CBAHI
المركز السعودي لاعتماد المنشآت الصحية
Saudi Central Board for Accreditation of Healthcare Institutions

Hospital Standards

Leadership Standard Intents

LD.1 The hospital has an effective governing body.

LD.1.1 There is a governing body that fulfills its main roles for mission and strategy setting as well as performance evaluation and oversight on the hospital processes and outcomes.

LD.1.2 The governing body has its organization, membership, roles and responsibilities, meetings procedure, performance evaluation, and committees defined in a written bylaws or a similar document.

LD.1.3 The governing body's responsibilities reflect its ultimate accountability for the quality of care and patient safety, and include the following:

- LD.1.3.1 Working together with the senior management and hospital leaders to create and regularly review the hospital's mission, vision, and values.
- LD.1.3.2 Appointing a qualified hospital director.
- LD.1.3.3 Evaluating on a regular basis the performance of the hospital director.
- LD.1.3.4 Ensuring that the hospital has an effective organizational structure displayed in an organizational chart that shows the titles (or names) and the reporting relationships.
- LD.1.3.5 Approving the scope of services provided by the hospital.
- LD.1.3.6 Approving the hospital strategic and operational plans.
- LD.1.3.7 Approving the hospital-wide policies and procedures.
- LD.1.3.8 Monitoring, evaluating, and continuously improving the outcome of the quality and patient safety plans and programs.
- LD.1.3.9 Approving the medical staff bylaws.
- LD.1.3.10 Approving the annual budget of the hospital.
- LD.1.3.11 Ensuring the provision of adequate resources (e.g. manpower, financial resources, and medical supplies).
- LD.1.3.12 Defining and approving delegations of authority.

LD.1.4 The governing body meets regularly and adequate minutes of the proceedings are maintained.

Standard Intent:

The Board of an organization is the group that is above all responsible for making sure that the organization's mission continues to be carried out, and that the organization never strays very far from its true focus. It's also, in general has the overall legal accountability for the conduct of the organization.

Developing a governing body system or bylaws with specific responsibilities and procedures has many advantages:

- It ensures that the mission of the organization will continue to be well-understood by those who are in a position to further it
- It helps to pave a smoother relationship between the board and other stakeholders including staff members.
- Select the executive staff through an appropriate process
- Provide ongoing support and guidance for the executive
- Ensure effective organizational planning
- Ensure adequate resources and their efficient utilization
- Determine and monitor the quality of services
- Assess its own performance

LD.2 A qualified hospital director is responsible for managing the hospital.

LD.2.1 The hospital director is qualified in healthcare management by education, training or experience.

LD.2.2 The hospital director has a good command of the English language.

LD.2.3 The hospital director ensures the hospital's compliance with all relevant laws and regulations.

LD.2.4 The hospital director ensures the recruitment and selection of competent and skilled hospital staff.

LD.2.5 The hospital director is accountable to the governing body for the clinical performance and professional conduct of the hospital staff.

LD.2.6 The hospital director ensures the implementation of the policies set by the governing body.

LD.2.7 The hospital director participates actively in supporting the safety of patients, staff and visitors (e.g. through leadership safety rounds, review of reported incidents).

LD.2.8 The hospital director identifies and works closely with other hospital leaders, collectively constituting the hospital leadership group.

LD.2.9 The hospital director ensures appropriate response to reports or enquiries from relevant authorities including accreditation agencies.

LD.2.10 The hospital director ensures the availability of adequate resources (e.g. human resources, equipment, supplies, and medications).

LD.2.11 The hospital director ensures all physical properties are kept in a good state of repair and operating conditions.

LD.2.12 The hospital director ensures the efficient utilization of all resources.

Standard Intent:

Hospital director (HD) has a legal and moral obligation to improve quality of patient care. HD is in a prime position to mandate policies and procedures, rules, regulations, and organizational climates.
To coordinate the functions of all departments and ensure their proper function, hospital director must hold a wide set of skills and knowledge including a degree in healthcare administration and experience of working in senior healthcare position.

LD.3 Hospital leaders ensure the hospital is in compliance with relevant laws and regulations.

LD.3.1 Hospital leaders identify all relevant laws and regulations.

LD.3.2 Hospital leaders ensure compliance with all relevant laws and regulations (e.g., laws and regulations related to recruitment, professional staff licensure and registration, waste management, food management, infection control, medications management, patient rights, radiation safety, and physical environment).

Standard Intent:

There are several issues hospitals need to consider when designing these services. Ethical behaviors are legal; therefore, hospitals should be in compliance with all relevant laws and regulations. The hospital should first identify and list all relevant laws and regulations which in turn be incorporated into and considered while formulating and putting hospital policies, procedures and plans. Hospital leaders are in charge of ensuring hospital implementation and maintaining compliance with those identified laws and regulations each one in his/her respective area of authority.

LD.4 Hospital leaders work collaboratively to develop the hospital's scope of services.

LD.4.1 Hospital leaders identify the scope of services provided by the hospital.

LD.4.2 The scope of services includes the range of services offered by the hospital (e.g., children hospital, maternity hospital, or general hospital).

LD.4.3 The scope of services includes the targeted age groups.

LD.4.4 The scope of services includes the number of patients seen annually.

LD.4.5 The scope of services includes the principal diagnostics and therapeutic modalities used in the hospital.

LD.4.6 The scope of services is approved by the governing body.

Standard Intent:

Hospital scope of services is a structural measure that reflects whether a hospital has the resources, facilities, staff, and equipment to provide care for the medical conditions it recognizes to treat or to care for the medical conditions affecting potential patients.

Comprehensive scope of services that includes all the standard's elements should be known to the staff and other customers. Based on this determination the hospital will accept, refer, or reject the cases to treat or to provide general or specialized care.

LD.5 A structure is in place for the hospital leaders to communicate and collaborate in order to fulfill the hospital's mission and plans.

LD.5.1 Hospital leaders form an executive management body (e.g., an executive management committee), led by the hospital director and includes the medical director, the nursing director, the quality director, selected heads of the departments, and other senior staff members as required.

LD.5.2 Hospital leaders are qualified in healthcare management by education, training, or experience.

LD.5.3 Hospital leaders have specific responsibilities as outlined in a current job description.

LD.5.4 Functions and meetings of the hospital leaders are outlined in specific terms of reference.

LD.5.5 Hospital leaders meet regularly (at least ten times per year) to evaluate the progress of the overall strategic plan, the quality and safety of care provided to patients, and all other clinical and non-clinical issues related to the hospital work.

LD.5.6 Discussions, decisions and actions taken by the hospital leaders are documented in a formal meeting minutes.

Standard Intent:

Executive Management Committee (EMC) is the highest level of organizational management (under the hospital governance) who has the responsibilities of managing an organization. The EMC role is to ensure the effective steering, coordination and control of organization business. Members of the EMC shall include the hospital's leaders of different services as well as main departments' heads and senior staff members as determined by the hospital director.

To ensure proper and scientific management of the day to day services provided, the hospital leadership group members must have a background in healthcare management as evidenced by education, training, or experience and their responsibilities must be clear in a written approved job description.

Executive management committee should have charters that describe its responsibilities, membership, meeting frequency, and the information it regularly reviews.

The Executive Management Committee ensures that everything the organization does supports its vision, purpose and aims.

LD.6 The hospital administrative work and day to day operations are consistent and organized.

LD.6.1 The hospital work is guided by a manual that contains all important hospital-wide guiding administrative policies and principles.

LD.6.2 The contents of the manual are communicated with and made accessible to the hospital staff.

LD.6.3 Contents of this manual reflect the general organization of the hospital work and include, but are not limited to, the following:

- LD.6.3.1 A brief general description of the hospital.
- LD.6.3.2 Vision, mission and values.
- LD.6.3.3 Organizational chart.
- LD.6.3.4 Scope and organization of services.
- LD.6.3.5 Standing meetings and committees.
- LD.6.3.6 Staff code of conduct and ethics.
- LD.6.3.7 Conflict of interest.
- LD.6.3.8 Admission/Discharge/Referral.
- LD.6.3.9 Visiting times.
- LD.6.3.10 Smoking policy.
- LD.6.3.11 Parking.

Standard Intent:

Hospital operations and staff practices should be regulated and organized by sets of policies and procedures and work protocols within the boundaries of laws and professional regulations to maintain and sustain systematic acceptable practices.
These organizational policies and/or procedures which considered administrative in content; and may direct a different levels of management; and reflects the philosophy and objectives of the hospital that affects all departments are called administrative policies and procedures.
These administrative policies and procedures are compiled in a manual. This manual must be accessible to all hospital staff physically (hard copy or electronic) and in a language they can read and understand.

LD.7 The hospital work, planning, and goals setting are guided by a clear vision and mission.

LD.7.1 The hospital has a clearly stated vision and mission statements.

LD.7.2 The vision and mission are communicated to the hospital staff.

LD.7.3 The vision and mission are displayed to patients, visitors, and the wider community.

LD.7.4 The mission reflects the scope of services provided by the hospital and the health needs of the population served.

LD.7.5 The mission and vision are regularly reviewed and modified as appropriate.

Standard Intent:

Organizational mission and vision statements serve as foundational guides in the establishment of organization objectives. An organization's mission statement is essentially its statement of purpose. It serves as a guide for all of the organization's decision-making.

Leaders should emphasize the mission statement to employees, which clarifies the purpose and primary objectives of the organization. Employees engagement with the change and decision making processes can be enhanced through the mission and vision statement of the organization. Articulating and repeating the positives of the move toward change in the organization will help employees stay motivated and engaged in the process.

The vision statement offers more of a direction and may include a perspective of organization values. It helps to provide inspiration to employees. Employees who feel invested in the organizational change are more likely to stay motivated and have higher levels of productivity.

A successful change will involve communicating and repeating mission and vision statements, which helps prevent people from becoming discouraged in the event of small failures along the way. The mission and vision statements are meant for employees and leaders of the organization, and also helps inspire consumers and other important stakeholders to get involved in the organization processes.

LD.8 The hospital work, planning, and goals setting are guided by a set of values and professional code of conduct.

LD.8.1 Hospital leaders collaboratively develop the hospital's set of values and the code of conduct.

LD.8.2 The professional code of conduct describes the hospital's expectations of the staff regarding their behavior and communication with each other and with their patients and other external customers.

LD.8.3 The professional code of conduct includes a process to handle inappropriate behaviors of the hospital staff.

LD.8.4 The professional code of conduct includes a process to resolve conflicts among staff and between staff and external customers.

Standard Intent:

Ethics involve people from different walks of life, different countries and different cultures all agreeing on some basic principles of how to conduct themselves. Since work transactions in healthcare organizations involve interactions with patients, community members, coworkers, and contractors who come from different backgrounds interacting with each other on a regular basis, organizational values and professional ethics provide

a common ground everyone can agree upon. Hospital leaders should establish the fundamental values and the ethical principles in which the organization operates. Ethical conduct makes the best use of resources, helps maintain quality and productivity, boosts morale and promotes teamwork, assists the organization to comply with laws and regulations, and ensures good and proper relationships with customers and vendors. If employees feel they are expected to act ethically and are treated ethically by their employer, they are less likely to engage in unethical behavior. Engaging in some unethical activities may lead to trouble with the law that may seriously affect the organization's ability to operate. Engaging in ethical behavior promotes a positive public image for the organization and increases public trust that helps organizational growth and enhances future opportunities.
Interestingly, certain values tend to predominate in certain industries, which perhaps reflect the culture of the industry.

LD.9 Hospital leaders work collaboratively to establish medical and non-medical hospital-wide committees that support integration of services and communication amongst staff.

LD.9.1 There is a policy and procedure that addresses the formation of hospital-wide committees, conduct and communication amongst the committee members, committee's recommendations approval process, and annual review of accomplishments.

LD.9.2 Medical committees provide oversight on specific areas of responsibilities that include:

- LD.9.2.1 Pharmacy and therapeutics.
- LD.9.2.2 Morbidity and mortality.
- LD.9.2.3 Infection control.
- LD.9.2.4 Cardio pulmonary resuscitation.
- LD.9.2.5 Credentialing and privileging.
- LD.9.2.6 Operating room.
- LD.9.2.7 Tissue review.
- LD.9.2.8 Blood utilization review.
- LD.9.2.9 Quality and patient safety.
- LD.9.2.10 Medical records review.
- LD.9.2.11 Patient rights.
- LD.9.2.12 Utilization review.

LD.9.3 Each committee has terms of reference that define:

- LD.9.3.1 Committee functions.
- LD.9.3.2 Chairperson and members with their titles.
- LD.9.3.3 Quorum.

LD.9.3.4 How often the committee is expected to meet (at least quarterly unless otherwise specified in this manual).

LD.9.3.5 Mechanism of disagreement resolution including when to resort for voting and members that are not allowed to vote.

LD.9.3.6 Distribution of the minutes to the executive management.

LD.9.4 There is an annual review of each committee's accomplishments and non-resolved issues submitted by the committee chair to the executive management.

LD.9.5 Feedback from the annual review is studied by the committee and recommendations are implemented.

Standard Intent:

Participation is a corner stone of the concept of quality management, and team work is an essential aspect of participation. Therefore, collaboration among hospital leaders and staff through hospital-wide committees and task forces to plan, decide, and monitor clinical and non-clinical services is essential for improving services. Those committees are expected to support using research and best practices to solve challenges and improve patient care services.

Hospital Committees are regular standing multidisciplinary groups that deemed necessary by hospital administration in formulating policies, coordinating and monitoring hospital-wide activities that are considered critical in the delivery of quality health care services.

Committees assist the governing board by bringing reports and recommendations for the board action. They only final decisions a committee may make are those for which the full board has granted authority to the committee.

"As health systems grow larger, more boards are delegating certain decisions to committees," according to The American Hospital Association's Center for Healthcare Governance. Thus, it's critical for committees to keep the full board informed to avoid becoming a "board within a board."

According to the size of the hospital and diversity of services provided, each function can be discussed in one separate committee or multiple functions can be under one committee. Most committees with one function responsibility work well with five to seven members. Committees that have broader responsibilities and functions may be a bit larger and include more stakeholders.

Each committee meetings should be documented in a meeting minute with attendance and clear recommendations and responsibilities. All meetings recommendations have to be followed for proper implementation and the committee's annual review must highlight the completed and suspended issues together with clear justifications of unresolved items.

LD.10 Hospital leaders drive effectively the quality improvement initiatives in the hospital.

LD.10.1 Hospital leaders are familiar with the basic concepts and tools used in continuous quality improvement, such as:

LD.10.1.1 Basic data analysis and interpretation of quality reports.

LD.10.1.2 Basic tools used in quality management (e.g., PDCA cycle).

LD.10.1.3 Root cause analysis.

LD.10.2 Hospital leaders participate actively in quality improvement plans and projects.

LD.10.3 Information about the quality and performance of the services offered (including the accreditation status) are communicated to the staff, governing body, public, community, and other customers in an appropriate format.

Standard Intent:

Achieving high levels of performance usually are not easily attainable without leadership support to ensure staff engagement and to provide the context for change and improvement. Therefore, leaders are required to actively engage in different activities of quality improvement, including training and support and participation in improvement teams.

Basic data analysis and interpretation of quality reports, different quality tools and root cause analysis, among others, are important means used in day to day effective management, thus, leaders must be trained on these basic concepts and tools.

To ensure the involvement of staff and community in the care process and to provide them with feedback about the hospital performance, effective communication means (e.g., web pages, newsletters, bulletin boards) should be used to provide staff, governing body, public, community, and other customers with information about the quality and performance of the services offered.

LD.11 Hospital leaders consider the community input during planning for health care needs of the population.

LD.11.1 Hospital leaders identify the relevant community leaders (e.g., members of the regional council, members of municipalities, patient's rights advocates, civil defense, health related commissions and councils, other society organizations and representatives).

LD.11.2 Local community leaders participate in planning for the current and future health care needs of the population (e.g., planning for health-relevant demographic changes, public health issues, groups with special needs).

LD.11.3 Hospital leaders plan with the community leaders to provide services related to health education and health promotion for patients and the wider community.

Standard Intent:

To provide better health services and improve health outcomes, some basic information is needed about patients' needs and their community features; such as address, age, gender, race and ethnicity, endemic diseases, health problems, etc. Improved collection of this information will allow hospitals to develop an understanding of the patients and communities they serve and to identify and address any differences in health outcomes they may face.
Hospitals must bear effort to list and involve all local community leaders in the area in identifying community healthcare needs and putting hospital strategies. Community leaders may include but not limited to members of the regional council, members of municipalities, patient's rights advocates, civil defense, health related commissions and councils, other society organizations and representatives.
Hospital planning sessions should consider inputs from local community leaders for the current and future health care needs of the population in addition to health education and health promotion for patients and the wider community.

LD.12 Hospital leaders work collaboratively to develop an effective planning process.

LD.12.1 The planning process includes soliciting inputs from patients and staff (e.g. feedback from patient satisfaction surveys and patient's/staff complaints).

LD.12.2 The planning process is consistent with the hospital's mission and strategic directions.

LD.12.3 The planning process considers cultural and religious needs of the local community.

LD.12.5 The planning process ensures coordination and integration of services throughout the hospital.

LD.12.6 The planning process ensures efficient use of different resources through regular evaluation by hospital leaders against plans and budgets.

LD.12.7 The planning process considers the upgrade or replacement of buildings, equipment, and other resources.

LD.12.4 The planning considers environmental and financial factors and is consistent with the hospital's mission and strategic direction.

Standard Intent:

A properly designed and facilitated planning process will efficiently guide the work team from organizational goals to specific objectives and actions for every member, that leads to better performance in all areas and a stronger team culture.
Planning has to be precise and effective for the success of the organization and its departments and units. Every organization unit has its own problems and these are taken

into account in working out the details of the plans. However, there are certain basic points to be considered in every type of planning to be effective.
Any planning effort that will take place in the hospital at any level must be guided by the hospital mission and supporting its strategic directions, goals and objectives.
Additionally, inputs from internal and external customers (e.g., through satisfaction surveys) should be considered together with cultural and religious needs of the local community.
Because planning will be done in almost all units of the hospital and cutting across all levels of management, leadership should ensure the coordination and integration of all services, to decrease redundancies, and to prevent duplication of efforts. Moreover, they have to monitor the efficient use of different resources and upgrading of the hospital structure elements.

LD.13 Hospital leaders work collaboratively to develop an effective budgeting process.

LD.13.1 The hospital has a finance director who is qualified by education and experience.

LD.13.2 Hospital leaders work together to address both the capital and the operating budgets.

LD.13.3 The budgeting process addresses the manpower in addition to other financial assets.

LD.13.4 The budgeting process allocates resources to all patient care units based on the scope and complexity of care, aiming to ensure a safe, efficient process.

LD.13.5 The hospital's budget is approved by the governing body.

Standard Intent:

The purpose of budgeting is to plan for future success through effective resource allocation. Budgeting helps to coordinate the activities of all the different department of the hospital into a master single plan, and to communicate the policies and targets to every department's head in the organization responsible for carrying out a part of that plan. Also it helps to establish a system of control by having a plan against which actual results can be progressively compared.
Budgeting is a good tool of communication and coordination between departments and leadership. It is used to measure performance against performance indicators and available resources.
Good budgetary process requires a qualified finance director with degree in finance, accounting, or business management. The hospital budget should reflect capital and operating budgeting for manpower, projects, and consumables for different departments and activities.

LD.14 Hospital leaders work collaboratively to ensure the provision of a safe and quality care.

LD.14.1 Hospital leaders encourage the use of research, evidence, and best practice information to develop and improve patient care services.

LD.14.2 Hospital leaders work collaboratively to develop and execute plans, policies, and procedures related to the patient care.

LD.14.3 Hospital leaders work collaboratively to solve challenges, conflicts, and problems affecting the patient care.

Standard Intent:

Participation is a corner stone of the concept of quality management, and team work is an essential aspect of participation. Therefore, collaboration among hospital leaders and staff through hospital-wide committees and task forces to plan, decide, and monitor clinical and non-clinical services is essential for improving services. Those committees are expected to support using research and best practices to solve challenges and improve patient care services.

LD.15 Hospital leaders work collaboratively to develop the hospital strategic plan.

LD.15.1 Hospital leaders work together to develop a strategic plan that is guided by the mission, vision, and values.

LD.15.2 The strategic plan is based on comprehensive evaluation of the internal and external environmental factors (e.g., SWOT analysis, PEST analysis).

LD.15.3 The strategic plan addresses all clinical and non-clinical services and programs.

LD.15.4 The strategic plan spans over a period of 3 - 5 years and is reviewed on a regular basis.

LD.15.5 The strategic plan includes the broad goals and objectives required to fulfill the hospital's mission.

LD.15.6 Goals and objectives are translated into operational plans with defined projects, clearly delineated responsibilities, and time frames.

LD.15.7 Resources required for executing the operational plans are properly allocated.

LD.15.8 Operational plans are implemented and closely monitored for progress toward achieving the goals and objectives.

LD.15.8.1 Key performance indicators are developed for each operational plan.

LD.15.8.2 Key performance indicators are reviewed regularly and corrective actions are taken when required.

LD.15.9 Heads of departments develop annual departmental plans in line with the hospital's strategic plan.

LD.15.10 The strategic plan is communicated to relevant staff.

LD.15.11 The strategic plan is approved by the governing body.

Standard Intent:

Achieving organization's mission requires generating short and long-term objectives. Strategic planning is the process of developing organizational objectives, strategies and tactics to achieve the mission of the organization. Strategic plans often mean a change in organizational structure or a move toward change. Change can be a difficult process and requires time, therefore, it is important for leaders to get employees on board with the change and decision making processes.
Hospital leaders are to ensure all planning activities (departmental plans) of the organization are in line with the strategic plan. Operational plans should reflect hospital performance in achieving its strategic goals and accomplishing its mission.

LD.16 Hospital leaders work collaboratively to plan for staffing needs, recruitment, and selection.

LD.16.1 Hospital leaders work together to develop a hospital-wide staffing plan.

LD.16.2 The staffing plan defines the total number and categories of staff required by all departments and their qualifications.

LD.16.3 The staffing plan ensures the services provided by staff meet the health care needs of the patients.

LD.16.4 The staffing plan is consistent with the hospital strategic plan.

LD.16.5 The staffing plan is reviewed at least annually.

LD.16.6 Hospital leaders ensure a uniform and fair process for recruitment and hiring of new staff members.

LD.16.7 Heads of departments participate in the selection of new staff.

Standard Intent:

Leadership group function includes a variety of activities, and key among them is deciding what staffing needs they have and whether to use independent contractors or hire employees to fill these needs, recruiting and training the best employees, ensuring they are high performers, and ensuring the personnel and management practices conform to various regulations.
Investment of people requires an equally significant approach to manage it. Having a strategic plan for the hospital staffing needs and decisions allows you to organize and account for demands in personnel while keeping organizational goals and vision in the forefront.

LD.17 The hospital has a process for delegation of function and authority.

LD.17.1 There is a policy and procedure that guides the process for delegation of function and authority between two qualified peers.

LD.17.2 The process of delegation is consistent with other relevant hospital policies.

Standard Intent:

A manager alone cannot perform all the tasks assigned to him. In order to meet the targets, the manager should delegate authority. Delegation of authority means division of authority and powers downwards to the subordinate. Delegation is about entrusting someone else to do parts of your job. Delegation of authority can be defined as subdivision and sub-allocation of powers to the subordinates in order to achieve effective results.
Authority can be defined as the power and right of a person to use and allocate the resources efficiently, to take decisions and to give orders so as to achieve the organizational objectives. Authority must be well- defined. All people who have the authority should know what is the scope of their authority is and they shouldn't misutilize it. Authority is the right to give commands, orders and get the things done. The top level management has greatest authority.
Authority always flows from top to bottom. It explains how a superior gets work done from his subordinate by clearly explaining what is expected of him and how he should go about it. Authority should be accompanied with an equal amount of responsibility. Delegating the authority to someone else doesn't imply escaping from accountability. Accountability still rest with the person having the utmost authority.

LD.18 Hospital leaders ensure an effective and efficient internal and external communication.

LD.18.1 The hospital implements a policy that outlines the process, including roles and responsibilities, for communication between the different departments, both vertical and horizontal.

LD.18.2 Departmental staff meetings are held on a regular basis and minutes are documented.

LD.18.3 Hospital-wide policies are properly communicated to all relevant staff.

LD.18.4 The hospital utilizes one or more of professional communication tools (e.g., intra-net, bulletin boards, periodic reports, newsletters, and website).

LD.18.5 The hospital implements a policy that outlines the process, roles and responsibilities for handling all incoming requests from other hospitals and external organizations.

LD.18.6 The response to the incoming requests is timely and informative.

Standard Intent:

To coordinate and integrate patient care, the leaders develop a culture that emphasizes cooperation and communication. The leaders develop formal (for example, standing committees, departmental meetings, joint teams) and informal (for example, newsletters, posters) methods for promoting communication among services, and

individual staff members. Coordination of clinical services comes from an understanding of each department's mission and services of each department and collaboration in developing common policies and procedures.
Throughout all phases of care, patient needs are matched with appropriate resources in and, when necessary, outside the organization. This is usually accomplished by using established criteria or policies that determine the acceptance of requests from outside organization. Incoming requests may include: medical reports, sick leaves confirmation, patient transfer, medical consultations, among others.

LD.19 Initiation of a new process or changing of an existing one is systematic and consistent throughout the hospital.

LD.19.1 All customers of a new or modified process are identified.

LD.19.2 Customers' needs and feedback are addressed when designing a new process (e.g., new procedure, new practice guideline) or changing an existing one.

LD.19.3 Hospital leaders ensure that the initiation of a new process or the changing of an existing one is always based on evidence, research, and best practice.

LD.19.4 Hospital leaders assess new or modified processes for risk and safety issues.

LD.19.5 Whenever applicable, new or modified processes undergo pilot testing before their routine use.

LD.19.6 Hospital leaders regularly evaluate new or modified processes through process and outcome indicators to ensure an optimal performance.

LD.19.7 Hospital leaders ensure the provision of staff training on new or modified processes.

Standard Intent:

Proper coordination and communication are required whenever change happen to processes or work regulations or a new process is planned to be implemented. Systematic approach or methodology must be identified to be followed in these two situations. The approach should include identification of internal and external process customers and their needs, risk assessment, be evidence based, piloting, and regular evaluation after full implementation. Changes must be communicated to all staff after adequate coordination with all units and staff that have input in the process.

LD.20 The hospital has a policy for controlling the development and maintenance of policies and procedures for key functions and processes.

LD.20.1 There is a unique identification for each policy with title, number, and dates of issue and revision.

LD.20.2 Policies are developed, approved, revised, and terminated by authorized individuals.

LD.20.3 Policies are dated and are current.

