

DNV GL STANDARD
DNV-DS-HC102



INTERNATIONAL ACCREDITATION REQUIREMENTS

Standard, Interpretive Guidelines and Surveyor Guidance for Hospitals

AUGUST 2014, VERSION 3.2

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FOREWORD

Driven by our purpose of safeguarding life, property and the environment, DNV GL enables organizations to advance the safety and sustainability of their business. Operating in more than 100 countries, our 16,000 professionals are dedicated to helping our customers, many operating in safety critical sectors including healthcare, to make the world safer, smarter and greener.

DNV GL has developed a suite of Standards, Interpretive Guidelines and Surveyor Guidance to meet the needs of different types of healthcare organizations. These are:

- DNV GL International Accreditation Standard for Hospitals
- DNV GL International Accreditation Standard for Primary Care Providers
- DNV GL International Accreditation Standard for Outpatient specialist Centres.

These Standards, Interpretive Guidelines and Surveyor Guidance document are based upon the NIAHO® accreditation standard that has been approved by the US Government's Centers for Medicare and Medicaid (CMS). The NIAHO® Interpretive Guidelines are periodically updated based on notices distributed from CMS and/or from other stakeholders and this may also lead to changes to these international requirements. When new or revised requirements are introduced to the international requirements these will be published together with a time frame that will indicate when hospitals are expected to be able to demonstrate compliance.

As part of the periodic revision of our Standards, Interpretive Guidelines and Surveyor Guidance we would of course welcome input from any interested stakeholder.

Please direct comments and suggestions to: DIASpost@DNVGL.com

CHANGES

Version	Reason for changes
1.0	Developed from DNV's NIAHO Standard in December 2010
2.0	Revised based on feedback from hospitals, US and UK surveyors and technical staff and DNV RI patient safety group
3.0	Periodic Revision
3.1	Minor errors corrected, no change in content
3.2	Change to DNV GL and minor formatting errors corrected

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Section 1 Scope

The requirements of this Standard are designed to support the development and continual improvement of healthcare quality and patient safety in hospitals. It also addresses general safety for workers, patients and other visitors within hospitals. For the purposes of this standard a “hospital” means an institution which:

- 1) is primarily engaged in providing healthcare, by or under the supervision of physicians, to inpatients¹ as well as outpatients and provides either;
 - (A) diagnostic and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, and/or;
 - (B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons, and/or;
 - (C) provides psychiatric services for the diagnosis and treatment of mentally ill persons;
- 2) maintains clinical records on all patients;
- 3) ensures patients are under the care of a physician, except patients receiving qualified psychologist services which then may be under the care of a clinical psychologist with respect to such services to the extent permitted under national and local regulatory standards, regulations and requirements;
- 4) has active physician involvement with patients during their treatment through qualified medical staff, physician-directed treatment with physician on-site availability on a daily basis to review patient progress, and consulting physicians on call and capable of being at the patient’s side within a moderate period of time;
- 5) provides 24-hour nursing services rendered or supervised by a (registered) professional nurse, and has a (registered) professional nurse on duty at all times present on the premises to render or supervise the nursing service provided;
- 6) has interdisciplinary team treatment for patients, requiring interdisciplinary teams of health care professionals, including physicians, to prepare and carry out an individualized treatment plan for each patient.

1) Inpatient care refers to care for a patient who is formally admitted (or ‘hospitalized’) to an institution for treatment and/or care and stays for a minimum of one night in the hospital or other institution providing in-patient care.

Section 2 Application

The requirements of this standard are generic and are intended to be applicable to all hospitals as defined above. Where any requirements of this standard cannot be applied due to the nature of the hospital 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 hospital's ability or responsibility to control the manner required by this standard. Any claims of exclusion shall be detailed and justification provided.

Compliance with national and local regulatory standards, regulations and requirements are of primary importance for any hospital. Where any part of this standard is in conflict with any legal requirement, the conflicting part of the standard may be eligible for exemption if the legal requirement meets or exceeds the intent of this standard.

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

These 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 hospital's effectiveness and efficiency. Application of the management systems approach principle leads to the following actions:

- a) defining the system by identifying or developing the processes that affect quality and safety objectives;
- b) structuring the system to achieve the quality and safety objectives in the most effective manner;
- c) understanding the interdependencies among the processes of the system;
- d) continually improving the system through measurement and evaluation, and;
- e) establishing resource constraints prior to action.

An effective management system approach should be built on the concept of continual improvement through a cycle of planning, implementing, reviewing and improving the processes and actions that an organization undertakes to meet goals. This is known as the PDCA (Plan-Do-Check-Act) principle:

Plan: Planning, including identification of hazard and risk and establishing goals,

Do: Implementing, including training and operational issues,

Check: Checking, including monitoring and corrective action,

Act: Reviewing, including process innovation and acting to make needed changes to the management system.

In order to improve quality and safety management the hospital needs to focus on the causes of non-conformities and undesirable events. Systematic identification and correction of system deficiencies leads to improved performance and control of quality and patient safety and general safety.

Section 3 Quality Management System (QM)

QM.1 – Quality Management System

- SR.1** The governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring that the hospital implements and maintains an effective quality management system. This quality management system shall ensure that corrective and preventive actions taken by the hospital are implemented, measured and monitored.
- SR.2** In addition to any other Quality Management System standard, the hospital is required to comply with QM.1 at all times as a part of its Quality Management System. Until the hospital achieves ISO 9001 Compliance/ Certification, the hospital shall follow at a minimum the ISO 9001 methodology specified in QM.2, SR.3 (below).
- SR.3** The hospital shall develop, implement and maintain an on-going system for managing quality and patient safety.
- SR.4** The hospital shall implement hospital-wide quality assessment and performance improvement efforts to address priorities for improved quality of care and patient safety and that corrective and preventive actions are implemented and evaluated for effectiveness.
- SR.5** The hospital shall assure that adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and reducing risk to patients.

QM.2 – ISO 9001 Quality Management System

- SR.1** Compliance with the ISO 9001 standard shall occur within three (3) years after the initial deemed DNV GL Hospital Accreditation. The Hospital shall either demonstrate compliance with the ISO 9001 Quality Management System principles through a DNV GL Hospital Accreditation survey or maintain Certification through an Accredited Certification Body. Only certificates covered by an accreditation by MLA (International Accreditation Forum Multilateral Recognition Agreement) signatory shall be eligible. The hospital shall maintain ISO 9001 compliance or formal Certification in order remain eligible for DNV GL Hospital Accreditation.
- SR.2** The Certification Body shall meet the following requirements:
- it shall be accredited under codes for EAC code 38 or NACE code 85.11 by a national accreditation body that is a member of IAF; and
 - it shall have certified or conducted a pre-assessment at a minimum of twelve (12) hospitals.
- SR.3** The hospital shall initiate and continue implementation of the ISO 9001 methodology to achieve compliance or certification as stated in QM.1. At a minimum the hospital shall be able to demonstrate at the time of the DNV GL Hospital Accreditation survey evidence of the following:

- a) control of Documents: the hospital'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 hospital ensures that suitable records are maintained for the requirements of this standard;
- c) internal Surveys (Internal Audits): the hospital conducts internal reviews of its processes and that resultant corrective/preventive action measures have been implemented and verified to be effective;
- d) corrective and Preventive Action: the hospital shall have a mechanism in place to document and monitor corrective and preventive action implemented in some manner to address improvement and changes, where appropriate;
- e) the hospital has established measurable quality objectives and the results are analysed and addressed; and
- f) appropriate information has been submitted to the oversight group for quality management as required in QM.6 SR.1 as well as top management for review and analysis during a management review process.

Interpretive Guidelines:

The ISO 9001 requirements are assessed during each survey of the organization. The organization has 3 years from initial accreditation to achieve compliance or certification to ISO 9001. If the organization is currently certified to ISO 9001, the Certification Body that currently certifies the organization shall be verified using current criteria established under SR.2a and SR.2b. This should be verified prior to the organization's accreditation survey.

The organization shall demonstrate that aspects consistent with ISO 9001 methodologies identified in SR.3a-SR.3f (above) are present. This may not be of level of compliance with ISO 9001 but will be in place in some manner. If the survey team is conducting the annual ISO periodic survey during the accreditation 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. A separate ISO 9001 report will be created to indicate any findings as a result of the ISO survey when applicable.

Surveyor Guidance:

The lead surveyor will be provided information regarding the organization with regard to their current compliance or certification status to ISO 9001 prior to the accreditation survey.

The lead surveyor will describe the process to the senior leadership for being in compliance with or attaining certification to ISO 9001 if the organization is not already ISO certified.

If the organization is already certified to ISO 9001 and the survey team is not conducting the periodic annual survey required by ISO at the time of the accreditation survey, the lead surveyor will verify that the Certification Body is itself accredited in accordance with QM.1, SR.2.

The survey team will verify that the organization has implemented mechanisms to demonstrate that similar practices in place consistent with ISO methodologies as listed in SR.3a – SR.3f are present in some manner and continued through the period the hospital is required to maintain compliance or certification to ISO 9001 at which time the full scope of the ISO 9001 requirements shall be met as stated within the timeframe under SR.1

QM.3 – Quality Outline/plan

SR.1 The hospital shall clearly outline its methodology, practice and related policies for addressing how quality and performance are measured, monitored, analyzed and continually improved to improve health outcomes and reduce risks for patients.

Interpretive Guidelines:

The organization will present documentation to the survey team that clearly defines how quality and performance are measured, monitored, analyzed and continually improved.

Surveyor Guidance:

The organization can document conformance in a variety of ways. An example would include a Quality Manual or Performance Improvement / Quality Management Plan. Verify that the organization has clearly defined how they measure quality and performance. The monitoring methods, data analysis and effectiveness of action(s) taken will be verified.

QM.4 – Management Representative

SR.1 A management representative shall be designated by top management and shall have the responsibility and authority for ensuring that the requirements of the Quality Management System are implemented and maintained.

Interpretive Guidelines:

The senior leadership is required to designate an individual as a Management Representative. A requirement of ISO 9001 is to define the Management Representative's responsibilities. The Management Representative is responsible for the process for internal reviews (internal audit) and management reviews to ensure that corrective and preventive action(s) are carried out and are measured for effectiveness. The role may be assigned to a current practitioner or employee.

Surveyor Guidance:

Verify documentation to demonstrate that the Management Representative has been identified and that there is a defined scope of responsibilities for this individual.

QM.5 – Documentation and Management Reviews

SR.1 Any variation, deficiency or non-conformity identified by the hospital shall be addressed by the hospital. Appropriate corrective or preventive action shall be determined, applied, and documented. This documentation shall become a part of the Management Review performed at regular intervals, at a minimum of once annually.

Interpretive Guidelines:

The organization is to have identified, applied and documented nonconformity (non-compliance) throughout the organization and the subsequent corrective/preventive action(s) taken. The organization can demonstrate this in various ways, as appropriate to the organizations size. There should be information present that validates that the organization has corrected the nonconformity and that the action(s)

implemented have been effective and sustained. The organization should be able to demonstrate that planned actions were effective by quantifiable measurement.

A management review is defined as a formal evaluation by top management of the status, adequacy and effectiveness of the quality management system (QMS).

The results of these activities are communicated to senior leadership, usually conducted as a part of management review.

Surveyor Guidance:

Review examples of the following: Nonconformity Reports, Root Cause Analysis, and corrective action plans/actions. The organization shall be able to demonstrate that the follow up processes for addressing non conformities are effective. If there are different means for reporting non-conformity, the surveyor will determine the consistency of the process to ensure its effectiveness.

QM.6 – System Requirements

- SR.1** A group or individual shall oversee the Quality Management System that includes representatives from management, physicians and other clinical staff as appropriate to the size and complexity of the hospital. This group or individual shall conduct Management Reviews;
- SR.2** The hospital shall have a written document defining the Quality Management System, to include all clinical and non-clinical services, as appropriate to the size and complexity of the hospital;
- SR.3** The hospital shall have a statement of the Quality Policy;
- SR.4** The hospital shall have measurable Quality Objectives; and
- SR.5** Measurement / Prioritization of activities shall:
- focus on high-risk, problem-prone areas, processes or functions;
 - consider the incidence, prevalence and severity of problems in these areas, processes or functions; and
 - affect health outcomes, improve patient safety and quality of care.

Interpretive Guidelines:

The Management Representative supports and facilitates the Quality Management System; however, it is the responsibility of senior leadership to review these activities and see that appropriate actions are taken for continual improvement. The Quality Manual or other similar document outlines the process that the organization has in place. This Quality Manual will include or reference the policies and procedures for the Quality Management System, Quality Policy, and Quality Objectives. The hospital shall prioritize high risk areas, processes or functions. Risk may be considered high due to high likelihood of failure/occurrence, high consequence, or a combination of both.

The organization shall carry out Management Reviews which encompass review of corrective/preventive actions taken, results from internal reviews (internal audits), customer (patient) satisfaction, data analysis (including litigation where applicable) and other performance improvement activities. The Management Review Process is to be carried out by senior leadership throughout the organization.

Surveyor Guidance:

Verify that the management reviews have taken place and there are appropriate minutes recorded.

The Quality Management System will be documented in a Quality Manual, Performance Improvement Plan or similar document as identified by the organization.

QM.7 – Measurement, Monitoring, Analysis

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

SR.2 Monitoring shall include the use of internal reviews (audits) of each department or service at scheduled intervals, not to exceed one year, and data related to these processes. Individual(s) not assigned to that department or service shall conduct the internal review (audit).

SR.3 Measurement, monitoring and analysis of processes throughout the hospital require established measures that have the ability to detect variation and identify processes where the degree of variation is a concern, identify both positive and negative outcomes, and effectiveness of actions taken to improve performance and/or reduce risks. The hospital shall define the frequency and detail of the measurement. Those elements to be measured at a minimum shall include the following:

- a) Threats to patient safety (i.e. falls, pt. 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) Anaesthesia/moderate sedation;
- e) Blood and blood components;
- f) Restraint use/seclusion;
- g) Effectiveness of pain management system;
- h) Infection control system, including hospital acquired infections (HAI) and antimicrobial resistance;
- i) Utilization Management System;
- j) Patient flow issues, to include reporting of patients held in the Emergency Department or Anaesthesia Recovery Units for extended periods of time (as defined by the hospital);
- k) Customer satisfaction, both clinical and support areas;
- l) Discrepant pathology reports;
- m) Unanticipated deaths, adverse and/or sentinel events;
- n) Near misses;
- o) Readmission rates;
- p) Other adverse events;

- q) Critical and/or pertinent processes, both clinical and supportive;
- r) Completeness and accuracy of healthcare / medical records; and
- s) Physical Environment Management Systems.

Interpretive Guidelines:

In order for the organization to continually improve its Quality Management System, the services and processes shall be measured to determine their effectiveness. Through an internal review (internal audit) mechanism, the organization 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.

The processes to be measured, monitored and analyzed shall be identified by the hospital shall be based on risk (see Section 4) and shall address the processes/issues listed in SR.3 above. These shall be measured to determine the effectiveness of these processes for continual improvement and preserving the safety of the patients and staff.

The organization should have collected and analyzed data in the respective areas listed above to demonstrate that these processes are closely monitored.

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

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.

Surveyor Guidance:

The organization can demonstrate the effectiveness of its Quality Management System through internal audits which as a minimum shall include the areas listed above. Where the audits/monitoring processes identifies deficiencies there shall be evidence that action plans have been developed and changes implemented.

Section 4 Safety Risk Management (RM)

RM.1 – Planning and Resources

- SR.1** The hospital shall ensure that a risk management system is established that addresses patient safety as well as other safety risks that may impact on patients, staff or other visitors to the hospital. The risk management system shall be implemented and maintained and the performance of the system reported to senior management for review and as a basis for improvement.
- SR.2** The organization shall ensure the approach to risk assessment is defined with respect to its objectives, scope, nature and timing so that it is proactive rather than reactive.
- SR.3** The hospital shall identify resource requirements and provide adequate resources for risk management, including the assignment of trained personnel for management, performance of work, and verification activities, including internal review.

Interpretive Guidelines:

The roles and responsibilities of personnel who perform and verify work affecting risk management should be defined and documented, particularly for people who need authority to do one of the following:

- I. initiate action to prevent or reduce the adverse effects of risk;*
- II. control further treatment of risks until the level of risk becomes acceptable;*
- III. identify and record any problems relating to the management of risks;*
- IV. initiate, recommend or provide solutions through designated channels; and*
- V. communicate and consult internally and externally as appropriate.*

The following may trigger either a new risk assessment or review of an existing one:

- VI. commencement of new work or changes to services that may alter or introduce new risks to patient staff or visitors;*
- VII. new construction / modifications to hospital facilities;*
- VIII. introduction of altered and unplanned staffing arrangements personnel);*
- IX. significant alterations to Standard Operating Procedures (SOPs) or working practices;*
- X. when unexpected events that may have relevance for the management of patient care or staff or visitor safety are observed;*
- XI. when actual or potential non-conformity with internal / external rules and regulations is identified (e.g. introduction of new legislation or following major accidents or incidents);*
- XII. when considering emergency response and contingency planning requirements; and*
- XIII. as part of the existing management system review process (e.g. annually or at another appropriate and predetermined frequency).*

RM.2 – Risk Assessment

- SR.1** The hazards associated with proposed work shall be identified and documented.
- SR.2** The organization shall ensure that suitable methodologies for assessing and recording risks are identified, implemented and maintained.

Interpretive Guidelines:

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.

RM.3 – Risk Management

- SR.1** The organization shall ensure suitable methodologies for the allocation of actions resulting from risk assessments, including time lines, responsible persons and associated reporting and approval mechanisms are identified, implemented and maintained.
- SR.2** Management shall establish the controls and put in place documented procedures for monitoring the effectiveness of the controls being applied to reduce or eliminate the hazards identified in the risk assessment process.

RM.4 – Reporting

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

Interpretive Guidelines:

The hospital shall be able to demonstrate that they have a hospital wide approved document which as a minimum shall include:

- I. Roles and responsibilities for the management of risk throughout the hospital;*
- II. Training requirements related to risk management and adverse event reporting;*
- III. Processes for assessing all risks throughout the hospital;*
- IV. Process for ensuring systematic management of all identified risks throughout the hospital;*
- V. Process for informing patient and or their families about unexpected adverse event; and*
- VI. Process for ensuring where deficiencies are identified (e.g. through risk assessment, adverse incidents, litigation, and customer satisfaction) action plans are developed and implemented to ensure continual management/improvement.*

Surveyor Guidance:

The organization shall provide a hospital wide approved document which as a minimum shall include:

- I. Roles and responsibilities for the management of risk throughout the hospital*
- II. Processes for assessing all risks throughout the hospital*
- III. Process for ensuring systematic management of all identified risks throughout the hospital*
- IV. Process for informing patient and or their families about unexpected adverse events*
- V. Process for ensuring where deficiencies are identified (e.g. through risk assessment, adverse incidents, litigation, and customer satisfaction) action plans are developed and implemented to ensure continual management/improvement.*

Evidence of implementation of the above shall be available.

Section 5 Governing Body (GB)

GB.1 – Legal Responsibility

- SR.1** The hospital shall have an effective governing body legally, (or organized group or individual(s) who assumes full legal authority and responsibility for operations of the hospital), responsible for the conduct of the hospital as an institution. The governing body is responsible for all services provided in the hospital including all contracted services. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital shall carry out the functions specified.
- SR.2** The governing body (or organized group or individual(s) who assumes full legal authority and responsibility for operations of the hospital), physicians, and administrative officials (to include the chief executive officer and chief financial officer) are responsible and accountable for ensuring the following:
- the hospital is in compliance with all applicable national and local legislation and regulations regarding the health and safety of its patients;
 - the hospital is licensed by the appropriate bodies;
 - personnel working in the hospital are properly licensed / registered;
 - the hospital meets all applicable national and local legislation and regulations.

Surveyor Guidance:

Verify that the organization has an organized governing body and/or has written documentation that identifies the individual or individuals that are legally responsible for the conduct of the organization operations.

Interview the organization leadership to determine the reporting structure regarding how information flows to and from the governing body or legally responsible individual(s). Verify all elements of the standard requirements exist.

GB.2 – Institutional Plan and Budget

- SR.1** The hospital shall have an overall plan that includes an annual operating budget that contains all anticipated income and expenses and is prepared according to generally accepted accounting principles.
- SR.2** The plan shall contain but not be limited to:
- acquisition of land;
 - improvement of land, buildings and equipment; and
 - replacement, modernization or expansion of buildings or equipment.
- SR.3** The plan shall be reviewed and updated annually.

SR.4 The plan shall be prepared under the direction of the governing body (or organized group or individual(s) who assumes full legal authority and responsibility for operations of the hospital) and by a committee that includes representatives of the governing body, the administrative staff, and the medical staff of the institution.

Surveyor Guidance:

Verify that an institutional plan and budget exist, includes descriptions of items and complies with all standard requirements. It is not within the scope of activities or responsibility of the surveyor to review and assess the amounts or structure of the institutional plan and budget.

Assess the process for developing the budget and the parties involved. Verify that the institutional plan and budget are updated at least annually and that the process is done under the direction of the governing body (or organized group or individual(s) who assumes full legal authority and responsibility for operations of the organization) and members of the administrative staff and medical staff.

GB.3 – Contracted Services

SR.1 The governing body or legally responsible individual(s) shall require annual management reviews of selected indicators to ensure that all contracted services (including all joint ventures or shared services) provide services that are safe and effective and that comply with the requirements of this document.

SR.2 The governing body or legally responsible individual(s) is/are responsible for services furnished by the hospital whether or not they are furnished under contract. The hospital shall evaluate and select contracted services (including all joint ventures or shared services and non-contracted services) entities/individuals based on their ability to supply products and/or services in accordance with the hospital's requirements. Criteria for selection, evaluation, and re-evaluation shall be established. The criteria for selection shall include the requirement that the contracted entity or individual to provide the products/services in a safe and effective manner and comply with the requirements of this document.

SR.3 A documented list of contracted companies and individuals, including their scope/nature of services shall be maintained.

Interpretive Guidelines:

The governing body or legally responsible individual(s) is responsible for assuring that organization services are provided in compliance with the above standards and according to acceptable standards of practice regardless of whether the services are provided directly by organization employees or by a contracted entity.

When services are provided by a contracted entity, the governing body or legally responsible individual(s) shall identify the criteria for selection and procurement of services, and the means of evaluating the contracted entity.

There may be arrangements where services are provided through one or more of the following: joint ventures; informal agreements; shared services; or, lease arrangements. These services are also subject to the criteria for selection and evaluation process.

Surveyor Guidance:

Determine the services that are carried out by a contracted entity and the scope of their responsibilities. In a sampling of these contracts, review a contract to see that it addresses the criteria for selection and the evaluation processes identified in the organization's policies and procedures. Verify that the organization has a mechanism in place to review the contract and performance of each entity no less than once annually.

Section 6 Chief Executive Officer (CE)

CE.1 – Qualifications

SR.1 The governing body or legally responsible individual(s) shall appoint a chief executive officer who is qualified through education and experience to be responsible for managing the hospital

CE.2 – Responsibilities

SR.1 The chief executive officer is responsible for operating the hospital, according to the authority conferred by the governing body or legally responsible individual(s). The chief executive officer 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.

SR.2 The chief executive officer shall ensure that the organization has defined and communicated the following:

- a) hospital mission or purpose;
- b) hospital values;
- c) ethics or code of behaviour;
- d) strategic objectives for the hospital; and
- e) the services provided.

SR.3 The chief executive officer shall ensure that there is a formal process for planning of services and that the process:

- a) is based the strategic objectives, mission and scope of the organization 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 hospital 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.

SR.4 The chief executive officer shall ensure that the hospital informs the public of:

- a) the services they provide; and
- b) the quality and performance of the services they provide.

Interpretive Guidelines:

Responsibilities shall include ensuring that the hospital identifies and is compliant with applicable national and local legislation and regulations and that it identifies and responds to relevant health policy documents where appropriate. The CEO shall also have overall responsibility for ensuring that care provided throughout the hospital is based on “recognized standards” where these exist. Recognized standards should be based on current scientific knowledge (evidence based clinical guidelines). Tasks to ensure that care given is based on recognized standards may be delegated through the organization provided that they are passed to competent individuals with adequate resources to perform the activities effectively.

The hospital shall be able to document the planning process which should feed into Departmental Scope of Service SM.3.

Surveyor Guidance:

Review the established requirements including education and experience required of the chief executive officer. This may be in the form of a job description or other document that adequately describes the scope of responsibilities.

Verify that the governing body or legally responsible individual(s) for the organization has appointed a chief executive officer and that he or she has met the requirement for this role within the organization and that he or she is responsible for managing the entire organization.

Review and verify that there are documents describing the hospital mission or purpose, values, ethics and strategic objectives. Assess through interviews with appropriate staff that the contents of the documents have been communicated.

Verify that there are processes or procedures in place to ensure that accurate and up-to-date information is made available to the public regarding the type of services provided and the quality and performance of those services. The data may be made available electronically or through written media.

Section 7 Medical Staff (MS)

MS.1 – Medical Staff

SR.1 The hospital shall have medical staff that is composed of fully licensed physicians or other professionals¹ who are licensed to practice without supervision and that provide preventive, curative, restorative, surgical, rehabilitative or other medical services to patients or that provide interpretative services for patients such as laboratory, pathology or radiology services.

1) For the purpose of this Standard the definition of “Physician” will depend on National licensing and regulatory requirements but may include Doctors of Medicine, Doctor of Dental Medicine, Doctor of Podiatric Medicine and Doctors of Ophthalmology.

MS.2 – Eligibility

SR.1 The governing body or legally responsible individual(s) shall determine, in accordance with applicable law and regulations, which categories of practitioners are eligible candidates for appointment to the medical staff.

Interpretive Guidelines:

The hospital shall have an organized medical staff that is composed of fully licensed physicians. In accordance with national license and regulatory requirements the medical staff may also include other non-physician’ practitioners who are approved by the medical staff and governing body or legally responsible individual(s) and eligible for appointment.

Surveyor Guidance:

Review documentation and verify that the governing body or legally responsible individual(s) has determined and stated the categories of practitioners who are eligible candidates for appointment to the medical staff.

Confirm that the governing body appoints all members to the medical staff in accordance with established policies that have been based on the individual practitioner’s scope of clinical expertise and in accordance with national licensing and regulatory requirements.

MS.3 – Accountability

SR.1 The medical staff shall be organized in a manner approved by and accountable to the governing body or legally responsible individual(s) and shall be responsible for the quality of the medical care provided to patients.

Interpretive Guidelines:

All patients shall be under the care of a member of the medical staff or under the care of a practitioner who is directly under the supervision of a member of the medical staff. All patient care is provided by or in accordance with the orders of a practitioner who has been granted privileges in accordance with local policies.

Surveyor Guidance:

Verify that the governing body is accountable for the medical staff and the quality of patient care services.

Validate the process by which the governing body monitors these activities of medical staff members.

MS.4 – Responsibility

SR.1 The responsibility for the organization and conduct of the medical staff shall be assigned to an individual physician.

Interpretive Guidelines:

The medical staff shall be accountable to the hospital's governing body or legally responsible individual(s) for the quality of medical care provided to patients. The responsibility for organization and conduct of the medical staff shall be assigned to an individual physician.

Surveyor Guidance:

Validate the process by which the governing body or legally responsible individual(s) monitors the quality of medical care provided to patients.

Verify that an individual physician is responsible for the conduct and organization of the medical staff.

MS.5 – Executive Committee

SR.1 The medical staff shall meet at regular intervals and minutes shall be maintained. If the medical staff has an executive committee, a majority of the members of the committee shall be physicians.

SR.2 The chief executive officer and the nurse executive of the hospital or designee shall attend each executive committee meeting on an ex-officio basis, with or without vote.

Surveyor Guidance:

Verify that the hospital has an executive committee and that physicians are members of the committee. If an executive committee is in place, the chief executive officer and nurse executive (or designee) are a part of the committee on an ex-officio. Review meeting minutes of the executive committee to verify the participation of the medical staff, CEO and CNO (or designee) attend these meetings.

MS.6 – Medical Staff Participation

SR.1 The medical staff shall participate in at least the following hospital 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; and
- g) Safety Risk Management System;
- h) Patient and family feedback oversight

SR.2 Reports and recommendations from these activities shall be prepared and shared with the medical executive committee and the governing body

Surveyor Guidance:

Verify through the review of minutes, data or other documentation that the medical staff participates in at least the following activities of the organization:

- I. Medication management oversight;*
- II. Infection control oversight;*
- III. Tissue review;*
- IV. Utilization review;*
- V. Medical record review; and,*
- VI. Quality Management System.*

Sample reports and recommendations from these activities to verify that information, data and other documentation are shared with the executive committee and the governing body and actions taken by medical staff and governing body or legally responsible individual(s) are evaluated to ensure implementation and effectiveness

MS.7 – Performance Data

SR.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.

SR.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) Anaesthesia 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; and

Interpretive Guidelines:

The governing body or legally responsible individual(s) shall ensure that the medical staff is accountable to the governing body for the quality of care provided to patients. The governing body or legally responsible individual(s) shall be provided with information (data) in order to evaluate the quality of care provided to patients.

The hospital shall define and measure the respective elements within this standard to generate a quality profile for each medical staff member to be used for evaluation.

Surveyor Guidance:

Verify that the governing body or legally responsible individual(s) is periodically appraised of the medical staff evaluation of patient care services provided hospital wide using indicators and other measures as stated within this standard.

View sample medical staff quality profiles or other documentation to validate that this data is being measured.

MS.8 – Continuing Education

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

Interpretive Guidelines:

In addition to the general continuing education for medical staff the hospital 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.

Surveyor Guidance:

View sample medical staff continuing education profiles or other documentation to validate that this requirement is being met.

