International Accreditation Standards for Healthcare Organisations

Version 4.2, February 2016
FOREWORD

This edition of the AACI Standards for healthcare organisations has been prepared by AACI Technical Committee and contains all the Standards and notes needed for AACI Accreditation process.

Subject to periodic revision, AACI will continue to evolve as interested parties specify improvements, corrections are identified and as conditions change. Many interested parties have advised on this version. AACI welcomes your advice as well. To comment on AACI Standards, or the framework for accreditation, please submit written comments, suggestions and remarks to AACI. The AACI Standard serves as a handbook for surveyors and for healthcare organisations seeking international accreditation against AACI Standards.

It is hoped that the AACI Standards will continuously improve, with the help of a very wide variety of people and healthcare organisations.

The mission of AACI is to develop person-centered standards for healthcare services and improve the safety, well-being and quality of life and quality of care throughout the world.

Please direct comments and suggestions to: info@aacihealthcare.com

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INTRODUCTION

General

This Introduction is designed to provide you with information on the following topics:

- Application
- The origin of the standards and how they are organized
- The international accreditation process
- Guidelines how to use this Set of standards

This AACI Standards rely on a management system approach. This implies that identifying, understanding and managing the system of interrelated processes for quality and safety improves the healthcare organisation’s effectiveness and efficiency.

The following principles are applied in this standard:

- Governance
- Leadership
- Risk Management
- Patient Focused Care

The AACI Standards have been designed so that they can be implemented in all healthcare services, settings and locations. It also addresses general safety for workers, patients and other visitors within healthcare organisations. This means that service providers can use the AACI Standards to continuously improve the quality and safety of their care by assessing and managing the performance of their services, and those provided on their behalf, against the AACI.

This document is based upon the Centers for Medicare and Medicaid (CMS) Conditions of Participation for Hospitals 42 C.F.R § 482 and State Operations Manual Regulations and Interpretive Guidelines for Hospitals, ISO 9001 Quality Management System Standard and EN 15224 Health care services - Quality management systems.

These Interpretive Guidelines also are periodically updated based on notices distributed from CMS.

When standard compliance is related to a laws and regulations, whichever sets the higher or stricter requirement applies.

Where any requirements of this standard cannot be applied due to the nature of the healthcare organisation and its processes, this can be considered for exclusion. Where exclusions are made, claims of conformity to this standard are not acceptable, unless such exclusions do not affect the healthcare organisation’s ability or responsibility to control the manner required by this standard. Any claims of exclusion shall be detailed and justification provided.
The requirements of these Standards are designed to support the development and continual improvement of healthcare quality and patient safety in the healthcare providers. Standards promote responsibility and accountability for the quality and safety of services provided.

By incorporating national and international best available evidences, this Standard also promote healthcare that is up to date, effective and consistent. Importantly, Standard for healthcare provides a basis for planning and managing services and measuring improvements as well as identifying and addressing gaps and deterioration in the quality and safety of the services provided.

The document uses the terms “should” (recommendation), “may” (allowance) and “can” (possibility). Organisations wishing to implement this standard would be expected to consider all recommendations where the term “should” is used.

The AACI set of Standards aim to give a shared voice to the expectations of the public, service users and service providers. They also provide a roadmap for improving the quality, safety and reliability of healthcare.

Terminology

**Health** The World Health Organization (WHO) definition of health is “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.” The International Classification of Functioning, Disability and Health (ICF), by WHO, identifies five health components; body function, body structure, activity, participation and environmental factors.

**Health care** In this standard health is not a stand alone concept but is used in several terms as a prefix. When used as a prefix the concept of health is based on the health components in of ICF by WHO. The concept of health relates to both health care and social care. This standard is focused on requirements for health care. What is included in health care can differ from country to country and this has to be considered in national applications. In this standard health care includes e.g. primary health care, pre-hospital and hospital care, tertiary care, nursing homes, hospices, preventive health care, mental health services, dental services, physiotherapy, occupational health services, rehabilitation and pharmacies.

**Clinical** The term “Clinical” can have different meanings in different countries. In this standard “clinical” refers to all types of interactions between patients and all kinds of health care professionals.

**Clinical risk** denotes any risk that could have negative effects on the outcomes for any of the quality requirements. The risk factors could be non-clinical, but the risk is considered a clinical risk if it could have any negative impact on any of the quality requirements. Aspects of clinical risk management are integrated in this standard.
Acronyms/Abbreviations

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<td>Adverse Drug Reaction</td>
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<td>BBP</td>
<td>Bloodborne Pathogens</td>
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<td>BID</td>
<td>Latin word meaning “twice daily”</td>
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<td>BSI</td>
<td>Blood Stream Infections</td>
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<td>CB</td>
<td>Certification Body</td>
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<td>CRNA</td>
<td>Certified Registered Nurse Anesthetist</td>
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<td>ECDC</td>
<td>European Center for Disease Control</td>
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<td>DON</td>
<td>Director of Nursing</td>
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<td>ECP</td>
<td>Exposure Control Plan</td>
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<td>Electrocardiogram</td>
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<td>HVAC</td>
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<td>IAF</td>
<td>International Accreditation Forum</td>
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<td>Pro re nata (Latin phrase meaning “as needed”)</td>
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<td>Safety Data Sheet</td>
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Module I

Healthcare organisation
Governance Standards
STANDARD 1
Regulatory Compliance

1.1 Compliance with applicable Laws and Regulations

1. The healthcare organisation must be in compliance with applicable national laws and regulations related to the health and safety of patients in the nationality.

2. The healthcare organisation must be approved as meeting standards for licensing established by the Ministry of Health or locality responsible for licensing healthcare organisations.

3. The healthcare organisation must ensure that all applicable laws and regulations are met.

4. In the absence of the national law addressing the specific healthcare requirement the healthcare organisation shall abide by these Standards.

1.2 Licensure and Certification

1. The healthcare organisation must have a policy in place to assure that personnel are licensed or meet other applicable standards that are required by applicable laws and regulations.

2. All staff that are required by the Ministry of Health, Medical Chamber, Nursing Chamber or any other regulatory body to be licensed or certified must possess a current license.

3. The healthcare organisation must assure that these personnel are in compliance with the applicable licensure and certification laws.

4. All staff must meet standards required by laws and regulations for healthcare personnel. This would include at a minimum:
   a) certification requirements;
   b) minimum qualifications;
   c) training/education requirements;
   d) permits
STANDARD 2
Leadership

2.1 Governing Body

1. The healthcare organisation must have an effective governing body responsible for the conduct of the healthcare organisation as an institution. If a healthcare organisation does not have an organized governing body, the persons legally responsible for the conduct of the healthcare organisation must carry out the functions specified in this part that pertain to the governing body.

2. In the absence of an organized governing body, there shall be written documentation that identifies the individual(s) that are responsible for the conduct of the healthcare organisation operations.

2.2 Medical Staff

1. The governing body must ensure the medical staff requirements are met. The governing body must determine, in accordance with applicable laws and regulations and Medical Chamber, which categories of practitioners are eligible candidates for appointment to the medical staff. The governing body has the authority, in accordance with applicable laws and regulations, to appoint the following practitioners to the medical staff:

   a) Doctor of Medicine;
   b) Doctor of Dental Medicine

2. The governing body has the authority, in accordance with applicable laws and regulations, to appoint some types of non-physician practitioners to the medical staff:

   a) Certified Nurse;
   b) Clinical Social Worker;
   c) Clinical Psychologist;
   d) PT/OT Specialist

3. The governing body determines whether to grant, deny, continue, revise, discontinue, limit, or revoke specified privileges, including medical staff membership, or a specific practitioner after considering the recommendation of the medical staff. In all instances, the governing body’s determination must be consistent with established healthcare organisation medical staff criteria, as well as with applicable laws and regulations.

4. Only the healthcare organisation’s governing body has the authority to grant a practitioner privileges to provide care in the healthcare organisation.

2.3 Managing Director

1. The governing body must appoint one Managing Director who is responsible for managing the entire healthcare organisation.
2. The Managing Director shall ensure;

a) compliance with applicable national and local legislation and regulations, including local licensing requirements; and
b) care shall be provided according to recognized standards.

3. The Managing Director shall ensure that the organisation has defined and communicated the following:

a) healthcare organisation mission or purpose;
b) healthcare organisation values;
c) ethics or code of behavior;
d) strategic objectives for the healthcare organisation;
e) and care shall be provided according to recognized standards;
f) the services provided.

4. The Managing Director shall ensure that there is a formal process for planning of services and that the process:

a) is based on the strategic objectives, mission and scope of the organisation as well as a health needs assessment that engages other local service providers and the community;
b) promotes improvements in the health, quality of life and independence of the population the healthcare organisation serves;
c) gathers input from service users, their families, local communities as well as knowledgeable staff;
d) considers environmental and financial factors; and

e) identifies the need for coordination between departments and functions and with relevant external services.

2.4 Medical Director

1. The healthcare organisation must appoint one Medical Director who has responsibility for medical staff and all clinical operations.

2. Medical Director must have the necessary medical, clinical and administrative experience as determined by the scope of services provided and the healthcare organisation.

2.5 Organisational plan and budget

1. The healthcare organisation must have an overall organisational plan that meets the following conditions:

a) The plan must include an annual operating budget that is prepared according to generally accepted accounting principles.
b) The budget must include all anticipated income and expenses. This provision does not require that the budget identify the components of each anticipated income or expense item by item.
c) The plan must provide for capital expenditures for at least a 3-year period, including and identifying the anticipated sources of financing for capital expenditure that relates to the following:
• acquisition of land
• improvement of land, buildings, and equipment
• replacement, modernization, and expansion of buildings and equipment.

2. The plan must be prepared under the direction of the governing board and by a committee consisting of representatives of the governing board, the administrative staff, and the medical staff of the healthcare organisation.

2.6 Outsourced services

1. The governing body must be responsible for services furnished in the healthcare organisation. The governing body must ensure that a contracted service will comply with all regulations required by applicable laws and regulations, Ministry of Health and Medical Chamber requirements.

2. The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.
STANDARD 3
Organisational Ethics

3.1 General

1. The healthcare organisation shall establish a framework for explicit set of ethical principles or code of conduct.

2. The framework for ethical management shall include admissions, transfer, discharge, disclosure of ownership and marketing and any professional conflicts that may not be in patients’ best interests. The organisation’s framework for ethical management supports ethical decision making in clinical care and nonclinical services.

3. The healthcare organisation shall comply with national and other applicable law, other requirements to which the healthcare organisation subscribes, and this set of standards. When national and other applicable law, other requirements to which the company subscribes, and this standard address the same issue, that provision which is most stringent applies.

NOTE 1 The ethical principles will include but not limited to:

a) confidentiality of patient and personnel information;
b) provide clear admission, transfer, and discharge policies;
c) avoidance of conflicts of interest;
d) complaints processes;
e) independence and objectivity;
f) encouragement of staff to raise ethical concerns;
g) accurately bill for its services; and
h) resolve conflicts when financial incentives and payment arrangements could compromise patient care.

NOTE 2 The healthcare organisation shall also respect the principles of the following international instruments:

a) Universal Declaration of Human Rights
b) ILO Conventions 100 and 111 (Equal remuneration for male and female workers for work of equal value; Discrimination)
c) ILO Convention 155 & Recommendation 164 (Occupational Safety & Health)
d) ILO Convention 159 (Vocational Rehabilitation & Employment/Disabled Persons)

NOTE 3 The framework also supports the organisation’s professional staff and patients when confronted by ethical dilemmas in patient care, such as donor and transplant decisions; disagreements between patients and their families, and between patients and their health care practitioners, regarding care decisions; and interprofessional disagreements. Such support is readily available.
3.2 Discrimination

1. The healthcare organisation shall not engage in or support discrimination in hiring, remuneration, access to training, promotion, termination or retirement based on race, national origin, religion, disability, gender, sexual orientation or age.

2. The healthcare organisation shall not allow behavior including gestures, language and physical contact that is sexually coercive, threatening, abusive or exploitative.
STANDARD 4
Quality Management System

4.1 General

1. The healthcare organisation shall develop, implement, and maintain an effective, ongoing, healthcare organisation-wide, risk rated quality system and performance improvement program.

2. The healthcare organisation’s governing body must ensure that the Quality Management System reflects the complexity of the scope of services offered, including those outsourced.

3. Information regarding all services including related quality data shall be published and easily available. This information shall be updated on a regular basis to ensure current conditions.

4. The healthcare organisation must maintain and demonstrate evidence of its Quality Management System.

5. The healthcare organisation’s top management shall identify:
   a) key measures in the organisation’s structures, processes, and outcomes to be used in the organisation wide quality improvement and patient safety plan;
   b) key measures for each of the organisation’s managerial structures, processes, and outcomes;
   c) key measures for each of the International Patient Safety Goals.

4.2 ISO 9001 Quality Management System

1. Compliance with the ISO 9001 standard must occur within three (3) years after the accreditation that first occurs.

2. The healthcare organisation must either demonstrate compliance with the ISO 9001 principles through an AACI accreditation survey or maintain certification through an Accredited Certification Body. Only certificates covered by an Accreditation Body recognised by an IAF MLA signatory shall be eligible.

3. The organisation shall maintain ISO 9001 compliance or formal certification in order remain eligible for AACI Accreditation.

4. An accredited CB shall meet the following minimum criteria:
   a) shall be accredited for IAF 38; and,
   b) must have licensed doctor of medicine in auditor team.

5. At a minimum the organisation must be able to demonstrate at the time of the accreditation survey evidence of the following:
   a) Control of Documents: the organisation’s documents (i.e. policies, procedures, forms) are structured in a manner to ensure that only the proper revisions are available for use;
b) Control of Records: the organisation ensures that suitable records are maintained for AACI standard requirements;
c) Internal Surveys: the healthcare organisation conducts internal reviews of its processes and resultant corrective/preventive action measures have been implemented and verified to be effective;
d) Quality Objectives: the healthcare organisation has established measurable quality objectives and the results are analyzed addressed; and
e) Management Review: appropriate information has been submitted to the oversight group for quality management as well as top management for review and analysis during a management review process;
f) Corrective and preventive actions;
g) Control of nonconforming product/service.

NOTE 1 The ISO 9001 requirements are assessed during each survey of the organisation. Once accredited the organisation has 3 years from the initial accreditation to achieved compliance or certification to ISO 9001.

NOTE 2 If the healthcare organisation is currently certified to ISO 9001, the Certification Body that currently certifies the organisation must be verified using current criteria established under 4.2.4.a) and 4.2.4.b). This should be verified prior to the organisation’s accreditation survey.

NOTE 3 The healthcare organisation shall demonstrate that the required ISO 9001 methodologies identified in 4.2.5. a)-g) are present. If the survey team is conducting the annual ISO 9001 periodic survey during the AACI survey, the survey team will assess the applicable ISO 9001 requirements and review the status of findings and corrective action(s) taken to validate they have been implemented.

4.3 Quality Plan

1. The healthcare organisation shall ensure that the Quality Plan requirements are met.

2. The Quality Plan must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors.

3. The healthcare organisation must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, healthcare organisation service and operations.

4.4 Quality Data

1. The healthcare organisation shall ensure that the Quality Data requirements are met.

2. Quality indicators including patient care data, and other relevant data, for example, information submitted to, or received from, the healthcare organisation’s Quality Management System.

3. The healthcare organisation shall use the data collected to monitor the effectiveness and safety of services and quality of care; and identify opportunities for improvement and changes that will lead to improvement.

4. The frequency and detail of data collection must be specified by the healthcare organisation’s governing body.
4.5 Measurement, Monitoring, and Analysis

1. The healthcare organisation shall evaluate all organized services and processes, both direct and supportive, including services provided by any contracted service.

2. The monitoring shall include the use of internal audits of each department or service at scheduled intervals, not to exceed one year and data related to these processes.

3. Individual(s) not assigned to that department or service shall conduct the internal audit. They shall be competent to perform these duties.

4. Measurement, monitoring and analysis of processes throughout the organisation require established measures that have the ability to detect variation identify problem processes, identify both positive and negative outcomes, and effectiveness of actions taken to improve performance and/or reduce risks. The governing body of the organisation shall define the frequency and detail of the measurement. Those functions to be measured at a minimum must include the following:

   a) Threats to patient safety (i.e. falls, patient identification, injuries);
   b) Medication therapy/medication use; to include medication reconciliation, look alike-sound alike medications and the use of dangerous abbreviations;
   c) Operative and invasive procedures; to include wrong site/wrong patient/wrong procedure surgery;
   d) Anesthesia/moderate sedation;
   e) Blood and blood components;
   f) Restraint use/seclusion;
   g) Effectiveness of pain management system;
   h) Infection control system, including healthcare organisation acquired infections (HAI);
   i) Utilization Management System;
   j) Patient flow issues, to include reporting of patients held in the Emergency Department or the PACU for extended periods of time (as defined by the organisation);
   k) Customer satisfaction, both clinical and support areas;
   l) Discrepant pathology reports;
   m) Unanticipated deaths, adverse and/or sentinel events;
   n) Near misses;
   o) Other adverse events;
   p) Critical and/or pertinent processes, both clinical and supportive;
   r) Medical record delinquency; and
   s) Physical Environment Management Systems.

**NOTE 1** In order for the organisation to continually improve its Quality Management System, the services and processes shall be measured to determine their effectiveness. Through an internal audit mechanism, the healthcare organisation will determine where corrective/preventive action(s) are to be taken and have a process in place to determine the effectiveness of action(s) taken.

**NOTE 2** The healthcare organisation should have collected and analyzed data in the respective areas listed above to demonstrate that these processes are closely monitored.

**NOTE 3** All departments and services provided are to be included as a part of the quality management oversight for the organisation, this will include, but not limited to: Inpatient services (medical and surgical), anesthesia services, contract services, outpatient services, rehabilitation services, obstetric services and other support services.

**NOTE 4** Sentinel event shall be defined as an unexpected occurrence or variation that led to death or serious physical or
psychological harm. This definition includes “never or adverse events” that are errors in medical care that are clearly identifiable, preventable and serious in their consequences for patients.

4.6 Quality Management Representative

1. A Quality Management Representative shall be appointed.

2. The Quality Management Representative shall have the authority and responsibility to ensure the requirements of the Quality Management System are implemented and maintained.

4.7 Management Review

1. Top management shall periodically review the adequacy, suitability, and continuing effectiveness of the healthcare organisation’s policy, procedures and performance results vis-a-vis the requirements of this standard and other requirements to which the healthcare organisation subscribes.

2. System amendments and improvements shall be implemented where appropriate.

3. Management review must be performed at regular intervals and at a minimum of once annually.

NOTE 1 Management Review is a formal evaluation by Top Management of the effectiveness, adequacy, and compliance of the Quality Management System. Results from the internal audits, customer/patient satisfaction, data analysis or other process improvement activities must be reviewed as a part of the Management Review process. The results of the audits must be demonstrated to be effective by quantifiable measures and communicated to Senior Leadership. Documentation can take the form of Root Cause Analysis, Performance Improvement Report, Non-Conformity Report, Specific Performance Projects and/or analysis or Failure, Mode and Effect Analysis (FMEA).

4.8 Quality Management System Requirements

1. The organisation is required to have the following as part of the Quality Management System:
   a) Quality Policy Statement;
   b) Measurable quality objectives;
   c) High Risk, Problem Prone processes or functions;
   s) Severity, prevalence, incidence, or problems in the processes or functions;
   e) Improve quality of care, patient safety, and effect healthy outcomes.

2. Multi-disciplinary committee will oversee the Quality Management System with membership consisting of Managing Director, Medical Director, Director of Nursing, Quality Management System Representative, Medical Staff, Pharmacy, Information Technology, Risk Management, Physical Environment and other ancillary departments as identified.

3. A written document including all clinical and non-clinical service areas defining their involvement in the Quality Management System.