LD.20.4 Policies are revised according to a defined revision due date (every 2-3 years, or when required).

LD.20.5 Policies are communicated to staff and are always accessible.

LD.20.6 A process is in place to ensure that new or updated policies are appropriately communicated to relevant staff.

LD.20.7 A process is in place to ensure that policies are always implemented.

LD.20.8 A process is in place to ensure that only the last updated versions of policies and other documents (e.g., organizational plans) are available for use in the hospital.

Standard Intent:

The hospital has to agree on a system to provide definitions of working documents used in delivery and support of care and to set guidelines for developing the hospital policies and procedures' approval, distribution, review, revision, termination and to provide the formats or frameworks used in administrative and patient care policies and procedures.

LD.21 Hospital leaders ensure the overseeing of contracts for clinical and administrative services.

LD.21.1 Policies and procedures are in place to ensure the quality and safety of all contracted services.

LD.21.2 Policies and procedures indicate how to track and monitor all contracted services for quality and safety (within the hospital premises and off-site).

LD.21.3 Hospital leaders ensure that the contracts clearly state the services to be provided by the contracted entity.

LD.21.4 Hospital leaders and other heads of departments participate in the selection, monitoring, and management of contracted services.

LD.21.5 Hospital leaders ensure that contracted services and providers both meet applicable laws and regulations.

LD.21.6 Hospital leaders ensure the services provided are consistent with the hospital's quality and safety standards.

LD.21.7 The quality of services provided is always considered by hospital leaders before contract renewal.

LD.21.8 The process for contracts oversight is documented.

Standard Intent:

Outsourcing involves contracting out of a business process or service to another party for different reasons including the willingness to focusing on the core business, cost saving, or reducing operational burden. Technology advancement has made outsourcing more common as professional expertise are made available and accessible to be contracted

from anywhere in the world. The purpose of outsourcing should not jeopardize the quality of contracted services or patient and staff safety. Hospital leaders should ensure the selection of best contractors and continue monitoring the services they provide to ensure that they are consistent with the hospital quality and safety standards. Currently, outsourcing takes many forms. Organizations hire service providers to handle distinct business processes or whole operations. The most common forms of outsourcing in hospitals are information technology, housekeeping, catering, security, waste disposal, some laboratory tests, and bio-med and general maintenance.

LD.22 Hospital leaders ensure coordination of care during off duty hours.

LD.22.1 The hospital has a qualified duty manager with a clear job description to coordinate the care during off duty hours.

LD.22.2 The duty manager has the resources required to function (e.g., efficient office space, information on vacant and occupied beds, authority to allocate beds between different specialties, authority to accept referrals from other hospitals).

Standard Intent:

To ensure proper operation of the facility during off duty hours and weekends, a duty manager should be assigned with a clear job description. The duty manager should be qualified by education and experience. The hospital should provide adequate resources for the duty manager to ensure ability to perform a good job.

LD.23 Hospital Leaders ensure there is a system for the safe management of medical supplies and devices.

LD.23.1 Hospital leaders and relevant heads of departments identify all medical supplies and devices that are essential for the provision of a safe quality care.

LD.23.2 Suppliers of medical supplies and devices are qualified and carefully selected and evaluated.

LD.23.3 Medical supplies and devices are stored safely and in accordance with manufacturer's recommendations.

LD.23.4 Medical supplies and devices are protected against theft, damage, contamination, or deterioration.

LD.23.5 Hospital leaders conduct regular inspections to ensure the safety of medical supplies and devices (e.g., storage conditions, integrity, contamination, expiration).

LD.23.6 Hospital leaders respond to any adverse effects resulting from the use of medical supplies and devices through prompt investigation and the use of recurrence prevention measures.

LD.23.7 Hospital leaders ensure the reporting of adverse effects resulting from the use of medical supplies and devices to the relevant regulatory authorities.

LD.23.8 The hospital has a process for safe segregation and disposal of expired, damaged, or contaminated medical supplies and devices.

LD.23.9 The hospital has a process to retrieve dispensed supplies and devices when recalled or discontinued by the manufacturer or relevant regulatory authorities for safety reasons.

Standard Intent:

Hospital services must ensure patient safety and proper utilization of the available resources by imposing safe management of medical supplies and devices. The safe management of supplies and devices begins with the proper selection of qualified suppliers and protection of supplies from damage and theft and deterioration. It also includes responding and reporting of adverse effect resulting from use of devices, as well as protecting staff and patient when those devices are damaged or contaminated.

LD.24 Hospital leaders work collaboratively to optimize the flow of patients.

LD.24.1 Hospital leaders address all variations contributing to waits, delays, and cancellations that impact smooth and timely flow of patients through hospital departments.

LD.24.2 Hospital leaders implement strategies to maximize the efficiency of the flow of patients.

Standard Intent:

Optimizing patient flow means moving patients smoothly through acute care settings. This is part of proper utilization of resources which include optimizing the flow of patients in different hospital department (such as operation rooms, emergency department, and clinics) and between the hospital and other acute care settings. This includes minimizing patient and staff waiting time and cancelling of scheduled services. Hospital leaders' efforts in this regard must include evaluating patient flow, testing changes for improvement, and measuring results.

LD.25 Each clinical and administrative department is directed by a qualified individual.

LD.25.1 Each department has an assigned department head.

LD.25.2 Qualifications, experience, and training of the appointed department head match the services provided by the department.

LD.25.3 When the department head is appointed on a part-time basis (e.g., a small hospital or a hospital that is part of a corporate chain), the department head:

LD.25.3.1 Ensures that work flow and patient safety are not compromised during his absence.

LD.25.3.2 Ensures that the department functions are well managed through regular scheduled visits.

LD.25.3.3 Provides guidance as well as continued assessment of the individual in charge of the department during his absence.

LD.25.3.4 The frequency and duration of the visits must be documented in the contract.

Standard Intent:

The departments' heads are the key individuals to put hospital plans in action. Effective leadership of departments is therefore of critical importance. Appropriate qualifications matching the scope of the department's services are essential and one of the quality foundations.

LD.26 The department head develops an organizational chart for the department.

LD.26.1 Each department has an organizational chart that clearly displays all sections/divisions within the department, titles (or names), lines of authority, accountability, and reporting relationships.

LD.26.2 The organizational chart is signed by the department head and approved by the hospital management.

LD.26.3 The organizational chart is communicated to the staff working in the department.

Standard Intent:

The order in which the authority and power in the department is exercised and delegated is important for executing the related activities and achieving the goals and objectives successfully. So, the organizational chart graphically illustrates the concept known as chain of commands and shows the flow of authority, responsibility and communication.

The department head makes sure that staff understand the flow of responsibilities and authority lines and that there is a current name/s titles available in the organizational chart to support good communication between professionals.

LD.27 The department head addresses all issues related to the customers of the department.

LD.27.1 The department head identifies all internal and external customers of the department (patients, families, visitors, staff, suppliers, and contractors).

LD.27.2 Whenever required, there is written agreement or verbal understanding between the department and other clinical departments and/or external customers, explaining the expectations of each party.

LD.27.3 The department head has a mechanism for identifying and handling customers' needs and feedbacks (e.g., responding to complaints, satisfaction surveys).

Standard Intent:

Department head cannot manage a quality service unless he understands the nature of what he is providing, fully realizes what his customers want from him and how they

perceive him from the start. Once he has identified who his customers are, he needs to assess what they need from his service and what are their feedback about the services provided.

LD.28 The department head develops and maintains the mission of the department and its scope of services.

LD.28.1 The department head develops a written mission for the department that is consistent with the hospital's mission.

LD.28.2 The department head provides a written scope of services provided by the department that is consistent with the hospital's scope of services.

LD.28.3 The department head ensures coordination and integration of services within the department and with other departments.

Standard Intent:

A Mission Statement defines the department's purpose and primary objectives. Its prime function is to define the key measure or measures of the department's success and its prime audience is the leadership team and stockholders. Mission statements are the starting points of the department's planning and goal setting process. They focus attention and assure that internal and external stakeholders understand what the department is attempting to accomplish.

The departments' heads also determine the scope and intensity of the various services to be provided by the departments directly or indirectly. Scope of services helps the head to make sure that policies and procedures and staff competencies are consistent with their scope of service and aspects of care.

Departments that lack the ability to coordinate and integrate plans and services act like a body without a head. Though employees have the ability and skill sets necessary to carry out directives, their work needs guidance. Coordination and integration starts at the executive level and carries down to the workers at the front line of all departments.

LD.29 The department head ensures the work of the department is guided by a clear set of departmental policies and procedures.

LD.29.1 The department head develops and maintains a manual for all relevant departmental policies and procedures.

LD.29.2 The department head collaborates with other department heads to develop multidisciplinary policies and procedures.

LD.29.3 The department head ensures and oversees the communication of policies and procedures to relevant staff and their implementation.

Standard Intent:

The department head is directly responsible for planning, organizing, executing, and controlling of services in the department. Organizing department services includes developing departmental policies and procedures and communicating them to staff.

Well-written policies and procedures allow employees to clearly understand their roles and responsibilities within predefined limits. Basically, policies and procedures allow management to guide operations without constant management intervention.
Each department needs to have policies and procedures to help them guide the actions of all individuals involved in the service. When policies and procedures are well thought out and, most importantly, implemented they provide common understanding and agreement on how things should be done at the service. Procedures provide clear instructions and guidelines on what should/must be done in a particular set of circumstances or with regard to a particular issue.
Policies and procedures help new staff familiarize themselves with the service's practices and gives them information about what to expect from the service. Policies should be 'living' documents that must be regularly reviewed to ensure that they meet all the needs of those working in the service, and take into account the possible changes that have happened in the service and within the wider community.

LD.30 The department head ensures sufficient resources and staffing are available for the delivery of safe and quality service.

LD.30.1 The department head defines and requests the resources required by the department for a safe and quality service (e.g., space, equipment, supplies, staffing, and other resources).

LD.30.2 The department head provides a written departmental staffing plan that defines the number, type, and qualifications required for each position to fulfill the department's responsibilities.

LD.30.3 The department head defines the qualifications- education, training, experience, license, and any other relevant certification- required by all categories of staff in the department.

LD.30.4 The department head ensures the provision of orientation, training, and continuing education for the staff working in the department.

LD.30.5 The department head monitors the performance of the staff.

Standard Intent:

The department head is directly responsible for planning, organizing, executing, and controlling of services in the department. Department heads are responsible for ensuring the availability of the required manpower and other resources to execute department plans and enforce the implementation of hospital-wide and departmental policies. His responsibility about the manpower resources starts with determining number of staff required and their qualifications, selection, orientation, training, and monitoring of their performance.

LD.31 The department head ensures performance measurement and improvement of the outcomes of the department.

LD.31.1 Performance measurement and improvement are consistent with the hospital wide quality improvement, patient safety, and risk management plans.

LD.31.2 Performance measurement and improvement are based on the important processes and priorities of the department.

LD.31.3 The department head selects and monitors the appropriate performance indicators (e.g., two indicators at a time).

LD.31.4 Performance measurement and improvement involve regular data collection and analysis and appropriate improvement actions/projects.

LD.31.5 The department interacts with other departments/committees to promote the quality improvement efforts when needed.

LD.31.6 Results of performance measurement and improvement are reported periodically to the hospital leadership (e.g., the executive management committee or the quality improvement committee) and shared with staff, departments, and committees as applicable.

LD.31.7 Staff members participate in quality improvement and patient safety activities and receive training on quality assessment and improvement.

Standard Intent:

Department outcome measurement is one of the most important activities that department head has to do. There are several compelling reasons to measure outcomes:

1. Measuring the effectiveness of an intervention: How do you know if a department performance was effective? If a performance was not effective, would you want to know so that it could be improved?

2. Identifying effective practices: With the information you collect, you can determine which services to continue and build upon. Some practices might be modified and replicated for other services or initiatives based on your results.

3. Identifying practices that need improvement: Some activities may need to change in order to improve the effectiveness of your program.

4. Proving your value to existing and potential stakeholders: Stakeholders including hospital administration are keenly aware of the need to document the success of your department.

5. Getting clarity and consensus around the purpose of your department: Everyone in your organization, from board members to service staff to volunteers, should understand what is going on in your department and what it is intended to achieve. Outcome measurement helps to clarify your understanding of your department work and help in the improvement efforts.

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Human Resources Standard Intents

HR.1 The hospital has human resources department/unit.

HR.1.1 The human resources department is well staffed and equipped to match the size and needs of the hospital.

HR.1.2 The head of the human resources department is qualified in managing human resources by education, training, or experience.

HR.1.3 Policies and procedures manual guides the work of human resources department.

HR.1.3.1 The manual includes items related to recruitment, hiring, resignation, termination, grievance and complaints, leaves, new employee orientation, on job training, and performance appraisal.

HR.1.3.2 The manual is made accessible and communicated to all staff members.

HR.1.3.3 Policies and procedures contained in the manual are implemented.

Standard Intent:

Human resource management (HRM), or human resource development, involves planning, implementing, and managing recruitment, as well as selection, training, career, and organizational development initiatives within an organization.
The goal of HRM is to maximize the productivity of an organization by optimizing the effectiveness of its employees while simultaneously improving the work life of employees and treating employees as valuable resources. Therefore, HRM comprises efforts to promote personal development, employee satisfaction, and compliance with employment-related laws.
To achieve balance between employer and employee goals and needs, HRM departments focus on these three general functions or activities: planning, implementation, and evaluation.
The planning function refers to the development of human resource policies and regulations. Human resource managers attempt to determine future HRM activities and plan for the implementation of HRM procedures to help companies realize their goals.
Implementation of HRM plans involves four primary activities: acquisition, development, compensation, and maintenance.
Acquisition entails the hiring of employees most likely to help an organization achieve its mission and goals.
The development function includes the training of employees to perform their tasks in line with organization strategy. This activity also involves organization efforts to control and change employee behavior via reviews, appraisals, incentives, and discipline.
Compensation covers the payment of employees for their services.
Maintenance includes employee relations and communication with leaders and the evaluation function: the assessment of HRM policies to determine whether they are effective.

HR.2 Heads of departments, in collaboration with the human resources department, develop, implement, and monitor departmental staffing plans.

HR.2.1 Each department has a written staffing plan, developed in collaboration with the human resources department, to fulfill its part of the hospital's mission.

HR.2.2 The departmental staffing plan defines the number, type, and qualifications of staff required for each department and their job responsibilities.

HR.2.3 The staffing plans are reviewed and updated at least annually and as needed.

HR.2.4 The staffing plans are monitored to identify deficiencies and take improvement actions accordingly.

Standard Intent:

Job analysis consists of determining—often with the help of other hospital areas—the nature and responsibilities of various employment positions. This can encompass determination of the skills and experiences necessary to adequately perform in a position, identification of job and industry trends, and anticipation of future employment levels and skill requirements. Job analysis also provides valid information about jobs that is used to hire and promote people, establish wages, determine training needs, and make other important HRM decisions

Staffing is the actual process of managing the flow of personnel into, within (through transfers and promotions), and out of an organization. Once the recruiting part of the staffing process has been completed, selection is accomplished through job postings, interviews, reference checks, testing, and other tools.

In an organization, there are several issues on which disputes may arise between the employees and the employers. Conflicts are almost inevitable. In such a scenario, it is the human resource department which acts as a consultant and mediator to sort out those issues in an effective manner. They first hear the grievances of the employees. Then they come up with suitable solutions to sort them out. In other words, they take timely action and prevent things from going out of hands.

Human resources functions may also be outlined as follows:

- Payroll & tax administration
- Liability protection
- Legal compliance
- Benefits negotiation
- Benefits administration

- Talent acquisition
- New hire induction and orientation
- Performance management
- Leadership training
- Employee development
- Time and attendance monitoring
- Managing employee grievances and conflicts
- Employee satisfaction monitoring and developing retention strategies
- Termination review and guidance

In order to have all those mentioned functions well performed and monitored, a qualified human resources manager is expected to lead the human resources department.
High-performance organizations are integrating workforce planning initiatives into their business and strategic planning processes more than ever, as workforce planning outputs continue to grow more robust, other leaders are likely to follow the example set by their counterparts at higher-performing organizations and rely more on this evolving resource to help feed the budgeting process.
With proper integration, workforce planning improves communication between human resources and business units and subsequently the ability to identify and retain the most important talent.
Discussions about the people and skills our businesses need to accomplish strategic initiatives, and those conversations make more feasible planning possible.
Departments and units are more able and willing to work with human resources to identify specific roles that, if left unfilled, could damage the organization's bottom line and simultaneously deliver greater returns if properly filled.

The objectives of strategic staff planning:

1. Supports the budgeting process
2. Supports the strategic/business planning process
3. Identifies shortage of qualified talent to fill critical roles

4. Serves as a mechanism for identifying critical talent

5. Identifies skills gaps in the workforce

6. Acts as a mechanism for identifying critical roles

HR.3 All categories of staff have clearly written job descriptions.

HR.3.1 There is a policy that describes a standardized format for job description.

HR.3.2 The job description is used when selecting employees for hire, performance evaluation, internal promotion, and transfer.

HR.3.3 All job descriptions are revised at least every three years and as needed.

HR.3.4 The job description defines the required knowledge, skills, and attitude to perform the job responsibilities.

HR.3.5 The job description clearly defines the roles and responsibilities.

HR.3.6 The job description specifies the reporting relationships.

HR.3.7 The job description is discussed with and signed by the staff member on hiring and is kept in the personnel file.

Standard Intent:

In line with the HRD role to perform Job Analysis: Job descriptions need to be developed for all individual staff members. The job descriptions are the basis for their assignments, orientation to their work, and evaluation of how well they fulfill job responsibilities. Every hospital has to have job description policy which include that the Job descriptions for each department are updated as needed to reflect staffing shortfalls or business needs. The hospital's intent for maintaining job descriptions is to have a floating guideline for each class of employee and for particular skilled positions.

HR.4 The hospital maintains personnel files for all employees.

HR.4.1 The hospital has a policy guiding the initiation, management, content update, and retention time and disposal of personnel files.

HR.4.2 Personnel files are complete and updated.

HR.4.3 Personnel files are kept confidential and only those who are authorized can access them.

HR.4.4 Personnel files contain the following minimum items:

HR.4.4.1 Qualifications; including current licensure, certification, or registration, if applicable.

HR.4.4.2 Current job description.

HR.4.4.3 References.

HR.4.4.4 Orientation, continuing education, and training records.

HR.4.4.5 Performance evaluations.

HR.4.4.6 Records of leave and sickness.

HR.4.4.7 Disciplinary actions, if any.

HR.4.4.8 Other documents as required by relevant laws and regulations.

Standard Intent:

Each staff member in the hospital, including those permitted by law and the hospital to work independently, has a record(s) with information about his or her qualifications; results of evaluations, including individual performance of job responsibilities and competencies; and work history. The records are standardized and kept current according to hospital policy.

HR.5 The hospital has a process for proper credentialing of staff members licensed to provide patient care.

HR.5.1 The hospital has a written policy describing the process used for the verification of credentials.

HR.5.2 The hospital gathers, verifies, and evaluates the credentials (license, education, training, certification and experience) of those medical staff, nursing staff, and other health professionals licensed to provide patient care.

HR.5.3 Credentials are verified from the original source.

HR.5.4 Job responsibilities and clinical work assignments/ privileges are based on the evaluation of the verified credentials.

HR.5.5 The hospital ensures the registration of all healthcare professionals with the Saudi Commission for Health Specialties.

HR.5.6 Staff licensed to provide patient care must always have and maintain a valid license to practice only within their profession.

HR.5.7 The hospital maintains an updated record of the current professional license, certificate, or registration, when required by laws, regulations, or by the hospital for every medical staff, nursing staff and other healthcare professionals.

HR.5.8 When verification of credentials is conducted through a third party, the hospital must request for a confirmatory documentation.

HR.5.9 Verification process applies to all clinical staff categories (full time, part time, visitor, and locum).

Standard Intent:

Physicians, dentists, and others who are licensed to provide patient care without clinical supervision represent those primarily responsible for patient care and care outcomes. Applicable laws, regulations, and the organization identify those permitted to work independently.

The organization is responsible for ensuring that these individuals are qualified to provide patient care without clinical supervision and for specifying the types of care they are permitted to provide in the organization. The organization needs to ensure that it has a qualified medical staff that appropriately matches its mission, resources, and patient needs.
To ensure this match, the organization evaluates medical staff members' credentials at appointment to the staff.
An individual's credentials consist of an appropriate current license, completion of medical education and any specialty education, and any additional training and experience. The organization develops a process to gather this information, verify its accuracy from the original source, and evaluate it in relation to the need of the organization and its patients. This process can be carried out by the organization or by an external agency. The process applies to all types and levels of staff (employed, honorary, contract, and private community staff members).

Primary source verification is required for (license, education, training, certification and experience) for the following staff:

- New hires during the last 4 months' track period for hospitals applies for the initial survey
- New hires starting from the effective date of the standard (Jan 2016) for hospitals applies for re-accreditation for the 1st time on CBAHI 3rd edition
- All hospital staff for hospitals applies for re-accreditation on CBAHI 3rd edition for the 2nd time.

Verification is accepted by any communication mean (e-mails, documented phone call, fax, secured website, etc.). In case there is no response for the verification request, another mean of communication must be used after one month from the first trial and this should be documented in the personnel files of the employees.

HR.6 New employees go through a general hospital orientation program before allowed to work independently.

HR.6.1 New employees, contract workers, students, and volunteers go through a general orientation program that provides the relevant initial training and information on the following:

HR.6.1.1 Hospital mission, vision, values, and organizational chart.

HR.6.1.2 Role of staff members in all programs related to facility management and safety (e.g., fire, safety, disasters, hazardous materials, utilities, and equipment failures).

HR.6.1.3 General information on infection control.

HR.6.1.4 General information on the paging and telephone system.

HR.6.1.5 General information on staff evaluation process.

HR.6.1.6 Definition of adverse and sentinel events along with the process of reporting.

HR.6.1.7 Hospital policy on abuse and neglect of children and adults.

HR.6.1.8 Hospital policy on credentialing and privileging.

HR.6.1.9 General information about staff health program.

HR.6.1.10 General information about important local cultural and social themes.

HR.6.1.11 General information about the hospital-wide quality, patient safety, and risk management plans.

HR.6.1.12 Ethical conduct and expected professional communication with patients and colleagues.

HR.6.1.13 Patient rights.

HR.6.2 The hospital provides all new employees with an "Employee Manual" or equivalent that contains a summary of the general orientation program as well as other relevant important information.

HR.6.3 The general orientation program is conducted before working independently.

HR.6.4 The general orientation program is documented in the employee's personnel file.

Standard Intent:

Orienting employees to their workplaces and their jobs is one of the most neglected functions in many organizations. An employee handbook and piles of paperwork are not sufficient anymore when it comes to welcoming a new employee to your organization.

The most frequent complaints about new employee orientation are that it is overwhelming, boring, or that the new employee is left to sink or swim. The result is often a confused new employee who is not productive and is more likely to leave the organization within a year.

Developing an effective employee orientation experience continues to be crucial. It is critical that new hire programs are carefully planned to educate the employee about the values, history and who is who in the organization.

A well thought out orientation program, whether it lasts one day or six months, will help not only in retention of employees, but also in productivity.

Organizations that have good orientation programs get new people up to speed faster, have better alignment between what the employees do and what the organization needs them to do, and have lower turnover rates.

Employers have to realize that orientation isn't just a nice gesture put on by the organization. It serves as an important element of the recruitment and retention process. Some key purposes are:

- **To Reduce Startup Costs: Proper orientation can help the employee get up to speed much more quickly, thereby reducing the costs associated with learning the job.**

- **To Reduce Anxiety: Any employee, when put into a new, strange situation, will experience anxiety that can impede his or her ability to learn to do the job. Proper orientation helps to reduce anxiety that results from entering into an unknown situation, and helps provide guidelines for behavior and conduct, so the employee doesn't have to experience the stress of guessing.**

- **To Reduce Employee Turnover:** Employee turnover **increases as employees feel they are not valued, or are put in positions where they can't possibly do their jobs. Orientation shows that the organization values the employee, and helps provide the tools necessary for succeeding in the job.**

- **To Save Time for the Supervisor: Simply put, the better the initial orientation, the less likely supervisors and coworkers will have to spend time** teaching the employee**.**

- **To Develop Realistic Job Expectations, Positive Attitudes and Job Satisfaction: It is important that employees learn as soon as possible what is expected of them, and what to expect from others, in addition to learning about the values and attitudes of the organization.**

While people can learn from experience, they will make many mistakes that are unnecessary and potentially damaging. The main reasons orientation programs fail: The program was not planned; the employee was unaware of the job requirements; the employee does not feel welcome.

HR.7 New employees go through a departmental and job orientation program before allowed to work independently.

HR.7.1 The departmental and job orientation program is defined in a departmental policy and includes the following:

HR.7.1.1 Departmental policies and procedures.

HR.7.1.2 Specific job responsibilities within the department as outlined in the job description.

HR.7.1.3 Safe operation of equipment and medical devices including troubleshooting and malfunctions reporting.

HR.7.1.4 Clarification on all topics provided in the general orientation as needed.

HR.7.2 Additional orientation is provided upon changing the job description or introducing a new technology or equipment.

HR.7.3 The departmental orientation is conducted by the head of the department or the immediate supervisor.

HR.7.4 An evidence of attending the departmental and job orientation program is signed by the new employee and documented in the personnel file.

Standard Intent:

Departmental and job specific orientation must be done at the level of each department to complete with the general orientation all the required orientation levels after which the employee should be able to work independently.
Contract workers and volunteer are also oriented to the organization and their specific assignment or responsibilities, such as patient safety and infection control.

HR.8 The hospital has a process for initial evaluation of the competency and conduct of the new employees.

HR.8.1 The hospital has a process described in a policy or other document for initial evaluation of the competency of the new employees.

HR.8.2 All new employees go through a probationary period for competency evaluation. During this period, clinical staff can only work under direct supervision.

HR.8.3 Competency evaluation during the probationary period is a structured process that aims to assess and review the employee's knowledge, performance, capability, conduct, and suitability for the role.

HR.8.4 The competency evaluation is documented in the personnel file.

Standard Intent:

New employees or employees who have moved into a new job will have performance evaluated early in the new assignment. The New Employee Performance Evaluation is an opportunity for the supervisor to review the employee performance prior to the end of the new hire (probationary) period to confirm a recommendation for continued employment or extend a probationary period.
The New Employee Performance Evaluation is an opportunity to reiterate goals and expectations with a new team member. Training and development needs are discussed and a plan is established as applicable. At this time, the new employee should determine if he/she is committed to continued employment.
New employees may have performance evaluated anytime during the new hire period as needed or appropriate. An employee who is consistently falling below expectations on duties or who falls below expectations on critical duties should not have continued employment confirmed.