MS.9 – Governing Body Role

- SR.1** The governing body or legally responsible individual(s) shall appoint or designate an individual/committee to approve members of the medical staff. Approval shall consider

recommendations of the existing members of the medical staff and ensure that the medical staff is accountable to the governing body or legally responsible individual(s) for the quality of care provided to patients.

- SR.2** The governing body or legally responsible individual(s) shall ensure that under no circumstances is medical staff membership in the hospital dependent solely upon certification, fellowship, or membership in a specialty body or society.
- SR.3** A complete application shall be acted on within a reasonable period of time, as specified by the hospital.

Interpretive Guidelines:

The governing body or legally responsible individual(s), with the advice of the medical staff, is responsible for the appointment of the individual practitioners of the medical staff.

The hospital cannot grant appointment that is solely based upon certification, fellowship or membership in a specialty body or society.

Surveyor Guidance:

Verify the timeframe for the credentialing and privileging process to see that actions are taken as required by the organization.

Review a sampling of records of medical staff appointments to determine as stipulated within the relevant policy that the governing body or legally responsible individual(s) is involved in appointments of medical staff members. The appointments shall not be based solely upon certification, fellowship or membership in a specialty body or society.

MS.10 – Clinical Privileges

- SR.1** The hospital shall have a process for determining the permissible clinical privileges to be granted to a physician based on documented procedures.
- SR.2** Granting or revision of clinical privileges should be made for a period not to exceed two years (unless prohibited by national laws).
- SR.3** All individuals who are permitted by the hospital to provide patient care services independently in the hospital shall have delineated clinical privileges.
- SR.4** There shall be a provision in the hospital for a mechanism to ensure that all individuals with clinical privileges provide services only within the scope of privileges granted.
- SR.5** The hospital 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.
- SR.6** The hospital 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; and,

c) gross-misconduct.

Interpretive Guidelines:

The organization shall develop criteria for determining the privileges to be granted to individual practitioners. There shall also be a procedure in place to ensure that these criteria have been met prior to privileges being granted.

The medical staff will define the criteria and there shall be a mechanism for consideration of automatic suspension of clinical privileges of a practitioner at a minimum when:

- I. The practitioner's professional license has been revoked or suspended for any reason;*
- II. Written medical record delinquency or deficiency requirements have not been met.*

Surveyor Guidance:

Review and verify that the organization has developed criteria for granting clinical privileges to individual practitioners and that a procedure exists for applying these criteria;

Verify the process in place to ensure practitioners only provide care to patients within the scope of the privileges granted

MS.11 – Temporary Clinical Privileges

- SR.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).
- SR.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 (as defined by the medical staff);
- SR.3** Temporary clinical privileges may only be granted for a period of time not to exceed one hundred twenty (120) days;
- SR.4** The hospital shall develop a process for approving practitioners for care of patients in the event of an emergency or disaster.
- SR.5** If the hospital 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 hospital 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 hospital.

Interpretive Guidelines:

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 (as defined by the medical staff);, for a period of time not to exceed 120 days.

Surveyor Guidance:

Review and verify that the hospital has a process in place to grant temporary privileges and the circumstances when this process may be completed.

Sample records and supporting documentation where a practitioner has been granted temporary privileges to validate the process that was followed.

MS.12 – Disciplinary or Rehabilitation Action

SR.1 The hospital 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 hospital operations. Any officer of the medical staff, CEO, or any officer of the board or legally responsible individual(s) may initiate this disciplinary or rehabilitative action.

Interpretive Guidelines:

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 organization. The organization 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, CEO or any officer of the board or legally responsible individual(s) may initiate the process for corrective or rehabilitative action.

The organization shall define examples of circumstances or criteria for applying the process for implementing corrective or rehabilitative action.

All hospital staff should be instructed in the process to follow when a practitioner is conducting him/herself in an unprofessional manner or present signs of impairment that would jeopardize the safety and quality of patient care.

Surveyor Guidance:

Review and verify that the organization addressed the mechanism for managing practitioners when corrective or rehabilitative action may be required.

Verify that the hospital has defined the circumstances when corrective or rehabilitative action may be taken.

Sample records and supporting documentation of a practitioner who has been subject to corrective and rehabilitative action and the process followed in order to promote patient safety and the quality of care provided.

MS.13 – Healthcare / Medical Record Maintenance

- SR.1** The hospital 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.
- SR.2** The hospital 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.

Interpretive Guidelines:

The organization 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.

The process for medical records completion and the actions taken shall be enforced by hospital 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.

Surveyor Guidance:

Review and verify that the process and respective policies and procedures are in place for addressing medical record delinquency.

Review and validate that the hospital has a means of determining its medical record delinquency rate and how this is defined.

Validate the enforcement of the organization's policies and procedures for practitioners delinquent in medical records completion.

Review and verify that the medical staff meets regularly to review and analyze medical records for the adequacy and quality of care provided. The organization shall maintain minutes or other records to verify the scope of the reviews conducted and the subsequent actions taken to address any findings.

MS.14 – History and Physical

- SR.1** The hospital shall ensure that a medical history and physical examination (HP) 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 HP shall be in the medical record prior to any high-risk procedure.
- a) An HP completed within 30 days prior to admission or registration shall include an entry in the medical record documenting an examination for any change in the patient's current medical condition completed by a medical physician or other qualified individual who has been granted these privileges by the medical staff in accordance with National and local legislation and regulations.
- b) This examination and update of the patient's current medical condition shall be completed and placed in the medical record within twenty four (24) hours after admission or registration, but prior to surgery or other procedure requiring anaesthesia services.

- SR.2** A physician's assistant or advance practice nurse may perform parts or the whole history and physical within the scope of their license and allowed/privileged by the hospital. The responsible physician shall review and approve the history and physical as specified by the medical staff.
- SR.3** The content of the HP examination shall be determined by an assessment of the patient's condition and any co-morbidities in relation to the reason for admission or surgery.

Surveyor Guidance:

Review and verify that the process and respective policies and procedures are in place for addressing the requirements for conducting History and Physical Examinations.

Review and validate within medical records that History and Physical examinations are being conducted appropriately.

MS.15 – Consultation

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

Surveyor Guidance:

Review and verify the circumstances and criteria which require consultation or management by a physician or other qualified licensed independent practitioner.

MS.16 – Autopsy

- SR.1** Authorized medical staff shall secure autopsies in accordance with legal requirements. Additionally, they may seek consent for an autopsy to facilitate learning. The hospital shall ensure that all staff involved in liaising with next of kin in relation to autopsies have sufficient understanding of the legal issues relating to autopsy and can provide appropriate and sensitive emotional support to next of kin
- SR.2** Mechanisms for documenting permission to perform an autopsy shall be defined.
- SR.3** There shall be a system for notifying the medical staff and specifically the attending practitioner when an autopsy is being performed.

Surveyor Guidance:

Verify that the organization has policies requiring practitioners to secure permission to perform autopsies where required as determined by national regulatory requirements.

Verify that there is a mechanism for documenting how permission is given to perform an autopsy.

For autopsies performed, validate the process for notifying the attending practitioner / regulatory bodies where applicable, when it was performed.

Verify that the medical staff has a process to review autopsies taking place within the hospital.

Section 8 Nursing Services (NS)

NS.1 – Nursing Service

- SR.1** The hospital shall have a nursing service with a plan of administrative authority and delineation of responsibilities for the delivery of patient care that meets service users' physical, emotional and social needs.
- SR.2** There shall be 24-hour nursing services and a registered nurse shall supervise and evaluate the nursing care for each patient. A registered nurse or licensed practical nurse shall be on duty at all times.
- SR.3** The nursing service shall develop and maintain a procedure to ensure that nursing personnel for whom licensure or registration is required have a valid and current licensure or evidence of registration. Nursing services shall be provided or supervised by a registered nurse.
- SR.4** The hospital shall complete a periodic skill mix assessment (see SM.3) where they can actively demonstrate that there are nurse to patient ratios on each shift that deliver safe and effective care that meets service users' physical, emotional and social needs.
- SR.5** All shifts in all clinical units where nursing care is provided shall be led by a registered nurse. A registered nurse shall make any decisions regarding delegation of nursing care to other nursing staff, based on individual patient need and staff qualifications.
- SR.6** Non-employee licensed nurses who are working in the hospital shall adhere to the policies and procedures of the hospital. The director of nursing services shall provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel that occur within the responsibility of the nursing service.

Interpretive Guidelines:

The hospital shall have an organized nursing service and shall provide on-site nursing services 24 hours a day, seven (7) days a week with at least one (1) registered nurse (RN) providing or supervising the service 24 hours a day, 7 days a week.

Nursing services shall be provided to all inpatients within the hospital. The hospital is required to have an RN on duty at all times (unless the exception applies under national legal and regulatory requirements).

An RN shall make all patient care assignments. The nurse executive and the hospital are responsible for ensuring that nursing personnel with the appropriate competence, qualifications and skills have been assigned to provide nursing care for each patient to meet their care needs.

If services are provided by contracted (non-employee) staff, the director of nursing service shall supervise and evaluate the clinical activities being performed by these individual(s). The non-employee staff are required to adhere to the policies and procedures of the organization and will receive an orientation regarding the organization's policies and procedures prior to working on-site for the organization.

Staffing: The hospital shall provide nursing services 24 hours a day, 7 days a week. An LPN can provide nursing services if an RN supervises that care. The RN shall be immediately available for the bedside care of those patients.

Surveyor Guidance:

Interview the nurse executive. The following may be requested prior to meeting the nurse executive:

- I. Organizational chart(s) for nursing services for all locations where the hospital provides nursing services;*
- II. Job descriptions or description of responsibilities for all nursing personnel including the nurse executive.*

The organization may have multiple patient care units. Sample at least one job description from each of these units. During the review of the organization, observe the nursing care in progress to determine how adequate staffing is determined as it applies to the delivery of care.

Review samples of the following documentation:

- III. staffing schedules;*
- IV. unit assignment sheets*
- V. nursing policies and procedures; and,*
- VI. internal survey and staffing variance reports .*

Interview patients to verify how nursing care has been provided. Secure hospital and patient permission before the interviews.

Review the nurse-staffing schedule (or similar documentation to apply staff) for a minimum of a one-week period. If minimal or less than desired staffing for the period is noted, review additional nurse-staffing schedules for a second week period to identify any patterns or trends for insufficient staffing.

Verify that nursing assignments include consideration of the complexity of the patient's care needs and that the nursing staff that care for the patients are competent and have the required qualifications.

Review the process for determining how nursing assignments and staffing are applied in the patient care setting. This process should encompass the following:

- VII. Patient needs;*
- VIII. Acuity of patients;*
- IX. Special needs of individual patients; and,*
- X. Competence and qualifications of nursing personnel.*

Verify the daily RN coverage for every unit of the hospital to determine that at least one RN for each unit and shift is on duty 24/7.

Review the recruitment efforts and methods used by the hospitals' administration by requesting copies of materials and demonstration of other methods to meet the nursing staff needs for the hospital.

If a nursing shortage exists, determine if it is a temporary shortage of qualified nursing personnel in the area or attributable to other reasons and how the hospital is addressing the issue.

NS.2 – Nurse Executive

SR.1 The nurse executive shall be a registered nurse.

- SR.2** The nurse executive is responsible for the operation of the service, including determining the types and numbers of staff necessary to provide nursing care for all patient care areas of the hospital and standards of nursing practice.
- SR.3** The nurse executive is responsible for the development, approval and implementation of all nursing service policies and procedures.

Interpretive Guidelines:

The nurse executive is a member of senior leadership and shall be appropriately qualified in accordance with national legal and regulatory requirements.

Operation of service: The nursing service shall ensure that patient needs are met. This includes ongoing assessments of patients' needs and nursing staff is provided to meet those needs.

Surveyor Guidance:

Review the nurse executive's job description. Verify that he or she has the appropriate education, licensure and experience for this position in the organization for operation of the nursing service.

Verify that the nurse executive determines appropriate staffing and personnel for patient care units as described in NS.1.

Review the organizational chart or plan for nursing services. Determine that the chart displays lines of authority that delegates responsibility within the department or nursing unit.

Verify that the nurse executive is involved in the development of and approves the nursing service patient care policies and procedures.

Evaluate the nursing service to ensure that it is appropriate according to the following:

- I. Physical layout and size of the hospital;*
- II. Number of patients;*
- III. Intensity of illness and nursing needs;*
- IV. Availability of nurses' aides and assistants and other support processes are provided (e.g., housekeeping services, unit secretaries);*
- V. Training and experience of personnel; and,*
- VI. Person-centered – empowers service users to make and act on choices, that service users are listened to and engaged as individuals, that service users receive the level and amount of information they wish.*

Section 9 Staffing Management (SM)

SM.1 – Licensure, Registration and Certification

SR.1 The hospital 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.

Surveyor Guidance:

Review and validate the hospital's policy and practice for performing primary and ongoing verification of the current licensure, registration and/or certification of all staff members as required by the organization, and national and regulatory requirements.

Review the process in place to enforce compliance and that data regarding verification and expirations is shared with Quality Management Oversight and/or Human Resources (Personnel) as needed.

SM.2 – Professional Scope

SR.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.

Surveyor Guidance:

Review the policy and verify that the hospital has a means of ensuring that all staff, including contract staff, students and volunteers are functioning within the limits of their scope of service as it has been defined by the hospital in accordance with national legal and regulatory requirements.

Verify the process for communicating any variations from provided services to Quality Management Oversight.

SM.3 – Department Scope of Service

SR.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; and
- e) Description of patient assessment and reassessment practices, including timeframes, where applicable;

SR.2 Hospital 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.).

Interpretive Guidelines:

The hospital will have a description of the scope of services provided, whether clinical or supportive, and each patient unit. This scope of service will address the following:

- I. The hours of operation;*
- II. Patient populations served;*
- III. Skill mix;*
- IV. Core staffing and methods for determining and modifying staffing to meet patient or process needs; and,*
- V. Description of assessment and reassessment practices, including timeframes.*

The hospital will describe and illustrate the sequence and interaction of these processes (services).

Surveyor Guidance:

Verify that the hospital has a description of the scope of services provided for all services including clinical or supportive, and encompasses each patient unit.

Verify that the scopes of service include the items listed above within the Interpretive Guidelines.

Review the documents and/or illustration that describe the sequence and interaction of these processes (services).

SM.4 – Determining and Modifying Staffing

SR.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.

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

Interpretive Guidelines:

The hospital will develop a method for determining and modifying staffing. Staffing will be validated through periodic reporting of variance from core staffing, and outline and deficiencies and justification for staffing modification. Validation of the measures regarding the impact of staffing on processes will be reported to Quality Management Oversight, when indicated.

Surveyor Guidance:

Review and verify the method(s) used by the hospital for determining and modifying staffing when indicated.

Validate that there is a means in place for reporting variances and other associated information to Quality Management Oversight.

SM.5 – Job Description

SR.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.

Surveyor Guidance:

Review and verify a sampling of job descriptions to verify that the hospital has identified the appropriate experience, educational and physical requirements and performance expectations for the positions reviewed. This includes contracted staff for nursing and/or other areas of the organization.

SM.6 – Orientation

SR.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.

SR.2 All staff, including medical staff, shall receive an orientation developed and approved by the hospital that includes general safety practices, emergency procedures, infection control, confidentiality and other issues as required by the hospital.

Interpretive Guidelines:

The hospital will require that all staff, including medical staff, contract staff, students and volunteers receive an orientation prior to working independently in their respective roles for the hospital.

This orientation will address, at a minimum, the following topics:

- I. Organizational structure;*
- II. Patient confidentiality and ethics;*
- III. Document control, retrieval and verification (specific to policies, procedures, and work instructions/protocols);*
- IV. Internal reporting requirements for adverse patient events;*
- V. Patient safety;*
- VI. General safety (work environment);*
- VII. Operation of equipment, including medical devices, in a safe manner;*
- VIII. Emergency procedures;*
- IX. Infection control and universal precautions; and,*
- X. Other issues as required by the hospital and national and regulatory requirements*

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.

Verify the process in place for members of staff including the medical staff completing a general orientation as noted within SR.1 and SR.2.

SM.7 – Staff Evaluations

SR.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.

SR.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; and
- i) requirements of national and local legislation and regulations as applicable
- j) other indicators as determined by the hospital

SR.3 Indicator measurement for contract staff may be modified based on hospital outcomes and frequency of service of individuals. Modification of this measurement(s) shall be made when needed and shall be justified by data analysis.

SR.4 The hospital 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.

- a) Reassessment of objective data shall follow any intervention.
- b) The outcomes of this aggregated data shall be reported to Quality Management oversight as needed to monitor staff performance improvement.

SR.5 The hospital 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 hospital, not to exceed one calendar year.

SR.6 The hospital 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.

Interpretive Guidelines:

The hospital 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:

- I. *Variations and problem processes identified through the analysis of outcomes measurement as required by the Quality Management System;*
- II. *High-risk, low volume procedures;*
- III. *New technology/equipment/processes;*
- IV. *Customer satisfaction feedback;*
- V. *Scheduled training session outcomes;*
- VI. *Staff learning needs assessments that include variations identified through prior staff performance measurement;*
- VII. *Staff feedback;*
- VIII. *Medical staff feedback; and,*
- IX. *Requirements of national legislation and regulatory requirements.*

The hospital 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 organization, not to exceed one calendar year.

The organization 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 hospital 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 hospital policy.

Surveyor Guidance:

In a sampling of personnel records, verify that the hospital has a performance/competency evaluation process that includes appropriate measures as stated within the Interpretive Guidelines (above).

Verify the policy and practice the hospital uses to validate the competency of staff occurs within a specified timeframe no less than once per calendar year.

Verify that the hospital requires and makes provisions for 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 hospital policy.

SM.8 – Health Promotion

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

Interpretive Guidelines:

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 hospital that may affect staff health shall be made freely available.

Surveyor Guidance:

Review and verify the health promotion policies and procedures (or health promotion plan).

Verify that staff is aware of where they can obtain help regarding use of tobacco, alcohol and other addictive substances.

Verify that staff has access to relevant information regarding factors that can impact on their health in the hospital.

Section 10 Patient Centered Care (PC)

PC.1 – Specific Rights

SR.1 The hospital shall inform, whenever possible, each patient and/or legal representative of the patient's rights in advance of providing or discontinuing care. The written listing of these rights shall be provided to the patient and /or family and shall include policies and procedures that address the following:

- a) Respect and dignity
- b) Patient participation and means for making informed decisions regarding his/her plan of care;
- c) Personal privacy;
- d) Provision of care in a safe setting;
- e) Freedom from all forms of abuse or harassment;
- f) Pain Management
- g) Confidentiality of clinical records;
- h) Patient access to clinical records as quickly as record keeping system permits and without the hospital impeding legitimate efforts of individuals to gain access to their own clinical records;
- i) Procedure for submission of a written or verbal grievance. (See PC.13- Grievance Procedure);
- j) When unexpected events occur, patients and/or their families can expect to receive an apology and explanation;
- k) Patient visitation rights; and
- l) Accommodation in single occupancy rooms are where this is not possible then multi-occupancy rooms shall be single-sex.

SR.2 The hospital shall demonstrate that they have mechanisms in place to ensure meaningful communication with service users in relation to the requirements in SR.1. The hospital shall demonstrate that such communication meets the needs of the different patient groups and populations served, including vulnerable individuals and hard to reach groups.

Interpretive Guidelines:

This standard requires that whenever possible, the hospital informs each patient and/or legal representative of the patient's rights in advance of providing or discontinuing care. The hospital will inform both inpatients and outpatients of their rights.

The hospital shall demonstrate that it has established and implemented policies and procedures that effectively ensure that patients and/or legal representative have the information necessary to exercise their rights and as a minimum shall consider all requirements of SR. 1.

The hospital has the responsibility to establish and implement policies and procedures that respect and support the patients' rights identified in SR.1 during the provision of care, including effectively ensuring that patients and/or legal representative have the information necessary to exercise their rights.

The hospital will provide for interpretation for certain individuals who speak languages other than the predominant language of the organization, use alternative communication techniques or aides for those who are deaf or blind, or take other steps as needed to effectively communicate with the patient.

The hospital's obligation to inform requires that the hospital present information in a manner and form that can be understood.

The hospital 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 hospital 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.

The hospital shall involve the patient or their legal representative in the development, implementation and revision of his/her plan of care. This shall, where appropriate, include addressing issues related to tobacco, alcohol and other addictive substances.

A patient may elect to delegate his or her right to make informed decisions to another person. To the degree permitted by national and regulatory requirements, and to the maximum extent practical, the hospital shall respect the patient's wishes and follow these accordingly.

Where delegation has occurred due to lack of capacity, as soon as the patient is able to be informed of his or her rights, the hospital should provide such information to the patient.

The patient or his or her representative should receive information provided in a manner that it is understood and to assure that the patient can effectively exercise the right to make informed decisions.

The patient and/or legal representative have the right to request or refuse treatment. This standard stresses, however, that the patient's right to make decisions about health care is not equivalent to an ability to demand treatment or services that are deemed medically inappropriate or unnecessary.

The right to personal privacy includes, as a minimum:

- I. patients have privacy during personal hygiene activities,*
- II. during medical/nursing treatments,*
- III. when requested by the patient as appropriate.*
- IV. limiting the release or disclosure of patient sensitive information*

The hospital should have procedures in place, in accordance with National and local legislation and regulations, to provide appropriate information to patient families or significant others in those situations where the patient is lacks capacity.

A patient's right to privacy may be limited in situations where a person shall be continuously observed, such as when restrained or in seclusion when immediate and serious risk to harm him/herself (such as when the patient is under suicide precautions or special observation status) or others exists.

The hospital shall have policies and procedures in place that ensure patients with physical and mental disabilities are not discriminated against in terms of access to diagnostic, therapeutic and nursing services.

The hospital staff should follow recognized standards of practice for patient environmental safety, infection control, and security. The hospital shall protect vulnerable patients, including newborns and children.

The hospital shall have mechanisms/methods in place that ensure patients are free of all forms of abuse, neglect, or harassment.

The hospital shall assure that any incidents of abuse, neglect or harassment are reported and analyzed, and the appropriate corrective, remedial or disciplinary action occurs, in accordance with applicable national and regulatory requirements.

Definition: Abuse is defined as the willful infliction of injury, unreasonable confinement, intimidation, or punishment, with resulting physical harm, pain, or mental anguish. This includes staff neglect or indifference to infliction of injury or intimidation of one patient by another. Neglect, for the purpose of this requirement, is considered a form of abuse and is defined as the failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness.

The hospital shall have sufficient safeguards in place to ensure that access to all information regarding patients is limited to those individuals designated by national and regulatory requirements and hospital policy. No unauthorized access or dissemination of clinical records is permitted. Clinical records are kept secure and are only viewed when necessary by those persons having a part in the patient's care.

Confidentiality applies to both central records and clinical record information that may be kept at other locations in the hospital, such as, patient units, radiology, laboratories, patient clinics, record storage areas, data systems, etc.

The hospital shall have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation. The hospital shall have a process for implementing these decisions.

The hospital shall:

- V. inform each patient (or representative, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, when he or she is informed of his or her other rights under this section;*
- VI. inform each patient (or representative, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time;*
- VII. not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, sexual orientation, gender identity, or disability;*
- VIII. ensure that all visitors designated by the patient (or representative, where appropriate) enjoy visitation privileges that are no more restrictive than those that immediate family members would enjoy.*

Surveyor Guidance:

Verify the hospital's policy for notifying all patients of their rights, both inpatient and outpatient.

Review the information that is provided to patients by the hospital.

Verify the method(s) used to inform patients of their rights.

Interview patients (with hospital and patient permission) to determine how the hospital has informed them about their rights.

Verify that the hospital has alternative means, such as written materials, signs, or interpreters, to communicate patients' rights, when necessary.

Validate that the hospital initiates activities that involve the patient or the patient's legal representative in the patient's care and the process for assuring that the patients have this information.

Verify that the hospital respects a patient's request for or refusal of certain treatments and the process followed when this occurs and how this is handled.

Verify that the hospital provides adequate information to patients and their representatives regarding the patient's health status, diagnosis and prognosis, and then how the patient is allowed to make informed decisions about their care planning and treatment.

In the review of patient care areas, verify that patients are provided privacy during examinations, procedures, treatments, surgery, personal hygiene activities and discussions about their health status/care and other appropriate situations.

Review and validate patient and staff incident and accident reports to identify any incidents or patterns of incidents concerning a safe environment.

Review and validate the system in place to protect patients from abuse, neglect and harassment of all forms, whether from staff, other patients, visitors or other persons. Review and verify that the hospital has a written procedure for investigating allegations of abuse and neglect including methods to protect patients from abuse.

Verify that the hospital has a process in place to notify appropriate agencies, including reporting requirements, as applicable, regarding incidents involving abuse, neglect or harassment, in accordance with national and regulatory requirements as well as notification to any law enforcement or other agency.

In review of patient care areas, verify that medical records are not accessible to people not involved with the patient's care.

Verify that the hospital promotes and protects the patient's right to access information contained in his/her clinical records and provides these records to patients within a reasonable timeframe.

Review the hospital policies on visitation and verify that they are being implemented accordingly.

Verify that the hospital has developed an active process for informing each patient (or representative, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights.

Verify that all patients (or representative, where appropriate) are informed that they can receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time.

Verify that patients have been able to receive all of the visitors that were designated by the patient (or representative, where appropriate) and that visitation privileges have been no more restrictive than those that immediate family members would enjoy.

PC.2 – Informed Consent

- SR.1** The hospital shall have approved documented processes for the taking of consent across all services provided.
- SR.2** 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.
- SR.3** The hospital shall identify which treatments/procedures require written consent. The approved document shall outline how this shall be documented.

Interpretive Guidelines:

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:

- I. Voluntarily;*
- II. With reasonable information to make an informed, purposeful decision;*
- III. By a mentally competent person.*

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.).

The hospital shall therefore demonstrate that it has considered where consent for treatment is required there is a documented process which as minimum shall include:

- IV. Process to be followed where the taking of consent is delegated;*
- V. Provision of patient information, (to include; risks associated with the treatment/procedure; benefits associated with the treatment/procedure; and alternatives available, if any); and*
- VI. Documentation of written consent.*

In the event of a medical emergency, the hospital 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 hospital to obtain patient written consent will include as a minimum;

- VII. high-risk procedures;*
- VIII. sedation;*
- IX. participation in research projects;*
- X. filming or videotaping.*

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.

A properly executed informed consent form contains at least the following:

- XI. Name of patient, and when appropriate, patient’s legal guardian;*
- XII. Name of hospital;*
- XIII. Name of specific procedure(s) or medical treatment);*
- XIV. Name of the responsible practitioner who is performing the procedure(s) or administering the medical treatment;*
- XV. Signature of patient or legal representative;*
- XVI. Date and time consent form is signed by the patient or the patient’s legal representative;*
- XVII. Statement that procedure/treatment including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient’s legal representative;*
- XVIII. Name of person who explained the procedure to the patient or guardian.*

Surveyor Guidance:

Verify that the hospital has specified which procedures or treatments require a written informed consent.

Verify that medical records contain consent forms for all procedures or treatments as required by hospital policy.

In a sampling of patient records, review and validate that consent forms are properly executed and contain at least the information identified above.

PC.3 – Language and Communication

- SR.1** The hospital shall ensure that it has access to competent, independent individuals to interpret for patients’ who do not speak the predominant language of the organization.
- SR.2** The hospital shall provide alternative communication aids for those who are, hearing impaired, vision impaired or have other specific needs.

Interpretive Guidelines:

The hospital shall evidence that it provides for interpretation for individuals who speak languages other than the predominant language of the organization. Wherever possible, interpreters should be independent (i.e. not family members). In addition the hospital shall evidence that it also provides alternative communication techniques or aides for those who are hearing impaired, vision impaired or have other specific needs, or take other steps as needed to effectively communicate with the patient.

PC.4 – Safeguarding Vulnerable People

- SR.1** The hospital shall have local systems in place to ensure that vulnerable people are cared for and managed appropriately.
- SR.2** Mechanisms shall be in place for referral to additional support services and for on-going continuation of care.

Interpretive Guidelines:

The hospital shall ensure that processes are in place for protecting vulnerable children and adults. Mechanisms and processes shall be in place to ensure that patients are assessed for being at risk of abuse or neglect. The process shall consider both the proactive measures that the organization should implement as well as the procedures to follow once a safeguarding issue has been either identified or suspected. The hospital should have in place a system to monitor which people have been assessed as at risk of being vulnerable and to coordinate/track what actions have been taken to manage that risk (including referral to specialist agencies).

PC.5 – Appointments and Recall

- SR.1** The hospital shall have an appointment system(s) to facilitate the provision of timely care for all patients within all care settings.
- SR.2** There shall be processes in place for ensuring that any patients who fail to attend an appointment are followed up in a timely manner. This shall include the management of persistent non-attendance.

Interpretive Guidelines:

It is important that the hospital has systems in place to ensure that all patients can access the services they need in a manner that is timely and coordinated both across internal services and with external stakeholders and agencies (e.g. primary care providers). The hospital shall provide evidence of the range of appointment systems it has in place across all care settings. The hospital shall also demonstrate the recall system(s) for patients when they fail to attend a given appointment. It is required that these systems consider also the management of those patients who persistently fail to attend.

PC.6 – Positive Patient Identification

- SR.1** There shall be a process in place, throughout all services provided by the hospital, for the positive identification of all patients.
- SR.2** Positive identification of all patients shall be considered on initial contact and throughout on-going care where applicable.
- SR.3** The hospital shall have a process for the reporting and management of patient misidentification.