NOTE 1 This document may be in the form of a process map, defining the interaction of administrative, clinical and support services (including contract services) defined by the scope of the organisation.
STANDARD 5
Utilization Review Systems

5.1 Utilization Review Plan

1. The organisation must have in effect a utilization review plan that provides for review of services furnished by the institution and by members of the medical staff to patients.

2. The healthcare organisation utilization review plan shall include a delineation of the responsibilities and authority for those involved in the performance of utilization review activities.

3. The responsibilities and authority for those involved in utilization review activities in a utilization review committee shall be described by the healthcare organisation.

4. A utilization review committee must have two or more practitioners from clinical staff, local stakeholders such as representatives of the local community and other service providers and ensure the committee reviews are not conducted by any individual who has a direct financial interest (for example, an ownership interest) in the healthcare organisation; or was professionally involved in the care of the patient whose case is being reviewed.

5.2 Scope and Frequency of Review

1. Review shall address at least the following:
   a) the organisation shall establish procedures for the review of the medical necessity of admissions;
   b) the appropriateness of the setting;
   c) the medical necessity of extended stays;
   d) the medical necessity of professional services.

2. The review may be done before, at, or after, admission and may be conducted by sampling. The review shall include medical necessity for the following:
   a) admissions;
   b) length of stay;
   c) professional services furnished, including medications;
   d) treatment plans reflect evidence based care pathways.

3. Before making a determination that an admission or continued stay is not medically necessary, the UR committee must consult the practitioner or practitioners responsible for the care of the patient, and afford the practitioner or practitioners the opportunity to present their views.

4. If the committee decides that admission to or continued stay in the healthcare organisation is not medically necessary, written notification must be given, no later than 2 days after the determination, to the healthcare organisation, the patient, and the practitioner or practitioners responsible for the care of the patient.
5. If the attending practitioner does not respond or does not contest the findings of the committee or subgroup or those of the physician who performed the initial review, then the findings are final.

6. If the attending physician contests the committee or subgroup findings, or if he presents additional information relating to the patient’s need for extended stay, at least one additional physician member of the committee must review the case.

7. If the two physician members determine that the patient’s stay is not medically necessary or appropriate after considering all the evidence, their determination becomes final. Written notification of this decision must be sent to the attending physician, patient, facility administrator, and the single locality agency no later than 2 days after such final decision and in no event later than 3 working days after the end of the assigned extended stay period.

NOTE 1 There are only 5 working days in a given week. Normally these days are Monday through Friday; however, the institution has the option to establish 5 other days as working days. When a holiday falls on a working day, that day is not counted as a working day.

NOTE 2 In no case may a non-physician make a final determination that a patient’s stay is not medically necessary or appropriate.
STANDARD 6
Patient Safety Systems

6.1 General

1. The healthcare organisation shall have a means for established clear expectations for identifying and detecting the prevalence and severity of incidents that impact or threaten patient safety. This shall include medical errors and adverse patient events.

2. The healthcare organisation’s Patient Safety System shall be documented and shall address the following:
   a) Detections;
   b) Preventative and corrective action;
   c) Defined processes to reduce risk;
   d) Implementation of action plans;
   e) On-going measurement to ensure action effectiveness;
   f) Management review of response and resource allocation utilizing the results of patient adverse events and other data analysis; and,
   g) Quality Management System policy and procedure of informing patients and/or their families about unexpected adverse events or “near misses”

3. The healthcare organisation must ensure that the program activities requirements are met.

4. The healthcare organisation must set priorities for its performance improvement activities that:
   a) focus on high-risk, high-volume, or problem-prone areas;
   b) consider the incidence, prevalence, and severity of problems in those areas; and
   c) affect health outcomes, patient safety, and quality of care.

5. Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the healthcare organisation.

6. The healthcare organisation must take actions aimed at performance improvement and, after implementing those actions; the healthcare organisation must measure its success, and track performance to ensure that improvements are sustained.

6.2 Performance Improvement Projects

1. As part of its quality assessment and performance improvement program, the healthcare organisation must conduct performance improvement projects. The number and scope of distinct improvement projects conducted annually must be proportional to the scope and complexity of the healthcare organisation’s services and operations.
2. The healthcare organisation must document what quality improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

3. The healthcare organisation’s governing body, medical staff, and administrative officials are responsible and accountable for ensuring the healthcare organisation-wide quality assessment and performance improvement efforts address priorities for improved and patient safety and that all improvement actions are evaluated:
   a) that clear expectations for safety are established;
   b) that adequate resources are allocated for measuring, assessing, improving, and sustaining the healthcare organisation's performance;
   c) those adequate resources are allocated for reducing risk to patients;
   d) that the determination of the number of distinct improvement projects is conducted annually.

6.3 **Patient safety Committee**

1. Multi-disciplinary committee will oversee the Patient Safety System with membership consisting of Managing Director, Medical Director, Director of Nursing, Quality Management System Representative, Medical Staff, Pharmacy, Information Technology, Risk Management, Physical Environment and other ancillary departments as identified.

2. This may be delegated to the Quality Management Committee as one of its functions and responsibilities
STANDARD 7
Staffing Management

7.1 Licensure, Registration and Certification

1. The healthcare organisation shall have a policy and practice for outlining and verifying that each staff member possesses a valid and current license, registration or certification. This written policy shall be strictly enforced and compliance data reported to Quality Management oversight.

7.2 Professional Scope

1. All staff, including contract staff, students and volunteers shall function within the limits of their current license, registration or certification. Variations shall be reported to Quality Management oversight.

7.3 Department Scope of Service

1. Each department, whether clinical or supportive, and each patient unit shall have a written scope of service that includes at least:

   a) the hours of operation;
   b) patient populations served;
   c) skill mix;
   d) core staffing and methods for determining and modifying staffing to meet patient or process needs;
   e) description of patient assessment and reassessment practices, including timeframes, where applicable; and
   f) healthcare organisation policies shall identify how often and under what circumstances each department’s scope of service shall be reviewed and updated. (e.g. if a new service is added or discontinued, change of population served, etc.).

7.4 Determining and Modifying Staffing

1. The method for determining and modifying staffing shall be validated through periodic reporting of variance from core staffing, outlining justification and linking that justification with patient and process outcomes, including any untoward patient events or process failures.

2. This validation shall be done and reported to Quality Management oversight, when indicated.

7.5 Job Description

1. All staff, whether clinical or supportive, including contract staff, students and volunteers shall have a current job description (or job responsibilities) available that contains the experience, educational and physical requirements, supervision (as indicated) and performance expectations for that position.
7.6 Orientation

1. All staff, whether clinical or supportive, including contract staff, students and volunteers shall receive an orientation to specific job duties and responsibilities, and their work environment. The orientation shall take place prior to the individual functioning independently in their job.

2. Members of staff shall receive an orientation developed and approved by the healthcare organisation that includes general safety practices, emergency procedures, infection control, confidentiality and other issues as required by the healthcare organisation.

**NOTE 1** The orientation will address the following topics:

- a) organisational structure;
- b) patient confidentiality and ethics;
- c) document control, retrieval and verification (specific to policies, procedures, and work instructions/protocols);
- d) internal reporting requirements for adverse patient events;
- e) patient safety;
- f) general safety (work environment);
- g) operation of equipment, including medical devices, in a safe manner;
- h) emergency procedures;
- i) infection control and universal precautions; and,
- j) other issues as required by the healthcare organisation and national and regulatory requirements

**NOTE 2** Orientation to specific job duties may be addressed within the department or service where the employee is assigned, but completed prior to the employee working independently.

7.7 Staff Evaluations

1. The performance/competency evaluation shall contain indicators that shall objectively measure the ability of staff to perform all job duties as outlined in the job description. Relevant indicators may be selected from the list of indicators for measurement as outlined below.

2. The staff shall be evaluated initially and on an on-going basis against indicators that measure issues and opportunities for improvement. The measures selected may include:

- a) variations and problem processes identified through the analysis of outcomes measurement as required by the Quality Management System;
- b) high-risk, low volume procedures;
- c) new technology/equipment/processes;
- d) customer satisfaction feedback;
- e) scheduled training session outcomes;
- f) staff learning needs assessments that include variations identified through prior staff performance measurement;
- g) staff feedback;
- h) medical staff feedback;
- i) requirements of national and local legislation and regulations as applicable; and
- j) other indicators as determined by the healthcare organisation

3. Indicator measurement for contract staff may be modified based on healthcare organisation outcomes and frequency of service of individuals. Modification of this measurement(s) shall be made when needed and shall be justified by data analysis.
4. The healthcare organisation shall aggregate objective performance data from sources that may include individual evaluations, incident reports, risk management, staff and patient feedback, and/or data analysis to identify variations for further training, coaching, and mentoring.

5. Reassessment of objective data shall follow any intervention.

6. The outcomes of this aggregated data shall be reported to Quality Management oversight as needed to monitor staff performance improvement.

7. The healthcare organisation shall have a policy and procedure for sharing results of individual performance evaluations/competence assessment with staff members that allows for staff feedback within a timeframe defined by the healthcare organisation, not to exceed one calendar year.

8. The healthcare organisation shall require each staff member, including contract staff, to participate in continuing education as required by individual licensing, registration, certification, professional association, national and local legislation and regulations. Compliance with this standard shall be reported to Quality Management oversight.

**NOTE 1** The healthcare organisation shall continually evaluate the performance/competency of staff. This process of evaluation shall include the use of indicators that will objectively measure the ability of staff to perform all job duties as outlined in the job description. These indicators may address one or more of the following:

- variations and problem processes identified through the analysis of outcomes measurement as required by the Quality Management System;
- high-risk, low volume procedures;
- new technology/equipment/processes;
- customer satisfaction feedback;
- scheduled training session outcomes;
- staff learning needs assessments that include variations identified through prior staff performance measurement;
- staff feedback;
- medical staff feedback; and,
- requirements of national legislation and regulatory requirements.

The healthcare organisation will have a policy and procedure outlining the process for sharing results of individual performance evaluations/competence assessment with staff members. This shall include processes for staff feedback within a timeframe defined by the organisation, not to exceed one calendar year.

The healthcare organisation shall aggregate the objective performance data from sources that may include; individual evaluations, incident reports, risk management, staff and patient feedback, and/or data analysis to identify variations for further training, coaching, and mentoring.

In order to continually improve the fulfillment of their job responsibilities, the healthcare organisation shall require each staff member, including contract staff, to participate in continuing education as required by individual licensure/certification, professional association, national and local legislation and regulations, or organisation policy.
7.8 Health Promotion

1. The healthcare organisation shall have policies and procedures in place that address health promotion and disease prevention amongst staff.

**NOTE 1** The policies and procedures should at a minimum address issues related to tobacco, alcohol and other addictive substances and it should be clear to staff where they can seek necessary medical and psychological support should they have concerns regarding these issues. Information on factors within the healthcare organisation that may affect staff health shall be made freely available.
STANDARD 8
Medical Staff

8.1 General

1. The healthcare organisation shall have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the healthcare organisation.

2. The healthcare organisation shall have medical staff that is composed of fully licensed physicians or other professionals who are licensed to practice without supervision.

3. The governing body has the authority to determine with applicable laws and regulations whether healthcare professionals included in the definition of a physician other than a doctor of medicine are eligible for appointment to the medical staff.

4. Physicians and non-physician practitioners shall be granted medical staff privileges to practice at the healthcare organisation by the governing body for practice activities authorized within the applicable laws and regulations.

5. All staff, including contract staff, students and volunteers shall function within the limits of their current license, registration or certification. Variations shall be reported to Quality Management oversight.

6. Each department, whether clinical or supportive, and each patient unit shall have a written scope of service that includes at least:
   a) the hours of operation;
   b) patient populations served;
   c) skill mix.

8.2 Medical Staff Organisation and Accountability

1. The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to the patients. The medical staff must be organized in a manner approved by the governing body. The responsibility for organisation and conduct of the medical staff must be assigned to the healthcare organisation Managing Director.

2. The medical staff must be accountable to the healthcare organisation’s governing body for the quality of medical care provided to the patients. The organisation of the medical staff must comply with these requirements.

3. The medical staff shall participate in at least the following organisation activities:
   a) medication management oversight;
   b) infection prevention and control oversight;
   c) tissue review;
d) utilization review;
e) medical record review;
f) quality management system;
g) safety risk management system;
h) patient and family feedback oversight.

4. Reports and recommendations from these activities shall be prepared and shared with the medical executive committee and the governing body.

8.3 Qualification description of the medical staff

1. The healthcare organisation must describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.

2. Documentation must describe the qualifications to be met by a candidate for medical staff membership/privileges in order for the medical staff to recommend the candidate be approved by the governing body. The documentation must describe the privileging process to be used in the healthcare organisation. The process articulated in the documentation must include criteria for determining the privileges that may be granted to individual practitioners and a procedure for applying the criteria to individual practitioners that considers:

   a) individual character;
   b) individual competence;
   c) individual training;
   d) individual experience; and
   e) individual judgment.

3. Documentation laws must apply equally to all practitioners in each professional category of practitioners. The medical staff then recommends individual candidates that meet those requirements to the governing body for appointment to the medical staff.

8.4 Performance Data

1. Practitioner specific performance data is required to be evaluated, analyzed and appropriate action taken as necessary when variation is present and/or standard of care has not been met as determined by the medical staff. Performance data shall be collected periodically, not to exceed a 2 year period or as required as a part of the peer review process. This may include comparative and/or national data if available.

2. Variation shall be analyzed for statistical and/or clinical or operational significance and the areas to be measured (as applicable) may include:

   a) blood use;
   b) prescribing of medications: prescribing patterns, trends, errors and appropriateness of prescribing for Drug Use Evaluations;
   c) surgical case review: appropriateness and outcomes for selected high-risk procedures as based on local service delivery and with clear reference and justification to norms derived from national and international standards or research;
   d) specific department indicators that have been defined by the medical staff;
   e) moderate sedation outcomes;
f) anesthesia events;
g) appropriateness of care for non-invasive procedures/interventions;
h) utilization data;
i) patient and family feedback and complaints;
j) significant deviations from established standards of practice;
k) timely and legible completion of patients’ medical records.

8.5 Continuing Education

1. All members of the medical staff shall participate in continuing education that is at least in part related to their patient care duties.

NOTE 1 In addition to the general continuing education for medical staff the healthcare organisation shall ensure that appropriate staff has the education, training, and demonstrated knowledge based on the specific needs of the patient population in the use of first aid techniques and certification in the use of cardiopulmonary resuscitation. This shall include recertification requirements.

8.6 Clinical Privileges

1. The healthcare organisation shall have a process for determining the permissible clinical privileges to be granted to a physician based on documented procedures.

2. Granting or revision of clinical privileges should be made for a period not to exceed three years (unless prohibited by national laws).

3. There shall be a provision in the healthcare organisation for a mechanism to ensure that all individuals with clinical privileges provide services only within the scope of privileges granted.

4. The healthcare organisation shall have a system in place to review individual performance data and identify when additional training or proctoring may be required before specific clinical privileges are continued or granted.

5. The healthcare organisation shall provide a mechanism for consideration of automatic suspension of clinical privileges in any of the following instances:
   a) revocation/restriction of professional license;
   b) non-compliance with completing healthcare / medical records.

6. The governing body, may grant temporary clinical privileges when there is urgent for an patient care need:
   a) for a period of time not to exceed four (4) months.
   b) the healthcare organisation shall develop a written procedure for approving practitioners for care of patients in the event of an emergency or disaster

7. The healthcare organisation shall establish written procedure for granting clinical privileges. The procedure(s) must evaluate each individual practitioner’s applicable scope of practice or privileges for that type of practitioner for which he/she has been granted privileges.
NOTE 1 Components of practitioner qualifications and demonstrated competencies shall include:

a) a request for clinical privileges;
b) evidence of current licensure;
c) evidence of training and professional education;
d) documented experience.

8. The medical staff must examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates. Only the healthcare organisation’s governing body has the authority to grant a practitioner privileges to provide care in the healthcare organisation.

9. The healthcare organisation shall maintain a separate credentials file for each individual medical staff member. The healthcare organisation shall ensure that the practitioner and appropriate healthcare organisation patient care areas/departments are informed of the privileges granted to the practitioner.

10. Components of practitioner qualifications and demonstrated competencies shall include:

a) a valid contract of employment;
a) evidence of current licensure;
a) evidence of training and professional education;
a) documented experience; and
a) supporting references of competence.

11. Whenever a practitioner’s privileges are limited, revoked, or in any way constrained, the healthcare organisation must, in accordance with Medical Chamber and Ministry of Health laws or regulations, report those constraints to the appropriate local authorities, registries, and/or data bases.

12. The medical staff makes recommendations to the governing body for each candidate for medical staff membership/privileges that are specific to the type of appointment and extent of the individual practitioner’s specific clinical privileges, and then the governing body takes final appropriate action.

13. When telemedicine services are furnished to the healthcare organisation’s patients through an agreement with a distant-site healthcare organisation, the governing body of the healthcare organisation whose patients are receiving the telemedicine services may choose to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site healthcare organisation when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the healthcare organisation’s governing body ensures, through its written agreement with the distant-site healthcare organisation, that all of the following provisions are met:

a) the individual distant-site physician or practitioner is privileged at the distant-site healthcare organisation providing the telemedicine services, which provides a current list of the distant-site physician’s or practitioner’s privileges at the distant-site healthcare organisation to the local hospital/healthcare organisation receiving these services;
b) the individual distant-site physician or practitioner holds a license issued or recognized by the applicable laws and regulations in which the healthcare organisation whose patients are receiving the telemedicine services is located.
NOTE 2 The distant-site healthcare organisation provides to the healthcare organisation a list of all its physicians and practitioners covered by the agreement, including their privileges at the distant-site healthcare organisation. The list may not include any physician or practitioner who does not hold privileges at the distant-site healthcare organisation. The list must be current, so the agreement must address how the distant-site healthcare organisation will keep the list current.

Each physician or practitioner who provides telemedicine services to the healthcare organisation’s patients under the agreement holds a license issued or recognized by the applicable laws and regulations where the healthcare organisation (not the distant-site healthcare organisation) is located.

NOTE 3 The healthcare organisation has evidence that it reviews the telemedicine services provided to its patients and provides feedback based on this review to the distant-site healthcare organisation for the latter’s use in its periodic appraisal of each physician and practitioner providing telemedicine services under the agreement.

8.7 Temporary Clinical Privileges

1. The chief executive officer or designee may grant temporary clinical privileges when there is urgent patient care need or when an application is complete without any negative or adverse information before action by the medical staff or governing body or legally responsible individual(s).

2. Temporary clinical privileges may only be granted on the recommendation of a member of the executive committee, President of the medical staff, or Medical Director.

3. Temporary clinical privileges may only be granted for a period of time not to exceed one hundred twenty (120) days.

4. The healthcare organisation shall develop a process for approving practitioners for care of patients in the event of an emergency or disaster.

5. If the healthcare organisation provides medical staff services through use of locum tenens or similar temporary medical service that may be used for a period not to exceed six (6) months, the healthcare organisation shall define the process regarding the approval of physicians and other practitioners providing such services. The medical staff shall complete the required credentialing and privileging requirements defined by the healthcare organisation.

NOTE 1 Under certain circumstances, such as urgent patient care need or when an application is complete without any negative or adverse information, the medical staff and governing body or legally responsible individual(s) may not be able to take immediate action on approving the privileges of a practitioner. Under these circumstances, the chief executive officer or designee may grant temporary clinical privileges on the recommendation of a member of executive committee, president of the medical staff or medical director for a period of time not to exceed 120 days.