HR.9 The hospital has a process for the regular evaluation of staff performance.

HR.9.1 There is a policy describing the process used in the regular evaluation of staff performance.

HR.9.2 The performance evaluation is based on objective criteria and is linked with the job description.

HR.9.3 The performance evaluation is a two-way process conducted at least annually.

HR.9.4 The outcome of the performance evaluation is used to set objectives for performance improvement and professional development.

HR.9.5 The performance evaluation is signed by both the employee and the supervisor and is documented in the personnel file.

Standard Intent:

Annual performance reviews are a key component of employee development.
The performance review is intended to be a fair and balanced assessment of an employee's performance.
The objective of the annual review is to provide all employees and their supervisors an opportunity to; discuss job performance; set goals for professional development; establish objectives for contributing to the department's mission; and to discuss expectations and accomplishments.
Performance reviews require the combined signatures of the employee, the employee's supervisor and the supervisor's supervisor and/or HRD to ensure consistency and fairness.

HR.10 The hospital identifies the staff training and educational needs.

HR.10.1 The hospital has a process in place for identification of the training and educational needs of the different categories of hospital staff.

HR.10.2 The training and educational needs are identified based on objective criteria that include, but are not limited to, the following:

HR.10.2.1 The hospital mission, vision and scope of services.

HR.10.2.2 Individual staff member's education and training history.

HR.10.2.3 Information from quality assessment and improvement activities.

HR.10.2.4 Needs generated by advancements made in the medical and healthcare management fields.

HR.10.2.5 Findings from department performance appraisals of individuals.

HR.10.2.6 Findings from peer review activities.

HR.10.2.7 Findings from the hospital's technology and safety management programs.

HR.10.2.8 Findings from infection control activities.

Standard Intent:

It is essential that any training plan should be linked into the business's long- term objectives. The training needs of an organization and staff should be thoroughly assessed to determine what skills would be required to achieve your strategic goals.

Questions that should be raised include:

- Do staff members need to be more flexible in order to cover a greater range of jobs?
- Do they need to know about new technology, computer systems or software?
- Has the member of staff just started?
- Does everyone in the business need to learn a specific task?

It is important to assess the training needs of the management team as well as other staff. A staff member may have strong skills in a particular field, but consider whether he/she and his/her managers need to improve your general management skills, e.g. finance, IT, marketing, project management and people management and development. Information will be required from a variety of sources in order to determine the development needs of managers and staff. Sources might include the strategic plan, analyzing the organization's strengths, weaknesses, opportunities and threats (SWOT analysis), employee records (development plans, training records, posts held, and qualifications), appraisals, discussions between managers and staff, and analysis of the external environment.
Job descriptions and personal specifications will enable supervisors to identify what skills employees require to carry out their jobs. He/she can also use these when recruiting to assess what skills a candidate already has and the skills they would need to develop in order to do the job well.

HR.11 The hospital supports continuing education for all staff members.

HR.11.1 There is a policy describing the structure and the process used in the continuing education of all categories of staff.

HR.11.2 The hospital grants financial support and time off for staff to attend educational activities.

HR.11.3 The hospital has an educational program with an ongoing schedule of educational activities and training based on the hospital needs.

HR.11.4 The department head recommends and evaluates the educational and training activities required to maintain staff competencies to provide care. This process is linked to performance improvement and documented in the personnel file.

Standard Intent:

Staff must receive appropriate education and training to remain effective and the leadership must support this and provide the necessary resources, this is a patient safety issue. Staff training and education needs to be monitored for its effectiveness as evidenced in the employee performance, this responsibility will rest mainly with department heads. Hospital must make sure there is adequate space, human and material resources for effective educational efforts.

HR.12 Staff members providing direct patient care are trained on cardiopulmonary resuscitation.

HR.12.1 All staff members who provide direct patient care (medical staff, nursing staff, and other healthcare professionals) maintain a valid certification in basic cardiac life support (BCLS) and certification is renewed every two years.

HR.12.2 The hospital identifies and provides training for other staff categories in areas related to advanced cardiac life support (ACLS), neonatal resuscitation program (NRP), pediatric advanced life support (PALS), and advanced trauma life support (ATLS). Examples include, but are not limited to:

HR.12.2.1 Physicians and nurses working in critical care areas must maintain additional certification in ACLS, PALS and NRP as appropriate to the patients' age groups.

HR.12.2.2 Internal medicine physicians must maintain additional certification in ACLS.

HR.12.2.3 Emergency department physicians must maintain additional certification in ACLS, PALS and ATLS.

HR.12.2.4 Pediatricians must maintain additional certification in PALS and NRP.

Standard Intent:

CPR done within five minutes of a person's collapse combined with professional care can increase survival rates by as much as 50 percent. That is why it is very critical to have all healthcare professional well trained and certified in cardiopulmonary resuscitation specific to their area of specialty to save anyone who experience arrest in the hospital scene.

HR.13 The hospital has a program that addresses staff health and safety.

HR.13.1 The hospital has a staff health and safety program that is consistent with laws and regulations and covers all staff members.

HR.13.2 The program is based on assessment and where necessary, reduction of occupational health and safety risks.

HR.13.3 The program is coordinated with the hospital's quality, safety, risk management, and infection control programs.

HR.13.4 The program includes, but is not limited to, the following:

- HR.13.4.1 Pre-employment medical evaluation of new employees.
- HR.13.4.2 Response to the health problems of the employees through direct treatment (e.g., a staff clinic) or referral.
- HR.13.4.3 Periodic medical evaluation of staff members.
- HR.13.4.4 Screening for exposure and/or immunity to infectious diseases.
- HR.13.4.5 Staff preventive immunizations.
- HR.13.4.6 Management of exposure to blood borne pathogens and other work-related conditions.
- HR.13.4.7 Measures to reduce occupational exposures and hazards, including the use of protective equipment and clothing, stress management, and ergonomics.
- HR.13.4.8 Staff education on the risks within the hospital environment as well as on their specific job-related hazards (e.g., lifting techniques, safe use of medical devices, and detecting, assessing, and reporting risks).
- HR.13.4.9 Documentation and management of staff incidents (e.g., injuries or illnesses, taking corrective actions, and setting measures in place to prevent recurrences).
- HR.13.4.10 There is appropriate record keeping and management (e.g., employee health records that are filed separately).

Standard Intent:

- Shall be assessed by Infection Control domain

HR.14 The hospital has a process for handling staff complaints and dissatisfaction.

HR.14.1 The hospital has a policy for handling staff complaints and dissatisfaction.

HR.14.2 Staff members are aware of the procedure to be followed to bring forward a complaint or a dissatisfaction issue.

HR.14.3 The hospital takes actions for addressing the complaints and dissatisfaction in a fair, objective, and timely manner.

Standard Intent:

Supervisors and employees should mutually strive to develop and maintain good working relationships.

Organizations are encouraged to have open and honest dialogue about work standards and performance. If such discussion does not prevent or solve a problem, additional actions may be taken, and more formal procedures are available.
There are three methods available to staff members for addressing employee relations problems:

- General Inquiry
- Informal Complaint Procedure
- Formal Complaint Procedure

HR.15 The hospital develops and implements strategies for retaining qualified staff.

HR.15.1 The hospital has a process for recognition and reward of distinguished staff.

HR.15.2 The hospital provides opportunities for professional development and promotion.

HR.15.3 The hospital carries out human resources policies in a fair and consistent way without discrimination.

HR.15.4 The hospital carries out exit interviews for resigning staff and uses the resulting information to make decisions about improving human resources processes.

Standard Intent:

HR department is responsible for retention of its distinguished employees. Employee retention can be represented by a simple statistic (for example, a retention rate of 80% usually indicates that an organization kept 80% of its employees in a given period).
A distinction should be drawn between low-performing employees and top performers, and efforts to retain employees should be targeted at valuable, contributing employees.
Employee turnover is a symptom of deeper issues that have not been resolved, which may include low employee morale, absence of a clear career path, lack of recognition, poor employee-manager relationships or many other issues. A lack of satisfaction and commitment to the organization can also cause an employee to withdraw and begin looking for other opportunities. Pay does not always play as large a role in inducing turnover as is typically believed.
The goal of employers is usually to decrease employee turnover, thereby decreasing training costs, recruitment costs and loss of talent and organizational knowledge.

HR.16 The hospital conducts staff satisfaction surveys on an ongoing basis.

HR.16.1 A staff satisfaction survey is conducted at least once per year.

HR.16.2 Data are aggregated and analyzed.

HR.16.3 Actions are taken to address areas for improvement.

Standard Intent:

There is a need to create a work environment that encourages employees to give quality service to customer needs. Satisfied employees generate customer satisfaction by excellence in performance that leads to organizational success thus resulting in

improved financial success. So there is a direct connection between employee satisfaction and customer satisfaction.

Employee satisfaction not only enhances the productivity, but also increases the quality of work. It is necessary for an organization to perceive as to what employees feel, think, desire along with discovering how the workforce devotion and commitment can be increased. With increasing employee devotion, service outcomes can be improved, productivity can be enhanced, commitment can get intensified and attrition rate can take a dip.

There is a cause-and-effect relationship between the customer satisfaction and employee satisfaction. It is unfeasible to uphold customer loyalty without employee loyalty. Customer service eventually depends on the community who provide that service. For that matter, employee loyalty and volunteerism are required especially for those employees who serve on front lines. Loyalty, devotion and volunteerism cannot be enforced on people. It can only be done by providing them encouraging and satisfying work environment.

Medical Staff Standard Intents

MS.1 The organization, functions, and responsibilities of the medical staff are documented and communicated to all medical staff members.

MS.1.1 The hospital has medical staff bylaws that govern the organization, functions, and responsibilities of the medical staff.

MS.1.2 Medical staff bylaws are approved by the governing body.

MS.1.3 Medical staff bylaws are consistent with acceptable medical staff practices and laws and regulations.

MS.1.4 Medical staff bylaws describe the organizational structure of the medical staff and the reporting relationships, including all medical departments and committees.

MS.1.5 Medical staff bylaws address:

MS.1.5.1 The medical staff ranking and the qualifications required for each rank.

MS.1.5.2 Categories of the medical staff membership (e.g., full time, part time, and locum).

MS.1.5.3 Roles and responsibilities of the medical staff members.

MS.1.5.4 Appointment, promotion, and reappointment of medical staff members.

MS.1.5.5 The process for verification of the medical staff credentials.

MS.1.5.6 Granting and maintaining clinical privileges, including temporary privileges (e.g., for locums and emergency situations).

MS.1.5.7 Disciplinary procedures for medical staff members, including corrective actions and appeals.

MS.1.6 Medical staff bylaws describe the acceptable standards of patient care and professional conduct, including:

MS.1.6.1 Admission, referral, transfer, and discharge processes.

MS.1.6.2 Documentation in medical records.

MS.1.6.3 The conduct of care expected for all levels of medical staff (e.g., daily rounds).

MS.1.6.4 The professional conduct (e.g., handling ethical issues) of the medical staff.

MS.1.7 The medical director and heads of medical departments ensure the medical staff bylaws are made accessible and communicated to all members of the medical staff.

MS.1.8 The medical director and heads of medical departments enforce the medical staff bylaws along with relevant rules and regulations.

Standard Intent:

The medical staff is defined as all physicians, dentists, and other professionals who are licensed to practice independently and who provide preventive, curative, restorative, surgical, rehabilitative, or other medical or dental services to patients; or who provide interpretative services for patients, such as pathology, radiology, or laboratory services. There must be a medical staff bylaw that describes the organization, functions, and responsibilities of the medical staff that are known to all of them.

MS.2 A qualified medical director is responsible for managing the medical staff and medical services.

MS.2.1 The medical director is a board certified physician or equivalent, qualified in healthcare management by education, training or experience.

MS.2.2 The medical director is responsible and accountable for the clinical performance of the medical staff, the quality of care they provide, as well as their professional conduct.

MS.2.3 The medical director recommends to the hospital director the appointment of the heads of clinical departments.

MS.2.4 The medical director has a current written job description that clearly describes his managerial roles and responsibilities.

Standard Intent:

The medical director is primarily responsible and accountable for the clinical performance of the medical staff and the quality of care they provide, as well as their professional conduct. He recommends to the hospital director the appointment of the head of clinical departments. The medical director must be qualified and well trained in healthcare management.

MS.3 The hospital has an effective process that supports the professional communication and coordination of care amongst medical staff.

MS.3.1 There is a medical executive committee or equivalent, chaired by medical director and includes the heads of clinical departments, to ensure that they work together to coordinate the provision of care.

MS.3.2 The medical executive committee holds regular formal meetings (at least monthly).

MS.3.3 The medical executive committee reviews and approves policies and procedures related to clinical departments.

MS.3.4 The medical executive committee reviews all relevant reports of other hospital committees for prioritizing the services needed and guiding the credentialing and privileging process.

Standard Intent:

The leaders of the hospitals should ensure that there will be a process that support the professional communication and coordination of care amongst medical staff. There must be regular meetings between the medical director and the head of clinical departments to review and approve policies and procedures as well as to coordinate the provision of care.

MS.4 Each clinical department is directed by a qualified individual.

MS.4.1 The department head is board certified or equivalent in his field and qualified in healthcare management by education, training or experience.

MS.4.2 The department head has a written job description that clearly describes his role and responsibilities.

MS.4.3 Responsibilities of the department head include:

MS.4.3.1 Defining medical staff qualifications required for the provision of effective and safe patient care.

MS.4.3.2 Recommending the need for further training/certification of a medical staff member.

MS.4.3.3 Monitoring admissions to ensure that the diagnostic and therapeutic interventions are within the staff capabilities and the available hospital resources.

MS.4.3.4 Ensuring that medical staff members work within the clinical privileges granted to them.

MS.4.3.5 Developing a written scope of services for the department.

MS.4.4 The department head has an ongoing method of peer review (e.g., peer review committee) to evaluate care provided as well as the performance of the medical staff.

MS.4.4.1 The department head regularly assesses important functions that include appropriateness of admissions, appropriateness and effectiveness of care, training and educational needs, length of stay, and appropriate utilization of resources.

MS.4.4.2 The department head defines criteria or indicators for selecting cases that must be referred for peer review.

MS.4.4.3 The activities of the peer review process are utilized as part of the physician’s performance evaluation.

MS.4.4.4 The department head shares the findings of the peer review with the medical director and works closely to improve and correct any deficiencies.

Standard Intent:

Clinical departments must be under the direction of individuals who are board certified in their field and qualified in healthcare management by education, training or experience. They must have a clear job description that clearly describes their role and responsibilities. The duties of the head of clinical departments include but not limited to:

- Developing a written scope of services for the department
- Defining medical staff qualifications required for the provision of effective and saf patient care.
- Recommending the need for further training/certification of a medical staff memb
- Monitoring admissions to ensure that the diagnostic and therapeutic intervention are within the staff capabilities and the available hospital resources.
- Ensuring that medical staff members work within the clinical privileges granted to them.
- Assessing the medical staff training and educational needs.
- Assessing appropriateness of admissions, appropriateness and effectiveness of care, length of stay, and appropriate utilization of resources.
- Defining criteria or indicators for selecting cases that must be referred for peer review.

MS.5 The credentialing and privileging of the medical staff is based on an informed group decision.

MS.5.1 The hospital has a credentialing and privileging committee chaired by the medical director or a designee.

MS.5.2 The credentialing and privileging committee provides oversight on the credentialing and privileging processes.

MS.5.3 The credentialing and privileging committee ensures that only qualified physicians and dentists are appointed and granted privileges.

MS.5.4 Applicants for initial appointment submit a complete set of documents required for the credentialing and privileging process, including:

MS.5.4.1 Curriculum vitae, detailing the professional history of the applicant.

MS.5.4.2 Education, training, certificates, courses, experience, published research, and other relevant credentials.

MS.5.4.3 List of references.

MS.5.4.4 List of the privileges requested for approval.

Standard Intent:

One of the important committees of any healthcare organizations is the credentialing and privileging committee that must be chaired by the medical director or a senior member of the medical staff. The committee provides oversight on the credentialing and privileging processes and ensures that only qualified physicians and dentists are

appointed in the desired department and the right position and granted privileges to operate or perform procedures based on their qualifications, training and experience.

MS.6 The hospital has clearly defined and documented processes used to credential, appoint, and grant clinical privileges to medical staff.

MS.6.1 All members of the medical staff must be registered with the Saudi Commission for Health Specialties before allowed to work independently.

MS.6.2 The hospital has a documented process for appointment, reappointment and granting of clinical privileges to all categories of medical staff.

MS.6.3 Medical staff appointment, reappointment and granting of privileges are in accordance with relevant laws and regulations.

MS.6.4 Medical staff appointment, reappointment and granting of privileges are based on:

MS.6.4.1 Evaluation of the verified credentials (license, education, training, and experience).

MS.6.4.2 Evaluation of the mental and physical health and capabilities.

MS.6.4.3 Competency, actual performance and outcomes of care.

MS.6.4.4 Category of the medical staff as stated in the professional registration with the Saudi Commission for Health Specialties (e.g., consultant, specialist).

MS.6.5 Appointment, reappointment and granting of privileges are recommended by the medical staff leaders (medical director, heads of clinical departments, credentialing and privileging committee, and senior medical staff members) and approved by the governing body, either directly or by appropriate delegation.

MS.6.6 The hospital has a process in place for appeals against credentialing or privileging decisions.

Standard Intent:

The healthcare organizations shall clearly define and document the processes used to credential, appoint, and grant clinical privileges to medical staff. The appointment, reappointment and granting of clinical privileges to all categories of medical staff must be in accordance with relevant laws and regulations and are recommended by the medical staff leaders within the organization. The opponent, re-appointment and privilege assignment is based on the processes mentioned in the substandard MS.6.4.1 through MS. 6.4.4. The organization reserves the rights of staff to appeal against unexpected credentialing and or privileging decisions made by the organization.

MS.7 Medical staff members have current delineated clinical privileges.

MS.7.1 Medical staff members are allowed to practice only within the privileges granted by the credentialing and privileging committee.

MS.7.2 Clinical privileges are reviewed and updated every two years and as needed.

MS.7.3 The hospital identifies the circumstances under which temporary or emergency privileges are granted.

MS.7.4 Temporary or emergency privileges are not granted for more than 90 days and are not renewable.

MS.7.5 When a new privilege is requested by a medical staff member, the relevant credentials are verified and evaluated prior to approval.

Standard Intent:

It mandatory that medical staff members are only allowed to practice within the privileges granted by the credentialing and privileging committee after verifying their relevant credentials. Medical staff clinical privileges are reviewed and updated every two years and as needed. The circumstances under which temporary or emergency privileges (not more than 90 days) are granted must be clearly defined. When a new privilege is requested by a medical staff member, the relevant credentials are verified and evaluated prior to approval

MS.8 The performance of the medical staff members is evaluated on an ongoing basis to ensure competency.

MS.8.1 The department head together with the medical director evaluate the performance and competency of medical staff members at least annually and when indicated by the findings of performance improvement activities.

MS.8.2 The hospital identifies the circumstances under which an unplanned review of the performance of a medical staff member may be initiated.

MS.8.3 The performance evaluation includes, but is not limited to, the following:

- MS.8.3.1 Assessment of patients.
- MS.8.3.2 Adverse events.
- MS.8.3.3 Moderate and deep sedation.
- MS.8.3.4 Quality of medical records.
- MS.8.3.5 Medication errors.
- MS.8.3.6 Sentinel events.
- MS.8.3.7 Outcome of high-risk procedures and surgeries.
- MS.8.3.8 Morbidities and mortalities.
- MS.8.3.9 Blood and blood product usage.
- MS.8.3.10 Discrepancies between pre and post-operative pathological diagnoses.
- MS.8.3.11 Appropriateness of admissions from the emergency room and outpatient department.

Standard Intent:

The organization is responsible through the department head and the medical director to evaluate the performance and competency of medical staff members at least annually

and when indicated by the findings of performance improvement activities. Such activities may include elements of sub-standards MS.8.3.1 through 8.3.11. ~~As well~~ the leaders must identify the circumstances under which an unplanned review of their performance is carried out.

MS.9 Medical staff leaders make use of the data and information resulting from the medical staff performance review.

MS.9.1 The data and information resulting from the medical staff performance review are used to:

MS.9.1.1 Provide feedback and counseling to the medical staff regarding their performance.

MS.9.1.2 Recommend plans for improvement.

MS.9.1.3 Amend clinical privileges as necessary, by expansion or limitation, a period of counseling and oversight, or other appropriate action.

MS.9.1.4 Make informed decisions regarding reappointment.

MS.9.1.5 Recommend training and continuous education as needed.

MS.9.2 The outcomes of the medical staff performance evaluation and actions taken are documented in the physician's credentials file.

Standard Intent:

The medical director and head of clinical departments use the collected data and information resulted from the medical staff performance to provide feedback and counseling to the medical staff regarding their performance, recommend plans for improvement. In addition, they may amend the granted clinical privileges as necessary, by expansion or limitation, a period of counseling and oversight, or other appropriate action and make informed decisions regarding staff reappointment and staff need for training and continuous education.

MS.10 Medical staff leaders support the hospital-wide quality improvement, patient safety, and risk management plans.

MS.10.1 Heads of clinical departments together with the medical director work closely with other hospital leaders through formal meetings to support the implementation of the hospital-wide quality improvement, patient safety, and risk management plans.

MS.10.2 Data and information resulting from the medical staff performance review are used to continuously improve the quality and safety by :

MS.10.2.1 Studying and minimizing variances in the processes.

MS.10.2.2 Taking actions to avoid preventable medical errors and adverse events.

MS.10.2.3 Recommending equipment needed in specified areas.

MS.10.3 Heads of clinical departments together with the medical director work closely with the quality management director/risk manager in handling incidents including near misses and sentinel events.

MS.10.3.1 Root cause analysis is properly conducted.

MS.10.3.2 Emphasis is on improving systems.

MS.10.3.3 Corrective actions are documented.

Standard Intent:

The heads of clinical departments together with the medical director work closely with the quality management director/risk manager in promoting and supporting the hospital-wide quality improvement, patient safety, and risk management plans. The information collected from the medical staff performance is used to:

- Studying and minimizing variances in the processes
- Recommending equipment needed in specified areas
- Taking actions to avoid preventable medical errors and adverse events
- Handling incidents including near misses and sentinel events.
- Focus on system improvements

MS.11 Heads of clinical departments review mortality and morbidity cases.

MS.11.1 Heads of clinical departments conduct mortality and morbidity meetings on a monthly basis to review all cases of mortality and significant morbidity.

MS.11.2 Mortality and morbidity meetings are documented and attendance is considered essential.

MS.11.3 The departmental mortality and morbidity meetings should focus on scientific discussion, improvement and prevention, with a non-punitive intent.

MS.11.4 Heads of clinical departments work with the medical director to select cases to be referred to the hospital mortality and morbidity committee.

MS.11.5 Heads of clinical departments send regularly mortality and morbidity findings to the medical director and the quality director.

Standard Intent:

The departmental mortality and morbidity committee is one of the essential hospital committees. Mortality and morbidity cases should be reviewed for a scientific discussion, improvement, and prevention, with a non-punitive intent. This should be done on regular basis (at least monthly) and its findings must be shared regularly with the medical director and the quality director.

MS.12 The hospital has a mortality and morbidity committee.

MS.12.1 There is a mortality and morbidity committee that is chaired by the medical director or a designee.

MS.12.2 The mortality and morbidity committee reviews mortalities in the hospital and the unusual or unexpected adverse outcomes of care.

MS.12.3 The mortality and morbidity committee receives cases for review from various sources (e.g., referral from the clinical departments, patient complaints, and the medical director).

MS.12.4 The mortality and morbidity committee evaluates cases for effectiveness, timeliness and appropriateness of care.

MS.12.5 The mortality and morbidity findings are regularly forwarded to the medical director and the quality director.

MS.12.6 The mortality and morbidity committee recommends actions for improvement and evaluates their effectiveness.

Standard Intent:

The hospital mortality and morbidity committee must be chaired by the medical director or a designee. It reviews mortalities in the hospital and the unusual or unexpected adverse outcomes of care and receives cases for review from various sources (e.g., referral from the clinical departments, patient complaints, and the medical director). The committee should evaluate cases for effectiveness, timeliness and appropriateness of care and recommend actions for improvement and evaluates their effectiveness.

MS.13 The hospital has a medical records review committee.

MS.13.1 There is a medical records review committee with members representing the medical staff, the nursing staff and other professionals privileged to write in the medical record.

MS.13.2 The medical records review committee oversees and monitors the documentation in medical records for quality, completeness, and timeliness.

MS.13.3 The medical records review committee regularly reviews a sample (e.g., 5% on a quarterly basis) of the medical records of discharged and in-patients for:

MS.13.3.1 History and physical examination.

MS.13.3.2 Assessment upon admission.

MS.13.3.3 Progress notes.

MS.13.3.4 Plan of care.

MS.13.3.5 Operative reports.

MS.13.3.6 Histopathology reports.

MS.13.3.7 Laboratory results.

MS.13.3.8 Radiology reports.

MS.13.3.9 Discharge summary.

MS.13.4 The medical records review committee recommends actions for improvement and evaluates their effectiveness.

Standard Intent:

The medical records review committee must include members representing the medical staff, the nursing staff and other professionals privileged to write in the medical record. It oversees and monitors the documentation in medical records for quality, completeness, and timeliness. The committee should regularly review a sample (e.g., 5% on a quarterly basis) of the medical records of discharged and in-patients through an approved checklist that includes but not limited to MS.13.3.1-MS.13.3.9.

MS.14 The hospital has a utilization review committee.

MS.14.1 There is a utilization review committee that is chaired by the medical director or a designee with representatives from relevant services such as medical staff, nursing staff, admission office and social services.

MS.14.2 The utilization review committee assesses the medical necessity of the services furnished by the hospital and the medical staff members to patients. This includes, but is not limited to, the following:

MS.14.2.1 Appropriateness of admissions.

MS.14.2.2 Appropriateness and quality of care.

MS.14.2.3 Length of stay.

MS.14.2.4 Drug usage.

MS.14.2.5 Efficiency in using various hospital resources (e.g., overutilization or underutilization).

MS.14.3 The utilization review committee recommends actions for improvement and evaluates their effectiveness.

Standard Intent:

The hospital must have utilization review committee that is chaired by the medical director or a designee with representatives from relevant services such as medical staff, nursing staff, admission office and social services. It assesses the medical necessity of the services furnished by the hospital and the medical staff members to patients. The major areas the committee review include appropriateness of admissions, appropriateness, and quality of care, the length of stay, drug usage and efficiency in using various hospital resources (e.g., overutilization or underutilization). The function of the resources utilization committee is to review the appropriateness of admissions, appropriateness, and quality of care, drug usage, and the length of stay. It assesses the medical necessity of the services furnished by the hospital and the medical staff members to patients and provides/ recommends actions for improvement and evaluates their effectiveness. Elements of substandard MS.14.2.1 through MS.14.2.5 are examples.