Interpretive Guidelines:

Positive patient identification is central to the provision of safe and effective care. Reducing, and where possible, eliminating patient identification errors, is fundamental to improving patient safety. The hospital shall demonstrate that the organization has considered and implemented a safe system for patient recognition in order to reduce incidents of patient misidentification in all care settings.

PC.7 – Assessment and Plan of Care

SR.1 The hospital 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.

SR.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) Pre-existing 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 hospital nursing policies;

SR.3 Nursing staff shall complete an assessment according to the hospital nursing policies in all other areas of the hospital. (outpatient, clinics, surgical centers etc.).

SR.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.

SR.5 The hospital 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.

Interpretive Guidelines:

A plan of care begins within twenty four (24) hours of admission of the patient. The plan of care includes planning the patient's care from admission through discharge and the respective care processes involved. If interdisciplinary findings are indicated, these shall also be a part of the plan of care and documented in the medical record. The plan of care is based on assessing the patient's nursing care needs (not solely those needs related to the admitting diagnosis) and developing appropriate goals, nursing interventions in response to those needs, and evaluate the patient's progress toward those goals.

The hospital should also identify where and when additional specific assessments should be undertaken. These may address the following issues:

- I. Venous Thromboembolism risk (VTE);
- II. Moving and handling;
- III. Falls;
- IV. Pain management;
- V. Pressure area care;
- VI. Nutrition and hydration;
- VII. Control and restraint; and
- VIII. Do not attempt resuscitation (DNAR).

The plan of care is maintained and updated based upon ongoing assessments of the patient's needs and the patient's response to interventions, in response to assessments.

The named primary nurse will be known to the patient and will be on duty for the majority of the shifts that the patient is on the unit. Where the primary nurse is off-duty, then the responsibility for the care will be delegated to an associate nurse for that shift.

Surveyor Guidance:

Verify through patient record checks that appropriate assessments have been performed and that a named primary nurse was overseeing the care of individual patients. Interview patients to check that they are aware of whom their primary nurse is. Check duty records to ensure that the named primary nurses were on duty for the majority of the patients stay on the unit.

PC.8 – Transfer of Care

SR.1 Systems for transfer of patients, (internal and external – including but not limited to transfers from and to other hospitals, primary care, tertiary care and social services), shall be agreed and implemented throughout the hospital and as a minimum shall consider:

- a) Medications;
- b) Escort for the patient;
- c) Informing patient and next of kin;
- d) Essential equipment;
- e) Essential medical history;
- f) Verbal/written handover requirements; and
- g) Documentation requirements.

Interpretive Guidelines:

Failure to provide comprehensive information during transfers can lead to mistakes being made including delayed decisions, unnecessary repeated investigations and incorrect treatment. There shall be agreed and defined systems for the transfer of all patients cared for within the hospital. Whether it is an internal or external transfer the processes shall consider as a minimum requirements a-g, as above.

PC.9 – Resuscitation Equipment and DNAR

- SR.1** The hospital shall have processes in place to ensure the continual availability of resuscitation/emergency equipment in all care settings.
- SR.2** The equipment shall be checked to ensure that it is both available and in good working order at all times and in all care settings. Timescales and responsibilities for checking the equipment will be determined.
- SR.3** Any patient identified as requiring a DNAR shall be managed in accordance with the hospitals approved documented process.

Interpretive Guidelines:

All hospitals have an obligation to provide an effective resuscitation service and to ensure appropriate equipment for resuscitation is available, in good working order at all times. The hospital shall demonstrate the processes in place for checking equipment in all care settings.

The hospital should have an agreed documented process for invoking DNAR's when clinically necessary and allowable by national and local legislation and regulations.

PC.10 – Discharge Planning Policies

- SR.1** Written policies shall be in place to establish a system for discharge planning that applies to all patients.
- SR.2** At an early stage of hospitalization, all patients who would be at risk for adverse health consequences or negative outcomes without benefit of appropriate discharge planning shall be identified.
- SR.3** SR.3 The hospital shall implement a screening process to identify patients with a high-risk of requiring post-hospital services.
- SR.4** SR.4 A discharge planning evaluation is provided for or upon the request of:
- the patients identified in SR.2 & SR.3;
 - any patients upon their request;
 - a person acting on the patient's behalf; or,
 - the patient's physician.

Interpretive Guidelines:

Poor planning and communication with ongoing care providers or patients themselves at discharge can often be the cause of patient safety incidents including a lack of continuity of care, medication miss management or a lack of social care support.

The hospital must define the discharge planning process and communicate it to all appropriate areas of the hospital. This process is imperative in the patient care delivery system to ensure that patients' needs are being met and to minimize the likelihood of having any patient re-hospitalized for reasons that could have been prevented. This applies to all types of hospitals and requires all hospitals to conduct appropriate discharge planning activities for all inpatients. It applies to patients who are admitted to the hospital as

inpatients. This does not apply to patients who appear in a hospital emergency department but are not admitted as hospital inpatients.

The hospital shall have policies and procedures regarding the discharge planning process. These policies and procedures should address:

- I. Scope of the discharge planning process;
- II. The hospital's high-risk screening procedure;
- III. Initiation of the discharge planning process;
- IV. Individual(s) who may initiate this process;
- V. When the process is initiated as a part of the plan of care;
- VI. Communication and coordination with local care providers and social services;
- VII. Reassessment of discharge plans; and,
- VIII. Preparations for post-hospital care and how patients or those responsible for the patient are kept informed of the progress.

Discharge plans should at a minimum consider the following issues

- IX. Informing patient and next of kin;
- X. Medications;
- XI. Essential equipment;
- XII. Communication with external agencies; and
- XIII. Documentation requirements.

The hospital must ensure that patients receive proper post-hospital care within the abilities of a hospital's authority under national and regulatory requirements. The patient has the right to refuse discharge-planning services, but the hospital may still make these services available to the patient. If a patient does exercise his or her right to refuse discharge planning, written documentation of the refusal should be completed.

For patients where death is the expected outcome of the service then planning shall include the preparation of patients and their families for death, the management of pain and symptoms and linkage with support groups and counseling. The hospital should ensure that spiritual and cultural needs are addressed.

Surveyor Guidance:

Verify that all patient records contain a discharge planning process including as a minimum the elements covered above in the interpretive guidelines.

Interview hospital staff who are involved in direct patient care to verify that discharge planning is an inherent part of patient care delivery process.

PC.11 – Discharge Planning Evaluation

SR.1 A registered nurse, social worker, or other appropriately qualified personnel shall develop, or supervise, the development of the evaluation.

SR.2 The discharge planning evaluation shall include:

- a) the likelihood of a patient needing post-hospital services;
- b) 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 hospital;
- c) a means to inform the patient or the patient's family of their freedom to choose relevant providers of post-hospital care services, and shall, when possible, respect patient and family preferences when they are expressed.

SR.3 The discharge planning evaluation shall be completed on a timely basis to avoid any unnecessary delays in discharge.

SR.4 The discharge planning evaluation shall be a part of the patient's medical record and be used when forming the discharge plan with the patient or individual acting on his or her behalf.

Interpretive Guidelines

The discharge planning process will identify the following factors when patients are leaving the hospital setting: physical health, cognitive ability of the patient and family support.

The personnel responsible for discharge planning should have experience in discharge planning, knowledge of social and physical factors that affect functional status at discharge, and knowledge of community resources to meet post-discharge clinical and social needs.

The hospital should have a screening process in place to identify patients who are at risk of requiring post-hospital service. The hospital needs to ensure the availability of services that the patient may need and determine the patient's ability for self-care or care to be provided by another party when necessary.

The discharge planning process will be initiated in a timely manner in order for arrangements to be made for the patient prior to discharge.

The documentation associated with the discharge planning process will be included as a part of the patient's medical record as a means of coordinating communication with other providers involved in the patient's care throughout the hospital. The patient's physician, a registered nurse, social worker, and/or other qualified staff member will be responsible for the development of information and materials to implement the discharge plan for the patient.

Surveyor Guidance:

Verify that the discharge planning is effective and an inherent part of the patient care delivery system through the following means:

- I. Interview staff to determine how patients are identified and require discharge planning;*
- II. Review the hospital's policy and procedures to verify that at-risk patients are provided discharge planning;*
- III. Sample records to see when the discharge planning process is initiated, the roles of individuals involved in the process, reassessments as needed and the implementation of the discharge plan.*

PC.12 – Discharge Plan Re-evaluation

- SR.1** The discharge plan shall be periodically re-evaluated on an on-going basis to provide for changes in the patient's condition or circumstances. The reassessment shall include a review of the discharge plans to ensure that they are responsive to discharge needs.
- SR.2** As needed, the patient and family members or interested persons shall be educated to prepare them for post-hospital care.

Interpretive Guidelines:

The hospital must have a mechanism in place for ongoing reassessment and evaluation of its discharge planning process.

Surveyor Guidance:

Sample patient records and other appropriate documentation to verify that the hospital is reevaluating the needs of the patients on an ongoing basis.

The surveyor may interview patients and their family members who are expecting discharge.

Discuss with staff the extent and frequency the discharge planning process is reassessed and how this process is evaluated for effectiveness.

PC.13 – Grievance Procedure

- SR.1** The hospital shall develop and implement a formal grievance procedure that provides for the following:
- A list of whom to contact;
 - The governing body's review and resolution of grievances or the written delegation of this function to an appropriate person or committee;
 - A referral process for quality of care issues to the Quality Management oversight; and
 - Specification of reasonable timeframes for review and response to grievances.
- SR.2** Grievance resolutions shall be in writing and directed to the patient. The grievance resolution shall include the following:
- hospital contact person;
 - Steps taken to investigate;
 - Results of the grievance process;
 - Process for escalation if unresolved; and
 - Date of completion.

Interpretive Guidelines:

The hospital shall develop and implement a formal grievance procedure to identify the process that will be followed and the required correspondence, including grievance resolution, to be provided to the patient. This as a minimum shall include SR.1 and SR.2.

Definition elements: A “patient grievance” is a formal or informal written or verbal complaint that is made to the hospital by a patient, or the patient’s representative, when a patient issue cannot be resolved promptly by staff present. If a complaint cannot be resolved promptly by staff present or is referred to a complaint coordinator, patient advocate, or hospital management, it is to be considered a grievance.

Surveyor Guidance:

Review and verify the hospital’s policies and procedures to assure that its grievance process encourages all personnel to alert appropriate staff concerning any patient grievance and that the hospital’s governing body has approved the grievance process.

Verify that the hospital’s process assure that all grievances are resolved in a timely manner.

Verify that information is provided to patients to explain the hospital’s grievance procedures.

Verify that time frames are established to review and respond to patient grievances.

Verify that the hospital provides written notices (responses) to patients as required.

Review the time frames established to review and respond to patient grievances and that these are being met.

Section 11 Medication Management (MM)

MM.1 – Management Practices

- SR.1** The hospital shall have a pharmacy service that meets the needs of the patients. Medications shall be administered in accordance with accepted professional principles. The pharmacy service shall be directed by a full time, part time, or consulting registered pharmacist responsible for developing, supervising, and coordinating all the activities of the pharmacy services. The pharmacy service shall have an adequate number of qualified personnel to ensure effective medication management services, including emergency services.
- SR.2** All medications shall be administered by or under the supervision of nursing or other qualified personnel. All drugs and biologicals shall be administered only upon the orders of the practitioner responsible for the care of the patient in accordance with approved hospital policies and procedures, and recognized standards of practice.
- SR.3** All compounding, packaging, and dispensing of medication shall be performed under the supervision of an approved pharmacist or physician in accordance with accepted professional principles.
- SR.4** All drugs and biologicals shall be controlled, secured and distributed in accordance with recognized standards of practice at all times. Only personnel authorized by the pharmacy service shall have access to locked areas.
- SR.5** Outdated, mislabeled, or otherwise unusable medications shall not be available for patient use.
- SR.6** Medications prescribed without specific duration or number of doses shall automatically be stopped after a reasonable time that has been predetermined by the hospital.
- SR.7** The hospital may allow a patient (or his or her caregiver/support person where appropriate) to self-administer both hospital-issued medications and the patient's own medications brought into the hospital, as defined and specified in the hospital's policies and procedures. If the hospital allows a patient to self-administer specific hospital-issued medications, then the hospital must have policies and procedures in place to:
- a) Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration.
 - b) Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s).
 - c) Instruct the patient (or the patient's caregiver/support person where appropriate) in the safe and accurate administration of the specified medication(s).
 - d) Address the security of the medication(s) for each patient.
 - e) Document the administration of each medication, as reported by the patient (or the patient's caregiver/support person where appropriate), in the patient's medical record.
 - f) Identify the specified medication(s) and visually evaluate the medication(s) for integrity.

SR.8 Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if the hospital:

- a) Establishes that such orders and protocols have been reviewed and approved by the medical staff and the hospital's nursing and pharmacy leadership;
- b) Demonstrates that such orders and protocols are consistent with nationally recognized and evidence-based guidelines;
- c) Ensures that the periodic and regular review of such orders and protocols is conducted by the medical staff and the hospital's nursing and pharmacy leadership to determine the continuing usefulness and safety of the orders and protocols; and
- d) Ensures that such orders and protocols are dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or by another practitioner responsible for the care of the patient.

SR.9 All staff that administers intravenous medications shall have specific and relevant training.

Interpretive Guidelines:

All medication management practices, including preparation and administration, shall be administered by or under the supervision of nursing or other qualified personnel in accordance with applicable hospital policy and national and regulatory requirements. Drugs and biologicals shall be prepared and administered in accordance with:

- I. the orders of the practitioner or practitioners responsible for the patient's care; and*
- II. recognized standards of practice.*

The hospital shall define a timeframe that medications will be administered after their scheduled time. This will commonly be at a minimum within 60 minutes (30 minutes before or 30 minutes after the scheduled time for administration) unless defined otherwise by the hospital). It is important to understand the timeframe established and medications are being administered in accordance with this policy. If medications are administered outside of the normal range of 60 minutes, the hospital will define the rationale applied to support the defined timeframe outlined within the policy.

The organization shall have a pharmacy service administered in accordance with accepted professional principles and directed by a full time, part time, or consulting registered pharmacist responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

Direction of pharmaceutical services may not require continuous on-premise supervision at the hospital's single pharmacy or at any pharmacy location but may be accomplished through regularly scheduled visits in accordance with national legal and regulatory requirements.

The pharmaceutical services staff shall be sufficient in types, numbers, and training to provide quality services, including twenty four (24) hour, seven (7) day emergency coverage. In the alternative, there shall be an arrangement for emergency services, as determined by the needs of the patients and as specified by the organization and within the scope and complexities of services provided.

All compounding, packaging, and dispensing of medication shall be under the supervision of a licensed pharmacist or physician.

All medications shall be kept and locked in secured container and/or room. In the event these drugs are stored in a container that is readily portable, it shall be stored in a locked room, monitored location, or

secured location that will ensure their security when not in use. Only personnel authorized by the pharmacy service shall have access to locked areas. As a minimum this shall include:

- III. Hospital policies and procedures need to define which personnel are authorized to have access to locked areas based on their own needs as well as national legal and regulatory requirements.
- IV. Non-controlled drugs and biologicals are to be stored in a secure area in a manner that prevents tampering and diversion.
- V. A medication is considered secure if unauthorized individuals are prevented from obtaining access.
- VI. A secure area is one in which staff are actively providing patient care or preparing to receive patients with procedures to ensure limited entry and exit to appropriate staff, patients, and visitors.
- VII. This includes critical care areas or labor and delivery suites which actively provide patient care around the clock and the operating room when staffed and providing care.
- VIII. All non-controlled substances are to be locked when a patient care area is not staffed.
- IX. When not in use, an operating room would not be considered secure and all drugs and biologicals are expected to be locked.

Drugs and biologicals are stored in accordance with manufacturer's directions and National and local legislation and regulations requirements.

The hospital shall have a pharmacy labeling, inspection, and inventory management system that ensures that outdated, mislabeled, or otherwise unusable medications are not available for patient use.

The hospital will ensure that medications prescribed without specific duration or number of doses shall automatically be stopped after a reasonable time that has been predetermined by the medical staff.

As appropriate, patients may need to self-administer non-controlled drugs and biologicals, The hospital will have policies and procedures in place regarding patient self-administration of non-controlled drugs and biologicals consistent with safe medication practices. There will be measures in place to properly secure such non-controlled drugs and biologicals. The policies and procedures will define the means for determining the competence to self-administer such drugs and biologicals and provide education to the patient as necessary to ensure safe self-administration of these drugs and biologicals.

The organization shall have the following core policies and procedures in place and operational:

- X. Personnel authorized to administer medications;
- XI. Security and monitoring of carts or emergency boxes, locked or unlocked, containing drugs and biologicals in all patient care areas to ensure their safe storage, availability in emergency situations, and patient safety;
- XII. Medications brought to the hospital by patients and their families; and
- XIII. Investigational medications.

Policies and practices to minimize and prevent medication errors based on recognized standards of practice shall be in place that include but are not limited to:

- XIV. Proactive review and analysis of external alerts, internal practice variances and adverse drug events
- XV. Labeling of medications
- XVI. High-alert medications - dosing limits, administration guidelines, packaging, labeling and storage;

- XVII. *Guidelines/criteria for selection from a menu of medication options addressing similar indications for use e.g. pain meds;*
- XVIII. *Limiting the variety of medication-related devices and equipment. For Example limit the types of general-purpose infusion pumps to one or two;*
- XIX. *Availability of up-to-date medication information;*
- XX. *Availability of pharmacy expertise. Pharmacist available on-call when pharmacy does not operate 24 hours a day;*
- XXI. *Avoidance of dangerous abbreviations;*
- XXII. *Alert systems for look-like and sound-alike drug names;*
- XXIII. *Use of hospital approved pre-printed order sheets whenever possible;*
- XXIV. *That orders to “resume previous orders” are prohibited;*
- XXV. *A voluntary, non-punitive, reporting system to monitor and report adverse drug events (including medication errors and adverse drug reactions);*
- XXVI. *The preparation, distribution, administration and proper disposal of hazardous medications;*
- XXVII. *Drug recalls;*
- XXVIII. *That patient-specific information is readily accessible to all individuals involved in provision of pharmaceutical care. The patient information shall be sufficient to properly order, prepare, dispense, administer and monitor medications as appropriate;*
- XXIX. *Identification of when weight-based dosing for pediatric populations is required;*
- XXX. *Training requirements for staff involved in administration of intravenous medications.*

Surveyor Guidance:

Verify that the pharmacist is properly licensed and is a full-time or part-time employee or employed on a consultative basis.

Review and verify the job description or written agreement to see that the responsibilities of the pharmacist are clearly defined and include development, supervision and coordination of all the activities of pharmacy services.

Verify that the pharmacy director is actively involved in those committees responsible for establishing medication-related policies and procedures.

Verify that the pharmaceutical services are provided by staff sufficient in number 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 organization.

In a sampling of patient records, review and verify medication orders (and the ordering process), medication administration records, and appropriate medication related documentation in the medical record.

In review of the pharmacy, review the process for the preparation and administration of medications. Verify that medications are prepared and administered in accordance with national legal and regulatory requirements, manufacturer’s directions, and hospital policy.

Review sample of medication administration records to verify that they conform to practitioner’s orders, the order is current and that the drug, dosage and route of administration are correct. These shall be in accordance with national legal and regulatory requirements, manufacturer’s directions and hospital policy.

- I. *Verify the process for ensuring correct patient identification*

- II. *Review the process for how medications are administered and how the nursing staff ensures the medications are taken.*
- III. *Review the process for administering of medications. The hospital shall define a timeframe that medications will be administered after their scheduled time. This will commonly be at a minimum within 60 minutes (30 minutes before or 30 minutes after the scheduled time for administration) unless defined otherwise by the hospital). It is important to understand the timeframe established and medications are being administered in accordance with this policy. If medications are administered outside of the normal range of 60 minutes, the hospital will define the rationale applied to support the defined timeframe outlined within the policy*

IV. *Review the process followed when medications are not given on time and what action(s) are taken*
Verify that the hospital maintains policies and procedures, approved by the organization, that identify who is authorized to administer medications, the nursing and other personnel (if other than nursing) administering medications are appropriately training or licensed, function under supervision as required and that the policies are followed and are in accordance with national legal and regulatory requirements.

Determine by inspection whether all medications are stored in a manner that prevents unauthorized access.

In the review of patient care areas:

- V. *Verify the process for patient identification.*
- VI. *Review and verify that the labels of individual medications conform to national legal and regulatory requirements.*
- VII. *Review and verify that medications provided in floor stock include:*
 - a) *the name and strength of the drug;*
 - b) *lot and control number of equivalent; and*
 - c) *expiration date.*
- VIII. *Review the hospital policies and procedures governing patient self-administration of drugs and biologicals*
- IX. *Review the intravenous medications practices*
- X. *Verify that training is provided to staff required to administer intravenous medications.*
- XI. *Verify that those administering intravenous medications are working within their scope of practice in accordance with hospital policy and national legal and regulatory requirements..*
- XII. *Review infusion records to verify the process followed is consistent with the training provided and policies and procedures are followed.*
- XIII. *Discuss the process for addressing adverse drug reactions and the procedure to be followed when this occurs.*

MM.2 – Formulary

SR.1 The hospital shall select a list of medications to be available within the hospital. The list shall be available to all appropriate staff at all times.

Interpretive Guidelines:

The organization shall select a list of medications (formulary) to be available within the organization. The list shall be available to all appropriate staff at all times.

The formulary may be maintained either electronically on the hospital's information management system or in a hardcopy form. The hospital will ensure a means of notifying the hospital staff and medical staff when changes are made to the formulary.

The hospital will have a process in place that addresses medication-related issues to include:

- I. Communicating with appropriate prescribers and staff;*
- II. Developing approved substitution protocols;*
- III. Educating appropriate physicians and other applicable health care professionals, and staff about these protocols; and*
- IV. Obtaining medications in the event of a disaster.*

The hospital will have a policy and procedure in place to address the process for requests for medications to be added to the formulary before the medications are available for dispensing and administration.

The hospital should have processes to approve and procure medications that are not on the hospital's formulary.

Surveyor Guidance:

Verify that the pharmacy has an established formulary of medications that are available in the hospital.

Verify that there is a process for creation and periodic review of a formulary system.

Validate the policy and procedure in place to address the process for requests for medications to be added to the formulary before the medications are available for dispensing and administration

Verify that the hospital has a process to approve and procure medications that are not on the hospital's formulary.

MM.3 – Controlled Medications

SR.1 Current and accurate records shall be kept of the receipt and disposal of all controlled medications.

SR.2 Abuses and losses of controlled medications shall be reported to the individual responsible for the pharmacy service, to the chief executive officer, and to external parties as appropriate.

Interpretive Guidelines:

The hospital shall maintain a record system to maintain current and accurate records of the receipt and disposal of all scheduled drugs that is in compliance with national legal and regulatory requirements..

This record system will address the following for all scheduled drugs:

- I. Accountability procedures to ensure control of the distribution, use, and disposal;*
- II. Current and accurate receipt and disposal;*
- III. Ability to trace the process for moving scheduled drugs throughout the service from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacture;*
- IV. Identify the pharmacist responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled;*

- V. *Accounting of all scheduled drugs and any discrepancies in count are reconciled promptly; and,*
- VI. *Capability to readily identify loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion.*

The hospital shall develop and implement policies and procedures to minimize abuses and losses of controlled substances. These procedures shall outline, in accordance with applicable National and local legislation and regulations, the reporting process to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

Surveyor Guidance:

Verify that the record system provides information on scheduled drugs in a readily retrievable manner.

Validate that the records can trace the movement of scheduled drugs throughout the service from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacturer.

Verify that this system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposal of all scheduled drugs.

Verify that the pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and periodically reconciled. Narcotic count sheets and reconciliation sheets could be sampled when discrepancies are present and the action(s) taken by the hospital to address these discrepancies.

Validate the hospital system to readily identify loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual losses or diversion to the time of detection and determination of the extent of loss or diversion.

Determine if controlled drug losses are reported to appropriate authorities in accordance with national and regulatory requirements.

MM.4 – Medication Orders

SR.1 All medication orders shall:

- a) include the name of the drug, the dosage and frequency of administration and the route of administration;
- b) be in writing and signed, including date and time, by the practitioner or practitioners responsible for the care of the patient as authorized to write such orders;

SR.2 Telephone or verbal orders are to be used infrequently and when used shall be accepted only by qualified and authorized personnel.

SR.3 Verbal orders shall be signed or initialed by the prescribing practitioner and shall be authenticated within 48 hrs.

Interpretive Guidelines:

Elements that shall be in any medication order (including all written, and verbal/telephone orders) include:

- I. *Name of patient;*

- II. Age and weight of patient, when appropriate;
- III. Date and time of the order;
- IV. Drug name;
- V. Dosage form (e.g., tablets, capsules, inhalants);
- VI. Exact strength or concentration;
- VII. Dose, frequency, and route;
- VIII. Quantity and/or duration;
- IX. Indication for use when appropriate (including orders for prn administration and/or multiple uses of medication);
- X. Specific instructions for use (i.e. more than one medication for same use such as a pain, nausea);
Name of prescriber.

All vaccines may be administered in accordance with a policy approved by the hospital after an individual assessment for contraindications.

Hospitals should establish policies and procedures that:

- XI. Describe limitations or prohibitions on use of verbal/telephone orders;
- XII. Provide a mechanism to ensure validity/authenticity of the prescriber;
- XIII. List the elements required for inclusion in a complete verbal/telephone order ;
- XIV. Describe situations in when verbal/telephone orders may be used;
- XV. List and define the individuals who may send and receive verbal/telephone orders; and,
- XVI. Provide guidelines for clear and effective communication of verbal/telephone orders.

If a hospital uses other written protocols or standing orders for drugs or biologicals that have been reviewed and approved by the medical staff, initiation of such protocols or standing orders requires an order from a practitioner responsible for the patient's care.

Surveyor Guidance:

Review and verify that medications prescribed for a patient include:

- I. Patient's full name;
- II. the prescriber's name;
- III. strength, quantity and route of administration of the drug dispensed; and,
- IV. appropriate directions and cautionary statements are included as well as the expiration date

In a sampling of patient records, validate that all drug orders, including verbal orders, contain the elements as described in the Interpretive Guidelines (above) and are written in the patient charts and signed by the practitioner caring for the patient.

In a sampling of patient records, verify that the prescriber has reviewed and authenticated the orders in accordance with organization policy and/or applicable national legal and regulatory requirements.

Verify the process for authentication of verbal orders to ensure these are within the timeframes as stated according to National and local legislation and regulations. If there is not a State or local law in place, verify that these orders are authenticated within 48 hours.

Verify there is a process for handling of verbal orders and there have been measures put in place to effectively reduce these when possible.

MM.5 – Review of Medication Orders

- SR.1** All medication orders shall be reviewed prior to administration of the first dose to a patient. Review shall be performed by qualified and competent personnel according to recognized standards of practice.
- SR.2** When a pharmacist is not available medications shall be retrieved from the pharmacy or storage area (including automated dispensing) only by licensed/registered staff designated by the pharmacy service and approved by the hospital. The following conditions shall be met:
- a) The licensed individual that obtains the medication shall have an orientation to the storage area for the medication.
 - b) All medications shall be separated according to patient safety risks, and high-risk medications in this area shall be segregated and unavailable.
 - c) There shall be a documented protocol requiring that the licensed/registered individual have access to appropriate information to process the order in a formal manner. Information shall include:
 - i. potential drug-drug interactions;
 - ii. potential allergies or cross sensitivities;
 - iii. proper dose ranges; and
 - iv. proper indications for administration.
 - d) The licensed/registered individual shall leave a duplicate dose with a copy of the order or comparable method for verification by a licensed/registered pharmacist upon arrival in the hospital;
 - e) The removal of the medication shall be documented, tracked and trended and the results analyzed to determine need for additional pharmacy staff or medication storage resources and appropriateness of any pharmacy after-hour practices, as appropriate; and
 - f) All high risk medications in this area shall be segregated and unavailable to unauthorized staff.

Interpretive Guidelines:

All medication orders (except in emergency situations) should be reviewed for appropriateness by a pharmacist or physician before the first dose is dispensed.

When a pharmacist or physician is not available and the pharmacy is closed, the hospital will define the process by a policy and procedure to ensure that following shall occur:

- I. The practitioner caring for the patient shall determine the urgency of administration;*
- II. The medications shall be retrieved from the pharmacy or storage area only by licensed staff designated by the pharmacy service and approved by the medical staff, in accordance with principles of patient safety and national legal and regulatory requirements*
- III. The licensed individual that obtains the medication shall have an orientation to the storage area for the medication;*
- IV. The hospital arranges for a qualified pharmacist to be available either on-call or at another location (e.g. at another organization that has 24-hour pharmacist availability) to answer questions or provide medications beyond those accessible to non-pharmacy staff;*

- V. *Quality control procedures (such as an independent second check by another individual or a secondary verification built into the system, such as bar coding) are in place to prevent medication retrieval errors;*
- VI. *These medications can be stored in a night cabinet, automated storage and distribution device, or a limited section of the pharmacy;*
- VII. *All high-risk medications in this area shall be segregated and unavailable;*
- VIII. *There shall be a documented protocol requiring that this licensed individual have access to appropriate information to process the order in a formal manner. Information shall include:*
 - a) *potential drug-drug interactions;*
 - b) *potential allergies or cross sensitivities;*
 - c) *proper dose ranges; and*
 - d) *proper indications for administration.*
- IX. *This licensed individual shall leave a duplicate dose with a copy of the order for verification by a licensed pharmacist upon arrival in the organization; and,*
- X. *The removal of the medication shall be documented, tracked and trended and the results analyzed to determine need for additional pharmacy staff or medication storage resources and appropriateness of any pharmacy after-hour practices.*

This process is continually evaluated to determine the medications accessed routinely and the causes of accessing the pharmacy after hours.

