighting equipment is regularly inspected and serviced at least annually; the date of the service is recorded on the apparatus.

Abatement systems include all fire safety systems such as fire-fighting equipment, fire-detection equipment, sprinkler systems, smoke detectors and structural abatement systems such as fire walls and fire doors.

The type of systems to be installed will depend on national requirements and compliance with such stipulations will be reflected in the certification as required in 5.4.1.1.

It is essential that the testing and servicing of all fire safety equipment is up to date, automatic abatement systems are regularly tested, fire and smoke detection systems are tested, and automatic abatement doors are not forced to remain open by means of wedging or putting objects against them.

5.4.1.4 Flammable materials are clearly labelled and safely stored.

Root criterion

Flammable materials are identified by the organisation and stored in accordance with the local fire safety regulations. Highlight issues such as kerosene, gas cylinders, alcohol, spirits, etc.

The storage precautions are applicable to all areas/services/departments where flammable materials are used. The appropriateness of the storage facility will be determined by the quantity and flashpoint of the materials stored.

Bulk storage requires approval and registration by the local fire safety authority. When a fire safety inspection by the relevant authority is conducted, all these storage areas need to be visited.

Compliance with such stipulations will be reflected in the certification required in 5.4.1.2.

5.4.1.5 Easily recognised and understood signs prohibiting smoking are displayed in areas where flammable materials and combustible gases are stored.

5.4.1.6 A floor plan, showing the location of fire fighting equipment, electrical distribution board, evacuation routes and emergency exits, is displayed.

5.4.1.7 Annual training of personnel in fire prevention and evacuation procedures is documented.

5.5 Emergency Planning

5.5.1 As part of risk management, the organisation develops a written plan to respond to emergencies.

Standard Intent

Community emergencies, epidemics and disasters, such as damage to patient care areas as a result of an earthquake, or flu that affects the personnel, may directly involve the organisation. Organisations should also be prepared for bomb threats,

fire, flooding, natural disasters, failure of water and electrical supplies, hostage taking, explosions and the consequent loss of vital services.

There may be a time when it is necessary to evacuate patients. This can only be done quickly and effectively if the personnel are trained in evacuation procedures.

To respond effectively, the organisation develops a plan and tests it. The plan provides processes for alternate care sites, if a needed and alternate source of medical supplies, communications equipment and other materials, such as food and water if an inpatient unit or day care centre exists on the premises.

5.5.1 Criteria

5.5.1.1 There is a written plan to deal with emergencies (including bomb threats, fire, flooding, natural disasters, failure of water and electrical supplies).

The plan makes provision for medical supplies to be available in emergencies. *The plan makes provision for communication equipment to be available in emergencies.* *Other materials and resources are available in emergencies as indicated in the plan.*

5.5.1.2 Documented evidence is available to show that the personnel participate in a rehearsal of the plan at least annually.

5.6 Prevention and Control of Infections

5.6.1 As part of risk management, the organisation designs and implements a coordinated programme to reduce the risk of infections in patients and healthcare workers.

Standard Intent

For an infection prevention and control programme to be effective, it must be comprehensive, encompassing both patient care and employee health. The programme is appropriate to the size and geographic location of the organisation, the services offered by the organisation, and the patients seen by the organisation.

Infections can enter the organisation via patients, their families, staff members, volunteers, visitors, other individuals and vectors. Thus, all areas of the organisation where these individuals or vectors are found must be included in the programme of infection surveillance, prevention and control.

One or more individuals, acting on a part time or part time basis, direct the programme. The qualifications needed depend on the activities they will carry out and the requirements may be met through education, training or experience. Coordination involves communication with all parts of the organisation to ensure that the programme is continuous and proactive.

Whatever the mechanism chosen by the organisation to co-ordinate the infection

control programme, medical and nursing personnel are represented and engaged in the activities. The individual, committee, or other mechanism must also monitor those housekeeping and other support service practices which may lead to the spread of infection, e.g. cleaning, linen supply, laundry services and waste disposal.

Information is essential to an infection control programme as it supports the following activities:

- tracking risks, rates and trends in nosocomial infections
- data analysis and
- interpreting and presenting findings.

In addition, infection control programme data and information are managed with those of the organisation's quality management and improvement programme.

Hand washing, barrier techniques and disinfecting agents are fundamental to infection prevention and control. The organisation identifies those situations in which the use of masks and gloves is required and provides training in their correct use. Soap and disinfectants are located in those areas where hand washing and disinfecting procedures are required. The personnel are educated in proper hand washing and disinfecting procedures.

5.6.1 Criteria

5.6.1.1 An individual member of staff is identified to be

5.6.1.2 responsible for infection control in the organisation.

5.6.1.2 All patient, staff and visitor areas of the facility are included in the documented infection control programme.

Public areas such as waiting rooms must be included in respect of sufficient space and ventilation in waiting areas.

'No smoking' signs are displayed and refuse bins are provided for cigarette butts.

Health education is provided for the patients (including posters and other visual aids).

5.6.1.3 Written policies and procedures guide the personnel in the implementation of the infection control programme.

Where national guidelines exist, these are adapted as needed.

5.6.1.4 Regular in-service training is given to all personnel in the field of infection control and is documented.

5.6.1.5 The infection control programme is monitored through a document audit process.

5.6.1.6 Hand washing and disinfecting facilities, including water, appropriate water taps, soap, paper towels or hand sanitizers are available in all relevant areas.

Evidence of training of all personnel in correct hand washing methods must be provided.
In addition, evidence of ongoing monitoring of the implementation of correct methods in all relevant areas of the facility must be available.

5.6.1.7 Personnel are constantly reminded of the importance of effective hand washing, e.g. posters are displayed.

5.6.1.8 PPE&C (gloves, masks, aprons etc.) is available and used correctly.

See all the criteria above.
This refers to the availability of items required by criteria in this section and the results of formal monitoring processes regarding their actual and correct use.

5.6.1.9 The organisation uses risk, rate and trend information to design or modify processes to reduce nosocomial infections to the lowest possible levels.

5.6.1.10 The organisation reports information on nosocomial infections and notifiable diseases to appropriate external public health agencies.

5.6.2 The organisation has a written plan for handling, segregating, storing and disposing of waste.

Standard Intent

Household waste, hazardous wastes, such as chemicals, hazardous gases and vapours, pharmaceutical and healthcare waste, are identified by the organisation and are safely controlled according to a plan. All clinical waste is regarded as hazardous or potentially hazardous. The plan is included in the organisation's risk management plan.

5.6.2 Criteria

5.6.2.1 There is a waste management system, consistent with current local byelaws and regulations.

5.6.2.2 The system includes safe handling, segregation, storing and disposing of different types of waste.

Arrangements need to include:

- *the availability of sharps containers*
- *the availability of refuse bins in all areas, including waiting rooms*
- *the correct use of incinerators or other waste disposal methods*
- *the disposal of waste water based on infection hazard.*

All non-infectious waste may be disposed of via regular sewerage systems.
Infectious wastewater should be sterilised using appropriate techniques such as using an autoclave and/or 24hr soaking in bleach or disinfectant.
When applicable, toxic chemical waste should be separated and collected by the appropriate authorities (this may be a government organisation or a private waste handling company).

5.6.2.3 Handling, segregation, storing and disposing of healthcare waste is included in the plan.

Unless the facility has access to proven, environmentally safe options for the management of healthcare waste, incineration may be seen as an appropriate response. Incineration should comply with the following recommendations:

- *construction should follow detailed plans or national guidelines where appropriate, thus avoiding flaws that can lead to incomplete destruction of waste, higher emissions, and premature failure of the incinerator*
- *placement of incinerators should aim to minimise exposures and thereby risks*
- *good practice guidelines and clear operational guidelines should be available, together with the appropriate tools*
- *the operators should be trained and management support should be available*

Proper operation of the incinerator is critical to achieving the desired combustion conditions and emissions. In summary, operation must:

- *use appropriate start-up and cool-down procedures*
- *achieve (and maintain) a minimum temperature before waste is burned*
- *use appropriate loading/charging rates (both fuel and waste) and ensure proper disposal of ash.*

Please note:

- *Materials that produce harmful by-products for the environment after incineration should not be incinerated, e.g. the mercury of broken thermometers*
- *Drugs, ampoules and vials should be disposed of appropriately*
- *Body fluids should be disposed of appropriately*
- *Safe recycling options should be identified and developed wherever possible (for plastic, glass, etc)*
- *A properly engineered design is needed to ensure that combustion conditions are appropriate, e.g., residence time and temperatures are sufficient to minimise products of incomplete combustion and*
- *Periodic maintenance to replace or repair defective components is essential.*

5.6.2.4 There is a colour coding system for the bags to be used for segregating the different types of waste.

SE 6: PRIMARY HEALTHCARE SERVICES

OVERVIEW OF PRIMARY HEALTHCARE SERVICES

Certain activities are basic to patient care, including planning and delivering care to each patient, monitoring the patient to understand the results of the care, modifying care when necessary and completing the follow-up. Many medical, nursing, pharmaceutical, rehabilitative and other types of healthcare providers may carry out these activities. Each provider has a clear role in patient care. The patient, his/her family or other trained caregivers may carry out some of this care.

A care plan for each patient is based on an assessment of needs. The care provided may be preventive, curative, rehabilitative or palliative and may include the use of medications, supportive therapies, or a combination of these approaches. A patient's illness or physical condition may require early attention, and should be "fast tracked", to prevent a long wait in the queue. Policies describing the recognition of such patients are available and procedures are in place to expedite early treatment.

It is essential that assessments are well documented and can be easily retrieved from the patient's record. As part of assessing patient care needs, diagnostic tests may be required. The health facility has access to laboratory and/or radiography services. These facilities are available within an appropriate time frame.

A health facility should be able to provide some form of emergency care, depending on its mission and resources, and the needs of the community. Some patients may present at the health facility with respiratory or cardiac distress, while others may respond adversely to medications administered at the health facility. Survival depends on, inter alia, the early recognition of cardiopulmonary arrest, early activation of trained responders, early cardiopulmonary resuscitation and early defibrillation, when indicated. The level of emergency care and resuscitation to be provided must be clearly defined in written documents. Those items of equipment deemed to be necessary for resuscitation are listed and regular equipment checks are carried out. Individuals in patient care areas are responsible for checking resuscitation equipment every day, or after each use, whichever comes first. Records of these tests are maintained. Resuscitation equipment is accessible within one minute in all patient care areas.

Guidelines are available for the assessment and treatment of patients for each programme. National Standardised Treatment Guidelines (NSTG) or equivalent are generally provided by Ministry of Health. Practice guidelines provide a means of improving quality and assist practitioners and patients in making healthcare decisions. Guidelines are found in the literature under many names, including practice parameters, practice guidelines, patient care protocols, and standards of practice and health facility pathways. Regardless of the source, the scientific basis of guidelines should be reviewed and approved by the health facility leaders and health facility practitioners, before implementation. This ensures that they meet the criteria established by those leaders and are adapted to the community, patient needs, and health facility resources. Once implemented, guidelines are reviewed on a regular basis to ensure their continued relevance.

Every patient is offered the education he or she requires. All personnel within the health facility work collaboratively to provide education in a coordinated manner. Education is focused on the specific knowledge and skills the patient and his/her

family will need to make decisions about care, participate in care, and continue care at home. Variables like educational literacy, beliefs and limitations are taken into account. Each health facility decides on the placement and format of educational assessment, planning and delivery of information in the patient's record. Education is routinely provided by the health facility in areas that carry high risk to patients. Standardised materials and processes are used where possible.

Learning occurs when attention is paid to the methods used to educate patients and their families. The health facility selects appropriate educational methods and people to provide the education.

Staff collaboration helps to ensure that the information patients and families receive is comprehensive, consistent, and as effective as possible.

Information provided by the health facility may include when to resume daily activities, preventive practices relevant to the patient's condition and, when appropriate, information on coping with disease or disability.

Standards

6.1 Organisation and Co-ordination

6.1.1 *The service is organised to provide a safe and effective service and is coordinated with other relevant services in the referral hospital and in the community.*

6.1.1 Criteria

6.1.1.1 The lines of communication between the health facility, referral hospital and community services are clearly defined.

This criterion is linked to criterion 1.1.1.5, which requires an organisational chart or document describing lines of authority and accountability from governance and within the service.

Examples
1. Protocol for referring a very ill patient from primary care level to a hospital
2. Protocol for referring a terminally ill patient for hospice care
3. Protocol for referring patients to community home care services.
4. List of relevant telephone numbers

6.1.1.2 Relations are established, and contact is maintained with other relevant services and agencies, including both governmental and non-governmental agencies.

The facility must, as a point of departure, establish who the "community" is that they serve. A comprehensive referral network with other community agencies supports continuity of care in terms of primary healthcare services, general practitioners, ambulatory care at a local hospital, educational services and social services. Formal structures need to have been established for communicating with the community served. Communication might take the form of regular meetings (with minutes) or take place through the Board or Advisory Board, where these exist.

Identify the services provided within the community served.
Look for meeting schedules and minutes of meetings with other agencies, where relevant, as well as lists, contact names and telephone numbers, etc.

Where no formal reports/minutes are available, oral information from the responsible person at the health facility will be sought.

6.1.1.3 An on-call roster is available for after hour, weekend and holidays emergency coverage (e.g. for infectious diseases).

Information showing where to obtain specialised medical assistance in the facility when needed should also be displayed.

A notice with information showing patients where to obtain medical help if the facility is closed should be displayed, e.g. poster/notice.

6.1.1.4 There is an organised process for referring patients.

In some cases, medical practitioners refer patients for a secondary consultation to confirm an opinion, to request more extensive diagnostic evaluations than may be available locally, or to have patients receive specialised treatment that the referring clinic is unable to provide.

A policy or guideline detailing the process must be available.

Compliance will be verified through ***documentation audits****:*

1. A template of a referral form/document could be provided. On this template, the reason for the referral should be made clear.

2. A copy of the completed referral form should be available in the patient record.

6.1.1.5 Radiology services are available for the level of care provided.

Where applicable, see also SE 10 Diagnostic Imaging Service.

6.1.1.6 Laboratory services are available for the level of care provided.

Where applicable, see also SE 9 Laboratory Service.

6.1.1.7 A register of specimens and results sent to an outside laboratory is available

The administration should include:

- *a referral request form in which the patient information, required investigation and results can be processed and authorised;*
- *a referral logbook in which the specimens referred are registered and the results can be processed;*
- *a folder in which the referral forms from the referral laboratory are kept.*

6.1.1.8 Ultrasound services are available for the level of care provided.

Where applicable, see also SE 10 Diagnostic Imaging Service.

6.2 Facilities and Equipment

6.2.1 The required furniture and equipment are available and functioning appropriately.

Standard Intent

In order to provide safe patient care, each unit requires adequate resources. The building is appropriate for a healthcare facility in terms of size and layout. There is a separate room for the handover between shifts, writing of reports and meetings**.**

An assessment is made as to whether the facility has the required furniture and equipment. Facilities will be required to complete an inventory of their furniture and equipment based on the standard lists and to report the percentage of total items they have in stock relative to the total recommended.

The physical facilities required include adequate office accommodation for the personnel.

Cleaning equipment is safely stored in a room or cupboard, used exclusively for this purpose. Toilet facilities are adequate for the patients and the personnel.

Lighting and ventilation meet the needs.

6.2.1 Criteria

6.2.1.1 Patient and staff accommodation in the outpatient service is adequate for the personnel to provide patient care.

6.2.1.2 The lay-out of the facility allows for effective flow of patient care.

6.2.1.3 The required furniture and equipment is available in accordance with established lists and is functioning properly.

In the absence of a national list of requirements, it is suggested that at least the following items be available in the facility at all times:

- *a generic examination table with a replaceable cover*
- *a functional stethoscope*
- *a functional otoscope / ophthalmoscope*
- *a functional thermometer*
- *a functional stadiometer to measure heights of adults and children*
- *a functional weighing scale for adults and babies*
- *a functional blood pressure device*
- *a penlight torch*
- *a sharps container.*

6.2.1.4 Stretchers and wheel chairs are available and are functioning properly.

6.2.1.5 Oxygen supplies (oxygen cylinders or air enrichers) meet the patient needs.

6.2.1.6 Where there are no piped oxygen installations, there is a documented procedure for ensuring that cylinder pressures (i.e. contents) are constantly monitored while patients are receiving oxygen.

6.2.1.7 Oxygen cylinders are stored in accordance with local safety standards.

6.2.1.8 Suction supplies meet the patient care needs.

6.2.1.9 There is a separate room for the personnel to hand over between shifts, write reports, hold meetings, etc.

6.2.1.10 Separate sanitary facilities are provided for the personnel.

6.2.1.11 Hand washing facilities, including water, appropriate water taps, soap and towels are available.

Assess the availability of water, soap, towels, and hand sanitizers.

6.2.1.12 Out Patients Department (OPD) facilities and waiting rooms are clean, well ventilated, well maintained and ensure privacy.

6.2.1.13 The consultation rooms are clean, well ventilated, well maintained and adequately equipped.

6.3 Assessment of Patients

6.3.1 The initial assessment of patients takes place at the point of first contact, to ensure that their needs are met.

Standard Intent

Matching patient needs to the healthcare facility's mission and resources depends on obtaining information on the patient's needs and condition through screening at the first point of contact.

The screening assessment leads to an understanding of the type of preventive, curative rehabilitative and palliative services needed by the patient. This information is used to determine the most appropriate setting(s) required to meet the patient's most urgent needs. Thus, admission to the health facility and/or referral to another setting may be required to meet the patient's needs.

The patient's needs may have been determined by a medical doctor or other healthcare professional before they entered the healthcare facility. If the patient's needs were not determined prior to entry, those needs are identified through a triage process, screening assessment, or medical history and physical examination. Diagnostic testing may also be required to:

- determine the patient's needs
- determine whether the health facility has the appropriate resources to treat the patient or
- establish whether the patient should be referred or transferred to another setting for care.

6.3.1 Criteria

6.3.1.1 There is a system, which includes patient identification, for initiating screening at the point of first contact.

Screening of the patient should take place on arrival at the facility to establish the type of care being sought, in order to ensure prompt direction and management.
Patients requiring urgent care are identified and attended to immediately.
The screening assessment should be fully documented in the patient's record.

6.3.1.2 The screening assessment leads to an understanding of the types of preventive, curative, rehabilitative and palliative services needed by the patient.

6.3.1.3 There is a system for ensuring that patients are seen within the shortest possible time.

Patients have the right to be attended to within the shortest possible time. Patients who are waiting are advised of any delays that may be experienced in receiving attention.

6.3.1.4 Patients who require early attention are identified (e.g. the very frail or ill, or women in an advanced stage of pregnancy).

6.3.1.5 There is a system for "fast tracking" patients requiring early attention.

6.3.1.6 Waiting times are monitored as part of the organisation's quality management and improvement programme and kept to the minimum.

6.3.2 All patients cared for by the health facility have their healthcare needs identified through a comprehensive assessment process.

Standard Intent

When a patient enters a health facility, the specific information required and the procedures for obtaining and documenting it, depend on the patient's needs and on the setting in which care is being provided.

The health facility defines, in writing, the scope and content of assessments to be performed by each clinical discipline within its scope of practice and applicable laws and regulations.

The health facility determines the time frame for completing assessments. This may vary in the different settings within the health facility. When an assessment is partially or entirely completed outside the health facility, the findings are verified on admission to the health facility.

These findings are used throughout the care process to evaluate patient progress and understand the need for reassessment. It is essential that assessments are well-documented and that they can be easily retrieved from the patient's record.

6.3.2 Criteria

6.3.2.1 Policies and procedures for assessing patients on arrival and during ongoing care are implemented.

6.3.2.2 Written procedures ensure that assessments are performed within appropriate time frames.

6.3.2.3 Patient assessments are conducted by personnel members who have been identified as competent to do so.

6.3.2.4 Policies and procedures guide the care of high-risk patients and the provision of high-risk services.

6.3.2.5 Current clinical guidelines relevant to the organisation's patients and services are used to standardise care processes.

6.4 Emergency Care

6.4.1 The health facility provides emergency treatment and care.

6.4.1 Criteria

6.4.1.1 Written guidelines for providing primary emergency services are available and are followed.

Guidelines are available and followed for the most frequently occurring and/or life threatening emergencies (these include guidelines for counselling and managing victims of sexual, domestic and gender violence and an emergency medication protocol for psychiatric patients).

6.4.1.2 Guidelines for paediatric emergency triage, assessment and treatment (ETAT) are available and are followed.

6.4.1.3 Information on cases and the outcome of emergency treatment are recorded in a register.

6.4.1.4 Case reviews are undertaken to assess the quality of treatment and care of patients requiring emergency care.

6.4.1.5 The service is organised in terms of personnel, facilities, equipment, and procedures, to evaluate, manage, stabilise and transfer patients with emergency conditions.

6.4.2 The health facility provides resuscitation in accordance with organisational policy.

6.4.2 Criteria

6.4.2.1 The health facility has a policy on resuscitation, which includes the level at which resuscitation is provided, by whom, and training and equipment requirements.

6.4.2.2 The availability of resuscitation equipment and medicines with clear instructions is specified in the organisation's policy on resuscitation.

6.4.2.3 The personnel are trained in resuscitation and records are kept of their participation in such training.

6.4.2.4 Equipment for early cardiopulmonary resuscitation (CPR) is available within one minute in each area of the facility.

6.4.2.5 Equipment for early cardiopulmonary resuscitation includes at least a CPR board, oral airways, an Ambu bag or equivalent, endotracheal tubes and laryngoscopes.

6.4.2.6 Where early defibrillation is indicated, there is a defibrillator with an ECG component.

6.4.2.7 The resuscitation equipment is available in adult and paediatric sizes.

6.4.2.8 There is a drug tray or trolley with appropriate facilities for intravenous therapy, insertion of naso-gastric tubing and drug administration (including paediatric sizes).

6.4.2.9 The drugs available in accordance with a specified list, include those for cardiac and respiratory arrest, coma, fits and states of shock (including paediatric doses), and plasma expanders.

6.4.2.10 A designated person checks and documents that resuscitation equipment and drugs are checked every day, or immediately after use (whichever is the sooner), by those who have been given this responsibility.

6.4.2.11 Records of these checks are kept, with reports on problems experienced, advice given, and any remedial action taken.

6.4.3 The clinic/health centre provides ambulance/emergency medical services.

Standard Intent

A comprehensive response and deployment plan addresses the location of facilities and the distribution of vehicles, personnel and other resources. These should be deployed in a way that optimises their use and provides uniform care across the area served.

6.4.3 Criteria

6.4.3.1 The organisation has a written response and deployment plan including the identification of response areas and the availability of response units.

The organisation's documented plan should include at least the following:
- *the identification of the service's catchment area*
- *the identification of vehicle and personnel requirements*
- *the provision of communication systems*
- *the prioritisation process for medical transport/ambulance requests;*
- *coverage of peak periods*
- *response to multiple-victim incidents*
- *disaster response.*

6.4.3.2 There is an effective system for facilitating communication between the personnel of the healthcare facility, the ambulance service and the receiving organisations.