8.8 Disciplinary or Rehabilitation Action

1. The healthcare organisation shall provide a mechanism for management of medical staff disciplinary or rehabilitative action. This documented action may result from unprofessional demeanor and conduct when this behavior is likely to be detrimental to patient safety or the delivery of quality care or is disruptive to healthcare organisation operations. Any officer of the medical staff, Managing Director, or any Member of the board or legally responsible individual(s) may initiate this disciplinary or rehabilitative action.

NOTE 1 There may be circumstances when a practitioner has been determined to have acted in an unprofessional manner or has presented signs of impairment that would prevent him/her from carrying out patient care safely or disrupting the operations.
of the organisation. The healthcare organisation shall provide a mechanism for managing the process for taking corrective or rehabilitative action when a practitioner’s conduct is in question. An officer of the medical staff, Managing Director or any member of the board or legally responsible individual(s) may initiate the process for corrective or rehabilitative action.

8.9 Medical Record Maintenance

1. The healthcare organisation shall develop the process and requirements for the preparation and maintenance of a complete and accurate healthcare / medical record for each patient and policies and procedures for dealing with healthcare / medical record delinquencies.

2. The healthcare organisation shall require that the medical staff have periodic meetings at regular intervals to review and analyze healthcare / medical records of the patients for adequacy and quality of care.

**NOTE 1** The healthcare organisation shall require that the preparation and maintenance of complete and accurate medical records be in place for each patient. There should be defined policies and procedures for dealing with medical record delinquencies.

**NOTE 2** The process for medical records completion and the actions taken shall be enforced by healthcare organisation policy. In order to ensure that there is an effective process in place, the medical staff shall regularly review and analyze medical records to ensure the adequacy and quality of patient care.

8.10 History and Physical

1. The healthcare organisation shall ensure that a medical history and physical examination (H&P) for each patient shall be done on admission or registration, but prior to surgery or other procedure requiring anesthesia services, and placed in the patient’s medical record within twenty four (24) hours after admission. The H&P shall be in the medical record prior to any high-risk procedure.

2. The updated examination of the patient, including any changes in the patient’s condition, must be completed and documented by a physician or other qualified licensed individual in accordance with applicable laws and regulations and healthcare organisation policy.

3. Healthcare organisation Policy must include a requirement that when a medical history and physical examination has been completed within 30 days before admission or registration, an updated medical record entry must be completed and documented in the patient’s medical record within 24 hours after admission or registration. A licensed practitioner who is credentialed and privileged by healthcare organisation’s policy to perform an H&P must conduct the examination. In all cases, the update must take place prior to surgery or a procedure requiring anesthesia services.

4. The update note must document a review of the examination for any changes in the patient’s condition since the patient’s H&P was performed that might be significant for the planned course of treatment and documentation of changes that are noted. The physician or qualified licensed individual uses his/her clinical judgment, based upon his/her assessment of the patient’s condition and co-morbidities, if any, in relation to the patient’s planned course of treatment to decide the extent of the update assessment needed as well as the information to be included in the update note in the patient’s medical record.

5. If, upon examination, the licensed practitioner finds no change in the patient’s condition since the H&P was completed, he/she may indicate in the patient’s medical record that the H&P was reviewed, the patient was examined, and that “no change” has occurred in the patient’s condition.
since the H&P was completed. Any changes in the patient’s condition must be documented by the practitioner in the update note and placed in the patient’s medical record within 24 hours of admission or registration, but prior to surgery or a procedure requiring anesthesia services. Additionally, if the practitioner finds that the H&P done before admission is incomplete, inaccurate, or otherwise unacceptable, the practitioner reviewing the H&P, examining the patient, and completing the update may disregard the existing H&P, and conduct and document in the medical record a new H&P within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia.

8.11 Consultation

1. The healthcare organisation shall define the circumstances and criteria under which consultation or management by a physician or other qualified licensed independent practitioner is required.

8.12 Autopsy

1. The medical staff shall attempt to secure autopsies in all cases of unusual deaths and those of medical-legal and educational interest.

2. Mechanisms for documenting permission to perform an autopsy shall be defined.

3. There shall be a system for notifying the medical staff and specifically the attending practitioner when an autopsy is being performed.
STANDARD 9
Risk Management

9.1 General

1. An ongoing program of safety risk management is used to identify and to reduce unanticipated adverse events and other safety risks to patients, staff or other visitors to the healthcare organisation.

2. Organisations need to adopt a proactive approach to risk management. One such way is a formalized risk management program whose essential components include:
   a) Risk identification
   b) Risk prioritization;
   c) Risk reporting;
   d) Risk management and mitigation;
   e) Investigation of adverse events; and
   f) Management of related claims.

3. Organisation must adopt risk analysis, such as process to evaluate near misses and other high-risk processes for which a failure would result in a sentinel event.

   NOTE 1 One tool that provides such a proactive analysis of the consequences of an event that could occur in a critical, high-risk process is failure mode and effects analysis.

4. To use this or similar tools effectively, the organisation’s leaders need to adopt and to learn the approach, to agree on a list of high-risk processes in terms of patient and staff safety, and then to use the tool on a priority risk process. Following analysis of the results, the organisation’s leaders take action to redesign the process or similar actions to reduce the risk in the process. This risk-reduction process is carried out at least once per year and documented.

9.2 Risk Assessment

1. The hazards associated with proposed work shall be identified and documented.

2. The healthcare organisation shall ensure that suitable methodologies for assessing and recording risks are identified, implemented and maintained.

   NOTE 1 There are many defined methodologies and approaches available for conducting hazard identification, risk assessment and control and the approach taken will vary depending upon the nature of the situation and the level of detail required.

9.3 Reporting

1. The healthcare organisation shall have documented procedures to define record, analyze and learn from incidents that impact safety. This shall include medical errors and adverse patient events.
2. The healthcare organisation shall have a policy and procedure for informing patients and/or their families about unexpected adverse events.

**NOTE 1** The healthcare organisation shall be able to demonstrate that they have an approved document which shall include:

- a) roles and responsibilities for the management of risk;
- b) training requirements related to risk management and adverse event reporting;
- c) processes for assessing all risk;
- d) process for informing patient and or their families about unexpected adverse event; and
- e) process for ensuring where deficiencies are identified action plans are developed and implemented to ensure continual management/improvement.
Module II

Patient Focused Care Standards
STANDARD 10
Patient’s Rights

10.1 General

1. The healthcare organisation must protect and promote each patient’s rights.

2. The healthcare organisation must display and ensure notices of patient rights. Whenever possible, this notice must be provided before providing or stopping care.

3. The healthcare organisation must inform each patient, or when appropriate, the patient’s representative of the patient’s rights, in advance of furnishing or discontinuing patient care whenever possible.

4. The patient has the right to participate in the development and implementation of his or her plan of care.

5. The healthcare organisation must inform each patient, or when appropriate, the patient’s representative as allowed by applicable laws and regulations, of the patient’s rights.

6. When an individual patient presents to the healthcare organisation with an advance directive, medical power of attorney or similar document executed by the patient, the healthcare organisation must make it part of the medical record. If a patient has an advanced directive not immediately available than the healthcare organisation must make an attempt to obtain a copy for the medical record. The healthcare organisation must have a written policy to describe the appropriate action to obtain said advanced directive.

7. When a patient is incapacitated or otherwise unable to communicate his or her wishes, and there is no written advance directive on file or presented, and the individual asserts that he or she is the patient’s spouse, domestic partner, patient, or other family member and thus is the patient’s representative, the healthcare organisation is expected to accept this patient’s transfer to an appropriate facility and to provide the necessary medical information along with the patient.

8. The patient’s rights should be provided and explained in a language or manner that the patient or the patient’s representative can understand.

9. The healthcare organisation shall ensure that patients and visitors are treated with respect and dignity at all times. This includes the recognition of cultural and spiritual sensitivities of patients and their communities. The healthcare organisation shall provide access to spiritual care or advice that meets the needs of the patients and their visitors, provide specific cross-cultural training for staff where needs are identified and take into account the cultural and spiritual needs when reviewing services and developing new ones.

10.2 Informed Consent

1. The healthcare organisation shall have approved documented processes for the taking of consent across all services provided.
2. The healthcare organisation shall identify which treatments/procedures require written consent.

3. A process for the provision of patient information shall be integral to the consent taking process. As a minimum all patient information, whether verbal or written, shall contain:
   a) risks associated with the treatment/procedure;
   b) benefits associated with the treatment/procedure; and
   c) alternatives available, if any;

4. Risk, benefits and alternative must be explained to the patient by attending physician and documented on the medical record by that physician. In addition the record must contain a statement signed by the patient that risks, benefits and alternatives to the contemplated procedure have indeed been explained to him/her by their physician and all question have been satisfactorily answered.

5. A properly executed informed consent form contains at least the following:
   a) name of patient, and when appropriate, patient’s legal guardian;
   b) name of healthcare organisation;
   c) name of specific procedure(s) or medical treatment);
   d) name of the responsible practitioner who is performing the procedure(s) or administering the medical treatment;
   e) signature of patient or legal representative;
   f) date and time consent form is signed by the patient or the patient’s legal representative;
   g) statement that procedure/treatment including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient’s legal representative;
   h) name of person who explained the procedure to the patient or guardian.

**NOTE 1** Patients have a fundamental legal and ethical right to determine what treatments they receive. Valid consent to treatment is fundamental in all forms of healthcare from providing personal care to undertaking surgical procedures. Such consent shall be considered valid when it is demonstrated that it is made:
   a) voluntarily;
   b) with reasonable information to make an informed, purposeful decision;
   c) by a mentally competent person.

6. The process shall address how the rights of mentally incompetent patients will be protected and how decision making for these patients will be addressed (e.g. proxy consent, best interest decisions, etc.).

7. In the event of a medical emergency, the healthcare organisation is not required to obtain a written consent, but timely efforts should be made to obtain an informed written consent from the patient’s authorized representative where permitted by national and regulatory requirements. The procedures/treatments which will require the healthcare organisation to obtain patient written consent will include as a minimum;
   a) high-risk procedures;
   b) sedation;
   c) participation in research projects;
   d) filming or videotaping.

**NOTE 2** For the purpose of this document “informed consent” means the patient or patient representative is given (in a language or means of communication he/she understands) the information, explanations of risks, benefits and alternatives, needed in
order to consent to a procedure or treatment. For surgery, informed consent should include that the patient is informed as to who will actually perform planned surgical interventions. When practitioners other than the primary surgeon will perform important parts of the surgical procedures, even when under the primary surgeon’s supervision, the patient shall be informed of who these other practitioners are, as well as, what important tasks each will carry out. It is however recognized that at the time of the surgery, unforeseen circumstances may require changing which individual practitioners actually are involved in conducting the surgery.

10.3 Patient Grievance

1. The healthcare organisation must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.

2. The patient should have reasonable expectations of care and services and the healthcare organisation should address those expectations in a timely, reasonable, and consistent manner.

3. The healthcare organisation must inform the patient and/or the patient’s representative of the internal grievance process, including whom to contact to file a grievance (complaint).

4. As part of its notification of patient rights, the healthcare organisation must provide the patient or the patient’s representative a phone number and address for lodging a grievance with the Ministry of Health or Medical Chamber.

**NOTE 1** A complaint is considered resolved when the patient is satisfied with the actions taken on their behalf.

**NOTE 2** Billing issues are not usually considered grievances for the purposes of these requirements.

**NOTE 3** A written complaint is not always considered a grievance. It is up to the healthcare organisation to decide how the complaint will be managed.

**NOTE 4** A written complaint is a complaint from an inpatient, an outpatient, a released/discharge patient, or a patient’s representative regarding the patient care provided, abuse or neglect, or the healthcare organisation’s compliance with applicable laws and regulations. For the purposes of this requirement, an email or fax is considered ‘written’.

10.4 Grievance review

1. The governing body must approve and be responsible for the effective operation of the grievance process, and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee. This includes the organisation’s compliance with all of the applicable laws and regulations, Ministry of Health and Medical Chamber requirements.

10.5 Utilization and Quality Control

1. The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Management system.
10.6 Grievance Submission

1. The healthcare organisation must establish a clearly defined procedure for the submission of a patient’s written or verbal grievance to the healthcare organisation.

2. The grievance process must specify time frames for review of the grievance and the provision of a response.

10.7 Grievance Resolution Notice

1. In the resolution of the grievance, the healthcare organisation must provide the patient with a written notice of its decision that contains:

   a) healthcare organisation contact person;
   b) steps taken on behalf of patient to investigate the grievance;
   c) results of the grievance process;
   d) reasonable date of completion within 14 days. If resolution cannot occur within this timeframe patient must be informed of the status of the complaint.

2. The written notice of the organisation’s determination regarding the grievance must be communicated to the patient or the patient’s representative in a language and manner the patient or the patient’s legal representative understands.

10.8 Language and Communication

1. The healthcare organisations shall ensure that it has access to competent, independent individuals to interpret for patients’ who do not speak the predominant language of the organisation. These individuals must have appropriate medical knowledge to interpret.

2. The healthcare organisation shall provide alternative communication aids for those who are, hearing impaired, vision impaired or have other specific needs.

10.9 Family Member Notification

1. The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to a healthcare organisation.

2. For every inpatient admission, the organisation must ask the patient whether the organisation should notify a family member or representative about the admission. If the patient requests such notice and identifies the family member or representative to be notified the healthcare organisation must provide such notice promptly to the designated individual.

3. The explicit designation of a family member or representative by the patient takes precedence over any non-designated relationship.

4. The organisation must ask the patient whether the organisation should notify his/her own physician.

NOTE 1 In the case of scheduled admissions, the patient’s own physician likely is already aware of the admission. However, if the patient requests notice to and identifies the physician, the healthcare organisation must provide such notice promptly to the designated physician, regardless of whether the admission was scheduled in advance or emergent.
**10.10 Right to Personal Privacy**

1. The patient has the right to personal privacy.

2. The patient has a basic right to respect, dignity, and comfort. “The right to personal privacy” includes at a minimum, that patients have privacy during personal hygiene activities, during medical/nursing treatments, and when requested as appropriate.

3. The right to personal privacy would also include limiting the release or disclosure of patient information such as the patient’s presence in the facility or location in the healthcare organisation, or personal information such as :
   - a) name;
   - b) age;
   - c) address;
   - d) health information - without prior consent from the patient.

**10.11 Safety**

1. The patient has the right to receive care in a safe setting.

2. Each patient should receive care in an environment that a reasonable person would consider to be safe.

3. The healthcare organisation must protect vulnerable patients, including newborns and children.

4. Respect, dignity and comfort would be components of an emotionally safe environment.

**10.12 Abuse, Harassment and Mobbing**

1. The patient has the right and the healthcare organisation must ensure that to be free from all forms of physical or mental abuse, corporal punishment, harassment and mobbing.

**10.13 Confidentiality of Patient Records**

1. The healthcare organisation must ensure the confidentiality of patient records.

2. The healthcare organisation has sufficient safeguards to ensure that access to all information regarding patients is limited to those individuals designated by law, regulation, and policy; or duly authorized as having a need to know.

3. Healthcare organisation staff and consultants, hired to provide services to the individual, should have access to only that portion of information that is necessary to provide effective responsive services to that individual.

*NOTE 1* The right to confidentiality means safeguarding the content of information, including patient paper records, video, audio, and/or computer stored information from unauthorized disclosure without the informed consent of the individual, parent of a minor child, or legal guardian.
NOTE 2 Confidentiality applies to both central records and clinical record information that may be kept at other locations in the organisation, such as patient units, radiology, laboratories, patient clinics, record storage area, and data systems.

10.14 Restraint and/or Seclusion

1. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff.

2. Restraint or seclusion shall only be used when less restrictive interventions have been tried and found to be ineffective and protecting the patient or others from harm.

3. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.

4. Patient care staff must demonstrate through their documentation in the patient’s medical record that the restraint intervention used is the least restrictive intervention that protects the patient’s safety, and that the use of restraint is based on individual assessments of the patient.

5. Criteria used to determine whether the use of a drug or medication, or combination of drugs or medications is a standard treatment or dosage for the patient’s condition includes all of the following:
   a) the drug or medication is used within the pharmaceutical parameters approved by the manufacturer for the indications that it is manufactured and labeled to address, including listed dosage parameters;
   b) the use of the drug or medication to treat a specific patient’s clinical condition is based on that patient’s symptoms, overall clinical situation, and on the knowledge of that patient’s expected and actual response to the medication.

6. Patients that are in restraint or seclusion shall be monitored and assessed by a physician or trained staff at least every 24 hours.

7. As with any use of restraint or seclusion, staff must conduct a comprehensive patient assessment to determine the need for other types of interventions before using a drug or medication as a restraint.

8. The condition of the patient who is restrained or secluded must be monitored by a physician or trained staff that has completed the training criteria determined by healthcare organisation policy.

9. When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1 hour after the initiation of the intervention by a physician or registered nurse who has been trained in accordance with the requirements.

10. When the simultaneous use of restraint and seclusion is employed, there must be adequate documentation that justifies the decision for simultaneous use as well as vigilance in continuously monitoring the patient so that the patient’s care needs are met.

NOTE 1 The requirements contained in this standard are not specific to any treatment setting within the healthcare organisation. They are not targeted only to patients on psychiatric units or those with behavioral/mental health care needs. Instead, the requirements are specific to the patient behavior that the restraint or seclusion intervention is being used to address.
10.15 Order for Restraint or Seclusion

1. The use of restraint or seclusion must be in accordance with the order of a physician or other qualified licensed practitioner who is responsible for the care of the patient as specified under authority of national legislation.

2. An order for restraint or seclusion must be obtained prior to the application of restraints, except in emergency situations when the need for intervention may occur quickly;

3. An order for restraint or seclusion is never to be written as a standing order or on an as needed basis (PRN).

4. The attending physician must be consulted as soon as possible. If the restrain is not ordered by that practictioner.

5. Each order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others may only be renewed in accordance with the following limits for up to a total of 24 hours:

   a) 4 hours for adults 18 years of age or older;
   b) 2 hours for children and adolescents 9 to 17 years of age;
   c) 1 hour for children under 9 years of age.
6. After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician who is responsible for the care of the patient and authorized to order restraint or seclusion by healthcare organisation policy in accordance with applicable laws or regulations must see and assess the patient and document the examination on the medical record.

7. Healthcare organisations have the flexibility to determine time frames for the renewal of orders for restraint of the non-violent, non-self-destructive patient. These time frames shall be addressed in healthcare organisation policies and procedures.

10.16 Staff Training for Restraint and/or Seclusion

1. The patient has the right to safe implementation of restraint or seclusion by trained staff.

2. The healthcare organisation must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in:

   a) at least the following techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion;
   
   b) the use of nonphysical intervention skills;
   
   c) choosing the least restrictive intervention based on an individualized assessment of the patient’s medical, or behavioral status or condition;
   
   d) safe application and use of all types of restraint or seclusion used in the healthcare organisation, including training in how to recognize and respond to signs of physical and psychological distress;
   
   e) in clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary;
   
   f) in monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by healthcare organisation policy associated with the 1-hour face-to-face evaluation;
   
   g) in the use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.

3. Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients’ behaviors.

4. The healthcare organisation must document in the staff personnel records that the training and demonstration of competency were successfully completed.

5. Staff personnel records must contain documentation that the training and demonstration of competency were successfully completed initially during orientation and on a periodic basis consistent with healthcare organisation policy.

6. Physicians who order restraints require a working knowledge of the healthcare organisation, policies and procedure for restraints applications orders and monitoring and measurement of patient outcomes.
10.17 Quality Monitoring

1. The healthcare organisation shall define prolonged restraints. Aggregate data must be analysed and reviewed in order to minimize and reduce the incidents of prolonged restraints. This information shall be reported regularly to the Quality Committee.

2. Corrective and preventive actions shall be documented and retained.
STANDARD 11
Nursing Services

11.1 General

1. The healthcare organisation must have an organized nursing service and must provide on premise nursing services 24 hours a day, 7 days a week with at least 1 registered nurse (RN) furnishing or supervising the service 24 hours a day, 7 days a week.