Corrective/Preventive action(s) are implemented as appropriate to reduce the amount of times non-pharmacist health care professionals are obtaining medications after the pharmacy is closed.

Surveyor Guidance:

Verify through a sampling of pharmacy records that documents the process when the pharmacist is not available, drugs are removed from the pharmacy (drug storage area) only by a designated individual (in accordance with national legal and regulatory requirements, if applicable) and only in amounts sufficient for immediate therapeutic needs.

Validate policies and procedures to determine who is designated to remove medications from the pharmacy or storage area and the amount a non-pharmacist may remove in the absence of a pharmacist. The individual(s) designated should be identified by name and have the appropriate qualifications.

Validate the system in place to ensure accurate documentation regarding the removal of medications (type and quantity) from pharmacy or the location where medications are stored after the pharmacy has closed.

Verify that a pharmacist or physician reviews all medication removal activity and correlates the removal with current medication orders in the patient medication profile.

Review and validate that the pharmacy routinely reviews the contents of the after-hours supply to determine if it is adequate to meet the after-hours needs of the hospital and implements appropriate corrective/preventive action to minimize entry into the pharmacy after the pharmacy has closed.

MM.6 – Oversight Group

SR.1 *The hospital is responsible for developing policies and procedures that minimize drug errors. The hospital may delegate this responsibility to an organized pharmacy oversight group.*

- SR.2** There shall be procedures for reporting transfusion reactions, adverse drug reactions, and errors in prescribing, preparing, and administering of drugs, in the aggregate, for trending and analysis.
- SR.3** Drug preparation, administration, and prescribing errors, adverse drug reactions, and incompatibilities shall be immediately reported to the attending physician and to the hospital-wide quality management program.

Interpretive Guidelines:

Policies and procedures shall be developed in order to minimize medication errors, adverse drug reactions, and drug incompatibility.

The hospital will develop and implement procedures for reporting transfusion reactions, adverse drug reactions, and errors in prescribing, preparing, and administration of medications. These errors and reactions shall be immediately reported to the patient's attending physician, or when appropriate the covering physician. When the covering physician is notified due to the attending physician not being available, the patient's attending physician shall be notified as soon as he/she is available.

The hospital will document the information obtained from the errors and reactions reported and have a means for aggregating this information and related data to be trended and analyzed and continually evaluated in order to identify and implement corrective/preventive action.

The hospital shall have a method to measure the effectiveness of its reporting system to identify whether or not their system(s) is identifying as many medication errors and adverse drug reactions that would be expected for the size and scope of services provided by their hospital. Such methods could include use of established benchmarks or studies on reporting rates published in peer-reviewed journals.

To improve incident reporting, the hospital should adopt a non-punitive system with the focus on the system and not the involved health care professionals.

Surveyor Guidance:

Verify that policies and procedures are developed in order to minimize medication errors, adverse drug reactions, and drug incompatibilities.

Validate that the hospital has an effective procedure that ensures drug administration errors, adverse drug reactions, and drug incompatibilities are immediately reported to the attending physician.

In a sampling of records, review medication errors and adverse drug reactions to determine that they are reported immediately in accordance with written procedures, and that medications administered and/or drug reactions are promptly recorded in the patient's medical record.

Determine if the hospital's definition of an adverse drug reaction and medication error is based on established benchmarks or studies on report rate published in peer review journals and/or from other sources.

To determine the effectiveness of the internal reporting mechanism, assess whether or not the identification of medication errors are as expected for the size and scope of services provided by the hospital. If the perception is such that medication errors are considered under-reported, determine the action(s) the hospital is taking to ensure accurate reporting of such errors. Also assess staff awareness of the internal reporting process when medication errors and adverse drug reactions are identified.

Verify the effectiveness of the reporting mechanism and the ability to retrieve data/information to be trended, analyzed and evaluated in order to implement and determine the effectiveness of corrective/preventive action(s). Verify such information is forwarded to quality management oversight.

Assess through interviews with hospital staff (nursing, pharmacy and medicine) awareness of the hospital's policy on reporting and documentation of medication errors and adverse drug reactions.

MM.7 – Available Information

SR.1 Accurate and up to date information relating to drug interactions and information on drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration shall be available to all staff involved with medication management.

Surveyor Guidance:

Verify that the sources of drug information (including information relating to drug interactions and information on drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration) are available to all professional staff.

Section 12 Operating Theatres (OT)

OT.1 – Organization

- SR.1** For Hospitals that provide services in an operating theatre, the services shall be well organized, appropriate to the scope of the services offered, and provided in accordance with acceptable standards of practice.
- SR.2** Operating theatres and the work within them shall be designed to assure the provision of high quality patient care that meets recognized standards of medical practice.

Interpretive Guidelines:

If the hospital provides any surgical services, they shall be organized and staffed in such a manner to ensure the health and safety of patients. This applies to all surgical services provided as an inpatient, day care or outpatient.

Practice should be to nationally recognized standards and guidance from professional organizations that are applicable to the scope and complexity of surgical services provided.

As a minimum the hospital policies and procedures shall include:

- I. Aseptic and sterile surveillance and practice, including scrub techniques*
- II. Infection Prevention and Control to include:
 - a) Identification of infected and non-infected cases;*
 - b) Sterilization and Disinfection Procedures*
 - c) Handling Infectious and Biomedical/Medical Waste*
 - d) Air Quality Testing**
- III. Housekeeping requirements/procedures;*
- IV. Duties of surgical assistants, scrub and circulating staff. These may be defined within job descriptions, but may vary depending on the cases for which these staff members are involved;*
- V. Conducting surgical counts in accordance with recognized standards of practice. The hospital will have a process in place to ensure that no foreign bodies are retained in patients following surgical procedures;*
- VI. The scheduling of patients for surgery;*
- VII. Patient care requirements including:
 - a) Pre-operative testing*
 - b) Clinical procedures*
 - c) Patient identification procedure and site verification process*
 - d) Tissue viability**
- VIII. Resuscitative techniques;*
- IX. Care of surgical specimens;*
- X. Malignant hyperthermia;*

- XI. *Procedure-specific protocols that identify requirements against all applicable surgical procedures performed. This will include a list of equipment, materials, and supplies necessary to properly carry out the surgical services provided;*
- XII. *Monitoring of temperature and humidity*
- XIII. *Safety practices*
- XIV. *Acceptable operating room attire*

Surveyor Guidance:

Review and verify the extent of surgical services provided by the hospital and verify that services are in accordance with acceptable standards of practice. In order to do this appropriately you are required to visit the theatre areas observing hospital approved protocols.

Review and validate policies and procedures to determine that minimum elements are addressed as specified in the Interpretive Guidelines (above).

Malignant hyperthermia rescue capability should be thoroughly assessed in those hospitals that perform a significant number of surgical procedures under general anesthesia

Verify that access to the operative and recovery area is limited to authorized personnel and that the traffic flow pattern adheres to recognized standards of practice.

Verify that the hospital has equipment available for rapid and routine sterilization of operating room materials and that the equipment used for this purpose is monitored, inspected, tested, and maintained by the hospital's biomedical equipment/clinical engineering program or via a contracted service.

Verify that there is a process in place for handling sterilized materials and that these materials are packaged, labeled, and stored in a manner that ensures sterility (e.g., in a moisture and dust controlled environment and policies and procedures for expiration dates have been developed and are followed in accordance with recognized standards of practice).

OT.2 – Staffing and Supervision

- SR.1** The hospital of the operating theatres shall be supervised by either a registered nurse with appropriate experience, or by a physician.
- SR.2** Staff working within operating theatres shall have relevant and specialized training. Individuals under training or observing shall be appropriately supervised.

Interpretive Guidelines:

The hospital surgical services (including both inpatient and outpatient) shall be supervised by an experienced registered nurse, ODP or physician. The registered nurse, ODP, or physician supervising the operating room shall possess appropriate education, experience working in surgical services, and specialized training in the provision of surgical services/management.

The hospital shall provide the appropriate equipment and the types and numbers of qualified personnel necessary to furnish the surgical services offered by the hospital in accordance with acceptable standards of practice.

Trained staff shall perform circulating duties in the operating room according to national legal and regulatory requirements and in accordance with policies and procedures permit

Surveyor Guidance:

Review the hospital's organizational chart regarding surgical services to confirm that there are lines of authority and delegation of responsibility indicated within surgical services.

Verify that a registered nurse, ODP or physician is assigned responsibility for supervision of surgical services. Request a copy of the supervisor's position description to determine that it specifies qualifications, duties and responsibilities of the position.

Verify that all staff working within the operating theatres has received relevant and specialized training

Review and verify that the hospital maintains appropriate staffing schedules to provide adequate staff and registered nursing supervision.

OT.3 – Available Equipment

SR.1 The following equipment shall be present and in operating condition and immediately available to each theatre:

- a) emergency call system;
- b) cardiac monitor;
- c) resuscitator/AMBU-bag;
- d) defibrillator;
- e) suction equipment; and,
- f) provisions for emergency airway intervention.

Surveyor Guidance:

Review and verify that the hospital has equipment immediately available to each surgical suite to include, at least, those items as listed above in SR.1

Validate that all equipment is working as intended and is maintained, inspected, and tested by the hospital's biomedical/clinical engineering department or contracted service.

Verify that a tracheotomy set is available (a cricothyroidotomy set should not be considered a substitute for this set)

OT.4 – Operating Room Register

SR.1 The operating room register shall be complete and up to date.

Interpretive Guidelines:

The operating room register will include at least the following information:

- I. *Patient's name;*
- II. *Date of birth Patient's hospital identification number;*

- III. *Date of the operation/procedure;*
- IV. *Inclusive or total time of the operation/procedure;*
- V. *Name of the surgeon and any assistant(s);*
- VI. *Name of scrub and circulating personnel*
- VII. *Type of anesthesia used and name of the administering practitioner;*
- VIII. *Operation/procedure performed in full;*
- IX. *Pre and post-op diagnosis;*

Surveyor Guidance:

Review and validate the OR register or equivalent record to ensure that it lists all surgery performed by the surgical services and includes the elements as listed above in the Interpretive Guidelines.

OT.5 – Post-Operative Care

SR.1 There shall be adequate provision for immediate post-operative care.

SR.2 Equipment, clinical staff, and plan of care provisions as well as criteria for transfer shall be developed and adopted by the medical staff and nurse executive designees.

Interpretive Guidelines:

The hospital will make adequate provisions for immediate post-operative care. These provisions will include that post-operative care is provided in accordance with acceptable standards of practice and there shall be a dedicated post-operative care area or recovery room separate to the operating theatre room.

The hospital will provide the appropriate equipment e.g. respiratory and cardiac monitoring, resuscitation equipment and clinical staff to adequately address the patients' plan of care in accordance with the complexity of surgery undertaken. The hospital will develop criteria for the discharge from the post-operative care area that have been approved by the hospital.

Prior to transfer, the hospital shall ensure that the patient has met the appropriate criteria for transfer and that the patient has an order for transfer from the patient's surgeon, anesthetist or practitioner.

If patients are not transferred to the post-operative care area, there shall be provisions for direct observation of the patient by a registered nurse in the patient's room to ensure there is a comparable level of care during the recovery phase.

Surveyor Guidance:

Review and validate the process and provisions for post-operative care, including transfer criteria.

Review and verify that the hospital provides the appropriate equipment and clinical staff to adequately address the patient's plan of care appropriate to the complexity of surgery undertaken.

OT.6 – Operative and Post-Operative Documentation and Reporting

SR.1 The hospital shall ensure continuity of care between the operating theatre, recovery unit and wards. Relevant information shall be documented prior to any transfers between units.

SR.2 As a minimum the limited amount of information that shall be documented immediately shall include:

- a) name , date of birth and hospital identification number of the patient;
- b) date and times of the surgery;
- c) name(s) of the surgeon(s)
- d) type of anaesthesia administered;
- e) complications, if any;
- f) pre-op and post-op diagnosis;
- g) procedures performed;
- h) specimens removed;
- i) blood administered;
- j) grafts or implants; and
- k) medications administered.

SR.3 Where information identified in the immediate post-operative/post procedure note is available in nursing documentation; it is acceptable if authenticated as accurate by the attending surgeon.

Interpretive Guidelines:

An operative report shall be written or dictated and signed by the surgeon immediately following surgery and before the patient is transferred to the next level of care. The operative report will contain at least the following:

- I. Name, date of birth and hospital identification number of the patient;*
- II. Date and times of the surgery;*
- III. Name(s) of the surgeon(s) and assistants or other practitioners who performed surgical tasks (even when performing those tasks under supervision);*
- IV. Pre-operative and post-operative diagnosis;*
- V. Name of the specific surgical procedure(s) performed;*
- VI. Type of anesthesia administered;*
- VII. Complications;*
- VIII. A description of techniques, findings, and tissues removed or altered;*
- IX. Surgeons or practitioners name(s) and 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); and,*
- X. Prosthetic devices, grafts, tissues, transplants, or devices implanted*
- XI. Immediate postoperative care required*

In the event there is a delay in dictation turnaround regarding the operative report, an immediate written postoperative note is required to include the elements as described in SR.2a – I (above). This information

shall be available in the medical record, and, as applicable, authenticated as accurate by the attending surgeon.

Surveyor Guidance:

In a sampling of surgical patients' medical records, validate that the records contain an operative report that includes the information specified in the Interpretive Guidelines (above).

In a sampling of medical records of surgical patients and a delay in dictation has been identified, validate that the medical record contains an immediate postoperative note that includes the information specified in SR.2a –I (above).

In the event that there is no delay in dictation during the time the surveyor is on-site, validate that the hospital has a process in place for the immediate postoperative note to be written and that this is enforced by the hospital.

Section 13 Anesthesia Services (AS)

AS.1 – Organization

SR.1 Anesthesia services shall be provided in an organized manner, and function under the direction of a qualified physician. The anesthesia service is responsible for all anesthesia services provided throughout the hospital (including all off site locations). Areas where anesthesia services are furnished may include:

- a) operating room suites, both in patient and out patient;
- b) obstetrical suites;
- c) radiology department;
- d) clinics;
- e) emergency department;
- f) psychiatry department; and
- g) special procedure areas (endoscopy, pain management clinics, etc.).

SR.2 Anesthesia services shall be appropriate to the scope of the services offered.

Interpretive Guidelines:

The hospital may or may not offer anesthesia/sedation services. If a hospital does provide any degree of anesthesia/sedation service to its patients, these services will be provided in an organized manner. The anesthesia/sedation services will be offered under the direction of a qualified physician who is also qualified as an anesthetist. This individual will be responsible for all anesthesia/sedation administered throughout the hospital.

All anesthetic agents that are administered for general or regional use or as sedation shall be subject to monitoring protocols to ensure safe clinical care and the ability to assess and react to complications or the need to convert to a general or regional anesthetic

“Anesthesia” involves the administration of a medication to produce a blunting or loss of:

- I. • pain perception (analgesia);
- II. • voluntary and involuntary movements;
- III. • autonomic function; and
- IV. • memory and/or consciousness, depending on where along the central neuraxial (brain and spinal cord) the medication is delivered.

In contrast, “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. The patient does not lose consciousness, but does not perceive pain to the extent that may otherwise prevail.

The additional definitions below illustrate differences among the various types of anesthesia services.

“Anesthesia services” in a hospital is subject to the anesthesia administration requirements:

- V. *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;*
- VI. *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. 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 the qualified practitioner.*
- VII. *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. An example of deep sedation would be a screening colonoscopy when there is a decision to use propofol, so as to decrease movement and improve visualization for this type of invasive procedure. 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 qualified practitioner as specified.*

“Anesthesia services” in a hospital NOT subject to the anesthesia administration and supervision requirements

- VIII. *Topical or local anesthesia;*
- IX. *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. For example, a patient undergoing an MRI or CT scan may receive minimal sedation with an oral medication to decrease the anxiety while undergoing these types of radiologic examinations;*
- X. *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. For example, a patient undergoing the reduction of a dislocated large joint (shoulder) may require this form of sedation to tolerate the procedure.*

Rescue Capacity: Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, the hospital shall 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. “Rescue” from a deeper level of sedation than intended requires an intervention by a practitioner with expertise in airway management and advanced life support (ACLS, ATLS, PALS, etc.) The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation and returns the patient to the originally intended level of sedation.

Anesthesia services throughout the hospital (including all off-site locations where anesthesia services are provided) shall be organized into one anesthesia service, under the direction of a qualified physician. Areas where anesthesia services are provided may include (but are not limited to):

- XI. Operating room suite(s), both inpatient and outpatient;*
- XII. Obstetrical suite(s);*
- XIII. Radiology department;*
- XIV. Clinic;*
- XV. Emergency department;*
- XVI. Psychiatry department;*
- XVII. Special procedures area (e.g., endoscopy suite, pain management clinic, etc.)*

The hospital establishes criteria for the qualifications for the director of the anesthesia services in accordance with national legal and regulatory requirements and acceptable standards of practice. The anesthesia service is responsible for developing policies and procedures governing the provision of all categories of anesthesia services, including specifying the minimum qualifications for each category of practitioner who is permitted to provide anesthesia services that are not subject to the anesthesia administration requirements.

A well-organized anesthesia service shall be integrated into the hospital's quality management system, in order to assure the provision of safe care to patients.

Surveyor Guidance:

Verify that a qualified physician is responsible for the direction of all anesthesia/sedation services offered hospital-wide. This may include, but is not limited to:

- I. Operating room suite(s), both inpatient and outpatient;*
- II. Obstetrical suite(s);*
- III. Radiology department;*
- IV. Clinic;*
- V. Emergency department;*
- VI. Psychiatry department;*
- VII. Special procedures area (e.g., endoscopy suite, pain management clinic, etc.).*

Review the defined scope of responsibilities or similar documentation that describes this role within the hospital. This individual will be responsible for planning, directing and monitoring all anesthesia/sedation services. The other responsibilities will encompass the implementation of staffing schedules (including on-call services).

Review the criteria and qualifications for physicians and other practitioners for attaining privileges for administering any type of anesthesia/sedation (sample various physicians and practitioners with these privileges). Verify that these privileges have been granted in accordance with the physician or practitioner's scope of practice, national legal and regulatory requirements, and that the criteria and qualifications include

competencies, training, education and (if required) experience regarding the administration of anesthesia/sedation

Review the qualifications of individuals authorized to administer general anesthesia, regional anesthesia and monitored anesthesia, including deep sedation/analgesia to determine if they satisfy the requirements.

Determine that there is documentation of current licensure or current certification status for all persons administering anesthesia.

Determine that there is documentation of current licensure and, as applicable, current certification for all persons administering anesthesia.

Review the qualifications of individuals authorized to furnish other anesthesia services, to determine if they are consistent with the hospital's anesthesia service policies.

Verify that the anesthesia/sedation services are planned and organized in a manner in which these services are continuously monitored, and appropriate to the scope of services offered.

In most cases, the physician responsible for the direction of these services will be an anesthesiologist. In the event it is not an anesthesiologist, review the qualifications of the physician responsible for these services to see that he or she is qualified to do so and has been appointed by the medical staff and governing body.

Verify that anesthesia services are integrated into the hospital's quality management system oversight.

AS.2 – Administration

SR.1 Anesthesia shall only be administered by the following:

- a) An anaesthesiologist or a suitably qualified physician (other than an anaesthesiologist);
- b) A dentist, oral surgeon, or podiatrist or other professional who is qualified to administer anaesthesia;

SR.2 If anesthesia services are provided for labor and delivery, the same standard of coverage as that of operating room anesthesia shall be provided.

Interpretive Guidelines:

The hospital will define the criteria and qualifications for those physicians who have privileges for administering anesthesia/sedation in accordance with national legal and regulatory requirements and acceptable standards of practice.

SR.1 defines those physicians and other practitioners who can administer anesthesia/sedation.

The organization's policies and procedures shall include criteria for determining the anesthesia service privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges, as required for any type of anesthesia services, including those not subject to the anesthesia administration requirements.. The hospital's governing body (or individual(s) responsible) shall approve the specific anesthesia service privileges for each practitioner who provides anesthesia services, addressing the type of supervision, if any, required. The privileges granted shall be in accordance with national and regulatory requirements and hospital policy. The type and complexity of procedures for which the practitioner may administer anesthesia shall be specified in the privileges granted to the individual practitioner.

Definition: “Immediately available” means that the anesthesiologist or operating practitioner is physically located within the area in which the anesthesia/sedation is being administered, he or she is prepared to promptly conduct hands-on intervention, and is not engaged in activities that could prevent the anesthesiologist or operating practitioner from quickly intervening.

The requirements concerning who may administer anesthesia do not apply to the administration of topical or local anesthetics, minimal sedation, or moderate sedation. However, the hospital shall have policies and procedures governing the provision of these types of anesthesia services. Further, the hospital shall assure that all anesthesia services are provided in a safe, well-organized manner by qualified personnel.

General anesthesia, regional anesthesia and monitored anesthesia, including deep sedation/analgesia, may only be administered by:

- I. A qualified anesthesiologist;*
- II. An MD or DO (other than an anesthesiologist);*
- III. A dentist, oral surgeon or podiatrist or other professional who is qualified to administer anesthesia under National and local legislation and regulations;*

The hospital's anesthesia services policies shall address the circumstances under which an MD or DO who is not an anesthesiologist, a dentist, oral surgeon or podiatrist or other qualified professional is permitted to administer anesthesia. In the case of a dentist, oral surgeon or podiatrist or other qualified professional, administration of anesthesia shall be permissible under State or local law and comply with all National and local legislation and regulations requirements concerning qualifications. The hospital should conform to generally recognized standards of anesthesia care when establishing policies governing anesthesia administration by these types of practitioners as well as MDs or DOs who are not anesthesiologists.

Surveyor Guidance:

Verify and review the criteria and procedure for determining the anesthesia service privileges to be granted to an individual practitioner.

For those practitioners who are privileged to administer anesthesia/sedation under the direction of an anesthesiologist, review the process and practice to ensure that the supervising anesthesiologist is immediately available to intervene as necessary.

AS.3 – Policies and Procedures

SR.1 Anesthesia services must be consistent with the needs and resources of the organization. Policies on anesthesia/sedation procedures shall include the delineation of pre-anesthesia and post-anesthesia responsibilities.

SR.2 The policies shall ensure that the following are provided for each patient:

- a) a pre-anesthesia evaluation shall be performed for each patient who will receive general, regional or monitored anesthesia. Patients who will be receiving moderate sedation shall be monitored and evaluated before, during and after a procedure by a trained practitioner, however a pre anesthesia evaluation is not required because moderate sedation is not considered to be “anesthesia” and is not subject to this requirement;
- b) a pre- anesthesia evaluation shall;
 - i. include a review of the medical history

- ii. include an interview and examination of the patient,
 - iii. include a documented airway assessment,
 - iv. include an anaesthesia risk assessment,
 - v. include an anaesthesia drug and allergy history, and
 - vi. be performed by an individual, qualified and privileged to administer anaesthesia/sedation, and will be performed within 48 hours prior to inpatient or outpatient surgery or procedure requiring anaesthesia services (the delivery of the first dose of medications for the purpose of inducing anaesthesia, marks the end of the 48 hour time frame).
- c) an intra-operative anaesthesia record shall be present for each patient who will receive general, regional or monitored anaesthesia. Patients who will be receiving moderate sedation shall be monitored and evaluated before, during and after a procedure by a trained practitioner, however an intra-operative anaesthesia record is not required because moderate sedation is not considered to be “anaesthesia” and is not subject to this requirement.
- d) if the patient is discharged less than 48 hours after the procedure, completion and documentation of the post-anaesthesia evaluation is still required. This is the case regardless of whether the procedure is performed on an inpatient or outpatient basis or when the patient is discharged
- e) for inpatient and outpatient surgery, a post-anaesthesia evaluation for proper anaesthesia recovery is completed and documented within 48 hours after surgery by the individual who administers the anaesthesia or, if approved by the medical staff, by any individual qualified and credentialed to administer anaesthesia;
- f) a post-anaesthesia evaluation for anaesthesia recovery is required for each patient who will receive general, regional or monitored anaesthesia. Patients who will be receiving moderate sedation shall be monitored and evaluated before, during and after a procedure by a trained practitioner, however a post-anaesthesia evaluation is not required because moderate sedation is not considered to be “anaesthesia” and is not subject to this requirement.
- g) the elements of an adequate post-anaesthesia evaluation should be clearly documented and conform to recognized standards of anaesthesia care, including:
- i. Respiratory function, including respiratory rate, airway patency, and oxygen saturation;
 - ii. Cardiovascular function, including pulse rate and blood pressure;
 - iii. Mental status;
 - iv. Temperature;
 - v. Pain;
 - vi. Nausea and vomiting; and
 - vii. Postoperative hydration.

Interpretive Guidelines

The hospital shall develop and implement policies and procedures regarding the administration of anaesthesia/sedation. This will include the responsibilities for both pre-anaesthesia/sedation and post-anaesthesia/sedation.

Policies and procedures for pre-anaesthesia/sedation shall address the following:

- I. Physical examination of the airway (by those qualified and privileged to administer sedation) shall be performed within 48 hours of administration of anaesthesia/sedation;*
- II. Assessment of risk to the patient for receiving anaesthesia/sedation;*
- III. Drug and allergy history regarding anaesthesia/sedation;*
- IV. Physical condition of the patient prior to induction of anaesthesia/sedation;*
- V. Patient consent for administration of anaesthesia/sedation*

- VI. *Equipment requirements, as well as the monitoring, inspection, testing and maintenance of anesthesia/sedation equipment in the hospital's biomedical equipment program*
- VII. *Infection control practices in place; and,*
- VIII. *Safety measures in place in areas where anesthesia/sedation is administered (including a protocol for supportive life functions, e.g., cardiac and respiratory emergencies.*
- IX. *Reporting and documentation requirements*

Intra-operative anesthesia/sedation/sedation records shall as a minimum include:

- X. *Name and hospital identification number of the patient;*
- XI. *Name(s) of practitioner(s) who administered anesthesia/sedation, and as applicable, the name and profession of the supervising anesthesiologist or operating practitioner;*
- XII. *Name, dosage, route and time of administration of drugs and anesthesia/sedation agents;*
- XIII. *Techniques used and patient position(s), including the insertion of any intravascular or airway devices*
- XIV. *Name and amount of IV fluids;*
- XV. *Blood or blood products; if applicable*
- XVI. *Time-based documentation of vital signs as well as oxygenation and ventilation parameters;*
- XVII. *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.*

Post-anesthesia/sedation follow-up reports shall be completed and documented within 48 hours following the procedure in which anesthesia/sedation has been administered and shall as a minimum include:

- XVIII. *Cardiopulmonary status;*
- XIX. *Level of consciousness;*
- XX. *Any follow-up care and/or observations;*
- XXI. *Any complications occurring during post-anesthesia/sedation recovery; and,*
- XXII. *Any follow-up care needed or patient instructions given.*

Surveyor Guidance:

Review the policies developed on anesthesia/sedation procedures.

Verify that the anesthesia/sedation services where provided incorporates that has been listed in interpretive guidelines.

Sample patient medical records to verify the following:

- I. *pre-anesthesia/sedation evaluation that includes all of the defined elements;*
- II. *an intra-operative anesthesia/sedation record documenting all pertinent events taking place during anesthesia/sedation that includes all of the defined elements;*
- III. *a post-anesthesia/sedation follow-up report is written for each patient by an individual who is qualified to administer anesthesia, or by a delegated practitioner who is qualified to administer anesthesia, within 48 hours after surgery and that the report includes all of the defined elements.*

- IV. *a post-anesthesia/sedation evaluation for proper anesthesia/sedation recovery in accordance with hospital policies and procedures. Also verify that this evaluation includes those items stated within the interpretive guidelines.*
- V. *post-anesthesia evaluation is completed by individual qualified and credentialed to administer anesthesia and in accordance with and hospital policies and procedures and reflect recognized standards of care.*

Section 14 Obstetric Services (OB)

OB.1 – Organization

SR.1 For hospitals that provide obstetric services these services shall be well organized, appropriate to the scope of the services offered, and clinical processes shall meet recognized standards.

Interpretive Guidelines

Hospitals that provide obstetric services are required to demonstrate that they operate within safe staffing levels in accordance with hospital policy taking into account national legal and regulatory requirements. All staff groups (nurses, nursing assistants, midwives, obstetricians, anesthetist and anesthetist assistants) shall be included.

As a minimum the obstetric services are required to have policies and procedures in place which as a minimum shall include:

- I. Antenatal Policies & Procedures:
 - a) booking appointments*
 - b) clinical risk assessment*
 - c) antenatal screening (maternal and fetal)**

- II. Intrapartum Policies & Procedures
 - a) Care of women in Labor*
 - b) Fetal Monitoring*
 - c) Caesarean Section*
 - d) Eclampsia*
 - e) Shoulder Dystocia*
 - f) Operative Vaginal Delivery*
 - g) Post-Partum Hemorrhage*
 - h) Management of a severely ill women**

- III. Postnatal Policies & Procedures
 - a) Immediate care of the Newborn*
 - b) Admission to Neonatal Unit*
 - c) Newborn Feeding**

The obstetrics services shall define the specialist training requirement of all staff who provide care within the obstetric services (nurses, nursing assistants, midwives, obstetricians, anesthetist and anesthetist assistants and pediatricians) In setting the training requirements the frequency of training updates shall be documented.

Surveyor Guidance

Verify that the obstetric services have agreed and documented minimum acceptable and safe staffing levels for all areas of the obstetric services as required in SR1.

Verify that the obstetric services have policies and procedures in place which as a minimum shall include those listed above.

Verify that the obstetrics services have agreed and documented the specialist training requirement of all staff who provide care within the obstetric services.