6.4.3.3 Response time standards are monitored against national laws, regulations, policies or guidelines.

Critical criterion

National requirements apply.
Response times are within acceptable limits.
Where national norms exist, these will be applied.
Analysed data of response times must be available.

6.4.3.4 The individuals who provide patient care in the ambulance services have the required training and experience.

Critical criterion

The personnel receive appropriate patient management training, depending on the level of service provided.

The personnel should also be trained to:
- *operate and maintain medical equipment*
- *operate and maintain communication equipment*
- *operate vehicles safely, including under conditions that warrant the violation of existing traffic laws.*

6.4.3.5 Medical transport/ ambulance vehicles are clean.

Critical criterion

The organisation's policy framework should include at least the following:
- *personnel training in respect of proper cleaning methods;*
- *the cleaning methods and chemicals to be used for cleaning vehicles;*
- *the sites at which vehicles may be cleaned;*
- *the correct management of healthcare waste;*
- *preventing pollution of the environment by cleaning chemicals and clinical/healthcare waste.*

6.4.3.6 The ambulances are fully equipped to deal with obstetric emergencies.

6.5 Continuity of Care

6.5.1 There are mechanisms for holding patients for observation.

6.5.1 Criteria

6.5.1.1 Policies and procedures for holding patients for observation are implemented.

6.5.1.2 Bedside facilities (bedside table/locker, chair/bench) are available.

6.5.1.3 Each patient has access to a nurse call system at all times.

The judgement used here is normally how long it takes a nurse to respond to a patient call (by asking patients admitted) and not necessarily a bell system.

The majority of facilities do not use an electronic bell system. Hand bells are an option, but are often removed. An alternative, which has been proven to work, is to fit bicycle bells to the heads of the beds.

6.5.1.4 Each bed space is provided with adequate lighting.

6.5.1.5 Ward screens are available to ensure privacy.

6.5.1.6 Patients have access to ablution facilities.

These should be available in the holding area, e.g. wash basins, toilet facilities

6.5.1.7 Processes are implemented to provide patients with access to food and water.

6.5.1.8 Personnel are allocated to record regular observations of the patient's condition.

6.5.2 The health facility designs and carries out processes for providing continuity of patient care services.

6.5.2 Criteria

6.5.2.1 Arrangements are in place to ensure that adequate referral services are available.

A policy or guideline detailing the process must be available.
*Compliance will be verified through **documentation audits**, including the availability of copies of completed referral forms in the patient record. Formal guidelines/protocols need to be available.*
A template of a referral form/ document could be provided.

6.5.2.2 Referrals outside the facility are to specific individuals and/or agencies in the patient's home community wherever possible.

6.5.2.3 There are written guidelines for referring emergency patients.

A policy or guideline detailing the process must be available. Compliance will be verified through documentation audits, including the availability of copies of completed referral forms in the patient record.

6.5.2.4 Patients and, as appropriate their families, are given follow-up instructions, which are provided in an understandable form and manner.

6.5.2.5 A copy of the referral letter is available in the patient's record.

6.6 Sexual and Reproductive Health

6.6.1 *A contraceptive service is provided to meet the needs of families in the community.*

Standard Intent

Every patient is offered access to contraceptive services and education on reproductive health. All personnel are trained to recognise and meet the specific needs of adolescents and youth. All personnel in the health facility work collaboratively to provide education in a coordinated manner. Education is focused on the specific knowledge and skills the patient will need to make decisions on the use of contraceptive methods. Variables like educational literacy, beliefs and limitations are taken into account. Standardised materials and processes are used where possible. Data is collected (e.g. logbook), analysed and used to provide relevant information for improving the service, e.g. the number of contraceptives/condoms used per month.

6.6.1 Criteria

6.6.1.1 Guidelines for providing contraceptive services are available and are followed.

Guidelines generally describe the use of official documentation/reports on specific services provided. These records could serve as sufficient proof of implementation.

6.6.1.2 The personnel show evidence of education for and competence in providing a contraceptive service.

6.6.1.3 A range of most frequently prescribed contraceptive methods is provided, including injectable hormonal contraceptives, oral hormonal contraceptives, barrier methods and emergency contraceptives.

6.6.1.4 The personnel who are authorised to insert intra-uterine contraceptive devices show evidence of current training and competence in the procedure.

6.6.1.5 A record of the chosen method for each patient is available.

6.6.1.6 Guidelines regarding the advice to be given to patients on sterilisation are available and are followed.

6.6.1.8 Guidelines for administering post-coital contraceptives are available and are followed.

6.6.1.9 Condoms are freely available from strategically placed condom dispensers.

This depends on local and country policy

6.6.1.10 Guidelines for post exposure prophylaxis (PEP) in the case of sexual violence are available and are followed.

6.6.2 An effective antenatal service is provided.

Standard Intent

A plan for each patient is based on an assessment of needs. The organisation defines, in writing, the scope and content of assessments to be performed by each clinical discipline within its scope of practice and applicable laws and regulations.

These findings will include the diagnosis of pregnancy and the measurements during follow up, which may include weight, blood pressure, and oedema, protein in urine, fever and activity of the foetus. It is essential that assessments are documented well and can be easily retrieved from the patient's record. The frequency of follow-up visits should be clearly indicated. National clinical guidelines and protocols are available to ensure up-to-date treatment of complications during pregnancies and side effects of treatment with regard to the foetus. National guidelines must be used if available.

6.6.2 Criteria

6.6.2.1 Guidelines for routine tests, observations and examinations to be conducted on pregnant women are available and are followed.

6.6.2.2 The personnel show evidence of education and competence in the provision of antenatal care.

6.6.2.3 Policies cover the screening for syphilis and treatment according to the result.

6.6.2.4 All tests, observations and examinations are recorded.

National recording guidelines and confidentiality rules apply. These could include a specially designed antenatal care (ANC) chart.
Ideally, nursing records should be available.

6.6.2.5 Guidelines for referring patients with complicated pregnancies to specialist services are available and are followed.

6.6.2.6 Guidelines for educating pregnant women in preparation for breast feeding are available and are followed.

6.6.2.7 Guidelines for caring for HIV-positive obstetric patients are available and are followed.

The guidelines should include:
- *counselling and testing pregnant patients*
- *the application of Prevention of Mother to Child Transmission (PMTCT) protocols*
- *the provision of PMTCT protocol medications*
- *the administration of anti-retroviral agents (ARVs) to pregnant mothers.*

6.6.3 Where midwifery services are provided, there are adequate resources to ensure safe and effective care.

6.6.3 Criteria

6.6.3.1 Guidelines for the provision of midwifery services are available and are followed.

6.6.3.2 Guidelines (such as Emergency Obstetric Care) are used to reduce the number of maternal deaths in the labour ward.

The guidelines need to include:
- *management of sepsis (parenteral antibiotics available)*
- *management of postpartum haemorrhage (oxytocin available)*
- *management of eclampsia (anticonvulsants available)*
- *management of obstructed labour (partograph).*

6.6.3.3 A registered/professional nurse with midwifery training/experience is present at every birth.

6.6.3.4 At least one person who is competent in the management of maternal and neonatal emergencies is available for consultation at all times.

6.6.3.5 Guidelines for managing labour are available and are followed.

Examples of the guidelines required:
- *performing an episiotomy and artificial rupture of the membranes*
- *dealing with the complications of labour*
- *referring patients with complicated labour.*

6.6.3.6 Observations during labour are recorded on a partograph.

6.6.3.7 Guidelines for the active management of the third stage of labour, including post-partum bleeding are available and are followed.

6.6.3.8 There is a system for safe disposal of placentas.

6.6.3.9 Information on cases and the outcome of deliveries are recorded in a register.

6.6.3.10 There is an established process for conducting vacuum extractions or for referring patients who need vacuum extractions.

6.6.3.11 There is an established process for conducting Caesarean sections or for referring patients who need Caesarean sections.

6.6.4 Equipment for delivering babies is safe and adequate.

6.6.4 Criteria

6.6.4.1 There is a delivery room with adequate lighting, including an anglepoise lamp, and ventilation.

6.6.4.2 The delivery room is furnished with a suitably positioned delivery table, which allows for use in the Trendelenburg or lithotomy positions.

6.6.4.3 Standard surgical/obstetric equipment is supplied in accordance with an approved list.

At least the following items are required:
- *scissors*
- *stitch set*
- *umbilical cord clip*
- *vacuum extractor*
- *forceps*
- *delivery packs.*

6.6.5 An effective post-delivery neonatal service is provided.

6.6.5 Criteria

6.6.5.1 Guidelines for neonatal resuscitation are available and are followed.

6.6.5.2 Resuscitation equipment is available, including suction apparatus and oxygen, paediatric manual ventilator (Ambu-bag) and masks for new-borns.

6.6.5.3 Standard neonatal equipment is supplied in accordance with an approved list.

The equipment will include:

- *a neonatal weighing scale*
- *a neonatal incubator*
- *a phototherapy unit.*

6.6.5.4 An Apgar rating is recorded for each newborn baby.

6.6.5.5 Policies and procedures guide the identification of newborn babies.

6.6.5.6 There are established security systems for protecting newborn babies.

It is important to make sure that babies are not lost or stolen.

6.6.5.7 There is an established programme for vaccinating newborn babies following delivery and prior to discharge.

6.6.6 An effective postnatal service is provided

6.6.6 Criteria

6.6.6.1 Guidelines for post-natal care are available and are followed.

6.6.6.2 The personnel show evidence of education for and competence in providing post-natal care.

6.6.6.3 All tests, observations and examinations are recorded.

6.6.6.4 Guidelines for referring patients with post-natal complications to specialist services are available and are followed.

6.6.6.5 Policies address the issues of breastfeeding (transmission risk) and its alternatives and the provision of breast milk substitutes in accordance with guidelines.

6.6.6.6 Policies address the follow-up testing of infants born to mothers with HIV infection in accordance with guidelines.

This includes referring babies for testing or sending samples to outside laboratories.

6.6.6.7 Guidelines for post-partum domiciliary care are available and are followed.

6.7 Child Health

6.7.1 The health facility provides immunisation in accordance with National Guidelines.

6.7.1 Criteria

6.7.1.1 Guidelines for providing an immunisation programme are available and are followed.

6.7.1.2 The facility manager reviews the coverage and practice of immunisation, the vaccine supply and maintenance of the cold chain.

6.7.1.3 Guidelines for immunising HIV-positive children are implemented.

6.7.2 Services are provided to promote the health and growth of children.

6.7.2 Criteria

6.7.2.1 Guidelines for measuring the growth and development of children and referring them appropriately where growth or developments are delayed are available and are followed.

6.7.2.2 The child health chart is completed after each visit.

6.7.2.3 Guidelines for assessment of milestones for children are available and are followed.

6.7.2.4 A programme promoting breastfeeding is followed.

6.7.2.5 Children with nutritional deficiency disorders are identified, managed or appropriately referred.

6.7.2.6 There is an oral rehydration service, which includes counselling.

6.7.2.7 The health facility is adolescent- and youth-friendly, and meets the specific healthcare needs of these groups in accordance with national guidelines.

6.8 Communicable Disease Management

6.8.1 There is a programme for preventing and treating diarrhoeal diseases.

6.8.1 Criteria

6.8.1.1 Guidelines for preventing and treating diarrhoeal infections are available and are followed.

6.8.1.2 There are protocols for stool collection, where appropriate.

6.8.1.3 There are guidelines and resources for treating dehydration.

6.8.2 There is a programme for preventing and treating sexually transmitted infections.

6.8.2 Criteria

6.8.2.1 Guidelines for managing sexually transmitted infections are available and are followed.

6.8.2.2 Guidelines relating to syphilis serology results are available and are followed.

6.8.2.3 There is a policy on the tracing of partners/contacts of patients with sexually transmitted infections (STIs).

6.8.2.4 Routine HIV testing and counselling is performed according to set methodologies defined in prevailing guidelines.

6.8.3 There is a programme for preventing and treating tuberculosis.

6.8.3 Criteria

6.8.3.1 There is a system for sputum microscopy.

6.8.3.2 The outcomes of sputum testing are monitored.

6.8.3.3 Tuberculosis (TB) treatment accords with current guidelines.

Attention should be paid to the management of a chronic cough.

6.8.3.4 There is an uninterrupted medicine supply for TB treatment.

6.8.3.5 The facility has a TB infection control management plan that is implemented.

For example: • *the use of masks for patients and personnel;* • *space and ventilation in waiting areas.*

6.8.3.6 The principles of directly observed treatment are adhered to.

6.8.3.7 Policies and procedures relate to community support of the directly observed TB treatment and are implemented.

6.8.3.8 Supporters (community or family) of the directly observed TB treatment are provided with appropriate training.

6.8.3.9 Patients with positive tuberculosis test results are counselled and provided with HIV testing.

6.8.3.10 Routine HIV testing and counselling is carried out according to set methodologies defined in prevailing guidelines.

6.8.4 There is a programme for preventing and treating malaria.

6.8.4 Criteria

6.8.4.1 Malaria prevention and treatment accords with current guidelines.

6.8.4.2 There is a system for testing for malaria.

6.8.4.3 There is an uninterrupted medicine supply for malaria management.

6.8.4.4 Oral and intravenous medication for malaria treatment is available.

6.8.4.5 There is a mechanism for referring patients with complications of malaria.

6.9 HIV Infection and AIDS Management

6.9.1 Management of HIV infection and AIDS accords with approved guidelines.

6.9.1 Criteria

6.9.1.1 Guidelines for preventing, caring for, supporting and treating patients with HIV infection and AIDS are available and are followed.

Voluntary counselling and testing (VCT), Routine HIV Testing (RHT) and treatment

6.9.1.2 There is a monitoring system that complies with national reporting requirements.

6.9.1.3 Facility infrastructure and equipment for VCT implementation are present.

This includes:
- *physical space to meet the VCT needs*
- *confidential area(s) for counselling purposes*
- *a safe area for blood testing*
- *the safe disposal of potentially infectious sharps*
- *sufficient sharps disposal receptacles to meet the needs*
- *sufficient quantities of all blood collection devices, reagents and other equipment necessary to perform VCT according to guidelines.*

6.9.1.4 Voluntary counselling and testing (VCT) is performed according to set methodologies defined in prevailing guidelines.

VCT includes:
- *pre-test counselling;*
- *the process of informed consent*
- *counselling is given in a language that the patient understands*
- *blood testing for HIV infection by test methodology laid out in guidelines*
- *post-test counselling*
- *defined referral following diagnosis.*

6.9.1.5 Rapid HIV Testing (RHT) is carried out according to set methodologies defined in prevailing guidelines.

6.9.1.6 VCT and/or RHT results are available on the day of testing.

6.9.1.7 There is an established system for encouraging partner notification.

6.9.1.8 Antiretroviral therapy (ART) is administered in accordance with prevailing guidelines.

- *Antiretroviral drug regimens are selected according to national guidelines.*
- *Patients are selected for eligibility for antiretroviral therapy according to national guidelines.*
- *HIV-positive patients are commenced on antiretroviral therapy according to national guidelines.*
- *Patients on antiretroviral therapy are monitored at protocol-defined intervals as stipulated in national guidelines.*
- *Patients receiving antiretroviral therapy are monitored for short-, medium- and long term side effects according to national guidelines.*
- *Recording of adverse medication effects include interactions with other medications administered.*
- *Failure of antiretroviral therapy is diagnosed and investigated according to national guidelines.*
- *Antiretroviral regimens are altered in accordance with national guidelines.*
- *Patients are counselled on an ongoing basis on expected outcomes, side effects and adherence issues related to ART.*
- *Antiretroviral agents are administered in the context of a robust treatment literacy campaign for patients.*
- *ART is administered in the context of a system to monitor patients defaulting appointments and ART pharmacy refills.*

6.10 Cancer Screening

6.10.1 A cancer screening and prevention programme is available.

6.10.1 Criteria

6.10.1.1 Guidelines for providing breast and cervical cancer prevention programmes are available and are followed.

6.10.1.2 There are policies and procedures for the taking of Papanicolaou (Pap) smears, and dealing with the results.

6.11 Care for non-communicable chronic diseases

6.11.1 The healthcare facility provides general primary care.

6.11.1 Criteria

6.11.1.1 Guidelines for assessing and treating patients with chronic non-communicable diseases (e.g. hypertension, diabetes, cardio-vascular, etc) are available and are followed.

This applies to uncomplicated cases, otherwise patients are referred upwards.

6.11.1.2 Appropriate equipment is available for conducting the assessments.

Specify: baumanometer, glucometer, scale, urinalysis reagent strips, ophthalmoscope.

6.11.1.3 Patients are provided with the necessary aids, as appropriate to their needs.

6.11.1.4 Equipment and materials for the provision of wound care are provided.

6.11.1.5 Wound care procedures/guidelines/standard operating procedures (SOP) are available and are followed.

6.11.2 The healthcare facility provides care and treatment for mental disorders, within its capabilities.

6.11.2 Criteria

6.11.2.1 Guidelines, including mental health legislation, for assessing and treating patients attending the mental health service are available and are followed.

There are guidelines for identifying patients suffering from substance abuse and providing the appropriate interventions.

6.11.2.2 There is access to mental health expertise, when required (a psychiatrist or psychologist, as appropriate).

6.11.3 The health facility provides preventive and promotive programmes for oral health, and curative dental services as appropriate to meet the needs of the community.

6.11.3 Criteria

6.11.3.1 Guidelines for oral health assessment, education and treatment are available and are followed.

6.11.3.2 Where there is an oral hygienist, he/she is competent to conduct oral examinations and to provide oral hygiene, in accordance with current documented guidelines.

6.11.3.3 There is a dental roster to ensure that dental personnel are available at all times, either on call or on the premises.

6.11.3.4 Dental practitioners have the necessary equipment to ensure that the procedures performed are undertaken safely and competently.

In order to render a high quality service, the dental department needs to acquire sophisticated quality equipment. This equipment is often of a microscopic nature, e.g.; drills and clamps, filling material and resins, excellent lamps and fine radiology and radiographic equipment. This equipment is expensive and needs to be maintained regularly with adequate proof of service.

6.11.3.5 Where radiographic equipment is used, this conforms to the Ionising Radiation regulations.

6.11.3.6 Appropriate shielding and protective clothing is worn in the presence of biohazards or radiographic equipment which conforms to the Ionising Radiation regulations.

The safe use of radiology and radiographic equipment requires screening protection for personnel and monitoring of exposure to radiation.

6.11.3.7 Medicines are available for dental use.

6.11.3.8 Materials are available for local anaesthesia.

6.11.3.9 The dental service works with the infection control personnel in the health facility to ensure that infection control policies and procedures are implemented.

6.12 Community-Based Home Care

6.12.1 Caregivers identify the needs of patients for home care, according to the following criteria.

Standard Intent

The World Health Organisation (WHO) defines home care "as the provision of health services by formal and informal caregivers in the home in order to promote, restore and maintain a person's maximum level of comfort, function and health including care towards a dignified death. Home care services can be classified into preventive, promotive, therapeutic, rehabilitative, long-term maintenance and palliative care categories."

Generally, home care is provided by carers from the community, supervised by professional nurses from governmental organisations or NGOs.

6.12.1 Criteria

6.12.1.1 Each patient referred for home care has a full assessment to identify his/her needs for home care.

6.12.1.2 Personnel, transport and resources are available to provide the service.

6.12.1.3 Guidelines are available for training, protection and support of care givers.

6.12.1.4 Homecare records are kept for each patient and include the type of care, medication and services provided.

These could be patient records or registers kept by the caregivers.

6.13 School Health Service

6.13.1 A school health service is provided, according to the identified needs of the community.

6.13.1 Criteria

6.13.1.1 Health promotion activities for children in schools are clearly defined.

6.13.1.2 Equipment for health education in schools is available.

6.13.1.3 The process of screening children, to identify barriers to learning, is clearly defined.

SE 7: INPATIENT CARE

These standards will apply to Clinics/Health Centres with inpatient facilities and at which minor surgical procedures are undertaken.

OVERVIEW OF INPATIENT CARE

A healthcare organisation's main purpose is patient care. Providing the most appropriate care in a setting that supports and responds to each patient's unique needs requires a high level of planning and coordination.

Certain activities are basic to patient care, including planning and delivering care to each patient, monitoring the patient to understand the results of the care, modifying care when necessary and completing the follow-up.

Many medical, nursing, pharmaceutical, rehabilitation and other types of healthcare providers may carry out these activities. Each provider has a clear role in patient care. Credentialing, registration, law and regulation, an individual's particular skills, knowledge and experience, and organisational policies or job descriptions determine that role. The patient, the family or trained caregivers may carry out some of this care.

A plan for each patient is based on an assessment of needs. That care may be preventive, curative, rehabilitative or palliative, and may include the use of anaesthesia, surgery, medication, supportive therapies, or a combination of these approaches. A plan of care is not sufficient to achieve optimal outcomes unless the delivery of the services is coordinated, integrated and monitored.

From entry to discharge or transfer, several departments, services and different health care providers may be involved in providing care. Throughout all phases of care, patient needs are matched with appropriate resources within and, when necessary, outside the organisation. This is accomplished by using established criteria or policies that determine the appropriateness of transfers within the organisation.

Processes for continuity and co-ordination of care among medical practitioners, nurses and other healthcare providers must be implemented in and between all services.

Leaders of various settings and services work together to design and implement the required processes to ensure co-ordination of care.

Standards

7.1 Management of the Service

7.1.1 During all phases of care, there are qualified individuals responsible for the patient's care.

Standard Intent

The individuals who bear overall responsibility for the patient's care or for a particular phase of care are identified in the patient's record or in a manner that is made known to the personnel. Those responsible for the patient's care include medical practitioners, nurses, members of professions allied to medicine, e.g. physiotherapy, etc.

7.1.1 Criteria

7.1.1.1 The individuals responsible for the patient's care are designated.

The focus will be on the "core" caregivers, i.e. doctors and nurses.
Evidence is required in the form of staff allocation lists, duty rosters and off-duty lists.

It is important to assess the availability of doctors, especially after-hours cover, including weekends and public holidays.

7.1.1.2 The individuals responsible for the patient's care are identified and made known to the patient and other staff members.

Name badges should be worn by all staff members at all times. Patient interviews will reveal whether staff members introduced themselves to patients.

7.1.2 The delivery of services is integrated and coordinated amongst care providers.

Standard Intent

The co-ordination of patient care depends on the exchange of information between the members of the multidisciplinary team. This can be through verbal, written or electronic means in accordance with appropriate policies determined by the organisation. Clinical leaders should use techniques to better integrate and co-ordinate care for their patients (for example, team delivered care, multi-departmental patient care rounds, combined care planning forums, integrated patient records, case managers). The process for working together will be simple and informal when the patient's needs are not complex.

The patient, family and others are included in the decision process when appropriate.

The patient's record contains a history of all care provided by the multidisciplinary team, and is made available to all relevant caregivers who are authorised to have access to its content.