2. The nursing service must be integrated into the healthcare organisation-wide Quality Management System.

3. The healthcare organisation must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care.

11.2 Personnel

1. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the healthcare organisation.

2. The healthcare organisation may have only one nursing service healthcare organisation-wide and the single nursing service must be under the direction of one RN.

3. The director of the nursing service must determine and provide the types and numbers of nursing care personnel necessary to provide nursing care to all areas of the healthcare organisation.

11.3 Staffing and Delivery of Care

1. The nursing service must have adequate numbers of licensed registered nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.

2. The nursing service must ensure that patient needs are met by ongoing assessments of patients’ needs and provides nursing staff to meet those needs. There must be sufficient numbers, types and qualifications of supervisory and staff nursing personnel to respond to the appropriate nursing needs and care of the patient population of each department or nursing unit.

3. There must be a RN physically present on the premises and on duty at all times. Every inpatient unit/department/location within the healthcare organisation-wide nursing service must have adequate numbers of RNs physically present at each location to ensure the immediate availability of a RN for the bedside care of any patient.

4. A RN would not be considered immediately available if the RN were working on more than one unit, building, floor in a building, or provider at the same time.
5. Staffing schedules must be reviewed and revised as necessary to meet the patient care needs and to make adjustments for nursing staff absenteeism.

11.4 Licensure

1. The nursing service must have a procedure to ensure that healthcare organisation nursing personnel for whom licensure is required have valid and current licensure that complies with applicable laws and regulations/licensure laws.

2. The director of the nursing service and the healthcare organisation are to ensure that nursing personnel with the appropriate education, experience, licensure, competence and specialized qualifications are assigned to provide nursing care for each patient in accordance with the individual needs of each patient.

11.5 Planning

1. The healthcare organisation must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient. A plan of care for each patient shall be developed within 24 hours of admission that reflects the findings of a completed nursing assessment and input of other disciplines, as appropriate. The nursing care plan may be part of an interdisciplinary care plan.

2. Nursing staff shall complete an assessment of a patient’s condition within twenty four hours of admission to an inpatient setting. The nursing assessment shall include but not be limited to:
   a) allergies;
   b) admitting problem;
   c) history of pain and current status;
   d) preexisting or other conditions (i.e. Pregnancy, COPD, Diabetes);
   e) current medications (what time last dose, including any illicit drugs);
   f) ADL needs;
   g) dietary requirements;
   h) all other requirements per organisation nursing policies;

3. Nursing staff shall complete an assessment according to the healthcare organisation nursing policies in all other areas of the organisation.

4. Nursing staff shall reassess the patient at regular time defined intervals and if the patient’s condition changes. The patient’s plan of care is reviewed and revised, as necessary when the patient’s condition has changed.

5. The healthcare organisation shall ensure that each patient will have a named primary nurse who will be responsible for overseeing the assessment and care of the individual patient.

6. A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient’s needs and the specialized qualifications and competence of the nursing staff available.

7. The healthcare organisation must ensure that there are adequate numbers of clinical nursing personnel to meet its patient nursing care needs. In order to meet their patient needs the healthcare organisation may supplement their healthcare organisation employed licensed nurses with volunteer and or contract non-employee licensed nurses.
NOTE 1 Nursing care planning starts upon admission. It includes planning the patient’s care while in the healthcare organisation as well as planning for discharge to meet post-healthcare organisation needs. A nursing care plan is based on assessing the patient’s nursing care needs (not solely those needs related to the admitting diagnosis) and developing appropriate nursing interventions in response to those needs. The nursing care plan is kept current by ongoing assessments of the patient’s needs and the patient’s response to interventions, and updating or revising the patient’s nursing care plan in response to assessments. The nursing care plan is part of the patient’s medical record and must comply with the requirements for patient records and other patient information.
STANDARD 12
Discharge Planning

12.1 General

1. The healthcare organisation must have in effect a discharge planning process that applies to all patients.
2. The healthcare organisation’s policies and procedures must be specified in writing.
3. The written discharge planning process must reveal a thorough, clear, comprehensive process that is understood by the healthcare organisation staff.
4. The healthcare organisation must identify at an early stage of all patients who are likely to suffer adverse health consequences upon discharge if there is no adequate discharge planning.
5. The following factors have been identified as important: functional status, cognitive ability of the patient, and family support.
6. Patients at high-risk of requiring post-healthcare organisation services must be identified through a screening process.
7. The healthcare organisation should reevaluate the needs of the patients on an ongoing basis, and prior to discharge, as they may change based on the individual’s status.
8. There is no set time frame for identification of patients requiring a discharge planning evaluation other than it must be done as early as possible. The timing is left up to the healthcare organisation, its staff, and attending physician.

12.2 Discharge Planning Evaluation

1. The healthcare organisation must provide a discharge planning evaluation to the patients upon the patient’s request, the request of a person acting on the patient’s behalf, or the request of the physician.
2. The needs assessment can be formal or informal.
3. A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of, the evaluation.
4. The discharge planning evaluation must include an evaluation of the likelihood of a patient needing post-healthcare organisation services and of the availability of the services.
5. The healthcare organisation is responsible for developing the discharge plan for patients who need a plan and for arranging its initial implementation.
6. The healthcare organisation’s ability to meet discharge planning requirements is based on the following:
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a) implementation of a needs assessment process with identified high-risk criteria;
b) evidence of a complete, timely, and accurate assessment;
c) maintenance of a complete and accurate file on community-based services and facilities including long term care, sub acute care, home care or other appropriate levels of care to which patients can be referred;
d) coordination of the discharge planning evaluation among various disciplines responsible for patient care;
e) the discharge planning evaluation must include an evaluation of the likelihood of a patient’s capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the healthcare organisation.

7. The healthcare organisation personnel must complete the evaluation on a timely basis so that appropriate arrangements for post-healthcare organisation care are made before discharge, and to avoid unnecessary delays in discharge.

8. The healthcare organisation must include the discharge planning evaluation in the patient’s medical record for use in establishing an appropriate discharge plan and must discuss the results of the evaluation with the patient or individual acting on his or her behalf.

NOTE 1 Ideally, discharge planning will be an interdisciplinary process, involving disciplines with specific expertise, as dictated by the needs of the patient. For example, for a patient with emphysema, the discharge planner could coordinate respiratory therapy and nursing care, and financial coverage for home care services and oxygen equipment, and patient/caregiver education utilizing cost effective, available community services in an expedient manner.

NOTE 2 Assessment should start as soon after admission as possible and be updated periodically during the episode of care.

12.3 Transfer or Referral

1. The healthcare organisation must transfer or refer patients, along with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed, for follow-up or ancillary care and as a minimum shall consider:

   a) escort for the patient;
   b) essential medical history;
   c) medications;
   d) essential equipment;
   e) verbal/written handover requirements; and
   f) documentation requirements.

12.4 Reassessment

1. The healthcare organisation must reassess its discharge planning process on an on-going basis.

2. The reassessment must include a review of discharge plans to ensure that they are responsive to discharge needs.

3. The healthcare organisation must have a mechanism in place for ongoing reassessment and evaluation of its discharge planning process which must be reported to the Quality Management system.
STANDARD 13
Outpatient Services

13.1 General

1. If the healthcare organisation provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.

2. The healthcare organisation must ensure that services, equipment, staff, and facilities are adequate to provide the outpatient services offered at each location in accordance with acceptable standards of practice.

3. If the healthcare organisation offers outpatient surgical services, the surgical and anesthesia services standard requires that the offered services must be consistent in quality with inpatient care in accordance with the services offered.

4. The healthcare organisation’s outpatient services must be integrated into its healthcare organisation-wide Quality Management System.

5. Acceptable standards of practice include standards that are set forth applicable laws and regulations, or guidelines, as well as standards and recommendations promoted by nationally and internationally recognized professional organisations.

13.2 Organisation

1. Outpatient services must be appropriately organised and integrated with inpatient services.

2. The healthcare organisation’s outpatient services must be appropriate to the scope and complexity of services offered.

3. The healthcare organisation’s outpatient services, at all locations, must be integrated with all inpatient support services.

4. The healthcare organisation must have written policies in place to assure the integration of outpatient services, including an established method of communication between outpatient service departments to corresponding inpatient services.

5. The healthcare organisation must coordinate the care, treatment and services provided to a patient. In order to provide continuity of care, it shall have an established method of communication between inpatient services and outpatient care in order to provide continuity of care to its patients.

13.3 Personnel

1. The healthcare organisation must assign an individual to be responsible for outpatient services and have appropriate professional and nonprofessional personnel available.
2. The outpatient services department must be accountable to a single individual who directs the overall operation of the healthcare organisation’s entire outpatient services (all locations, all outpatient services).

3. The healthcare organisation shall define in writing the qualifications and competencies necessary to direct the outpatient services. Qualifications include necessary education, experience and specialized training consistent with applicable laws and regulations and acceptable standards of practice.

4. Adequate types and numbers of qualified professional and nonprofessional personnel must be available to provide patients with the appropriate level of care and services offered by the healthcare organisation’s outpatient department.
STANDARD 14
Surgical Services

14.1 General

1. If the healthcare organisation provides surgical services, all inpatient and outpatient services must be well organized and provided in accordance with acceptable standards of practice in accordance with the complexity of services offered. These standards will be consistent with relevant recognised national and international standards as well as statutory and regulatory requirements.

2. A qualified surgeon shall be appointed as a director of surgical services by the healthcare organisation, and shall oversee all surgical services.

3. The medical staff is accountable to the governing body for the quality of care provided to patients. The medical staff shall develop policies and procedures consistent with subsection 1 above to assure provision of safe care. These policies will include provisions for pre, intra, and post operative care, including appropriate follow-up indicated by acceptable standards as noted above.

4. Monitoring and measurement of surgical procedures for quality of patient care at levels consistent with organisational needs and established regulatory requirements will be established and ongoing. Results will be reviewed by the director of surgical services, medical staff, and quality oversight for continual improvement.

14.2 Organisation and Staffing

1. When the healthcare organisation offers surgical services, the healthcare organisation must provide the appropriate equipment and the appropriate types and numbers of qualified personnel necessary to furnish the surgical services offered by the healthcare organisation in accordance with acceptable standards of practice.

2. The scope of surgical services provided by the healthcare organisation should be defined in writing and approved by the medical staff. This shall include types of practitioners who conduct procedures and their scope of practice in keeping with all requirements noted above in 14.1

3. The medical staff documentation must include criteria for determining and delineating the privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges. Surgical privileges are granted in accordance with the competencies of each practitioner. The medical staff appraisal procedures must evaluate each individual practitioner’s training, education, experience, and demonstrated competence as established by the Healthcare organisation’s Quality Management System, credentialing process, the practitioner’s adherence to healthcare organisation policies and procedures, and in accordance with scope of practice and other applicable laws and regulations.

4. The RN or physician supervising the operating theatre must demonstrate appropriate education, background working in surgical services, and specialized training in the provision of surgical services/management of surgical service operations.
5. Qualified registered nurses may perform circulating duties in the operating theatre. In accordance with applicable laws and regulations and approved medical staff policies and procedures, LPNs may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies.

**NOTE 1** The healthcare organisation should address its required qualifications for the supervisor of the healthcare organisation’s operating theatre in its policies and the supervisor’s personnel file should contain information demonstrating compliance with the healthcare organisation’s established qualifications.

**NOTE 2** The circulating nurse must be an RN. An LPN may assist an RN in carrying out circulatory duties (in accordance with applicable laws and regulations and medical-staff approved healthcare organisation policy) but the LPN must be under the supervision of the circulating RN who is in the operating theatre and who is available to immediately and physically respond/intervene to provide necessary interventions in emergencies. The supervising RN would not be considered immediately available if the RN was located outside the operating theatre or engaged in other activities/duties that prevent the RN from immediately intervening and assuming whatever circulating activities/duties were being provided by the LPN.

When a practitioner may perform certain surgical procedures under supervision, the specific tasks/procedures and the degree of supervision (to include whether or not the supervising practitioner is physically present in the same operating theatre, in line of sight of the practitioner being supervised) be delineated in that practitioner’s surgical privileges and included on the surgical roster.

### 14.3 Delivery of Service

1. Surgical services delivery must be consistent with needs and resources.

2. Policies governing surgical care delivery must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.

3. Policies governing surgical care should contain:
   a) aseptic and sterile surveillance and practice, including scrub techniques;
   b) identification of infected and non-infected cases;
   c) housekeeping requirements/procedures;
   d) patient care requirements:
      • preoperative work-up;
      • patient consents and releases;
      • clinical procedures;
      • safety practices;
      • patient identification procedures;
   e) duties of scrub and circulating nurse;
   f) safety practices;
   g) the requirement to conduct surgical counts in accordance with accepted standards of practice;
   h) scheduling of patients for surgery;
   i) personnel policies unique to the operating theatre;
   j) resuscitative techniques;
   k) DNR (Do Not Resuscitate) status;
   l) care of surgical specimens; malignant hyperthermia;
   m) appropriate protocols for all surgical procedures performed. These may be procedure-specific or general in nature and will include a list of equipment, materials, and supplies necessary to properly carry out job assignment;
   n) sterilization and disinfection procedures;
   o) acceptable operating room attire;
p) handling infections and biomedical/medical waste;
q) outpatient surgery post-operative care planning and coordination, and provisions for follow-up care.

4. Policies and procedures must be written, implemented and enforced. Surgical services’ policies must be in accordance with acceptable standards of medical practice and surgical patient care.

5. The use of an alcohol-based skin preparation in inpatient or outpatient anesthetizing locations is not potentially hazardous. Fire risk-reduction measures are taken by following manufacturers instructions for use. This shall be noted on the surcisal record.

6. Prior to surgery or a procedure requiring anesthesia services and except in the case of emergencies a medical history and physical examination must be completed and documented no more than 30 days before or 24 hours after admission or registration. An updated examination of the patient, including any changes in the patient’s condition, must be completed and documented within 24 hours after admission or registration when the medical history and physical examination are completed within 30 days before admission or registration.

NOTE 1 A review of recommendations produced by various expert organisations concerning use of alcohol-based skin preparations in anesthetizing locations indicates there is general consensus that the following risk reduction measures are appropriate. Using skin prep solutions that are:

a) packaged to ensure controlled delivery to the patient in unit dose applicators, swabs, or other similar applicators;
b) provide clear and explicit manufacturer/supplier instructions and warnings.

They should also document the implementation of these policies and procedures in the patient’s medical record.

14.4 Informed Consent

1. A properly executed informed consent form for the operation must be in the patient’s chart before surgery, except in emergencies.

2. A well-designed informed consent process shall include discussion of the following elements:

a) a description of the proposed surgery, including the anesthesia to be used; the indications for the proposed surgery;
b) material risks and benefits for the patient related to the surgery and anesthesia, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner’s clinical judgment. Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity;
c) treatment alternatives, including the attendant material risks and benefits;
d) the probable consequences of declining recommended or alternative therapies;
e) who will conduct the surgical intervention and administer the anesthesia;
f) whether physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery, in accordance with the healthcare organisation’s policies. Important surgical tasks include: opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, implanting devices and placing invasive lines;
g) documentation on the patient record by the responsible surgeon that he or she has explained the above noted risks, benefits and alternatives to the patient;
h) documentation on the patient record by the patient that the responsible surgeon has explained the above noted risks, benefits and alternatives and questions have been reasonably satisfied;

i) if a patient has an advance directive which would apply to surgical service delivery, all areas of potential conflict must be resolved prior to surgery and noted on the patient record by the responsible surgeon except in the case of an emergency when patient instruction is not available.

3. For surgeries in which residents will perform important parts of the surgery, discussion is encouraged to include the following:

   a) that it is anticipated that physicians who are in approved post graduate residency training programs will perform portions of the surgery, based on their availability and level of competence;
   b) that it will be decided at the time of the surgery which residents will participate and their manner or participation, and that this will depend on the availability of residents with the necessary competence;
   c) the knowledge the operating practitioner/teaching surgeon has of the resident’s skill set and the patient’s condition;
   d) that residents performing surgical tasks will be under the supervision of the operating practitioner/teaching surgeon;
   e) whether, based on the resident’s level of competence, the operating practitioner/teaching surgeon will not be physically present in the same operating room for some or all of the surgical tasks performed by residents;
   f) whether, as permitted by applicable laws and regulations, qualified medical practitioners who are not physicians will perform important parts of the surgery or administer the anesthesia, and if so, the types of tasks each type of practitioner will carry out, and that such practitioners will be performing only tasks within their scope of practice for which they have been granted privileges by the healthcare organisation.

NOTE 1 Surgical Informed Consent Policy: The healthcare organisation’s surgical informed consent policy should describe the following:

   a) who may obtain the patient’s informed consent;
   b) which procedures require informed consent;
   c) the circumstances under which surgery is considered an emergency, and may be undertaken without an informed consent;
   d) the circumstances when a patient’s representative, rather than the patient, may give informed consent for a surgery;
   e) the content of the informed consent form and instructions for completing it;
   f) the process used to obtain informed consent, including how informed consent is to be documented in the medical record;
   g) mechanisms that ensure that the informed consent form is properly executed and is in the patient’s medical record prior to the surgery (except in the case of emergency surgery);
   h) if the informed consent process and informed consent form are obtained outside the healthcare organisation, how the properly executed informed consent form is incorporated into the patient’s medical record prior to the surgery;
   i) if there are additional requirements under applicable laws and regulations for informed consent, the healthcare organisation must comply with those requirements.
14.5 Operating room Equipment

1. The following equipment must be available to the operating theatre:
   a) call-in system;
   b) cardiac monitor;
   c) resuscitator;
   d) defibrillator;
   e) aspirator;
   f) tracheotomy set;
   g) any other equipment required as essential by current standard of care and the anticipated procedure.

2. There must be adequate provisions for immediate post-operative care. Adequate provisions for immediate post-operative care means:
   a) post-operative care must be in accordance with acceptable standards of practice;
   b) the post-operative care area or recovery room is a separate area of the healthcare organisation and access is limited to authorized personnel;
   c) policies and procedures specify transfer requirements to and from the recovery room. Depending on the type of anesthesia and length of surgery, the postoperative check before transferring the patient from the recovery room should include some of the following:
      • level of activity;
      • respirations;
      • blood pressure;
      • level of consciousness;
      • patient colour;
      • other parameters as determined by the anesthesia service or relevant authority;
   d) if the patients are not transferred to the recovery room, determine that provisions are made for close observation until they have regained consciousness, e.g., direct observation by a qualified RN in the patient’s room.

14.6 Operating room Register

1. The operating room register must be complete and up-to-date.

2. The register includes at least the following information:
   a) patient’s name;
   b) patient’s healthcare organisation identification number;
   c) date of the operation;
   d) inclusive or total time of the operation;
   e) name of the surgeon and any assistant(s);
   f) name of nursing personnel (scrub and circulating);
   g) type of anesthesia used and name of person administering it;
   h) operation performed;
   i) pre and post-op diagnosis; and
   j) age of patient.
14.7 Reporting and Documentation

1. An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon. This shall be accomplished prior to patient discharge from the recovery area.

2. The immediate report includes at least:

   a) name(s) of the surgeon(s) and assistants or other practitioners who performed surgical tasks (even when performing those tasks under supervision);
   b) pre-operative and post-operative diagnosis;
   c) name of the specific surgical procedure(s) performed;
   d) type of anesthesia administered;
   e) complications, if any;
   f) a description of techniques, findings, and tissues removed or altered;
   g) a description of the specific significant surgical tasks that were conducted by practitioners other than the primary surgeon/practitioner (significant surgical procedures include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues);
   h) prosthetic devices, grafts, tissues, transplants, or devices implanted, if any;
   i) blood or blood products administered;
   j) any other pertinent information potentially effecting immediate recovery care.
STANDARD 15
Anesthesia Services

15.1 General

1. If the healthcare organisation furnishes anesthesia services, they must be provided in a well-organized manner under the direction of a qualified doctor of medicine. The service is responsible for policy for delivery of all anesthesia and sedation administered in the healthcare organisation.