MS.15 The hospital has a blood utilization committee.

MS.15.1 There is a blood utilization committee that is chaired by the medical director or a designee with representatives from relevant services such as medical staff, nursing staff and blood bank.

MS.15.2 The blood utilization committee ensures the optimal use of blood and blood products by establishing Indications/triggers for the transfusion of blood, blood components and blood derivatives.

MS.15.3 The blood utilization committee approves all policies and procedures that involve the ordering and administration of blood and blood products, including:

MS.15.3.1 Handling of blood outside the laboratory.

MS.15.3.2 Use of blood warmers and infusion devices.

MS.15.3.3 Venous access.

MS.15.3.4 Addition of fluids and drugs other than 0.9%NaCL.

MS.15.3.5 Bedside Identification of the blood product and the intended recipient.

MS.15.3.6 Monitoring of patient during and after blood administration.

MS.15.4 The blood utilization committee ensures the optimal utilization of therapeutic phlebotomy and apheresis services.

MS.15.5 The blood utilization committee monitors practices related to blood ordering and blood administration.

MS.15.6 The blood utilization committee recommends actions for improvement and evaluates their effectiveness.

Standard Intent:

The blood utilization committee functions include but not limited to approving all policies and procedures that involve the ordering and administration of blood and blood products, ensure the optimal utilization of therapeutic phlebotomy and apheresis services and monitors practices related to blood ordering and administration. The committee ensures that all steps related to the procurement and administration of blood are safe by regularly collecting data on the various processes involved in blood preparation and administration. The committee utilizes the collected information to improve the blood bank services

MS.16 The hospital has a tissue review committee.

MS.16.1 There is a tissue review committee that conducts analysis and review of tissues removed during surgeries and procedures.

MS.16.2 The tissue review committee ensures there is a hospital policy that governs how to obtain and handle specimens and tissues.

MS.16.3 The tissue review committee monitors the following:

MS.16.3.1 The collection and transportation of specimens to the laboratory.

MS.16.3.2 The accuracy and completeness of histopathology forms (e.g., site of biopsy, number of biopsies, clinical history, previous biopsies).

MS.16.3.3 The accuracy of fine needle aspirations.

MS.16.3.4 The accuracy of frozen section specimens.

MS.16.4 The tissue review committee defines and approves the list of specimens exempted from submission to surgical pathology or microscopic examination.

MS.16.5 The tissue review committee reviews the appropriateness of all surgical procedures performed in the hospital, correlating pre- and post-operative surgical diagnoses with pathological findings.

MS.16.6 The tissue review committee recommends actions for improvement and evaluates their effectiveness.

Standard Intent:

There is tissue review committee to review and approve all policies related to specimen collection, handling, and processing of all surgical and cytology specimens in the organization. The committee also monitors the appropriateness of all surgical procedures performed in the hospital, correlating pre- and post-operative surgical diagnosed with pathological findings as part of the physicians' performance evaluation. The committee recommends improvements in the system based on its findings and reports

MS.17 The hospital has an operating room committee.

MS.17.1 There is an operating room committee with representatives from relevant services such as medical staff, nursing staff, operating room staff, infection control, and safety personnel.

MS.17.2 The operating room committee approves all policies required for proper conduct of the work in the operating room including, but are not limited to, the following:

MS.17.2.1 Infection control measures.

MS.17.2.2 Supply of equipment and disposables.

MS.17.3 The operating room committee develops a code of ethical conduct in the operating room to protect patient privacy and dignity.

MS.17.4 The operating room committee monitors performance in the operating room including cancellation rate and makes improvements accordingly.

Standard Intent:

The operating room committee must include representatives from relevant services such as medical staff, nursing staff, operating room staff, infection control, and safety personnel. It approves all policies required for proper conduct of the work in the operating room including; infection control measures and supply of equipment and disposables. The committee also develops a code of ethical conduct in the operating room to protect patient privacy and dignity and monitors performance in the operating room including cancellation rate and makes improvements accordingly.

MS.18 The hospital has a cardiopulmonary resuscitation committee.

MS.18.1 There is a cardiopulmonary resuscitation committee with representatives from relevant services such as medical staff, nursing staff, intensive care staff and emergency staff.

MS.18.2 The cardiopulmonary resuscitation committee ensures there is an effective system to handle all cases requiring cardiopulmonary resuscitation at all times.

MS.18.3 The cardiopulmonary resuscitation committee ensures that the cardiopulmonary resuscitation team members have cardiac life support training as appropriate to the patient population served by the hospital.

MS.18.4 The cardiopulmonary resuscitation committee discusses all codes in the hospital, recommends actions for improvement, and evaluates those actions for effectiveness.

MS.18.5 A summary of the cardiopulmonary resuscitation committee's discussions is forwarded to the medical director and the quality director.

Standard Intent:

The hospital has a cardiopulmonary resuscitation committee with representatives from relevant services such as medical staff, nursing staff, intensive care staff and emergency staff. The committee ensures that there is a unified cardiopulmonary resuscitation system in the organization with team members that has the appropriate life support training relevant to the patient population. The committee also ensures the availability and standardization of resuscitation medication, supplies and equipment. All "code" cases are discussed in the committee with a view to improve the resuscitation services. Reports and recommendations are forwarded to the medical director and the quality director.

MS.19 The hospital has a pharmacy and therapeutics committee.

MS.19.1 There is a pharmacy and therapeutics committee with representatives from relevant services involved in drug prescribing, ordering, dispensing, administering, as well as patient monitoring processes.

MS.19.2 The pharmacy and therapeutics committee provides oversight of the hospital formulary and medications use.

MS.19.3 The pharmacy and therapeutics committee meets on a regular basis (at least quarterly).

MS.19.4 The pharmacy and therapeutics committee recommends actions for improvement and evaluates their effectiveness.

Standard Intent:

Medication management is not only the responsibility of the pharmaceutical service but also of all those involved in medication procurement, storage, prescribing, transcribing, dispensing, administering and monitoring. The pharmacy and therapeutics committee provides oversight of the hospital formulary and medications use. The committee meets on regular basis, at least quarterly to review and approve all policies related to medication management and all newly introduced or discontinued medications. The committee also reviews reports from medication errors and adverse effects with a view to improve safe medication practices and reduce adverse events.

Provision of Care Standard Intents

PC.1 The hospital provides patients with information on care and services provided.

PC.1.1 The hospital clearly defines the services it provides.

PC.1.2 The hospital provides patients, families, and the wider community with information on the services it provides using an appropriate format and language (e.g., displayed posters, brochures, handouts, websites, and news media).

PC.1.3 The hospital provides patients with information on how to access its services.

Standard Intent:

Hospitals must make sure to define in a clear method their scope of service. Information about the different services and departments must be available to patients, their families and the wider community in all appropriate format and language. The mentioned information must include the way patients can access the hospital services.

PC.2 Patients are screened before accepted for care in the hospital.

PC.2.1 The hospital implements a policy that defines screening methods and tests required before accepting patients for care.

PC.2.2 Screening is aimed to identify and match patient needs with hospital's mission and available resources.

PC.2.3 In outpatient settings, screening is performed before registration.

PC.2.4 Screening of patients in the emergency room is performed during triage process or before deciding for admission to inpatient areas.

Standard Intent:

Matching patient needs with the hospital's scope of service depends on obtaining information on the patient's needs and condition through screening, usually at the point of first contact whether it is in outpatient setting before registration or in the emergency room where triage criteria, visual evaluation, and a physical examination are applied. Only those patients for whom the hospital has the clinical capability to provide the needed services, consistent with its treat, are considered.

PC.3 The hospital has a consistent process for registration and admission of patients.

PC.3.1 A policy and procedure defines the process used for elective admissions and patients admitted for a day procedure.

PC.3.2 A policy and procedure defines the process used for admission of emergency patients.

PC.3.3 A policy and procedure defines the process used for registration of outpatients.

PC.3.4 The hospital has a process for managing patients requiring admission when no bed is available.

PC.3.5 The hospital has a process for managing patients under observation in the emergency room.

PC.3.6 Staff members are aware of and implement a consistent process for registration and admission of patients in different service settings.

Standard Intent:

The process for registration and admission to the hospital must be standardized and the staff are familiar with and follow the standardized process. The following must be considered:

- Registration for outpatient services.
- Admission for inpatient services.
- Admission to day procedures.
- Admission directly from the emergency service.
- The process for holding patients for observation in the emergency room.

PC.4 The hospital ensures a uniform standard of care.

PC.4.1 The hospital implements policies and procedures to ensure that a uniform standard of care is provided to all patients.

PC.4.1.1 All patients receive the same standard of care across all hospital settings and departments.

PC.4.1.2 All patients receive the same standard of care at all times (e.g., during working hours, after working hours, during weekends and holidays).

PC.4.1.3 All patients receive the same standard of care regardless of race, gender, or religion.

PC.4.1.4 All patients receive the same standard of care regardless of their ability to pay or source of payment.

PC.4.2 Patient care services are in accordance with professional standards and applicable laws and regulations.

Standard Intent:

Patient care must be standardized, uniform, professional and matching the lows and regulation including:

- All hospital departments
- At all the time including after working hours, weekends and holidays
- Regardless of race, gender and religion
- Regardless of the patient ability to pay or the source of payment

PC.5 The hospital ensures easy accessibility to care and services.

PC.5.1 Hospital departments and services are physically accessible to all patients.

PC.5.2 The hospital adopts an efficient appointment system.

PC.5.3 The hospital has a process to minimize language barriers by communicating with patients in their primary language or have interpreter services provided at all times.

PC.5.4 The hospital ensures effective communication with patients having special communication needs (e.g., sign language for the hearing impaired patients, and assistance modalities for sight impaired patients).

Standard Intent:

The hospital must ensure easy physical accessibility of all hospital departments to all patients. In addition, the hospital must identify any barriers and implemented processes to eliminate or to reduce them such as:

- Adopting an appointment system.
- Providing special communication needs to minimize Language barriers.

PC.6 The hospital has a systematic process for the initial assessment of patients.

PC.6.1 The hospital implements a policy and procedure that defines the assessment process and its scope and content for all care settings (inpatients, outpatients, critical care and emergency room).

PC.6.2 The hospital implements a policy and procedure that defines the assessment process and its scope and content for all categories of patients (adults, geriatrics, pediatrics, pregnant women, trauma patients and others).

PC.6.3 The hospital implements a policy and procedure that defines the assessment process and its scope and content for all disciplines (physicians, nurses, physiotherapists, social service and others).

PC.6.4 The policy defines the staff categories qualified by license, certification, and experience to assess patients.

PC.6.5 The initial assessment aims to identify the general patient's medical and nursing needs and a provisional diagnosis so that care and treatment can be initiated.

Standard Intent:

An effective patient assessment is an ongoing, dynamic process results in decisions about the patient's treatment needs. The scope of assessment policy and procedure must address the following:

- All hospital settings
- All patient categories
- All disciplines (healthcare workers)
- Only qualified individuals conduct the assessments
- The main aim of the assessment

PC.7 The initial assessment includes screening patients for pain, functional limitations, and malnutrition.

PC.7.1 The hospital implements a policy that defines the criteria and process for screening patients for pain, functional limitations including risk for fall, and malnutrition.

PC.7.2 Screening criteria are developed by qualified individuals.

PC.7.3 When pain is present from the initial screening, the patient receives a comprehensive pain assessment.

PC.7.4 Patients with functional impairment are referred for functional assessment.

PC.7.5 Patients identified as malnourished or at risk for malnutrition are referred for a nutritional assessment.

Standard Intent:

The patient's initial assessment should include screening for the pain, functional needs and nutritional needs. The hospital should develop the appropriate screening criteria for staff to follow during the assessment. Such criteria should be developed by the appropriate staff (for example, screening for nutritional needs to be developed by a dietician). Patients' that screen positive should be referred to the appropriate specialty for a full assessment (for example, patients' that are at risk for nutritional needs are further assessed by a dietician).

PC.8 The initial assessment includes the need for discharge planning.

PC.8.1 The hospital has criteria to identify patients requiring discharge planning before or upon admission.

PC.8.2 A proposed discharge date is set soon after admission.

PC.8.3 Staff members are aware of the discharge planning process particularly for common cases with predictable outcome.

Standard Intent:

The hospital must have criteria to identify patients requiring discharge planning before or upon admission. The discharge planning must be part of all patient initial assessment and include a proposed discharge date is set soon after admission. Staff members are aware of the discharge planning process particularly for common cases with the predictable outcome.

PC.9 Initial assessment of patients is completed and documented in the medical record on a timely manner.

PC.9.1 The hospital implements a policy that defines the time frame for completing the medical, nursing, and other assessments required for different care settings and services.

PC.9.2 Medical and nursing assessments are completed and documented within the first 24 hours of admission for routine elective cases.

PC.9.3 Medical and nursing assessments are completed and documented earlier whenever indicated by the patient's condition and the hospital policy.

PC.9.4 Assessments completed within 30 days prior to admission or an outpatient visit can be used with a documented update of any significant changes.

PC.9.5 Assessments completed more than 30 days prior to admission or an outpatient visit must be repeated.

PC.9.6 Medical and nursing assessments are completed and documented for all patients prior to surgery, anesthesia or invasive procedures.

Standard Intent:

The patient's medical and nursing needs are identified from the initial assessments, which are completed and documented in the clinical record within the first 24 hours after admission as an inpatient or earlier as indicated by the patient's condition. When the initial medical assessment is conducted in outpatient setting prior to care in the hospital as an inpatient, it must be within the previous 30 days. If at the time of admission as an inpatient the medical assessment is greater than 30 days old, the medical history must be updated and the physical examination repeated. For medical assessments performed and documented 30 days or less prior to admission, any significant changes in the patient's condition since the assessment are noted at admission.

PC.10 Medical assessment is completed and documented for each patient.

PC.10.1 Each patient undergoes an initial medical assessment that includes a health history and physical examination, covering the following:

PC.10.1.1 Main complaint.

PC.10.1.2 Details of the present illness.

PC.10.1.3 Systems review.

PC.10.1.4 Past history including previous admissions and surgeries.

PC.10.1.5 Allergies and prior adverse drug reactions.

PC.10.1.6 Drug history.

PC.10.1.7 Family history.

PC.10.1.8 Psycho-social history.

PC.10.1.9 Economic factors.

PC.10.1.10 Pain (screening followed by assessment if required).

PC.10.1.11 Risk for fall (screening followed by assessment if required).

PC.10.1.12 Physical status and functionality (screening followed by assessment if required).

PC.10.1.13 Complete physical examination.

PC.10.1.14 Diagnostic test(s) as indicated by the patient's condition.

PC.10.1.15 Need for additional or specialized assessment as indicated by the patient's condition.

PC.10.1.16 Need for discharge planning as indicated by the patient's condition.

PC.10.1.17 Provisional diagnosis.

PC.10.2 The most responsible physician ensures all patients under his care have a complete medical assessment with all diagnostic tests and referrals as required to reach a final diagnosis.

PC.10.3 Medical assessment is performed by the most responsible physician or a member of the team who is qualified by license, certification, and experience.

PC.10.4 Diagnostic tests (e.g., laboratory and radiology) are available as indicated by the hospital's scope of service and the professional standards of care.

PC.10.5 Diagnostic tests (e.g., laboratory and radiology) are appropriately and timely ordered to aid in reaching a final diagnosis.

PC.10.6 The medical assessment is documented in the patient's medical record.

Standard Intent:

The patient's initial medical assessment must cover all essential basic elements such as those mentioned in the substandard 10.1.1 through 10.1.17. In addition, an appropriately ordered diagnostic tests (laboratory and radiology) must be documented and available in the patient's file. It is the responsibility of a qualified and licensed physician under the supervision of the most responsible physician.

PC.11 Nursing assessment is completed and documented for each patient.

PC.11.1 The nursing assessment is performed by a staff nurse.

PC.11.2 The nursing assessment identifies the patient's nursing needs.

PC.11.3 The nursing assessment must be timely and complete.

PC.11.4 The nursing assessment is documented in the patient's medical record.

Standard Intent:

Nursing assessments are primary to the initiation of care and may also identify a need for other assessments. The Nursing assessments are conducted by individuals qualified as registered nurse. The Nursing assessments must be completed and documented in patient's file in timely manner. Please identify timely.

PC.12 Additional and specialized assessments are performed for identified patient groups.

PC.12.1 There are criteria implemented to identify patient groups who need additional or specialized assessments.

PC.12.2 Additional assessment includes, but is not limited to, the following categories:

PC.12.2.1 Patients in severe or chronic pain.

PC.12.2.2 Children.

PC.12.2.3 Frail and elderly.

PC.12.2.4 Suspected victims of abuse, neglect, and domestic violence.

PC.12.2.5 Drug abuse.

PC.12.2.6 Psychiatric disorders.

PC.12.2.7 Women in labor.

PC.12.2.8 Terminally ill and dying patients.

PC.12.3 Specialized assessment includes patients with dental, hearing, eye or speech defects.

PC.12.4 When additional or specialized assessments are required, they are completed and documented in the patient's medical record.

Standard Intent:

The information gathered at the initial medical and/or nursing assessment, may indicate that the needs further or more in-depth assessment such as dental, hearing, vision and/or specialized additional assessment in some categories of patients. These assessments must be completed and documented in patient's file.

PC.13 The hospital has a process to manage patients of suspected abuse, neglect, or domestic violence.

PC.13.1 The hospital has a policy and procedure that defines the initial screening criteria and subsequent assessment of cases subjected to abuse, neglect, or domestic violence.

PC.13.2 The screening criteria are developed by qualified individuals.

PC.13.3 The policy defines the staff members responsible for assessment and management of such cases in accordance with the applicable laws and regulations.

PC.13.4 Staff members are aware of the relevant laws and regulations and are educated about managing cases of abuse and neglect.

Standard Intent:

The assessment of patients subjected to abuse, neglect, or domestic violence are shaped by the culture of the patient population. These assessments are not intended to be proactive case-finding processes. Rather, the assessment of those patients responds to their needs and condition in a culturally acceptable and confidential manner. The assessment process is modified to be consistent with local laws and regulations and professional standards related to such populations and situations and to involve the family when appropriate or necessary.

PC.14 Patients are assessed, reassessed, and managed for pain.

PC.14.1 The hospital addresses pain (acute/chronic) assessment and management as a patient's right.

PC.14.2 The hospital implements a policy that clearly defines:

PC.14.2.1 Requirements for a comprehensive pain assessment and management.

PC.14.2.2 Frequency of pain re-assessment.

PC.14.2.3 Role of staff in pain assessment and re-assessment.

PC.14.2.4 Items included in pain assessment (intensity, type, duration, frequency, location, and progress).

PC.14.2.5 Pain relieving measures, including medications and their dosage, frequency, and route.

PC.14.3 Patients in pain receive pain assessment and management according to the policy.

PC.14.4 The process of pain assessment and management is documented in the patient's medical record.

Standard Intent:

Pain can be a common part of the patient experience and may be associated with the condition or illness for which the patient is being treated. Pain may also be an expected part of certain treatments, procedures, or examinations. As part of care planning, whatever the origin of pain, unrelieved pain has adverse physical and psychological effects. Thus, patients in pain have the right to appropriate assessment and management of pain. Based on the scope of services provided, the hospital must develop to clearly define its process to assess and to manage pain appropriately, Including the requirements for pain assessment, the frequency of pain re-assessment, the role of staff in pain assessment and re-assessment, the items included in pain assessment and the pain relieving measures. The pain assessment and re-assessment must be documented in the patient's medical record.

PC.15 In-hospital patients have their overall care managed and coordinated by one qualified physician.

PC.15.1 Each patient has one qualified physician responsible for the overall care rendered to that patient and is referred to as the most responsible physician (MRP).

PC.15.2 The most responsible physician must have the privilege to admit patients and to be a most responsible physician.

PC.15.3 The most responsible physician carries the overall responsibility and accountability for the outcome of care provided to the patient.

PC.15.4 The most responsible physician provides the principal care plan and coordinates when required for additional plans of other healthcare providers.

PC.15.5 Transfer of patient responsibility from one physician to another is guided by a hospital policy and is documented in the patient's medical record.

Standard Intent:

Each patient admitted to hospital must be under care of one physician (MRP) who is privileged to deliver required care to patient and will be accountable for outcome of care through developing an appropriate care plan and coordinate with other care providers if additional care required. Hospital must have a policy to guide patient care transfer from physician to other physician to ensure proper and continuum of care provided to patient.

PC.16 A comprehensive plan of care is developed collaboratively and documented for each patient.

PC.16.1 The plan of care is developed through a collaborative approach between the healthcare team(s), patient, and family.

PC.16.2 The plan of care is based on the assessment findings and aimed to meet all patients' needs.

PC.16.3 The patient and family are involved in developing the plan of care.

PC.16.4 The plan of care contains the measurable goals/desired outcomes towards discharge.

PC.16.5 The plan of care is completed within 24 hours of admission or earlier based on the patient's condition and needs. (Nursing plan of care is completed whenever possible before the end of the shift).

PC.16.6 The plan of care is reviewed by the most responsible physician on a daily basis.

PC.16.7 The plan of care is modified as appropriate upon any significant change in the patient's condition or when new treatments are added or discontinued.

PC.16.8 The plan of care includes a provisional date of discharge set within 24 hours of admission.

PC.16.9 The plan of care is documented in the patient's medical record.

Standard Intent:

The plan of care outlines care and treatment to be provided to an individual patient. The plan of care identifies a set of actions that the health care team will implement to resolve or support the diagnosis identified by assessment. The overall goal of a plan of care is to achieve optimal clinical outcomes. The planning process is collaborative and uses the data from the initial assessment and from periodic reassessments performed by physicians, nurses, and other health care practitioners to identify and to prioritize the treatments, procedures, nursing care, and other care to meet the patient's needs. The patient and family are involved in the planning process with the health care team.
The plan of care is developed within 24 hours of admission as an inpatient. Based on the reassessment of the patient performed by the patient's health care practitioners, the plan of care is updated as appropriate to reflect the evolving condition of the patient. The plan of care is documented in the patient's record. The plan of care for a patient must be related to his/her identified needs. Those needs may change as the result of clinical improvement or new information from a routine reassessment. The plan of care is revised based on these changes and is documented in the record as notes to the initial plan, or they may result in a new plan of care. One method of developing care plans is to identify and establish measurable goals. Measurable goals can be selected by the responsible physician in collaboration with the nurse and other health care practitioners. Measurable goals are observable, achievable targets related to patient care and expected clinical outcomes. They must be realistic, specific to the patient, and time-

based to provide a means for measuring progress and outcomes related to the plan of care.

PC.17 Patients are reassessed to ensure effectiveness of care plans.

PC.17.1 All patients are reassessed at appropriate intervals to determine:

PC.17.1.1 Response to treatment.

PC.17.1.2 Compliance with treatment.

PC.17.1.3 Complications and side effects.

PC.17.1.4 Plan for continued treatment or completion of treatment.

PC.17.2 Medical reassessment must be performed at least once daily, including weekends and holidays, and in response to any significant change in the patient's condition.

PC.17.3 Nursing reassessment must be performed on every shift with a frequency dictated by the patient's condition, response to treatment, and physician's order.

PC.17.4 Reassessments are documented in the patient's medical record.

PC.17.5 The hospital defines situations where re-assessments are performed more infrequently (e.g., long stay patients mainly requiring a nursing care).

Standard Intent:

Reassessment by all the patient's health care practitioners is key to understanding whether care decisions are appropriate and effective. Patients are reassessed throughout the care process at intervals based on their needs and plan of care or as defined in hospital policies and procedures. The results of these reassessments are noted in the patient's record for the information and use of all those caring for the patient. Reassessment by a physician is integral to ongoing patient care. A physician assesses an acute care patient at least daily, including weekends, and when there has been a significant change in the patient's condition. Reassessments are conducted and results are entered in the patient's record

- At regular intervals during care.
- Nursing staff reassessment at every shift or as needed based on the patient's condition.
- Daily by a physician for acute care patients or as needed based on the patient's condition.
- In response to a significant change in the patient's condition. if the patient's diagnosis has changed and the care needs require revised planning; and to determine if medications and other treatments have been successful and the patient can be transferred or discharged.

PC.18 Clinical practice guidelines, pathways, and protocols are developed or adopted to guide priority clinical care services.

PC.18.1 The hospital implements the national clinical practice guidelines, pathways, and protocols that are consistent with current evidence- based practice.

PC.18.2 Clinical practice guidelines, pathways, and protocols are updated at least every two years and as required with emphasis on the most common diagnoses.

PC.18.3 Clinical practice guidelines, pathways, and protocols are documented in the patient's medical record.

Standard Intent:

The hospital should identify priority clinical care services or areas for whom standardization of care is critical, for example, management of patients presenting with chest pain, abdominal pain, stroke and etc. The use of practice guidelines, clinical protocols or pathways, that are evidence based, for those priority services enables staff to provide safe integrated patient care with the least available resources and time and ensures better outcomes. Such guidelines and protocols should be reviewed at least every 2 years to ensure its relevance and up to date status. The use of practice guidelines, pathways and protocols should be documented in the patients' files.

PC.19 The hospital ensures uniform patient care processes during invasive interventions.

PC.19.1 The hospital implements a policy for the assessment and management of patients undergoing invasive procedures.

PC.19.2 The policy defines all essential requirements that must be documented in the patient's medical record including, but are not limited to:

- PC.19.2.1 Date and time of the procedure.
- PC.19.2.2 Name, designation and signature of the physician performing the procedure and the names of all assistants.
- PC.19.2.3 Location of the procedure.
- PC.19.2.4 Nature and indication of the procedure.
- PC.19.2.5 Any anesthesia or analgesia used with dosage and type.
- PC.19.2.6 Patient monitoring.
- PC.19.2.7 Procedure outcome.
- PC.19.2.8 Complications
- PC.19.2.9 Laboratory specimens.
- PC.19.2.10 Specific post procedural orders.

PC.19.3 Invasive procedures are documented in the patient's medical record (or in an appropriate form) as per the policy.

Standard Intent:

Because invasive intervention carries a high level of risk, the hospital must develop a policy to guide the process from the planning till the end of the procedure, including

documentation of the procedure and monitoring the patient status including the elements mentioned in sub standards PC.19.2.1 through PC.19.2.10.

PC.20 Provision of care is continued, integrated, and coordinated.

PC.20.1 Information about the patient's care and response to treatment is shared between medical, nursing, and other care providers (e.g., patient rounds, multidisciplinary teams, case management for patients requiring complex care).

PC.20.2 The patient's medical record is available to the authorized care providers to facilitate the exchange of information.