Verify that staff have received training in accordance with hospital policy.

Section 15 Laboratory Services (LS)

LS.1 – Organization

- SR.1** The hospital shall maintain, or have available, adequate laboratory services, either directly or through contractual services, to meet the needs of its patients.
- SR.2** The hospital shall ensure that all laboratory services provided to its patients are performed in a certified laboratory.
- SR.3** The hospital shall have the capability to perform necessary laboratory studies, including blood gas analysis and electrolyte determination 24 hours a day.
- SR.4** A documented scope of laboratory services shall be available to the medical staff.
- SR.5** The laboratory shall have policies and practices for proper receipt and reporting of tissue specimens.
- SR.6** The hospital and a pathologist shall determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.

Interpretive Guidelines:

The hospital shall maintain, or have available, adequate laboratory services whenever its patients need those services. The hospital may maintain laboratory services at the hospital or may make laboratory services available through contractual agreements. All laboratory services will be provided in a laboratory that has been certified in accordance with national legal and regulatory requirements.

The hospital will have a documented scope and complexity of the laboratory services available. This will include the capability to perform necessary laboratory studies, including blood gas analysis and electrolyte determination 24 hours a day. The hospital shall have a current license appropriate to the level of services performed.

The medical staff and a pathologist shall determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations. There will be documented policies and practices for proper receipt and reporting of tissue specimens.

Surveyor Guidance:

Determine the total number of laboratories, the location of each laboratory, and every location where laboratory procedures are performed.

Determine which services are provided directly by the hospital and which are provided through contractual arrangements. If provided under a contractual arrangement, verify that the provider has been approved by the organization.

Validate that the laboratory services are provided and operating under a current license.

Review a sampling of records and determine if the laboratory services, including those provided to emergency services, are provided in accordance with the hospital's policies.

Review a sampling of tissue records (accession records, worksheets, and test reports) to verify whether the laboratory follows the written protocol.

Review the written policies and tissue reports to assure that tissue specimens are examined in accordance with the written policies.

Section 16 Blood Supply and Management (BM)

BM.1 – Organization

- SR.1** The hospital 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.
- SR.2** The preparation of blood and blood products used for patient care shall be prepared:
- in units that have effective quality systems, including quality management in place
 - using quality standards
 - in units that have effective documentation systems in place
 - using appropriately trained staff
 - subject to regular quality assessment.
- SR.3** 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 *Trypanosomacruzi* (Chagas disease) and *Plasmodium* species (malaria); as well as testing for blood groups and compatibility.
- SR.4** If an organization 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 that ensures blood and blood products comply with the requirements in SR.1, SR.2 and SR.3.
- SR.5** The hospital shall 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 that they are available for prompt retrieval.

Interpretive Guidelines:

The hospital shall demonstrate that they have policies and procedures in place to ensure the safe transfusion of blood and blood products addresses all elements covered in SR.1 – SR.5

This standard requires that the hospital have a system in place for quality-assured screening for transfusion transmissible infections and processes to take appropriate action when notified that blood or blood products received are at increased risk of transmitting potential infections; as a minimum including those listed under SR.3. Definition: "Look back" is considered to include: the quarantine of products from a window period donor; notification of consignees (facilities having received such window period products) to quarantine those products; and on completion of the licensed, more specific (confirmatory) test, notification of any transfusion recipient.

If the hospital regularly uses the services of an outside blood bank, it shall have an agreement with the blood bank to govern the procurement, transfer, and availability of blood and blood products. This applies to

hospitals that receive blood and blood products from an outside source and only performs compatibility (cross match) testing in preparation for transfusion to patients.

The agreement(s) and practice policies developed between the hospital and blood bank shall be consistent with applicable national legal and regulatory requirements and written with the means of addressing any changes and can be incorporated into operating procedures rather than by constructing a new agreement.

Under certain circumstances, and if permissible under national legal and regulatory requirements, such as emergencies when blood or blood products are required, hospitals may receive blood from a source other than the contracted blood bank.

The agreement between the notification process and procedure shall include the elements as stated in SR.2(a) – SR.2(e).

If the blood bank notifies the organization that the result of the more specific test or other follow up testing is negative, absent other informative test results, the organization may release the blood and blood products from quarantine.

Surveyor Guidance:

Verify that the hospital has policies and procedures in place to ensure the safe transfusion of blood and blood products and addresses all elements covered in SR.1 – SR.5.

Verify that the agreement with the blood bank that governs the procurement, transfer, and availability of blood and blood products and that ensures blood and blood products comply with the requirements in SR.1, SR.2 and SR.3.

Verify that the hospital has a system in place for quality-assured screening for transfusion transmissible infections and processes to take appropriate action when notified that blood or blood products received are at increased risk of transmitting potential infections; as a minimum including those listed under SR.3.

Verify that the hospital maintains 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 in such a manner they are available for prompt retrieval.

Section 17 Medical Imaging (MI)

MI.1 – Organization

- SR.1** The hospital shall maintain, or have readily available, diagnostic radiology services that meet professionally approved standards and national legal and regulatory requirements. The medical imaging services, particularly ionizing medical imaging procedures, shall be free from hazards for patients and personnel.
- SR.2** If therapeutic services are also provided, they shall meet professionally approved standards and national legal and regulatory requirements.

Interpretive Guidelines:

The organization shall maintain, or have readily available, diagnostic radiology services that meet professionally approved standards and national legal and regulatory requirements for radiation safety.. The scope and complexity of radiological services offered should be specified in writing and approved by the hospital. These services shall be readily available 24 hours a day. This applies to radiology services that may be provided by the hospital or through a contractual arrangement.

If diagnostic radiology services are provided under a contract arrangement, the services may be provided either on the hospital premises or in an adjacent or other nearby location. In all circumstances, these services shall be readily accessible to the organization's facility 24 hours a day.

If radiology services are provided through a contractual arrangement the hospital shall ensure that systems are in place to verify that the contracted entity and its employees or agents are properly qualified.

Surveyor Guidance:

Verify that the hospital maintains (or provides in some manner) radiology services that meet the needs of the patients.

Verify that the radiology services are provided in accordance with national legal and regulatory requirements, and are maintained or available 24 hours a day to meet the patient needs.

If radiology services are provided through a contractual arrangement, verify that the contracted entity adheres to applicable policies and procedures of the organization and that the contracted entity and its employees or agents are properly qualified.

MI.2 – Radiation Protection

- SR.1** 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.
- SR.2** Staff 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.
- SR.3** Any high radiation readings shall be investigated and reported to Quality Management oversight.

Interpretive Guidelines:

The hospital shall develop and implement policies and procedures to provide a safe environment for patients and staff.

The hospital policies and procedures shall address the safety standards for the following:

- I. Adequate shielding for patients, personnel and facilities;*
- II. Labeling of radioactive materials, waste, and hazardous areas;*
- III. Transportation of radioactive materials between locations within the hospital;*
- IV. Securing radioactive materials, including determining limitations of access to radioactive materials;*
- V. Testing and maintenance of equipment for prevention of radiation hazards;*
- VI. Maintenance monitoring and measuring devices for equipment;*
- VII. Proper storage of radiation monitoring badges when not in use;*
- VIII. Storage and disposal of radio nuclides and radio pharmaceuticals as well as radioactive waste; and,*
- IX. Methods of identifying patients who may be pregnant.*

The hospital shall implement and ensure compliance with its established safety standards.

The hospital shall require any staff member who may be exposed to radiation or working near radiation sources wear badges to identify levels for amount of radiation exposure. This includes certain radiology technologists, radiologists, nursing and maintenance staff.

The hospital shall make sure that any high radiation readings are investigated and reported to Quality Management Oversight.

Surveyor Guidance:

Review locations where radiological services are provided.

Verify that hospital policies and procedures include the safety standards as listed above in the interpretive guidelines. Verification is also required that these safety standards are being implemented.

Verify that the hospital investigates and reports any high radiation readings to Quality Management Oversight.

MI.3 – Equipment

SR.1 Periodic inspection of equipment shall be performed, in accordance to manufacturer's recommendations. Hazards shall be identified and promptly corrected.

SR.2 Documentation of preventative maintenance and repairs of radiology equipment shall be maintained.

Interpretive Guidelines:

The hospital shall have policies and procedures in place to ensure that periodic inspections of radiology equipment are conducted. 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. The hospital shall maintain repair documentation and records for periodic maintenance.

Either the hospital staff or a qualified contract entity shall ensure that equipment is inspected in accordance with manufacturer's instructions, national legal and regulatory requirements and hospital policy.

Surveyor Guidance:

Review the records (often maintained in Biomedical/Clinical Engineering) to verify that periodic inspections are conducted in accordance with manufacturer's instructions, national legal and regulatory requirements and hospital policy.

Select the equipment numbers to trace back through the records system to verify calibration and periodic preventive maintenance performed.

Review the process for detection and correcting identified problems and the timeliness of the response.

MI.4 – Order

SR.1 Medical imaging services shall be provided only on the order of practitioners with clinical privileges or, consistent with national and regulatory requirements. Other practitioners providing this service shall be approved and authorized by the medical staff and the governing body.

Interpretive Guidelines:

The hospital policies shall identify that medical imaging services shall be provided only on the order of practitioners with clinical privileges or, consistent with national legal and regulatory requirements. Other practitioners providing this service shall be approved and authorized by the medical staff and the governing body.

Surveyor Guidance:

Review medical records to determine that radiology services are provided only on the orders of practitioners. The practitioners ordering radiology services shall have these clinical privileges. This also applies to practitioners outside the hospital who have been authorized by the hospital to order radiology services, consistent with national legal and regulatory requirements.

MI.5 – Supervision

SR.1 A qualified full-time, part-time, or consulting radiologist shall supervise the ionizing radiology services. They shall be responsible for interpreting radiology tests that are determined by the hospital to require a radiologist's specialized knowledge.

SR.2 For purposes of this standard, a radiologist is a physician who is qualified by education and experience in radiology.

Interpretive Guidelines:

In accordance with national legal and regulatory requirements, and hospital policy the hospital shall approve the qualifications of the individual(s) responsible for the supervision of radiology services.

The hospital shall develop and implement policies that identify which radiology tests require interpretation by a radiologist.

Surveyor Guidance:

Review the radiologist's credentialing file to verify that he or she has met the qualifications established by the hospital for appointment. If these services are provided by a contracted entity, the survey team will verify that the hospital has a verification process for those providing these services on behalf of the contracted entity. The radiologist may be required to go through the medical staff credentialing and privileging process of the hospital.

Verify that the hospital has policies that identify which radiology tests require interpretation by a radiologist and verify records to determine that a radiologist who interprets those tests has been credentialed and approved by the organization as a qualified radiologist.

MI.6 – Staff

SR.1 Only staff designated as qualified by National and local legislation and regulations may use the medical imaging equipment and perform medical imaging procedures.

Interpretive Guidelines:

The hospital should maintain appropriate policies, developed and approved by the organization, consistent with national legal and regulatory requirements, to designate which personnel are qualified to use the radiology equipment and administer procedures.

Surveyor Guidance:

Review and verify which staff are using various radiological equipment and/or administering patient procedures to ensure they have been deemed competent to use and perform as needed. This may be done through a sample review of staff personnel files to determine these individuals meet the qualifications established by the medical staff for the tasks that are performed.

MI.7 – Records

SR.1 Records of medical imaging services shall be maintained in accordance with National and local legislation and regulations.

Interpretive Guidelines:

The hospital shall ensure that records of medical imaging services are maintained in accordance with national legal and regulatory requirements.

Surveyor Guidance:

Review hospital records to verify that records of medical imaging services are maintained in accordance with national legal and regulatory requirements.

MI.8 – Interpretation and Records

- SR.1** The radiologist or other practitioner who interprets radiology images and outcomes shall sign the written reports of the interpretations.
- SR.2** The hospital shall maintain the following for at least 5 years or in accordance with National and local legislation and regulations:
- a) copies of reports and printouts; and
 - b) films, scans, and other imaging records.

Interpretive Guidelines:

The hospital shall maintain records for all radiology procedures performed in accordance with the national and regulatory requirements. As a minimum, the records should include copies of reports and printouts, and any films, scans or other image records, as appropriate.

The hospital should have policies and procedures that ensure the integrity of authentication and protect the privacy of radiology records. Medical records, which include radiology films, image records, scans, reports, and printouts shall be secure, properly stored, be accessible and retrievable in a timely manner when needed for any care, procedure, treatment, or test provided or conducted within the past 5 years or in accordance with national and regulatory requirements.

Surveyor Guidance:

Review a sampling of radiology records to verify that reports are signed by the practitioner who reads and evaluates images or scans.

Review the hospital's policies, procedures and practices for maintaining radiology records. The documented procedure for control of records should accurately define these radiology records and the retention, storage and accessibility of these records. Verify that the hospital maintains radiology records for at least 5 years or in accordance with national and regulatory requirements.

Section 18 Nuclear Medicine Services (NM)

NM.1 – Organization

- SR.1** If the hospital provides nuclear medicine services; those services shall meet the needs of the patients in accordance with acceptable standards of practice as defined by the hospital. The nuclear medicine services shall be free from hazards for patients and personnel.
- SR.2** The organization of the nuclear medicine service shall be appropriate to the scope and complexity of the services offered.
- SR.3** There shall be a director who is a physician qualified in nuclear medicine.
- SR.4** The qualifications, training, functions, and responsibilities of nuclear medicine staff shall be specified by the service director and approved by the hospital.

Interpretive Guidelines:

If the hospital provides nuclear medicine services, directly or through a contractual arrangement, they shall be appropriate to the scope and complexity of services offered to its patients. The services shall be in accordance with acceptable standards of practice as well as any standards and recommendations of recognized professional organizations.

Nuclear medicine services shall be under the direction of a senior individual who shall be qualified in nuclear medicine.

The medical staff and physician responsible for nuclear medicine services shall define the appropriate qualifications, training, functions, and responsibilities of nuclear medicine staff.

Surveyor Guidance:

Review and validate the type(s) of services provided and the location where these services are provided.

Review and verify that the senior individual responsible for nuclear medicine services is qualified based upon education, experience and specialized training in nuclear medicine, appropriate to the scope and complexity of services offered.

In review of a sampling of personnel files for nuclear medicine staff, verify that they have the appropriate qualifications.

NM.2 – Radioactive Materials

- SR.1** Radioactive materials shall be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice as defined by the hospital.
- SR.2** The hospital shall maintain records of the receipt and disposition of radiopharmaceuticals.

SR.3 In-house preparation of radiopharmaceuticals shall be by or under the direct supervision of an appropriately trained registered pharmacist, or physician or nuclear medicine professional deemed competent by the hospital.

Interpretive Guidelines:

The hospital shall prepare, label, use, transport, store, and dispose of radioactive materials in accordance with National and local laws, hospital policy, regulations and guidelines. The hospital should define through policies and procedures practices to include:

- I. Handling of equipment and radioactive materials;*
- II. Protection of patients and personnel from radiation hazards;*
- III. Labeling of radioactive materials, waste and hazardous areas;*
- IV. Transportation of radioactive materials between locations within the hospital;*
- V. Security of radioactive materials, including determining who may have access to radioactive materials and controlling access to radioactive materials;*
- VI. Testing of equipment for radiation hazards;*
- VII. Maintenance of personal radiation monitoring devices;*
- VIII. Storage of radionuclides and radiopharmaceuticals as well as radioactive waste; and*
- IX. Disposal of radionuclides, unused radiopharmaceuticals, and radioactive waste.*

Records shall be maintained regarding the receipt and disposition of radiopharmaceuticals and have a stated timeframe for retention of these records in accordance with National and local legislation and regulations and hospital policies or guidelines.

An appropriately trained nuclear medicine professional deemed competent by the organization shall oversee the preparation of radiopharmaceuticals.

Surveyor Guidance:

Review and validate that radioactive materials and waste are prepared, labeled, used, transported, stored and disposed of in accordance with National and local legislation and regulations and hospital policies and acceptable standards of practice.

Verify that safety precautions are followed in the functioning of the nuclear medicine service and those personnel and patients wear appropriate body shielding (e.g., lead aprons or lead gloves) when appropriate.

When radiopharmaceuticals are prepared in-house, verify that the preparation is performed by an appropriately trained registered pharmacist, physician or a nuclear medicine professional deemed competent by the organization.

Review and verify written policies and procedures to govern the preparation, labeling, use, transporting, storage, and disposal of radioactive materials in accordance with acceptable standards of practice as defined by the organization.

NM.3 – Equipment and Supplies

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

SR.2 The equipment shall be maintained in safe operating conditions and inspected, tested, and calibrated at least annually by qualified personnel.

SR.3 Documentation of equipment testing and preventative maintenance shall be maintained.

Interpretive Guidelines:

The hospital shall 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.

Nuclear medicine equipment shall be inspected, tested and calibrated at least annually by qualified personnel in accordance with National and local laws, regulations and guidelines and appropriate documentation (records) maintained.

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

NM.4 – Interpretation

SR.1 The approved practitioner shall interpret and sign all diagnostic tests.

SR.2 The hospital shall maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures.

SR.3 The hospital shall maintain copies of nuclear medicine reports for at least five (5) years or in accordance with National and local legislation and regulations.

Interpretive Guidelines:

Only practitioners approved by the organization may interpret and sign the interpretation of diagnostic procedures and tests as defined within hospital policy.

The hospital shall maintain records for all nuclear medicine procedures. At a minimum, these records will include signed and dated reports of nuclear medicine interpretations, consultations, and procedures. This documentation is a part of the patient's medical record and shall comply with National and local laws, hospital policy, regulations and guidelines and be no less than 5 years.

Surveyor Guidance:

Review and verify that only practitioners approved by the organization to interpret diagnostic procedures.

Review and verify that reports of nuclear medicine interpretation, consultations and procedures are signed and dated only by practitioners authorized by the organization to perform these interpretations.

Verify that copies of nuclear medicine reports are adequately maintained for at least 5 years.

Section 19 Rehabilitation Services (RS)

RS.1 – Organization

SR.1 If the hospital 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.

Interpretive Guidelines:

Rehabilitative services (including contractual services) may include physical therapy, occupational therapy, audiology and speech pathology services.

The hospital will adhere to acceptable standards of practice include compliance with any applicable national and regulatory requirements, as well as standards and recommendations promoted by recognized professional organizations.

Surveyor Guidance:

Review the extent of rehabilitation services and if these services are provided directly by the hospital or through a contractual arrangement.

Validate that these services are provided in a manner that ensures the patient's health and safety.

Verify that rehabilitation services are integrated into the hospital's quality management system oversight.

RS.2 – Management and Support

SR.1 The hospital shall ensure that there is the appropriate management and support for this core process. These requirements shall include:

- a) a director/manager who has the responsibility and accountability for these services
- b) the director/manager shall have the qualifications, experience and/or training defined by the hospital
- c) services shall be provided by qualified physical therapists, physical therapists assistants, occupational therapists, occupational therapist assistants, speech-language therapists, or audiologists as defined by the hospital and consistent with National and local legislation and regulations.

Interpretive Guidelines:

The hospital shall manage and support the service(s) as necessary to maintain the level provided. In order to support these services, the appropriate equipment and qualified personnel shall be in place and follow acceptable standards of practice.

The rehabilitation services offered shall be under the direction of a qualified individual that will have the accountability, qualifications, and experience appropriate for this position. The staff (employed or contracted) shall meet the required qualifications, as defined by the organization to provide these services.

Surveyor Guidance:

Review the hospital's policies and procedures to verify that the scope of rehabilitation services offered is defined in writing and these services are under the direction of a qualified individual.

Verify that staff providing rehabilitative services meet the qualifications as defined by the organization and are consistent with national and regulatory requirements. These shall be performed by qualified individuals as listed above in SR.

If services are provided under a contractual arrangement, determine that the agreement requires the staff to be appropriately qualified and scope of services provided.

Sample personnel files to verify current licensure, certifications and ongoing training, consistent with applicable national and regulatory requirements.

RS.3 – Treatment Plan / Orders

SR.1 The treatment plan, rehabilitative services provided and the personnel qualifications shall be in accordance with acceptable standards of practice as defined by the hospital.

SR.2 Rehabilitative services shall only be provided under the orders of a qualified and registered practitioner who has been authorized to order these services in accordance with acceptable standards of practice as defined by the hospital and National and local legislation and regulations.

SR.3 All orders for rehabilitative services, treatment plan, results, and notes shall be documented in the patient's medical record.

Interpretive Guidelines:

The hospital shall have an individualized plan of treatment, based on the patient's specific rehabilitation needs, input from family/caregivers and therapeutic treatment goals for the patient that are documented in the patient's record prior to the initiation of treatment. As a minimum, this treatment plan will include:

- I. The order from the practitioner for the service(s) in collaboration with individuals qualified to provide the service(s);*
- II. The type, amount, frequency and duration of services;*
- III. Measurable short-term and long-term goals, results and notes; and,*
- IV. Reviews and revisions, as necessary, to account for changes in the patient's response to therapeutic intervention.*

Surveyor Guidance:

Sample patient records to verify that rehabilitation services are provided under the orders of a qualified and registered practitioner who has been authorized by the hospital.

In the review of patient records, verify that there are treatment plans which as a minimum will include those elements listed within the interpretive guidelines.

Verify that changes in the treatment plan are documented in the patient's medical record to include the evaluation, test results, or orders, and practitioner approvals of changes.

Section 20 Emergency Department (ED)

ED.1 – Organization

- SR.1** The hospital shall meet the emergency needs of its patients in accordance with acceptable standards of practice as defined by the hospital.
- SR.2** Emergency Services shall be organized and integrated with other departments under the direction and supervision of a qualified member of the medical staff.
- SR.3** The hospital shall be responsible for developing and maintaining policies and procedures governing the care delivered.

Interpretive Guidelines:

The hospital's emergency services shall be integrated with the other departments of the hospital (e.g. surgical services, laboratory, ICU, diagnostic services) and be accessible in the delivery of emergency care for patients.

The emergency department will be under the direction of a qualified member of the medical staff.

The hospital will define and document the criteria that include the qualifications for the director of emergency service in accordance with national and regulatory requirements.

The hospital will ensure that policies and procedures are developed and implemented to govern the emergency services provided.

Surveyor Guidance:

Verify that emergency services are organized under the direction of a qualified member of the medical staff.

Review and validate policies and procedures (including triage of patients) and that they are evaluated and updated on an ongoing basis in accordance with hospital standards.

Review and validate the coordination and communication between the Emergency Department and other hospital services/departments (e.g. laboratory, diagnostic services, surgical services).

ED.2 – Staffing

- SR.1** The emergency department shall be appropriately staffed at all times by medical and nursing staff qualified in emergency care, as outlined within the written scope of service.
- SR.2** A qualified professional as defined by the hospital shall perform patient triage upon presentation to the emergency department.

Interpretive Guidelines:

The hospital 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.

The hospital shall also provide nursing staff qualified in emergency care, as outlined in the written scope of service, to be present when emergency services are provided.

The hospital 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.

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

Surveyor Guidance:

Verify that a qualified member of the medical staff is on premises and available to supervise the provision of emergency services 24 hours a day.

Verify that the hospital provide nursing staff qualified in emergency care, as outlined in the written scope of service, to be present when emergency services are provided.

Verify that 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.

Verify that the hospital has emergency planning procedures in place to address the need for appropriate staffing levels during times of emergency/disaster.

ED.3 – Emergency Services Not Provided

SR.1 If emergency services are not provided at the hospital, the hospital has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.

Interpretive Guidelines:

This requirement applies hospital-wide (on-campus and off-campus locations) that do not provide emergency services.

The organization has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.

The hospital shall have appropriate policies and procedures in place for dealing with emergency care situations at the hospital. This includes emergencies that occur to hospital patients, staff, visitors, and others at any hospital location and to individuals who come to the hospital or any of its off-campus locations seeking/requiring emergency care.

Surveyor Guidance:

Review and verify that the organization has implemented written policies and procedures for the management of medical emergencies.

Interview staff to ensure they are aware of the policies and procedures for managing medical emergencies

Discuss with staff their role and responsibilities if such an emergency is encountered how they will respond and the this is consistent with the policies and procedures in place

Review and validate that emergency care policies and procedures address both on-campus and off-campus locations.

ED.4 – Off-Campus Departments

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

Interpretive Guidelines:

This requirement applies to off-campus departments that do not provide emergency services.

The hospital will implement written policies and procedures for appraising and referring emergencies that occur in off-campus departments. This includes emergencies involving patients, staff, visitors or others or individuals who come to those locations seeking/requiring emergency care.

Initial treatment and stabilization of patients requiring emergency care shall be provided within the capabilities and complexities of services provided and the staff on-site at these off-campus departments.

Surveyor Guidance:

Review and validate that written policies and procedures address the appraisal and referral of medical emergencies that occur in off-campus departments. As appropriate, when visiting the off-campus departments, validate that the staff are aware of these policies and procedures.

Interview staff to ensure they are aware of the policies and procedures for managing medical emergencies

Discuss with staff their role and responsibilities if such an emergency is encountered how they will respond and the this is consistent with the policies and procedures in place

Section 21 Outpatient Services (OS)

OS.1 – Organization

SR.1 If the hospital provides outpatient services, the services shall be appropriately organized and integrated with inpatient services.

Interpretive Guidelines

If the hospital provides outpatient care to its patients, these services shall be organized and integrated with inpatient services, as appropriate.

The organization of the hospital's outpatient services shall be appropriate to the scope and complexity of services offered.

All outpatient services provided by the hospital shall meet the needs of the patients, in accordance with acceptable standards of practice. The hospital shall ensure that services, equipment, staff, and infrastructure are adequate to provide the outpatient services offered at each location in accordance with acceptable standards of practice.

Outpatient services shall be integrated into the hospital's quality management system oversight.

Surveyor Guidance:

Verify the extent of outpatient services provided; and,

Verify that the outpatient services are organized in a manner appropriate to the scope and complexity of services offered.

Review medical records of outpatients who were later admitted to the hospital in order to determine that pertinent information from the outpatient record has been included in the inpatient record.

Verify that outpatient services are integrated into the hospital's quality management system oversight.

OS.2 – Staffing

SR.1 The hospital shall assign one or more individuals to be responsible for outpatient services.

SR.2 The hospital shall have appropriate professional and non-professional personnel available at each location where outpatient services are offered, based on the scope and complexity of outpatient services.

Interpretive Guidelines

In order to support these services the hospital shall ensure that an individual is responsible for outpatient services and have appropriate professional and nonprofessional staff available.

Surveyor Guidance:

Verify that the hospital has an individual responsible for outpatient services and has appropriate professional and nonprofessional staff available.

OS.3 – Scope of Service

SR.1 A documented scope of service shall be available for each patient care site that includes core staffing for each site with associated staff responsibilities.

Interpretive Guidelines:

The hospital shall designate an individual responsible for the overall operation of the hospital's entire outpatient services (all outpatient services). The hospital should define in writing the qualifications and competencies necessary to direct the outpatient services.

Adequate types and numbers of qualified professional and nonprofessional personnel shall be available to provide patients with the appropriate level of care and services.

Surveyor Guidance:

Verify that the hospital has designated an appropriately qualified individual to manage and be responsible for outpatient services.

Review and validate the application of policies and contracts, if services provided are under an arrangement.

Review the scope of services for patient care and document core staffing for each area.

Section 22 Dietary Services (DS)

DS.1 – Organization

- SR.1** Dietary Services are organized processes that shall be carried out internally or through a contract with a nutrition management company. Provider services shall interact on a regular basis with the medical staff on dietetic policies affecting patient care.
- SR.2** The hospital shall ensure that there is the appropriate management and support for this service. The person responsible for the management, direction and accountability of dietary services shall be; a full time employee and shall have the qualifications, experience and training defined by the hospital.
- SR.3** The person responsible for the management of Dietary Services shall ensure that the appropriate administrative and technical personnel are competent and adequate to carry out this process for the hospital.
- SR.4** The hospital shall have a qualified dietician employed on a full-time or part-time basis or contracted as a consultant for the hospital and available as needed.

Interpretive Guidelines:

The nutritional needs of the patients are met in accordance with hospital policy and national and regulatory requirements for food and dietary personnel as well as food service standards, laws and regulations. These activities are carried out by food and dietetic services. This can be completed with qualified hospital staff or through a contractual basis with a nutrition management company.

The individual responsible for Food and Dietetic Services shall be appropriately qualified and responsible for operational management, implementing training and education for dietary staff, and assuring that there are policies and procedures developed and implemented to address at least the following:

- I. Work assignments, supervision of work and personnel performance;*
- II. Safety practices for food handling;*
- III. Provision for emergency food supplies; and,*
- IV. Supervision of the menu planning function, purchasing of foods and supplies, and retention of required records.*

The hospital shall have written policies and procedures that address at least the following:

- V. Availability of a diet manual and therapeutic diet menus to meet patients' nutritional needs;*
- VI. Frequency of meals served;*
- VII. Process for ordering and delivery of food to respective patient areas;*
- VIII. Accommodation of non-routine occurrences (e.g., parenteral nutrition (tube feeding), total parenteral nutrition, peripheral parenteral nutrition, change in diet orders, early/late trays, nutritional supplements, etc.); and,*
- IX. Guidelines for acceptable hygiene practices of food service personnel and the sanitation protocols for the preparation and cleaning areas.*

The hospital shall have a qualified dietician to supervise the nutritional aspects of patient care. If the qualified dietitian does not work full-time, and when the dietitian is not available, the hospital shall make adequate provisions for dietary consultation that meets the needs of the patients. The qualified dietician shall be responsible for:

- X. Approving menus and nutritional supplements provided to patients;*
- XI. Provide dietary counseling to patients and those responsible for the patient upon discharge;*
- XII. Performing and documenting nutritional assessments;*
- XIII. Evaluating patient tolerance to therapeutic diets as appropriate;*
- XIV. Collaborating with other hospital services (e.g., medical staff, nursing services, pharmacy service, social work service, etc.) to plan and implement patient care as necessary to meet the nutritional needs of the patients; and*
- XV. Maintaining pertinent patient data necessary to recommend, prescribe, and/or modify therapeutic diets as needed to meet the nutritional needs of the patients;*

Surveyor Guidance:

Verify that the individual responsible for food and dietetic services has an appropriate job description to verify that his or her responsibility and authority for the direction of the food and dietary service has been clearly delineated.