2. Areas where anesthesia services are furnished may include (but are not limited to):
   a) operating room suites, both in patient and out patient;
   b) obstetrical suites;
   c) radiology department;
   d) clinics;
   e) emergency department;
   f) psychiatry department;
   g) special procedure areas (endoscopy, pain management clinics, etc.).

3. Anesthesia services shall be appropriate to the scope of the services offered. Policy and procedures shall be in keeping with recognized national/international standards of care and supervision, statutory and regulatory requirements, and the organisational governing body and medical staff.

4. The anesthesia services must be under the direction of one individual who is a qualified doctor of medicine. This individual is approved by the healthcare organisation’s governing body upon the recommendation of the medical staff. Documentation of this individual’s qualifications must be consistent with the recomendations of recognized national/international standards.

5. The anesthesia department will be responsible for the development of specific criteria granting delineated privileges to those members of the medical staff who deliver anesthesia and/or sedation services within the healthcare organisation. Privileges for various classes of delivery will then be approved by the governing body upon the recommendation of the medical staff.

NOTE 1 The definitions below illustrate distinctions among the various types of “anesthesia services” and sedation that may be offered by a healthcare organisation.

Anesthesia

a) General anesthesia: a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory support is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired. For example, a patient undergoing major abdominal surgery involving the removal of a portion or all of an organ would require general anesthesia in order to tolerate such an extensive surgical procedure. General anesthesia is used for those procedures when loss of consciousness is required for the safe and effective delivery of surgical services.

b) Regional anesthesia: the delivery of anesthetic medication at a specific level of the spinal cord and/or to peripheral nerves, including epidurals and spinals and other central neuraxial nerve blocks, is used when loss of consciousness is
not desired but sufficient analgesia and loss of voluntary and involuntary movement is required. Regional anesthesia is not anesthesia, however, given the potential for the conversion and extension of regional to general anesthesia in certain procedures, it is necessary that the administration of regional and general anesthesia be delivered or supervised by a practitioner.

c) **Monitored anesthesia care (MAC):** anesthesia care that includes the monitoring of the patient by a practitioner who is qualified to administer anesthesia. Indications for MAC depend on the nature of the procedure, the patient’s clinical condition, and/or the potential need to convert to a general or regional anesthetic. Deep sedation/analgesia is included in MAC.

d) **Deep sedation/analgesia:** a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. Because of the potential for the inadvertent progression to general anesthesia in certain procedures, it is necessary that the administration of deep sedation/analgesia be delivered or supervised by a practitioner.

**Sedation**

a) **Moderate sedation/analgesia:** ("Conscious Sedation"): a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

b) **Minimal sedation:** a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilator and cardiovascular functions are unaffected. This is also not anesthesia.

c) **Topical or local anesthesia:** the application or injection of a drug or combination of drugs to stop or prevent a painful sensation to a circumscribed area of the body where a painful procedure is to be performed. There are generally no systemic effects of these medications, which also are not anesthesia, despite the name.

d) **Analgesia** involves the use of a medication to provide relief of pain through the blocking of pain receptors in the peripheral and/or central nervous system and does in and of itself meet the definition of anesthesia. The patient does not lose consciousness, and does not perceive pain to the extent that may otherwise prevail. However if additional pain control or sedation is anticipated, it is likely that the requirements of anesthesia supervision would be indicated.

**NOTE 2** Healthcare organisations must address whether the sedation typically provided in the emergency department or other procedure areas involves anesthesia or analgesia in order to serve the patient in a safe manner. Practitioners should not exceed their clinical privileges granted by the governing body.

**NOTE 3** Healthcare organisation anesthesia services policies and procedures are expected to also address the minimum qualifications and supervision requirements for each category of practitioner who is permitted to provide analgesia and sedation services, particularly moderate sedation.
15.2 Rescue Capacity

1. In order to provide patient care in a safe setting, healthcare organisations must ensure that procedures are in place to rescue patients whose level of sedation becomes deeper than initially intended, for example, patients who inadvertently enter a state of deep sedation/analgesia when moderate sedation was intended.

2. Rescue from a deeper level of sedation than intended requires an intervention by a practitioner with expertise in airway management, advanced life support, and the qualifications to correct the adverse physiologic consequences of the deeper-than-intended level of sedation so as to return the patient to the originally intended level of sedation.

NOTE 1 These regulations require the healthcare organisation to assure that any staff administering drugs for analgesia must be appropriately qualified, and that the drugs are administered in accordance with accepted standards of practice.

15.3 Monitoring and Measuring

1. The anesthesia services policies and procedures will undergo periodic review and re-evaluation at least annually.

2. Analysis of significant unexpected adverse events, medication errors, and other quality or safety concerns related not only to anesthesia, but also to those clinical activities defined as sedation and analgesia, must be done. Results of this activity must be reported to quality management.

3. Ongoing monitoring and measurement of specified relevant clinical and administrative quality indicators is required. These indicators must be chosen with priority to the impact and effect of the related anesthesia department process on the integrity of the quality management system. Selected indicators shall also include oversight in collaboration with other clinical and support disciplines (e.g., surgery, pharmacy, nursing, infection prevention/control, life safety, material management, etc.) that are involved in delivering anesthesia services to patients in the various areas in the healthcare organisation.

4. Results of this surveillance shall be reviewed by the medical staff and Quality Management. Records of corrections, corrective actions, preventive actions, or modifications for continual improvement made as a result of this activity shall be maintained.

NOTE 1 Healthcare organisations are free to develop their own specific organisational arrangements in order to deliver all anesthesia services in a well-organized manner. Although not required under the standard to do so, a well-organized anesthesia service would develop the healthcare organisation’s anesthesia policies and procedures in collaboration with several other healthcare organisation disciplines (e.g., surgery, pharmacy, nursing, safety experts, material management, etc.) that are involved in delivering these services to patients in the various areas in the healthcare organisation.

15.4 Organisation and Staffing

1. Anesthesia must be administered only by:

   a) a qualified anesthesiologist;
   b) a doctor of medicine (other than an anesthesiologist);
   c) a dentist, oral surgeon, who is qualified to administer anesthesia under local law;
   d) a CRNA under the supervision of a credentialed physician not otherwise involved in a procedure.
and who is immediately available for assistance. An credentialed physician is considered “immediately available” when needed only if he/she is physically located within the same area as the CRNA, e.g., in the same operative suite, or in the same labor and delivery unit, or in the same procedure room, and not otherwise occupied in a way that prevents him/her from immediately conducting hands-on intervention, if needed.

2. If anesthesia services are provided for labor and delivery, the same standard of coverage as that of operating room anesthesia will be provided and comply with published and nationally/internationally recognized authorities.

3. This standard does not recognize the delivery of any anesthetic by an RN, supervised or otherwise.

4. If a patient has received epidural analgesia, there will be a physician or other qualified licensed practitioner immediately available to manage any complication for the analgesia or the specific obstetrical condition.

5. A well-organized anesthesia service must be integrated into the healthcare organisation’s required Quality Management System in order to assure the provision of safe care to patients.

15.5 Delivery of Services

1. Anesthesia services must be consistent with needs and resources.

2. Policies on anesthesia procedures must include the delineation of pre-anesthesia and post-anesthesia responsibilities.

3. The policies must ensure that the following are provided for each patient:

   a) patient consent consistent with the required elements of a consent as defined previously in Standard 14, specifically addressing the documentation of direct physician and patient discussions of risk, benefit and alternatives;
   b) infection control measures;
   c) safety practices in all anesthetizing areas;
   d) protocol for supportive life functions;
   e) quality and outcome reporting requirements;
   f) documentation requirements;
   g) equipment requirements, as well as the monitoring, inspection, testing, and maintenance of anesthesia equipment in the healthcare organisation’s biomedical equipment program.

4. A pre-anesthesia evaluation must be performed for each patient who receives general, regional or monitored anesthesia care. While current practice dictates that the patient receiving moderate sedation be monitored and evaluated before, during, and after the procedure by trained practitioners, a pre-anesthesia evaluation performed by someone qualified to administer anesthesia is not required because moderate sedation is not considered to be anesthesia, and thus is not subject to that requirement under this regulation.

5. A pre-anesthesia evaluation shall:

   a) include a review of the medical history;
   b) include an interview and examination of the patient;
   c) include a documented airway assessment;
   d) include an anesthesia risk assessment;
e) include an anesthesia drug and allergy history;
f) utilize consultation data no older than 30 days in origin;
g) be performed by an individual, qualified and privileged to administer anesthesia/sedation, and will be performed within 48 hours prior to inpatient or outpatient surgery or procedure requiring anesthesia services (the delivery of the first dose of medications for the purpose of inducing anesthesia, marks the end of the 48 hour time frame).

**NOTE 1** The evaluation must be performed by someone qualified to administer anesthesia as specified in standard:

- a) a qualified anesthesiologist;
- b) a doctor of medicine (other than an anesthesiologist);
- c) a dentist, oral surgeon who is qualified to administer anesthesia under applicable laws and regulations.

Although the standard generally provides broad authority to physicians to delegate tasks to other qualified medical personnel, the more stringent standards do not permit delegation of the pre-anesthesia evaluation to practitioners who are not qualified to administer anesthesia.

6. There must be an intraoperative anesthesia record or report for each patient who receives general, regional or monitored anesthesia. Current standard of care stipulates that an intraoperative anesthesia record, at a minimum, includes:

- a) name and healthcare organisation identification number of the patient;
- b) name(s) of practitioner(s) who administered anesthesia, and as applicable, the name and profession of the supervising anesthesiologist or operating practitioner;
- c) name, dosage, route and time of administration of drugs and anesthesia agents;
- d) techniques(s) used and patient position(s), including the insertion/use of any intravascular or airway devices;
- e) name and amounts of IV fluids, including blood or blood products if applicable;
- f) time-based documentation of vital signs as well as oxygenation and ventilation parameters; and
- g) any complications, adverse reactions, or problems occurring during anesthesia, including time and description of symptoms, vital signs, treatments rendered, and patient’s response to treatment.

7. A post-anesthesia evaluation completed and documented by an individual qualified to administer anesthesia no later than 48 hours after surgery or a procedure requiring anesthesia services.

8. The post-anesthesia evaluation for anesthesia recovery must be completed in accordance with local law and with healthcare organisation policies and procedures that have been approved by the medical staff and that reflect current standards of anesthesia care. The elements of an adequate post-anesthesia evaluation should be clearly documented and conform to current standards of anesthesia care, including:

- a) respiratory function, including respiratory rate, airway patency, and oxygen saturation;
- b) cardiovascular function, including pulse rate and blood pressure;
- c) mental status;
- d) temperature;
- e) pain;
- f) nausea and vomiting;
- g) postoperative hydration;
- h) depending on the specific surgery or procedure performed, additional types of monitoring and assessment may be necessary.
NOTE 2 The post anesthesia evaluation must be completed and documented by any practitioner who is qualified to administer anesthesia; this need not be the same practitioner who administered the anesthesia to the patient.

The calculation of the 48-hour timeframe begins at the point the patient is moved into the designated recovery area. The evaluation generally should not be performed immediately at the point of movement from the operative area to the designated recovery area. Rather, accepted standards of anesthesia care indicate that the evaluation should not begin until the patient is sufficiently recovered from the acute administration of the anesthesia so as to participate in the evaluation, e.g., answer questions appropriately, perform simple tasks, etc.

While the evaluation should begin in the PACU/ICU or other designated recovery location, it may be completed after the patient is moved to another inpatient location or, for same day surgeries, if applicable laws and regulations and healthcare organisation policy permits, after the patient is discharged, so long as it is completed within 48 hours.

The 48-hour timeframe for completion and documentation of the post-anesthesia evaluation is an outside parameter. Individual patient risk factors may dictate that the evaluation be completed and documented sooner than 48 hours. This should be addressed by healthcare organisation policies and procedures.

For those patients who are unable to participate in the post-anesthesia evaluation (e.g., post-operative sedation, mechanical ventilation, etc.), a post-anesthesia evaluation should be completed and documented within 48 hours with notation that the patient was unable to participate. This documentation should include the reason for the patient’s inability to participate as well as expectations for recovery time, if applicable.

For those patients who require long-acting regional anesthesia to ensure optimum medical care of the patient, whose acute effects will last beyond the 48-hour timeframe, a post-anesthesia evaluation must still be completed and documented within 48 hours. However, there should be a notation that the patient is otherwise able to participate in the evaluation, but full recovery from regional anesthesia has not occurred and is not expected within the stipulated timeframe for the completion of the evaluation.
STANDARD 16
Emergency Services

16.1 Organisation and Direction

1. If emergency services are provided, the healthcare organisation must ensure that specific emergency services organisation and direction requirements are met.

2. If emergency services are provided at the healthcare organisation the services must be organized under the direction of a qualified member of the medical staff.

3. The healthcare organisation must meet the emergency needs of its patients in accordance with acceptable standards of practice.

4. Emergency services shall be organized and integrated with other departments under the direction and supervision of a qualified member of the medical staff.

5. The medical staff shall be responsible for developing and maintaining policies and procedures governing the medical care delivered.

NOTE 1 Emergency Services integration would include at a minimum:

a) coordination and communication between the Emergency Department and other healthcare organisation services/departments;

b) physical access for emergency department patients to the services, equipment, personnel, and resources of other healthcare organisation departments/services;

c) the immediate availability of services, equipment, personnel, and resources of other organisation departments/services to emergency patients;

d) that the provision of services, equipment, personnel and resources of other organisation departments/services to emergency department patients is within timeframes that protect the health and safety of patients and is within acceptable standards of practice.

16.2 Personnel

1. The healthcare organisation must ensure the emergency services personnel requirements are met.

2. The emergency services must be supervised by a qualified member of the medical staff.

3. Adequate medical and nursing staff qualified in emergency care, as outlined in the written scope of service, must be present to meet the written emergency procedures and needs determined by the organisation.

4. A qualified registered nurse shall perform patient triage upon presentation to the emergency department.

5. The healthcare organisation shall ensure that a qualified member of the medical staff is on premises and available to supervise the provision of emergency services 24 hours a day.
6. The healthcare organisation shall staff the emergency department with the appropriate numbers and types of professionals and other staff who possess the skills, education, certifications, specialized training and experience in emergency care when emergency services are provided.

7. The healthcare organisation shall have emergency planning procedures in place to address the need for appropriate staffing levels during times of emergency/disaster.

16.3 Emergency services not provided

1. If emergency services are not provided at the healthcare organisation, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.

16.4 Off-campus Departments

1. The medical staff shall have written policies and procedures for appraising and referring emergencies that occur in off-campus departments where emergency services are not provided.
17.1 General

1. If healthcare organisation provides obstetric services these services shall be well organized, appropriate to the scope of the services offered, and clinical processes shall meet recognized standards and national legal and regulatory requirements.

2. As a minimum the obstetric services are required to have policies and procedures in place which as a minimum shall include:
   
a) Antenatal Policies & Procedures:
   • booking appointments;
   • clinical risk assessment;
   • antenatal screening (maternal and fetal);

b) Intrapartum Policies & Procedures:
   • care of women in labor;
   • fetal monitoring;
   • caesarean section;
   • eclampsia;
   • shoulder dystocia;
   • operative vaginal delivery;
   • post-partum hemorrhage;
   • management of a severely ill women;

c) Postnatal Policies & Procedures:
   • immediate care of the newborn;
   • admission to neonatal unit;
   • newborn feeding.

3. The obstetrics services shall define the specialist training requirement of all staff who provide care within the obstetric services (nurses, nursing assistants, midwives, obstetricians, anesthetists and anesthetist assistants and pediatricians)

4. In setting the training requirements the frequency of training updates shall be documented.

17.2 Anesthesia Services

1. If anesthesia services are provided for labor and delivery, the same standard of coverage as that of operating room anesthesia will be provided and comply with the National legislation recommendations.

2. If a patient has received epidural analgesia, there will be a practitioner immediately available to manage any complication for the analgesia or the specific obstetrical condition.
STANDARD 18
Radiologic services

18.1 General

1. The healthcare organisation shall maintain, diagnostic radiology services that meet professionally approved standards and national legislation for radiation safety and staff qualifications and requirements according to patient needs. The medical imaging services, particularly ionizing medical imaging procedures shall be free from hazards for patients and personnel.

2. The scope and complexity of radiological services offered should be specified in writing and approved by the medical staff and governing body. These services must be readily available at all times.

3. If therapeutic services are also provided, they shall meet professionally approved standards and laws for radiation safety and staff qualifications and requirements.

4. The healthcare organisation’s radiological services, including any contracted services, must be integrated into its organisation-wide Quality Management System.

5. Radiological services may be provided by the healthcare organisation directly or through an outsourced arrangement. Outsourced diagnostic radiology services may be provided either on the organisation premises or in an adjacent or other nearby, readily accessible facility.

18.2 Safety for Patients and Personnel

1. The healthcare organisation must develop and implement policies and procedures to provide a safe environment for patients and staff.

2. The healthcare organisation policies and procedures must address the safety standards for the following:
   a) adequate shielding for patients, personnel and facilities;
   b) labeling of radioactive materials, waste, and hazardous areas;
   c) transportation of radioactive materials between locations within the healthcare organisation;
   d) securing radioactive materials, including determining limitations of access to radioactive materials;
   e) testing and maintenance of equipment for prevention of radiation hazards;
   f) maintenance monitoring and measuring devices for equipment;
   g) proper storage of radiation monitoring badges when not in use;
   h) storage and disposal of radio nuclides and radio pharmaceuticals as well as radioactive waste;
   i) methods of identifying patients who may be pregnant.

3. Proper radiation safety precautions shall be maintained, including adequate shielding for patients, staff, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.
4. Staff who work in radiation areas shall be monitored continually for the amount of radiation exposure by the use of exposure meters or badge dosimeters. This includes licensed independent practitioners who may be exposed to ionizing radiation during procedures, certain radiology technologists, radiologists, nursing and maintenance staff.

5. Any high radiation readings must be investigated and reported to Quality Management Oversight.

**18.3 Facilities**

1. The healthcare organisation must have policies and procedures in place to ensure that periodic inspections of radiology equipment are conducted.

2. Periodic inspection of equipment shall be performed, at least minimally according to manufacturer’s recommendations.

3. Hazards shall be identified and promptly corrected. When these periodic inspections have identified that equipment is not operating or malfunctioning, this equipment is removed from service and repaired and verified prior to being put into operation for patient care.

4. Documentation of preventative maintenance, repairs and calibration of radiology equipment shall be maintained.

**18.4 Order**

1. Medical imaging services shall be provided only on the order of practitioners with clinical privileges or, consistent with national and regulatory requirements.

2. The healthcare organisation must develop and implement policies that have been approved by the medical staff to designate which radiology tests require interpretation by a radiologist.

3. Other practitioners providing this service shall be approved and authorized by the medical staff and the governing body.

**18.5 Personnel**

1. The healthcare organisation must ensure that appropriate personnel are provided to meet the needs of radiology department.

2. A qualified full-time, part-time, or consulting radiologist shall supervise the ionizing radiology services and shall interpret those radiology tests that are determined by the medical staff to require a radiologist’s specialized knowledge.

**18.6 Records**

1. Records of medical imaging services must be maintained, in accordance with national and local legislation and regulations.