PC.20.3 Information about patient care and progress is exchanged during change- of- shift reporting (handover), between shifts, and during transfers and referrals between healthcare providers.

Standard Intent:

Continuity of care is enhanced when all patient-care providers have the information needed from the patient's current and past medical experiences to help in decision making, and, when multiple decision makers are providing care, these decision makers agree on the care and services to be provided. The patient's record(s) is a primary source of information on the care process and the patient's progress and thus is an essential communication tool. For this information to be useful and to support the continuity of the patient's care, it needs to be available during inpatient care, for outpatient visits, and at other times as needed and kept up to date. Medical, nursing, and other patient care notes are available to all of the patient's health care practitioners who need them for the care of the patient. For patient care to appear seamless, the hospital needs to design and to implement processes for continuity and coordination of care among physicians, nurses, and other healthcare practitioners in all hospital settings.

PC.21 Physician orders are documented in a consistent location within the medical record.

PC.21.1 There is a physician's order form where physicians document all orders relating to the patient care.

PC.21.2 Only physicians are allowed to write in the physician order form (except for telephone and verbal orders).

PC.21.3 Physician orders include medications and non-medication orders.

PC.21.4 All orders are acknowledged by the nurse in charge of the patient, dated and timed.

Standard Intent:

Physician orders must be documented in the patient record. Such as orders for laboratory testing, administration of medications, specific nursing care instructions, type of nutrition therapy, need for rehabilitative therapy, and the like. Such orders are ordered by individuals qualified to do so. Such orders must be easily accessible if they are to be acted on in a timely manner. Locating orders on a physician order form.

Documented orders help staff understand the specifics of an order, when the order is to be carried out, and who is to carry out the order.

PC.22 Sufficient medical staff are available to meet patients' needs.

PC.22.1 Medical staff members are available in sufficient number at all times with no significant variation during holidays or weekend days.

PC.22.2 There is at least one qualified physician available at all times for each specialty according to the hospital's scope of services.

PC.22.3 Medical and other relevant staff who are "on call" are within the hospital premises during the on call hours.

PC.22.4 Medical and other relevant staff who are on call respond promptly to incoming consultations and care related requests.

Standard Intent:

To ensure constant and proper continuity of patient's care at all times including holidays and weekend, hospital must design an on call Rota including medical, nursing and other relevant staff to meet patient's need according to scope of service of the hospital. The on call staff should be residing within the hospital and their response to calls should be monitored to ensure optimal response time to emergencies.

PC.23 A nursing pre-operative checklist is completed to control the transfer and handover of patients to the operating room.

PC.23.1 There is a nursing pre-operative checklist that is completed by the assigned nurse.

PC.23.2 The checklist uses the "Yes", "No" and "Not Applicable" format.

PC.23.3 Patients are not transferred to the operating room if the checklist is not completed except in dire emergencies.

PC.23.4 The assigned nurse endorses all the findings of the pre-operative checklist to the receiving nurse in the operating room.

PC.23.5 The receiving nurse in the operating room reviews all the findings of the pre-operative checklist with the assigned nurse and confirms in writing.

PC.23.6 The nursing pre-operative checklist contains the following elements as a minimum:

PC.23.6.1 The nursing pre-operative checklist contains the following elements as a minimum:

PC.23.6.2 Evidence of completed relevant consents.

PC.23.6.3 Evidence of completed history and physical examination by medical and nursing staff.

PC.23.6.4 Evidence of site marking.

PC.23.6.5 Availability of results of requested investigations.

PC.23.6.6 Availability of requested blood or blood products.

PC.23.6.7 Evidence of removal of dentures and loose objects such as eye lenses, eyeglasses, and removable nails.

PC.23.6.8 Evidence of removal of jewelry and patient's valuables.

Standard Intent:

Hospital design a nursing preoperative checklist with a policy that control handover process for patients transferred to operating room. The nursing preoperative checklist includes elements in sub-standards PC.23.6.1 to PC.23.6.8 to ensure proper and full assessment including clinical, nursing, radiological and laboratory in addition to others elements considered important ant not to jeopardize patient life. The checklist utilized during handover between nursing and operating room endorsers.

PC.24 The hospital meets the unique needs of terminally ill patients in a culturally and age-appropriate manner.

PC.24.1 The hospital assesses and responds to the unique needs of end of life patients, including psychological, spiritual, social, and cultural assessment.

PC.24.2 The hospital provides an effective palliative care for terminally ill patients (e.g., management of pain and management of other distressing symptoms).

PC.24.3 Family members are involved in care decisions.

PC.24.4 Family members are educated on how to care for their patient.

PC.24.5 When required, the hospital provides referral and transfer services to other facility that can provide palliative care (e.g., bed or resources availability).

PC.24.6 When applicable, the hospital provides or arrange for a nursing home care (e.g., inability to refer, or patient/family wish).

Standard Intent:

Patients who are approaching the end of life require care focused on their unique needs. Dying patients may experience symptoms related to the disease process or curative treatments or may need help in dealing with psychosocial, spiritual, and cultural issues associated with death and dying. Their families and caregivers may require respite from caring for a terminally ill family member or help in coping with grief and loss.

The hospital's goal for providing care at the end of life considers the settings in which care or service is provided (such as a hospice or palliative care unit), the type of services provided, and the patient population served. The hospital develops processes to manage end-of-life care. These processes

- ensure that symptoms will be assessed and appropriately managed;
- ensure that terminally ill patients will be treated with dignity and respect;
- assess patients as frequently as necessary to identify symptoms;
- plan preventive and therapeutic approaches to manage symptoms; and

- Educate patients and staff about managing symptoms.

Pain is a common part of the patient experience, and unrelieved pain has adverse physical and psychological effects. A patient's response to pain is frequently within the context of societal norms and cultural and religious traditions. Thus, patients are encouraged and supported in their reporting of pain. Dying patients have unique needs that may also be influenced by cultural and religious traditions. Concern for the patient's comfort and dignity guides all aspects of care during the final stages of life. To accomplish this, all staff members are made aware of patients' unique needs at the end of life. These needs include treatment of primary and secondary symptoms; pain management; response to the patient's and family's psychological, social, emotional, religious, and cultural concerns; and involvement in care decisions.
The hospital's care processes recognize and reflect the right of all patients to assessment and management of pain and the assessment and management of a patient's unique needs at the end of life.

PC.25 Policies and procedures guide the handling, use, and administration of blood and blood products.

PC.25.1 There are policies and procedures that are developed collaboratively by the blood utilization committee, guiding the handling, use, and administration of blood and blood products.

PC.25.2 Only physicians order blood and in accordance with a policy clarifying when blood and blood products may be ordered.

PC.25.3 The physician obtains informed consent for transfusion of blood and blood products. Elements of patient consent include:

PC.25.3.1 Description of the transfusion process.

PC.25.3.2 Identification of the risks and benefits of the transfusion.

PC.25.3.3 Identification of alternatives including the consequences of refusing the treatment.

PC.25.3.4 Giving the opportunity to ask questions.

PC.25.3.5 Giving the right to accept or refuse the transfusion.

PC.25.4 Two staff members verify the patient's identity prior to blood drawing for cross match and prior to the administration of blood.

PC.25.5 In dire emergencies, patient/family signs consent for "transfusion without NAT testing".

PC.25.6 Blood is transfused according to accepted transfusion practices from recognized professional organizations.

PC.25.7 Policies and procedures guide the administration of blood transfusions.

PC.25.8 Patients receiving blood are closely monitored.

PC.25.9 Transfusion reactions are reported and analyzed for preventive and corrective actions.

PC.25.10 Side effects or complications are immediately reported to the medical staff and blood bank and the transfused unit is sent to the blood bank for further investigations.

Standard Intent:

The use of blood in the organization is supervised and closely monitored by the blood utilization committee. Blood must be handled and used in accordance with standards of practice and in a consistent manner in order to ensure the safety of the recipient.
Policies and procedures are developed and approved by the blood utilization committee covering the administration of blood (including patient's identification, accepted practices, monitoring during and after the transfusion and reporting of transfusion errors) and when to administer blood without a consent. Only physicians can order blood for transfusion. Patients are informed for the reason for transfusion and sign an informed consent for blood transfusion that must include the elements in the substandard PC.25.3.1 through PC.25.3.5.
All transfusion reactions are immediately reported to the blood bank and investigated by the appropriate blood bank staff in order to avoid its recurrence. A report is given to the blood utilization committee to ensure the implementation of corrective actions.

PC.26 Patients at risk for developing venous thromboembolism are identified and managed.

PC.26.1 Patients are screened for the risk of developing venous thromboembolism.

PC.26.2 Patients at risk receive prophylaxis according to current evidence-based practice.

Standard Intent:

The hospital must develop a risk assessment tool to identify patients for risk of venous thromboembolism and to start appropriate prophylaxis either mechanical, pharmacological or both according to risk severity and to reassess whenever patient's condition changed. The hospital must adopt an international guideline and policy of venous thromboembolism prophylaxis.

PC.27 The hospital provides safe psychiatric care services in accordance with professional standards and applicable laws and regulations.

PC.27.1 Psychiatric care is provided by qualified physicians.

PC.27.2 There are admission and discharge criteria for psychiatric patients.

PC.27.3 The need for psychiatric care and choice of modality are based on sound clinical principles and a thorough clinical evaluation of medical condition and co-morbidities.

PC.27.4 The physical layout of the psychiatry service area allows for:

PC.27.4.1 Quiet and separate counseling of patients and families.

PC.27.4.2 Access only by authorized staff.

PC.27.4.3 Quick assistance from security.

PC.27.4.4 A means to separate adults from pediatrics.

PC.27.5 Seclusion areas are adequately lit, equipped with special safety features, and provide protection for patients and staff.

Standard Intent:

There must be a qualified physician to provide care for psychiatric patients as well as an admission and discharge criteria for psychiatric patients. This must include the need for psychiatric care and choice of modality are based on sound clinical principles and a thorough clinical evaluation of the medical condition and co-morbidities. The physical layout of the psychiatry service area must allow for quiet and separate counseling of patients and families, access only by authorized staff, quick assistance from security and means to separate adults from pediatrics. Seclusion areas are adequately lit, equipped with special safety features, and provide protection for patients and staff.

PC.28 Policies and procedures guide the care of psychiatric patients.

PC.28.1 There are policies and procedures to guide the care of psychiatric patients which include, but are not limited to, the following:

- PC.28.1.1 Use of patient restraints.
- PC.28.1.2 Use of sedation.
- PC.28.1.3 Management and care of violent patients.
- PC.28.1.4 Management of patients with depression.
- PC.28.1.5 Risk assessment for identification of patients at risk for suicide.
- PC.28.1.6 Environmental assessment for patients at risk for suicide.
- PC.28.1.7 Management of patients at risk for suicide.
- PC.28.1.8 Management of patients with psychosis.
- PC.28.1.9 Use of safe seclusion.
- PC.28.1.10 Guidelines for the use of electroconvulsive therapy (ECT).

PC.28.2 The policies and procedures are developed by qualified psychiatrist in collaboration with other relevant professionals.

PC.28.3 Staff members are aware of and implement all relevant policies.

Standard Intent:

Hospital providing psychiatric care must develop and implement policies that regulate the care of psychiatric services. The policies must be developed by qualified psychiatrist in collaboration with relevant professionals. Policies should be at least based on the substandard PC.28.1.1 through PC.28.1.10.

PC.29 A Policy and procedure guide the care of patients on restraints.

PC.29.1 The hospital implements a policy and procedure that defines the Indications for restraints.

PC.29.2 Monitoring requirements for both physical and chemical restraints are clearly identified in the policy including equipment needed and the type and frequency of monitoring and its documentation.

PC.29.3 Patients are restrained only after an order by the most responsible physician or designee.

PC.29.4 The restraint order should be renewed at least every 24 hours.

PC.29.5 Patients are restrained as described in the relevant policy.

Standard Intent:

Hospitals provide a variety of services, some of which are considered high risk that can cause harm to the patient as restraint. Restraint must be limited for only indicated patients. Hospital must develop a policy to guide the process of restraint to ensure patient safety as priority. Only the most responsible physician or a designee can give orders for restraint and the orders should be reviewed at least every 24 hours to verify the need to continue the restraint.

PC.30 Restraints are applied safely and in accordance with professional standards and applicable laws and regulations.

PC.30.1 The most responsible physician assesses and decides on the indication, the most suitable type, and the time required for applying restraints.

PC.30.2 The most responsible physician performs periodic assessment and reassessment as dictated by the patient's condition (particularly, blood circulation to the limbs restrained).

PC.30.3 The least restrictive and most effective means of restraints are always used.

PC.30.4 Use of restraints must be appropriate and safe for patient and staff, used as a last resort, and in conformance with applicable laws and regulations.

PC.30.5 Patient's dignity and rights are protected and preserved, including preventing visibility by others and covering the patient when attending to the patient's physical needs.

PC.30.6 Nursing staff provide periodic monitoring of the restrained patient.

PC.30.7 Patients are reassessed on a frequent basis (at least hourly and as appropriate).

PC.30.8 Appropriate interventions are performed when the patient's circulation is being impaired.

PC.30.9 Appropriate interventions are performed for side effects related to major tranquilizers.

PC.30.10 All assessments, reassessments, monitoring findings, orders, and interventions are properly documented in the patient's medical record.

PC.30.11 An alarm system is available in the room and at nursing station for immediate help or assistance.

PC.30.12 Staff members involved in restraint are trained and competent.

Standard Intent:

Restraints as high risk to cause patient harm, hospital must follow professional standards to ensure patient safety, that include the elements in the substandard PC.30.1 through PC.30.12

PC.31 Crash carts are readily available for cardio- pulmonary resuscitation (CPR).

PC.31.1 The hospital has standardized crash carts that are readily available in all patient care areas.

PC.31.2 The crash carts are adequately equipped and supplied with age specific requirements, including emergency medications, defibrillator, oxygen cylinder, suction machine, intubation/airway access equipment, venous access equipment, and intravenous fluids.

PC.31.3 On every shift, there is a documented process for checking the crash cart by a qualified staff.

PC.31.4 The crash carts checking includes the defibrillator battery, full oxygen tank, suction machine, pharmaceutical care lock number, ambu bags and reservoirs, drug calculation charts, endo-tracheal tube (for neonates, pediatrics, and adults) and sharp box.

PC.31.5 The crash carts are re-stocked/replenished after each use.

Standard Intent:

Availability of standardized crash cart in all areas of the hospital where diagnostic or treatment services are provided to patients is a critical factor in successful resuscitation of patients in cardiopulmonary arrest. Adequate equipment with age specific requirement with standardized process of checking the equipment availability and functionality with process of restocking after each use with proper documentation.

PC.32 The hospital has an effective system for the safe provision of care to patients requiring cardio-pulmonary resuscitation.

PC.32.1 The hospital implements a policy and procedure that guides cardio-pulmonary resuscitation across all hospital areas.

PC.32.2 The policy and procedure defines the following:

PC.32.2.1 A simple number to dial (such as 999) or other mechanism to call when summoning help for a code.

PC.32.2.2 The CPR team composition and the team leader.

PC.32.2.3 Roles and responsibilities of the staff who first discover the code, the team leader and the code team members.

PC.32.2.4 The team member responsible for documenting events with date and time.

PC.32.2.5 How the medications given during the resuscitation are prescribed.

PC.32.2.6 How the medications in the emergency cart are timely replenished.

PC.32.2.7 The CPR form that is used to standardize documentation of the CPR.

PC.32.3 The CPR form includes at least the following information:

PC.32.3.1 The name of the patient.

PC.32.3.2 The date, time and location of the code.

PC.32.3.3 Names of the responders to the code.

PC.32.3.4 Medications and treatments used (e.g., electrical shocks, central lines, intubation) and times of administration.

PC.32.3.5 The outcome of the code.

PC.32.4 Clinical staff are trained on how to use the alarm system or call the code.

PC.32.5 CPR team members have the proper training on cardio-pulmonary life support.

PC.32.6 CPR team is led by:

PC.32.6.1 A physician or an anesthesiologist who is certified in ACLS for adult codes.

PC.32.6.2 A physician who is certified in PALS for pediatric codes.

PC.32.6.3 A physician who is certified in NRP for neonatal codes.

PC.32.7 All codes are reported to the cardiopulmonary resuscitation committee.

Standard Intent:

Successful resuscitation of patients in cardiopulmonary arrest is dependent on the immediate implementation of basic life support and the timely intervention with advanced life support.

These services must be available to all patients, 24 hours a day, every day in all hospital areas. Essential to providing these critical interventions is the quick availability of standardized medical technology, medications for resuscitation, and staff that is properly trained in resuscitation.

Basic life support must be implemented immediately upon recognition of cardiac or respiratory arrest, and a process must be in place for providing advanced life support in fewer than 5 minutes. This could include reviews of actual in-hospital resuscitations as well as mock cardiac arrest response training. Resuscitation must be based on clinical evidence and target the population served (**for example**, if the hospital has a pediatric population, medical technology for pediatric resuscitation must be available).

The Hospital develops and implements a resuscitation policy and procedure that follows the elements in the substandard PC.32.2.1 through PC.32.2.7.

The hospital develops a special form for documenting all code events and the form should include at least the elements of the substandard PC.32.3.1 through PC.32.3.5. All forms are submitted to the CPR committee that should review all codes in order to improve the resuscitation services in the organization. Team leaders for any code should have the appropriate advanced certification in life support according to the age group managed.

PC.33 The hospital has an effective process for responding to patients with deteriorating conditions.

PC.33.1 The hospital establishes a rapid response team(s) of qualified staff to provide rapid response for deteriorating patients outside the intensive care unit.

PC.33.1.1 Team is composed of qualified staff educated on the rapid response process.

PC.33.1.2 Team provides coverage 24 hours a day, 7 days a week.

PC.33.2 There are written criteria communicated to the staff to define how and when to call for a rapid response team before the patient "coded".

PC.33.3 Activities of the rapid response teams are documented.

PC.33.4 There is a regular evaluation of the activities and outcomes of the rapid response teams.

Standard Intent:

Staff who do not work in critical care areas may not have adequate knowledge and training to assess and monitor patients with critical conditions. However, a significant number of patients outside of critical care areas experience critical inpatient events. Often, a patient will exhibit early warning signs (**for example**, a worsening of vital signs or a subtle change in neurological status) shortly before experiencing significant clinical decline, resulting in a major event. The literature identifies physiological criteria that can assist staff in early detection of deteriorating patients.

A majority of patients who experience cardiopulmonary or respiratory arrest demonstrate clinical deterioration prior to arrest. When staff are able to identify these patients early and request additional assistance from specially trained individuals, clinical outcomes improve.

All clinical staff require education and training to provide the knowledge and skills to recognize and intervene when patient assessments identify physiological signs that are outside of the normal range, indicating a potential for patient deterioration. Early response to changes in a patient's condition is critical to potentially preventing further deterioration. Hospitals that develop a systematic approach to early recognition and intervention of patients whose condition is deteriorating may reduce cardiopulmonary arrests and patient mortality.

PC.34 Policy and procedure guides the care of vulnerable dependent patients.

PC.34.1 The hospital has policies to define and guide the care of vulnerable dependent patients (e.g., immune-compromised, comatose, elderly and frail, disabled, terminally ill, neonates, infants, and children).

PC.34.2 Policies define at least the following information:

PC.34.2.1 Relevant clinical care management plans.

PC.34.2.2 Infection control guidelines.

PC.34.2.3 Security and safety guidelines.

PC.34.2.4 Ethical guidelines.

PC.34.3 Staff members are aware of and implement all relevant policies and associated care plans.

PC.34.4 Patient's medical record reflects the use of these policies and plans.

Standard Intent:

Hospitals care for patients with a variety of health care needs. Some patients are considered high risk because of their age, their condition, or the critical nature of their needs. Children and the elderly are commonly placed in this group, as they frequently cannot speak for themselves, do not understand the care process, and cannot participate in decisions regarding their care. Similarly, the frightened, confused, comatose, or emergency patient is unable to understand the care process when care needs to be provided efficiently and rapidly.

When serving any of the high-risk patients, the hospital establishes and implements guidelines and procedures for the services provided for and the patients served.

PC.35 The hospital has a policy for patients permitted to leave the organization during the planned course of treatment.

PC.35.1 The policy defines categories of patients permitted to leave the hospital during hospitalization.

PC.35.2 The policy defines the maximum duration to go for out on pass.

PC.35.3 The policy defines the assessment requirements before leaving the hospital and upon return.

PC.35.4 The policy defines how medications will be dispensed in amounts enough to cover the out on pass period.

Standard Intent:

There must be a process to guide when the hospital permits patients to leave the hospital for a period of time (such as on a weekend "pass").

The policy include:

- Defines categories of patient permitted to leave.
- Duration.
- Assessment required before leave.
- How to dispense medications during out in pass period.

PC.36 The hospital has an effective process for consultations between specialty services.

PC.36.1 The consulting physician completes a consultation request that defines:

PC.36.1.1 Date and time of consultation.

PC.36.1.2 Name and designation of consulting physician.

PC.36.1.3 Name and designation of consulted physician.

PC.36.1.4 Urgency of consultation (24 hours for routine inpatient consults and one hour or less for emergency cases).

PC.36.1.5 Case summary.

PC.36.1.6 Rationale for consultation.

PC.36.2 The consulted physician indicates in writing:

PC.36.2.1 Date and time of consultation visit.

PC.36.2.2 Name and designation.

PC.36.2.3 Opinion and recommendations, including the need to transfer the patient under his name.

PC.36.3 The consulting physician approves and follows up the implementation of the plan of care as set by the consulted physician.

Standard Intent:

Patients who need opinion from another specialty, hospital must design an effective consultation process with a well design consultation request form that must be clearly and timely completed by both the consulting and the consulted physicians and include and name and time, the urgency of consultation, case summary, rationale for consultation and the opinion and recommendation and the need for transfer the patient under his care.

PC.37 Policy and procedure guides the transfer of patients between hospital units.

PC.37.1 The most responsible physician assesses the need for transfer and matches the condition of the patient with admission criteria of the unit.

PC.37.2 Verbal or written agreement as received from the receiving unit is documented in the patient's medical record, including the name of the receiving physician.

PC.37.3 The most responsible physician assesses the transfer requirements, both staff and equipment.

PC.37.4 Summary of the patient medical and nursing assessment findings including reason for transfer, diagnoses, clinical findings, and current medications is available in the patient's medical record before transfer.

PC.37.5 The physician and the nurse at the receiving unit assess the patient at arrival to ensure safe and smooth handover.

Standard Intent:

As patients move through the hospital from departments and services to another, many different health care practitioners may be involved in providing care. The continuity of care is enhanced when all patient-care providers have the information needed from the patient's current and past medical experiences to help in decision making. When multiple decision makers are providing care, the decision makers agree on the care and services to be provided. Indeed, hospital must develop a process of communication to facilitate smooth handover of patient care between hospital units. Both medical and

nursing staff must receive the patient from the transferring unit and re-assess the patient to ensure safe and smooth handover.

PC.38 The hospital has an efficient discharge process.

PC.38.1 The patient and the family are involved in the discharge process with clear follow up instructions.

PC.38.2 Discharge is based on the patient's condition and relevant policies or criteria.

PC.38.3 Patients' needs after discharge are assessed as early in the care process as possible.

PC.38.4 The discharge process identifies the post-service needs and supports continuity of care after discharge.

PC.38.5 The post-service needs are communicated to relevant staff members.

PC.38.6 Staff members ensure coordination with various departments involved in the discharge process.

PC.38.7 Whenever required, staff members ensure coordination with outside organizations and post-service providers as appropriate to the patient's needs.

PC.38.8 Staff members ensure that all patients' needs are met prior to discharge.

PC.38.9 Policies and procedures guide the transfer of patients to other organizations.

Standard Intent:

Discharging a patient to a health care practitioner outside the hospital, another care setting, home, or family is based on the patient's health status and need for continuing care or services. The patient's physician or individual responsible for his or her care must determine readiness for discharge based on the policies and relevant criteria or indications of referral and discharge established by the hospital. Criteria may also be used to indicate when a patient is ready for discharge. Continuing needs may mean referral to a medical specialist, rehabilitation therapist, or even preventive health needs coordinated in the home by the family. An organized process is required to ensure that any continuing needs are met by appropriate health care practitioners or outside organizations. The process includes referring patients to sources of care outside the region when required. When indicated, the hospital begins to plan for the continuing needs as early in the care process as possible. The family is included in the discharge planning process as appropriate to the patient and his or her needs.

PC.39 The hospital has a safe and efficient process for initiating transfer to other organizations.

PC.39.1 Policy and procedure guides the transfer of patients to other organizations.

PC.39.2 Transfer is based on the patient's health needs for continuing care and the resources available for both referring and receiving organizations.

PC.39.3 The most responsible physician determines the need for transfer, the most suitable time for transfer, resources required during transfer, and whether the receiving organization can meet the patient's health and supportive needs.

PC.39.4 There are written transfer criteria for staff to follow.

PC.39.5 There is a written acceptance for transfer of responsibility for the patient's care by the receiving provider/organization.

PC.39.6 The hospital communicates with all potential receiving organizations and necessary arrangements are made whenever applicable.

Standard Intent:

Transferring a patient to an outside organization is based on the patient's status and need for continuing health care services. Transfer may be in response to a patient's need for specialized consultation and treatment, urgent services, or less-intensive services, such as sub-acute care or longer-term rehabilitation. Criteria help to identify when a transfer is necessary in order to ensure that the patient's needs are met.

PC.40 The hospital ensures safe transportation of patients during transfer to other organizations.

PC.40.1 The most responsible physician assesses the transportation needs of the patient according to his condition.

PC.40.2 Transportation needs of the patient are communicated to the relevant staff.

PC.40.3 The transportation is provided promptly and safely in emergency cases (e.g. trauma, or cardiac emergency).

PC.40.4 The most responsible physician ensures that all patient's health needs during transportation are met.

PC.40.5 Adequate equipment and supplies are available during transportation.

PC.40.6 A qualified staff member accompanies the patient during transportation.

PC.40.7 The patient is monitored as appropriate during transfer.

PC.40.8 Handover is completed to staff at the receiving organization.

Standard Intent:

Transferring a patient directly to another health care organization may be a brief process with an alert and talking patient, or it may involve moving a comatose patient who needs continuous nursing or medical oversight. In either case, the patient requires monitoring and may need specialized medical technology, but the qualifications of the individual doing the monitoring and the type of medical technology needed are significantly different.

Thus, the condition and status of the patient determine the qualifications of the staff member monitoring the patient and the type of medical technology needed during transfer.