Verify that the dietitian is qualified for this role and has an appropriate job description to verify he or she has the experience, specialized training, and required licensure or certification (as required by national and regulatory requirements).

Verify that the dietician is meeting the expectations of the role of the job as identified within the interpretive guidelines above.

If the dietitian is not full-time, determine the frequency in which the nutritional needs of the patients are assessed, and that the hospital makes adequate provisions for qualified consultant coverage when this dietitian is not available. This would include evening and weekend coverage.

DS.2 – Services and Diets

SR.1 Dietary Services shall be provided and menus/diets offered that meet the needs of the patients.

SR.2 All therapeutic diets shall be prescribed by a practitioner or practitioners responsible for the care of the patient.

SR.3 All nutritional needs of patients shall be met in accordance with recognized dietary practices that are consistent with the orders of the practitioner or practitioners responsible for the care of the patients.

Interpretive Guidelines:

Menus provided by the hospital shall be nutritionally balanced and meet the special needs of the patients. In the event a patient refuses the food served, the patient should be offered an appropriate substitute that is of equal nutritional value in order to meet their nutritional needs. Religious beliefs should also be taken into consideration if applicable

Review the screening criteria to identify patients at nutritional risk and how the process is carried out from assessment and re-assessment to ensure that their nutritional needs are being met.

The following represent examples of patients who require nutritional assessment. The organization may define additional criteria for the provision of nutritional assessments:

- I. All patients requiring artificial nutrition by any means (i.e., parenteral nutrition (tube feeding), total parenteral nutrition, or peripheral parenteral nutrition);*
- II. Patients whose medical condition or physical status (current or future status based upon care plan) interferes with their ability to ingest, digest or absorb nutrients;*
- III. Patients whose diagnosis or presenting signs/symptoms indicates a compromised nutritional status (e.g., anorexia nervosa, bulimia, electrolyte imbalances, dysphagia, malabsorption, end stage organ diseases, etc); and,*
- IV. Patients whose medical condition is directly impacted by their nutritional intake (e.g., diabetes, congestive heart failure, food/drug interactions, etc).*

The hospital shall have policies which outline the process for nutritional assessment of all patients.

For all therapeutic diets provided to patients as a result of a nutritional assessment or as prescribe, such diets should be:

- V. Prescribed in writing by a qualified practitioner or a qualified dietitian;*
- VI. Documented in the patient's medical record (include the patient's tolerance to the diet); and,*
- VII. And evaluated for nutritional adequacy to meet the patient's needs.*

Surveyor Guidance:

Review medical records to verify that patients who require nutritional assessments have been assessed appropriately. Where therapeutic diet orders are prescribed and authenticated by the practitioner(s) responsible for the care of the patient verify that this is also documented in the medical records. In the sampling of medical records reviewed, verify that:

- I. The patient's nutritional needs have been met;*
- II. The appropriate therapeutic diets have been ordered; and,*
- III. The patient's dietary intake and nutritional status is being monitored and re-assessed as appropriate.*

DS.3 – Dietary Manual

SR.1 The hospital shall maintain a dietary manual (hardcopy or electronic) that defines the current therapeutic diets used by the hospital.

SR.2 The dietary manual shall be approved by a dietitian (full-time, part-time or contracted) and the hospital.

SR.3 The dietary manual shall be a document that is communicated, controlled and available to all staff and practitioners who are directly or indirectly responsible for ensuring that appropriate nutritional services are implemented.

Interpretive Guidelines:

A therapeutic diet manual shall be approved by the dietitian and the organization. This therapeutic diet manual should be reviewed in accordance with hospital policy. The therapeutic diet manual shall be readily available to all medical, nursing and food service personnel.

Surveyor Guidance:

Review the therapeutic diet manual to determine that it is current and readily available to all appropriate staff. The therapeutic diet manual should include the diets currently available to patients and meet current national and regulatory standard.

Section 23 Organ, Tissue and Eye Procurement (TO)

TO.1 – Organization

SR.1 The organization shall have documented processes in place for the procurement of organs, tissue, and eyes that address the following:

- a) Timely notification of the department or organization responsible for procurement for all individuals whose death is imminent or who have died in the hospital;
- b) Communication and education of the procurement policy to all relevant members of staff;
- c) Communication and procurement requests to the family; and
- d) Determination of medical suitability for organ donation.

SR.2 Procurement policies and protocols shall be reviewed and approved by the organization's governing body and medical staff respectively.

TO.2 – Respect for Patient Rights

SR.1 The organ, tissue and eye procurement policies, procedures and practices shall demonstrate the respect for individual patient and family rights that reflect their views, religious beliefs and other special circumstances that have been communicated by the patient and/or family to the organization personnel.

TO.3 – Documentation

SR.1 Documents and records of organ procurement will be legible, easily retrievable and stored in a safe and secure manner.

TO.4 – Organ Transplantation

SR.1 If the organization performs organ transplantation, the organization shall:

- a) Define the term “organ” as to what transplantation is done. The consistency in terms shall apply to a kidney, liver, heart, lung or pancreas.
- b) Gather and analyse data related to the performance of organ transplantation. This data shall be made available to authorized transplantation network and regulatory authorities as required by national and local law.

TO.5 – Transplant Candidates

- SR.1** The organization shall ensure the appropriate candidates for receipt of transplanted organs have been screened, matched and medically cleared prior to receipt of any organs.
- SR.2** Candidate information shall be documented, accurate and available at the time of the organ transplantation.
- SR.3** Authority for transplantation shall be co-signed by the patient or designated representative of the patient and the practitioner(s) performing the transplantation.

Section 24 Restraint or Seclusion (RT)

RT.1 – Patient Rights

SR.1 The hospital shall develop a hospital wide policy for restraint and seclusion that states:

- a) all patients have the right to be free from physical or mental abuse, and corporal punishment.
- b) all patients have the right to be free from restraint or seclusion, of any form, that is not medically necessary,
- c) restraint or seclusion shall not be imposed by staff as a means of coercion, discipline, convenience, or retaliation;
- d) patients subject to restraint or seclusion are provided the necessary access to legal review according to national and local legislation and regulations; and,
- e) seclusion may only be used for the management of violent or self- destructive behaviour that jeopardizes the immediate physical safety of the patient, a staff member, or others.

Interpretive Guidelines:

An object may be a restraint by functional definition. Anything that prevents the patient access to his or her body, moving their arms, legs, or ambulating in a normal manner is a restraint.

A device is considered a restraint if it is applied to someone who is physically able to get up and they are prevented from doing so. Under this definition, many commonly used hospital devices and practices could meet the definition of a restraint, including:

- I. Tucking a patient's sheets in so tightly that he or she cannot move; or*
- II. Wrist holders, highly padded mitts or other types of devices would be considered a restraint. Using a side rail to prevent a patient from voluntarily getting out of bed.*
- III. A restraint such as a soft wrist restraint, an arm restraint, wrapping or bundling, or some similar type of intervention to prevent an infant or toddler from removing invasive lines or reopening a surgical site, meets the definition of physical restraint and the requirements apply.*
- IV. Placing hand mitts on infants would not be considered restraint but pinning or otherwise attaching those same mitts to bedding would meet the definition of physical restraint and the requirements would apply.*
- V. Devices that serve multiple purposes such as Geri chair or side rails, when they have the effect of restricting a patient's movement and cannot be easily removed by the patient, constitute a restraint.*
- VI. Physical holding of a patient for the purpose of conducting routine physical examination or tests is permitted. However, patients do have the right to refuse treatment. This includes the right to refuse physical examinations or tests. Holding a patient in a manner that restricts the patient's movement against his or her will would be considered a restraint. This includes therapeutic holds.*

For the use of side rails the following should be considered:

- VII. It is standard practice to raise the side rails when a patient is on a stretcher, recovering from anesthesia, sedated, experiencing involuntary movement, or on certain types of therapeutic beds to prevent the patient from falling out of the bed*

- VIII. *Devices that protect the patient from falling out of bed are not restraints. However, raising all four side rails in order to restrain a patient, (as this may immobilize or reduce the ability of a patient to move his or her arms, legs, body, or head freely) to ensure the immediate physical safety of the patient then the rule applies. A patient's history of falls without current evidence of falling is not a reason to use restraints.*
- IX. *A disoriented patient may see the side rail as a barrier to be climbed over or may attempt to wriggle through split rails or to the end of the bed to exit the bed. As a result, this patient may have an increased risk for a fall or other injury by attempting to exit the bed with the side rails raised. The risk presented by side rail use should be weighed against the risk presented by the patient's behavior as ascertained through individualized assessment.*
- X. *Raising fewer than four side rails when the bed has more than two side rails, would not necessarily immobilize or reduce the ability of a patient to move*

A functional definition does not name each device and situation that can be used to inhibit an individual's movement, and promotes looking at situations on a case-by-case basis. Therefore, if the effect of using an object fits the definition of restraint for that patient at that time, then for that patient at that time, the device is a restraint.

Regardless of whether a restraint is voluntarily or involuntarily, this standard applies. A request from a patient or family member for the application of a restraint which they would consider to be beneficial is not a sufficient basis for the use of a restraint intervention.

Exemptions from requirements of the restraint or seclusion standards include:

- XI. *The use of handcuffs or other restrictive devices applied by law enforcement officials who are not employed by or contracted by the hospital when the use of such devices is for custody, detention, and public safety reasons, and is not involved in the provision of health care. The application, monitoring, and removal of forensic devices are the responsibility of the law enforcement officers. The hospital and its staff are responsible for providing safe and appropriate care to the patient;*
- XII. *A voluntary mechanical support used to achieve proper body position, balance, or alignment so as to allow greater freedom of mobility than would be possible without the use of such a mechanical support. Some patients lack the ability to walk without the use of leg braces, to sit upright without neck, head or back braces;*
- XIII. *A medically necessary and voluntary positioning or securing device used to maintain the position, limit mobility or temporarily immobilize during medical, dental, diagnostic, or surgical procedures is not considered a restraint;*
- XIV. *Physically holding a patient during a forced psychotropic medication procedure is considered physical restraint and is not included in this exception;*
- XV. *Recovery from anesthesia that occurs when the patient is in the intensive care unit or recovery room is considered part of the surgical procedure; therefore, medically necessary restraint use in this setting would not need to meet the requirements of this standard. However, if the intervention is maintained when the patient is transferred to another unit, or recovers from the effects of the anesthesia (whichever occurs first), a restraint order would be necessary and the requirements of the standard(s) shall be followed;*
- XVI. *Age or developmentally appropriate protective safety interventions (such as stroller safety belts, swing safety belts, high chair lap belts, raised crib rails, and crib covers) that a safety-conscious child care provider outside a health care setting would utilize to protect an infant, toddler, or preschool-aged child would not be considered restraint or seclusion for the purposes of this standard. The use of these safety interventions needs to be addressed in the hospital's policies or procedures.*

If the use of the medication for the patient meets the definition of a drug used as a restraint, the assessment, monitoring and documentation requirements apply. The use of PRN orders is prohibited for drugs or medications that are being used as restraints.

The standard is not intended to interfere with the clinical treatment of patients who need medication in appropriate doses that are standard medical or psychiatric treatment for the patient's condition. Medications such as the following are not considered restraints when based on the assessed needs of the particular patient with careful monitoring to minimize adverse effects.

- XVII. Therapeutic doses of psychotropic medication for patients who are suffering from serious mental illness to improve their level of functioning so that they can more actively participate in their treatment;*
- XVIII. Therapeutic doses of anti-anxiety medications to calm the patient who is anxious;*
- XIX. Appropriate doses of sleeping medication prescribed to treat insomnia; and*
- XX. Appropriate doses of analgesic medication ordered for pain management.*

Therefore, a notation that certain medications are a standard treatment for a patient's medical or psychiatric conditions and are NOT subject to the requirements of the restraint standard is acceptable in the following circumstances:

- XXI. The medication is used within the pharmaceutical parameters and the manufacturer for the indications it is manufactured and labeled to address, including listed dosage parameters.*
- XXII. The use of the medication follows national practice standards established or recognized by the medical community and/or professional medical association or organization.*
- XXIII. The use of the medication to treat a specific patient's clinical condition is based on that patient's symptoms, overall clinical situation, and on the physician's or other LIP's knowledge of that patient's expected and actual response to the medication.*

An additional component of "standard treatment" for a medication is the expectation that the standard use of a medication to treat the patient's condition enables the patient to more effectively or appropriately function in the world around them than would be possible without the use of the medication. If the overall effect of a medication is to reduce the patient's ability to effectively or appropriately interact with the world around the patient, then the medication is not being used as a standard treatment for the patient's condition.

An example: "A patient has Sundowner's Syndrome, a syndrome in which a patient's dementia becomes more apparent at the end of the day than the beginning of the day. The patient may become agitated, angry, or anxious at sundown. This may lead to wandering, pacing the floors, or other nervous behaviors. The unit's staff find the patient's behavior bothersome, and ask the physician to order a high dose of a sedative to keep him in bed. The patient has no medical symptoms or condition that indicates that he needs a sedative. In this case, for this patient, the sedative is being used as a restraint for staff convenience. Such use is not permitted by the regulation. The regulation does not allow a drug to be used to restrain the patient for staff convenience, to coerce or discipline the patient, or as a method of retaliation."

Seclusion can only be used in emergency situations if needed to ensure the immediate safety of the patient exhibiting violent or self-destructive behavior (and others) and less restrictive interventions have been determined to be ineffective.

In a therapeutic time out, the staff and patient collaboratively determine when the patient has regained self-control and is able to return to the treatment milieu. In seclusion, this judgment is made by the clinicians—that is, an agitated patient may feel that he or she should be released, even though the patient's behavior continues to be violent or self-destructive.

A situation where a patient is restricted to a room or area alone and staff are physically intervening to prevent the patient from leaving the room or area is also considered seclusion.

RT.2 – Safety

SR.1 The hospital shall keep the patient safe and protect their rights when restraints or seclusion are applied and ensure that:

- a) procedures are implemented that are in line with the restraint or seclusion policy and are designed to protect patient rights and dignity and ensure safety of the patient, staff and others;
- b) restraint or seclusion are only imposed to ensure the immediate physical safety of the patient, staff or others and shall be discontinued at the earliest possible time;
- c) restraint or seclusion are only used when less restrictive interventions have been determined to be ineffective to protect the patient or others from harm;
- d) the type or technique of restraint or seclusion used shall be the least restrictive intervention that will be effective to protect the patient or others from harm; and
- e) the use of restraint or seclusion shall be in accordance with a written modification to the patient's plan of care, and implemented in accordance with safe and appropriate restraint and seclusion techniques;

Interpretive Guidelines:

Restraint or seclusion shall not be used unless it is to meet the patient's individual clinical needs. The uses of restraint or seclusion should be discontinued as soon as possible.

Restraint use associated with non-violent or non-self-destructive behavior may be indicated, but only when it directly supports medical healing.

When a patient's violent or self-destructive behavior presents an immediate and serious danger to the patient or others, immediate action is needed. While staff should be mindful of using the least intrusive intervention, it is critical that staff considers all interventions available to them and that the intervention selected be effective in protecting the patient or others from harm.

A patient may experience a severe medication reaction that causes him or her to become violent or a patient may be withdrawing from alcohol and having delirium tremors (DTs). The patient is agitated, combative, verbally abusive, and attempting to hit staff. Regardless of facility type, such emergencies generally pose a significant risk for patients and others. For the safety of the patient and others, the use of restraint or seclusion may be necessary to manage the patient's violent or self-destructive behavior that jeopardize the immediate physical safety of the patient, a staff member, or others when less restrictive interventions have been determined to be ineffective to protect the patient, staff, or others from harm. It is not targeted only at patients on psychiatric units or those with behavioral/mental health care needs. The patient protections contained in this standard apply to all patients when the use of restraint or seclusion becomes necessary

The use of restraint or seclusion is a last resort when alternatives or less restrictive measures have been determined ineffective to protect the patient or others from harm, not a standard response to a behavior or patient need

Further, the decision to use a restraint is implemented following a comprehensive individual assessment that concludes that for this patient at this time, the use of less intrusive measures pose a greater risk than the risk of using a restraint or seclusion.

The comprehensive assessment should include a physical assessment to identify medical problems that may be causing behavior changes in the patient. For example, temperature elevations, hypoxia, hypoglycemia, electrolyte imbalances, drug interactions, and drug side effects can cause confusion, agitation, and combative behaviors. Addressing these medical issues can often eliminate or minimize the need for the use of restraints.

When assessing and planning the care for the patient, the hospital should consider whether he/she has a medical condition or symptom that indicates a current need for a protective intervention to prevent the patient from walking or getting out of bed. A restraint shall not serve as a substitute for adequate staffing to monitor patients.

Comprehensive assessment of the patient and the environment, in conjunction with individualized patient care planning, should be used to determine those interventions that will best ensure the patient's safety and well-being with the least risk

The most appropriate intervention that will ensure the safety of the patient is to be selected following a comprehensive assessment of the patient, the environment, and the patient's individualized treatment plan.

Hospital policies should address the frequency of assessment and the assessment parameters (for example, vital signs, circulation checks, hydration needs, elimination needs, level of distress and agitation, mental status, cognitive functioning, skin integrity). Hospital policies should guide staff in how to determine an appropriate interval for assessment and monitoring based on the individual needs of the patient, the patient's condition, and the type of restraint used. It may be that a specific patient needs continual face-to-face monitoring; or that the patient's safety, comfort, and well-being are best assured by periodic checks.

The hospital is responsible for providing the level of monitoring and frequency of reassessment that will ensure the patient's safety.

The use of a restraint or seclusion intervention is documented in the patient's plan of care or treatment plan based on an assessment and evaluation of the patient.

The plan of care or treatment plan should be reviewed and updated in writing within a timeframe specified by hospital policy. The plan should reflect an individualized approach that is in the best interest of the patient and promotes the patient's health, safety, dignity, self-respect, and self-worth.

The risks associated with any intervention shall be considered within the context of an ongoing process of assessment, intervention, evaluation, and re-evaluation.

The use of restraint or seclusion interventions shall never act as a barrier to the provision of safe and appropriate care, treatments, and other interventions to meet the needs of the patient.

Surveyor Guidance:

Review hospital policies relative to the use of restraint or seclusion to verify that they have been designed to protect patient rights and all elements of National and local legislation and regulations and regulations are included.

These policies should conform to National and local legislation and regulations and indicate which physicians are permitted to order restraints.

Verify that the hospital has defined who has the authority to discontinue restraints (based on National and local legislation and regulations and hospital policies) and under what circumstances restraints are to be discontinued.

In a sampling of medical records of patients where restraint or seclusion has been applied, review and validate that restraint or seclusion was appropriately used based upon the patient's physical or mental condition before the application of restraint or seclusion.

Verify that the rationale for restraint is described and the least restrictive technique was selected.

Verify that staff attempted other less restrictive measures before applying restraint or seclusion.

Interview hospital staff to identify how they assess the patient and determine that the least restrictive interventions would be ineffective to protect the patient, staff, and others from harm.

Review and validate if the hospital has applied the same type of restraint to other patients regardless of their respective medical condition.

Verify that the plan of care is updated according to hospital policy and reflects continuous assessment, intervention, evaluation, and reassessment as required.

RT.3 – Orders

SR.1 Orders for restraint or seclusion shall:

- a) be obtained prior to the application of restraints, except in emergency situations when the need for intervention may occur quickly;
- b) be made by the physician who is responsible for the care of the patient;
- c) not be written as a standing order or on an “as needed” basis;
- d) lead to the attending physician be contacted as soon as possible if the order has been initiated by another authorized person;

SR.2 Orders for restraint or seclusion used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, staff member or others shall:

- a) be limited to no more than 4 hours for adults 18 years of age or older; 2 hours for children and adolescents 9 to 17 years of age; and 1- hour for children under 9 years of age;
- b) only be renewed in accordance with the limits in a) for up to a total of 24 hours;
- c) lead to the patient being seen and assessed by a physician after 24 hours before a new order for the use of restraint or seclusion is issued; and,
- d) require a new order be obtained prior to re-initiation of restraint or seclusion if the restraint or seclusion is discontinued prior to the expiration of the original order.

SR.3 Each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed, as authorized by hospital policy.

Interpretive Guidelines

When the restraint or seclusion is not ordered by the patients attending physician, the order shall be followed by consultation with the patient's treating physician as soon as possible.

Consultation ensures that the physician who has overall responsibility and authority for the management and care of the patient is aware of and involved in the intervention.

This also promotes continuity of care and elicits information from the attending physician that might be relevant in choosing the most appropriate intervention for the patient.

Organization policies determine who is considered the treating (attending) physician

Hospital policies and procedures should address the definition of "as soon as possible" based on the needs of their particular patient population.

When the attending physician is unavailable, responsibility for the patient shall be delegated to another physician, who would then be considered the attending physician.

The attending practitioner shall be able to conduct both a physical and psychological assessment of the patient in accordance with State law, their scope of practice, and hospital policy

When implementing a protocol that includes the use of an intervention that meets the definition of a restraint, a separate order shall be obtained for the restraint.

The patient's medical record shall include documentation of an individualized patient assessment indicating that the patient's symptoms and diagnosis meet the-triggering criteria identified in the protocol. Restraint or seclusion use is an exception, not a routine response to a certain condition or behavior.

Hospitals that utilize protocols would be expected to provide evidence that there has been medical staff involvement in the development, review, and quality monitoring of their use.

A registered nurse can initiate restraint in an emergency situation. In emergency situations, an order shall be obtained either during the emergency application of the restraint or seclusion, or immediately after the restraint has been applied. The hospital should address this process in its restraint policies and procedures. Hospital procedures shall specify who can initiate the use of restraint or seclusion in an emergency prior to obtaining an order from a physician.

Time limits on the length of each order only apply when restraint or seclusion are used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others.

The length-of-order requirement identifies critical points at which there is mandatory contact with a physician responsible for the care of the patient.

A trained RN can reassess the patient when the original order is about to expire, and then contact the physician to obtain direction as to whether to renew the order (for up to 4 hours, 2 hours, or 1 hour, as permitted by the regulation) and whether other steps are to be taken.

If a patient remains in restraint or seclusion for the management of violent or self-destructive behavior 24-hours after the original order,, a face-to-face assessment by a physician or other LIP shall occur before a new order for the continued use of restraint or seclusion is written.

The regulation does not require the ordering physician to be physically present to re-evaluate the need for continuing restraint for non-violent and non-self-destructive behaviors. Hospitals have the flexibility to

determine time frames for the restraint of the non-violent, non-self-destructive patient. These time frames should be addressed in policies and procedures.

Surveyor Guidance:

Review the medical records of patients that required restraint or seclusion to verify that:

- I. The attending physician was consulted of the need for restraint or seclusion, as soon as possible, according to hospital policy*
- II. The attending physician was contacted prior to the expiration of orders for restraint or seclusion*

RT.4 – Assessment, Evaluation and Documentation

SR.1 When restraint or seclusion is used the patient shall be evaluated face-to-face within 1-hour after the initiation of the intervention by a member of trained staff.

- a) The face-to-face evaluation shall include;
 - i. The patient's immediate situation;
 - ii. The patient's reaction to the intervention;
 - iii. The patient's medical and behavioural condition; and,
 - iv. The need to continue or terminate the restraint or seclusion.
- b) If the 1-hour face-to-face evaluation is not conducted by a physician then the physician responsible for the care of the patient shall be consulted as soon as possible after completion of the evaluation.

SR.2 Patients that are in restraint or seclusion shall be monitored and assessed by a physician or trained staff at least every 24 hours.

- a) The Hospital shall define in writing the frequency of assessment and the assessment parameters (for example, vital signs, circulation checks, hydration needs, elimination needs, level of distress and agitation, mental status, cognitive functioning, skin integrity).
- b) The appropriate interval for assessment and monitoring shall be based on the individual needs of the patient, the patient's condition, and the type of restraint used.

SR.3 If restraint and seclusion are used simultaneously, the patient must be continually monitored face-to-face, by an assigned, trained staff member; or continually monitored by trained staff using both video and audio equipment. Monitoring shall be:

- a) in close proximity to the patient; and,
- b) ongoing without interruption

SR.4 When restraint or seclusion is used, there shall be documentation in the patient's medical record of the following:

- a) a description of the patient's behaviour and the intervention used;
- b) alternatives or other less restrictive interventions attempted (as applicable);
- c) the patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and,

- d) the patient's response to the intervention(s) used, including the rationale for continued use of the intervention;
- e) the hourly face- to-face medical and behavioural evaluation and assessment findings if restraint or seclusion is used to manage violent or self- destructive behaviour that jeopardizes the immediate physical safety of the patient, a staff member, or others;
- f) monitoring and assessment activities;
- g) written modification to the patient's plan of care or treatment based on an assessment and evaluation of the patient;
- h) the plan of care or treatment should be reviewed and updated in writing within a timeframe specified by hospital policy;
- i) the hospital policy shall identify any additional elements of documentation required e.g.name, title, and staff designation.

Interpretive Guidelines:

The 1-hour face-to- face evaluation includes both a physical and behavioral assessment of the patient. Therefore, the practitioner who conducts this evaluation shall be able to complete both a physical and behavioral assessment of the patient in accordance with national and local legislation and regulation, his or her scope of practice, and hospital policy. An evaluation of the patient's medical condition would include a complete review of systems assessment, behavioral assessment, as well as review and assessment of the patient's history, drugs and medications, most recent lab results, etc. The purpose is to complete a comprehensive review of the patient's condition to determine if other factors, such as drug or medication interactions, electrolyte imbalances, hypoxia, sepsis, etc., are contributing to the patient's violent or self-destructive behavior.

When a trained RN or PA conducts the 1-hour evaluation, the physician is consulted, but is not required to come to the hospital to see and evaluate the patient 1-hour after the initiation of the restraint or seclusion. The physician can determine the need for immediate or further onsite evaluation based upon the patient's symptoms, condition and history. Telephone consultation may be acceptable for this consultation.

The 1-hour face-to-face evaluation only applies when restraints, use of a medication as a restraint, or seclusion are used to manage violent or self-destructive behavior.

If a patients violent or self-destructive behavior is resolved and the restraint or seclusion is discontinued before the practitioner arrives to perform the one hour face to face evaluation, a practitioner is still required to see the patient face to face within one hour after the initiation of the intervention. Ending the intervention prior to the 1-hour point does not mean that the mandated assessment and consultation are no longer necessary. The patient's behavior warranted the use of a restraint or seclusion which indicates a serious change in a patient's condition and shall be assessed.

All restraint interventions shall be based on the individual clinical needs of a particular patient at a particular time as demonstrated by documented ongoing assessments of that patient. Ongoing assessment and monitoring of the patient's condition are crucial for prevention of patient injury.

The selection of an intervention and determination of the necessary frequency and level of assessment and monitoring should be individualized, taking into consideration variables such as the patient's condition, cognitive status, risks associated with the use of the chosen intervention, and other relevant factors.

Staff determines the appropriate level of monitoring and frequency of assessment based on hospital policy, an individualized patient assessment, and type of intervention used and the attending physician should be kept informed about the patient's status.

After 24 hours, a face-to-face assessment by a physician shall occur before a new order is written for restraints or seclusion for the violent or self-destructive patient

Restraint or seclusion shall be ended at the earliest possible time, regardless of the length of time identified in the order. Restraint or seclusion may only be employed while the unsafe situation continues. Once the unsafe situation ends, the use of restraint or seclusion should be discontinued.

If restraint or seclusion is discontinued prior to the expiration of the original order, a new order shall be obtained prior to reinitiating the use of restraint or seclusion. Staff cannot discontinue an order and then restart it because that would constitute a PRN order.

A temporary release that occurs for the purpose of caring for a patient's needs, for example, toileting, feeding, and range of motion, is not considered a discontinuation of the intervention:

- I. Example: When a trial period of observation out of restraints is initiated and the patient again exhibits the symptoms that prompted the prior use of restraints, and the patient is placed in restraint again, a new order would be required. This episode cannot be considered as part of the original episode/order as it would be considered a PRN order which is not permitted.*
- II. Example: A patient is released from restraint or seclusion. If this patient later exhibits violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others that can only be handled through the use of restraint or seclusion, a new order would be required.*
- III. Example: When patient's behavior responds to the intervention in 20 minutes, the restraint or seclusion should be discontinued, even if the order was given for up to 4 hours.*

Where simultaneous use of restraint and seclusion is allowable by National law and hospital policy then continual face-to-face monitoring (that is, moment to moment) is only required when restraint and seclusion are used simultaneously to address violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. Monitoring in "close proximity" to the patient is intended to ensure that staff is immediately available to intervene and render appropriate interventions to meet the patient's needs.