2. The radiologist or other practitioner who interprets radiology images and outcomes must sign, date and time the written reports of his/her interpretations.
3. The organisation must maintain the following for at least 5 years or in accordance with a national legislation:

a) copies of reports and printouts; and,

b) films, scans, and other image records.
STANDARD 19
Nuclear Medicine Services

19.1 Organisation

1. If the healthcare organisation provides nuclear medicine services; those services must meet the needs of the patients in accordance with acceptable standards of practice. Acceptable standards of care are as those defined by a recognized and reputable national or international advisory body or authority with respect to the delivery of nuclear medical administration and patient care.

2. The healthcare organisation of the nuclear medicine service shall be appropriate to the scope and complexity of the services offered.

3. There shall be a director who is a doctor of medicine qualified in nuclear medicine.

4. The qualifications, training, functions, and responsibilities of nuclear medicine staff shall be specified by the service director and approved by the medical staff.

5. The services must be in accordance with acceptable standards of practice defined above as well as any standards and recommendations defined by the medical staff.

19.2 Delivery of service

1. Radioactive materials shall be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice as defined by the medical staff. The nuclear medicine services shall be free from unacceptable and uncontrolled hazards for patients and personnel.

2. In-house preparation of radio-pharmaceuticals shall be by or under the direct supervision of an appropriately trained registered pharmacist or doctor of medicine. This director must be a member of the Pharmacy and Therapeutics Committee and attend all meetings. Another departmental physician delegate may be appointed as required by circumstance.

3. The healthcare organisation must define through written policies and procedures practices to include:

   a) handling of equipment and radioactive materials;
   b) protection of patients and personnel from radiation hazards;
   c) labeling of radioactive materials, waste and hazardous areas;
   d) transportation of radioactive materials between locations within the healthcare organisation;
   e) security of radioactive materials, including determining who may have access to radioactive materials and controlling access to radioactive materials;
   f) testing of equipment for radiation hazards;
   g) maintenance of personal radiation monitoring devices;
   h) storage of radionuclides and radiopharmaceuticals as well as radioactive waste;
   i) disposal of radionuclides, unused radiopharmaceuticals, and radioactive waste;
j) any other real or potential, unacceptable, uncontrolled hazards for patients and personnel;

k) periodic investigative surveys to assure the conditions noted above, (a-i) must be made and documented at reasonable intervals as defined by the quality leadership. Results must be reported to the Pharmacy and Therapeutics Committee as well as the Quality Oversight Department for review.

19.3 Facilities

1. Equipment and supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for safe and efficient performance.

2. The healthcare organisation must develop and implement a preventive maintenance process to ensure that nuclear medicine equipment is maintained in safe operating condition to ensure accurate results and patient, staff, and public safety.

   a) the equipment, including nuclear medicine equipment requiring calibration (as stated by the manufacturer or other reasonable standard of care recommendation) must be calibrated at least annually by qualified personnel. Records of same must be maintained.

   b) results of these records must be reported to the Pharmacy and Therapeutics Committee as well as the Quality Oversight Department for review.

   c) the healthcare organisation shall ensure that equipment which does not conform to requirements is identified and controlled to prevent its unintended use without appropriate review. This includes taking action appropriate to the effects or potential effects to patient care when the failure is detected after care has been given. Appropriate records of these actions must be kept and reported as noted in 19.2.3.k).

3. Supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for the safety for the patients, staff, and public.

19.4 Records

1. The healthcare organisation must maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures. Only practitioners approved by the medical staff may interpret and sign the interpretation of diagnostic procedures and tests.

2. The healthcare organisation must maintain copies of nuclear medicine reports for at least 5 years.

3. The practitioner approved by the medical staff to interpret diagnostic procedures must sign and date the interpretation of these tests.

4. The healthcare organisation must maintain records of the receipt and disposition of radio-pharmaceuticals in accordance with applicable standards. Significant deviations of accounting must be reported to the department director, the governing authority of the hospital, and any other statutory or regulatory authority as required.
STANDARD 20
Rehabilitation Services

20.1 General

1. If the healthcare organisation provides rehabilitation, physical therapy, occupational therapy, audiology or speech pathology services, the service(s) shall be provided in a manner that ensures the patient’s health and safety.

2. The healthcare organisation will adhere to acceptable standards of practice include compliance with any applicable National laws, regulations or guidelines, as well as standards and recommendations promoted by nationally recognized professional organisations.

20.2 Management

1. The healthcare organisation shall ensure that there is the appropriate management and support for this core process. These requirements shall include:
   
   a) a director who has the responsibility for the management, direction and accountability for ensuring services are carried throughout the organisation;
   
   b) the director shall have the qualifications, experience and/or training defined by the healthcare organisation and appropriate for this position;
   
   c) staff who meet the qualifications as defined by the medical staff and organisation and consistent with national law shall be performed by qualified physical therapists, physical therapists assistants, occupational therapists, occupational therapist assistants, speech-language pathologists, or audiologists.

20.3 Treatment plan

1. The healthcare organisation shall have a written treatment plan that is in accordance with the practitioner’s orders who are authorized by the medical staff to order the services. The orders, treatment plan and results, notes and other related documentation shall be maintained in the patient’s medical record.

2. The treatment plan and the personnel qualifications must be in accordance with National legislation.
STANDARD 21
Pharmaceutical Services

21.1 General

1. Provision of pharmaceutical services shall meet the needs of the patients’ therapeutic goals by promoting a safe medication use process that ensures optimal selection of medications, dose, dosage form, frequency, route, duration of therapy and that substantially reduces or eliminates adverse drug events and duplication of treatment.

2. The pharmacy or drug storage area must be administered in accordance with applicable laws, regulations and guidelines governing pharmaceutical services.

3. There must be sufficient personnel to respond to the pharmaceutical needs of the patient population being served. The pharmaceutical services staff must be sufficient in types, numbers, and training to provide quality services, including 24 hour, 7-day emergency coverage, or there is an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff.

4. A single pharmacist must be responsible for the overall administration of the pharmacy service and must be responsible for developing, supervising, and coordinating all the activities of the healthcare organisation wide pharmacy service.

5. The pharmacy director should be actively involved in those committees responsible for establishing medication-related policies and procedures.

NOTE 1 Direction of pharmaceutical services may not require continuous on-premise supervision at the healthcare organisation’s single pharmacy or at any pharmacy location but may be accomplished through regularly scheduled visits, in accordance with applicable laws and regulations and accepted professional principles.

6. Pharmaceutical services shall include:
   a) the procuring, manufacturing, compounding, packaging, dispensing, ordering, distributing, disposition, use, and administering of all medications, biologicals, chemicals and the use of medication related devices.
   b) provision of medication-related information to healthcare organisation, healthcare professionals and patients necessary to optimize therapeutic outcomes.

7. The healthcare organisation’s pharmacy services must be integrated into its healthcare organisation-wide Quality Management System.

21.2 Administration of Drugs and Biologicals

1. Drugs and biologicals must be prepared and administered in accordance with applicable laws and regulations, the orders of the practitioner or practitioners responsible for the patient’s care and accepted standards of practice.
2. Drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with applicable laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

3. The healthcare organisation may allow a patient (or his or her caregiver/support person) to self-administer both organisation-issued medications and the patient’s own medications brought into the healthcare organisation, as defined and specified in the organisation’s policies and procedures, under the supervision of the pharmacy and therapeutics committee.

4. The healthcare organisation shall ensure that a practitioner responsible for the care of the patient has issued an order, consistent with organisation policy, permitting self-administration and that patient/family competence has been assessed by authorised personnel. The following instructions shall be required:

   a) instruct the patient (or the patient’s caregiver/support person) in the safe and accurate administration of the specified medication(s);
   b) address the security of the medication(s) for each patient;
   c) document the administration of each medication, as reported by the patient (or the patient’s caregiver/support person), in the patient’s medical record;
   d) identify the specified medication(s) and visually evaluate the medication(s) for integrity.

5. Drugs and biologicals not specifically prescribed as to time or number of doses must automatically be stopped after a reasonable time that is predetermined by the medical staff.

6. Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the healthcare organisation-wide Quality Management System.

### 21.3 Education, Monitoring and Measuring

1. Medication preparation and administration education and training shall be included in healthcare organisation orientation or other continuing education for nursing staff and other authorized healthcare personnel.

2. Training or continuing education topics regarding medication preparation and administration may include but are not limited to the following:

   a) safe handling and preparation of authorized medications;
   b) knowledge of the indications, side effects, drug interactions, compatibility, and dose limits of administered medications;
   c) equipment, devices, special procedures, and/or techniques required for medication administration.

3. Policies and procedures must address the required components of the training and if the training provided during healthcare organisation orientation imparts sufficient education or whether ongoing in-services or continuing education will be required to demonstrate competence.

4. Monitoring and measuring results of training must be reported to the pharmacy and therapeutic committee and Quality oversight for review and action as may be required.
21.4 Policy and Procedure for Physician Orders

1. All orders for drugs and biologicals, must be documented and signed by a practitioner who is authorized by healthcare organisation policy, and medical staff rules and regulations in accordance with the pharmacy and therapeutics committee supervision.

2. All practitioner orders for the administration of drugs and biological must include at least the following:
   a) name of the patient;
   b) name of the prescriber, date and time of the order;
   c) drug name;
   d) dose, frequency, and route;
   e) exact strength or concentration, when applicable;
   f) quantity and/or duration, when applicable;
   g) specific instructions for use, when applicable;

3. Policies and procedures must address the methodology of the medical, nursing, and other applicable professional staff on the conditions and criteria for using standing orders, orders sets, preprinted orders, verbal or telephone orders, orders from non-staff physicians and any other order than specifically written as defined above. Said conditions and criteria shall meet any regulatory requirements as well as pharmacy and therapeutic committee policies approved by a medical staff.

4. Verbal orders, if used, shall be used infrequently.

5. Healthcare organisations are expected to develop appropriate policies and procedures that govern the use of verbal orders and minimize their use, such as:
   a) describe limitations or prohibitions on the use of verbal orders;
   b) provide a mechanism to ensure validity/authenticity of the practitioner issuing a verbal order;
   c) list the elements required for inclusion in the verbal order process;
   d) describe situations in which verbal orders may be used;
   e) define the types of personnel who may issue and receive verbal orders;
   f) establish protocols for clear and effective communication, verification, and authentication of verbal orders.

6. When verbal orders are used, they must only be accepted by persons who are authorized to do so by healthcare organisation policy and procedures consistent with applicable laws and regulations.

7. Healthcare organisations may adopt policies and procedures that permit the use of standing orders to address well defined clinical scenarios involving medication administration.

8. The specific criteria for a nurse or other authorized personnel to initiate the execution of a particular standing order must be clearly identified in the protocol for the order, i.e., the specific clinical situations, patient conditions or diagnoses in which initiating the order would be appropriate.

9. An order that has been initiated for a specific patient must be added to the patient’s medical record at the time of initiation, or as soon as possible thereafter. Likewise, standing order policies and procedures shall specify the process whereby the physician or other practitioner responsible for the care of the patient acknowledges and authenticates the initiation of all standing orders after the fact, with the exception of influenza and pneumococcal polysaccharide vaccines, which do not require such authentication.
10. The policies and procedures must also establish a process for monitoring and evaluating the use of standing orders, including proper adherence to the order’s protocol. There must also be a process for the identification and timely completion of any requisite updates, corrections, modifications, or revisions.

21.5 Medication Delivery and Schedule of Administration

1. Medications should be dispensed in a manner that is safe and meets the needs of the patient:
   a) quantities of medications are dispensed which minimize diversion and potential adverse events while meeting the needs of the patient;
   b) medications are dispensed in a timely manner. The healthcare organisation must have a system that ensures that medication orders get to the pharmacy and medications get back to patients promptly;
   c) whenever possible, medications are dispensed in the most readily available form. If possible, unit doses that have been repackaged by the pharmacy can be used; and
   d) all concerns, issues or questions are clarified with the individual prescriber before dispensing.

2. Appropriate timing of medication administration must take into account the complex nature and variability among medications:
   a) the indications for which they are prescribed;
   b) the clinical situations in which they are administered;
   c) and the needs of the patients receiving them.

3. The policies and procedures must address at least the following:
   a) medications not eligible for scheduled dosing times;
   b) medications eligible for scheduled dosing times;
   c) administration of eligible medications outside of their scheduled dosing times and windows;
   d) evaluation of medication administration timing policies, including adherence to them.

NOTE 1 The chemical properties, mechanism of action, or therapeutic goals of some medications require administration at the exact time prescribed, or within a narrow window of its prescribed scheduled time, to avoid compromising patient safety or achievement of the intended therapeutic effect. However this is not true of all pharmaceuticals. Policies allowing rational use of personnel available and therapeutical requirements of the drug and the patient in question must be develop by a Pharmacy and Therapeutics Committee and approved by the medical staff.

NOTE 2 Medications Not Eligible for Scheduled Dosing Times:

The policies and procedures must identify medications, which are not eligible for scheduled dosing times, either in general or in specific clinical applications. Examples:

   a) stat doses (immediate);
   b) first time or loading doses (initial large dose of a drug given to bring blood, tissue or fluid levels to an effective concentration quickly);
   c) one-time doses; doses specifically timed for procedures;
   d) time-sequenced doses; doses timed for serum drug levels;
   e) investigational drugs; or
   f) drugs prescribed on an as needed basis (prn doses).
NOTE 3 Medications Eligible for Scheduled Dosing Times:

a) medications eligible for scheduled dosing times are those prescribed on a repeated cycle of frequency, such as once a day, BID (twice a day), TID (three times a day), hourly intervals (every 1, 2, 3 or more hours), etc. The goal of this scheduling is to achieve and maintain therapeutic blood levels of the prescribed medication over a period of time.

b) medication administration policies and procedures typically establish standardized dosing times for the administration of all “scheduled” medications. For example, medications prescribed for BID (twice a day) administration might, under a given healthcare organisation’s policies and procedures, be scheduled to be administered at 08:00 and 16:00 hours. Another healthcare organisation might choose to schedule BID medications at 07:30 and 14:30. Use of these standardized times facilitates the medication administration process, e.g., by providing to the healthcare organisation’s pharmacy that morning doses of all BID drugs must be dispensed and delivered to patient units in time for the scheduled administration. For the nursing staff, the scheduled administration time might prompt prioritization of additional activities that may be required, in the case of particular drugs, such as vital sign assessment or the collection and review of blood work, to ensure safe and timely medication administration.

NOTE 4 Time-Critical Scheduled Medications

Time-critical scheduled medications are those for which an early or late administration of greater than thirty minutes might cause harm or have significant, negative impact on the intended therapeutic or pharmacological effect. Accordingly, scheduled medications identified under the healthcare organisation’s policies and procedures as time-critical must be administered within thirty minutes before or after their scheduled dosing time, for a total window of 1 hour. It is possible for a given medication to be time critical for some patients, due to diagnosis, clinical situation, various risk factors, or therapeutic intent, but not time-critical for other patients.

Therefore, healthcare organisation policies and procedures must address the process for determining whether specific scheduled medications are always time-critical, or only under certain circumstances, and how staff involved in medication administration will know when a scheduled medication is time critical.

Examples of time-critical scheduled medications/medication types may include, but are not limited to:

a) antibiotics;
b) anticoagulants;
c) insulin;
d) anticonvulsants;
e) immunosuppressive agents;
f) pain medication;
g) medications prescribed for administration within a specified period of time of the medication order;
h) medications that must be administered apart from other medications for optimal therapeutic effect; or
i) medications prescribed more frequently than every 4 hours.

NOTE 5 Non-Time-Critical Scheduled Medications

Non-time critical scheduled medications are those for which a longer or shorter interval of time since the prior dose does not significantly change the medication’s therapeutic effect or otherwise cause harm. For such medications greater flexibility in the timing of their administration is permissible.
21.6 Blood Transfusions Management

1. Blood transfusions and intravenous medications must be administered in accordance with applicable laws and regulations and approved medical staff policies and procedures. If blood transfusions and intravenous medications are administered by personnel other physicians, the personnel must have special training for this duty.

2. Education and training regarding these procedures are included in the nurse’s healthcare organisation orientation. Nursing staff that receive training for intravenous medication administration and/or blood transfusion administration during healthcare organisation orientation or during other continuing education programs shall meet the requirements of this regulation.

**NOTE 1** The competencies must be documented in the nurse’s record. Content of the training must be based on applicable laws and regulations. For intravenous medication administration and blood transfusion and must address at least the following:

   a) fluid and electrolyte balance;
   b) venipuncture techniques, including both demonstration, and supervised practice; and,
   c) for blood transfusion training:
      • blood components;
      • blood administration procedures based on healthcare organisation policy, and applicable laws and regulations;
      • requirements for patient monitoring, including frequency and documentation of monitoring;
      • the process for verification of the right blood product for the right patient;
      • identification and treatment of transfusion reactions.

21.7 Controlled Medications

1. All controlled substances must be locked within a secure area.

2. Healthcare organisations are permitted flexibility in the storage of non-controlled drugs and biologicals when delivering care to patients, and in the safeguarding of drugs and biologicals to prevent tampering or diversion. Supervision and control of all pharmaceuticals must be maintained as required by statutory rules and regulations.

3. When a patient care area is not staffed, both controlled and non-controlled substances must be locked away securely.

4. Healthcare organisation policies and procedures are expected to ensure that these areas are secure, with entry and exit limited to appropriate staff, patients and visitors.

5. Due to their mobility, mobile nursing medication carts, anesthesia carts, epidural carts and other medication carts containing drugs or biologicals (hereafter, all referred to as “carts”) must be locked in a secure area when not in use. Healthcare organisation policies and procedures are expected to address the security and monitoring of carts, locked or unlocked, containing drugs and biologicals in all patient care areas to ensure their safe storage and to ensure patient safety.

6. Medication automated distribution units with security features, such as logon and password or biometric identification, are considered to be locked, since they can only be accessed by authorized personnel who are permitted access to the medications. Such units must be stored in a secure area.

**NOTE 1** An area in which staff are actively providing care to patients or preparing to receive patients, i.e., setting up for procedures before the arrival of a patient, would generally be considered a secure area.
NOTE 2 The operating theatre is considered secure when the theatre is staffed and staff is actively providing patient care.

NOTE 3 When the theatre is not in use (e.g., weekends, holidays and after hours), it would not be considered secure. A healthcare organisation may choose to lock the entire theatre, lock non-mobile carts containing drugs and biologicals, place mobile carts in a locked room, or otherwise lock drugs and biologicals in a secure area. If an individual operating theatre is not in use, the healthcare organisation is expected to lock non-mobile carts, and ensure mobile carts are in a locked room.

21.8 Unusable drugs

1. Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use. They shall be sequestered and labeled as unusable.

2. The healthcare organisation must have a pharmacy labeling, inspection, and inventory management system that ensures that outdated, mislabeled, or otherwise unusable drugs and biologicals are not available for patient use.

21.9 Medication errors

1. The development of policies and procedures to minimize medication errors shall be based on accepted professional principles; external alerts and proactive review of facility reported and reviewed adverse drug events. The medical staff shall develop these policies.

2. Policies and procedures to minimize drug errors shall include:

   a) high-risk medications - dosing limits, administration guidelines, packaging, labeling and storage;
   b) limiting the variety of medication-related devices and equipment. For example limit the types of general-purpose infusion pumps to one or two;
   c) availability of up-to-date medication information;
   d) availability of pharmacy expertise (pharmacist available on-call when pharmacy does not operate 24 hours a day).

NOTE 1 For high risk medications and high-risk patients (pediatric, geriatric or patients with renal or hepatic impairment) there should be systems in place to minimize adverse drug events. Such systems could include but not limited to: checklists, dose limits, pre-printed orders, special packaging, special labeling, double-checks and written guidelines. “High-risk medications” are those medications involved in a high percentage of medication errors and/or sentinel events and medications that carry a higher risk for abuse, errors, or other adverse outcomes.