A consistent process for how patients are transferred from one organization to another is required to ensure that patients are transferred safely. Such a process addresses

- how responsibility is transferred between practitioners and settings;
- criteria for when transfer is necessary to meet the patient's needs;
- who is responsible for the patient during transfer;
- what medications, supplies, and medical technology are required during transfer;

- a follow-up mechanism that provides the condition of the patient during transfer and upon arrival to the receiving organization; and
- What is done when transfer to another source of care is not possible?

The hospital evaluates the quality and safety of the transfer process to ensure that patients were transferred with qualified staff and the correct medical technology for the patient's condition.

PC.41 The receiving organization of a transferred patient receives the necessary information for continuity of care.

PC.41.1 A summary of the patient's condition (e.g., a discharge summary) is sent with the patient to the receiving organization. The summary includes:

PC.41.1.1 Reason for the patient's admission.

PC.41.1.2 Patient diagnosis.

PC.41.1.3 Brief summary of hospitalization and services provided (therapies, consultations, procedures to date).

PC.41.1.4 Medication list and time of last dose(s) given.

PC.41.1.5 Patient condition and physical status at the time of transfer.

PC.41.1.6 Rationale for transfer.

PC.41.1.7 Results of the patient's diagnostic investigations (e.g., laboratory and radiology).

Standard Intent:

To ensure continuity of care, patient information is transferred with the patient. A copy of the discharge summary or other written clinical summary is provided to the receiving organization with the patient. The summary includes the patient's clinical condition or status, the procedures and other interventions provided, and the patient's continuing needs.

PC.42 The hospital ensures the continuity of care after discharge or referral.

PC.42.1 Whenever required, follow up appointments are arranged for the patient prior to discharge.

PC.42.2 The patient receives information on how and when to re-access health and supportive services when required.

PC.42.3 The hospital provides a discharge summary for all inpatients upon discharge.

PC.42.4 A copy of the discharge summary is kept in the patient's medical record.

PC.42.5 A copy of the discharge summary is given to the patient.

PC.42.6 As appropriate, a copy of the discharge summary is provided to the healthcare provider responsible for the patient's continuing or follow-up care.

PC.42.7 The discharge summary is complete and typewritten.

Standard Intent:

When referring a patient to another organization, the referring hospital must determine if the receiving organization provides services to meet the patient's needs and has the capacity to receive the patient. This determination is usually made well in advance, and the willingness to receive patients and the transfer conditions are described in formal or informal affiliations or agreements. This advance determination ensures continuity of care and that the patient's care needs will be met. Transfers may occur to other sources of specialized treatment or services without formal or informal transfer agreements.

PC.43 The hospital has a process for the donation, procurement, and transplantation of organs and tissues.

PC.43.1 The hospital complies with existing laws and regulations on organ and tissue donation, procurement, and transplantation.

PC.43.2 If the hospital performs organ transplants, it collaborates and coordinates with the Saudi Center for Organ Transplantation (SCOT).

PC.43.3 The hospital ensures appropriate retrieval, processing, preservation, and storage of organs/tissues for transplants.

PC.43.4 The hospital establishes guidelines for the donation of organs from one living person to another in accordance with laws and regulations.

Standard Intent:

The shortage of available organs for transplant has encouraged Saudi center for organ transplantation (SCOT) to increase that supply.

The hospital is responsible for defining the process of obtaining and recording consent for cell, tissue, and organ donation in relation to international ethical standards and the manner in which organ procurement is organized according to law and regulation.

The hospital has a responsibility to ensure that adequate controls are in place to prevent patients from feeling pressured to donate.

The hospital supports the choice of patients and families to donate organs and other tissues for research or transplantation. Information is provided to patients and families on the donation. Hospital staff are trained on the donation process that supports patient and family choices. Staff are also trained in the contemporary concerns and issues related to organ donation and availability of transplants.

The hospital cooperates with other hospitals and Saudi center for organ transplantation (SCOT) for all or a portion of the procurement, banking, transportation, or transplantation process.

Nursing Care Standard Intents

NR.1 Qualified nursing director is responsible for managing nursing services in the hospital.

NR.1.1 The hospital has a full-time nursing director.

NR.1.2 The nursing director is licensed and registered with the Saudi Commission for Health Specialties.

NR.1.3 The nursing director is qualified by appropriate education, training, and experience (minimum bachelor degree of science in nursing and five years of managerial experience).

NR.1.4 The nursing director is responsible for the direction, provision, and quality of nursing services provided to patients.

NR.1.5 The nursing director develops the nursing organizational chart as well as the nursing education and quality improvement.

NR.1.6 The hospital designates a deputy director of nursing to coordinate nursing activities and handle administrative and clinical issues during the absence of the nursing director.

Standard Intent:

Nursing services are an integral part of the clinical services of any health care organization, and to be able to operate efficiently and fulfill its mission, the nursing department services are under the direction of one individual who is qualified by documented training, expertise, and experience, and is licensed and registered with the Saudi Commission for healthcare Specialties. This Individual assumes professional responsibility for the Nursing services provided. When this individual is absent the hospital designates a deputy to coordinate nursing activities and handle administrative and clinical issues Responsibilities include:

- Direction, provision, and quality of nursing services provided to patients.
- Develops the nursing organizational chart as well as the nursing education and quality improvement

NR.2 The nursing director assumes a leadership position in the hospital.

NR.2.1 The nursing director represents the nursing staff as one of the hospital leaders.

NR.2.2 The nursing director participates with the other hospital leaders in the decision making processes, including planning and budgeting.

NR.2.3 The nursing director participates in the hospital's multi-disciplinary structures (e.g., committees such as quality improvement, infection control and pharmacy and therapeutics).

NR.2.4 The nursing director oversees and assures that committees' recommendations are implemented at the nursing level.

Standard Intent:

Nursing Director is involved in decision-making processes. He or she is one of the hospital leaders, works collectively and collaboratively with other hospital leaders to develop the program, policies, and services needed to fulfill the hospital mission, these include the procurement and management of essential supplies, financial management, quality management, patient safety, and others. She or he participates in organization decision-making groups and hospital wide committees such as , leadership executive, quality improvement and patient safety , infection control, Pharmacy and therapeutic , and other committees, oversees committee's activities and recommendations and ensure implementation at nursing level.

NR.3 The nursing director assumes the authority, responsibility, and accountability for assuring proper and effective nursing services.

NR.3.1 The nursing director establishes, oversees, and approves nursing policies and procedures and nursing professional standards of practice and patient care.

NR.3.2 Nursing policies, procedures, and standards include all nursing units (e.g. intensive care, medical, surgical, emergency room, operating room, and dialysis units).

NR.3.3 Nursing policies, procedures, and standards are accessible to all nursing staff at all times.

NR.3.4 Nursing staff are familiar with the nursing policies and procedures.

NR.3.5 The nursing director ensures participation with other hospital leaders in the development of practices that promote patients and staff safety (e.g., infection control, safe medication management, safe use of medical equipment, and fire safety).

NR.3.6 The nursing director together with other relevant staff work to develop essential policies and procedures including, but are not limited to, the following:

NR.3.6.1 Admission procedures.

NR.3.6.2 Basic hygiene of patients and skin care.

NR.3.6.3 Patient and family rights.

NR.3.6.4 How to transcribe physician’s orders.

NR.3.6.5 Patient education.

NR.3.6.6 General infection control policies.

NR.3.6.7 Calling physicians.

NR.3.6.8 Patient transfer (internal and external).

NR.3.6.9 Patient discharge.

NR.3.7 The nursing director implements an effective method for organizing the delivery of patient care (e.g. functional, team, primary care).

NR.3.8 The nursing director ensures the implementation of a policy and procedure that defines patient care delivery method(s).

Standard Intent:

The oversight of nursing services includes developing, approving, implementing, and maintaining policies and procedures and nursing professional standards of practice and patient care. Nursing policies and procedures and standards reflect the department's goals and services as well as the knowledge, skills, and availability of staff required to assess and to meet patient care needs. The nursing director work in collaboration with other leaders and hospital staff to develop the essential policies (NR.3.6.1 through NR.3.6.9.) tailored to the particular Services and include all Units (e.g. intensive care, medical, surgical, emergency room, operating room, and dialysis units). Nursing policies, procedures and standards must be available at all times to all nursing staff, There is a process to ensure that staff members have read and are familiar with policies, procedures, and plans relevant to their work. This process may be part of the orientation of staff members to their department and their responsibilities or may be part of group-wide or hospital wide special training session. Staff providing patients 'care should follow an effective method that organizes the delivery of care, such method needs to define a policy and implemented.

NR.4 Nursing reference manuals and policies are readily available and accessible to all nursing units.

NR.4.1 There are nursing reference manuals and policies that are available and accessible to all nursing units. This includes, but is not limited to, the following:

- NR.4.1.1 Nursing policies and procedures manual.
- NR.4.1.2 Current nursing practice manuals/books.
- NR.4.1.3 Infection control manual.
- NR.4.1.4 Safety manual or safety policies.
- NR.4.1.5 Operating manuals for the safe use of equipment.
- NR.4.1.6 Laboratory services guide.
- NR.4.1.7 Dietary manual.
- NR.4.1.8 Material Safety Data Sheet (MSDS).

NR.4.2 Policies and content of manuals are implemented as evidenced by the daily practice and the patient's medical record.

Standard Intent:

Information related to the delivery of care and standard of professional practice must be readily available and accessible to all nursing units, those information help nurses to perform their work safely and needed in their daily practices. The sub-standards NR.4.1.1 through NR.4.4.8 highlights the essential documents and manuals.

NR.5 The nursing director ensures the competency of the nursing staff.

NR.5.1 The nursing director participates in the recruitment and hiring of qualified nurses as outlined in the leadership chapter.

NR.5.2 The nursing director monitors the performance of the nursing staff and assures their ongoing competency.

NR.5.2.1 The nursing department develops policies and procedures to define the nursing competency assessment program aiming to ensure that nursing skills and knowledge remain current.

NR.5.2.2 Nursing staff competencies are assessed on an ongoing basis (at least annually, and whenever needed).

NR.5.2.3 Nursing staff competencies are assessed by using different methods (e.g. written test, return demonstration, peer review, feedback from health professionals and supervisors).

NR.5.3 Nursing competencies to be assessed include, but are not limited to, the following:

NR.5.3.1 Monitoring patient's vital signs and knowledge of acceptable deviations from the norm.

NR.5.3.2 Assessment/reassessment of patients according to the scope of services (e.g. critical care, labor and delivery, and surgical units).

NR.5.3.3 Medications administration.

NR.5.3.4 Intravenous therapy (insertion, maintenance, discontinuing).

NR.5.3.5 Infection control guidelines.

NR.5.3.6 Patient falls (assessment of risk and methods to prevent falls).

NR.5.3.7 Use of pulse oximetry.

NR.5.3.8 Nursing role in cardiac/respiratory arrest.

NR.5.3.9 Nasogastric, gastrostomy and feeding tubes.

NR.5.3.10 Urinary catheters.

NR.5.3.11 Sterile dressings.

NR.5.3.12 Skin care and prevention and care of pressure ulcers.

NR.5.3.13 Nursing role in disaster, fire, and other emergencies.

NR.5.3.14 Use of restraints.

NR.5.3.15 Operation of blood sugar testing equipment.

NR.5.3.16 Managing chemical spills.

NR.5.3.17 Use of blood, blood products, and blood –related procedures (e.g., phlebotomy and blood administration).

Standard Intent:

Recruiting, evaluating, and appointing nursing staff are best accomplished through the management of nursing leadership**.** Nursing Director involves in recruiting, retaining and maintaining competent staff nurse in right numbers to meet the needs of the patients and community served by the organization. Policies and procedures developed to define the nursing competencies related to the job specific requirement (NR.5.3.1 through

NR.5.3.17.) staff providing care to patients are evaluated at the time they begin providing care before the probationary or orientation period is completed. This evaluation of necessary skills, and knowledge and desired work behaviors, is carried out by the department or service to which the staff member is assigned, before or at the time of starting to perform work responsibilities. Ongoing evaluation ensures that training occurs when needed or at least annually and that the staff member is able to assume new or changed responsibilities.

NR.6 Sufficient nurses are available to meet the needs of patients.

NR.6.1 The nursing director develops a staffing plan that maintains an adequate staffing level in all nursing units.

NR.6.2 The staffing plan identifies an evidence-based estimation of the number of staff needed per shift, considering all relevant factors (e.g., patient acuity, patient care hours, size of the hospital, scope of services provided).

NR.6.3 Nursing staff are allocated according to the skill level, qualifications, patients volume and acuity, and in accordance with laws and regulations and nursing licensing boards.

Standard Intent:

Appropriate and adequate staffing is critical to patient care, Staff planning is carried out by department/service leaders. The planning process uses recognized evidence-based methods for determining levels of staffing. For example, a patient acuity system is used to determine the number of licensed nurses with pediatric intensive care experience to staff a 10-bed pediatric Intensive care unit. The staffing plan is written and identifies the number and types of required staff and the skills, knowledge, and other requirements needed in each unit, and is based on patient volume and patient acuity.

NR.7 The nursing department provides regularly updated work schedule.

NR.7.1 There is a nursing scheduling policy that defines:

NR.7.1.1 Duration of working shifts (e.g., 12 hours, or 8 hours).

NR.7.1.2 Assignment of overtime when needed.

NR.7.1.3 On-call requirements.

NR.7.1.4 Vacation schedules.

NR.7.1.5 Method for approving change of schedule.

NR.7.1.6 Participation in education/training activities.

NR.7.1.7 Participation in designated committees, departmental meetings, and quality improvement activities.

NR.7.2 The work schedule provides an adequate number of staff on every shift.

Standard Intent:

The nursing staffing plan should ensure adequate staffing with pre-identified skills mixture all the times according to the mission and scope of service. Vacancy rates, staff

schedules should be controlled to ensure safe services 24 hours a day / 7 days a week and take into consideration assignment of overtime when required, on-call requirement, vacation schedule, participation in education, training and designated committees.

NR.8 There is a process for assignment of nurses out of their normal working areas.

NR.8.1 The nursing director ensures that nurses assigned out of their normal working area have the competency required for safe and effective patient care.

NR.8.2 The nursing director maintains a list of cross-trained nurses and makes it available for all nursing units.

Standard Intent:

The nursing staffing plan must consider the reassignment of staff from one department or service to another in response to changing patient needs or staff shortages should be based on their training and competency, this is achieved by developing a cross-training program.

Planned and actual staffing is monitored on an ongoing basis, and the plan is updated as necessary.

NR.9 Nursing services are provided by qualified nurses.

NR.9.1 The nursing director ensures the availability of adequate number of licensed registered nurses to provide nursing care for all patients.

NR.9.2 Each unit has a head nurse/nurse manager with the required nursing and managerial experience.

NR.9.3 Nursing services are provided by registered nurses in accordance with their license and scope of practice.

NR.9.4 Qualified registered nurses are readily available to provide bedside nursing care to all patients twenty-four hours a day, seven days a week.

NR.9.5 Nursing assistants or aides are supervised by a registered nurse at all times.

NR.9.6 Nursing assistants have clearly defined job description and responsibilities.

NR.9.7 There is an education program for nursing assistants performing patient-care services to orient them to their role.

Standard Intent:

The nursing director ensures the availability of head unit/nurse manager with the required nursing, managerial experience, adequate number of licensed registered nurses to provide nursing care for all patients and nursing assistants or aides supervised by registered nurses. All nursing staff must have a clearly defined job description and an education program to orient them to their role.

NR.10 There is a comprehensive nursing assessment for each patient upon admission.

NR.10.1 The nursing assessment is timely completed by a registered nurse.

NR.10.2 The scope and content of the nursing assessment is defined in hospital policies and may include:

NR.10.2.1 History of the patient's main complaint.

NR.10.2.2 Drug allergies.

NR.10.2.3 Physical condition.

NR.10.2.4 Psychosocial status.

NR.10.2.5 Pain assessment.

NR.10.2.6 Nutritional Status.

NR.10.2.7 Discharge planning.

NR.10.2.8 Skin assessment.

NR.10.2.9 Fall risk assessment.

NR.10.3 The nursing assessment identifies nursing care needs for each patient upon admission.

NR.10.4 All patients are reassessed at appropriate intervals (at least on every shift) to determine their response to treatment and to plan for continued treatment and discharge.

NR.10.5 The nursing assessment is documented in the patient's medical record.

Standard Intent:

Patient assessment is an ongoing, dynamic process that takes upon admission. Patient assessment consists of three primary processes

1. Collecting information and data on the patient's physical, psychological, and social status, and his or her health history
2. Analyzing the data and information, to identify the patient's health care needs
3. Developing a plan of care to meet the patient's identified needs

When a patient has been admitted to a hospital for inpatient a complete assessment needs to be performed related to the reason(s) the patient has come for care. The primary outcome from the patient's initial assessments is an understanding of the patient's nursing needs so care and treatment can begin. To accomplish this, the hospital determines the minimum content of the initial nursing assessments (NR.10.2), the time frame for completion of assessments, and the documentation requirements for assessments

Patients are reassessed throughout the care process at intervals based on their needs and plan of care or as defined in hospital policies and procedures. Reassessments are conducted and results are entered in the patient's record

- at regular intervals during care or at least every shift;
- in response to a significant change in the patient's condition

NR.11 There is a nursing plan of care for each patient.

NR.11.1 A nursing plan of care is developed for all inpatients.

NR.11.2 The nursing plan of care is consistent with the medical plan of care.

NR.11.3 The nursing plan of care is reviewed on every shift, upon any significant change in the patient's condition, and when new treatments are added or current treatments are discontinued.

NR.11.4 The nursing plan of care is documented in the patient's medical record.

Standard Intent:

The plan of care outlines care and treatment to be provided to an individual patient. The plan of care identifies a set of actions that the health care team will implement to resolve or support the diagnosis identified by assessment. The overall goal of a plan of care is to achieve optimal clinical outcomes. The plan of care is developed within 24 hours of admission as an inpatient and consistent with the medical plan of care. Based on the reassessment of the patient performed, the plan of care is updated as appropriate to reflect the evolving condition of the patient. The plan of care is documented in the patient's record. The plan of care for a patient must be related to his/her identified needs. Those needs may change as the result of clinical improvement or new information from a routine reassessment**.** The plan of care is revised based on these changes or at least every shift and is documented in the record as notes to the initial plan, or they may result in a new plan of care.

NR.12 The nursing department ensures adequate supplies and equipment for the safe and effective provision of care.

NR.12.1 The nursing department ensures the availability of equipment and supplies necessary for the safe and effective provision of care. This includes, but is not limited to, the following:

- NR.12.1.1 Scales appropriate to the age group and mobility needs of the patient.
- NR.12.1.2 Stretchers with safety straps.
- NR.12.1.3 Equipment for taking vital signs.
- NR.12.1.4 Wheelchairs with safety straps.
- NR.12.1.5 Sharp boxes.
- NR.12.1.6 Footstools.
- NR.12.1.7 Lifting devices.
- NR.12.1.8 Soft restraints.
- NR.12.1.9 Bed rails.
- NR.12.1.10 Devices for treatment and prevention of skin breakdown.
- NR.12.1.11 Patient call bell.
- NR.12.1.12 Oxygen and suction.

NR.12.1.13 Glucometer.

NR.12.1.14 Nebulizers.

NR.12.1.15 Blood warmers.

NR.12.1.16 ECG machines.

NR.12.2 The Nursing department has a process to maintain adequate supplies and linen to meet patient needs.

NR.12.2.1 Critical levels are identified.

NR.12.2.2 Ordering requests are made when critical levels are reached and as needed.

NR.12.2.3 There is an emergency backup process when there are issues/delays receiving supplies.

NR.12.2.4 There is a method to track issues with supplies and linen so that patterns can be studied for quality improvement.

Standard Intent:

Nursing Department ensures adequate essential supplies (including linen) and equipment needed for each unit in order to provide safe patient care, the supplies and equipment vary from unit to units as per the scope of care (as in substandard NR.12.1.1 through NR.12.1.16. As these resource needs may change or may not be fully met, the Nursing department need to identify the minimum critical level for re-ordering , a top up system could be implemented, This helps ensure that adequate supplies and equipment and other resources are available to meet patients' needs at all times. A process should be in place that addresses how to respond to resource shortages to ensure safe and effective care for all patients. The process involves items mentioned in substandard NR.12.2.1 through NR.12.2.4

Quality Management & Patient Safety Standard Intents

QM.1 Hospital leaders support a hospital-wide continuous quality improvement program.

QM.1.1 Hospital leaders provide resources required for the continuous quality improvement program, including human, financial, and time resources.

QM.1.2 Hospital leaders actively participate in quality improvement activities including improvement teams.

QM.1.3 Hospital leaders implement the recommendations resulting from the continuous quality improvement program.

QM.1.4 Hospital leaders support staff to make and participate in quality improvement initiatives and to attend quality improvement educational activities.

Standard Intent:

The leaders, members in supervisory levels and the entire staff of the Hospital are expected to involve in quality implementation in the Hospital. Hospital leaders are required to provide resources needed for the continuous quality improvement initiatives, including human, financial, and time resources.
The Hospital is expected to have the structure for performing high-quality care and improve its performance. This should include policy and procedures, plans, materials, and equipment.
There should be a continuous quality improvement and initiatives. It is expected that the Hospital works on developing expectations or standards of quality for inputs, processes, or outcomes. The hospital must have a multidisciplinary quality improvement committee that has members from the leadership group (the hospital director, medical director, nursing director, quality management director). Hospital leaders participate in quality improvement activities including improvement teams and implement the recommendations resulting from the continuous quality improvement program.

QM.2 Hospital leaders support staff training on their roles and responsibilities related to the continuous quality improvement program.

QM.2.1 Staff are trained on quality improvement by qualified professionals.

QM.2.2 Training on quality improvement includes the utilization of quality improvement methodologies and tools (e.g., PDCA, lean six sigma, cause-and-effect analysis, process map, Pareto chart, brain storming).

QM.2.3 Staff are trained (formally or through orientation and mentoring) on continuous quality improvement in accordance with their roles and responsibilities in the quality improvement program.

Standard Intent:

The leaders and other members of the hospital staff need to have proper education on quality concepts. The awareness of quality in the Hospital is expected to be translated ultimately into a successful quality involvements and improvement.
The leaders are the ones who drive the quality initiatives and activities, therefore, they should be familiar with the basic concepts and tools used in continuous quality and the basic data analysis

QM.3 The hospital has a quality management department that is directed by a qualified individual.

QM.3.1 The hospital has a quality management director responsible for directing all aspects of the quality management department.

QM.3.2 The quality management director is qualified by education, training, and experience in healthcare quality.

QM.3.3 The quality management department provides ongoing consultation to all departments (e.g., on the development and use of indicators to evaluate and improve performance).

QM.3.4 The quality management director reports to the hospital leadership.

Standard Intent:

The hospital is required to have a quality management department. This department should have adequate staff and other resources and must be headed by a qualified person responsible for directing all aspects of the quality management.
The quality management department is responsible for providing ongoing consultation to all departments and is a resource for quality training and quality education.

QM.4 The hospital develops a quality improvement program that provides a structured framework for monitoring and improving performance as well as supporting innovation.

QM.4.1 The quality improvement program covers processes of care involving high risk, high volume, problem-prone, and high cost areas.

QM.4.2 The quality improvement program is in line with the hospital strategic plan.

QM.4.3 The quality improvement program is integrated with the risk management and patient safety activities.

QM.4.4 The quality improvement program is based on a documented quality improvement plan that is revised at least annually, with defined scope, goals, and objectives.

Standard Intent:

Quality management program need to be planned and in a systematic way, designs processes while measuring, assessing and improving quality. The program is collaborative, and involves all appropriate personnel of both clinical & non-clinical staff. Its primary focus is on improving systems and processes while continuing to recognize the competence and importance of system members. Thus, it is designed to improve patient outcomes through improved clinical, leadership and support processes. Its goal and purpose shall be to strive, within available resources, for optimal outcomes with continuous improvement.
The quality program requires qualified staff to support data collection throughout the hospital. Staff throughout the hospital may need assistance in data validation and analysis, implementing improvements, and evaluating if the improvements were sustained.

QM.5 There is a multidisciplinary committee responsible for the coordination of the quality improvement program.

QM.5.1 The hospital has a multidisciplinary quality improvement committee that has members from the leadership group (the hospital director, medical director, nursing director, quality management director) and other members/invitees as appropriate.

QM.5.2 The quality improvement committee provides coordination and oversight of the quality improvement program throughout the hospital.

QM.5.2.1 The quality improvement committee is responsible for development, implementation, and evaluation of the quality improvement program.

QM.5.2.2 The quality improvement committee approves all quality improvement initiatives.

QM.5.2.3 The quality improvement committee receives quality reports and provides feedback to the relevant stakeholders.

QM.5.3 The quality improvement committee meets regularly and maintains appropriate documentation of its activities.

Standard Intent:

The hospital needs to oversee the entire quality improvement initiatives and direct the related activities. The prime method of the overseeing these activities is through a multidisciplinary quality and patient safety committee that has members from the leadership group (the hospital director, medical director, nursing director, quality management director) and other members/invitees as appropriate.
The quality and patient safety committee provides coordination and oversight of the quality
Improvement program and monitors the quality and safety activities throughout the hospital. It is responsible for approving the quality improvement initiatives. The committee receives quality reports and provides feedback to the relevant stakeholders.

QM.6 The hospital monitors its performance through regular data collection and analysis.

QM.6.1 The performance monitoring is based on valid data that reflect the actual performance.

QM.6.1.1 Hospital leaders define and implement a set of hospital performance indicators/measures that focus on important managerial and clinical areas.

QM.6.1.2 Clinical indicators are referenced to current evidence based practice whenever applicable.

QM.6.2 For each indicator, there is a clear definition, sample size, data collection method, frequency, analysis, and expression (e.g., a ratio, with defined numerator and denominator).

QM.6.3 Indicators represent key care and service structures, processes and outcomes based on the mission and scope of services.

QM.6.4 Data are collected and aggregated on a regular basis from qualitative and quantitative sources.

QM.6.5 Data are coordinated with other performance monitoring activities such as patient safety and risk management.

Standard Intent:

The hospital must have a process for data collection and monitoring. The indicators must assess particular health structures, processes, and outcomes. They can be rate- or mean-based, providing a quantitative basis for quality improvement, or sentinel, identifying incidents of care that trigger further investigation. They can assess aspects of the structure, process, or outcome of health care.

Monitoring health care quality will not be possible without the use of clinical indicators. They create the basis for quality improvement and prioritization in the health care system. To ensure that reliable and valid clinical indicators are used, they must be designed, defined, and implemented.

QM.7 Hospital leaders select a set of structure indicators based on the mission and scope of services.

QM.7.1 Hospital leaders utilize the information provided by structure indicators.

QM.7.2 Structure indicators may include, but are not limited to, the following:

QM.7.2.1 Availability of essential supplies and equipment.

QM.7.2.2 Availability of medical records.