7.1.2 Criteria

7.1.2.1 There is a regular schedule of ward rounds with medical personnel.

7.1.2.2 Information exchanged includes a summary of the care provided.

7.1.2.3 Information exchanged includes patient response to treatment.

7.2 Facilities and Equipment

7.2.1 Adequate facilities are available for providing safe care to patients in the ward.

Standard Intent

In order to provide safe patient care, each unit requires adequate resources. The physical facilities required include adequate office accommodation for the personnel, sluice rooms which are hygienically clean at all times, treatment and dressing rooms, and adequate storage space for clean linen. Cleaning equipment is safely stored in a room or cupboard used expressly for this purpose. There are adequate toilet and bathing facilities for the number of patients in the ward.

There is adequate lighting and ventilation. Emergency call systems are available at bedsides and in bathrooms and toilets. The emergency call system is connected to the emergency power system.

Where there is no piped oxygen and vacuum supply, there are mobile oxygen cylinders and vacuum pumps. All the necessary fittings for oxygen and suction are in place and working satisfactorily. Each bed is serviced by at least one electrical socket outlet. Each ward is provided with a socket outlet that is connected to the emergency power supply.

Resuscitation equipment is immediately accessible from each section of the ward.

Where midwifery services are provided, each delivery room has:

- at least one cardio-tocograph machine
- an infant warming and resuscitation cart
- an incubator with adjustable temperature and separate oxygen supply
- a foetal monitor
- equipment for inhalation analgesia and
- a suction machine.

7.2.1 Criteria

7.2.1.1 Patient and staff accommodation in the service is adequate to meet patient care needs.

7.2.1.2 Oxygen supplies (oxygen cylinders or air enrichers) meet the patient care needs.

7.2.1.3 Suction supplies meet the patient care needs.

7.2.1.4 Where there are no piped oxygen installations, there is a documented procedure for ensuring that cylinder pressures (i.e. contents) are constantly monitored while patients are receiving oxygen.

7.2.1.5 There is a dedicated area in the ward kitchen for preparing infant feeds, where applicable.

7.2.1.6 There is a separate room for the personnel to hand over between shifts, write reports, hold meetings etc.

7.2.1.7 Separate sanitary facilities are provided for the personnel.

7.2.1.8 Separate ablution facilities are available in the ward for the patients.

7.2.1.9 There is a separate scullery/sluice room for patients' eliminations, waste and laundry.

7.2.2 Adequate resources are available for providing safe care to patients in the ward.

7.2.2 Criteria

7.2.2.1 Bed devices (frames/cot-sides, cradles, bed blocks, etc) are available and functional.

7.2.2.2 Bedside facilities (bedside table/locker, chair/bench) are available.

7.2.2.3 Each patient has access to a nurse call system at all times.

7.2.2.4 Each bed space is provided with adequate lighting.

7.2.2.5 Ward screens are available to ensure privacy.

7.2.2.6 Resuscitation equipment is available in accordance with the policies of the organisation.

7.2.2.7 Equipment and materials are provided for the patients' personal hygiene.

Equipment and materials for personal hygiene include:
- *washing bowls*
- *kidney dishes*
- *bedpans*
- *male urinals*
- *pressure relieving aids*
- *incontinence material.*

7.2.2.8 Mattresses, bed linen, towels and pyjamas for patients are available and in good condition.

This includes the following aspects.

- *Pillows and plastic sheets that are clean and in good condition.*
- *There is evidence that beds are made with clean linen daily and as required.*
- *Patients who have insufficient self-help skills are assisted with daily care and bathing is assisted.*
- *Where indicated, patients are assisted with shaving, oral/dental toilet and nail and hair care.*

7.2.2.9 Equipment and materials for facilitating patients' mobility are available and in good condition.

This will include:

- *handgrips or trapezes on beds*
- *walkers*
- *crutches*
- *wheelchairs.*

7.2.2.10 Equipment and materials for monitoring patients' vital signs are provided.

This will include:

- *a stethoscope*
- *a blood pressure device*
- *a stopwatch*
- *a thermometer*
- *a flashlight/torch for checking pupils.*

7.2.2.11 Equipment and materials for wound care and treating fractures are provided.

This will include:

- *skin disinfection material*
- *gauze, sterile and unsterile, in different sizes*
- *elastic binders/bandages in different sizes*
- *adhesive tape*
- *suture-removal instruments (tweezers, scissors, stitch cutters)*
- *wound irrigation equipment (bowls, trays, receivers, irrigation fluid, syringes 20 ml, oil, zinc ointments, bandages, scissors)*
- *basic material for fractures (plaster of Paris, different sizes of under-plaster stockings, plaster-removing equipment).*

7.3 Policies and Procedures

7.3.1 Policies and procedures/SOPs guide the care of patients and the provision of services.

Standard Intent

Policies and procedures are important to help the personnel understand the facility's patients and services, and to respond in a thorough, competent and uniform manner. The clinical and managerial leaders take responsibility for identifying the needs of the patients and the services to be provided. They use a

collaborative process to develop policies and procedures and to train the personnel in their implementation.

It is particularly important that the policies or procedures indicate:

- how planning will occur
- the documentation required for the care team to work effectively
- special consent considerations
- monitoring requirements
- special qualifications or skills of the personnel involved in the care process; and
- the availability and use of resuscitation equipment, including equipment for children

Clinical guidelines are frequently helpful and may be incorporated in the process. Monitoring provides the information needed to ensure that the policies and procedures are adequately implemented and followed for all relevant patients and services.

Policies and procedures should focus on high risk patients and procedures, e.g.

- the care of emergency patients
- the handling, use and administration of blood and blood products
- the management of contaminated blood supplies (expired, opened or damaged containers)
- the care of patients with communicable and non-communicable diseases
- the care of immuno-suppressed patients
- the use of restraint and the care of patients in restraint
- the care of frail, dependent elderly patients
- the care of young, dependent children and
- the security of newborn babies.

7.3.2 Criteria

7.3.2.1 Policies and procedures for nursing care are available and are followed as indicated in the statement of intent above.

7.3.2.2 Nurses use performance checklists/protocols/guidelines for complex skills, e.g. intravenous infusions, catheterisation, nasogastric intubation.

7.3.2.3 The personnel are trained and use the policies and procedures to guide care.

7.3.2 *Clinical practice guidelines are used to guide patient care and reduce unwanted variation.*

Standard Intent

Practice guidelines provide a means to improve quality and assist practitioners and patients in making clinical decisions. Guidelines are found in the literature under many names, including practice parameters, practice guidelines, patient care protocols and standards of practice. Regardless of the source, the scientific basis of guidelines should be reviewed and approved by the organisation's leaders and clinical practitioners before implementation. This ensures that the guidelines meet

the criteria established by the leaders and are adapted to the community, patient needs and the resources of the organisation. Once implemented, guidelines are reviewed on a regular basis to ensure their continued relevance.

7.3.2 Criteria

7.3.2.1 Clinical practice guidelines, relevant to the patients and services of the organisation, are used to guide patient care processes.

7.3.2.2 Guidelines are used in clinical monitoring as part of a structured clinical audit.

7.3.2.3 Guidelines are reviewed and adapted on a regular basis after implementation.

7.4 Patient Care

7.4.1 The patient needs identified in the care plan are addressed.

Standard Intent

A single, integrated plan is preferable to the entry of a separate care plan by each provider.

Collaborative care and treatment team meetings or similar patient discussions are recorded.

Individuals qualified to do so order diagnostic and other procedures. These orders must be easily accessible if they are to be acted on in a timely manner. Locating orders on a common sheet or in a uniform location in patient records facilitates the correct understanding and execution of orders.

An organisation decides:
- which orders must be written rather than verbal
- who is permitted to write orders and
- where orders are to be located in the patient record.

The method used must respect the confidentiality of patient care information.

When guidelines and other related tools are available and relevant to the patient population and mission of the organisation, there is a process for evaluating and adapting them to the needs and resources of the organisation, and for training the personnel to use them.

Patients and their families or decision-makers receive adequate information to participate in care decisions. Patients and families are informed as to what tests, procedures and treatments require consent and how they can give consent, e.g. verbally, by signing a consent form, or through some other mechanism. Patients and families understand who may, in addition to the patient, give consent. Designated staff members are trained to inform patients and to obtain and document patient consent. These staff members clearly explain any proposed treatments or procedures to the patient and, when appropriate, the family. Informed consent includes:

- an explanation of the risks and benefits of the planned procedure
- identification of potential complications and
- consideration of the surgical and non-surgical options available to treat the patient.

In addition, when blood or blood products may be needed, information on the risks and alternatives is discussed.

The organisation lists all those procedures that require informed written consent. Leaders document the processes for obtaining informed consent. The consent process always concludes with the patient signing the consent form, or the documentation of the patient's verbal consent in the patient's record by the individual who provided the information for consent. Documentation includes the statement that the patient acknowledged full understanding of the information. The patient's surgeon or other qualified individual provides the necessary information and the name of this person appears on the consent form.

7.4.1 Criteria

7.4.1.1 The initial assessment results in the identification of the patient's medical, nursing or other healthcare needs.

7.4.1.2 There is documented evidence that patients' vital signs are monitored, registered and interpreted according to a regular daily schedule.

7.4.1.3 Procedures for the elimination of patients' secretions are implemented.

This will include:
Patient eliminations (urine, stool) are observed and recorded daily.
Patients are assisted with elimination processes, where necessary.

Measures must be in place to manage:
- *incontinence with incontinence materials;*
- *diarrhoea*
- *enemas*
- *menstruation*
- *heavy transpiration*
- *coughing up of sputum*
- *nausea and vomiting.*

7.4.1.4 Wound care procedures/guidelines/standard operating procedures (SOP) are available and are followed.

7.4.1.5 Wound dressings are inspected daily and where indicated the wound is inspected.

7.4.1.6 When indicated, the dressing is changed.

Clips, sutures, drains and/or tampons are removed as indicated.

7.4.1.7 Measures are in place to prevent immobility and prevent the complications of immobility.

7.4.1.8 There is evidence that the patient is encouraged to become active and to use aid appliances, where necessary, to stimulate the rehabilitation process.

7.4.1.9 There is evidence that the patient, when confined to bed or immobile, receives assistance with lifting, moving, positioning, turning in bed and transferring from and back to bed.

7.4.1.10 There is evidence that pressure relieving techniques (care of skin, turning in bed on schedule, observing and preventing potential bedsores) are implemented and documented.

7.4.1.11 Patients receive professional physiotherapy care and assistance with rehabilitation if required.

7.4.2 Compassionate care is provided to patients in pain and to the dying.

Standard Intent

While pain may be a part of the patient experience, unrelieved pain has adverse physical and psychological effects. The patient's right to appropriate assessment and management of pain is respected and supported. The organisation has processes for:

- identifying patients with pain during initial assessment and reassessment
- communicating with, and providing education for, patients and families about pain management in the context of their personal, cultural and religious beliefs and
- educating healthcare providers in pain assessment and management.

Dying patients have unique needs for respectful, compassionate care. Concern for the patient's comfort and dignity guides all aspects of care during the final stages of life. To accomplish this, all the personnel are made aware of the unique needs of patients at the end of life. These needs include treatment of primary and secondary symptoms, pain management, responding to the concerns of the patient and family and involving them in care decisions.

7.4.2 Criteria

7.4.2.1 The organisation implements processes for addressing the patient's needs for appropriate assessment and management of pain.

7.4.2.2 The organisation educates health professionals in assessing and managing pain.

7.4.2.3 Policies and procedures regarding the care of dying and deceased patients are implemented.

7.5 Surgical Services

7.5.1 Based on the results of the assessment, each patient's surgical care is planned and documented.

7.5.1 Criteria

7.5.1.1 Medical assessments are carried out and documented before patients go to surgery.

7.5.1.2 The results of surgical patients' diagnostic tests are recorded before surgery.

7.5.1.3 Surgical patients' preoperative diagnoses are recorded before surgery.

7.5.1.4 The anaesthetic assessment identifies any drug sensitivities.

7.5.1.5 An intra-operative report and a post-operative diagnosis are documented.

7.5.1.6 The names of the surgeon, and other personnel as required by law, are documented.

7.5.1.7 The patient's clinical status is monitored during the immediate post-surgery period.

7.6 Patient and Family Education

7.6.1 Each patient's educational needs are assessed and written in his or her record.

Standard Intent

Learning occurs when attention is paid to the methods used to educate patients and families. The organisation selects appropriate educational methods and people to provide the education.

Staff collaboration helps to ensure that the information patients and families receive is comprehensive, consistent, and as effective as possible.
Education is focused on the specific knowledge and skills that the patient and his or her family will need to make decisions about care, participate in care, and continue care at home.

Variables like educational literacy, beliefs and limitations are taken into account.

Each organisation decides the placement and format for educational assessment, planning and delivery of information in the patient's record.

Education is provided to support care decisions of patients and families. In addition, when a patient or family directly participates in providing care, for example changing dressings, feeding and administering medication, they need to be educated.
It is sometimes important that patients and families are made aware of any

financial implications associated with care choices, such as choosing to remain an inpatient rather than being an outpatient.

Education in areas that carry high risk to patients is routinely provided by the organisation, for instance instruction in the safe and effective use of medications and medical equipment.

Community organisations that support health promotion and disease prevention education are identified and, when possible, ongoing relationships are established.

7.6.1 Criteria

7.6.1.1 Patients and families learn about participation in the care process.

7.6.1.2 Patients and families learn about any financial implications of care decisions.

7.6.1.3 Patients are educated about relevant high health risks, e.g. the safe use of medication and medical equipment, or medicine and food interactions.

7.6.1.4 The patient and family are taught in a language and format that they can understand.

7.6.1.5 Information given to the patient and family is noted in the patient's record.

7.8.1.6 There is evidence in the patient health record that he or she gave informed consent

7.7 Discharge Process

7.7.1 There is an organised process for appropriately discharging patients.

Standard Intent

The organisation begins to plan for the patients' continuing needs as early in the care process as possible. Instructions for discharge and follow-up visits must be clear and provided in writing.

7.7.1 Criteria

7.7.1.1 There is a documented process for appropriately discharging patients.

7.7.1.2 The organisation works with the family, healthcare practitioners and agencies outside the organisation to ensure timely and appropriate discharge.

7.7.1.3 The medical practitioner gives patients (and their families when appropriate) understandable follow-up instructions in the discharge note at referral or discharge.

SE 8: OPERATING THEATRE AND ANAESTHETIC SERVICES

These standards will apply only to Clinics with inpatient facilities and at which minor surgical procedures are undertaken.

OVERVIEW OF OPERATING THEATRE AND ANAESTHETIC SERVICES

Services in the operating theatre and anaesthetic services carry high risk. It is essential that there is collaboration between the personnel in the theatre, the infection control and health and safety personnel and those responsible for supplying and maintaining equipment.

Anaesthesia, sedation and surgical interventions are common and complex processes in a health care organisation. They require complete and comprehensive patient assessment, integrated care planning, continued patient monitoring and criteria-determined transfer for continuing care, rehabilitation and eventual discharge.

Anaesthesia and sedation are commonly viewed as a continuum from minimal sedation to full anaesthesia. As patient responses may move along that continuum, the use of anaesthesia and sedation is organised in an integrated manner. This chapter includes anaesthesia and moderate and deep sedation, during which the protective reflexes needed by the patient for ventilator functions are at risk.

The anaesthesia and surgery standards are applicable wherever anaesthesia and/or moderate or deep sedation is used and surgical and other invasive procedures requiring consent are performed. Such settings include clinic/healthcare centre operating theatres, day surgery or day clinic/healthcare centre units, dental and other outpatient clinics, emergency services and others. While major surgery is generally not performed in clinics/health centres, a number of minor procedures might be undertaken.

The organisation ensures that an adequate number of suitably qualified and experienced personnel are available at all times to provide a safe operating theatre and anaesthetic service.

Standards

8.1 Management and Staffing

8.1.1 The operating theatre and anaesthetic service is managed and staffed to provide a safe and effective service.

Standard Intent

Theatre management personnel work with organisational leaders to ensure adequate and suitable management processes and staffing of the theatre, anaesthetic service, and recovery room.

The qualifications of those persons who administer anaesthesia in the clinic/healthcare centre are documented in accordance with current professional society standards.
There may not be a formally constituted theatre users' committee, but the function must be performed at some level. Representatives of the theatre nursing staff should be included.

Privileges assigned to individuals may not be documented, but the organisation places restrictions on who may administer anaesthetics.

8.1.1 Criteria

8.1.1.1 A senior professional, who is suitably qualified and/or experienced, is in charge of the theatre and recovery area.

A copy of the guidelines of the professional or reputable body is available, which is used as the basis for the organisation's staffing structure? *The individual's qualifications and experience will be compared with the post description to ascertain that person's suitability for the position.*

8.1.1.2 Operating theatre rosters ensure that registered nurses with suitable qualifications and/or experience are present during all shifts, for theatre duties, anaesthetic assistance, and for recovery room duties.

8.1.1.3 Anaesthesia is administered only by qualified practitioners, who are privileged by the organisation to do so.

There may not be documented individually assigned privileges. Instead, the organisation may place restrictions on who may administer anaesthetics. The national regulations will apply in countries where anaesthetics are administered by professionals other than medical practitioners (e.g. nurse anaesthetists). If the organisation cannot provide documented evidence of the above, this criterion will be scored PC.

8.1.1.4 Anaesthesia is commenced and terminated only in the presence of a staff member, whose sole duty it is to assist the anaesthetist, until such time as the latter indicates that assistance is no longer required.

A copy of the guidelines of the professional or reputable body is available, which is used as the basis for the organisation's staffing structure?
Check duty rosters and staff allocation/work lists for each operating theatre, i.e. scrub nurse, floor nurse and anaesthetic nurse allocated for each procedure.

Establish what happens after hours, i.e. how many people of what categories are on call to handle emergencies. Is the anaesthetic nurse also expected to be the floor nurse?

8.1.1.5 There is at least one suitably trained and/or experienced anaesthetic nurse per operating theatre.

The term here applies to the nurse assigned to assist the anaesthetist during the induction process and to be available to attend to his/her needs for the duration of the anaesthetic. It does not apply to a nurse who administers anaesthetics.

8.1.1.6 Nurses, who are trained in recovery room care, are available until the patient has fully recovered.

While various categories of staff may be trained and experienced in recovery room care, there must always be a professional nurse, who has recovery room, anaesthetics or critical care training and experience.

8.1.1.7 The anaesthetist is responsible for supervising the recovery period and authorising the patient's discharge.

This applies whether the anaesthetic is administered by a medical practitioner or nurse anaesthetist.

While the person who administered the anaesthetic may delegate the immediate post-anaesthetic observation and care to the recovery room nurses, he or she remains responsible for assessing the patient prior to discharging him/her from theatre and for signing the form stating that the patient is fit to leave theatre.

There may not be a dedicated recovery room or recovery room staff and the patient will be returned to consciousness in the theatre and transferred directly to the ward.

8.2 Facilities, Equipment, Supplies and Medications

8.2.1 Facilities for safe surgical and anaesthetic care are provided and maintained.

Standard Intent

The design of the operating theatre provides space for the reception, anaesthesia, surgery, recovery and observation of patients. Access to the operating theatre suite is controlled. Anyone entering the area is required to change into theatre attire and wash their hands.

There are areas for the disposal and collection of used equipment and waste, including contaminated waste and sharps. Safe and adequate storage space for

pharmaceutical and surgical supplies is available. This includes separate lockable cupboards for medicines requiring control in accordance with legislation or organisational policy and for inflammable substances.

Theatre personnel are provided with office facilities or a day station, a restroom, washrooms, toilets, changing facilities and a separate space for their personal clothing and theatre clothing.

There are facilities for scrubbing-up procedures in each theatre, with hot and cold running water and elbow-operated taps. There is an anaesthetist's chair, an operating table with Trendelenburg position control, at least one lateral padded straight arm support, and an infusion pole. Equipment for patients awaiting surgery includes blood pressure monitoring equipment, vacuum points with ancillary fittings and oxygen points with flowmeters and all ancillary fittings. Space and facilities are available for setting up surgical trays and for autoclaving instruments**.**

8.2.1 Criteria

8.2.1.1 The design of the operating theatre complex provides space for the reception, anaesthesia, surgery, recovery and observation of patients.

8.2.1.2 Access to the theatre suites is controlled.

8.2.1.3 There is direct access to the operating theatres from the receiving, scrubbing-up and recovery areas.

8.2.1.4 The accommodation for patients awaiting surgery is suitably equipped.

The assessor must assess what arrangements are in place to accommodate patients awaiting surgery. The patient must be taken directly into the operating theatre from the ward or be kept temporarily in the recovery room where the necessary equipment and personnel are available.

8.2.1.5 There is safe and adequate storage space for pharmaceutical and surgical supplies.

8.2.1.6 There is access to sterilisation and disinfection facilities.

The operating theatre and sterilising department may run as adjacent units or may be entirely separate.

The theatre suite must have access to some form of sterilisation equipment for emergencies, e.g. flash autoclaves.

8.2.1.7 There is a system for controlling the environmental temperature and humidity that ensures safe limits for anaesthetised patients (temperature between 22°C and 25°C and relative humidity between 40% and 70%).

The type of air-conditioner will be assessed in relation to the type of surgery done.

8.2.1.8 There is either an uninterrupted power supply (UPS) or a battery backup system for the theatre lamp, which is regularly tested, with such tests being fully documented.

This will be assessed during the on-site assessment of the theatre suite.
It may be necessary to check with the maintenance manager about the servicing and testing of the UPS.

8.2.1.9 There is a functional operating theatre table, which is regularly tested, with such tests being fully documented.

8.2.1.10 The theatre has a lockable refrigerator for medications, the temperature of which is measured and recorded daily.

8.2.2 The anaesthetic equipment, supplies and medications used comply with the recommendations of professional anaesthetic organisations, or alternate authoritative sources.

8.2.2 Criteria

8.2.2.1 The provision and use of anaesthetic mixture components and other peri-operative medication complies with the guidelines of a professional society or similar reputable professional body.

This relates to criterion 8.1.1.4 and whether a copy of the guidelines of the country's professional body or a copy of another reputable guideline is available and is used to guide the choice of anaesthetic apparatus.
This will be assessed during an assessment in the theatre suite and applies to criteria 8.2.2.1 to 8.2.2.4.

8.2.2.2 The provision and use of breathing circuits complies with the guidelines of a professional society or similar reputable professional body.

8.2.2.3 The provision and use of ancillary equipment complies with the guidelines of a professional society or similar reputable professional body.

8.2.2.4 The provision and use of monitoring equipment complies with the guidelines of a professional society or similar reputable professional body.

8.2.2.5 An anaesthesia trolley is available for the exclusive use of the anaesthetist in each theatre.

8.2.2.6 Expiry dates of medications are checked regularly, with documented records of such checks.

8.2.2.7 A tracheotomy tray is available.

8.2.2.8 Theatre personnel ensure that all equipment is included in the organisation's equipment replacement and maintenance programme.