The use of PRN orders for drugs or medications is only prohibited when a drug or medication is being used as a restraint. The following are exceptions:

- IV. **Geri chair.** If a patient requires the use of a Geri chair with the tray locked in place in order for the patient to safely be out of bed, a standing or PRN order is permitted. Given that a patient may be out of bed in a Geri chair several times a day, it is not necessary to obtain a new order each time.*
- V. **Raised side rails.** If a patient's status requires that all bedrails be raised (restraint) while the patient is in bed, a standing or PRN order is permitted. It is not necessary to obtain a new order each time the patient is returned to bed after being out of bed.*
- VI. **Repetitive self-mutilating behavior.** If a patient is diagnosed with a chronic medical or psychiatric condition, such as Lesch-Nyham Syndrome, and the patient engages in repetitive self-mutilating behavior, a standing or PRN order for restraint to be applied in accordance with specific parameters established in the treatment plan would be permitted. Since the use of restraints to prevent self-injury is needed for these types of rare, severe, medical and psychiatric conditions, the specific requirements (1-hour face-to-face evaluation, time-limited orders, and evaluation every 24 hours*

before renewal of the order) for the management of violent or self-destructive behavior do not apply.

Surveyor Guidance:

Validate the competency of personnel conducting the 1-hour face-to-face evaluation. The 1-hour face-to-face evaluation includes both a physical and behavioral assessment of the patient. Therefore, the practitioner who conducts this evaluation shall be able to complete both a physical and behavioral assessment of the patient in accordance with State or local law, his or her scope of practice, and hospital policy.

Generally, practitioners such as social workers, psychologists and other mental health workers are not qualified to conduct a physical assessment, nor is it in their scope of practice.

Review a sampling of medical record for patients where restraint or seclusion was applied and review documentation to confirm that:

- I. The patient received a face-to-face medical and behavioral evaluation within 1 hour of the intervention by an appropriate person identified in hospital policy;*
- II. Consultation with the attending physician has taken place as soon as possible following the 1-hour face-to-face evaluation;*
- III. The patient's condition and reaction to the intervention was documented;*
- IV. The patient was monitored and reassessed according to timeframes defined by hospital policy; and,*
- V. The patient was reassessed according to criteria established by hospital policy.*

RT.5 – Monitoring

SR.1 The use of restraint and seclusion shall be monitored and evaluated on a continual basis as part of the hospital's Quality Management System.

- a) Evidence of prolonged restraint, as defined by the hospital, and, if possible, actions taken to reduce or eliminate the use of restraints shall be analysed by the treatment team.
- b) Aggregated data regarding the use of restraint shall be collected and analysed for the identification of patterns and trends. Analysis shall be implemented in the event a patient is injured through the use of restraint or a staff member is injured through the application of a restraint.

Interpretative Guidelines:

The data collected will be aggregated and analyzed to ensure that only clinically necessary restraints are used with a focus on patient safety.

Actions are to be implemented to ensure that standards for restraint or seclusion are applied appropriately as they relate to the patient with non-violent/ non-self-destructive behavior and the patient with violent/self-destructive behavior.

As a means of documenting this assessment and monitoring, the use of restraints shall be recorded within a log or other data collection mechanism for monitoring. The documentation shall include identification of:

- I. Shift;*
- II. Date, time of order;*

- III. *Staff who initiated the process;*
- IV. *The length of each episode;*
- V. *Date and time each episode was initiated;*
- VI. *Day of the week each episode was initiated;*
- VII. *Type of restraint or seclusion used (including physical restraint or drug used as restraint);*
- VIII. *Compliance with requirements defined in the standards;*
- IX. *Whether injuries were sustained by the individual or staff;*
- X. *Age of individual; and,*
- XI. *Gender of individual.*

Data shall be analyzed for the identification of patterns and trends including:

- XII. *Patterns of excessive use*
- XIII. *Use of physical restraint or drugs used as restraint to substitute for adequate staffing, monitoring, assessment, or investigation of the reasons behind patient behavior such as wandering or getting up in the night, which may be indicative of unmet patient care needs*
- XIV. *Opportunities for improving compliance with the requirements of the standards*

Twenty-four hours of restraint or seclusion for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others is an extreme measure which could potentially seriously harm the patient. When there is evidence of prolonged restraint, as defined by the organization, and, if possible, actions taken to reduce or eliminate the use of restraints shall be analyzed and presented for management review.

Intensive analysis shall be implemented in the event a patient is injured through the use of restraint or a staff member is injured through the application of a restraint.

Surveyor Guidance:

Review the aggregate data regarding the use of restraints and seclusion to see if the hospital has identified patterns and trends.

Confirm that the organization can demonstrate implementation of corrective or preventive action where analysis of data reflects variation.

Verify the hospital had conducted an intensive analysis in the event a patient is injured through the use of restraint or a staff member is injured through the application of a restraint.

RT.6 – Restraint or Seclusion: Staff Training Requirements

SR.1 Staff caring for patients that are subjected to restraint or seclusion shall be trained and able to demonstrate competence in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion.

- a) Training shall occur before performing any of these actions, as part of orientation, and subsequently on a periodic basis consistent with hospital policy.

SR.2 The hospital shall require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:

- a) techniques to identify staff and patient behaviours, events, and environmental factors that may trigger circumstances that require restraint or seclusion;
- b) the use of non-physical interventional skills, including de-escalation and dealing with aggressive behaviour;
- c) choosing the least restrictive intervention based on an individualized assessment of the patient's medical or behavioural status or condition;
- d) the safe application and use of all types of restraint or seclusion used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia);
- e) clinical identification of specific behavioural changes that indicate that restraint or seclusion is no longer necessary;
- f) 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 hospital policy associated with the hourly face-to-face evaluation; and

SR.3 At a minimum, physicians authorized to order restraint or seclusion by hospital policy in accordance with National and local legislation and regulations shall have a working knowledge of the hospital policy regarding the use of restraint or seclusion. Physician training requirements shall be specified in hospital policy.

SR.4 Individuals providing staff training shall be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors.

SR.5 The hospital shall document in the staff personnel records that the training and demonstration of competency were successfully completed.

Interpretive Guidelines

Staff who have direct contact with patients shall be trained and able to demonstrate competency before applying restraints, implementing seclusion, providing care for a patient in restraint or seclusion, or with assessing and monitoring the condition of the restrained or secluded patient.

The hospital shall identify the appropriate clinical staff that shall be trained in the application, monitoring, patient care, and discontinuation of restraint or seclusion. Non-nursing staff shall be included to the extent that they are involved with restraint use. Application of restraint or seclusion by an untrained staff member, including contract staff, would constitute a violation of this requirement.

Training shall be comprehensive and shall involve demonstration and return demonstration

The written training curriculum reflects the defined competency skill sets defined for each level of clinical personnel. The hospital is expected to provide education and training at the appropriate level to the appropriate staff based upon the specific needs of the patient population being served. Hospital policies and emergency procedures for managing violent or self-destructive behaviors in included in the training curriculum. It is appropriate to have different levels of training for different individuals depending upon their involvement with restraints.

The training curriculum shall be reviewed at least annually and revised as indicated, incorporating relevant findings from QA/PI activities.

Accurate recordkeeping of training sessions, including titles of the employees who attend shall be stored onsite where the actual documents will be easily accessible for review. In order to ensure that the employee training is complete, all the required components of the program shall be covered.

Surveyor Guidance:

Review hospital policy and training records to verify:

- I. Competency skill sets for clinical staff are identified;*
- II. Training content and frequency are identified to meet the standard;*
- III. Trainers are qualified as evidenced by education, training, and experience;*
- IV. All staff that applies or monitors restraint or seclusion, including Physical Therapy, Radiology, and Respiratory Care staff receive training and have demonstrated competency related to use of restraint and seclusion;*
- V. Policy describes training requirements for physicians and licensed independent practitioners; and,*
- VI. Training has been provided for the medical staff, LIP's and hospital staff as defined.*

Review and validate that the hospital has documented instructional training for the use of all restraint techniques used and the alternatives to the use of restraint and seclusion

Review selected personnel files to verify that clinical staff have demonstrated appropriate competency

Section 25 Infection Prevention and Control (IC)

IC.1 – Infection Prevention and Control System

- SR.1** The hospital shall have a process in place to maintain a sanitary environment for hospital patients, staff, and others. This process shall provide the means for avoiding and transmitting infections and communicable diseases.
- SR.2** The hospital shall have a documented process, policies and procedures to define how infections and communicable diseases are prevented, controlled and investigated throughout the hospital.
- SR.3** The Infection Prevention and Control System shall be evaluated at least annually. This evaluation shall be forwarded to Quality Management oversight.
- SR.4** The documented process shall define the following:
- a) A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases. The designated infection control officer or officers shall have the appropriate qualifications and experience as defined by the organization and shall govern the policies for controlling infections and communicable diseases;
 - b) any designated practitioner shall have completed a course in basic surveillance by a recognized body or show evidence that they have supervision by a qualified infection control practitioner. If in the role five (5) years or longer there shall be evidence of pertinent continuing education related to infection control, minimally every two (2) years;
 - c) the process for identifying, reporting, investigating and controlling infections and communicable diseases; and
 - d) the maintaining and control of records to account for incidents related to infections and communicable diseases.
- SR.5** Infections and communicable diseases shall be measured and analyzed to identify any patterns or trends.
- SR.6** The hospital shall ensure that the Infection Control System and associated activities address issues identified throughout the hospital and there are prevention, correction, improvement and training programs.
- SR.7** Significant infection control data/information shall be disseminated no less than quarterly to the hospital oversight group responsible for the management of infection, prevention and control.
- SR.8** Surveillance methodology shall be appropriate for the population(s) served and approved no less than annually by the Infection Control oversight. The inpatient and outpatient populations shall be reported to this oversight group as an annual summary of reported illnesses.

Interpretive Guidelines:

The hospital shall maintain an infection control program for the prevention, control, and surveillance of infections (which includes, but is not limited to hospital acquired infections) and communicable diseases of patients and personnel (which includes, but is not limited to patient care staff).

The following definitions apply:

Infectious disease – a change from a state of health to a state in which part or all of a host's body cannot function normally because of the presence of an infectious agent or its product.

Infectious agent – a living or quasi-living organism or particle that causes an infectious disease, and includes bacteria, viruses, fungi, protozoa, helminthes, and prions

Communicable disease – a disease associated with an agent that can be transmitted from one host to another

Infection control professional – a person whose primary training is in either nursing, medical technology, microbiology, or epidemiology and who has acquired specialized training in infection control

The infection control surveillance program will include specific measures for prevention, detection, control, intervention, education, collection of data and investigation of infections and communicable diseases in the hospital that covers patients and hospital staff. The infection control program shall be continually evaluated for effectiveness and when necessary, corrective and/or preventive action taken to reduce risks of infections.

The infection control program will encompass recognized systems of infection control guidelines to reduce the risk and transmission of infections and communicable diseases.

The hospital shall provide for and maintain a sanitary environment to avoid the sources and transmission of infections and communicable diseases. All areas of the hospital shall be regularly cleaned and sanitary including all hospital units, campuses and off-site locations. The infection control surveillance program will include monitoring of housekeeping and maintenance (including when applicable areas of the hospital are under repair, renovation or construction) as well as any other activities to ensure the hospital maintains a sanitary environment.

The hospital shall provide adequate resources to accomplish the activities of the infection control program – when assessing the need for resources; the organization should consider the patient population and complexity of services provided as a part of the process for evaluation and provision of resources.

Hospitals are to develop a written policy for storage of items under sinks.

The organization shall have a documented process, policies and procedures to define how infections and communicable diseases are prevented, controlled and investigated throughout the organization. These policies and procedures shall address the following:

- I. Maintenance of a sanitary physical environment, including;*
 - a) Ventilation and water quality control issues;*
 - b) Safe air handling systems in areas of special ventilation, such as operating rooms, intensive care units, and isolation rooms;*
 - c) Food sanitation, storage and handling;*
 - d) Cleaning and disinfecting surfaces, carpeting, and furniture;*
 - e) Textiles reprocessing, storage and distribution;*
 - f) Disposal of regulated and non-regulated waste; and,*
 - g) Pest control.*
- II. Measures related to hospital staff*
 - a) Evaluation of immunization status for designated infectious diseases;*
 - b) Circumstances when screens are to be conducted of staff for infections or other risks when individuals may be exposed;*

- c) *When restrictions will be imposed on staff from providing direct patient care and/or required to remain away from the hospital entirely;*
- d) *Measures to evaluate staff and volunteers exposed to patients with infections and communicable diseases; and,*
- e) *orientation and on-going training regarding the prevention and control of infections and communicable diseases.*

III. *Mitigation of risks associated with patient infections present upon admissions to include:*

- a) *Early identification of patients who require isolation and techniques for precaution in accordance with hospital policy; and,*
- b) *Appropriate use of personal protective equipment (i.e. gowns, masks, gloves, eye protection).*

IV. *Mitigation of risks contributing to healthcare-acquired infections*

- a) *Implementing appropriate prophylaxis to prevent surgical site infections such as a protocol to assure that antibiotic prophylaxis is administered to prevent surgical site infections for appropriate procedures and discontinued appropriately after surgery;*
- b) *Addressing aseptic technique practices used in surgery and invasive procedures outside the operating room, including sterilization of instruments;*
- c) *Promotion of hand washing hygiene among all staff and employees, including use of alcohol-based hand sanitizer measures, specific to prevention of infections caused by Multi-Drug - resistant organisms (MDRO). This applies to, but is not limited to, organisms such as methicillin-resistant staphylococcus aureus (MRSA), clostridium difficile (C.dif), vancomycin-resistant enterococci (VRE), and multidrug-resistant gram-negative bacteria;*
- d) *Measures specific to prevention of central-line associated bloodstream infection (CLABSI), such as a bundle or protocol for reducing infections of central venous catheters specifying aseptic precautions for line insertions, care of inserted lines, and prompt removal when the line is no longer needed;*
- e) *Measures specific to prevention of other device-associated infections such as those associated with ventilators, tube feeding, urinary catheters, etc.(VAP, CAUTI);*
- f) *Isolation procedures and requirements for immuno-suppressed patients;*
- g) *Safe Injection Practice Program;*
- h) *Care techniques for tracheostomy care, respiratory therapy, burns and other situations that reduce a patient's resistance to infection;*
- i) *Use of disinfectants, antiseptics and germicides;*
- j) *Appropriate use of facility and medical equipment including negative and positive pressure room equipment, portable air filtration equipment, enclosed beds, UV lights, and other equipment used to control the spread of infectious agents;*
- k) *Adherence to recognized guidelines for infection prevention and control precautions; and,*
- l) *Education of patients, visitors, caregivers, and staff about infections and communicable diseases and methods to reduce transmission in the hospital and community.*

V. *Active Surveillance methods for:*

- m) *Obtaining and review data on infections and communicable diseases selected for monitoring;*
- n) *Monitoring and evaluating practices of asepsis; and,*
- o) *Authority and indications for obtaining microbiological cultures from patients and the environment as indicated.*

VI. *A designated Infection Control Officer and his or her scope of responsibilities;*

- p) *Development and implementation of infection control measures;*
- q) *Mitigation of risks associated with patient infections and risks contributing to healthcare-acquired infections;*
- r) *Program evaluation and revisions (as necessary);*
- s) *Coordination with emergency preparedness and health authorities to address communicable disease threats, bioterrorism, and outbreaks; and,*

- t) *Compliance with the requirements for reporting to local health authorities.*
- VII. *Roles and responsibilities for infection control within the hospital and how various committees and departments interface with the infection control program*
- VIII. *The hospital leaders are responsible for implementing and ensuring corrective/preventive action(s) are implemented and effective in addressing infection control issues.*
- IX. *A process for identifying, reporting, investigating preventing, controlling infections and communicable diseases; to include both inpatient and outpatient populations as well as hospital staff;*
- X. *Records to be maintained and controlled to account for incidents related to infections and communicable diseases;*
- XI. *Log of incidents related to infections and communicable diseases is maintained (safe and secure from unauthorized access, up-to-date, and readily accessible and retrievable) and documents infections and communicable diseases in patients and staff (patient care staff and non-patient care staff, including employees, contract staff and volunteers).*
- XII. *To protect privacy, the hospital may use codes instead of names in the log with a separate reference document to interpret codes to address these incidents*
- XIII. *Although not required, the hospital is encouraged to categorize the types of incidents such as:*
- a) *Healthcare-associated infection including surgical site infections following inpatient or outpatient procedures*
 - b) *Patients or staff with identified communicable diseases that local or national health agencies require to be reported*
 - c) *Patients or staff identified by laboratory cultures as colonized or infected with multi drug-resistant organisms (MDROs), as defined by the hospital*
 - d) *Patients who meet hospital criteria for requiring isolation precautions during their hospitalization*
 - e) *Patients or staff with signs and symptoms that have been requested be reported or recorded by local or national health agencies*
 - f) *Patients or staff who are known or suspected to be infected with epidemiologically-significant pathogens that are identified by the hospital or local or national health agencies*
- XIV. *How infections and communicable diseases are measured and analyzed to identify any patterns or trends;*
- XV. *A process for adequately addressing issues identified throughout the organization and for the prevention, correction, improvement and training programs to address these issues;*
- XVI. *A means of reporting data/information at least quarterly to the organization oversight group responsible for the infection control function (i.e. Infection Control Committee);*
- XVII. *How education of patients, family members and caregivers about infections and communicable diseases is conducted;*
- XVIII. *Orientation of all new hospital personnel, including contract staff, students and volunteers, to infections, communicable diseases, and to the infection control program; and,*
- XIX. *A procedure for meeting the reporting requirements of the local health authority as required.*

Surveyor Guidance:

Interview the infection control officer to verify the scope and activities of the hospital's infection control program and hospital issues regarding infection control.

Review the personnel file of the infection control officer(s) to verify that he or she is qualified through education, training, experience, and certification or licensure to oversee the infection control program.

Review and validate that appropriate policies and procedures have been developed and implemented to identify, prevent, monitor, report, investigate and measure the control of infections and communicable diseases. This should include the mitigation of risks associated with patient infections present on admission as well as the mitigation of risks contributing to healthcare-associated infections.

Determine whether the infection control program is hospital-wide and identifies all hospital locations and take these various locations into account under the program and there is active surveillance in place.

Review how areas of the hospital are monitored to include: areas where food is stored, prepared and served, refrigerators, ice machines; air handlers, autoclave rooms/areas, ventilation systems, inpatient rooms, patient care areas, laboratory, surgical areas, supply storage and where equipment is stored and cleaned.

During the survey, all surveyors should observe the sanitary condition of the physical environment, cleanliness of rooms, surfaces, patient equipment, air inlets, mechanical rooms, food service activities, treatment and procedure areas, surgical areas, central supply and storage areas, etc.

Review the (Infection Control Committee) meeting minutes to evaluate compliance with requirements and follow-up on corrective and preventive actions taken.

Review a sampling or records for incidents related to infections and communicable diseases, including those identified through employee health services to ensure that these were acted upon and corrective action taken to minimize risks. Also review compliance with reporting requirements to the local health authority. Verify that a log is maintained of incidents related to infections and communicable diseases and is easily accessible and retrievable by the infection control officer and other appropriate staff.

Verify that there is coordination with national and local emergency preparedness and health authorities as required by law to address communicable disease threats, bioterrorism, and outbreaks.

Verify that the infection control program is under the scope of the hospital quality management system and whether infection control issues are reported to the Medical Staff, Leadership and Nursing to ensure that corrective action(s) are implemented and effective.

Review the on-going evaluation of the infection control program and revisions made to the program based in part on this evaluation.

Section 26 Medical Records Service (MR)

MR.1 – Organization

- SR.1** Administrative responsibility for medical records shall rest with the medical record service of the hospital.
- SR.2** The hospital shall provide these services in accordance with the scope and complexities of services offered and allocate the appropriate resources to ensure efficient functioning.

Interpretive Guidelines:

The hospital shall have administrative responsibility for all medical records- both inpatient and outpatient. The medical record service shall reflect the scope and complexities of services offered.

Definition: "Medical records" refers to the 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.

Surveyor Guidance:

Verify that the medical records service is defined to meet the needs of the hospital and the patients with respect to the scope and complexities of services.

MR.2 – Complete Medical Record

- SR.1** The hospital shall maintain an accurately written, promptly completed medical record for each inpatient and outpatient.
- SR.2** The hospital shall have a process for providing services for the completion, filing, and retrieval of the medical record. The process for completion of the medical record shall address timeframes.
- SR.3** There is a process in place to verify the authenticity of all record entries.

Interpretive Guidelines:

The hospital shall maintain a medical record for each inpatient and outpatient evaluated or treated in any part or location of the hospital.

The hospital shall ensure that all medical records accurately and completely document all orders, test results, evaluations, care plans, treatments, interventions, care provided and the patient's response to those treatments, interventions and care.

The hospital will define the process for providing medical record services to encompass the completion, filing and retrieval of medical records. In the event records are stored outside of the medical records office or off-premises through a contractual arrangement, the hospital shall ensure there is a process in place to protect and retrieve these records in a timely manner.

The record shall be completed promptly after discharge in accordance with national and regulatory requirements and hospital policy.

Surveyor Guidance:

Review the area(s) where medical records are maintained by the hospital.

Verify that a medical record is maintained for each person treated or receiving care.

Verify that medical records are stored and maintained in area(s) that ensure the records are secure, protected from damage by flood, fire, and other casualties, and access is limited to authorized staff.

Verify that the hospital has a process to ensure that records are accurate, completed promptly, easily retrieved and readily accessible in all area(s) where medical records are maintained.

MR.3 – Retention

SR.1 Medical records (original or legally reproduced form) shall be retained for a period of at least five (5) years, or more if required by National and local legislation and regulations.

SR.2 The coding and indexing system should allow for timely retrieval by diagnosis and procedure, in order to support clinical audit.

Interpretive Guidelines:

Medical records shall be retained in their original or legally reproduced form and maintained in accordance with national and regulatory requirements and hospital policy. These records may be in the form of a hard copy, microfilm, computer memory, or other electronic storage media. The hospital shall have a process to promptly retrieve the complete medical record of every individual evaluated or treated in accordance with national and regulatory requirements.

Surveyor Guidance:

Verify that the control of medical record is in place and these records are retained in accordance with national and regulatory requirements and hospital policy.

Verify that the hospital uses a coding and indexing system that allows for timely retrieval of patient records by diagnosis and procedures.

MR.4 – Confidentiality

SR.1 Confidentiality of medical records shall be assured.

SR.2 Individuals who are authorized by the patient to receive information from or copies of records shall follow the local and national guidance on confidentiality.

SR.3 The hospital shall also ensure that the medical record cannot be altered or accessed by unauthorized individuals.

SR.4 Original medical records shall be released by the hospital only in accordance with National and local legislation and regulations, court orders, or subpoenas.

Interpretive Guidelines:

The hospital shall have a means of ensuring that access to all information regarding patient's records is limited to those individuals designated by law, regulation, and policy or duly authorized as having a need to know.

The process shall be designed to protect improper or inadvertent release of private information to unauthorized individuals.

Patient information will include; patient paper records, video, audio, and/or computer stored information.

Surveyor Guidance:

Verify that the hospital has a means of ensuring that access to patients' records is limited to those individuals designated by law, regulation, and policy or duly authorized as having a need to know.

Validate the policy and procedure for release of patient information and verify that copies of medical records and other confidential patient information are released outside the hospital only upon written authorization of the patient, legal guardian, or person with an appropriate "power of attorney" to act on the patient's behalf, or only if there is a properly executed subpoena or court order, or as mandated by national and regulatory requirements.

Verify the methods in place to prevent unauthorized persons from gaining physical access or electronic access to information in patient records.

Validate the hospital's current practices in place for protecting and securing the confidentiality of patient records.

MR.5 – Record Content

SR.1 The medical record shall contain information to:

- a) justify admission and continued hospitalization;
- b) support the diagnosis; and
- c) describe the patient's progress and response to medications and services.

SR.2 All entries shall be:

- a) legible, complete, dated and timed; and
- b) authenticated by the person responsible for providing patient care in accordance with hospital policy.

SR.3 Authentication may include written signatures. Electronic authentication is permissible.

SR.4 All orders shall be dated, timed and authenticated promptly by the prescribing practitioner.

- a) Practitioners shall 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 document may not reflect when the entry was authenticated;
- b) If a pre-printed order set is used, the ordering practitioner shall date, time, and authenticate the last page of the order set, with the last page also identifying the total number of pages in the order set; and

- c) Changes, such as additions, deletions, or strike-outs of components that do not apply, that have been made in the body of the pre-printed order set are initialled and all internal pages have been signed or initialled by the ordering practitioner.

SR.5 Verbal orders shall be authenticated within forty eight (48) hours.

- a) Telephone or verbal orders are to be used infrequently and when used shall be accepted only by personnel authorized by the medical staff.
- b) Verbal orders shall be authenticated by the ordering practitioner or a practitioner responsible for the care of the patient. If there is not National and local legislation and regulations that designates a specific timeframe for the authentication of verbal orders, the orders shall be authenticated within 48 hours.
- c) For the limited time period defined all such orders may be dated, timed and authenticated by another practitioner who is responsible for the patient's care and who is authorized to write orders in accordance with hospital policy and National and local legislation and regulations.

Interpretive Guidelines:

The medical record shall contain information such as notes, documentation, records, reports, recordings, test results, and assessments to:

- I. Justify admission and continued hospitalization;*
- II. Support the diagnosis; and,*
- III. Describe the patient's progress and response to medications and services*

All entries in the patient's medical record shall comply with SR.1 – SR.5 as above.

Surveyor Guidance:

Review a sample of medical records during the survey. Validate that that MR.1 - MR.5 is consistently applied throughout the hospital.

Determine if there is national and regulatory requirements that qualifies for the exception to the 48 hour requirement for verbal order authentication.

Verify that the hospital has policies and procedures in place for addressing verbal orders including a process for read-back and verification to ensure accuracy of such orders.

Interview staff and review examples of verbal orders to verify this process for authentication and the read-back and verification process

MR.6 – Identification of Authors

SR.1 The hospital shall have a system to identify the author of each entry within the medical record.

Interpretive Guidelines:

The organization shall have a system to identify the author of each entry in the medical record. Entries may be made only by individuals as specified in hospital policies.

If the hospital allows rubber stamps, the individual whose signature the stamp represents shall place in the administrative offices of the hospital a signed statement to the effect that he/she is the only one who has the

stamp and is the only individual allowed to use it. No other individual can be authorized to use the stamp under any circumstance. This process should be documented in the specified hospital policy.

Surveyor Guidance:

Verify that the hospital has a means of identifying authors for each entry in the patient medical record. The organization shall have a policy in place that states who is allowed to document in the medical record and the means for identifying the author. Review a sampling of records to verify the consistency of this process.

In the event that stamps can be used, verify that the stamps have been approved and are only used by the individual identified on the stamp.

MR.7 – Required Documentation

SR.1 All records shall document the following, as appropriate:

- a) Evidence of a physical examination, including a health history, performed no more than thirty (30) days prior to admission or within twenty four (24) hours after admission:
 - i. the history and physical shall be completed and documented no more than thirty (30) days before or twenty four (24) hours after admission or registration, but prior to surgery or procedure requiring anaesthesia services; and placed in the patient’s medical record within twenty four (24) hours after admission or registration, but prior to surgery or procedure requiring anaesthesia services.
 - ii. when the history and physical is completed within thirty (30) days prior to admission or registration, an updated medical record entry documenting an examination for any changes in the patient’s condition shall be completed and documented in the patient’s medical record within twenty four (24) hours after admission or registration, but prior to surgery or procedure requiring anaesthesia services.
- b) Admitting diagnosis;
- c) Results of all consultative evaluations of the patient and appropriate finding by clinical and other staff involved in the care of the patient;
- d) Documentation of complications, hospital acquired infections, and adverse reactions to drugs and anaesthesia;
- e) Properly executed informed written consent forms for procedures and treatments specified by the medical staff, or by National and local legislation and regulations if applicable, signed by the patient or his/her authorized representative;
- f) Medical care plans, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition;
- g) Discharge summary with outcome of hospitalization, the prognosis, and provisions for follow up care;
- h) Final diagnosis with completion of medical records within thirty (30) days following discharge.

Interpretive Guidelines:

The medical record shall contain a history and physical examination (H & P) for all inpatients and outpatients. The H & P shall be performed by an authorized practitioner no more than thirty (30) days prior to admission or within 24 hours after admission.

The H & P shall be placed in the patient's medical record within 24 hours after admission. In the event the H & P is completed within thirty (30) days prior to admission, the hospital shall ensure that the H & P is updated to document any changes in the patient's condition.

The patient's medical record shall document the following:

- I. Admitting diagnosis;*
- II. Results of all consultative evaluations of the patient and appropriate finding by clinical and other staff involved in the care of the patient,*
- III. Documentation of complications, organization acquired infections, and unfavorable reactions to drugs and anesthesia;*
- IV. 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;*
- V. Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow up care;*
- VI. Final diagnosis with completion of medical records within thirty, (30) days following discharge; and*
- VII. Properly executed informed written consent forms for procedures and treatments specified by the organization or by national and regulatory requirements if applicable, signed by the patient or his/her authorized representative.*

A properly executed consent form should reflect the patient consent process. All inpatient and outpatient medical records shall contain a properly executed informed consent for prior to conducting any procedure or other type of treatment when informed consent is required. A properly executed consent form shall be consistent with hospital policy as well as applicable national and regulatory requirements and at a minimum contain the following elements:

- VIII. Hospital name where procedure or treatment is to take place*
- IX. Description of the procedure or treatment for which consent is being given*
- X. Name of the responsible practitioner performing the procedure or administering treatment*
- XI. Statement that the procedure or treatment, including the benefits, risks, and alternative therapies, was explained to the patient or the patient's legal representative*
- XII. Signature of the patient or patient's legal representative*
- XIII. Date and time the informed consent is signed by the patient or patient's legal representative Name of the practitioner who conducted the consent*

Surveyor Guidance:

Determine that medical records contain a physical examination and medical history completed for each patient by an authorized practitioner.

In a sampling of patient medical records, verify that the completion of the H&P was within the specified time frame and appropriate documentation noted.