QM.7.2.3 Availability of blood and blood products.

QM.7.2.4 Availability of emergency medications.

QM.7.2.5 Vacancy rates in all departments.

QM.7.2.6 Surgical volumes.

QM.7.2.7 Staffing ratios.

Standard Intent:

'Structure' denotes the attributes of the settings in which care occurs. This includes the attributes of material resources (such as facilities, equipment, and financing), of human resources (such as the number and qualifications of personnel), and of organizational structure (such as medical staff, organization, methods of peer review, and methods of reimbursement).

'Structure' refers to health system characteristics that affect the system's ability to meet the health care needs of individual patients or a community. Structural indicators describe the type and amount of resources used by a health system or organization to deliver programs and services, and they relate to the presence or number of staff, clients, money, beds, supplies, and buildings.

The assessment of structure is a judgement on whether care is being provided under conditions that are either conducive or inimical to the provision of good care.

QM.8 Hospital leaders select a set of process indicators based on the mission and scope of services.

QM.8.1 Hospital leaders utilize the information provided by process indicators.

QM.8.2 Process indicators may include, but are not limited to, the following:

QM.8.2.1 The timing and use of antibiotics prior to surgery.

QM.8.2.2 Blood and blood products administration.

QM.8.2.3 Documentation in medical records.

QM.8.2.4 Delay of physicians answering nurses' phone calls and pagers.

QM.8.2.5 Waiting times for treatment.

QM.8.2.6 Venous thrombo-embolism prophylaxis for surgical patients.

QM.8.2.7 Neuropathy testing in diabetic patients.

Standard Intent:

'Process' denotes what is actually done in giving and receiving care, i.e. the practitioner's activities in making a diagnosis, recommending or implementing treatment, or other interaction with the patient.
Process indicators assess what the provider did for the patient and how well it was done. Processes are a series of inter-related activities undertaken to achieve objectives. Process indicators measure the activities and tasks inpatient episodes of care.

QM.9 Hospital leaders select a set of outcome indicators based on the mission and scope of services.

QM.9.1 Hospital leaders utilize information provided by outcome indicators.

QM.9.2 Outcome indicators may include, but are not limited to, the following:

QM.9.2.1 Mortality rates.

QM.9.2.2 Healthcare associated infections.

QM.9.2.3 Staff satisfaction.

QM.9.2.4 Patient satisfaction.

QM.9.2.5 Unplanned return to the operating room.

QM.9.2.6 Return to the emergency room within 24 hours.

QM.9.2.7 Unplanned transfer to the critical care unit.

QM.9.2.8 Resuscitation of patients (cardiac/respiratory arrest).

QM.9.2.9 Readmission to the hospital within 30 days of discharge.

QM.9.2.10 Various adverse events (e.g., falls, injuries, and pressure ulcers).

QM.9.2.11 Medication errors.

QM.9.2.12 Sentinel events.

QM.9.2.13 Patient complaints.

QM.9.2.14 Length of stay.

Standard Intent:

'Outcome' measures attempt to describe the effects of care on the health status of patients and populations. Improvements in the patient's knowledge and salutary changes in the patient's behavior may be included under a broad definition of outcome, and so may represent the degree of the patient's satisfaction with care.

Outcomes are states of health or events that follow care, and that may be affected by health care. An ideal outcome indicator would capture the effect of care processes on the health and wellbeing of patients and populations.

QM.10 Data collected are aggregated and analyzed.

QM.10.1 Data collected are analyzed by staff qualified in data management.

QM.10.2 Data collected are regularly aggregated and analyzed to yield useful trends and variances.

QM.10.3 Data are utilized for internal and external benchmarking to identify deficiencies and opportunities for improvement.

QM.10.4 Information is communicated to the appropriate stakeholders in a way they can understand and use.

Standard Intent:

Practice improvements are much needed in health care. To make information-driven decisions and improvements, data that are tracked across time, across organizations, across patient populations, or across some other variable must be aggregated, analyzed and transformed into useful information. Without staff qualified in data management, transforming data into information would be difficult. Information generated from data analysis should be reported to concerned hospital leaders and staff to support their decision making and practice improvement processes.

QM.11 The hospital uses the information resulting from data analysis to make improvements.

QM.11.1 Information resulting from data analysis is used for prioritizing quality improvement projects as well as strategic and operational planning.

QM.11.2 When appropriate, the hospital tests improvement interventions prior to full implementation.

QM.11.3 After implementing improvement interventions, the hospital measures their effectiveness to ensure that interventions have achieved a sustained improvement.

Standard Intent:

As hospitals work toward meeting patients' needs and implementing quality improvement efforts, they are faced with number of competing issues, while keeping in mind several external considerations such as urgency, cost, impact and feasibility. Therefore, it is necessary to utilize gathered information from different hospital units and services and apply prioritization methods to provide a structured mechanism for objectively ranking issues and making decisions.

QM.12 Quality improvement teams are selected by the service leaders and these teams use quality tools to improve processes.

QM.12.1 Quality improvement teams are assigned by the service leaders.

QM.12.2 The quality improvement team includes staff members who are involved in the process under study.

QM.12.3 The quality improvement team uses the quality tools to improve processes (e.g., brainstorming and fishbone charts).

Standard Intent:

Healthcare services are of multidisciplinary nature. Therefore, improvements need to be done by multidisciplinary teams encompassing representatives from all concerned units. Teams with strong support from leadership and staff, experience with improvement and measurement methods, and an accurate understanding of the investigated process would be more successful.

QM.13 The hospital develops and maintains a risk management program.

QM.13.1 The risk management program addresses potential managerial and clinical risks.

QM.13.2 The hospital defines the scope and objectives of the risk management program as well as the individual responsible for the program.

QM.13.3 The hospital educates the staff on their roles and responsibilities related to the activities of the risk management program.

QM.13.6 The hospital adopts a proactive approach to identify, analyze, and reduce potential risks (e.g. failure mode and effects analysis).

QM.13.7 Heads of clinical departments and other clinical leaders participate in the risk management program.

QM.13.8 Heads of clinical departments and other clinical leaders develop, implement, and evaluate interventions to safeguard patients from unintended consequences of care/treatment.

QM.13.9 The risk management program addresses patient safety issues and makes use of the information developed from investigation of the following:

QM.13.9.1 All litigations involving the hospital and its staff.

QM.13.9.2 Adverse incidents including near misses and sentinel events.

QM.13.9.3 Patient complaints.

QM.13.9.4 Cases of irregular discharges.

QM.13.9.5 Data and reports related to patient safety issues.

QM.13.9.6 Mortality and significant morbidity cases.

QM.13.10 The effectiveness of the risk management program is evaluated regularly and improved as required.

QM.13.11 The hospital maintains appropriate documentation of the risk management activities.

QM.13.12 The risk management activities and their results are communicated to the staff and other relevant groups and used as a basis for improvement of the hospital's processes.

QM.13.13 Relevant information developed from the risk management activities is integrated and coordinated with the quality improvement and patient safety activities.

QM.13.4 The hospital performs a systematic process to identify and analyze potential risks for severity and likelihood of occurrence.

QM.13.5 The hospital develops interventions to manage identified potential risks (e.g., reduction and/or prevention).

Standard Intent:

The Hospital is required to have a risk management plan. The plan must address potential managerial and clinical risks. Neglecting to have comprehensive risk management plans in place can compromise patient care, increase liability risks, and result in financial losses. If the hospital is to successfully initiate and to maintain improvement and reduce risks to patients and staff, leadership support and proper planning are essential. The risk management program must address patient safety issues and makes use of the information developed from investigations related to incidents, deviations from norms or complaints from patients.

The Hospital is expected to identify a qualified individual responsible for the program. This person is responsible for identifying and analyzing risks and the likelihood of their occurrence. The Hospital staff should be oriented to the risk management in order to take part in reducing risk in the Hospital.

QM.14 The hospital has an incident (occurrence/variance) management mechanism that supports improvements of care processes.

QM.14.1 There is a policy and form that are utilized for reporting incidents including adverse events and near misses.

QM.14.2 The hospital defines reportable incidents.

QM.14.3 Incidents are reported and investigated in a timely manner.

QM.14.4 Immediate remedial actions are taken as well as actions to prevent recurrence of similar incidents.

QM.14.5 Patients receive response when involved in significant incidents with documentation in the medical records.

QM.14.6 Incidents are monitored over time and the resulting information is used for improvement.

QM.14.7 Staff are educated on the incident reporting process.

Standard Intent:

The Hospital is required to have incident reporting and management policy. It is developed to provide guidelines for the notification of incidents or events that have occurred involving patients, staff, visitors, equipment, and services; It also focuses on continuous improvement systems that foster a culture of team spirit and transparency. The incident reporting management describes the activities of an organization to identify, analyze, and correct hazards to prevent a future re-occurrence, it's also intended to:

- Provide a safe working environment for users of the facility.
- Promote a fair and just culture where staff members are supported in reporting adverse incidents.
- Promote a system-centered approach rather than a person-centered approach to problem resolution.
- Identify trends at unit/department/section as well as hospital-wide for complaints, claims, and adverse incidents.
- Ensure that opportunities for improvement are identified and maximized

QM.15 The hospital has a process to handle sentinel events.

QM.15.1 There is a policy for management of sentinel events.

QM.15.2 Sentinel events are identified in the hospital's policy and include the following:

QM.15.2.1 Unexpected death.

QM.15.2.2 Unexpected loss of limb or function.

QM.15.2.3 Wrong patient, wrong procedure, or wrong site.

QM.15.2.4 Retained instrument or sponge.

QM.15.2.5 Serious medication error leading to death or major morbidity.

QM.15.2.6 Suicide of a patient in an inpatient unit.

QM.15.2.7 Infant abduction or discharge to a wrong family.

QM.15.2.8 Maternal death.

QM.15.2.9 Hemolytic blood transfusion reaction.

QM.15.2.10 Air Embolism.

QM.15.3 Reportable sentinel events are reported to CBAHI within five working days of the internal notification of the event.

QM.15.4 The hospital forms a team to complete the root cause analysis along with an action plan for all sentinel events. The team should bring together those who have an intimate knowledge of the normal process.

QM.15.5 The root cause analysis and risk reduction plan are sent to CBAHI within thirty working days from the date of the internal notification of the event.

QM.15.6 Reportable sentinel events are reported as required to other relevant authorities.

Standard Intent:

The hospital must also be able to identify significant unexpected or adverse events and intensively analyze them to understand their underlying causes and, as a result, make the necessary improvement interventions.

To be able to effectively improve quality and safety of care and reduce risks, the hospital must constantly use indicators to measure its performance and use the resulting information to identify processes which can be improved.

QM.16 The hospital develops and maintains a patient safety program.

QM.16.1 Hospital leaders adopt a just culture that promotes both professional accountability and reporting of adverse events/near misses.

QM.16.2 Hospital leaders provide direction and resources to support the patient safety program.

QM.16.3 The hospital assigns a qualified individual to provide coordination and supervision of the organization-wide patient safety program.

QM.16.4 Hospital leaders establish a multidisciplinary patient safety committee (can be integrated with quality improvement committee) to provide direction and oversight of the patient safety program.

QM.16.5 Hospital leaders conduct patient safety culture assessment at least once annually. Data are analyzed and improvements are made accordingly.

QM.16.6 Hospital leaders conduct regular leadership patient safety rounds in patient care services to encourage reporting of incidents/near misses and to identify potential risks and hazards.

QM.16.7 The hospital adopts safe practices that have been proven to improve patient safety and reduce harm to patients such as those from the World Health Organization (WHO) and other national and international organizations concerned with patient safety.

QM.16.7.1 The hospital develops and implements policies, procedures, protocols, and guidelines for implementation of the patient safety practices.

QM.16.7.2 The hospital provides equipment/devices with technological features proven to reduce errors and improve safety.

QM.16.8 Relevant information developed from patient safety activities is integrated into quality improvement and risk management activities.

QM.16.9 Patient safety activities and their results are communicated to the staff and other relevant groups and used as the base for improving the hospital's processes.

Standard Intent:

The Hospital must have a Patient Safety Program that focuses on the continuous enhancement of safety for all patients, visitors and employees and to reduce the risk to patients and decrease medical errors. The program collects and analyzes aggregate data to support patient care and hospital management. The aggregated data can help the hospital understand its current performance and identify opportunities for improvement as well as to compare with hospital historical data and bench mark with an exemplary performing hospitals or the best practice.

Leadership commitment to patient safety is essential. There should be ongoing patient safety education for physicians, employees and patients. The education programs should create a culture of safety in which employees are encouraged to come forward when they or others make mistakes, allowing the opportunity to improve the care we deliver and prevent potential errors.

QM.17 The hospital has a process to ensure correct identification of patients.

QM.17.1 At least two patient identifiers (e.g., patient full name and medical record number) are required whenever taking blood samples, administering medications or blood products, or performing procedures.

QM.17.2 The hospital has a standardized approach to patient identification (e.g., use of ID bands with standardized information).

QM.17.3 Patients are actively involved in the process of patient identification.

Standard Intent:

To assure correct patient identification and eliminate errors that can have fatal consequences, there should be a standard process for patient identification throughout the healthcare institution.

The identification process should include at least two identifiers (e.g., patient full name and medical record number). The identification process is required in any circumstance involving patient interventions e.g., performing procedures (such as inserting a catheter or performing lumbar puncture), before providing treatment (such as administering medication, or blood and blood products) and before any diagnostic procedures (such as taking blood samples or radiological investigations).

When possible, patients are required to be involved in the identification process.

QM.18 The hospital has a process to prevent wrong patient, wrong site, and wrong surgery/procedure.

QM.18.1 There is a process implemented to prevent wrong patient, wrong site, and wrong surgery/procedure during all invasive interventions performed in operating rooms or other locations.

QM.18.2 The process consists of three phases: verification, site marking, and time out.

QM.18.3 A pre-procedure verification of the patient information is carried out including the patient's identity, consent, full details of the procedure, laboratory tests and images, and any implant or prosthesis.

QM.18.4 The surgical/procedural site is marked before conducting the surgery/procedure.

QM.18.4.1 The site is marked especially in bilateral organs and multiple structures (e.g. fingers, toes, and spine).

QM.18.4.2 The site is marked by the individual who will perform the procedure.

QM.18.4.3 The patient is involved in the marking process.

QM.18.4.4 The marking method is consistent throughout the hospital.

QM.18.4.5 The mark is visible after the patient is prepped and draped.

QM.18.5 A final check (time-out) is conducted before the procedure is initiated.

QM.18.5.1 The time-out is conducted in the location where the procedure will be done, just before starting.

QM.18.5.2 The time-out is initiated by a designated member of the team and involves the members of the team, including the individual performing the procedure, the anesthesia providers, and the nurse(s) involved.

QM.18.5.3 The entire procedure team uses active communication during the time out.

QM.18.5.4 During the time-out, the team members agree on the correct patient identity, the correct procedure to be performed, the correct site, and when applicable, the availability of the correct implant or equipment.

QM.18.6 The hospital documents its processes for preventing wrong patient, wrong site, and wrong surgery/procedure.

Standard Intent:

Preventing medical errors is an essential component of patient safety and surgery is an area of health care in which preventable medical errors and near misses can occur. Clinicians must be aware of the surgery-associated injuries, deaths, and near misses and the process to prevent them.

An important aspect in this regard is the process to prevent wrong-site surgery, which encompasses surgery performed on the wrong side or site of the body, a wrong surgical procedure performed, and surgery performed on the wrong patient. This process also includes "any invasive procedure performed in settings other than the operating room.

Hence, all health care facilities should develop and implement policy and procedure to include the three phases of this process (verification, site marking, and time out.) and to ensure its timely documentation in the patient medical record.

QM.19 The hospital ensures availability and safety of infusion pumps.

QM.19.1 Infusion pumps are available with adequate numbers throughout patient care areas.

QM.19.2 Infusion pumps have "free-flow" protection.

QM.19.3 Infusion pumps have documented preventative maintenance, inspection and testing on a regular basis.

Standard Intent:

To assure that fluids and medication are administered in a controlled manner so that all infusions are set to be infused in the ordered prescribed time, infusion pumps should be utilized.

For efficacy and patient safety reasons, a timeframe that infusions are administered is very important to be adhered to. Some infusions need to be given in a very short time while others need to be given over a long period of time.

All healthcare institutions should ensure that there is an adequate infusion pump available in every patient care unit. The available pumps should have the safety function of “free-flow” protection. (Anti-free-flow devices prevent blood from draining from the patient, or infuscate from freely entering the patient when the infusion pump is being set up).

All infusion pumps should have documented regular preventative maintenance, inspection, and testing.

QM.20 The hospital ensures the safety of the alarm systems of patient care equipment.

QM.20.1 All alarm systems for patient care equipment (such as infusion pumps and monitors) have documented preventative maintenance, inspection and testing on a regular basis.

QM.20.2 All staff are trained on the safe use of alarm systems for patient care equipment and the use of appropriate settings for sound.

Standard Intent:

Alarms on clinical devices are intended to call the attention of healthcare providers to patient or device conditions that deviate from a predetermined normal status. These alarms are generally considered to be a key tool in improving the safety of patients. Therefore, from the design perspective alarms should be easy to set, their status (e.g. on/off, limit values) should be easily determined if not directly visible, and the identification of and specificity of a triggered alarm should be clear and easy to determine.

From the user perspective, users must be adequately trained on the safe use of alarm systems for patient care equipment and the use of appropriate settings for sound.

All alarm systems should have documented regular preventative maintenance,

inspection, and testing.

QM.21 The hospital ensures appropriate communication of patient care information during patient handovers.

QM.21.1 Patient care information is appropriately documented in a clearly understandable form to all care providers within and between care settings.

QM.21.2 The hospital implements a standardized approach to handover communication between staff (e.g., Situation, Background, Assessment, Recommendation-SBAR), change of shift, and between different patient care units in the course of a patient transfer.

Standard Intent:

Ineffective communication among health care professionals is one of the leading causes of medical errors and patient harm.

The intent of this standard is to ensure that healthcare institutions develop and implement a process to which patient care information resulted from handover communication between staff is documented in a structured standardized approach (e.g. SBAR).

QM.22 The hospital has a process for effective identification, assessment, and intervention for patients who are at risk for pressure ulcers.

QM.22.1 All patients are assessed for pressure ulcers on admission using a standard risk assessment tool.

QM.22.2 All patients are re-assessed for pressure ulcers every twenty four hours.

QM.22.3 The hospital implements evidence-based interventions that prevent pressure ulcers.

Standard Intent:

Pressure ulcer is one of the most avoidable complications in any healthcare institution. Hence, pressure ulcer risk factors early detection is essential for those at risk of developing pressure ulcers. To ensure the appropriate identification of those risk factors, appropriate patient assessment on admission utilizing appropriate tool is very important, and to be followed by appropriately time-framed re-assessment is essential too that do not exceed 24 hour period.

Pressure ulcer evidenced-based related intervention should be implemented, documented, available and easily accessible to all healthcare staff in any healthcare institution.

QM.23 The hospital has a process for effective identification, assessment, and intervention for patients who are at risk for falling.

QM.23.1 Patients are assessed for the risk of fall on admission.

QM.23.2 Patients are reassessed for the risk of fall after a change in risk factors (e.g., post-operatively, after receiving sedating medications) and upon transfer from another unit.

QM.23.3 The hospital implements evidence-based interventions for falls reduction according to the risks identified.

Standard Intent:

Many injuries in hospitals are related to patient falls. Identification of patient risk of fall plays a major role in decreasing the number of falls. There must be a standard falls risk assessment utilized in the healthcare institution that is specific to age group and setting. Reassessment of the risk of fall situations should be identified by the healthcare institution, disseminated and educated to healthcare providers. Examples of these situations change in risk factor (post-operative after sedating medication), and upon transfer from another unit, after a fall, and others.

In addition, healthcare institution should implement evidenced-based interventions according to the risks identified. These interventions should be, documented, available and accessible to all healthcare staff upon the required need.

QM.24 The hospital implements evidence-based interventions to prevent catheter and tubing misconnections.

QM.24.1 Patients and families are informed not to connect or disconnect devices or infusions.

QM.24.2 High-risk catheters (e.g., epidural, intra-thecal, arterial) must always be labeled.

QM.24.3 All lines (tubes or catheters) are always traced from the patient to the point of origin before connecting any new device or administering medications or infusion.

QM.24.4 All lines (tubes or catheters) are always traced from the patient to the point of origin upon the patient's arrival to a new setting or service as part of the hand-off process. The hospital standardizes this "line reconciliation" process as part of the hand-over communication.

QM.24.5 The hospital prohibits the use of standard luer-connection syringes for oral medications or enteric feedings.

QM.24.6 The hospital conducts acceptance testing (for performance, safety, and usability) and, as appropriate, risk assessment on new tubing and catheter purchases to identify the potential for misconnections and take appropriate preventive measures.

Standard Intent:

Catheter and tubing misconnections can contribute to severe consequences, hence, medications can be administered via the wrong route or catheter can be connected to the wrong equipment or machines.

To assure patient safety and minimize error, patient and family should be informed not

to connect or disconnect infusions. High-risk catheters (e.g. epidural, intrathecal, arterial) must always be labeled. All lines are always traced from the patient to the point of origin before connecting any new device of administering medications or infusion. All lines (tubes or catheters) are always traced from the patient to the point of origin upon the patient's arrival to a new setting or service as part of the hand-off process. The hospital standardizes this "line reconciliation" process as part of the hand-over communication.
To assure oral medications are not administered via any other route, syringes used for oral medication administration should not possess the standard Luer-connection that is used for IV syringes. The process of procurement of all tubings and catheters should go through a standardized process that includes acceptance testing (for performance, safety, and usability) and as appropriate, risk assessment on new tubing catheter to identify the potential for misconnections and take appropriate preventive measures.

QM.25 There is a written policy on verbal or telephone orders and telephone reporting of critical test results.

QM.25.1 The policy defines situations for accepting verbal or telephone orders.

QM.25.2 The policy defines the time frame for orders authentication.

QM.25.3 The policy defines staff who may accept verbal or telephone orders.

QM.25.4 The complete verbal or telephone order or critical test result is written down by the receiver of the order or test result.

QM.25.5 The complete verbal or telephone order or critical test result is read back by the receiver of the order or test result.

QM.25.6 The order or test result is confirmed by the individual who gave the order or test result.

Standard Intent:

Verbal and telephone orders can put patient care at risk if it is not controlled by clear standardized guidelines. To reduce errors and assure patient safety, healthcare institutions should establish comprehensive protocols and guidelines on ensuring effective communication, which is timely, accurate, complete, clear, and understood by the recipient.

Communication-related guidelines should address verbal and telephone orders where situations for accepting verbal or telephone orders are clearly identified, the time frame for orders authentication, staff who may accept verbal or telephone orders.

The whole process of telephone or verbal orders and critical test reporting should include the documentation of the order or the result (writing down by the receiver,

reading back by the receiver, and the confirmation by the individual who gave the order or test result).

Patient & Family Education Standard Intents

PFE.1 Hospital leaders support patient and family education.

PFE.1.1 The hospital develops policies and procedures to ensure effective patient and family education process.

PFE.1.2 There is an appropriate structure and efficient resources for patient/family education throughout the hospital.

PFE.1.3 According to the size of the hospital and its scope of services, the hospital assigns adequate health educators to cover the needs of patient/family education (e.g., diabetic educator, nurse educator).

PFE.1.4 The hospital provides different teaching methods for the health education process such as pamphlets, diagrams, models to practice on, videos, or other teaching methods.

PFE.1.5 The job description of the clinical staff (e.g. nurses, physicians, dietitians) reflects their role in patient/family education.

PFE.1.6 Clinical staff and health educators are knowledgeable about their essential role in patient education.

PFE.1.7 There are discussions of patient education efforts in staff meetings as an integral part of the care process.

Standard Intent:

To increase patient's and family's understanding of the patient's health status, health care options, and consequences of options selected, many different staff in the organization shall educate patients and families. In the course of patient care, every patient/family interaction is an opportunity to educate. So, all staff categories will be involved in the process of patients and families' education. That is why it is important that staff members be knowledgeable about their role in the education process and discussion of educational activities be evident in their different meetings. The hospital should decide how it organizes its educational resources in an efficient and effective manner. Thus, organizations may decide to appoint an education committee or create an education service or unit. Health educators need to be assigned based on the hospital scope of services and high volume services.

PFE.2 The hospital ensures proper communication between the health educator and the patient/family.

PFE.2.1 Patient/family education is provided in an easy language understandable by the patient/family.

PFE.2.2 Sufficient time is provided to allow the patient to understand the information provided and interact with the health educator.

Standard Intent:

The information given to the patient should be appropriate for the patient's age, literacy level, education, and language skills. Patient materials should be geared between sixth- and eight-grade reading levels. Use of medical terminology or jargon should be avoided. The education subjects should be provided in the patient's preferred language and the hospital has to has alternative educational means for the patients with special needs (e.g., sign language for the hearing-impaired patients, and assistance modalities for sight impaired patients).

PFE.3 Each patient's educational needs are assessed and planned.

PFE.3.1 Staff conduct educational needs assessment for every patient by:

PFE.3.1.1 Assessing learning needs.

PFE.3.1.2 Assessing literacy skills.

PFE.3.1.3 Assessing caregiver/patient's readiness and ability to learn.

PFE.3.1.4 Assessing patient's capability and motivation to provide self-care.

PFE.3.1.5 Assessing caregiver/patient's appropriate educational materials and methods that meet their learning skills.

PFE.3.1.6 Assessing who will provide care after discharge (caregiver and/or patient).

PFE.3.2 Staff use the assessment findings for planning and delivery of education as appropriate to the plan of care.

PFE.3.3 Staff provide the caregiver/patient with educational materials that meet their learning skills (e.g. written and verbal notes, pictures, demonstration).

PFE.3.4 When the patient is unable/unsuitable to learn (e.g., comatose, child, mentally disabled), education is provided to the family or the caregiver.

Standard Intent:

Effective education begins with an assessment of the patient and family's learning needs. This assessment determines not only what needs to be learned, but also how the learning can best occur. Learning is most effective when it suits an individual's learning preferences, religious and cultural values, and reading and language skills, and when it occurs at appropriate points in the care process.

The goals of the patient educator are to provide support and information, to correct misconceptions, to assist patient in understanding their role, and to identify learning needs. Next, he starts to set goals and priorities to decide which ones he will teach to his

learner to change his/her behavior. This will provide patient/ family educational plan that shall be integrated in the overall plan of care. This plan serves as the blueprint for the patient and family education activities used by the Interdisciplinary health care team members.

Family members are the vital links in the transition from hospital to home care or will be the primary target of the education process in case of patients unable/unsuitable to learn. Families must be included in discussions and demonstrations. Family is any person who plays an important role in the patient's life.