8.2.3 Emergency and protective equipment and supplies are provided in the operating theatre.

8.2.3 Criteria

8.2.3.1 Emergency resuscitation equipment and supplies are available.

8.2.3.2 Emergency and resuscitation equipment and supplies have clearly defined instructions for use.

8.2.3.3 Emergency resuscitation equipment shows evidence of regular checking.

8.2.3.4 There is a mechanism for summoning assistance in the operating theatre.

8.2.3.5 There is appropriate shielding and protective clothing in the presence of biohazards (including lasers) or radiographic equipment.

8.2.3.6 Hazard or warning notices are displayed.

8.2.4 Recovery room facilities and equipment are available to provide safe and effective care.

Standard Intent

The number of beds/trolley spaces in the recovery room provides sufficient space for at least one patient from each operating theatre that it services, and is sufficient for peak loads. The provision, use and maintenance of recovery room equipment comply with the guidelines for practice of the professional society.

8.2.4 Criteria

8.2.4.1 The recovery area forms part of the operating theatre complex.

8.2.4.2 There are enough recovery beds for the patients from the operating theatre.

8.2.4.3 There is adequate lighting.

8.2.4.4 The provision, use and maintenance of recovery room equipment comply with the professional society's guidelines.

8.2.5 The sterilising and disinfecting unit is designed to allow for effective sterilising and disinfecting of equipment and supplies.

Standard Intent

Even in a small one-room unit, the separation of activity sites and the flow of work can be achieved by careful planning. There should be a dedicated area for cleaning equipment and instruments.

There are many methods of sterilising equipment. Whatever methods are used, the personnel need to ensure that the equipment used is effective. There must, therefore, be established systems for ensuring that sterility is obtained through the sterilisation processes.

The number of autoclaves required will depend upon the size of the clinic/healthcare centre and the services provided, how much is processed on site and how much is acquired pre-packed and sterilised and whether the needs of both the operating theatre suite and other departments/services are catered for.

8.2.5 Criteria

8.2.5.1 The design of the sterilising and disinfecting unit, and the layout of equipment, ensures flow of work from the soiled to the clean side of the unit.

8.2.5.2 There is a washing and decontamination area, with stainless steel sinks and running water, and a sanitary sewage system.

8.2.5.3 There is a pre-packing area with storage facilities for clean materials.

8.2.5.4 There is a storage area for sterile packs with racks that allow for an adequate circulation of air.

8.2.5.5 Adequate light and ventilation are available.

8.2.5.6 There are one or more autoclaves or their equivalents that are capable of sterilising porous loads (gowns, drapes and dressings), as well as wrapped and unwrapped instruments.

8.2.5.7 Where ethylene oxide is used as a sterilising agent, the installation complies with relevant safety standards and legislation.

8.2.5.8 Autoclave sterility is tested daily and the test results are recorded.

8.2.5.9 The sterility of each pack is shown on indicator tapes that are suited to the processes used.

8.3 Policies and Procedures

8.3.1 Policies and procedures are developed relating to the activities in the operating theatre and anaesthetic service.

Standard Intent

Policies and procedures are necessary to guide the administration of the operating theatre and anaesthetic services to ensure the smooth operation of those services, and to ensure that personnel act swiftly and in a coordinated manner in an emergency. Those policies and procedures are made available to all theatre, recovery room and anaesthetic personnel, and are known and implemented.

Biohazards that need to be monitored and notified include radiation, laser and electrical hazards. Policies and procedures are available to ensure that informed consent is documented, the patient is correctly identified, and the nature of and the site for surgery are correctly documented. Processes during the surgery, such as the use of instruments and counting procedures, are documented to ensure co-ordination and safety.

The implementation of policies will be assessed on site. For example, the assessor will require the person in charge to describe their performance step by step, while showing where and when/how to get the required equipment. At the same time, expiry dates, functioning of equipment and sterilisation issues will be checked.

8.3.1 Criteria

8.3.1.1 There are written policies and procedures to guide the activities of the theatre and the anaesthetic service.

Policies and procedures could relate to:
- *the duties of theatre and recovery room nurses;*
- *theatre cleaning*
- *notification of biohazards*
- *medications controlled by legislation or organisational policy*
- *patient positioning.*

8.3.1.2 Policies and procedures are developed relating to the preparation of patients for surgery.

Policies and procedures relating to the preparation of patients for surgery include:
- *the scheduling of patients for listed and emergency surgical procedures;*
- *patient identification;*
- *verification of the nature and site of the operation;*
- *verification of the last oral intake;*
- *checking of consent documents;*
- *the instruments required for specific operations;*
- *aseptic techniques.*

8.3.1.3 Policies and procedures are developed relating to intra-operative recording.

Policies and procedures relating to intra-operative recording include:

- *the recording of tissue and specimen collection*
- *counting procedures for swabs, instruments and needles, and procedures to be adopted in the event of incorrect counts*
- *details of each surgical procedure, including complications, to be recorded in the theatre register/log book.*

8.3.1.4 Policies and procedures are developed relating to the anaesthetic service.

Guidelines of professional societies and associations are available and followed whenever anaesthesia is administered. This includes nurses who assist the anaesthetist and who monitor the recovery of patients. Implementing these guidelines is particularly important with regard to the qualifications, training and experience required by staff members in the service, and also the provision, maintenance and use of medical equipment and drugs.

Controlling bodies also develop guidelines and regulations relating to professional practice

Policies and procedures relating to the anaesthetic service include:

- *the required qualifications of persons who administer anaesthetics and of persons who assist the anaesthetist*
- *anaesthetic equipment hazards*
- *the pre-operative assessment and pre-medication;*
- *assessing the fitness of patients to leave the recovery area.*

8.3.1.5 There are guidelines relating to the administration of major regional anaesthesia.

8.3.1.6 There are guidelines relating to the use of conscious sedation, where applicable.

8.3.1.7 Policies and procedures comply with current guidelines of the professional society.

8.4 Pre-Operative and Operative Care

8.4.1 A pre-anaesthetic assessment is conducted and recorded.

Standard Intent

Because anaesthesia carries a high level of risk, its administration is carefully planned. The patient's pre-anaesthetic assessment is the basis for that plan and for the use of post-operative analgesia. The pre-anaesthetic assessment provides information needed to:

- select the type of anaesthesia to be administered and plan anaesthetic care
- identify any drug sensitivities
- safely administer the appropriate anaesthetic and
- interpret the findings of patient monitoring.

An anaesthesiologist or other qualified individual conducts the pre-anaesthetic assessment.

Anaesthetic care is carefully planned and documented in the anaesthetic record. The plan considers information from other patient assessments and identifies the anaesthetic to be used, the method of administration, other medications and fluids, monitoring procedures, and the anticipated post-anaesthetic care.

The anaesthetic planning process includes educating the patient and his or her family or decision-maker regarding the risks, potential complications, and options related to the planned anaesthesia and postoperative analgesia. This discussion occurs as part of the process of obtaining consent for anaesthesia. The anaesthesiologist or the qualified individual who will administer the anaesthetic provides this education.

8.4.1 Criteria

All the criteria related to this standard will be assessed by undertaking an audit of randomly selected records of patients who have undergone surgical procedures.

Documented evidence of the requirements will be sought and marked accordingly.

8.4.1.1 An anaesthetic assessment of the patient is performed before the anaesthesia is administered.

8.4.1.2 The medical assessment of surgical patients is documented before the start of the anaesthesia.

8.4.2 Each patient's physiological status is monitored and recorded during anaesthesia and surgery.

Standard Intent

The anaesthetist monitors and records the physiological status of the patient during anaesthesia, and enters the anaesthetic, drugs and intravenous fluids used in the patient's anaesthetic record.

The anaesthetist has access to the patient care notes, and is familiarised with the findings of the medical examination. It is important that each health professional has access to the records of other care providers, in accordance with organisational policy.

8.4.2 Criteria

*All the criteria related to this standard will be assessed by undertaking an **audit** of randomly selected **records of patients** who have undergone surgical procedures.*

If copies of the intra-operative records are not available in the patient records, establish whether they are kept elsewhere, e.g. in the anaesthetists' records.

Wherever the records are kept, documented evidence will be sought and the criteria marked according to findings.

8.4.2.1 The patient's physiological status is continuously monitored and recorded during anaesthesia and surgery.

8.4.2.2 The anaesthesia used is entered in the patient's anaesthetic record.

8.4.3 Each patient's post-anaesthetic status is monitored, and the patient is discharged from the recovery area in accordance with accepted guidelines.

Standard Intent

Physiological monitoring provides reliable information about the patient's status during the administration of anaesthesia and the recovery period. Monitoring methods depend on the patient's pre-anaesthetic status, anaesthetic choice, and the complexity of the surgical or other procedure performed during anaesthesia. In all cases, however, the monitoring process is continuous, and the results are entered into the patient's record.

Monitoring during anaesthesia provides the basis for monitoring during the post-anaesthetic recovery period. The on-going, systematic collection and analysis of data on the patient's status in recovery may support decisions about moving the patient to other settings and less intensive services. Only a suitably qualified and experienced registered nurse or designated member of the medical staff may carry out monitoring in the recovery area. Recording of monitoring data provides the documentation to support discharge decisions**.**

The anaesthetist or other qualified individual decides whether the patient can be discharged from the recovery area to the inpatient ward or from the organisation (as in the case of ambulatory anaesthesia). Standardised criteria developed by medical personnel are used to make discharge decisions. The decision to discharge the patient from the recovery area is entered into the patient's record. The time of arrival in, and discharge from, the recovery area are recorded. The signatures of those who handed over and those who received the patient are recorded.

8.4.3 Criteria

8.4.3.1 During the post-anaesthetic recovery period, patients receive monitoring appropriate to their condition.

8.4.3.2 Monitoring findings are entered in the patient's record.

*This will be assessed from the **patient record audit**.*

8.4.3.3 Established criteria are used to make decisions regarding the patient's discharge from the recovery room.

*The criteria may be documented in a policy/procedure or printed on the recovery room section of the intra-operative record. A documented record of their application will be sought during the **patient record audit**.*

8.4.3.4 The decision to discharge the patient is recorded.

*This will be assessed from the **patient record audit.***

This criterion will be rated NC if the person who administered the anaesthetic failed to sign the record. (See the 8.1.1.7 guideline.)

Recovery room nurses must record the name and designation of the person who gave permission for the patient to be discharged from the recovery room.

8.4.3.5 Recovery area arrival and discharge times are recorded.

8.4.3.6 The signatures of those handing over and those receiving the patient are recorded.

SE 9: LABORATORY SERVICES

OVERVIEW OF THE LABORATORY SERVICES

Laboratory investigations and rapid reporting systems are essential for patient assessment and the implementation of treatment plans.

The facility may have its own laboratory service or it may have an arrangement with an outside laboratory service. In either case, the service must meet applicable standards, laws and regulations.

The selection of an outside source to receive laboratory specimens for analysis is based on an acceptable record and compliance with laws and regulations.

Laboratory services must be available at those times required by the organisation, including emergency and after-hour services.

Standards

9.1 Management of the Service

9.1.1 Laboratory services are available to meet the needs of services and patients, in compliance with and national laws, regulations and standards.

Standard Intent

The organisation has a system for providing the laboratory services, including clinical pathology services, required by its patient population, clinical services offered, and healthcare providers' needs.

The laboratory services are organised and provided in a manner that meets applicable national standards, laws and regulations.

Laboratory services, including those required for emergencies may be provided within the organisation, by agreement with another organisation, or both. Laboratory services are available after normal hours for emergencies.

Outside sources are convenient for the patients. The organisation selects outside sources based on the recommendations of the director or other individual responsible for laboratory services. Outside sources of laboratory services meet applicable laws and regulations and have acceptable records of accurate, timely services. Patients are informed when an outside source of laboratory services is owned by the referring medical practitioner.

Laboratory results are validated to ensure that they are those of the correct patient and medical practitioner. Validations include the name of the validating officer.

Results are reported within a time frame based on patient needs, services offered, and the needs of the clinical personnel. Emergency tests, after-hours and weekend testing needs are included. Appropriate specimen containers are available in the organisation, with instructions for their correct use.

9.1.1 Criteria

9.1.1.1 Adequate, convenient and regular laboratory services are available to meet the organisation's needs.

Root criterion that addresses a number of issues.

With "adequate" one should take into consideration the level of service provided by the hospital, the available specialties, whether this is a referral laboratory or not, physical facilities, work space, availability and functional status of equipment, availability of required number of qualified personnel in terms of workload, etc.

Also to be taken into account, are the alternative arrangements (referral of tests to other laboratories) in case the laboratory cannot provide the service.

"Convenient" refers to the location and accessibility of the laboratory, as well as the hours of operation (also included in the statement on "regular services").

"Regular" refers to the hours of operations and whether an after-hours service is available or not, this should be measured against the needs of the hospital and other clients that the laboratory may serve, e.g. surrounding hospitals and clinics.

The types of services to be provided are guided by national regulations and should be in line with the services provided by the facility itself.

9.1.1.2 The laboratory services are organised and provided in a manner that meets applicable national standards, laws and regulations.

National requirements need to be considered and these may include: licensing, staffing norms and qualifications, scope of practice, etc. This criterion also requires the existence of policies and procedures to guide all managerial functions and operational activities in the laboratory and the presence of a laboratory manual. Such policies may be originated at higher levels (national, head office) or in the local laboratory itself.

9.1.1.3 Emergency laboratory services are available, including after-hours services.

Laboratory policy needs to define the alternative arrangements to be in place should the on-site laboratory not provide any after-hours service.
There should be a system available in which the 24 hour service is defined, when the emergency services can be used, who is on duty and which outside laboratory is on call.

9.1.1.4 The organisation has established the expected report time for results.

This aspect is policy-driven and documented evidence is required of such reporting times for the various tests. This information needs to be available in the various clinical departments, including outpatients and casualty/emergency departments. Consultation with clinicians is important as the patient care aspects are included in the next criterion.

9.1.1.5 Laboratory results are reported within a suitable time frame to meet patient needs.

Policy needs to define the process for informing clinical personnel when delays are expected because of the impact this may have on patient care.
This criterion measures the adherence to the time frames stipulated in 9.1.1.4 and compliance is assessed by reviewing a sample of patient records and laboratory result forms.

9.1.1.6 Laboratory results are validated and include unique patient identity, date of testing/reporting, name and location of the requesting medical practitioner.

A policy should be in place for post-examination of the laboratory results, where authorised personnel systematically review the results of the examinations and

evaluate the results in conformity with the administrative and clinical information available regarding the patient and requesting physician and authorise the release of the results.
A list of references and critical values needs to be available.

9.1.1.7 The validating officer is identified and recorded.

A staff member should be allocated to take responsibility for the validation processes within the laboratory. The validation officer is responsible for implementing and monitoring internal and external quality control policies and policies to validate quality of the laboratory results.

9.1.1.8 A list of referral laboratories which have been duly approved is available for tests not performed onsite.

A good referral system is essential for all the laboratory tests that are not performed in house. A referral system should also be in place in case a specific service is not provided, in case of an unexpected shortage of personnel (due to illness/absence), in case of an unforeseen stock out of essential materials or in case specific instruments are out of order.

A list of the referral laboratories should be available, including information about the selection and yearly monitoring of the referral laboratories.

Note: Experience shows that it is exceptional when a laboratory has a complete referral system, documented and in place, but nearly all of them have some sort of arrangement. The ins and outs of these systems are hardly described and are merely verbal arrangements between doctors or laboratory technicians of various clinics. It is important to check this process, as the quality of specimens (and therefore the reliability of results) relies strongly on proper specimen handling (including transportation). Also, it is important for general safety issues (for instance, drivers on the road with HIV+ material that is not properly wrapped, etc).

9.1.1.9 There is a documented, implemented procedure for packaging specimens and transporting them to the referral laboratories.

When specimens are referred to the referral laboratory, the quality of the specimens needs to be guaranteed during shipment. Policies for proper shipment should therefore be available. The policies need to include:

- *a guideline on how to pack the different specimens*
- *a guideline for organised and timely pick-up schedules from and to the referring laboratory*
- *a guideline for a formalised timeframe between sending specimens and receiving results*
- *the availability of a specimen transportation cool box with hazardous/infectious sticker, and*
- *the availability of cooling elements, transportation tubes and racks.*

9.1.1.10 A register is kept of the referred specimens and the results.

This criterion defines the specific requirements for referral administration as defined in 9.1.1.9. The administration should include:

- *a referral site list and related administration about the quality of the referral sites*
- *a referral request form on which the patient information, required investigation and results can be processed and authorised*
- *a referral logbook in which all the referral specimens and results are recorded*
- *a logbook in which the referral result forms are stored, and*
- *a logbook where externally obtained results are noted.*

9.1.2 A qualified individual is responsible for managing the laboratory service.

Standard Intent

The laboratory service is under the direction of an individual who is qualified by virtue of documented training, expertise and experience, in accordance with applicable laws and regulations. This individual has professional responsibility for the laboratory facility and for the services provided. When this individual provides clinical consultations or medical opinions, he/she is a medical practitioner or a pathologist. Speciality and subspecialty laboratory services are under the direction of appropriately qualified individuals. The responsibilities of the laboratory director include:

- developing service-related policies and procedures and ensuring that they are implemented and reviewed regularly.
- managing relevant human resource functions, e.g. job descriptions, personnel evaluation, personnel training, and
- developing, co-ordinating, and monitoring the required quality control and improvement systems.

9.1.2 Criteria

9.1.2.1 The laboratory is under the direction of a qualified individual.

National requirements need to be taken into consideration and the required evidence can be obtained from various sources such as post specifications or a job description. There should be evidence of registration with the relevant professional body/council.

9.1.2.2 The responsibilities of this person include maintaining quality control programmes.

To implement the quality management system, the laboratory manager or assigned professional laboratory personnel should participate as members of the various quality improvement committees of the institution, if applicable or assigned. Quality management systems consist of collective policies, plans, practices, and the supporting infrastructure by which an organisation aims to reduce and eventually eliminate non-conformances to specifications, standards, and customer expectations in the most cost-effective and efficient manner. The laboratory manager is responsible for the supervision of the development, implementation and monitoring of internal and external quality control policies.

9.1.2.3 The responsibilities of this person include administrative supervision.

These responsibilities include the development, implementation and monitoring administrative policies in collaboration with the administrative and medical personnel. Policies are required for:

- *patient identification including a patient request form and in flow and result registers*
- *procedures development (laboratory services)*
- *a documentation control system, and*
- *supervising personnel, allocating key functions while recognising that in small laboratories individuals may be allocated multiple functions.*

9.1.2.4 The responsibilities of this person include monitoring and reviewing all the laboratory services.

A policy should be in place that lists the provided laboratory services. The required laboratory services should be defined as described in criteria 9.1.1.1. The laboratory manager is responsible for:

- *selection of the laboratory services, which should be based on the medical services provided and should be discussed with the medical personnel regularly;*
- *regular review and adaptation of the laboratory services.*

9.1.3 Individuals with adequate training, skills, orientation and experience perform tests and interpret the results.

Standard Intent

The organisation identifies the laboratory personnel who may perform testing and who may direct or supervise testing. Supervisory and technical personnel have appropriate and adequate training, experience and skills, and are oriented to their work. Technical personnel are given work assignments consistent with their training and experience. In addition, there are enough staff members to perform laboratory tests promptly and to provide the necessary laboratory services during all hours of operation and for emergencies.

The organisation is able to identify and contact experts in specialised diagnostic areas, such as parasitology or virology, when needed.

9.1.3 Criteria

9.1.3.1 Qualified individuals are assigned to perform and supervise the provided laboratory services.

National requirements will apply and assessment of compliance is made against laboratory policies, post requirements and job descriptions.

The laboratory personnel should have:

- *relevant educational and professional qualifications; and*
- *relevant training and experience.*

9.1.3.2 There are enough staff members to meet service needs.

National requirements will apply and the facility's organogram and personnel establishment should be the basis for assessing such compliance. It is important to

take note of any vacancies that may exist. Assess whether the laboratory personnel are capable of performing all the laboratory services provided efficiently and without having any negative effect on the quality outcome

9.1.3.3 On-going in-service training is provided to all personnel members.

A documented departmental in-service training programme is needed. See Standards 2.3.1, 2.4.1, 2.4.2 (esp. 2.4.2.4), 2.4.3.

Continuous medical training topics:
- *training on provided laboratory services (chemistry, haematology, phlebotomy)*
- *skills training (e.g. how to operate a pipette)*
- *stock management training*
- *waste management training, and*
- *administrative training.*

The assessor may ask a staff member to demonstrate any of the above, to check the level of knowledge and skill.

9.1.3.4 Records of the training provided are kept for each personnel member.

Documented evidence of attendance at training sessions is required. Such documents should be available in the personnel files of the specific staff members.

A policy for future training should be available.

9.2 Facilities and Equipment

9.2.1 Laboratory buildings are adequate to provide a safe and effective laboratory service.

Standard Intent

Departmental managers need to work closely with organisational managers to ensure that facilities and equipment are adequate. Departmental managers keep organisational managers informed about inadequate facilities, additional equipment requirements and the current state of facilities and equipment.

The general state of the laboratory will be checked. The walls, floor and ceiling should be in a good condition. As few items/instruments as possible should be placed on the floor.

9.2.1 Criteria

9.2.1.1 The laboratory is a separate designated area within, or in close proximity to, the health facility.

The separate rooms of the laboratory for specimen collection and specimen processing must be a clearly sign posted.

Depending on the clinic and the number of different activities, more than one designated room may be necessary.

*The phlebotomy activities should **not** be performed in the available testing laboratories. They should be performed in a separate room that provides safe and confidential sample collection.*

TB activities should also be performed in a dedicated separate area. The (inter)national infrastructural requirements should be followed.

9.2.1.2 The size of the laboratory is appropriate to the services provided.

The size of the laboratory is dependent on (inter)national guidelines and the utilisation of the provider.

The recommended minimum size for a laboratory room with very limited activities/workload is 12m². A more standard size laboratory is preferred and is easily 16-25 m². Besides the defined size some activities should not be performed in the primary routine laboratory.

- *Bacteriology should be performed in a separate area*
- *Phlebotomy should be performed in a separate area*
- *TB diagnostics should be performed in a separate area, and*

The size of the bacteriology, phlebotomy and TB areas depends on the (inter)national requirements and the utilisation of the provider.

9.2.1.3 The ceiling and walls are clean and painted in a light colour.

The walls should be checked for stains that indicate the spill of blood products.

9.2.1.4 The floor has a smooth and continuous surface.

The floor should consist of concrete (not cracked) or tiles (not broken).
Wooden floors are not acceptable.

9.2.1.5 The ceiling is not leaking and does not show signs of moisture.

The ceiling must not have stains which suggest (old) leakage of the roof. Assess whether the stains are old or recent. When they are old, they suggest that the leakage has been repaired and that the ceiling has not yet been painted.

9.2.2 Laboratory fixtures and fittings are adequate to provide a safe and effective laboratory service.

Standard Intent

The laboratory has to be constructed in such a way that it can provide the projected laboratory services. The laboratory has to have sufficient and proper laboratory benches, washing and staining facilities, sufficient power and water requirements and preferably a controlled temperature. The following specific details should be monitored.