Examples of high-risk drugs may include investigational drugs, controlled medications, medications with a narrow therapeutic range, psychotherapeutic medications and look-alike/sound-alike medications and those new to the market or new to the healthcare organisation.

NOTE 2 Standardization of prescribing and communication practices to include:

   a) avoidance of dangerous abbreviations;
   b) all elements of the order – dose, strength, units (metric), route, frequency, and rate;
   c) alert systems for look-like and sound-alike drug names;
   d) use of facility approved pre-printed order sheets whenever possible;
   e) that orders to resume previous orders are prohibited;
   f) a voluntary, non-punitive, reporting system to monitor and report adverse drug events (including medication errors and adverse drug reactions);
   g) the preparation, distribution, administration and proper disposal of hazardous medications;
21.10 Monitoring

1. Healthcare organisations are required to ensure that the attending physician is made immediately aware of drug administration errors, adverse drug reactions, and incompatibilities. When the attending physician is unavailable, the covering physician must be notified.

2. The healthcare organisation must adopt policies and procedures that identify the types of events that must be reported immediately to pharmacy and therapeutic committee and Quality oversight.

3. When appropriate, such events must also be reported to the healthcare organisation-wide Quality data program.

4. The immediate reporting requirement shall apply to drug administration errors, adverse drug reactions or incompatibilities that have harmed or have the potential to harm the patient.

5. If the outcome of the drug administration error is unknown, the physician must also be notified without delay.

**NOTE 1 Drug administration error:**

Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

**Adverse drug reaction:**

An adverse drug reaction is defined as an adverse drug reaction (ADR) as any unexpected, unintended, undesired, or excessive response to a drug that:

a) requires discontinuing the drug (therapeutic or diagnostic);
b) requires changing the drug therapy;
c) requires modifying the dose (except for minor dosage adjustments);
d) necessitates admission to a healthcare organisation;
e) prolongs stay in a health care facility;
f) necessitates supportive treatment;
g) significantly complicates diagnosis;
h) negatively affects prognosis;
i) results in temporary or permanent harm, disability, or death.

An allergic reaction (an immunologic hypersensitivity occurring as the result of unusual sensitivity to a drug) and an idiosyncratic reaction (an abnormal susceptibility to a drug that is peculiar to the individual) are also considered ADRs.

**Drug incompatibilities:**

A drug incompatibility occurs when drugs interfere with one another chemically or physiologically. Drugs known to be incompatible must not be mixed, administered together, or administered within a timeframe where they will interfere with each other.
NOTE 2 Healthcare organisations can minimize the risk of administering incompatible medications by making available pertinent resources, such as drug incompatibility charts and online incompatibility references. The incompatibility information needs to be readily available to staff administering medications. The information needs to be kept up-to-date as the information is frequently updated by drug manufacturers.

21.11 Available Information

1. Information relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff.

2. The medical staff will define and promote when clinical pharmacology consults are needed and indicated.

21.12 Records

1. Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.

2. Components of a record system to maintain current and accurate records of the receipt and disposition of scheduled drugs would include:

   a) accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs;
   b) records of the receipt and disposition of all scheduled drugs must be current and must be accurate;
   c) records trace the movement of scheduled drugs throughout the service;
   d) the pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled;
   e) the record system, delineated in policies and procedures, tracks movement of all scheduled drugs from the point of entry into the healthcare organisation to the point of departure either through administration to the patient, destruction or return to the manufacturer. This system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs.
22.1 Organisation and Policies

1. The healthcare organisation must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.

2. The healthcare organisations shall assure that the individuals so designated are qualified through education, training, experience, or certification.

3. Infection control policies shall be specific to each department, service, and location, including off-site locations, and be evaluated and revised when indicated.

4. The infection control officer(s) must develop and implement policies governing the control of infections and communicable diseases. Infection control policies should address the roles and responsibilities for infection control within the healthcare organisation:
   a) how the various healthcare organisation committees and departments interface with the infection control program;
   b) how to prevent and report infectious/communicable diseases to the infection control program.

5. The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.

6. The infection control officer(s)’ responsibility is to identify, investigate, report, prevent and control infections and communicable diseases in addition to the following activities:
   a) maintenance of a sanitary healthcare organisation environment;
   b) development and implementation of infection control measures related to healthcare organisation personnel; healthcare organisation staff, for infection control purposes, includes all healthcare organisation staff, contract workers (e.g., agency nurses, housekeeping staff, etc.), and volunteers;
   c) mitigation of risks associated with patient infections present upon admission;
   d) mitigation of risks contributing to healthcare-associated infections;
   e) active surveillance;
   f) monitoring compliance with all policies, procedures, protocols and other infection control program requirements;
   g) program evaluation and revision of the program, when indicated;
   h) coordination as required by law with locality emergency preparedness and health authorities to address communicable disease threats, bioterrorism, and outbreaks;
   i) complying with the reportable disease requirements of the local health authority;
   j) close association and consultation with the directors of sterilization and disinfection services.
   k) monitoring, measuring and validation of this service shall be ongoing. Reports shall be submitted to the proper management for review and action as needed.
7. The infection control officer(s)' shall also be responsible for all staff healthcare requirements at the minimum to include the following:

a) hand washing methods and compliance;  
b) measures and authority for evaluating healthcare organisation staff immunization status for designated infectious diseases, as recommended by the ECDC;  
c) policies articulating the authority and circumstances under which the healthcare organisation screens staff for infections which are likely to cause significant infectious disease or other risk. In the case of a reportable disease, management shall be consistent with the requirements of the applicable public health authority;  
d) policies addressing when infected healthcare organisation staff are restricted from providing direct patient care and/or are required to remain away from the healthcare facility entirely;  
e) new employee and regular update training in preventing and controlling healthcare-associated infections and methods to prevent exposure to and transmission of infections and communicable diseases;  
f) measures to evaluate staff and volunteers exposed to patients with infections and communicable disease;

8. The infection control process shall have and implement policies and procedures, based on national guidelines that address the following:

a) maintenance of a sanitary physical environment;  
b) ventilation and water quality control issues, including measures taken to maintain a safe environment during internal or external construction/renovation;  
c) maintaining safe air handling systems in areas of special ventilation, such as operating rooms, intensive care units, and airborne infection isolation rooms;  
d) techniques for food sanitation;  
e) techniques for cleaning and disinfecting environmental surfaces, carpeting and furniture;  
f) techniques for textiles reprocessing, storage and distribution;  
g) techniques for disposal of regulated and non-regulated waste;  
h) techniques for pest control.

22.2 Mitigation of risks

1. The healthcare organisation shall have mitigation program and active surveillance which must include:

a) provisions to monitor compliance with all policies, procedures, protocols and other infection control program requirements;  
b) policies and procedures developed in coordination with applicable emergency preparedness and health authorities to address communicable disease threats, bioterrorism, and outbreaks;  
c) procedures for meeting the reporting requirements of the local health authority;  
d) policies for mitigation of risks associated with patient infections present upon admission;  
e) policies for the early identification of patients who require isolation in accordance with ECDC and WHO guidelines;  
f) policies for use of personal protective equipment including gowns, gloves, masks and eye protection devices;  
g) policies and techniques for isolation precautions as recommended by the ECDC and WHO.

2. The top management must ensure that the healthcare organisation-wide Quality Management System and staff in-service training programs address problems identified by the infection control
officer or officers through the infection prevention and control program; and be responsible for
the implementation of successful corrective action plans in affected problem areas.

3. To reflect the importance of infection control the regulations specifically require that the healthcare
organisation’s Quality Management System and training programs must be involved in addressing
problems identified by the infection control program.

4. The healthcare organisation leaders must monitor adherence to corrective action plans, as well
as assess the effectiveness of actions taken, with implementation of revised corrective actions
as needed.

*NOTE 1 Education on the principles and practices for preventing transmission of infectious agents within the healthcare
organisation should be provided to anyone who has an opportunity for contact with patients or medical equipment, e.g.,
nursing and physicians; therapists and technicians, such as those involved in respiratory, physical, and occupational therapy
and radiology and cardiology services; phlebotomists; housekeeping and maintenance staff; volunteers; and all students and
trainees in healthcare professions.*

### 22.3 Reporting

1. Infection control data shall be provided to the Quality control Committee or other responsible
oversight group at least quarterly.

2. Methodology in infection prevention and control shall be appropriate to the scope of practice
and patient population served. Information reflecting this surveillance shall be reported to the
Quality control Committee in an annual summary.

### 22.4 Bioterrorism

1. Healthcare facilities would confront a set of issues similar to naturally occurring communicable
disease threats when dealing with a suspected bioterrorism event. The required response is
likely to differ based on whether exposure is a result of a biological release or person-to-person
transmission.
STANDARD 23
Medical Records

23.1 General

1. The healthcare organisation must have a medical record service that has administrative responsibility for medical records. A medical record must be maintained for every individual evaluated or treated in the healthcare organisation.

**NOTE 1** The term “medical records” includes at least written documents, computerized electronic information, radiology film and scans, laboratory reports and pathology slides, videos, audio recordings, and other forms of information regarding the condition of a patient.

23.2 Organisation and Staffing

1. The healthcare organisation of the medical record service must be appropriate to the scope and complexity of the services performed.

2. The healthcare organisation must employ adequate personnel to ensure prompt completion, filing, and retrieval of records.

3. The medical records service must be organized, equipped, and staffed in accordance with the scope and complexity of the healthcare organisation’s services and in such a manner as to comply with the requirements of this regulation and other applicable laws and regulations. There must be an established medical record system that is organized and employs adequate personnel to ensure prompt:

   a) completion of medical records;
   b) filing of medical records; and
   c) retrieval of medical records.

23.3 Form and Retention of Record

1. The healthcare organisation must maintain a medical record for each inpatient and outpatient.

2. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible.

3. Every medical record must be complete with all documentation of orders, diagnosis, evaluations, treatments, test results, care plans, discharge plans, consents, interventions, discharge summary, and care provided along with the patient’s response to those treatments, interventions, and care.

4. The record must be completed promptly after discharge in accordance with applicable laws and regulations and healthcare organisation policy but no later than 30 days after discharge.
5. Medical records must be retained in their original or legally reproduced form for a period of at least 5 years or in accordance with the national law.

6. The healthcare organisation must have a medical record system that allows the medical record of any patient, inpatient or outpatient, evaluated and/or treated at any location of the healthcare organisation within the past 5 years to be accessible by appropriate staff, 24 hours a day, 7 days a week, whenever that medical record may be needed.

7. Medical records must be properly stored in secure locations where they are protected from fire, water damage and other threats.

8. The medical record system must ensure that medical record entries are not lost, stolen, destroyed, altered, or reproduced in an unauthorized manner.

NOTE 1 Medical records are retained in their original or legally reproduced form in hard copy, microfilm, computer memory, or other electronic storage media.

23.4 Identification of Authors

1. The healthcare organisation must have a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.

2. The medical record system must correctly identify the author of every medical record entry and must protect the security of all medical record entries.

NOTE 1 These requirements apply to both manual and electronic medical record systems.

23.5 Confidentiality

1. The healthcare organisation must have a procedure for ensuring the confidentiality of patient records.

2. Information from or copies of records, may be released only to authorized individuals, and the healthcare organisation must ensure that unauthorized individuals cannot gain access to or alter patient records.

3. Original medical records must be released by the healthcare organisation only in accordance with applicable laws and regulations, court orders, or subpoenas.

4. Patient records must be secure at all times and in all locations. This includes open patient records for patients who are currently inpatients in the healthcare organisation and outpatients in outpatient clinics.

5. The healthcare organisation staff and consultants, hired to provide services to the individual, should have access to only that portion of information that is necessary to provide effective responsive services to that individual.

NOTE 1 The right to confidentiality means safeguarding the content of information, including patient paper records, video, audio, and/or computer stored information from unauthorized disclosure without the specific informed consent of the individual, parent of a minor child, or legal guardian.

NOTE 2 Confidentiality applies to both central records and clinical record information that may be kept at dispersed locations.
23.6 Content of Record

1. The medical record must contain information to justify admission, support the diagnosis, and describe the patient’s progress and response to medications and services.

2. All entries shall be legible, complete dated and timed. They must be authenticated by the person responsible for providing care consistent with healthcare organisation policy.

3. The medical record must contain information such as notes, documentation, records, reports, recordings, test results and assessments to support the diagnosis and describe the patient’s progress and response to medications and services.

4. The medical record must contain complete information/documentation regarding evaluations, interventions, care provided, services, care plans, discharge plans, and the patient’s response to those activities. Co-morbidities identified in the patient record must be considered and treated as required in the overall patient plane of care.

NOTE 1 The requirements for dating and timing do not apply to orders or prescriptions that are generated outside of the healthcare organisation until they are presented to the healthcare organisation at the time of service. Once the healthcare organisation begins processing such an order or prescription, it is responsible for ensuring that the implementation of the order or prescription by the healthcare organisation is promptly dated, and timed in the patient’s medical record.

NOTE 2 In the case of a pre-established electronic order set, the same principles would apply, so that the practitioner would date, time and authenticate the final order that resulted from the electronic selection/annotation process, with the exception that pages with internal changes would not need to be initialed or signed if they are part of an integrated single electronic document.

5. Where an electronic medical record is in use, the healthcare organisation must demonstrate how it prevents alterations of record entries after they have been authenticated. Information needed to review an electronic medical record, including pertinent codes and security features, must be readily available to surveyors to permit their review of sampled medical records while on-site in the healthcare organisation.

6. A practitioner must review and authenticate all record electronic or otherwise in order to prevent mistaken acceptance of a document which might be automatically authenticated without the physician’s review.

7. The practitioner must separately date and time his/her signature authenticating an entry, even though there may already be a date and time on the document, since the latter may not reflect when the entry was authenticated. For certain electronically generated documents, where the date and time that the physician reviewed the electronic transcription is automatically printed on the document, the requirements of this section would be satisfied. However, if the electronically generated document only prints the date and time that an event occurred (e.g., EKG printouts, lab results, etc.) and does not print the date and time that the practitioner actually reviewed the document, then the practitioner must either authenticate, date, and time this document itself or incorporate an acknowledgment that the document was reviewed into another document (such as the H&P, a progress note, etc.), which would then be authenticated, dated, and timed by the practitioner.

8. All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner.
9. All verbal orders must be authenticated based upon applicable laws and regulations. If there are no applicable laws and regulations that designate a specific time frame for the authentication of verbal orders, verbal orders must be authenticated within 48 hours.

10. All records must document the following, as appropriate. Evidence of a medical history and physical examination completed and documented no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be placed in the patient’s medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.

11. All patient records, both inpatient and outpatient, must contain the results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient. This information must be promptly filed in the patient’s medical record in order to be available to the physician or other care providers to use in making assessments of the patient’s condition, to justify treatment or continued healthcare organisation, to support or revise the patient’s diagnosis, to support or revise the plan of care, to describe the patient’s progress and to describe the patient’s response to medications, treatments, and services.

12. All records must document complications, HAI, and unfavorable reactions to drugs and anesthesia.

13. All records must document all practitioners’ orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient’s condition.

14. All records must document the discharge summary with outcome of healthcare organisation, disposition of case, and provisions for follow-up care.

15. All records must document the final diagnosis with completion of medical records within 30 days following discharge.

16. When rubber stamps or electronic authorizations are used for authentication, the healthcare organisation must have policies and procedures to ensure that such stamps or authorizations are used only by the individuals whose signature they represent. There shall be no delegation of stamps or authentication codes to another individual.

17. In some instances, the ordering practitioner may not be able available. In this case the attending practitioner must authenticate his or her verbal order.

**NOTE 3** Authentication of medical record entries may include written signatures, initials, computer key, or other code. For authentication, in written or electronic form, a method must be established to identify the author.

**NOTE 4** All practitioners responsible for the patient’s care are expected to have knowledge of the patient’s healthcare organisation course, medical plan of care, condition, and current status.
STANDARD 24
Laboratory Services

24.1 General

1. The healthcare organisation must maintain, or have available, adequate laboratory services to meet the needs of its patients.

2. The healthcare organisation must ensure that all laboratory services provided to its patients are performed in a facility certified in accordance with applicable laws and regulations.

3. The healthcare organisation’s laboratory services, including any outsourced services, must be integrated into its healthcare organisation-wide Quality Management System.

24.2 Adequacy of Laboratory Services

1. Emergency laboratory services must be available 24 hours a day.

2. In a healthcare organisation with multiple healthcare organisation campuses, these emergency laboratory services must be available onsite 24/7 at each campus.

3. At a healthcare organisation with off-campus locations the medical staff must determine which, if any, laboratory services must be immediately available to meet the emergency laboratory needs of the patients who are likely to seek care at each off-campus location.

4. A written description of services provided must be available to the medical staff.

5. The laboratory must make provision for proper receipt and reporting of tissue specimens.

6. The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.

NOTE 1 The licensure may be accomplished by having one certificate for the entire healthcare organisation’s laboratory services, by having one certificate for each laboratory, or by the healthcare organisation having a mixture.

NOTE 2 The emergency laboratory services available must reflect the scope and complexity of the healthcare organisation’s operations at the location and be provided in accordance with applicable laws and regulations, and guidelines and acceptable standards of practice.

24.3 Blood Supply & Management

1. The healthcare organisation shall have a blood use policy based on current scientific knowledge and that reduces unnecessary transfusions and minimizes the risks associated with transfusion. The policy shall describe the appropriate use of alternatives to transfusion where possible.
2. Blood and blood products used for patient care shall be subject to quality-assured screening for transfusion transmissible infections, including HIV, hepatitis B, hepatitis C, *Treponema pallidum* (Syphilis) and, where relevant, other infections that pose a risk to the safety of the blood supply, such as *Trypanosoma cruzi* (Chagas disease) and *Plasmodium* species (malaria); as well as testing for blood groups and compatibility.

3. If an healthcare organisation uses the services of an external blood bank, it shall have an agreement with the blood bank that governs the procurement, transfer, and availability of blood and blood products and to ensure blood and blood products comply with the requirements.

4. The healthcare organisation must maintain adequate records, which identify the source and disposition of all units of blood and blood components for no less than ten (10) years from the date of disposition, and they shall be stored in such a manner they are available for prompt retrieval.

5. The preparation of blood and blood products used for patient care shall be prepared:
   a) in units that have effective quality systems, including quality management in place;
   b) using quality standards;
   c) in units that have effective documentation systems in place;
   d) using appropriately trained staff;
   e) subject to regular quality assessment.
STANDARD 25
Organ, Tissue and Eye Procurement

25.1 General

1. If applicable the healthcare organisation must have written policies and procedures to address its organ procurement responsibilities.

2. The healthcare organisation must have a written agreement with an Organ Procurement Organisation (i.e. Eurotransplant). At a minimum, the written agreement must address the following:

   a) the healthcare organisation must have an agreement with at least one tissue bank and at least one eye bank;
   b) the criteria for referral, including the referral of all individuals whose death is imminent or who have died in the healthcare organisation;
   c) includes a definition of “imminent death”; includes a definition of “timely notification”;
   d) addresses the OPO’s responsibility to determine medical suitability for organ donation;
   e) specifies how the tissue and/or eye bank will be notified about potential donors using notification protocols developed by the OPO in consultation with the healthcare organisation-designated tissue and eye bank(s);
   f) provides for notification of each individual death in a timely manner to the OPO in accordance with the terms of the agreement;
   g) ensures that the designated requestor training program offered by the OPO has been developed in cooperation with the tissue bank and eye bank designated by the healthcare organisation;
   h) permits the OPO, tissue bank, and eye bank access to the healthcare organisation’s death record information according to a designated schedule, e.g., monthly or quarterly;
   i) includes that the healthcare organisation is not required to perform credentialing reviews for, or grant privileges to, members of organ recovery teams as long as the OPO sends only “qualified, trained individuals” to perform organ recovery;
   j) the interventions the healthcare organisation will utilize to maintain potential organ donor patients so that the patient organs remain viable;
   k) healthcare organisations must notify the OPO of every death or imminent death in the healthcare organisation. When death is imminent, the healthcare organisation must notify the OPO both before a potential donor is removed from a ventilator and while the potential donor’s organs are still viable. The healthcare organisation should have a written policy, developed in coordination with the OPO and approved by the healthcare organisation’s medical staff and governing body, to define imminent death;
   l) the healthcare organisation shall ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its options to donate organs, tissues, or eyes, or to decline to donate;
   m) the individual designated by the healthcare organisation to initiate the request to the family must be an organ procurement representative or a designated requestor.