Verify the content and completeness of the H&P per organization policy

In some cases the organization may accept an H&P that has been completed in the practitioners office, when this is allowed, verify the process for ensuring that the appropriate documentation is present and completed per the requirements of the organization and the H&P was completed within the required timeframe.

Verify that the H&P was completed no more than 30 days before or 24 hours after admission or registration and in all cases involving surgery or procedures requiring anesthesia services or moderate/conscious sedation prior to the surgery or procedure

Verify this documentation of the H&P was placed in the medical record within 24 hours after admission or registration, and in all cases involving surgery or procedures requiring anesthesia services or moderate/conscious sedation prior to the surgery or procedure

Where the H&P is completed within 30 days before admission or registration and in all cases involving surgery or procedures requiring anesthesia services or moderate/conscious sedation, the hospital shall ensure that this H&P is updated to document any changes in the patient's condition.

If there are no changes to the H&P as written, the physician can simply document an update note stating:

- I. that the H&P has been reviewed,*
- II. that the patient has been examined, and*
- III. that the physician concurs with the findings of the H&P completed on the specified date or that "no change" has occurred in the patient's condition since the H&P was completed.*

Review a sample of medical records (inpatient and outpatient) to verify conformance to the appropriate elements specified in the interpretive guidelines.

Verify that the hospital has specified which procedures and treatments require informed consent.

Ascertain that the completed forms contain at least the information specified in the Interpretive Guidelines (above).

Compare the hospital standard informed consent form to the hospital's policy regarding informed consent to verify that the form is consistent with the policy. If there is applicable national and regulatory requirements, verify that the form is consistent with the requirements of that law.

Section 27 Utilization Review (UR)

UR.1 – Documented Plan

SR.1 The hospital shall maintain a documented utilization review plan that provides for review of organizational and medical staff services to patients.

SR.2 The responsibilities and authority for those involved in utilization review activities in a Utilization Review (UR) Committee shall be described by the hospital and shall:

- a) Have representation from clinical staff;
- b) Involve local stakeholders such as representatives of the local community and other service providers;
- c) Ensure the committee reviews are not conducted by any individual who:
 - i. Has a direct financial interest (for example, an ownership interest) in the hospital; or
 - ii. Was professionally involved in the care of the patient whose case is being reviewed.

SR.3 Requirement for all review findings in the aggregate to be reported to Quality Management Oversight.

SR.4 Review shall address at least the following:

- a) medical necessity of admissions and extended stays;
- b) appropriateness of setting;
- c) medical necessity of professional services; and
- d) how well the services provided are contributing to increasing the health, quality of life and independence of the local population.

Interpretive Guidelines:

The hospital UR plan should include a delineation of the responsibilities and authority for those involved in the performance of UR activities, define the requirement for all review findings to be reported to the Quality Management Oversight body, and ensure that there is no conflict of interest (financial or otherwise) by those individuals participating in the review.

Surveyor Guidance:

Verify that the hospital has a utilization review plan for those services furnished by the hospital.

Sample records and reports, and supporting documentation that UR activities are being performed as described in the hospital UR plan.

Verify the composition of the UR committee.

Review for any conflicts of interest.

Interview the chairperson of the UR Committee and/or other representative members of the committee to validate their role in carrying out the UR plan.

This may include a review of the minutes of the UR committee.

UR.2 – Sampling

SR.1 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; and,
- d) treatment plans reflect evidence based care pathways.

Surveyor Guidance:

Review the UR plan and other supporting documentation to determine that the medical necessity for patients is reviewed with respect to admission, length of the stay, and professional services (including medications).

Section 28 Physical Environment (PE)

PE.1 – Facility

- SR.1** The facility shall be constructed, arranged, and maintained to ensure patient safety, and to provide areas for diagnosis and treatment and for special hospital services appropriate to the needs of the community.
- SR.2** The condition of the physical plant and the overall hospital environment shall be developed and maintained in such a manner that the safety and well-being of patients, visitors, and staff are assured.
- SR.3** The hospital shall maintain adequate facilities for its services.
- a) Diagnostic and therapeutic facilities shall be located for the safety of patients.
- b) Facilities, supplies, and equipment shall be maintained to ensure an acceptable level of safety and quality.
- c) The extent and complexity of facilities shall be determined by the services offered.
- SR.4** The hospital shall have a process in place, as required and/or recommended by National and local legislation and regulations or related professional organizations, to maintain a safe environment for the hospital's patients, staff, and others.
- SR.5** The hospital shall have a documented process, policies and procedures to define how unfavorable occurrences, incidents, or impairments in the facility's infrastructure, Life Safety, Safety, Security, Hazardous Material/Waste, Emergency, Medical Equipment, and Utilities Management Systems are prevented, controlled investigated, and reported throughout the hospital.
- SR.6** The hospital shall evaluate the facility's physical environment management systems at least annually. This evaluation shall be forwarded to Quality Management oversight.
- SR.7** Occurrences, incidents, or impairments shall be measured and analyzed to identify any patterns or trends.
- SR.8** The hospital, through its senior leadership shall ensure that the physical environment and associated management systems adequately address issues identified throughout the hospital and there are prevention, correction, improvement and training programs to address these issues.
- SR.9** Significant physical environment data/information shall be disseminated regularly to Quality Management oversight.

Interpretive Guidelines:

This standard shall apply to all locations of the hospital, including all off-site facilities.

The hospital's department that is responsible for the hospital's buildings and equipment (both facility equipment and patient care equipment) shall be evaluated for maintaining the appropriate work environment and related infrastructure to be safe for all staff, patients and visitors.

The hospital shall ensure that the condition of the physical plant and overall hospital environment is developed and maintained in a manner to ensure the safety and wellbeing of patients. This includes ensuring that routine and preventive maintenance and testing activities are performed as necessary, in accordance with all National and regulatory requirements, as documented within hospital policy and any manufacturer's recommendations, by establishing maintenance schedules and conducting ongoing maintenance inspections to identify areas or equipment in need of repair. The routine and preventive maintenance and testing activities should be incorporated into the hospital's Quality Management System.

"Adequate facilities" means the hospital has facilities that:

- I. Allow safe access for all service users including those with disabilities and special needs*
- II. Designed and maintained in accordance with National legal and regulatory requirements and hospital policy; and*
- III. 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 hospital may be required to have external sources responsible for maintaining treatment areas and the hospital will ensure that these services are providing a safe environment for all staff, patient and visitors.

Surveyor Guidance:

The survey team will delegate one surveyor to review and evaluate the physical environment of the hospital. However, each surveyor, during their respective review of areas within the hospital, should assess the hospital's compliance with the physical environment standards. If warranted, based upon the size and complexity of services provided, the Life Safety Code may be reviewed and evaluated separately by a qualified surveyor.

Verify that the condition of the hospital is maintained in a manner to assure the safety and wellbeing of patients (e.g., condition or ceilings, walls, and floors, presence of patient hazards, etc.).

Review the hospital's routine and preventive maintenance schedules to determine that ongoing maintenance inspections are performed and that necessary repairs are completed.

Verify that the hospital has developed and implemented a comprehensive plan to ensure that the safety and wellbeing of patients are assured during emergency situations.

Observe the facility layout and determine if the patient's needs are met. Toilets, sinks, specialized equipment, etc. should be accessible.

PE.2 – Life Safety Management System

SR.1 The hospital 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 firefighting authorities. The fire control plan shall provide for the following:

- a) Use of alarms;
- b) Transmission of alarm to fire department;
- c) Response to alarms;
- d) Isolation of fire;

- e) Evacuation of immediate area;
- f) Evacuation of smoke compartment;
- g) Preparation of floors and building for evacuation; and
- h) Extinguishment of fire.

SR.2 Hospitals subject to inspection by National or local fire control agencies shall maintain shall maintain written evidence of the inspections, demonstrate that any corrective actions identified are followed-up and that appropriate approvals are valid.

SR.3 Health care occupancies shall conduct unannounced fire drills, but not less than one (1) drill per shift per calendar quarter that transmits a fire alarm signal and simulates an emergency fire condition. When fire drills are conducted between 9:00 p.m. (2100 hours) and 6:00 a.m. (0600 hours), a coded announcement shall be permitted to be used instead of audible alarms. False alarms may be used (up to 50% of total drills) if all elements of the fire plan are exercised. Business occupancies shall conduct at least one unannounced fire drill annually per shift.

- a) Fire drills shall be thoroughly documented and evaluate the hospital's knowledge to the items listed in PE.2, SR.1.
- b) At least annually, the hospital shall evaluate the effectiveness of the fire drills, The report of effectiveness shall be forwarded to Quality Management oversight.

SR.4 The Life Safety Management System shall address applicable Alternative Life Safety Measures (ALSM) that shall be implemented whenever life safety features, systems, or processes are impaired or deficiencies are created or occur. Thorough documentation is required.

SR.5 All alternative life safety measures shall be approved by the authority having local jurisdiction.

SR.6 The Life Safety Management System shall require that Life Safety systems (e.g., fire suppression, notification, and detection equipment) shall be tested and inspected (including portable systems).

SR.7 The Life Safety Management System shall require a process for reviewing the acquisition of bedding, draperies, furnishings and decorations for fire safety.

SR.8 Construction, Repair, and Improvement operations shall involve the following activities:

- a) The hospital shall assess, document, and minimize the impact of construction, repairs, or improvement operations upon occupied area(s). The assessment shall include, but not be limited to, provisions for infection, prevention and control, utility requirements, noise, vibration, and alternative life safety measures (ALSM).
- b) In occupied areas where construction, repairs, or improvement operations occur, all required means of entry and exit and required fire protection features shall be in place and continuously maintained or where alternative life safety measures acceptable to the authority having local jurisdiction are in place.
- c) All construction, repairs, or improvement operations, shall be in accordance with local building and fire codes. Should standards and codes conflict, the most stringent standard or code shall prevail.

Interpretive Guidelines:

The hospital, regardless of size or number of beds, shall meet the applicable provisions of the National or local fire control jurisdiction for all inpatient care locations, emergency departments, and outpatient care locations.

The hospital will maintain and update, as necessary, a fire control plan that includes the elements of SR.4. The hospital will also have supporting documentation to verify the regular inspection and approval by National or local fire control agencies.

The Life Safety Management System shall:

- I. address applicable Alternative Life Safety Measures to be implemented whenever life safety systems, processes, or deficiencies are created or occur;*
- II. require that Life Safety systems (e.g., fire alarm and detection equipment) shall be is tested and inspected (including portable systems); and,*
- III. require a process for reviewing purchasing and reviewing that bedding, draperies, furnishings and decorations are contributing to enhancing fire safety requirements.*

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

Surveyor Guidance:

When applicable, verify the consideration, assessment, and recommendation for waivers of specific National and local provisions have been handled by the Fire Authority surveyor survey process.

Review and validate the hospital's written fire control plans to verify they contain the required provisions of the National and local legislation and regulations and regulations. Review and verify that hospital staff has a process in place to report all fires as required.

In the review of respective areas of the hospital, interview staff throughout the facility to verify knowledge of their role and responsibilities during a fire.

Review and validate the documentation of inspection and approval reports from State and local fire control agencies.

Review and validate that the Life Safety Management System addresses the elements as described within the Interpretive Guidelines.

The surveyor should validate compliance with the inspection, testing, and maintenance of fire detection, notification, and suppression equipment and systems.

If construction, repairs, or improvement operations are taking place and affects occupied areas, verify that the hospital has made provisions for the respective elements as described in the Interpretive Guidelines (above).

If there is no renovation or construction taking place within the hospital, verify that the hospital follows a process to implement alternative life safety measures and includes the infection control practitioner and has the resources to account for utility requirements, and eliminating, to the extent possible, noise and vibration.

Validate there was documentation relating to the renovation or construction area which ensures:

- IV. That the means of egress were checked daily.*

- V. *That the means of egress were continuously maintained free from obstructions or impediments.*
- VI. *That an assessment was performed of work relating to the impact on the occupied area(s) shall be conducted and include provisions for infection control, utility requirements, noise, vibration, and alternate life safety measures*
- VII. *That the authority having local jurisdiction approved the alternate life safety measures.*

PE.3 – Safety Management System

- SR.1** The hospital shall provide a Safety Management System that shall maintain safe and adequate facilities for its services. Diagnostic and therapeutic facilities shall be located for the safety of patients.
- SR.2** The Safety Management System shall require that facilities, supplies, and equipment be maintained and ensure an acceptable level of safety and quality. The extent and complexity of facilities shall be determined by the services offered.
- SR.3** The Safety Management System shall require proper ventilation, light and temperature controls in pharmaceutical, food preparation, and other appropriate areas.
- SR.4** The Safety Management System shall require that the hospital maintain an environment free of hazards and manages staff activities to reduce the risk of occupational related illnesses or injuries.
- SR.5** The Safety Management System shall require periodic surveillance of the hospital grounds to observe and correct safety issues that may be identified.
- SR.6** The Safety Management System shall address safety recalls and alerts.

Interpretive Guidelines:

The hospital 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.

The Safety Management System will require:

- I. That facilities, supplies, and equipment be maintained and ensure an acceptable level of safety and quality;*
- II. The hospital maintains an environment free of hazards and manages staff activities to reduce the risk of occupational related illnesses or injuries; and,*
- III. A process for addressing safety recalls and alerts.*

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

Surveyor Guidance:

Review and verify that diagnostic, treatment, and other specialized services are provided in areas appropriate for the service provided.

Review and verify that the physical facilities are large enough and properly equipped for the scope of services provided and the number of patients served.

Verify that there is an effective Occupational Health service

Review and verify that the hospitals processes for addressing National and locally produced safety recalls and alerts are adhered to.

Review surveillance records and corrective and preventative action(s).

PE.4 – Security Management System

SR.1 The hospital shall develop a Security Management System that provides for a secure environment.

SR.2 The Security Management System shall provide for identification of patients, staff and others.

SR.3 The Security Management System shall address issues related to abduction, elopement, visitors, workplace violence, and investigation of property losses and be proportional to the risk.

SR.4 The Security Management System shall establish emergency security procedures to include all hazard events and be proportional to the risk.

SR.5 The Security Management System shall require vehicular access to emergency service areas.

SR.6 The Security Management System shall require a process for reporting and investigating security related issues.

Interpretive Guidelines:

The hospital will maintain safe and secure facilities that are designed and maintained in accordance with National and local laws, hospital policy, regulations and guidelines and reflect the scope and complexity of the services it offers in accordance with recognized standards of practice.

Surveyor Guidance:

Review and validate the Security Management System to ensure that it addresses the respective elements as stated within SR.1 – SR.6.

Review the process for the identification of patients; staff; contractors and volunteers.

Review security procedures in place

Where corrective/preventive action(s) have been taken, review and verify the documentation in place to ensure the effectiveness of action(s) taken

PE.5 – Hazardous Material (HAZMAT) Management System

- SR.1** The hospital shall provide a HAZMAT Management System to manage hazardous materials and waste.
- SR.2** The HAZMAT Management System shall provide processes to manage the environment, selection, handling, storing, transporting, using, and disposing of hazardous materials and waste.
- SR.3** The HAZMAT Management System shall provide processes to manage reporting and investigation of all spills, exposures, and other incidents.
- SR.4** The hospital monitors staff exposure levels in hazardous environments and report the results of the monitoring to the Quality Management System.
- SR.5** The procurement, placement, and use of alcohol-based hand rub dispensers and alcohol-based skin preparations within the hospital shall be organized to take account of the fire risks that they may pose.
- SR.6** The volume, placement and security of stored nonflammable medical gases will be done safely.

Interpretive Guidelines:

The term waste refers to common rubbish, hazardous material as well as biohazardous wastes. The storage and disposal of rubbish shall be in accordance with National and local legislation and regulations, hospital policy and guidelines.

There shall be proper ventilation in at the following areas: • Areas using ethylene oxide, nitrous oxide, gentaldehydes, xylene, pentamidine, or other potentially hazardous substances;

Surveyor Guidance:

Verify that the hospital has developed and implemented policies and processes for the selection, handling, storing, transporting, using, and disposing of hazardous materials and waste in accordance with National and local legislation and regulations, hospital policy and guidelines.

Review and verify that processes are in place for the reporting and investigation of all spills, exposure and other incidents involving hazardous materials.

Review documents to ensure employee and environmental monitoring is being conducted.

PE.6 – Emergency Management System

- SR.1** The hospital shall provide a comprehensive Emergency Management System to respond to emergencies in the hospital or within the community and region that may impact the hospital's ability to provide services.
- SR.2** The Emergency Management System shall require that the hospital conduct a hazard vulnerability analysis to identify potential emergencies in the hospital and the community.
- SR.3** The Emergency Management System shall establish an emergency process to address the potential hazards to the hospital and the community. The hospital shall conduct an hospital-wide emergency management exercise, including the triage and disposition of patients. The hospital-wide emergency

management exercises, including the triage and disposition of patients, shall be conducted no less frequently than twice per year.

- a) Emergency management exercises shall test the most threatening hazard(s) identified in the HVA and tax the resources of the hospital.
- b) At least every other emergency management exercise shall be conducted with the community to evaluate surge capacity, the integration of Incident Command and interoperability of communications.
- c) The hospital shall formulate an After Action Report of all emergency management exercises to identifying opportunities for improvements and revise its emergency management plan according to the identified opportunities for improvement.

SR.4 The Emergency Management System 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.

SR.5 The Emergency Management System 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 organizational, community, or regional crisis.

SR.6 The hospital shall have policies, procedures, and decision criteria for the determination of protection in place or evacuation of patients in the event of a disaster.

Interpretive Guidelines:

Assuring the safety and wellbeing of patients would include developing and implementing appropriate emergency preparedness plans and capabilities. The organization shall develop and implement a comprehensive plan to ensure that the safety and wellbeing of patients are assured during emergency situations. The organization shall coordinate with National, regional, and local emergency preparedness and health authorities to identify likely risks for their area (e.g., natural disasters, bioterrorism threats, disruption of utilities such as water, sewer, electrical communications, fuel; nuclear accidents, industrial accidents, and other likely mass casualties, etc.) and to develop appropriate responses that will assure the safety and wellbeing of patients. The following issues should be considered when developing the comprehensive emergency plans(s):

- I. The differing needs of each location where the certified hospital operates;*
- II. The special needs of patient populations treated at the hospital (e.g., patients with psychiatric diagnosis, patients on special diets, newborns, etc.);*
- III. Security of patients and walk-in patients;*
- IV. Security of supplies from misappropriation;*
- V. Pharmaceuticals, food, other supplies and equipment that may be needed during emergency/disaster situations;*
- VI. Communication to external entities if telephones and computers are not operating or become overloaded (e.g., ham radio operators, community officials, other healthcare facilities if transfer of patients is necessary, etc.);*
- VII. Communication among staff within the hospital itself;*
- VIII. Qualifications and training needed by personnel, including healthcare staff, security staff, and maintenance staff, to implement and carry out emergency procedures;*
- IX. Identification, availability and notification of personnel that are needed to implement and carry out the hospital's emergency plans; • Identification of community resources, including lines of communication and names and contact information for community emergency preparedness*

coordinators and responders; • Transfer or discharge of patients to home, other healthcare settings, or other hospitals; • Transfer of patients with hospital equipment to another hospital or healthcare setting; and • Methods to evaluate repairs needed and to secure various likely materials and supplies to effectuate repairs.

X. *Provisions if gas, water, electricity supply is shut off to the community;*

The hospital shall provide for a comprehensive Emergency Management System in order to respond to emergencies in the organization or that occur in the community that impact the hospital's ability to provide services.

In order to prepare for such an emergency, the hospital shall conduct a hazard vulnerability analysis to identify potential emergencies or other circumstances that may impact the hospital and the community. The hospital shall maintain documentation that this analysis has been conducted and that the hospital has prioritized activities to address and prepare for these vulnerabilities.

Emergency management exercises shall be based upon the most probable emergencies or other circumstances that may impact the hospital and the community. A report, After Action Report, shall be created after each exercise documenting opportunities for improvement. The organization's emergency management plan shall be revised based upon the identified opportunities for improvement.

In SR.4b., the "community" represents local, regional, National public safety forces and/or public health agencies.

Surveyor Guidance:

Review and verify that the hospital has developed and implemented a comprehensive plan to ensure that the safety and wellbeing of patients are assured during emergency situations. This plan shall address the elements listed above within the Interpretive Guidelines.

Review and validate that the hospital has conducted a hazard vulnerability analysis to identify potential emergencies in the organization and the community. Determine the method used to prioritize and made preparations to address the potential hazards to the organization and community.

Review and validate:

- I. That the organization has conducted appropriate and timely emergency management exercises.*
- II. That after action reports identified opportunities for improvements*
- III. That the organization revised its emergency management plan according to the identified opportunities for improvement.*

PE.7 – Medical Equipment Management System

SR.1 The hospital shall establish a Medical Equipment Management System that provides processes for the acquisition, storage, prescribing, appropriate selection, safe usage and safe disposal of medical equipment and devices.

SR.2 The Medical Equipment Management System shall address issues related to the hospital's initial service inspection, the orientation, and the demonstration of use for rental or physician owned equipment.

SR.3 The Medical Equipment Management System shall address criteria for the selection of equipment.

- SR.4** The Medical Equipment Management System shall address incidents related to serious injury or illness or death
- SR.5** The Medical Equipment Management System shall have a process for reporting and investigating equipment management problems, failures, and user errors.
- SR.6** The Medical Equipment Management System shall address a process for determining timing and complexity of medical equipment maintenance.
- SR.7** The Medical Equipment Management System shall address the process of receiving and responding to recalls and alerts.

Interpretive Guidelines:

The hospital will ensure that medical equipment is maintained to ensure an acceptable level of safety and quality.

There shall be a regular periodic maintenance and testing program for medical devices. A qualified individual such as a clinical or biomedical engineer, or other qualified maintenance person shall monitor, test, calibrate and maintain the equipment periodically in accordance with the manufacturer's recommendations, appropriate risk assessments, and/or National and local legislation and regulations and guidance. Equipment maintenance may be conducted using hospital staff, contracts, or through a combination of hospital staff and contracted services

When the organization utilizes the method of conducting a risk assessment regarding the testing, calibration and maintenance of equipment, this process should be formalized and consistent in order to reduce malfunctions, damage or otherwise inoperable equipment. 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:

- I. consulting manufacturer recommendations*
- II. applicable codes and standards or accreditation requirements,*
- III. local or reported field experience*
- IV. health and safety information relevant to potential hazards*
- V. appropriate training and education of staff regarding the use of equipment*
- VI. likelihood of an injury or illness occurring and the likely severity of any injury or illness resulting from the use of equipment*

The organization will identify actions necessary to eliminate or control risk and maintain appropriate records.

The equipment to be maintained would encompass the hospital's need for medical equipment (e.g. biomedical equipment, radiological equipment, patient beds, stretchers, IV infusion equipment, ventilators, laboratory equipment) for both day-to-day operations and equipment that would be needed in likely emergency/disaster situations such as mass casualty events resulting from natural disasters, mass trauma, disease outbreaks, internal disasters, and that the hospital makes adequate provisions to ensure the availability of that equipment when needed.

The hospital will develop and implement a Medical Equipment Plan that addresses the following:

- VII. *Issues related to use of demonstration or rental equipment and how appropriate training is provided to ensure safe operation;*
- VIII. *Defined criteria for the selection of new equipment;*
- IX. *The process of reporting and investigating incidents related to serious injury or illness or death A process for reporting and investigating equipment management problems, failures, and user errors;*
- X. *A process for determining timing and complexity of medical equipment maintenance; and,*
- XI. *A process of receiving and responding to recalls and alerts.*

Surveyor Guidance:

Review and validate that there is a process in place to address the repair/periodical maintenance program for equipment.

Review and validate, through a document sampling, that a clinical or biomedical engineer routinely checks medical devices and equipment.

Review and verify that the hospital maintains maintenance logs for significant medical equipment (e.g. cardiac monitors, IV infusion pumps, ventilators).

Interview the person in charge of medical equipment and determine if there is an adequate repair/periodical maintenance program.

Verify that all medical devices and equipment are routinely checked by a clinical or biomedical engineer.

Review maintenance logs for significant medical equipment (e.g., cardiac monitors, IV infusion pumps, ventilators, etc.).

Verify that supplies maintained in such a manner as to ensure that safety

Verify that supplies are stored as recommended by the manufacturer

Verify that supplies are stored in such a manner as to not endanger patient safety

Verify that the hospital has identified supplies and equipment that are likely to be needed in emergency situations

Verify that the hospital made adequate provisions to ensure the availability of supplies and equipment when needed

PE.8 – Utility Management System

- SR.1** The hospital shall require a Utility Management System that provides for a safe and efficient facility that reduces the opportunity for hospital-acquired illnesses.
- SR.2** The Utility Management System shall provide for a process to evaluate critical operating components.
- SR.3** The Utility Management System shall develop maintenance, testing, and inspection processes for critical utilities.
- SR.4** The Utility Management System shall contain a process to address medical gas systems and HVAC systems (e.g., includes areas for negative pressure).

- SR.5** The Utility Management System shall provide for emergency processes for utility system failures or disruptions.
- SR.6** The Utility Management System shall provide for reliable emergency power sources with appropriate maintenance as required.
- SR.7** The Utility Management System shall require proper ventilation, light and temperature controls in operating rooms, sterile supply rooms, special procedures, isolation and protective isolation rooms, pharmaceutical, food preparation, and other appropriate areas.
- SR.8** There shall be emergency power and lighting in at least the operating, recovery, intensive care, emergency rooms, and in other areas where invasive procedures are conducted, stairwells, and other areas identified by the hospital (e.g., blood bank refrigerator, etc.). In all other areas not serviced by the emergency supply source, battery lamps and flashlights shall be available.
- SR.9** There shall be facilities for emergency gas and water supply.
- SR.10** All relevant utility systems shall be maintained inspected, and, tested.

Interpretive Guidelines:

The hospital shall ensure that the condition of the physical plant and overall hospital environment is developed and maintained in a manner to ensure the safety and wellbeing of patients, visitors, and staff. The hospital 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.

There should be proper ventilation, light and temperature controls in pharmaceutical, food preparation, and other appropriate areas;

The hospital will maintain, and regularly test and inspect, emergency power and lighting in at least the operating, recovery, in other areas where invasive procedures are conducted, intensive care, and emergency rooms, stairwells, and other areas identified by the organization (e.g. blood bank refrigerator). Where areas are not supplied with an emergency supply source, the hospital will make provisions for battery lamps and flashlights.

The hospital shall have systems for emergency gas and water needs to provide care to inpatients and other persons who may come to the hospital in need of care. This includes making arrangements with local utility companies and others for the provision of emergency sources of water and gas. The hospital should consider nationally accepted references or calculations made by qualified staff when determining the need for at least water and gas.

Emergency gas includes fuels such as propane, natural gas, fuel oil, liquefied natural gas, as well as any gases the hospital uses in the care of patients such as oxygen, nitrogen, nitrous oxide, etc.

The hospital should have a plan to protect these limited emergency supplies, and have a plan for prioritizing their use until adequate supplies are available. The plan should also address the event of a disruption in supply (e.g., disruption to the entire surrounding community).

Surveyor Guidance:

Review and validate the hospital's Utility Management System to ensure that there is a process in place to provide for a safe and efficient facility that reduces the opportunity for hospital-acquired illnesses.

Review and validate the condition of the hospital and that it is maintained in a manner to assure the safety and wellbeing of patients (e.g. condition of ceilings, walls, and floors, presence of patient hazards).

Review and validate the hospital's routine and preventive maintenance schedules to determine that ongoing maintenance inspections are performed and that necessary corrective/preventive action(s) are taken.

Review and verify that the facility layout is appropriate to meet patient's needs. Toilets, sinks, specialized equipment should be accessible.

The hospital will maintain, test and inspect their utility systems and have adequate facilities for emergency gas and water supply, to provide safe care for patients.

Verify that the Utility Management System provides for:

- I. A process to evaluate critical operating components;*
- II. A means of addressing medical gas systems and HVAC systems;*
- III. A means for providing emergency processes for utility system failures or disruptions; and,*
- IV. A means for providing for reliable emergency power sources with appropriate maintenance.*
- V. Verify that the quality of the water supply and distribution system has been deemed acceptable for its intended use (drinking water, irrigation water, lab water, dialysis);*
- VI. Emergency gases have been deemed acceptable and can be adequately supplied as needed; and,*
- VII. Review the system used by hospital staff to determine the hospital's emergency needs for gas and water. Verify that the system accounts for not only inpatients, but also staff and other persons who come to the hospital in need of care during emergencies.*
- VIII. Determine the source of emergency gas and water supplies, Review the quantity and availability of these supplies to the hospital, and that they are available within a short time through period additional deliveries.*
- IX. Verify that arrangements have been made with utility companies and others for the provision of emergency sources of critical utilities, such as water and gas.*
- X. Verify that the utility systems have been tested, inspected and maintained for the safety of patient care and applicable to the services provided.*

Review and verify that proper ventilation is in place in at least the following areas:

- XI. Areas using ethylene oxide, nitrous oxide, guteraldehydes, xylene, pentamidine, formaldehyde , or other potentially hazardous substances;*
- XII. Locations where oxygen is transferred from one container to another;*
- XIII. Isolation rooms and reverse isolation rooms Pharmaceutical preparation areas (hoods, cabinets); and,*

Review and verify that adequate lighting is in place in all the patient care areas, and food and medication preparation areas.

Temperature, humidity and airflow in the operating rooms shall be maintained within acceptable standards to inhibit bacterial growth and prevent infection, and promote patient comfort.

Review and verify that each surgical suite has separate temperature control.

Review and verify that food products are stored under appropriate conditions (e.g. time, temperature, packaging, location) based on accepted sources, or other recognized standard.

Review and verify that pharmaceuticals are stored at temperatures recommended by the product manufacturer and according to hospital policy.