- Laboratory benches and equipment should be of a material that can support the laboratory instruments (strong) and should be of a material that cannot affect the surface of the table. Preferably the laboratory tables are constructed of concrete that is tiled. No wooden tables are allowed.

- At least one washing unit is available for standard cleaning and washing activities. When staining is performed, two units are preferred.
- The number and quality of the available electrical sockets should be sufficient for the projected activities.
- The water supply should be guaranteed to provide washing and staining activities.

9.2.2 Criteria

9.2.2.1 There are sufficient laboratory benches for the projected activities.

The number and size of the laboratory tables should provide sufficient space for laboratory instruments and the laboratory activities to be performed.
When instruments are close to each other, preventing their proper operation and/or performance of other activities, or when instruments are placed on the floor, the number of laboratory benches should be expanded.

When electrical instruments are close to the washing or staining area, consideration should be given to moving them to a different location.

9.2.2.2 Laboratory benches are strong enough for the projected activities (e.g. large instruments).

Benches are made from tiled concrete or other strong dedicated materials.
Bench surfaces should preferably be covered with a material resistant to chemicals (no wood). Benches should be level in order to allow the instruments to be positioned horizontally. Some instruments are both long and wide and therefore some instruments extend beyond the bench, becoming slightly tilted. Benches should be reinforced when heavy or shaking instruments are available.

9.2.2.3 There is either an uninterrupted power supply (UPS), battery backup system and/or an automated voltage stabilizer (AVS) present for critical equipment.

Critical instruments should be connected to the power supply using an UPS or an AVS. The size of the UPS/AVS is dependent on the capacity of the instrument. The UPS/AVS systems are tested regularly and the results are fully documented.

9.2.2.4 Each laboratory compartment as adequate ventilation, with room temperature below 25˚C, and a temperature record is kept.

The laboratory needs to be temperature controlled, because when the temperature is high, it can influence the laboratory procedures and instruments.

The availability of an air-conditioning system is desirable, in order to guarantee a constant temperature.

9.2.3 There is sufficient laboratory equipment that is adequate to provide a safe and effective laboratory service.

Standard Intent

In order to provide effective laboratory services, it is essential that specific equipment is available. Laboratory management and personnel are responsible for the selection and availability of the critical instruments, their operation according to manufacturer's instructions and their appropriate maintenance. The following aspects must be considered.

- Processes for the selection and procurement of new instruments.
- The availability of an equipment inventory management system.
- The maintenance of the available equipment through inspection, testing and calibration.
- Monitoring of and acting on equipment hazard notices, recalls, reportable incidents, problems and failures.
- The availability of a system where activities are documented.

Testing, maintenance and calibration frequencies are related to the laboratory's use of equipment and its documented history of service.

9.2.3 Criteria

9.2.3.1 Sufficient equipment is available to provide the required laboratory services for the projected activities.

AT LEAST THE FOLLOWING EQUIPMENT SHOULD BE AVAILABLE:

- *Amicroscope*
- *centrifuge (complete configuration)*
- *refrigerator with freezer compartment*
- *rocking platform, glucometer*
- *haemoglobin (Hb) analyser*
- *pressure cooker / autoclave*
- *UPS/AVS for critical instruments*
- *pipette, thermometer and timer, and*
- *fume hood (TB related activities).*

9.2.3.2 All equipment is in good working order and is operating appropriately.

Documented systems need to reflect on-going monitoring of equipment maintenance activities and operation, as stated above, as well as any corrective actions taken when indicated by findings.

Assess whether corrective and preventive activities (CAPA) are being performed.

Check working order through demonstration and check overall quality by monitoring cleanliness, positioning, etc.

9.2.3.3 Records are maintained to indicate that all equipment is regularly inspected, maintained and calibrated.

Owners' manuals should be available and equipment should be maintained in accordance with manufacturers' instructions.
An internal and external maintenance policy and related administration should be available

Records of function and repair should be available.

9.3 Reagents, Chemicals and Kits

9.3.1 The supplies of laboratory consumables, reagents, chemicals and kits are adequate to provide a safe and effective laboratory service.

Standard Intent

The organisation has identified those reagents and supplies needed to regularly guarantee the laboratory services provided to its patients. There is an effective process for ordering and ensuring that essential reagents and other supplies are available at all times. All reagents are stored and dispensed according to defined procedures. The periodic evaluation of all reagents, such as monitoring expiry dates, ensures accuracy and precise results. Written guidelines ensure the complete and accurate labelling of reagents and solutions.

9.3.1 Criteria

9.3.1.1 The available supplies, consumables, reagents, chemicals and kits are sufficient for projected activities.

Consider the level of service, the range of tests offered, the utilisation and the type of equipment in use.

Assess the available materials in relation to the stock management and procurement activities.

9.3.1.2 Specific laboratory reagents, chemicals and kits are used appropriately

Pay particular attention to the following aspects.

- *Consumables are not re-used.*
- *Reagents and kits are not expired.*
- *Proper specimen collection materials are used, e.g. the Vacutainer (or similar) system for blood collection should be mandatory.*
- *Products are from quality assured manufacturers.*
- *Kits used are part of the national algorithms.*
- *Reagents and kits are stored according to the guidelines of the manufacturer.*

9.3.1.3 All reagents and chemicals are stored and dispensed according to guidelines.

Documentation should be available in the form of policies, guidelines, safe work procedures and/or manufacturer's guidelines, against which the actual arrangements will be assessed. The assessment needs to include all storage areas such as fridges, cupboards, work stations and storerooms as well as the processes involved with receiving, issuing and disposing of substances.

The materials should be checked regarding:
- *expiry dates,*
- *storage temperature,*
- *protection from heat and sun, and*
- *labels and dates, etc.*

9.3.1.4 All reagents and solutions are completely and accurately labelled.

Labelling identification requirements include:
- *the name of the person who prepared the reagent/solution*
- *the name of the reagent/solution*
- *the strength or other reagent specification*
- *the date prepared or received, and*
- *expiry date.*

A random check needs to be done in all areas of the laboratory where these items are used and stored.

9.3.1.5 All reagents are periodically evaluated for accuracy of results.

Service policies/procedures/protocols/guidelines should be available to guide this practice and assessment of compliance will be done against these documents. Records should be available of such periodic evaluations performed on reagents, including water used in the laboratory.

The performance of evaluations and the results are usually recorded in the internal quality control (IQC) log books.

9.3.1.6 All reagents are stored in a lockable storage room or cupboard.

The working materials must be readily available and, therefore, do not have to be locked away during the time of performing laboratory activities.
At the end of the day, the laboratory must be closed in order to prevent unauthorised access and/or use.

9.3.1.7 Where required, reagents are stored in the correct environment, e.g. controlled temperature, humidity, exposure to direct sunlight.

Requirements to be monitored:
- *the availability of an air-conditioning unit to control the temperature and humidity, and*
- *the availability of a cupboard for storing materials that may not be exposed to direct sunlight.*

9.3.1.8 Dangerous reagents and chemicals are separately and securely stored.

A policy that defines the storage of dangerous reagents and chemicals must be implemented.

Dangerous solutions that have been commercially prepared are provided with a hazard sign. The hazard sign defines the storage requirements.

Some reagents and solutions (such as the reagents for TB activities) fall under a specific dangerous category and require a secure storage area.

9.3.1.9 All reagents are checked for expiry dates.

Randomly check expiry dates at different locations (storage room, refrigerator etc.) in the laboratory.

Note:
Be aware of different annotations and dates that define the date of manufacture.

9.3.1.10 There is a documented stock management system that keeps track of current stock.

There is a documented process for managing laboratory stock, which must include the following information:

- *a laboratory material list (item description, manufacturer, supplier, catalogue identification, etc), and*
- *a register/log book of incoming and outgoing stock.*

Specific information of in- and out-going products can be monitored through a digital and a BIN card system. At least, the following information should be available on the BIN cards:

- *the name and provider of the product*
- *package size*
- *the number of packages available for each product*
- *the number of packages received and used, including dates*
- *a reference to minimum and maximum levels, and*
- *an authorisation signature for in- and outflow activities.*

9.3.1.11 Re-order levels are defined.

In order to guarantee that materials are available at all times, re-order levels have to be assigned for all the laboratory products used.

The re-order levels are important for defining when to take action with regard to procurement and, therefore, a system should be available to monitor this process.

9.4 Management of Specimens (Samples) and Results

9.4.1 Procedures are followed for collecting, identifying, safely transporting and tracking specimens/samples, and reporting the results.

Standard Intent

Procedures are developed and implemented for:

- requesting laboratory tests (laboratory request form)
- specimen collection and identification
- specimen storage, preservation and transport, and
- reviewing and authorising the laboratory results.

There should be at least two log-books: only one patient logbook and at least one logbook for laboratory results. Depending upon the size of the provider and the national requirements of the Ministry of Health, different logbooks for various disciplines are required or mandatory. Logbooks for laboratory results should not be directly linked to names. Patient log-books should contain name, date of visit, date of birth, gender, which services are requested, what material should be collected and the unique laboratory identification number. In the laboratory log-books only the unique laboratory number and results are registered. In other words, both log-books are required to match results to patient names.

Ideally, monthly overviews of the number of tests performed are generated.

Procedures should be available for administration, collection and reporting activities of specimens tested on site or sent to outside referral laboratories.

9.4.1 Criteria

9.4.1.1 Policies and procedures (SOPs) for handling specimens are implemented.

Procedures and guidelines are available for all specimens that are collected and investigated. In the specimen collecting guidelines, topics such as proper collection, safe handling and storage must be addressed.
Policies for specimen acceptance and/or rejection must be available. These criteria are based on information available in the manufacturers' manuals and general guidelines.

9.4.1.2 Request forms are available and contain relevant information.

On a provider-specific laboratory request form, the opportunity is provided to define which laboratory test has to be performed on a specific material of a specific patient.
The information on the laboratory request form should contain at least the following:

- *patient name*
- *unique patient identification number*
- *clinical diagnosis*
- *gender*
- *date of birth*
- *identity of the requestor*
- *sample type*

- *test requested*
- *date and time of sample collection*
- *result and authorisation, and*
- *name of facility/ward.*

9.4.1.3 Specimen labels include unique patient identification and adequate supporting information.

This should be compatible with the information on the request form.
The material should have at least 2 identification codes. One should be the unique laboratory number and the other, preferably, the date of birth.
The date the specimen was taken and the specimen type should be indicated as well.

9.4.1.4 Specimens are registered (handwritten or digital) legibly and in an organised manner.

An inflow register is available in which the information of the patient and requested test is recorded. In small facilities the inflow register and result register are compiled in one administration book. When providers are bigger and have more utilisation, separate books are usually used for inflow and results.

9.4.1.5 Results are registered in a log-book.

Guidelines for the content of the logbook can be national because they are provided by the MoH of the relevant country. In the logbooks, the results are recorded for the specific tests for each specimen
The logbook should indicate who did which test.

9.4.1.6 Laboratory results are stored in lockable cupboard.

Laboratory notebooks should be kept in a lockable cupboard that is not accessible to unauthorised personnel.

9.4.1.7 Policies and procedures (SOPs) regarding reporting and reviewing results are implemented

SOP's should be available for:
- *patient, specimen and result registration*
- *specimen collection guidelines*
- *specimen acceptance and rejection criteria, and*
- *reporting strategy (paper-based and telephonic).*

9.4.2 Established norms and ranges are used to interpret and report clinical laboratory results.

Standard Intent

The laboratory establishes reference intervals or "normal" ranges for each test performed. The range is included in the clinical record, either as part of the report or by including a current listing of such values, approved by the laboratory

director. Ranges are furnished when an outside source performs the test. The reference ranges are appropriate to the organisation's patient population and are reviewed and updated when methods change.

9.4.2 Criteria

9.4.2.1 The laboratory has established reference ranges for relevant tests.

A list with reference and critical values should be available and up to date.
The reference ranges and critical values are based on the laboratory services provided and will be determined by factors such as national arrangements, type of equipment and requirements of the medical personnel, etc. In many instances, these ranges may be determined at national or district level, in which case this criterion will be scored NA with an explanatory comment.
The reference list should be used for the review and final authorisation of the laboratory results.

In the case of a test indicating a critical value, there is a system in place to ensure that the result is communicated to the requesting healthcare professional immediately.

9.4.2.2 The range is included in the clinical record at the time test results are reported.

Test ranges should be available to the medical personnel
Ranges should be appropriate to the organisation's patient profile and should be reviewed and updated as needed. Ranges should be available for tests performed by outside sources (referral laboratories).

9.5 Quality Control

9.5.1 Quality control procedures are followed and documented.

Standard Intent

The quality of the laboratory services can be monitored using internal and external quality control guidelines. Designing and implementing internal and external quality control activities is essential for the final quality assurance of the laboratory results.

Sound quality control systems are essential to providing excellent pathology and clinical laboratory services. Quality control procedures could include

a) validation of the test methods used for accuracy, precision and reportable range
b) daily surveillance of results by qualified laboratory personnel
c) rapid corrective action when a deficiency is identified
d) testing of reagents, and
e) documentation of results and corrective actions.

Proficiency testing determines how well an individual laboratory's results compare with other laboratories that use the same methodologies. Such testing can identify performance problems not recognised by internal mechanisms. Thus, the

laboratory participates in an approved proficiency testing programme when one is available. Alternatively, when approved programmes are not available, the laboratory exchanges samples with a laboratory in another organisation for peer comparison testing purposes. The laboratory maintains a cumulative record of participation in a proficiency testing process. Proficiency testing, or an alternative, is carried out for all speciality laboratory programmes, when available.

9.5.1 Criteria

9.5.1.1 There is a documented quality control system.

A quality control system is implemented that describes the range and frequency of the internal quality controls on the services performed at the laboratory (e.g. select a few Malaria slides each week to be scored by all personnel.

9.5.1.2 The laboratory participates in an external quality control programme.

Check whether the laboratory participates in EQA programmes. The programmes can be both national and international.

For primary health care, EQA programs for HIV, TB and Malaria are usually available through the ministry of health of the specific country.

When there is an active EQA program, check whether the administration records are kept appropriately.

9.5.1.3 There is a current register of quality control results and of the corrective and preventive actions taken.

A quality control register is available and up to date. Check the last entries and see if at any time corrective and preventive actions have been taken, recorded and controlled.

9.6 Prevention and Control of Infection

9.6.1 The laboratory service implements infection prevention and control processes.

9.6.1 Criteria

9.6.1.1 The service identifies the procedures and processes associated with the risk of infection, and implements strategies to reduce risk.

A manual or procedure guide, describing the risks of infections in the laboratory and defining the measures that have been taken to prevent infection, should be available.

9.6.1.2 Suitable processes are followed for cleaning and decontaminating laboratory surfaces and equipment.

Ensure that defined procedures are available and followed by the laboratory personnel, including non-laboratory personnel (e.g. cleaning personnel).

Find out if checklists are available and the recordings are relevant and up to date

9.6.1.3 Protective clothing is worn correctly.

Ensure that guidelines for protective measures are available.
Check whether protective clothing and other items are available to minimise the risk of infection. Protective clothing is defined very broadly, e.g. laboratory coat, gloves and masks

9.6.1.4 Individuals who handle specimens are trained in the proper handling of dangerous specimens.

Check whether the laboratory personnel are adequately instructed to handle specimens. This would mean that the laboratory manager regularly briefs the personnel on how to work with potentially infectious materials.

Records should be kept of the laboratory meetings in order to show compliance.

Check whether the personnel are following the documented infection control guidelines.

9.6.1.5 Organisational policy on post-exposure prophylaxis (PEP) is implemented.

Ensure that a PEP procedure is available, updated and implemented.
Personnel must know the content of the procedure and be aware of what to do if they are injured in the laboratory.
Records in which accidents are recorded should be available.

9.6.1.6 Organisational policy on handling, storing and disposing of healthcare waste is implemented.

A waste management policy and procedure is available in which the collection, storage and subsequent disposal of waste has been described.
A colour coded system is implemented; the system is usually based on (inter)national guidelines.

Check whether the procedures for collecting waste are adequately performed, i.e. disposal bins are not overfilled and are clearly labelled, waste is correctly separated, etc. The removal of the waste is performed according to the guidelines used within the facility.

Check the incineration guidelines, where applicable.
All personnel, including cleaning personnel, are aware of the waste management procedure.

SE 10: DIAGNOSTIC IMAGING SERVICE

OVERVIEW OF THE DIAGNOSTIC IMAGING SERVICE

The organisation is responsible for ensuring that the diagnostic imaging service meets the needs of its patient population, the clinical services offered, and the healthcare providers.

These needs may be met by a service within the organisation, or may be outsourced. In either case, the diagnostic imaging service must comply with all applicable local and national standards, laws and regulations.

The organisational leaders ensure that where a diagnostic imaging service is provided by the facility, there are radiation safety programmes in place, and that individuals with adequate training, skills, orientation and experience are available to undertake diagnostic imaging procedures and interpret the results.

The diagnostic imaging service allows for immediate decision-making by practitioners, through the provision of emergency services and the provision of emergency reports, as necessary.

Standards

10.1 Management of the Service

10.1.1 A diagnostic imaging service is provided by the organisation,

Standard Intent

The organisation has a system for providing the diagnostic imaging services required by its patient population, the clinical services offered, and healthcare provider needs.

Diagnostic imaging services, including those required for emergencies may be provided within the organisation, by agreement with another organisation, or both. The diagnostic imaging service is available after normal hours for emergencies.

Outside sources are convenient for the patients and reports are received in a timely manner, which supports continuity of care. These sources are selected by the organisation on the recommendation of the director or another individual responsible for radiology and diagnostic imaging services. Outside sources of diagnostic imaging meet applicable laws and regulations and have acceptable records of accurate, timely service. Patients are informed when the referring physician owns the outside source of diagnostic imaging.

10.1.1 Criteria

10.1.1.1 An adequate, convenient and regular diagnostic imaging service is available.

It is important to note that this criterion addresses a number of issues.

With "adequate" one should take into consideration the level of service that is required, e.g. is a Radiologist available for consultation, etc.

The service should meet the needs of the population that it serves, e.g. if the service is only available 2 or 3 days a week, but the need is for a daily service, this would warrant a PC score.

If equipment is broken, supplies are lacking, staffing levels are inadequate and the full scope of the required service cannot be rendered, the criterion should be scored down.

The referral of a significant number of patients to facilities with more equipment will also indicate that services are not adequate.

"Convenient" refers to the patient experience; bear in mind that sometimes patients are "unnecessarily" referred somewhere else because of a shortage of staff, broken equipment, a lack of supplies, etc.

"Regular" refers to a daily service. This would include the after-hour service (also dealt with in the next criterion). If a service is not available when required, this criterion will be scored PC.

10.1.1.2 An emergency diagnostic imaging service is available after normal hours.

If there is no after-hour service to deal with emergency cases, the score will be PC/NC, depending on the situation.
See also the intent statement.

10.1.1.3 The selection of an outside source is based on an acceptable record and compliance with applicable laws and regulations.

This criterion is usually not applicable to government facilities, as specific patterns for referring patients for specialised examinations are usually used. If the specific service is not available in the public sector and patients are referred to private facilities for specialised investigations, this criterion becomes applicable. In the latter case, there needs to be applicable documentation, such as a Service Level Agreement (SLA), a Memorandum of Understanding (MOU), contract or memorandum.

10.1.2 The diagnostic imaging service meets applicable local and national standards, laws and regulations.

Standard Intent

The organisation ensures that the personnel are knowledgeable about the relevant legal requirements relating to diagnostic imaging. This is ensured by having available copies of the most recent radiation safety report and the local rules relating to the current Ionising Radiation regulations, together with other applicable documents that provide guidance relating to legality.

The organisation satisfies the statutory requirements of the Ionising Radiation regulations, according to the most recent radiation safety report.
There are organisational arrangements for obtaining advice on radiation protection and how to deal with a suspected case of overexposure.

10.1.2 Criteria

10.1.2.1 Written policies and procedures address compliance with applicable standards, laws and regulations.

Root criterion

Policies and procedures should include at least the following:

- *The qualifications of staff,*
- *Radiation safety, including radiation safety inspections, signage in the department, the handling and disposal of hazardous material, over-exposure, the wearing of dosimeters*
- *X-rays of pregnant women*
- *Requesting X-rays*
- *Reporting on films including the time frames for reporting, and*
- *The availability of emergency drugs and equipment.*

This is a root criterion for this standard. If any of the following criteria (10.1.2.2 – 10.1.2.6) are rated NC or PC, this criterion should be rated PC, i.e. this criterion cannot be compliant unless all the rest are compliant.

10.1.2.2 A copy of the local rules relating to the current Ionising Radiation regulations is available and the requirements are met.

Botswana arrangements will apply and will include:

- *A copy of the Radiation Protection Act and Regulations*
- *Relevant guidelines and policies from the Radiation Protection Inspectorate.*

10.1.2.3 A copy of the most recent radiation safety report is held.

Critical Criterion

In the case of new units, Radiation Control do not necessarily perform an inspection (the only exception is radiotherapy), but they base their decision whether to issue a licence on the QA results of the supplier. Therefore, in the case of new units, one should make it compulsory for the hospital to produce the QA results from the supplier.

Previously a routine 3-5 yearly visit to all Radiology Units was done and this occasionally still happens. In cases where there is no evidence of a recent visit (1-3 years) by the Radiation Protection Inspectorate, this criterion will be scored on documented evidence of the continuation with the internal QC tests (processing conditions, darkroom fog, screen film contact, reject analysis, etc.) and annual equipment maintenance (which covers the radiation safety aspects).

10.1.2.4 The organisation satisfies the statutory requirements of the Ionising Radiation regulations.

This criterion is linked with the one above (10.1.2.3). Documented evidence should be available that the deficiencies identified in the above-mentioned report have been addressed. The licence holder normally has 21 days to implement the requirements from Radiation Control Protection Inspectorate after their inspection, unless they can show proof why they are not in a position to do so.

10.1.2.5 A radiation protection supervisor is identified and available to assist a radiation protection inspector in complying with the Ionising Radiation regulations.

National arrangements will apply, but the following will be required:

At hospital level there should be a responsible person whose name appears on the licensing documentation from the RPI as the "license holder/responsible person" who is normally the Owner or the head of the hospital facility. The licence appoints a person experienced and qualified in radiation health safety as RSO.

The "Radiation Safety Expert" is a person at a higher level, for instance at District/Regional/National level, who can be contacted in case of problems/enquiries.

10.1.2.6 A patient register is held in the diagnostic imaging department.

A patient register/index should be available in the department. This can be in the form of a register or an electronic system. If an electronic system is used, adequate arrangements for back-up of data should be in place.

10.1.3 A radiation safety programme is in place, followed and documented.

Standard Intent

The organisation has an active radiation safety programme that includes all components of the organisation's radiology and diagnostic imaging services. The radiation safety programme reflects the risks and hazards encountered. The programme addresses safety practices and prevention measures for radiology and diagnostic imaging personnel, other personnel and patients. The programme is coordinated with the organisation's safety management programme.