NOTE 1 The definition for “imminent death” shall be defined by the healthcare organisation. The definition for “imminent death” should strike a balance between the needs of the OPO and the needs of the healthcare organisation’s care givers to continue treatment of a patient until brain death is declared or the patient’s family has made the decision to withdraw supportive measures.

NOTE 2 “Timely notification” is agreed upon by the healthcare organisation and the OPO.
25.2 Organ Transplantation Responsibilities

1. If a healthcare organisation performs any type of transplants, it must provide organ transplant related data.

2. The healthcare organisation must have policies and procedures, developed in cooperation with the OPO, that ensure that potential donors are maintained in a manner that maintains the viability of their organs.

3. The healthcare organisation must have policies in place to ensure that potential donors are identified and declared dead within an acceptable time frame by an appropriate practitioner.

NOTE 1 For purposes of these standards, the term “organ” means a human kidney, liver, heart, lung, or pancreas.
Module III
Ancillary Services
STANDARD 26
Food and Dietetic Services

26.1 General

1. The healthcare organisation must have organized dietary services that are directed and staffed by adequate qualified personnel.

2. A healthcare organisation that has a contract with an outside food management company and has a dietician who serves the healthcare organisation on a full-time, part-time, or consultant basis, must maintain at least the minimum standards specified in this chapter and provides for constant liaison with the healthcare organisation medical staff for recommendations on dietetic policies affecting patient treatment.

3. The healthcare organisation’s food and dietetic services must be organized, directed and staffed in such a manner to ensure that the nutritional needs of the patients are met in accordance with practitioners’ orders and acceptable standards of practice.

26.2 Policy

1. The healthcare organisation must be in compliance with applicable laws and regulations requirements for food and dietary personnel as well as food service standards, laws and regulations.

2. The healthcare organisation shall have written policies and procedures that address at least the following:
   a) availability of a diet manual and therapeutic diet menus to meet patients’ nutritional needs;
   b) frequency of meals served;
   c) system for diet ordering and patient trays delivery;
   d) accommodation of non-routine occurrences (e.g., parenteral nutrition, peripheral parenteral nutrition, change in diet orders, early/late trays, nutritional supplements, etc.);
   e) integration of the food and dietetic service into the healthcare organisation-wide Quality Management System and Infection Control programs including results of monitoring and supervision control surveys;
   f) guidelines for acceptable hygiene practices of food service personnel; and
   g) guidelines for kitchen sanitation.

26.3 Diets

1. Menus must meet the needs of the patients.

2. Patients who refuse the food served should be offered substitutes that are of equal nutritional value in order to meet their basic nutritional needs.

3. Therapeutic diets must be prescribed by the practitioner or practitioners responsible for the care of the patients.
4. In accordance with applicable laws and regulations and healthcare organisation policy, a dietitian may assess a patient’s nutritional needs and provide recommendations or consultations for patients, but the patient’s diet must be prescribed by the practitioner responsible for the patient’s care.

5. Nutritional needs must be met in accordance with recognized dietary practices and in accordance with orders of the practitioner or practitioners responsible for the care of the patients.

6. A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.
STANDARD 27
Physical Environment

27.1 Facilities

1. The healthcare organisation shall be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special healthcare organisation services appropriate to the needs of the community.

2. The healthcare organisation shall maintain adequate facilities and supplies for its services to ensure an acceptable level of safety and quality.

3. Pertinent physical environment data/information shall be distributed regularly to Quality Management oversight.

4. The condition of the physical plant and the overall healthcare organisation environment must be developed and maintained in such a manner that the safety and well being of patients are assured.

5. The healthcare organisation shall have written plans that document and identify the following seven areas: Safety, Security, Emergency Management, Hazardous Materials (HAZMAT), Life Safety (includes Fire Safety), Medical Equipment, and Utility Systems.

6. The extent and complexity of facilities shall be determined by the services offered.

**NOTE 1** “Adequate facilities” means the healthcare organisation has facilities that:

- a) allow safe access for all service users including those with disabilities and special needs;
- b) designed and maintained in accordance with National legal and regulatory requirements and healthcare organisation policy; and
- c) designed and maintained to reflect the scope and complexity of the services it offers in accordance with recognized standards of practice.

Certain areas of the healthcare organisation may be required to have external sources responsible for maintaining treatment areas and the healthcare organisation will ensure that these services are providing a safe environment for all staff, patient and visitors.

27.2 Safety Management Program

1. The healthcare organisation shall develop and maintain a Safety Management Program that provides a safe and hazard-free physical environment, which includes identifying and monitoring areas that pose safety risks.

2. The healthcare organisation shall address safety recalls and alerts.

3. The healthcare organisation shall conduct routine inspections of the facility in order to identify safety concerns.
4. The healthcare organisation will maintain safe and adequate facilities that are designed and maintained in accordance with National and local laws, regulations and guidelines and reflect the scope and complexity of the services it offers in accordance with recognized standards of practice.

5. The healthcare organisation shall require periodic surveillance of the healthcare organisation grounds to observe safety issues that may be identified and make corrective/preventive action(s) as needed.

6. Results of efforts shall be reported to Quality Management.

27.3 Security Management Program

1. The healthcare organisation shall develop and maintain a Security Management Program that provides a secure physical environment, which includes the identification and monitoring of security issues within the healthcare organisation.

2. The healthcare organisation shall implement a written policy that prohibits harassment/mobbing in the workplace. The policy shall provide measures for employee awareness, on-going training, and investigation of harassment issues, as well as ensure confidential grievance procedures for all employees.

3. The healthcare organisation shall establish and maintain a violence prevention program as part of the facility’s security program.

4. The healthcare organisation shall ensure that all patients, staff, visitors, and others are identified.

27.4 Emergency Management Program

1. The healthcare organisation shall develop and utilize an Emergency Management Program to address the safety and well being of patients in emergency situations.

2. The healthcare organisation shall require that the organisation conduct a hazard vulnerability analysis (HVA) to identify potential emergencies in the organisation and the community.

3. The Emergency Management Program processes shall address alternative means to support essential building functions such as electricity, water, ventilation, fuel, medical gas and vacuum systems, and other identified utilities.

4. The Emergency Management Program shall include memorandums of understanding for utilization of resources (space, personnel, and equipment) with local and regional healthcare facilities and public health agencies in cases of organisational, community, or regional crisis.

5. The healthcare organisation shall have policies, procedures, and decision criteria for the determination of protection in place or evacuation of patients in the event of a disaster.

6. Emergency management exercises shall be based upon the most probable emergencies or other circumstances that may impact the healthcare organisation and the community. A report, shall be created after each exercise documenting opportunities for improvement.
7. The organisation’s emergency management plan shall be revised based upon the identified opportunities for improvement.

\textit{NOTE 1} The “community” represents local, regional, National public safety forces and/or public health agencies.

\section*{27.5 Hazardous Materials (HAZMAT) Program}

1. The healthcare organisation shall develop and maintain a HAZMAT Program that addresses the management of utilization, selection, storing, handling, transportation, and disposition of hazardous materials and waste.

2. To manage the risks within the environment in which patients are treated and staff work the healthcare organisation must develop and maintain environmental plans.

3. Environmental plans must be consistent with the national or local environmental legislation.

4. The healthcare organisation shall maintain a hazardous materials and waste inventory.

5. The healthcare organisation shall ensure investigation and reporting of spills, exposures, and other incidents.

6. The healthcare organisation shall ensure use of personal protective equipment when exposed to hazardous materials and waste.

7. The healthcare organisation shall require appropriate labeling of hazardous materials and waste.

8. The healthcare organisation shall require exposure levels to be monitored for healthcare organisation staff in hazardous material areas.

9. The healthcare organisation shall maintain all required documentation (regulations, permits, licenses, etc.).

10. The healthcare organisation must have procedures for the proper routine storage and prompt disposal of waste.

11. The healthcare organisation shall meet the following requirements for the installation and use of alcohol-based hand rub dispensers.

12. The organisation shall establish procedures to ensure that contaminated and potentially contaminated waste is identified, handled, recorded and stored effectively in order to ensure cross contamination of other areas or items does not occur.

13. Alcohol-based prep solutions used in anesthetizing areas are a potential fire hazard and must be used in accordance with the manufacturer’s recommendations and recorded in the medical record.

14. The use of alcohol-based hand rub dispensers shall not conflict with any laws and regulations that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in healthcare facilities.

15. In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments.
NOTE 1 The organisation should consider sources of waste including but not limited to:

- clinical waste;
- medical equipment;
- needles, syringes and sharps;
- clothing and PPE;
- paper and plastic waste;
- waste water, including that from sinks and showers;
- air, filters and air handling systems;
- discarded equipment used in the healthcare facility.

NOTE 2 When transporting and storing waste, the organisation should consider issues including but not limited to:

- providing adequate facilities and procedures for the short and long term storage of waste;
- ensuring appropriate containers and other materials are used during storage and transportation (e.g. carts, bags, sharps containers);
- adequately segregating waste to minimize risk of cross contamination and drug diversion.

27.6 Fire Safety

1. The healthcare organisation shall develop and follow a Life Safety Program to ensure that the life safety from fire requirements is met by implementing requirements of all applicable laws and regulations.

2. The healthcare organisation shall have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with fire fighting authorities.

3. The written fire control plan must also address:

- reduction of fire risks;
- detection of fire and smoke by use of alarms including their transmission to fire department, as well as response to alarms;
- isolation, abatement of fire and smoke containment;
- evacuation procedures for proximate area and smoke compartment;
- safe and unobstructed exit from the healthcare organisation when fire emergencies occur.

4. The healthcare organisation must maintain written evidence of regular inspections and approval by all applicable fire control agencies and applicable national and local law and legislation.

5. Fire drills must be conducted regularly according to national law. The healthcare organisation must evaluate the effectiveness of the fire drills. The report of effectiveness shall be forwarded to Quality Management oversight.

6. The healthcare organisation shall assess, document, and minimize the impact of construction, repairs, or improvement operations upon occupied area(s). The assessment shall include provisions for infection, prevention and control, utility requirements, noise, vibration, and alternative life safety measures.

7. All alternative life safety measures shall be approved by the authority having local jurisdiction.
8. When construction, repairs, or improvement operations impacts occupied areas, the healthcare organisation will also make provisions to include, as appropriate, infection control practices to be followed, utility requirements, and account for noise and vibration. The healthcare organisation may have also implemented appropriate alternative life safety measures which are required to be approved by the authority having National or local jurisdiction.

27.7 Medical Equipment Program

1. The healthcare organisation shall develop and maintain a Medical Equipment Policy that provides for selection, safe use, inspection, testing, and maintenance of equipment to ensure an acceptable level of safety and quality.

2. This policy shall also address medical equipment inventory and identification, as well as an equipment alert/recall system in use. Plans must provide for initial service inspections, proper training, and demonstration of use for rental and physician owned equipment, as well as the criteria for the selection of medical equipment.

3. There must be a regular periodical maintenance, testing and calibration program for medical devices and equipment. A qualified individual must monitor, test, calibrate, and maintain the equipment periodically in accordance with the manufacturer’s recommendations, risk based, industry practices and/or healthcare organisation experience, and applicable laws and regulations.

**NOTE 1** As a part of this risk assessment process to determine maintenance intervals that consider safety, equipment availability and service life the following should be considered:

- a) consulting manufacturer recommendations;
- b) applicable codes and standards or accreditation requirements;
- c) health and safety information relevant to potential hazards;
- d) appropriate training and education of staff regarding the use of equipment;
- e) likelihood of an injury or illness occurring and the likely severity of any injury;
- f) illness resulting from the use of equipment.

27.8 Utility Systems Program

1. The healthcare organisation shall develop and maintain a Utility Systems Program that ensures a safe and effective facility that decreases the risk for healthcare organisation acquired illness.

2. The healthcare organisation must identify critical operating components and have methods for regular maintenance, inspections, and testing for these utility systems.

3. The healthcare organisation must have a dependable emergency power source with relevant required maintenance procedures with inspection logs.

4. The healthcare organisation shall have provisions for emergency gas and water supply.

5. There shall be emergency power and lighting in at least the operating, recovery, intensive care, and emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights must be available.

6. There shall be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, laboratory, and other appropriate areas.
7. The healthcare organisation shall ensure that the condition of the physical plant and overall environment is developed and maintained in a manner to ensure the safety and wellbeing of patients, visitors, and staff.

8. The healthcare organisation will ensure that routine and preventive maintenance and testing activities are performed as necessary, in accordance with national and local laws, regulations, and guidelines and manufacturer’s recommendations, by establishing maintenance schedules and conducting ongoing maintenance inspections to identify areas in need of repair.
STANDARD 28
Sterilization and Disinfection Services

28.1 General

1. When applicable the healthcare organisation shall establish and maintain procedures to ensure measures required for sterilization and disinfection are effectively identified, specified, implemented and monitored for all relevant materials and activities with regard to infection risk must establish procedures for the sterilization process and verify the process is controlled and monitored.

2. The healthcare organisation shall review the specific procedure(s) for the sterilization and disinfection process selected and the methods for controlling and monitoring the process.

3. If review of the device history records (including process control and monitoring records, acceptance activity records, etc.) reveals that the sterilization process is outside the organisation’s tolerance for operating or performance parameters:
   a) determine whether the non-conformances were handled appropriately;
   b) review the equipment adjustment, calibration and maintenance;
   c) provide for appropriate mitigation of incurred damage.

4. If the sterilization and disinfection process is software controlled, the healthcare organisation must confirm that the software was validated.

5. The personnel shall be appropriately qualified and/or trained to implement the sterilization and disinfection process.

6. Where the results of a process cannot be fully verified by subsequent inspection and tests, the process shall be validated with a high degree of assurance and approve according to established procedures. The validation activities and results, including the date and signature of the individual(s) approving the validation and where appropriate the major equipment validated, shall be documented.

**NOTE 1** When planning and conducting disinfection and sterilization activities, the organisation should consider issues including but not limited to:

   a) potential health and safety hazards associated with processes adopted (e.g. exposure to harmful chemicals, excessive heat / pressure);
   b) ensuring all disinfectants contain sufficient active compound for their intended use under a given circumstance (e.g. when organic matter may be present, loss of active ingredient over time);
   c) ensuring adequate methods and resources are available to deal with routine work and any spillages or other incidents during handling and transport of waste and potentially infectious material inside and outside the healthcare facility.

**NOTE 2** Validation measures should consider issues including but not limited to:

   a) an ability to maintain adequate conditions throughout the cycle, including contact times;
   b) manufacturer’s recommendations regarding materials used (agents used and materials to be subjected to treatment);
c) ensuring methods are available for effective decontamination of mixed waste (e.g. infectious waste that have radioactive materials);
d) material compatibility issues (e.g. interaction with stainless steel or rubber seal);
e) implementing monitoring measures to ensure the methods have been effective (e.g. cycle recording and use of indicators).

28.2 Selection of medical devices and equipment

1. The organisation shall establish procedures for the selection of equipment, medical devices and other items which may require be disinfecting and / or sterilizing, to ensure this can be carried out effectively.

NOTE 1 When planning the purchase or medical devices, equipment or other items which may become contaminated, a formal specification and approval process should be adopted to ensure items will be fit-for-purpose with regard to infection risk.

NOTE 2 When planning and conducting selection of medical devices and equipment, the organisation should consider issues including but not limited to:

a) ensuring that validated methods are available for decontamination of sensitive equipment, especially if not suitable for autoclaving (e.g. sensitive medical devices);
b) engaging relevant internal and external parties (e.g. in-house decontamination specialists, suppliers) to ensure processes support selection of these items (e.g. appropriateness of available means of disinfection / sterilization);
c) ensuring process flow / timing, space, storage and transport requirements can be met with respect to need for adequate and validated disinfection and / or sterilization;
d) ensuring risk of transferring infection via medical instruments, equipment and other items is considered as part of assessment for selection, processing / reprocessing.

28.3 Storage and segregation

1. The healthcare organisation shall establish effective procedures for the handling and storage of processed / reprocessed medical devices and other equipment to ensure they remain fit-for-purpose with regard to infection risk.
STANDARD 29
Information Security Management

29.1 General

1. The healthcare organisation shall establish and maintain a documented information Security Management (ISM). This shall address the assets to be protected, the healthcare organisation’s approach to risk management, the control objectives and controls, and the degree of assurance required.

2. The ISM policy shall be established and maintained. The policy shall be reviewed regularly, and in case of influencing changes, to ensure it remains appropriate.

3. The ISM policy shall be approved by management, published and communicated, as appropriate, to all employees.

29.2 Outsourcing

1. When the responsibility for information processing has been outsourced to another organisation the healthcare organisation shall maintain the security of information.

2. The security requirements of a healthcare organisation outsourcing the management and control of all or some of its information systems, networks and/or desk top environments shall be addressed in a contract agreed between the parties.

29.3 Equipment security

1. Equipment shall be sited or protected to reduce the risks from environmental threats and hazards, and opportunities for unauthorized access.

2. Security procedures and controls shall be used to secure equipment used outside an organisation’s premises.

3. Information shall be erased from equipment prior to disposal or re-use.

4. Organisations shall have and implement a clear desk and a clear screen policy in order to reduce the risks of unauthorized access, loss of, and damage to information.

29.4 Access control

1. The requirements for access control shall be defined and documented, and access shall be restricted to what is defined in the access control policy.

2. There shall be a formal user registration and de-registration procedure for granting access to all multi-user information systems and services.
3. The allocation and use of privileges shall be restricted and controlled.

4. The allocation of passwords shall be controlled through a formal management process.

5. Users shall be required to follow good security practices in the selection and use of passwords.

6. Users shall be required to ensure that unattended equipment has appropriate protection.

**NOTE 1** The allocation of passwords should be controlled through a formal management process, the approach of which should:

a) require users to sign a statement to keep personal passwords confidential and work group passwords solely within the members of the group (this could be included in the terms and conditions of employment);

b) ensure, where users are required to maintain their own passwords, that they are provided initially with a secure temporary password which they are forced to change immediately;

c) the use of third parties or unprotected (clear text) electronic mail messages should be avoided. Users should acknowledge receipt of passwords;

d) passwords should never be stored on computer system in an unprotected form.

### 29.5 Business continuity management

1. It order to counteract interruptions to business activities and to protect critical business processes from the effects of major failures or disasters the healthcare organisation shall develop a managed process for business continuity.

2. A strategy plan, based on appropriate risk assessment, shall be developed for the overall approach to business continuity.

3. Plans shall be developed to maintain or restore business operations in a timely manner following interruption to, or failure of, critical business processes.

**NOTE 1** A business continuity management process should be implemented to reduce the disruption caused by disasters and security failures (which may be the result of, for example, natural disasters, accidents, equipment failures, and deliberate actions) to an acceptable level through a combination of preventative and recovery controls.

**NOTE 2** The consequences of disasters, security failures and loss of service should be analysed. Contingency plans should be developed and implemented to ensure that business processes can be restored within the required timescales. Such plans should be maintained and practised to become an integral part of all other management processes. Business continuity management should include controls to identify and reduce risks, limit the consequences of damaging incidents, and ensure the timely resumption of essential operations.
International Accreditation Standards for Healthcare Organisations