10.1.3 Criteria

10.1.3.1 There is an established radiation safety programme that addresses potential safety risks and hazards encountered within or outside of the department.

10.1.3.2 The safety programme is part of the organisation's safety management programme.

10.1.3.3 Written policies and procedures address the handling and disposal of hazardous materials.

10.1.3.4 Identified radiation safety risks are addressed by specific processes or devices that reduce those risks, e.g. lead aprons, radiation badges, etc.

10.2 Facilities and Equipment

10.2.1 Equipment and machines used to conduct diagnostic imaging studies are adequate and appropriate for the service provided.

Standard Intent

Diagnostic imaging personnel work to ensure that all equipment functions at acceptable levels and in a manner that is safe for the operator(s). Radiology and diagnostic imaging equipment management programme provides for:

- selecting and acquiring equipment
- identifying and inventorying equipment
- assessing equipment use through inspection, testing, calibration and maintenance
- monitoring and acting on equipment hazard notices, recalls, reportable incidents, problems and failures and
- documenting the management programme.

Testing, maintenance and calibration frequency are related to the use of equipment and its documented history of service.

10.2.1 Criteria

10.2.1.1 The organisation identifies the equipment required for the projected activities.

10.2.1.2 A diagnostic imaging equipment management programme is implemented.

10.2.1.3 There is an inventory of equipment.

10.2.1.4 There is documented evidence that equipment is tested and calibrated in accordance with organisational policy/SOP (standard operating procedure).

10.2.1.5 There is documented evidence that equipment is maintained in accordance with organisational policy/SOP.

10.2.2 X-ray film and other supplies are regularly available.

Standard Intent

The organisation has identified the quantities of film, reagents and supplies necessary to provide a radiology and diagnostic imaging service to its patients. There is an effective process for ordering or securing essential film, reagents and other supplies. All supplies are stored and dispensed in accordance with defined procedures. The periodic evaluation of reagents ensures accuracy and precise results. Written guidelines ensure the complete and accurate labelling of film, reagents and solutions.

10.2.2 Criteria

10.2.2.1 Essential quantities of film, reagents and supplies are available.

10.2.2.2 All reagents and solutions are completely and accurately labelled.

10.2.2.3 Film and reagents are periodically evaluated for accuracy and results.

10.3 Diagnostic Imaging Procedures

10.3.1 Individuals with adequate training, skills and experience perform X-ray procedures and interpret the results.

Standard Intent

The organisation identifies those staff members who may perform procedures and those who may interpret X-ray films and report the findings.
These staff members have appropriate and adequate training, experience and skills, and are oriented to their work. Radiographers are given assignments consistent with their training and experience. There are enough staff members to provide the necessary staffing during all hours of operation and for emergencies.

10.3.1 Criteria

10.3.1.1 A qualified individual manages the diagnostic imaging service.

Linked to SE 2 Human resource management

10.3.1.2 Those individuals who may perform X-ray procedures and those who may interpret and report the results are identified.

This criterion requires the availability of an organisational chart which reflects the persons required to provide an adequate service for the facility. However, where there are a number of vacant posts, this criterion can only be scored PC. The organisational chart is a graphic representation of responsibility, relationships and formal lines of communication within the service.

Performing of X-rays:
National arrangements will apply.
The following persons may perform radiological examinations: radiologists, radiographers, medical doctors, dentists and authorised by the Radiation Control Board. In all instances these persons need to be registered as Radiation Workers.

In most cases hospital policy does not allow for anybody other than the first three categories (radiologists, radiographers and supplementary radiographers) to perform X-rays.

Interpret/report results: National arrangements will apply. Only radiologists and medical doctors can perform this function. If no radiologist is available in the department, interpretation of the X-rays will be done in the ward and the interpretation should be recorded in the patient's record. If a radiologist is available, formal reporting will be done in the department by the radiologist.

10.3.1.3 There is a mechanism that ensures that procedures are performed only by radiographers, radiologists, or specially trained doctors and other persons who are authorised to do so by a radiation protection advisor.

Critical criterion

Medical imaging practitioners that are registered with professional council are allowed to perform X-rays in medical diagnostic imaging.

10.3.1.4 X-rays are done only upon a signed request from a qualified medical practitioner.

X- Ray examinations may only be requested by a medical practitioner, a dentist or "any other appropriately trained and registered health professional.
In most cases hospital policy does not allow for anybody other than radiologists, radiographers and supplementary radiographers to perform X-rays.

Where medical practitioners sign blank forms in advance this criterion will be scored NC.

10.3.1.5 X-rays are interpreted and reported on by appropriately trained and experienced personnel.

The difference between interpretation and reporting should be noted. A medical practitioner interprets X-rays and should document his/her findings in the patient's record. Radiologists formally report on X-rays. Trained radiographers and sonographers can also report on X-rays.

10.3.1.6 Experts in specialised diagnostic areas are contacted, when needed.

Although the statement of intent states "contact experts in specialised diagnostic areas such as radiation physics, radiation oncology, or nuclear medicine, when the need for such services arises" , other investigations can also be considered to be of a specialised nature, e.g. barium studies, IVP's, fluoroscopic investigations, etc. and can be included under this criterion.

10.3.1.7 A roster of experts for specialised diagnostic areas is maintained.

This criterion is linked with the previous one requesting a roster of these experts and contact details of these experts.

10.3.1.8 Quality control procedures are implemented.

Sound quality control systems are essential to providing excellent radiology and diagnostic imaging services.

Quality control procedures include:

- *validation of the procedural methods used for accuracy and precision*
- *daily surveillance of imaging results by qualified radiology personnel*
- *rapid corrective action when a deficiency is identified*
- *testing reagents and solutions*
- *documenting results and corrective actions.*

10.3.2 Reporting and recording policies and procedures within the diagnostic imaging service ensure safety and legality.

Standard Intent

X-ray request forms and the ensuing reports must identify the correct patient and the correct site of X-ray. The organisation defines the time period for reporting diagnostic imaging test results. Results are reported within a time frame based on patients' needs, the services offered and the needs of the clinical personnel. Mechanisms are in place to ensure that X-ray results are reported on immediately in an emergency.

The X-ray films are the property of the patient, and may be taken away by the patient. Where this is done, the patient must be asked to bring the films for future visits. Where the organisation stores films they are kept according to national regulations.

10.3.2 Criteria

10.3.2.1 Imaging request forms contain the patient's name, examination requested, relevant previous examinations, name of the requesting officer and clinical information to explain the request.

Critical criterion

The above details should be provided when an X-ray is requested. Some aspects are usually not included in the completed form, which will usually warrant a PC score by default.

10.3.2.2 Diagnostic imaging results are reported on by a qualified person within a time frame that meets clinical needs.

10.3.2.3 X-ray reports by a qualified person contain a clear conclusion (including recommendations for future treatment if appropriate).

10.3.2.4 A copy of the report is filed in the patient's record.

This criterion is only applicable in cases where reporting is done by a Radiologist

In the case where there is no Radiologist, the expectation is that the treating doctor will record his/her interpretation of the film ***in the patient's clinical notes****.*

10.3.2.5 Films are available at each visit of the patient.

A system needs to be in place for the movement of films throughout the organisation, to ensure their eventual return to the Radiology department.

In the private sector, X-rays are the property of the patient, who is responsible for bringing them to consultations. More recently the patient is given a CD and the radiology service retains an electronic copy.

10.3.2.6 Policy defines the length and method of storage of X-ray films.

10.3.3 Where ultrasound services are provided, individuals with adequate training, skills and experience perform the procedures and interpret the results.

Standard Intent

The organisation identifies those staff members who may perform ultrasound procedures and those who may interpret and report the findings. These staff members have appropriate and adequate training, experience and skills, and are oriented to their work.

10.3.3 Criteria

10.3.3.1 A qualified individual manages the ultrasound service.

10.3.3.2 Those individuals who may perform ultrasound procedures and those who may interpret and report the results are identified.

10.3.3.3 Ultrasound procedures are performed only by individuals with specific training.

10.3.3.4 Ultrasound images are interpreted and reported on by appropriately trained and experienced staff members.

10.3.3.5 Experts in specialised diagnostic areas are contacted, when needed.

10.3.3.6 A roster of experts for specialised diagnostic areas is maintained.

10.3.3.7 Quality control procedures are implemented.

SE 11 MEDICATION MANAGEMENT

OVERVIEW OF MEDICATION MANAGEMENT

Depending on the size, structure and functions of the health facility, there may be a pharmacy with qualified pharmacists to dispense medication, or medical and nursing personnel may issue certain medications within the service. Whatever the system, the health facility implements systems to ensure, that all pharmaceutical practices are in accordance with current legislation.

Medication management is not only the responsibility of the pharmaceutical service but also of managers and clinical care providers. Medical, nursing, pharmaceutical and administrative personnel participate in a collaborative process to develop and monitor the policies and procedures.

Each health facility has the responsibility of identifying the individuals with the requisite knowledge and experience, who are permitted by laws, regulations or registration to prescribe or order medications. The health facility also identifies any additional individuals, who are permitted to prescribe or order medications in emergency situations. Policies and procedures define the documentation required for medications ordered or prescribed and for verbal medication orders.

Medications depend on suitable storage for their potency. In particular, vaccines which are exposed to high ambient temperatures and/or freezing will quickly lose their potency. The cold chain is the system of transporting and storing vaccines within the safe temperature range of 2 - 8°C. For vaccines to be effective, the cold chain must be maintained from the place of manufacture to the point of administration. Each time that vaccines are exposed to the wrong temperature, their potency is reduced. To know if vaccines are potent at the time of administration, it is important that they be monitored for exposure to heat and cold as they pass through the cold chain. While domestic refrigerators are not designed to meet the requirements of vaccine storage, safe storage is possible if healthcare facilities follow simple guidelines. Guidelines may be obtained from the Health authorities or from the manufacturers and distributors of vaccines. Foodstuffs must not be stored in the medication refrigerator. Patient care units store medications in a clean and safe environment, which complies with laws, regulations and professional practice standards.

The safe administration of medications requires a strict and comprehensive protocol. The patient, physician, nurse and other care providers work together to monitor patients on medications. The purposes of monitoring are to evaluate the response to medication, to adjust the dosage or type of medication, when necessary, and to evaluate the patient for adverse effects.

The health facility identifies the adverse effects to be recorded and those that must be reported and it establishes the mechanism for reporting adverse events. The reporting process is part of the health facility's performance improvement programme. The programme is focused on preventing medication errors through understanding the types of errors that occur. Improvements in medication processes and staff training are used to prevent errors in the future. The pharmaceutical service participates in such staff training, where appropriate.

Standards

11.1 Management of the Service

11.1.1 Medication use is organised throughout the facility to meet the needs of patients.

Standard Intent

As an important resource in patient care, the use of medication is managed effectively and efficiently throughout the organisation.

Applicable laws and regulations are incorporated into the organisational structure and the operations of the medication management system used in the organisation.

Where the organisation dispenses medication it must be an approved licensed site with the relevant personnel having approved licences issued for that site in accordance with national legislation.

A registered pharmacist directly supervises the activities of the pharmacy or pharmaceutical service.

11.1.1 Criteria

11.1.1.1 A designated individual, who is suitably qualified, has clearly defined responsibilities and accountability for all aspects of the pharmaceutical service.

This refers to a person appointed to the management position in terms of the job specifications.

Where pharmacy technicians or similar individuals are employed, Botswana laws and regulations will apply.

This criterion will be scored as PC if:
- there is no documented job description or job specification
- the position is filled by someone in an acting capacity, and
In the case where an unqualified person manages the service, the score will be NC.

11.1.1.2 Individuals who dispense medications act in accordance with legislation affecting pharmacy practice and current pharmaceutical, medical and nursing guidelines.

11.1.1.3 The scope of and limitations to the responsibilities and activities of the personnel who manage medications are clearly defined.

11.1.1.4 The pharmaceutical service is coordinated with other related services within the health facility.

Evidence of collaboration with other healthcare professionals is also required. This would include:

- *regular Pharmacy and Therapeutic Committee meetings or regular relevant meetings such as Management meetings, HOD meetings or clinical meetings and the circulation of the minutes of these meetings*
- *regular visits to the relevant areas by the pharmacists or pharmacy assistants to observe the storage and control of medication and to check prescriptions.*

The compilation of medication-related policies and procedures (including policies on adverse drug reactions and medication errors) should be seen as part of this collaboration.

11.2 Facilities and Equipment

11.2.1 Adequate facilities are available for the safe storage and dispensing of medications.

Standard Intent

Secure storage systems ensure that pharmaceuticals and related substances are held under conditions that conform to statutory requirements and the manufacturer's requirements.

There are arrangements for ensuring the security of medicines, including alarm systems, door access controls, and safes/vaults for storing controlled medicines.

Medications stored and dispensed from areas outside the pharmacy, for example patient care units, comply with the same safety measures.
There is a register, log or other mechanism to monitor and account for controlled substances.

Deep freeze, refrigeration, cold room and cool area facilities are provided for safe storage of certain medications. There is a mechanism for ensuring that the correct temperature is maintained throughout the life of the medications. Deep freezers and refrigerators are defrosted when necessary. Doors, hinges and seals are all functional.

11.2.1 Criteria

11.2.1.1 The design and layout of the pharmacy must permit a logical, safe flow of work, adequate storage space, effective communication and supervision, and ensure effective cleaning and maintenance.

11.2.1.2 Secure facilities for the storage of medications include, but are not limited to, lockable storage facilities, ceiling cages, burglar guards and alarm systems with keypads.

11.2.1.3 The storage area is easily accessible from the dispensing room.

11.2.1.4 Medication storage areas are protected from heat and light and are effectively ventilated.

11.2.1.5 A dedicated refrigerator is available for those medications requiring storage at low temperatures.

Suitable arrangements should be made for maintaining the cold chain when the refrigerator needs to be cleaned or defrosted.

11.2.1.6 A monitoring log is kept of the refrigerator temperature.

The log should be kept in close proximity to the refrigerator. Any remedial action taken to address discrepancies should be recorded.

11.2.1.7 The work bench for preparing medicines for dispensing should be clean, tidy and well organised.

11.2.1.8 The area where medicines are dispensed to the patients is easily accessible, adequately furnished and allows for reasonable privacy when advice is given.

11.3 Policies and Procedures

11.3.1 There is a collaborative effort to develop and monitor policies and procedures for the pharmaceutical service.

Standard Intent

Safe pharmaceutical practices are guided by organisational policies and procedures. Medical, nursing, pharmacy and administrative personnel participate in a collaborative process to develop and monitor the policies and procedures.

The clinical and managerial leaders use a collaborative process to develop policies and procedures and train the personnel to implement them correctly.

It is particularly important that the policies or procedures indicate:

- how planning will occur
- the documentation required for the care team to work effectively
- special consent considerations
- monitoring requirements
- special qualifications or skills of personnel involved in the care process, and
- the availability and use of resuscitation equipment, e.g. the relevant medication.

Clinical guidelines are frequently helpful and may be incorporated in the process. Monitoring provides the information required to ensure that the policies and procedures are adequately implemented and followed for all relevant patients and services.

Policies and procedures should focus on high risk procedures, e.g.

a) safe prescribing, ordering, transcribing and administering medications in the organisation.
b) documentation requirements.
c) the use of verbal medication orders.
d) the availability and use of medication samples.
e) documentation and management of any medications, brought into the

organisation for or by the patient.
f) self-administration of medication by the patient.
g) dispensing of medications at the time of the patient's discharge, and
h) the security of staff, equipment and stock.

11.3.1 Criteria

11.3.1.1 Policies and procedures are developed and implemented for identified processes, which include at least those from a) to h) in the intent above.

11.3.1.2 Policies and procedures are implemented to ensure that medications are procured according to national guidelines regarding specific agents and approved suppliers.

11.3.1.3 Policies and procedures are implemented to ensure that medications are transported to the facility in accordance with manufacturers' guidelines, with specific emphasis on maintaining cold chain requirements.

11.3.1.4 Policies and procedures are implemented to ensure that medications are dispensed on the written instructions/prescription of a designated healthcare worker who is qualified and/or experienced in their use.

11.4 Access to Appropriate Medication

11.4.1 An appropriate selection of medications for prescribing or ordering is stocked or readily available.

Standard Intent

Every organisation must decide which medications to make available for prescribing and ordering by the care providers. This decision is based on the organisation's mission, patient needs, and the types of services provided. The organisation develops a list of all the medications it stocks or that are readily available from outside sources. In some cases, laws or regulations may determine the medications on the list or the source of those medications. Medication selection is a collaborative process, which considers patient needs and safety as well as economics. The organisation has a method, such as a committee, for monitoring and maintaining this medication list and for monitoring the use of medication within the organisation.

Managing medication use in an organisation requires an understanding of the sources and uses of medications not prescribed or ordered within the organisation.

On occasion, medications not readily available to the organisation are needed. There are also occasions where medications are needed at times when pharmacies are closed. Each organisation needs to plan for these situations and to educate the personnel regarding the procedures to follow should they occur. When patient emergencies occur, quick access to appropriate emergency medications is critical. Each organisation plans the location of emergency medications, and the medications to be supplied in these locations. To ensure access to emergency medications when needed, the organisation establishes a procedure or process to

prevent theft or loss of the medications, and to ensure that medications are replaced when used or when damaged or out of date. Each organisation also needs to determine its role in providing medications to patients at discharge. Those who prescribe or order medication know what medications, if any, are available and how to obtain them.

11.4.1 Criteria

11.4.1.1 There is a list of the medications stocked in the organisation or readily available from outside sources.

This refers to the Essential Drug List or equivalent in the public sector, in which case the score can be either NA or C with a qualifying comment.

11.4.1.2 Priority essential drugs are in stock.

The scoring will depend on the availability and appropriateness of medicines to be able to treat all conditions relevant to the level of care.
Government facilities usually have Essential Drug Lists, or equivalent, for the different levels of health facilities, e.g. primary health care clinic, district or regional hospital, etc.

The presence of a selection of tracer drugs (selected because of frequent need, emergency cases or high number of requests) can be verified as a sample of the total stock.
The following should be available:

- *ACT (artemisinin combination tablets)*
- *Amoxicillin suspension*
- *Gentamycin and benzyl penicillin injection for sepsis*
- *Vitamin capsules*
- *Iron tablets*
- *Folic acid tablets*
- *Oral rehydration solution sachets*
- *Metformin tablets*
- *Hypertension treatment: Calcium channel blocker (Nifedipin tablets) And/or a hydrochlorothiazide diuretic*
- *Tetanus toxoid injections for pregnant women*
- *Paracetamol tablets, and*
- *Male condoms.*

11.4.1.3 There is a process for obtaining required medications that are not stocked, or normally available to the organisation.

The scoring will depend on the availability and appropriateness of medicines to be able to treat all conditions relevant to the level of care.

Government facilities usually have Essential Drug Lists, or equivalent, for the different levels of health facilities, e.g. primary health care clinic, district or referral hospital, etc.

11.4.1.4 There is a process for healthcare workers to obtain medicines within the facility when the pharmacy is closed.

The guideline should advise on the process and explain the scoring, e.g. after-hours cupboard, pharmacist on call roster.

11.4.1.5 There is a list of medications available in the emergency cupboard, where relevant.

11.4.1.6 There is a system for recalling drugs, when required.

11.5 Control and Storage of Medication

11.5.1 *Medications are stored in a secure and clean environment.*

Standard Intent

The pharmacy or pharmaceutical service stores and dispenses medications in a clean and secure environment, which complies with laws, regulations and professional practice standards. In particular, medications are clearly labelled, which includes the following:

- generic name and strength of medicine
- dose, frequency and duration of course
- date of dispensing and expiry date
- name of patient
- name/address of supplier
- child safety warning
- batch number.

Medications stored and dispensed from areas outside the pharmacy, for example patient care units, comply with the same safety measures.

There is a registry, log or other mechanism for monitoring and accounting for controlled substances.

11.5.1 Criteria

11.5.1.1 Medications are stored in a locked storage device or cabinet, which is accessible only to authorised personnel.

11.5.1.2 There is a system for ensuring that maximum and minimum stock levels are maintained.

Stock control systems in the pharmacy and related departments may be manual or electronic.

Some pharmacies have a dual system: stock in the store is controlled, but stock in the dispensary is usually "open", hence no stock control system is in place in the dispensary unless an electronic dispensing system is in use.

It is important to note that this criterion also refers to other related departments, e.g. the inpatient ward, casualty, etc. Stock control systems in these departments should also be implemented. Special attention should be given to the control of medication in emergency cupboards/rooms.

11.5.1.3 Medications are legibly marked and securely labelled.

11.5.1.4 Medications controlled by law or organisational policy are stored in a cabinet of substantial construction, for which only authorised personnel have the keys.

Evidence is sought during the visit to the unit/department.
Observe where the keys are kept (they may be kept by a registered pharmacist or a registered nurse only) and ask questions about access to the cabinet. Controlled drugs/narcotics/barbiturates and other dangerous drugs need to be stored under lock and key at all times, but national requirements will be taken into account with regard to the medication that needs to be safely stored.

The "substantial" construction is interpreted to be a cupboard/container that is mounted on the wall or fixed to the floor. Mostly, these are steel cabinets but solid wooden cupboards will also be accepted. A double lock is not a requirement.

11.5.1.5 Medications controlled by law or organisational policy are accurately accounted for in a specific register.

Compliance needs to be measured against Medicine and Related Substance Act, and other related national laws and regulation, but will be assessed by means of "spot checks" as well as studying the register.

This applies to all areas in the facility where controlled medication/dangerous drugs are stored.

11.5.1.6 Hazardous and flammable materials are stored, in accordance with relevant regulations.

11.5.1.7 All pharmaceuticals, vaccines or medical consumables are regularly checked for expiry dates and checks are recorded.

11.5.1.8 An inventory management system, manual (stock cards) or automated, is in place and functioning appropriately, e.g. to monitor and control stock losses.

11.5.1.9 Separate designated storage areas are provided for materials under quarantine, e.g. expired stock, compounded products.

These items must <u>not</u> be mixed with other pharmaceutical supplies that are still in use; they should be kept separately and be clearly marked. As long as the volume of quarantined items is small, these products may be stored on a shelf in a clearly marked cardboard box. Other suitable containers may be used, or these items may be stored in a specific room.

11.6 Prescribing of Medication

11.6.1 There is a process to ensure the safe and legal prescribing of medication.

11.6.1 Criteria

11.6.1.1 Only those permitted by national laws and regulations prescribe medication.

11.6.1.2 Prescriptions conform to legal requirements.

11.6.1.3 Prescription pads and order books are accessible to authorised persons only.

11.6.1.4 There is a process for placing limits, when appropriate, on the prescribing or ordering practices of individuals.

11.6.1.5 The use of verbal/telephonic medication orders is documented.

11.7 Dispensing Medication

11.7.1 The organisation adheres to laws, regulations and professional standards of practice when dispensing medications.

Standard Intent

A registered pharmacist reviews each prescription or order for medication. When questions arise, the individual who prescribed or ordered the medication is contacted.

The dispenser signs the prescription. When pharmacy technician or interns dispense, they are supervised, and their signatures, as dispensers, are countersigned by a registered pharmacist.

The organisation dispenses medications in the most ready-to-administer form possible, to minimise opportunities for error during distribution and administration. The central pharmacy and other medication distribution points throughout the organisation use the same system. The system supports accurate dispensing of medications in a timely manner.

11.7.1 Criteria

11.7.1.1 Pharmacy personnel act in accordance with legislation and current pharmaceutical, medical and nursing guidelines.

This criterion can be seen as an overarching one for this standard. This criterion should be scored NC if a pharmacy technician works without supervision.

11.7.1.2 Medications are prepared and dispensed in a safe and clean environment.

11.7.1.3 There is a uniform medication dispensing and distribution system in the organisation.

"Uniform" implies that there should be a policy framework detailing how these actions are carried out. This includes dispensing, the distribution of medication throughout the facility by a delivery person, the container (lockable/sealed), the delivery note, etc.

It is important to note that the score may be affected if the way in which medication is dispensed or issued after hours does not conform to the same rules as daytime practice.

11.7.1.4 The system supports accurate and timely dispensing.

In order to measure compliance, the pharmacy/facility will have to provide waiting time monitoring data on (against their own policy and standard for both outpatients and discharged inpatients) and data on dispensing errors.
In the absence of such data, a judgement call might be required. Observe queues and the movement of patients in the outpatient area of the facility, or look at the number of patient files piling up in the pharmacy.

11.7.1.5 Medications are securely and legibly labelled with relevant information as required by organisational policy.

This is checked during the visits to the various areas.

National regulations must be applied, but must include at least the following:

- *the name of the patient and the facility number (if applicable);*
- *the proprietary name/approved name or name of each active ingredient*
- *directions for using the medicine*
- *the number of dose units in the container*
- *date of dispensing*
- *expiry date and batch number*
- *additional labels with warnings and storage instructions in accordance with local requirements.*

11.7.1.6 A register is maintained of all medicines dispensed.

11.7.1.7 The person prescribing and dispensing the medicine has access to patient information that would contra-indicate particular medicines.

Information required by the person dispensing medicines should include allergic reactions, side effects and drug interactions to previously dispensed medicines.

11.7.1.8 The person dispensing the medicine informs the patient of available generic equivalents.

11.7.1.9 There is a mechanism for facilitating communication between the prescriber and the pharmacy regarding drug reactions.

11.7.1.10 Prescriptions are securely stored in accordance with legislation or organisational policy.

11.8 Administration of Medication

11.8.1 Medications are administered in a manner that ensures safety and effectiveness.

11.8.1 Criteria

11.8.1.1 Only those permitted by national laws and regulations administer medications.

11.8.1.2 Medications are verified against the prescription or order, including the dosage and route of administration.

11.8.1.3 Patients are identified before medications are administered.

11.8.1.4 Medications are administered as prescribed.

11.8.1.5 The therapeutic results of medication are monitored.

11.8.1.6 Adverse drug reactions are observed, monitored and reported.

11.8.1.7 Medication errors are reported in accordance with policy.

SE 12: FACILITY MANAGEMENT SERVICES

OVERVIEW OF THE FACILITY MANAGEMENT SERVICES

The Facility Management department concerns itself with the management and maintenance of the facility's plant, machinery, buildings, and equipment.

Laws, regulations and inspections by governmental and local authorities determine in large part, how a facility is designed, used and maintained. All organisations, regardless of their size and resources, must comply with these requirements, as part of their responsibilities to their patients, families, staff and visitors. Organisations begin by complying with laws and regulations. Over time, they become more knowledgeable about the details of the physical facility they occupy. They begin to proactively gather data and carry out strategies to reduce risks and enhance the patient care environment.

Buildings, grounds, plant and machinery are provided and maintained, and do not pose hazards to the occupants. Utility systems (electrical, water, oxygen, ventilation, vacuum and other utility systems) are maintained to minimise the risks of operating failures.

Ensuring that buildings, grounds, plant and machinery are provided and maintained requires that the personnel be knowledgeable and competent.

Standards

12.1 Facilities and Equipment

12.1.1 Functional facilities are available to provide safety and comfort for patients, visitors and personnel.

Standard Intent

Laws, regulations and inspections by government and local authorities determine in large part how a facility is designed, used and maintained. All organisations, regardless of size and resources, must comply with these requirements as part of their responsibilities to their patients, families, staff and visitors.

Buildings, grounds, plant and machinery are provided and maintained, and do not pose hazards to the occupants. The construction of the building in terms of walls, ceilings, floors, doors and windows must be sound. The general appearance will be examined for neatness, condition of paintwork, signs of leakage, mould spots, etc.

Utility systems (electrical, water, oxygen, ventilation, mosquito screening and other utility systems) are maintained to minimise the risks of operating failures. Ensuring that buildings, grounds, plant and machinery are provided and maintained requires that the personnel be knowledgeable and competent.

12.1.1 Criteria

12.1.1.1 Laws, regulations and other requirements applicable to the organisation's facilities are available in writing to the personnel.

A copy of the national facility requirements document should be available.

12.1.1.2 The building is appropriate as a healthcare facility in terms of size and lay-out.

A copy of the national facility requirements document should be available. *Overcrowding is one of the most important factors to be considered.*

12.1.1.3 Mosquito net screening is available at external windows and doors throughout the facility, where applicable.

The effectiveness of the screening will be examined, i.e. screening should be intact and doors should not be left open.

12.1.1.4 All rooms are adequately ventilated.

Rooms and departments should have at least 2 doors or windows that allow adequate ventilation and are connected to other ventilated areas.

12.1.1.5 Where required, air-conditioning is installed in laboratories, pharmacies, operating theatres and sterilising departments and is tested and maintained.

Air-conditioning needs to meet the standards.
Documented evidence of the following is required:

- *the commissioning of the installation, certifying compliance with the applicable standards and*
- *regular inspections, testing and maintenance of filters as determined by the policies and procedures*

12.1.1.6 Temperature and ventilation control mechanisms are installed and maintained in the pharmacy, laboratory, kitchens, laundries and other relevant areas.

Ventilation in these departments needs to be monitored to ensure adequate air change and temperature control. This monitoring need to be included in the facility's Inspection and Preventive Maintenance (IPM) programme. Take note of national legislated requirements that may apply to areas where ventilation and temperature need to be controlled especially for reasons related to health and safety. This includes the use of fans, where applicable.

12.1.1.7 Toilet/washroom facilities are clean and in working order.

12.1.1.8 There is a separate area for the personnel, with adequate secure storage facilities for outdoor clothing, handbags and personal possessions.

12.1.1.9 Sufficient office/administrative space are available for the personnel.

12.2 Buildings, Plant, Installations and Machinery

12.2.1 The maintenance service is managed to ensure the provision of a safe and effective service.

Standard Intent

A suitably qualified individual, with proven competence, is appointed to manage the service. The accountabilities and responsibilities of this individual are clearly defined.

Management ensures that enough competent personnel are available to manage routine and emergency functions and meet the needs of a safe and effective health service. Personnel may be employed by the organisation or be contracted out. Where there are contracted personnel, there must be clear contracts outlining their responsibilities. The roles of the personnel need to be clearly defined, and management needs to ensure that they maintain their competence.

12.2.1 Criteria

12.2.1.1 A designated, competent individual is responsible for supervising the maintenance of buildings, plant and installations.

Compliance is measured against the job specifications.
This individual has the necessary competence to manage the maintenance service and would have a technical background that is suitable for the needs of the facility.
A Partially Compliant (PC) rating is allocated in the event of this position being filled by a person without the necessary competence, or by someone in an acting capacity.

12.2.1.2 Where these services are outsourced, the organisation's personnel have access at all times to a list of these private contractors with their contact numbers.

There must be documented evidence that clearly specifies the functions/responsibilities of each consultant/service provider, together with details of any administrative specific requirements relating to call-out procedures, such as obtaining authority, issuing order numbers, etc, especially in after-hours emergency situations.

12.2.1.3 Written agreements ensure 24-hour technical back-up services.

Documented call-out procedures need to be prominently displayed in each department, together with a current standby duty roster.

12.2.1.4 Written policies and procedures guide the organisation's personnel in the implementation of all service-related requirements.

12.2.1.5 There is a dedicated work area for maintenance activities.

12.2.1.6 Basic maintenance equipment and tools are available.

A toolbox with basic equipment and tools should be available for repair and maintenance activities. The specific content is dependent upon the size of the provider, number of personnel and activities undertaken.

12.2.1.7 Basic technical spare parts are available.

A basic spare set should be available for repair and maintenance activities. The specific content is dependent upon the size of the provider, number of personnel and activities undertaken.

12.2.2 The organisation implements a documented preventive planned maintenance programme for buildings, plant, installations and machinery.

Standard Intent

The organisation plans for regular in-house inspection of facilities, and testing of plant and machinery to avoid hazards. The organisation's personnel may carry out the testing, or the manufacturer's technicians may carry out these tasks. Whatever the system in use, the organisation has a documented plan for testing plant and machinery.

Building maintenance will include the monitoring of the following aspects:

- the general appearance of the inside and outside structure, which includes the construction of walls, floors, doors and windows
- the condition of the paintwork
- water leaks, mould spots
- electrical wiring, e.g. exposed wires, switches, electrical sockets and
- maintenance of the grounds (no litter, neat garden and grass kept short).

12.2.2 Criteria

12.2.2.1 The organisation plans and budgets for upgrading or replacing systems, buildings or components needed for the continued operation of a safe and effective facility.

Documentation detailing the planning and budgeting for refurbishment activities must be presented.

12.2.2.2 There are site and floor plans that depict the locations and layout of the main services (e.g. water, sanitation, electricity supply).

12.2.2.3 The facility has an established, documented, preventive maintenance management plan.

A "maintenance management programme" means a system which will include:

- *a schedule indicating when the prescribed Inspection and Preventive Maintenance (IPM) procedures are due on each item*
- *a record of when procedures or repairs were carried out and by whom*
- *a description of what was done and a list of parts replaced or fitted*
- *the results of qualitative and/or quantitative tests performed*
- *the various tasks, procedures and measurements/observations that need to be performed for each IPM and*
- *a means of "flagging" recurring or critical problems for risk management purposes.*

Maintenance management programmes may either be computerised or manual provided that they meet the requirements described in this guideline.

12.2.2.4 Regular inspections of all buildings, plant, installations and machinery are documented.

There must be established, documented processes for correcting any deficiencies found during the inspection. The results of the remedial action must be monitored and documented as part of the risk management and quality improvement processes.

12.2.2.5 A documented procedure for reporting defects in maintenance installations during and after normal working hours is known to the personnel.

12.2.3 Electrical installations are regularly inspected, tested, maintained and when appropriate, improved.

Standard Intent

The effective and efficient operation of all key systems in the organisation is essential for patient, family, volunteer and visitor safety and for meeting patient care needs.

The organisation needs to protect patients and personnel in emergencies, such as system failure, interruption or contamination.

An uninterrupted source of electricity is essential to meet patient care needs, both routine and urgent, twenty four (24) hours a day. Regular and alternate sources can be used.

Critical instruments that provide required emergency services need to be connected to an emergency power system. Critical instruments are available in several different departments, e.g. refrigerators in the pharmacy and the laboratory, and lights and equipment in the operating theatre and delivery room.

Critical points to be lighted by emergency power are identified and listed. These include:

- operating theatres and recovery rooms
- lights and sockets in the delivery rooms
- strategic lights and sockets in ward corridors
- the neonatal nursery and
- casualty and trauma areas.

Emergency electricity supplies**:**

- each patient care area is provided with at least one socket outlet which is connected to the emergency power supply
- all emergency supply socket outlets are appropriately demarcated.
- emergency and backup power sources are tested.

12.2.3 Criteria

12.2.3.1 Electrical power is available twenty four (24) hours a day, seven (7) days a week, from regular or emergency sources.

The primary source of power is normally a national supply grid. In the case of health facilities in very remote areas, the primary source may be a diesel-powered generator, photovoltaic cells ("solar panels") or even a small hydroelectric plant at a nearby river. Whatever the primary source, there must be an alternative source to provide a backup supply of electrical power.
There is a documented procedure defining the actions to be taken in the event of a power failure.

12.2.3.2 Sufficient light sources are available to provide adequate light (no dark areas) in all areas such as the entrance, waiting rooms, halls and offices.

12.2.3.3 Sufficient electrical socket outlets are provided in all areas to avoid overloading of individual outlets and to minimise fire risks.

The use of a number of extension cords and adaptors usually indicates that the number of socket outlets is insufficient.

12.2.3.4 Provision has been made for an emergency electrical supply.

An operational backup generator or solar power system is available to provide backup power.

12.2.3.5 There is documented evidence that relevant personnel are regularly trained to use/operate electrical supply systems and to access power in emergencies.

In most instances, the standby generator will start automatically in the event of a power failure. However, some older units need to be started manually. Usually, all operations pertaining to the correct functioning of the standby generator are handled by the organisation's technical personnel (maintenance department). However, in smaller facilities where technical backup may be limited, suitable persons need to be identified and trained in the procedures to be followed. Such training needs to be held at regular intervals and must be fully documented.

12.2.3.6 Servicing and testing of the uninterrupted power supplies (UPS) and/or battery backup systems is documented.

*The standards related to critical equipment require that an uninterrupted power supply system (UPS) be installed where the life-support and/or critical monitoring equipment used does **not** have internal battery backup. Documented evidence of maintenance and testing is required.*

It is important to note the special circumstances in respect of the theatre lamp/s. An auto start standby generator can take anything from 10 to 20 seconds to come on line, while a manual start unit would take infinitely longer, for obvious reasons. Even ten seconds of darkness during an operation could seriously compromise both patient and staff safety, and the same goes for life support and critical monitoring equipment hence the requirement for UPS and/or battery backup for both this type of device and the operating lamps/lights.

12.2.3.7 Emergency generators are tested on full load in accordance with manufacturers' specifications and such tests are documented.

12.2.3.8 Sufficient fuel, e.g. diesel, is available to provide power for twenty four (24) hours.

In order to assess this criterion, it is essential to check the manufacturer's manual and compare the specifications with the amount of available fuel.

12.2.4 Water supplies are regularly inspected, tested, maintained and when appropriate, improved.

Standard Intent

An uninterrupted source of clean water is essential to meet patient care needs, both routine and urgent, twenty four (24) hours a day. Drinkable water needs to be available in all essential areas as medical departments, wards, OPD and ablution facilities. Storage areas such as a well, storage tanks or other backup systems must be safe from contamination. Regular and alternate sources can be used.

Water quality can change suddenly due to many causes, some of which can be outside the organisation, such as a break in the supply line to the organisation, or contamination of the water source. The frequency of water quality monitoring is based, in part, on previous experience with water quality problems. The monitoring can be carried out by individuals designated by the organisation, such as personnel from the clinical laboratory, or by public health or water control authorities outside the organisation. Records of all checks are available.

Monitoring data is collected and documented for the medical utility management programme and is used for planning and improvement purposes.

12.2.4 Criteria

12.2.4.1 Regular and/or emergency water supplies, including drinkable water, are available twenty four (24) hours a day, seven days a week in all essential areas.

The continuous availability of portable (drinkable) water is vital. In most instances, the institution obtains its primary supply from the water utilities provider. In outlying districts, however, the primary source may be a river or borehole. Whatever the source, there needs to be an alternative supply in case the primary supply is, for whatever reason, rendered unusable. (Refer to the requirement in criterion 12.2.4.3 below).

The criterion implies that the water should be suitable and safe for human consumption. A compliance rating depends on the availability of documented evidence that these water supplies are regularly tested. Otherwise, a PC rating should apply.

12.2.4.2 Water filters are available to remove mud and dust particles.

This applies when water is collected from a river or similar water supply, e.g. a well.

12.2.4.3 Should the water supply be contaminated or interrupted, the areas and services at risk have been identified and provision has been made for an alternative water supply.

In many instances, the only alternative or backup water supply is either a borehole or reservoir tanks. The capacity of these tanks varies and their ability to meet the facility's needs in terms of duration, depends on the ratio of tank size to the rate of

consumption. Please note that these alternate water supplies must be tested for quality.

These plans need to consider the various scenarios based on local circumstances for e.g, where a reservoir tank is the only alternate source, there needs to be an established system for ensuring that there is some form of immediate warning when there is a failure of the primary supply, so that rationing can be implemented while the tank is still full. In addition, plans need to be documented with regard to refilling the tank in the event of a prolonged breakdown in the normal supply. This could be done using a water tanker (by arrangement with the water utilities provider, department of defence, etc).

12.2.4.4 There is documented evidence that relevant personnel are regularly trained to ensure that all operations to secure safe water are properly performed.

Where necessary, any operations pertaining to the changeover to the emergency water supply are handled by the organisation's technical personnel (maintenance department). However, in smaller facilities where technical backup may be limited, suitable persons need to be identified and trained in the procedures to be followed. Such training needs to be held at regular intervals and must be fully documented.

12.2.4.5 All drinkable water supplies are tested on a regular basis and the results are documented.

Explain when such testing is recommended, e.g. when bottled water is not available for drinking purposes.

Policies and procedures are required with regard to the periodicity and format of the tests. Regardless of whether tests are conducted in-house or by contracted water treatment specialists, records of such tests should be available. Note that testing also applies to the water used for steam boilers to ensure that it will not cause corrosion and pitting of the shell. The water would then be dosed if necessary, as determined by the test results.

12.2.5 Medical gas systems are regularly inspected maintained and when appropriate, improved.

Standard Intent

The organisation plans its oxygen supplies according to the needs of the patients served.

Policies and procedures relating to the storage, testing and safety of gas supplies are available and are implemented.

Gas cylinders are stored in outside facilities, chained in the upright position, and have "no smoking" and "no oil" signs.

Emergency oxygen supplies ensure that:

- where there is no piped oxygen supply, there is at least one mobile oxygen supply per ward, and more depending on the number of beds/cots in the ward and

- all the necessary fittings for oxygen are suitable for the ages of the children admitted, and are working satisfactorily.

12.2.5 Criteria

12.2.5.1 Medical gas (oxygen, nitrous oxide and medical air) supplies are available according to the operational requirements of the facility.

In larger facilities, Oxygen is normally supplied by a Vacuum Insulated Evaporator (VIE), Nitrous Oxide by a bank of manifold connected cylinders, and Medical Air by oil-free compressors via appropriate filters and driers. In all these cases, backup is provided in the form of manifold connected cylinder banks, mostly fitted with automatic switchover valves and alarms that operate in the event of a failure in the primary supply.

Some facilities may have Entonox in their maternity wards and possibly in their trauma/emergency units, while Carbogen and Carbon Dioxide may still be found in the theatres of older facilities.

Where there is no piped gas, the facility should have a documented policy that relates to the number of cylinders and related ancillary equipment required to adequately satisfy the patient profile and/or load requirements, such as pressure regulators, flow-meter regulators, etc. with special attention being given to emergency situations that may arise.

12.2.5.2 Medical gas supply systems comply with safety standards.

Documented certification is required of such compliance with national requirements.

Basic safety considerations include the following:

- *cylinders should be protected from extremes of weather and stored in a dry, well-ventilated area away from heat or ignition sources*
- *cylinders (full or empty) should be secured in the upright position either by chains or straps to prevent them from falling - smaller cylinders may be placed in specially made stands*
- *oxidising and flammable gases must be stored in separate rooms that are constructed of materials with a minimum fire rating of one(1) hour and*
- *the cylinder store must be equipped with acceptable fire extinguishing facilities, and signage at the entrance should include a sign indicating that it is a flammable gas store with symbolic signs for "no smoking", "no naked flames", "no oil" and "no entry".*

12.2.5.3 Where there is piped gas, the enclosure, gas bank, pressure regulators, related control/alarm systems and all outlet points are clean and in good operating condition.

Policies and procedures on the maintenance and cleaning of the gas bank enclosure and all related equipment need to be in place and to be implemented.

Please note that the inspection needs to include all outlet points, i.e. in all departments where piped oxygen is delivered, as well as all low-level oxygen alarms wherever these are installed in the facility.

12.2.5.4 Where there is piped gas, the main oxygen supply system is fitted with an alarm, which operates automatically in the event of low pressure in the gas supplies and is regularly tested.

Some facilities have a bulk VIE for the main oxygen supply with banks of cylinders as backup. In others, there are only cylinder banks. Regardless of which system is in use, the primary objective of this criterion is to ensure that there is an alarm if the pressure within the pipeline drops below the normal operating level (± 410 kPa). It should be noted that there may also be separate alarm systems for the VIE and the gas bank manifolds.

Documented evidence is required of regular testing of these alarms, including any slave alarms that may be installed in the rest of the facility.

12.2.5.5 Where there is piped gas, medical gas alarm systems are regularly tested and these tests are documented.

Documented evidence is required of such testing of these alarms.

12.2.5.6 Backup supplies of medical gas are available and strategically positioned to ensure timely deployment in emergencies.

There must be a documented policy that details where and how these supplies are stored, and the procedures to be followed to ensure rapid distribution to the relevant patient care areas in the event of a failure in the pipeline system. This policy must include medical air for ventilators in areas in which they are used.

12.2.6 Medical vacuum systems are regularly inspected, maintained and when appropriate, improved.

Standard Intent

The organisation plans its vacuum supplies according to the needs of the patients served.

Policies and procedures relating to the testing and safety of vacuum systems are available and implemented.

Vacuum systems are regularly tested in accordance with the specifications of the suppliers.

Emergency vacuum supplies ensure that:

- where there is no vacuum supply, there is at least one mobile vacuum pump per ward, and more depending on the number of beds/cots in
- the ward and
- all the necessary fittings for suction are suitable for the ages of the children admitted and are working satisfactorily.

12.2.6 Criteria

12.2.6.1 Where there is a piped vacuum system, it is externally ventilated and able to provide sufficient suction to all piped vacuum points in the facility.

This criterion requires that the "exhaust" outlet pipe from the vacuum pump leads to the outside of the enclosure or room in which the vacuum pumps are housed. The system needs to be capable of providing sufficient suction to all points in the facility. Regular tests need to be performed to ensure this and to detect any degradation in the level of vacuum e.g. due to fluids having been accidentally sucked into the line. (The tests can be performed using a standard suction regulator or vented gauge).

12.2.6.2 Piped vacuum systems are regularly tested, and these tests are documented.

12.2.6.3 Alternative vacuum/suction units are available and strategically positioned to ensure timely deployment in emergencies.

Portable electrically operated suction units are usually available. However, in the event of the standby generator failing during a power grid failure, there is need to be adequate alternative suction facilities (e.g. manually operated suction pumps) for use as emergency backup. At the very least, there should be one on each emergency/resuscitation trolley, but obviously more would be required in areas such as delivery rooms.

Theatres should have backup electrical power in the form of a UPS that would allow for portable electric suction pumps to be used. Backup suction must include systems that function without electricity. Battery powered units may be a problem as the batteries could become depleted during a long power failure. They also require extra maintenance in the form of battery care and charging, etc.
Foot operated machines could be considered.

12.2.7 The sewerage system is regularly inspected, tested, maintained and when appropriate, improved.

Standard Intent

An appropriate sewerage system must be available and maintained. This will include disposal of waste water, surface water and sewage. The infrastructure, including drainage points, pipes, pumps and mains, needs to be protected to prevent spillage and contamination of the environment.

12.2.7 Criteria

12.2.7.1 There is an appropriate and effective sewerage system.

An appropriate and effective sewerage system is defined as an enclosed circuit that transports water from taps, sinks and toilet areas to either a closed sewerage system or a septic tank.

Measures must be in place for the management of solid waste, sewage treatment and water pollution prevention.

12.2.7.2 Septic tank systems are properly managed and functional.

12.2.7.3 All drains are appropriately covered.

12.3 Medical Equipment

12.3.1 Medical equipment is available and properly maintained to meet the needs of the patient population.

Standard Intent

Healthcare organisations are responsible for ensuring that appropriate medical equipment is available and ready for use at all times. There is an accountable, systematic approach to ensuring that cost effective, safe and appropriate medical equipment is available to meet the demands of quality patient care.

Managers take responsibility for ensuring that medical equipment is available, appropriately maintained and calibrated and that the personnel are competent to use it.

12.3.1 Criteria

12.3.1.1 A designated individual supervises the management of medical equipment in the organisation.

The person appointed under this criterion needs to have a level of competence/qualification as determined by national arrangements. Compliance is to be assessed against the specifications/requirements for the post. The organisational framework with regard to the staff establishment and organogram will reflect such a position.

12.3.1.2 Policies and procedures guide the management of medical equipment.

A policy that describes proper management of equipment must be in place. Factors to be addressed, at the least, are:

- *the responsibilities are defined*
- *medical equipment is procured on the basis of the services provided and*
- *the critical instruments are well maintained.*

12.3.1.3 The supply of medical equipment is adequate to meet the needs of the service.

12.3.1.4 There is an inventory of all medical equipment.

There should be a coordinated process to ensure that all new equipment is added to the inventory.

12.3.1.5 Records are kept of the checking and maintenance of medical equipment.

This documented audit should include all equipment currently in use in terms of:

- *the availability of commissioning certificates*
- *the availability of owner's and service manuals*
- *age and physical condition*
- *the current position in the technology life cycle*

- *suitability for its intended function*
- *risk profile (based on service/repair history)*
- *the extent of its projected life expectancy.*

12.3.1.6 There is a documented procedure known to the personnel for reporting defects in medical equipment during and after normal working hours.

The system needs to include:
- *the party/parties responsible for providing it (e.g. in-house, district or regional clinical engineering department, outside service provider or a combination;*
- *individual responsibilities in cases where support is provided from more than one source;*
- *the procedures that need to be followed in order to obtain assistance;*
- *documented records of all call outs;*
- *properly completed incident reports, where necessary.*

12.4 Information and Communication Technology (ICT) Equipment

12.4.1 ICT equipment is available and properly maintained to meet the needs of the services.

Standard Intent

Healthcare organisations are responsible for ensuring that appropriate ICT equipment is available and ready for use at all times. There is an accountable, systematic approach to ensuring that cost-effective, safe and appropriate ICT equipment is available to meet the demands of quality patient care.

Managers take responsibility for ensuring that ICT equipment is available, appropriately maintained, calibrated and that the personnel are competent to use it.

12.4.1 Criteria

12.4.1.1 Policies and procedures guide the management of ICT equipment.

12.4.1.2 A designated individual supervises the management of ICT equipment in the organisation.

12.4.1.3 The supply of ICT equipment is adequate to meet the needs of the services.

12.4.1.4 There is an inventory of all ICT equipment.

12.4.1.5 All desktop and server computers are attached to an uninterrupted power supply (UPS) with surge protection.

12.4.1.6 There is a data back-up system.

12.4.1.7 Records are kept of the checking and maintenance of ICT equipment.

12.4.1.8 Where technical ICT support is not available at facility level, an arrangement is in place to obtain such support from outside.

12.4.1.9 There is documented evidence that relevant personnel are regularly trained to use/operate ICT equipment.

12.4.1.10 There is a documented procedure known to the personnel for reporting defects in ICT equipment during and after normal working hours.

12.4.1.11 Computers are equipped with officially licensed software only.

12.4.1.12 Operating system patches/updates are installed as they become available.

12.4.1.13 Each computer is equipped with an up-to-date virus scanner.

12.4.1.14 Basic technical spare parts are available.

SE 13: SUPPORT SERVICES

OVERVIEW OF SUPPORT SERVICES

The organisation may employ its own personnel to provide support services, such as laundry, housekeeping and catering or support services may be outsourced, in which case the organisation delegates one or more staff members to supervise such contracted services. Documented agreements exist for all outsourced services.

In organisations without an inpatient unit, food may be prepared for day care or crèche facilities. In this case, the same criteria for safe and hygienic food preparation apply.

The managers/supervisors of the services work with other organisational leaders and managers to improve the quality of service delivery throughout the organisation, and to ensure that services comply with criteria relating to management, leadership, human resource development, infection control, environmental safety and quality improvement.

Standards

13.1 Food Service Management

13.1.1 The food service is managed to ensure the provision of a safe and effective service.

13.1.1 Criteria

13.1.1.1 A written agreement is available where the service is outsourced.

13.1.1.2 A suitably qualified or experienced person manages/supervises the service.

Departmental and service managers are primarily responsible for ensuring that the mission of the organisation is met, through the provision of management and leadership at departmental level. Good departmental or service performances require clear leadership from a suitably qualified individual. In assessing the qualifications of the individual, one should always be guided by the organisation specific post requirements.

13.1.1.3 The manager/supervisor is responsible for the day-to-day operation of the service.

13.1.1.4 The responsibilities of the manager/supervisor are defined in writing.

A current job description/performance management agreement, signed by the incumbent and the supervisor/manager, must be available.
Key performance areas must be clearly stated.

13.1.1.5 The departmental manager ensures that written policies and procedures are available to guide the personnel in all service-related aspects.

Policies and procedures ensure that the personnel receive the guidance needed to carry out the required functions.

A system needs to be in place to ensure that departmental policies and procedures are known and are implemented.

Policies and procedures on the following aspects are available:

- *wearing jewellery on wrists and hands and wearing nail polish while preparing food*
- *hand washing procedures and routines*
- *cleaning food preparation areas and equipment*
- *disposing of kitchen waste and*
- *food preparation procedures and routines.*

13.1.2 There are enough suitably qualified and competent personnel to provide a safe and effective service.

Standard Intent

Orientation and induction programmes ensure the competence of personnel before they begin to carry out their functions.

The personnel act in accordance with job descriptions, and are evaluated in accordance with their assigned responsibilities. The in-service training needs of the personnel in the service are continuously assessed and appropriate training is provided.

13.1.2 Criteria

13.1.2.1 Personnel employed by the organisation are managed in terms of the employer's policies and procedures relating to job descriptions, orientation and induction, in-service training and staff performance appraisals.

13.1.2.2 Food handlers have appropriate medical examinations e.g. throat swabs and chest X-rays.

13.1.2.3 The manager has established an orientation and induction programme for service personnel.

13.1.2.4 Contracted personnel are managed as determined in the written service agreement.

13.1.2.5 The organisation ensures that contracted personnel are oriented to relevant organisational policies and procedures.

13.1.2.6 The organisation ensures that contracted personnel participate in relevant organisational in-service training programmes (e.g. infection control, health and safety).

13.1.3 The food service department is designed to allow for the effective storage, preparation and serving of food.

Standard Intent

The service manager needs to work closely with the organisation's managers to ensure that facilities and equipment are adequate. Management is kept informed of inadequate facilities, additional equipment requirements and the current state of facilities and equipment.

13.1.3 Criteria

13.1.3.1 Where a kitchen is provided within the facility, it is designed to allow for the effective storage, preparation and serving of food.

13.1.3.2 There is a section of the kitchen dedicated to the preparation of infant feeds.

13.1.3.3 There are separate hand-washing facilities in the food preparation area, with soap and paper towels.

Evaluate the availability of appropriate, easily accessible and sufficient hand-washing facilities with hot and cold water as well as adequate supplies of soap and paper towels in the food preparation area.

13.1.3.4 There is a mechanism for preventing unauthorised individuals from entering food preparation areas.

13.1.3.5 The temperature, ventilation and humidity levels are adequate to provide for satisfactory working conditions and cleanliness.

Evaluate the natural/artificial ventilation of the kitchen (e.g. windows, fans, air-conditioners) and the availability of a system for monitoring the daily kitchen temperature.

13.1.3.6 Windows in the preparation area have fly screens or another effective method of fly control is available.

These methods could include fly screens, fly traps, ultra-violet insect control, etc.

13.1.3.7 There is adequate lighting.

13.1.3.8 There is a fire extinguisher and a fire blanket in the kitchen.

13.1.3.9 There is evidence that personnel have been trained in the use of fire extinguishers and fire blankets.

13.1.4 Basic hygiene measures are implemented.

13.1.4 Criteria

13.1.4.1 The food service area meets health and safety regulations.

13.1.4.4 Equipment, floors, walls and ceilings are kept clean.

13.1.4.5 Personnel are constantly reminded of the importance of effective hand washing (i.e. posters).

13.1.4.6 Preparation surfaces are cleaned and dried between being used for different activities.

13.1.4.7 There are adequate, clean and conveniently placed change rooms, toilets and ablution facilities for food handlers.

This refers to the availability, convenience, number in relation to staff complement and cleanliness of these facilities and easy access to these areas. Refer to the statement of intent for the requirements.

13.1.4.8 Food handlers have access to lockers for their outer clothing.

13.1.4.9 Enough suitable refuse containers are provided in or near each change room, hand washing facility and toilet area.

This refers to the availability of, and easy access to, refuse containers in the above mentioned areas, the correct use of these containers and whether they are cleaned regularly to prevent overflow.

13.1.5 Menus are planned to meet patient needs.

Standard Intent

Menus are planned by a dietician or other individuals with acceptable food management qualifications and/or experience.

13.1.5 Criteria

13.1.5.1 **A suitably qualified and/or experienced person advises on meal development.**

This refers to the involvement of a dietician or other experienced person in planning meals and special diets.

13.1.5.2 There is a planned weekly menu suitable for different seasons.

13.1.5.3 Wherever possible, patient food preferences are respected and substitutions made available.

13.1.5.4 Cultural preferences are taken into account.

13.1.6 Food products and meals are hygienically stored, prepared and served.

Standard Intent

Foods are stored and prepared in accordance with written protocols. High-risk foods which may be contaminated and which may contaminate other foods are kept separately. This includes such foods as meat, poultry and fish.

13.1.6 Criteria

13.1.6.1 Foods, which are of a potentially high risk, unprepared food and prepared items, are kept separately.

Ensure that dairy products, meat, fish, vegetables, cooked and raw foods are stored separately from one another.

13.1.6.2 Separate cutting boards are kept for raw and cooked food.

13.1.6.3 Food is kept for a minimal amount of time after cooking and before serving.

13.1.6.4 Food waste is put in covered containers and removed without delay from places where food is prepared.

13.1.6.5 There is a mechanism for ensuring that food handlers report if they or their family suffer from diarrhoea or vomiting, throat infections, skin rashes, boils or other skin lesions, or eye or ear infections.

13.1.6.6 Food handlers wear protective clothing.

13.1.7 Food is stored under conditions that ensure security, hygiene and freshness.

Standard Intent

Foods are stored under conditions that ensure security, hygiene and freshness.

13.1.7 Criteria

13.1.7.1 Foods are stored at acceptable temperatures.

13.1.7.2 Foods are stored separately from non-foods.

13.1.7.3 Different types of food are kept separately.

13.1.7.4 Foods are stored off the ground on racks or shelving of an impenetrable material.

13.1.7.5 Fridges and freezers can be opened from the inside through a safety release mechanism.

This applies to walk-in refrigerators and will not apply to Category 5 and Category 6 facilities.

13.1.7.6 Stock is rotated using the First In First Out (FIFO) principle.

13.1.8 Where food is provided by families or others from outside the health facility, there are mechanisms to ensure that nutrition and hygiene are maintained.

13.1.8 Criteria

13.1.8.1 Where families or others provide food, they are educated about the patient's diet limitations.

13.1.8.2 Food is provided at regular intervals.

13.1.8.3 The food provided meets the nutritional needs of the patient.

The health facility personnel should ensure that the food meets the patient's dietary needs in terms of content, freshness and preparation methods.

13.1.8.4 Hygienic food preparation and serving methods are implemented.

Where food preparation takes place in the vicinity of the health facility, observation and advice should be provided relating to hygienic food preparation. Particular attention should be paid to hand washing, the use of clean utensils and the control of flies and other vectors.

13.2 Linen Service Management

13.2.1 The linen service is managed to ensure the provision of a safe and effective service.

Standard Intent

Linen management encompasses all aspects of the provision of clean linen for all patient care services. The laundry service may be provided on site or off site. Whatever system is used, the processes will be assessed in terms of the provision and distribution of linen, stock control, the collection of soiled and infected linen, laundering processes and the redistribution of linen.

Departmental and service managers are primarily responsible for ensuring that the mission of the organisation is met through the provision of management and leadership at departmental level. Good departmental or service performances require clear leadership from a suitably qualified individual.

13.2.1 Criteria

13.2.1.1 A written agreement is available where the service is outsourced.

13.2.1.2 A suitably qualified and/or experienced person manages/supervises the service.

This requires an individual in the organisation who has the officially assigned duties of overseeing and taking responsibility for the management aspects of the laundry service. In some instances, these duties may be shared between the facility manager and a private, outsourced company.
Where the position is filled by someone in an acting capacity, this criterion will be scored PC.

In assessing the qualifications of the individual, one should always be guided by the organisation specific post requirements.

13.2.1.3 The manager/supervisor is responsible for the day-to-day operation of the service.

A current job description/performance management agreement, signed by the incumbent and the supervisor/manager, must be available.
Key performance areas must be clearly stated.

This function may also be performed by the person in charge of the clinic/facility manager.

13.2.1.4 The responsibilities of the manager/supervisor are defined in writing.

13.2.1.5 The departmental manager ensures that written policies and procedures are available to guide the personnel in all service-related aspects.

Policies and procedures ensure that the personnel receive the guidance needed to carry out the required functions.

A system needs to be in place to ensure that departmental policies and procedures are known and are implemented.

Policies and procedures on the following aspects of a linen service are available:

- *handling soiled and infected linen*
- *separation of the laundry into areas for clean and soiled laundry*
- *wearing protective clothing*
- *searching used linen for sharps*
- *marking linen to identify ownership*
- *washing patients' private clothing.*

13.2.2 There are enough suitably qualified and competent personnel to provide a safe and effective service.

Standard Intent

Orientation and induction programmes ensure the competence of personnel before they begin to carry out their functions.

The personnel act in accordance with job descriptions and are evaluated in accordance with their assigned responsibilities. The in-service training needs of personnel in the service are continuously assessed and appropriate training is provided.

13.2.2 Criteria

13.2.2.1 Personnel employed by the organisation are managed in terms of the employer's policies and procedures relating to job descriptions, orientation and induction, in-service training and staff performance appraisals.

13.2.2.2 Contracted personnel are managed as determined in the written service agreement.

13.2.2.3 The organisation ensures that contracted personnel are oriented to relevant organisational policies and procedures.

13.2.2.4 The organisation ensures that contracted personnel participate in relevant organisational in-service training programmes (e.g. infection control, health and safety).

*13.2.3 Where the laundry is within the facility, it is designed to allow for safe and effective processing of laundry***.**

Standard Intent

Departmental managers need to liaise with organisational managers to ensure that facilities and equipment are adequate. The organisation's managers are kept informed of inadequate facilities, additional equipment requirements, and the current state of facilities and equipment.

13.2.4 Criteria

3.2.3.1 The space in the laundry is adequate to deal with the calculated or estimated dry weight of articles to be processed and the type of washing equipment.

The requirements will vary according to the size of the facility. Allocated space and equipment should be adequate to deal with the current work load e.g. where laundry is processed by hand once or twice a week.

13.2.3.2 The laundry provides a clear flow of laundry from the soiled to the clean side with no crossover of these lines.

Critical criterion
There should be clearly indicated demarcation lines/barriers to ensure adequate separation between "clean" and "dirty" areas.

13.2.3.3 The size and number of washing machines are adequate to meet the number of loads per hour, considering peak loads.

There should be an assessment of the equipment needs in order to avoid delays, taking into account factors such as the number of beds, occupancy rate, the operating hours of the laundry and the number of available personnel. The same should be done to determine the needs for other equipment such as ironers/laundry presses, driers, etc.

13.2.3.4 Ironers/laundry presses are adequate to ensure the processing of laundry items without undue delays.

13.2.3.5 Linen is securely stored.

13.2.*4 Where linen is provided by families or others from outside the health facility, there are mechanisms in place to prevent and control infections.*

13.2.4 Criteria

13.2.4.1 There are processes that support the patient's right to bed-linen provision for comfort.

13.2.4.2 There are processes to ensure the right of the patient to dignity by the provision of appropriate bed-clothes.

13.2.4.3 The family or others providing linen are guided on the type of linen that is suitable.

13.2.4.4 Personnel ensure that the family or others provide clean linen on a regular basis.

13.2.4.5 There are processes in place for the handling of contaminated linen.

13.3 Housekeeping Management

13.3.1 The housekeeping service is managed to ensure the provision of a safe and effective service.

Standard Intent

Departmental and service managers are primarily responsible for ensuring that the mission of the organisation is met through the provision of management and leadership at departmental level. Good departmental or service performances require clear leadership from a suitably qualified individual

13.3.1 Criteria

13.3.1.1 A written agreement is available where the service is outsourced.

13.3.1.2 A suitably qualified and/or experienced person manages/supervises the service.

This requires an individual in the organisation who has the officially assigned duties of overseeing and taking responsibility for the management aspects of the laundry service. In some instances, these duties may be shared between the facility manager and a private, outsourced company.

Where the position is filled by someone in an acting capacity, this criterion will be scored PC.

In assessing the qualifications of the individual, one should always be guided by the organisation-specific post requirements.

13.3.1.3 The manager/supervisor is responsible for the day-to-day operation of the service.

13.3.1.4 The responsibilities of the manager/supervisor are defined in writing.

A current job description/performance management agreement, signed by the incumbent and the supervisor/manager, must be available.
Key performance areas must be clearly stated.

13.3.1.5 The departmental manager ensures that written policies and procedures are available to guide the personnel in all service-related aspects.

Policies and procedures ensure that the personnel receive the guidance needed to carry out the functions of the housekeeping service.

A system needs to be in place to ensure that departmental policies and procedures are known and are implemented.

Policies and procedures relating to the following aspects of the service are available:

- *supervising cleaning personnel*
- *mixing and using cleaning chemicals*
- *storing cleaning materials safely*
- *hygienic storage of mops and brooms*
- *appropriate cleaning methods and materials for various surfaces*
- *cleaning at times those are least disturbing to the patient care services.*

13.3.2 There are enough suitably trained personnel to provide a safe and effective service.

Standard Intent

Orientation and induction programmes ensure the competence of personnel before they begin to carry out their functions.

The personnel act in accordance with job descriptions, and are evaluated in accordance with their assigned responsibilities. The in-service training needs of personnel in the service are continuously assessed and appropriate training provided.

13.3.2 Criteria

13.3.2.1 Personnel employed by the organisation are managed in terms of the employer's policies and procedures relating to job descriptions, orientation and induction, in-service training and staff performance appraisals.

13.3.2.2 Contracted personnel are managed as determined in the written service agreement.

13.3.2.3 The organisation ensures that contracted personnel are oriented to relevant organisational policies and procedures.

13.3.2.4 The organisation ensures that contracted personnel participate in relevant organisational in-service training programmes (e.g. infection control, health and safety).

13.3.3 Facilities and equipment are adequate to provide a safe and effective cleaning service.

Standard Intent

Departmental managers need to liaise with the organisation's managers to ensure that facilities and equipment are adequate.

13.3.3 Criteria

13.3.3.1 Adequate and secure storage areas are available for equipment and chemicals.

The requirements will vary according to the size of the facility and space available. Specific requirements that need to be reviewed are:

- *The allocated storage space should be adequate to deal with all housekeeping equipment and activities.*
- *The specific storage area should be clean, tidy and securely locked.*
- *Documented evidence of maintenance and replacement of equipment should be available where applicable, e.g. buffers, polishers, mops, buckets.*
- *Equipment currently in use should be disinfected regularly and kept clean and dry when not in use.*

13.3.3.2 Chemicals for cleaning are safely stored out of the reach of patients, children and visitors.

Critical criterion
This refers to a dedicated chemical store or storage space for cleaning materials.

- *The storage area should be neat and tidy,*
- *all chemicals should be stored above floor level*
- *the store should be locked at all times.*
- *Access needs to be controlled.*
- *necessary warning signs are displayed.*

13.3.3.3 There is adequate storage place for brooms and mops.

This refers to all storage areas for mops and brooms in the facility and ensures that infection control measures are not compromised. Mops and brooms should be stored with their heads up. They should be clean and dry when not in use, and be routinely disinfected while in use. There may be a system for taking mop heads to the laundry every day to be washed and exchanging them for clean ones. A special system for preparing the mop heads according to the manufacturer's instructions may also be used.

If mops and brooms are stored in the open in the sluice room this criterion will be marked PC.

13.3.3.4 Mops and brooms are cleaned and dried before being stored.

A documented procedure or guideline describes how cleaning materials/equipment must be cleaned and dried and when cleaning materials need to be replaced.

13.3.3.5 Cleaning cupboards are adequately ventilated.

13.3.4 Safe waste disposal takes place according to the infection control programme.

Standard Intent

The personnel play an important role in the removal of clinical waste from departments. Protocols need to be developed to guide the personnel in ensuring their own safety, the safety of others and the safety of the environment when implementing the waste removal systems.

13.3.4 Criteria

13.3.4.1 Waste is segregated in accordance with policies, procedures and municipal by-laws.

This applies to all areas in the facility where waste is generated. *Assess that the waste categories are collected according to the colour-coding guidelines.* *Assess the use of protective clothing by the waste handler and housekeeping personnel – is it being used correctly?* *Also assess the way waste is transported to the collection area. Transport should be organised in such a way that it is safe and that patients will not be affected.*

13.3.4.2 The colour of bag and type of container appropriate to the type of waste generated are available.

This refers to the implementation of the organisation's policy in all areas where waste is generated. *The waste should be collected according to the prescribed colour-coding systems.*

13.3.4.3 Waste is protected from theft, vandalism or scavenging by animals.

This refers to all waste storage areas; take tidiness into account, as well as the security and protection of general, clinical and chemical waste (this includes pharmaceutical and radiological waste), plate waste, etc.

Waste is collected at appropriate times so that hazards are not caused.

Collection times should be appropriate for all collection points to prevent waste from building up (this is a potential hazard).