PFE.4 Patients and their families receive education to help them give informed consent, participate in care process, and understand any financial implications of care choices.

PFE.4.1 Patients and families are educated about informed consent.

PFE.4.2 Patients and families are educated about participation in the care process and decisions.

PFE.4.3 Patients and families are educated about any financial implications of care decisions.

Standard Intent:

Patient participation means involvement of the patient in decision making or expressing opinions about different treatment methods, which includes sharing information, feelings, and signs and accepting health team instructions. Given the importance of patient participation in healthcare decision making which empowers patients and improves services and health outcomes, the hospital needs to educate the patient and family to participate in decision making about health care options. Education provided as part of the process of obtaining informed consent for treatment is an example of patient participation in the care process. Education is also provided to support other care decisions of patients and families. On occasion, such as when the patient and family will bay for care, it is important that they are educated about the financial implications associated with care choices, to decide whether to proceed with the plan provided or to choose another alternative.

PFE.5 Patients and their families are given the necessary education and information by clinical staff and health educators as appropriate to their needs.

PFE.5.1 The hospital provides the patient with the necessary education and information about the primary illness and all possible complications.

PFE.5.2 The hospital provides the patient with the necessary education and information about infection control practices, adding emphasis on basic hand washing.

PFE.5.3 The hospital provides the patient with the necessary education and information about the required treatments and procedures.

PFE.5.4 The hospital provides the patient with the necessary education and information about the appropriate and safe use of the medical equipment or appliances.

PFE.5.5 The hospital provides the patient with the necessary education and information about any surgical procedure needed and its benefits and potential risks.

PFE.5.6 The hospital provides the patient with the necessary education and information about the pre-operative preparations needed and their importance.

PFE.5.7 The hospital provides the patient with the necessary education and information about post-operative care (e.g., breathing exercises, diet, and wound care).

PFE.5.8 The hospital provides the patient with the necessary education and information about the necessary medications, the frequency, potential side effects, and food-drug interactions.

PFE.5.9 The hospital provides the patient with the necessary education and information about radiological procedures, their benefits, and the potential risks involved.

PFE.5.10 The hospital provides the patient with the necessary education and information about the rational and benefits of any dietary restrictions.

PFE.5.11 The hospital provides the patient with the necessary education and information about the conditions in which the patient needs to seek medical assistance and how to access it if necessary.

PFE.5.12 The hospital ensures that the patient has his follow up clinic appointments.

PFE.5.13 The hospital provides the patient with the necessary education and information about how to carry out activities of daily living.

PFE.5.14 The hospital provides the patient with the necessary education and information about community resources for additional care and how to access emergency services if necessary.

PFE.5.15 The hospital ensures that the patient can always state the name of his most responsible physician.

Standard Intent:

The organization routinely provides education in areas that carry high risk to patients. Education supports the return to previous functional levels and maintenance of optimal health. Education includes both the knowledge needed during the care process and the knowledge needed after the patient is discharged to another care site or home. Thus, education can include information on community resources for additional care and required follow-up care and how to access emergency services if necessary. The organization uses different educational methods and processes to educate patients and their families on at least the topics highlighted in the standard.

PFE.6 The patient/family education is evaluated for effectiveness.

PFE.6.1 Clinical staff and health educators obtain feedback from the patient and/or family to ensure proper understanding (e.g., demonstrates learning, verbalizes understanding).

Standard Intent:

The patient's and family's understanding of learning needs shall be continually evaluated by members of the health care team. Evaluating learning objectives can be done via return demonstration and/or verbal discussion/follow-up care. When behavioral objectives are not met, revision of the educational plan with alternate educational strategies are utilized and re-evaluated by members of the health care

PFE.7 All patient education activities are documented in the patient's medical record.

PFE.7.1 The educational needs assessment and planning is documented in the patient's medical record.

PFE.7.2 The patient's response to education is documented in the patient's medical record.

Standard Intent:

When teaching takes place, all instructions should be documented as soon as they are given include who the learner was - the patient and/or a family member, the needs assessment, the educational plan, and the patient response. The documentation should be evident in the patient's medical record with clear identification of the staff member/s involved in the education process.

Patient & Family Education and Rights Standard Intents

Anesthesia Care Standard Intents

AN.1 Qualified anesthesiologist is responsible for managing anesthesia services in the hospital.

AN.1.1 The head of the department of anesthesia is a qualified anesthesiologist by education, training, and experience.

AN.1.2 The head of the department of anesthesia supervises the development and implementation of policies and procedures related to anesthesia practices throughout the hospital.

AN.1.3 The head of the department of anesthesia enforces the implementation of infection control guidelines inside the operating and recovery rooms.

Standard Intent:

Anesthesia services are under the direction of an individuals who is qualified by documented training, expertise, and experience, consistent with applicable laws and regulations. This individual assumes professional responsibility for the anesthesia services provided that includes:

- Developing, implementing, and maintaining policies and procedures;
- Administrative oversight;
- Maintaining any necessary quality control program;
- Recommending outside sources of anesthesia services (including moderate and deep sedation)
- Monitoring and reviewing all anesthesia services (including moderate and deep sedation).

AN.2 Anesthesia staff members have the appropriate qualifications.

AN.2.1 Qualified anesthesiologists provide anesthesia services.

AN.2.2 Qualified anesthesiologist is present inside the operating room throughout the operation.

AN.2.3 Anesthesia consultant administers and supervises anesthesia for major/specialized operations or high risk patients, including:

AN.2.3.1 Pediatric operations.

AN.2.3.2 Cardio-pulmonary operations.

AN.2.3.3 Neurosurgery operations.

AN.2.3.4 Transplant operations.

AN.2.4 Anesthesia staff are certified in advanced life support as appropriate to the patient's age.

Standard Intent:

Anesthesia staff is qualified by documented training, expertise, and experience, consistent with applicable laws and regulations. Anesthesia consultant administers and supervises anesthesia for major/specialized operations or high-risk patients, including:

- Pediatric operations
- Cardio-pulmonary operations.
- Neurosurgery operations.
- Transplant operations.

AN.3 Policies and procedures guide the provision of anesthesia care.

AN.3.1 Policies and procedures include, but are not limited to, the following:

AN.3.1.1 Staff responsibilities in the provision of anesthesia care.

AN.3.1.2 Pre-anesthesia and pre-induction assessments.

AN.3.1.3 Intra-operative monitoring of anesthetized patients.

AN.3.1.4 Safe handling and storage of anesthetic medications/ agents.

AN.3.2 Policies are collaboratively developed with other relevant disciplines (e.g., surgery, nursing, and laboratory).

Standard Intent:

Provision of anesthesia care guided by policies and procedures developed collaboratively with other relevant disciplines (e.g., surgery, nursing, and laboratory) to include the staff responsibilities, patient assessments, monitoring during anesthesia and handling of anesthesia agents.

AN.4 The provision of anesthesia care is guided by the required equipment and anesthesia products.

AN.4.1 There is a multifunctional anesthesia machine and all other equipment required to meet the needs of patients, including equipment and tools required for difficult intubation.

AN.4.2 Anesthesia machines are regularly checked and maintained as evidenced by a readily accessible record of preventive maintenance.

Standard Intent:

Provision of anesthesia care guided by the required equipment and anesthesia products to meet the needs of patients and are regularly checked and maintained as evidenced by a readily accessible record.

AN.5 Sufficient information is communicated to the patient prior to administration of anesthesia to help making an informed decision.

AN.5.1 Informed consent for anesthesia is obtained from the patient/family after explaining the anesthesia plan, risks, benefits, and alternatives.

AN.5.2 The consent process is documented and witnessed.

Standard Intent:

When the planned care includes surgical or invasive procedures, anesthesia consent is obtained. This consent process provides the information of the anesthesia plan, risks, benefits, and alternatives and documents the identity of the individual providing the information and witness.

AN.6 Pre-anesthesia assessment and anesthesia planning are conducted for each patient prior to any inpatient or outpatient surgery/procedure, by an individual qualified to administer anesthesia.

AN.6.1 The pre-anesthesia assessment should be completed and dated in less than thirty days prior to the scheduled surgery/procedure date. A review and update of the patient's current condition is documented in the medical record before conducting the procedure.

AN.6.2 The pre-anesthesia assessment includes:

AN.6.2.1 Patient interview and physical examination, including airway assessment and limited intra-vascular access.

AN.6.2.2 Medical history including anesthesia, drug and allergy history.

AN.6.2.3 Other additional pre-anesthesia evaluation if applicable and as required in accordance with the standard practice prior to administering anesthesia (e.g., stress tests or additional specialist consultations).

AN.6.2.4 Notation of anesthesia risk according to established standards of practice (ASA classification).

AN.6.2.5 Anesthetic plan and discussion of the risks and benefits.

AN.6.2.6 Documentation of an informed consent.

AN.6.2.7 Appropriate pre-medication and prophylactic antibiotic orders (if indicated).

AN.6.3 The anesthesiologist reassesses the patient immediately prior to induction of anesthesia focusing on the physiologic stability and readiness of the patient for anesthesia. Findings are documented in the patient's medical record.

Standard Intent:

Patients planned to have anesthesia should have a pre-anesthesia assessment performed by an anesthetist. The assessment should be less than 30 days old prior to the procedure and should be based on the elements of the substandard AN.6.2.1 through AN.6.2.7. In addition to the documented pre-anesthesia assessment, the anesthetist performing the procedure should perform and document an immediate pre-induction assessment to ensure the physiological stability of the patient at the time.

AN.7 There is an anesthesia record for documentation of planned anesthesia care.

AN.7.1 The planned anesthesia care is documented in anesthesia record for each patient during anesthesia. The following information must be documented:

AN.7.1.1 Age, sex, weight, height, and pre-operative vital signs.

AN.7.1.2 The anesthetic agent.

AN.7.1.3 The dosage, time, and route of administration of all medications and anesthetic agents used.

AN.7.1.4 The techniques used to administer the anesthesia.

AN.7.1.5 If blood is used, the amount of blood, rationale for administration, and the time given.

AN.7.1.6 Investigations carried out e.g. blood glucose, blood gases.

AN.7.1.7 Unusual events or complications.

AN.7.1.8 The patient's status at the end of the procedure.

AN.7.1.9 Intravenous fluids given.

AN.7.1.10 The anesthesiologist and anesthesia assistant(s).

Standard Intent:

The planned anesthesia care must be documented in the patient`s medical record and includes important history and physical examination related information as well as the anesthetic agent, the techniques used to administer the anesthesia, the amount of blood and fluids used, and the name of staff performing the anesthesia. At a minimum the information mentioned in substandard AN.7.1.1 through AN.7.1.10 must be documented.

AN.8 The patient's physiological status is continuously monitored and documented during anesthesia.

AN.8.1 There is a policy and procedure for monitoring of patients during anesthesia (type and frequency).

AN.8.2 The patient's physiological status is continuously monitored and documented during anesthesia.

Standard Intent:

Physiological monitoring provides reliable information about the patient's status during anesthesia period. Monitoring methods depend on the patient's pre-anesthesia status, anesthesia choice, and complexity of the surgical or other procedure performed during anesthesia. In all cases, however, the overall monitoring during anesthesia is a continuous process, and the results are written into the patient's record.

AN.9 Post-anesthesia patients are safely transported to the recovery room.

AN.9.1 Patients transported to the recovery room shall be accompanied by a qualified member of the anesthesia care team.

AN.9.2 The patient shall be continually evaluated and treated during the transport with monitoring and support appropriate to the patient's condition.

AN.9.3 Upon arrival to the recovery room, the patient is properly handed over and re-evaluated.

AN.9.4 The patient's status and time of arrival to the recovery room are documented.

Standard Intent:

Post-anesthesia patients are safely transported to the recovery room under the supervision of a qualified staff. Physiological monitoring must be carried out during transfer till the patient is handed over and re-evaluated. The overall monitoring process, and the results must be documented in the patient's record.

AN.10 Qualified staff members provide post-anesthesia care in the recovery room.

AN.10.1 Qualified anesthesiologist is in charge of the recovery room at all times.

AN.10.2 Qualified staff members provide post-anesthesia care in the recovery room.

Standard Intent:

Qualified anesthesiologist should be in charge of the recovery room. The post-anesthesia care in the recovery room must be provided by a qualified member of staff.

AN.11 Post-anesthesia patients are continuously monitored and managed in the recovery room.

AN.11.1 A policy defines the monitoring requirements for patients during post-anesthesia phase.

AN.11.2 There is a recovery from anesthesia record for documentation of monitoring findings and services provided in the recovery room.

Standard Intent:

There must be a policy that defines the continuous monitoring and management of patients in the recovery room and its documentation in the patient medical record.

AN.12 Patients are safely discharged from the recovery room.

AN.12.1 There are written criteria for the discharge of patients from the recovery room.

AN.12.2 Staff in the recovery room are familiar with the discharge criteria.

AN.12.3 Patients are discharged from the recovery room when the discharge criteria are met.

AN.12.4 Patients are discharged from the recovery room by a qualified anesthesiologist or another qualified individual.

AN.12.5 Time of discharge from the recovery room and the handover process to unit staff are documented.

Standard Intent:

Discharge from the post-anesthesia recovery areas or discontinuation of recovery monitoring must be carried out by a fully qualified anesthesiologist according to an approved criterion. The time of discharge and the handover process to the unit must be documented in the patient medical record.

AN.13 Moderate and deep sedation/analgesia are performed only in areas identified in a hospital policy.

AN.13.1 The hospital identifies in a policy where moderate and deep sedation/analgesia are performed.

AN.13.2 The areas where moderate and deep sedation/analgesia are performed have adequate equipment and supplies that include at a minimum:

AN.13.2.1 Wall suction or suction machine.

AN.13.2.2 Oxygen source.

AN.13.2.3 Pulse oximetry.

AN.13.2.4 Automated blood pressure monitor or means of taking blood pressure.

AN.13.2.5 ECG Monitor.

AN.13.2.6 Crash cart with defibrillator, medications, IV access, and intubation equipment that is appropriate to the age of the patient.

Standard Intent:

Sedation—in particular, moderate and deep sedation—poses risks to patients and thus needs to be provided in areas identified in a hospital policy. These approved and privileged areas must include but not limited to:

- Wall suction or suction machine.
- Oxygen source.
- Pulse oximetry.
- Automated blood pressure monitor or means of taking blood pressure.
- ECG Monitor

AN.14 There are policies and procedures for moderate and deep sedation/analgesia in the hospital.

AN.14.1 Policies are collaboratively developed and approved by the head of anesthesia in collaboration with relevant disciplines.

AN.14.2 Policies for moderate and deep sedation/analgesia identify the permissible medications, dosage, route of administration, reversal agents and pediatric considerations.

AN.14.3 Moderate and deep sedation/analgesia is only used for patients having short diagnostic or therapeutic procedures.

Standard Intent:

The organization must have a policy for providing anesthesia services (including moderate and deep sedation) collaboratively developed and approved by the head of anesthesia in collaboration with relevant disciplines. The policy must clearly state the type of anesthesia, the medications used and fact that deep sedation is only used for patients having short diagnostic or therapeutics procedures.

AN.15 Qualified staff perform moderate and deep sedation/analgesia.

AN.15.1 Physicians who perform moderate and deep sedation/analgesia have competency-based privileges granted to perform moderate and deep sedation/analgesia.

AN.15.2 Clinical staff who participate in caring for patients receiving moderate or deep sedation are certified in advanced life support as appropriate to the age of the patients served.

AN.15.3 Clinical staff who participate in conducting sedation must successfully complete a proper education/training on moderate and deep sedation.

Standard Intent:

The physician or dentist responsible for the patient receiving moderate and deep sedation must be qualified and have competency-based privileges. They must be certified in advanced life support as appropriate to the patient's age and successfully complete education/training on moderate and deep sedation.

AN.16 Patients going for procedures under moderate or deep sedation are properly prepared.

AN.16.1 Informed consent is obtained after the physician educates the patient regarding the risk and benefits of the sedation and the consent is signed by the patient, guardian, or next of kin if the patient is unable to sign.

AN.16.2 An intravenous access is inserted and maintained until the patient is fully recovered.

Standard Intent:

All patients going for procedures under moderate or deep sedation should sign an informed consent is obtained after the physician educates them regarding the risk and benefits of the sedation. An intravenous access must be inserted and maintained until the patient is fully recovered. ?

AN.17 A pre-moderate and deep sedation/analgesia assessment is completed by a qualified physician.

AN.17.1 The pre-sedation assessment is performed by a qualified physician and includes:

AN.17.1.1 History and physical examination.

AN.17.1.2 History of medication allergy and adverse experience with sedation and analgesia as well as with anesthesia.

AN.17.1.3 History of systemic illness or major organ impairment.

AN.17.1.4 Verification of the patient (NPO) status.

AN.17.1.5 American Society of Anesthesiologists (ASA) physical status class.

AN.17.1.6 Vital signs.

AN.17.1.7 Age and weight.

AN.17.1.8 ECG findings.

AN.17.2 The pre-sedation assessment is documented in the patient's medical record.

Standard Intent:

The pre-moderate and deep sedation assessment must be carried by a qualified physician and documented in the patient medical record. The assessment includes:

- History and physical examination.
- History of medication allergy and adverse experience with sedation and analgesia as well as with anesthesia.
- History of systemic illness or major organ impairment.
- Verification of the patient (NPO) status.
- American Society of Anesthesiologists (ASA) physical status class.
- Vital signs.
- Age and weight.

AN.18 Patients are continuously monitored during and after moderate and deep sedation/analgesia.

AN.18.1 Patients are monitored during and after moderate and deep sedation/analgesia, including the following parameters:

AN.18.1.1 Vital signs.

AN.18.1.2 Oxygen saturation.

AN.18.1.3 Skin color.

AN.18.1.4 Level of consciousness/response to stimuli.

AN.18.1.5 ECG findings.

AN.18.2 Patient monitoring is continued during the recovery period until the patient is stable and adequate function is restored.

AN.18.3 Findings of monitoring are documented in the patient's medical record.

AN.18.4 The patient is always attended by a physician and nurse during and immediately after procedures involving moderate and deep sedation/analgesia.

Standard Intent:

Monitoring of patients receiving moderate and deep sedation is a continuous process that extends to the complete recovery from sedation. Monitoring findings must be documented in the patient medical record. It includes but not limited to the following:

- Vital signs.
- Oxygen saturation.
- Skin color.
- The level of consciousness/response to stimuli.

- ECG findings.

The patient is always attended by a physician and a nurse at all times.

AN.19 Patients who have received moderate or deep sedation are safely discharged.

AN.19.1 There are written criteria for the discharge of patients recovered from moderate or deep sedation.

AN.19.2 Patients are discharged when the criteria are met.

AN.19.3 When patients are transferred back to the unit:

AN.19.3.1 Patients are discharged to the unit by a qualified physician.

AN.19.3.2 The physician writes a follow up instructions for the nurses.

AN.19.4 When patients are directly discharged home:

AN.19.4.1 The physician writes a discharge order.

AN.19.4.2 Patients are discharged in the company of a responsible adult who assumes responsibility and is capable of taking care of the patient.

AN.19.4.3 Patient/family education and follow-up care instructions are provided prior to discharge.

Standard Intent:

Safe patient discharge from moderate or deep sedation recovery must be by a qualified physician according to an approved criterion. Patient/family education and follow-up care instructions are provided prior to discharge.

Operation Room Standard Intents

OR.1 Qualified individual directs the operating room.

OR.1.1 The operating room is directed by a qualified medical staff (e.g., surgical or anesthesia staff).

Standard Intent:

The operating room requires a director who run the day to day work as well as all other related activities. This person may be a surgeon or anesthesiologist based on job description requirements with management and clinical background with decision making authorities.

OR.2 Qualified nurse manager supervises nursing services in the operating room.

OR.2.1 The nurse manager in charge of the operating room is a qualified registered nurse with training, education, and experience in operative care.

OR.2.2 The nurse manager of the operating room develops and collaborates with other disciplines for developing all required and related policies and procedures.

Standard Intent:

Operation theatre is one of the critical clinical areas in the health care institute, nurse manager of operation room should be licensed nurse by local licensing body and have comprehensive training on surgical operation with clinical experience in operation room based on the requirement of job description. The person must develop and collaborates with other disciplines for developing all required and related policies and procedures.

OR.3 The nurse manager ensures the competency of the nursing staff.

OR.3.1 The nursing staff receive ongoing training on the following general and operating room- related needs:

- OR.3.1.1 Use of equipment.
- OR.3.1.2 Use of defibrillator.
- OR.3.1.3 Use of pulse oximetry.
- OR.3.1.4 Infection control.
- OR.3.1.5 Blood transfusion.
- OR.3.1.6 Central sterilization policy.
- OR.3.1.7 Maintenance of a sterile field.
- OR.3.1.8 Draping and gowning.
- OR.3.1.9 Surgical table operation and safe positioning of patients.
- OR.3.1.10 Assistance in operations of their specialty surgical area.
- OR.3.1.11 Pre and post-procedural handling and disposing of surgical equipment.
- OR.3.1.12 Safe operation of variable surgical equipment according to specialty.

OR.3.2 Nursing staff competencies are assessed by using different methods (e.g. written test, return demonstration).

Standard Intent:

Nursing staff working in the operating room should be competent and skillful to carry out all nursing care activities carried out inside the operating room. The measurement of their competency should be implemented through a comprehensive program that is based on written examination to ensure that the staff has the knowledge, also, there should be training on the skills and return demonstration by nurse manager to be sure that all the staff are meeting the requirements of operating theatre nurse. Substandard OR.3.1.1 through OR.3.1.12 highlights the minimum required competencies.

OR.4 Patients who are admitted for surgery have medical assessment performed and plan of care documented prior to surgery.

OR.4.1 Prior to surgery, the most responsible physician performs medical assessment and ensures documentation of the following:

OR.4.1.1 History and physical examination.

OR.4.1.2 Pre-operative diagnosis.

OR.4.1.3 Diagnostic tests (laboratory, radiology, etc.) as ordered.

OR.4.1.4 Signed informed consent.

OR.4.1.5 Planned procedure.

OR.4.2 In emergency situations where a complete medical assessment cannot be documented, a brief note is written by the most responsible physician.

Standard Intent:

The most responsible physician must perform medical assessment and document in the patient medical record. The assessment should include history and physical examination, preoperative diagnosis, diagnostic tests (laboratory, radiology, etc.) as ordered, signed informed consent and planned procedure. In a case of an emergency situation where a complete medical assessment cannot be documented, a brief note is written by the most responsible physician.

OR.5 Policies and procedures guide the care of patients in the operating room.

OR.5.1 Policies and procedures guide the care of patients in the operating room. This includes, but is not limited to, the following:

OR.5.1.1 Handover process between unit nurse and operating room nurse and operating room reception.

OR.5.1.2 Prevention of wrong patient, wrong surgery/procedure, or wrong site.

OR.5.1.3 Infection control measures in operating room and recovery room including isolation precautions.

OR.5.1.4 Handling patients with infectious diseases (e.g. Tuberculosis, AIDS, and Hepatitis).

OR.5.1.5 Equipment daily checks and periodic maintenance.

OR.5.1.6 Environmental controls in operating room and recovery room.

OR.5.1.7 Safe labeling, handling, storage and transportation of laboratory specimens in operating and recovery rooms.

OR.5.1.8 Safe handling, storage and transportation of commonly used chemicals in operating and recovery rooms.

OR.5.1.9 Safe handling, transportation and storage of blood in operating and recovery rooms.

OR.5.2 Policies are collaboratively developed with operating room nurses, anesthesia staff, surgeons, and laboratory staff as per level of involvement.

Standard Intent:

Availability of multidisciplinary policies and procedures to guide the care in operating room. Policies must outline all aspects of safe care to patients such as observing the implementation of the international patient safety goals, infection control measures, equipment daily checks, handling laboratory specimens, chemical and blood (as in substandard OR.5.1.1 through 5.1.9)

OR.6 There is a policy for patient acceptance into the operating room.

OR.6.1 There is a policy for accepting patients in the operating room that mandates the following:

OR.6.1.1 Patient identification by name and medical record number as listed on the patient's ID band.

OR.6.1.2 The consent form is checked for completion.

OR.6.1.3 The operation/ procedure and the surgeon's name are checked.

OR.6.1.4 The site of surgery and its preparation and whether it is marked or not are checked.

OR.6.1.5 The laboratory and radiology results and pregnancy test as appropriate are checked.

OR.6.1.6 The pre-anesthesia sheet is checked for completion.

OR.6.1.7 The history and physical examination are checked for documentation.

OR.6.1.8 The requisition for blood is verified to ensure blood is reserved in the blood bank, if needed.

OR.6.2 The policy is collaboratively developed by the head of surgery, head of anesthesia, and the nurse manager.

Standard Intent:

Accepting patient in OR is vital aspect of patient care because it ensures that the nurse is receiving right patient for right procedure and all patient information and operation requirement are completed prior sending patient to the operative room. Hospital should

establish specific criteria that known to all operative room staff (substandard OR.6.1.1 through 6.1.8)

OR.7 The hospital has a process to prevent inadvertent retention of instruments or sponges in surgical wounds.

OR.7.1 The hospital develops and implements a policy and procedure to prevent inadvertent retention of instruments or sponges in surgical wounds.

OR.7.2 The count process includes instruments, sharps, sponges, and others as applicable.

OR.7.3 The policy addresses procedures that are exempted from the counting process (e.g., cataract, cystoscopy).

OR.7.4 The count process is standardized.

OR.7.5 The policy addresses the procedure to follow in case of a count discrepancy.

OR.7.6 The count process is documented in the count sheet.

Standard Intent:

Instruments and sponge counting is very important procedure that should be conducting throughout the surgery to ensure that no items are missing or left inside incision. The policy should outline steps of counting and action to be taken in case any item gets missing during the procedure (Substandard OR.7.1 through OR.7.6).

OR.8 The hospital develops and implements a policy for day surgery cases.

OR.8.1 The policy defines the types of surgical procedures that are performed as “day surgery”.

OR.8.2 The policy addresses the categories of patients who are not candidates for day surgery.

OR.8.3 The policy defines a process for patients who have to be admitted to the hospital from the day surgery unit.

OR.8.4 The most responsible physician writes a discharge order.

OR.8.5 Patients are discharged in the company of a responsible adult who assumes responsibility and is capable of taking care of the patient.

OR.8.6 Patient/family education and follow-up care instructions are provided prior to discharge.

Standard Intent:

Day surgery is vital in any hospital as it play role in decreasing bed occupancy rate, however, the day care practice should have policies and procedure that control cases that admitted for day surgery procure, admission and discharge criteria to ensure maximum benefits to patients.

OR.9 An operative report is documented immediately after the surgery/procedure.

OR.9.1 There is always an operative report that includes:

OR.9.1.1 Pre and post-operative diagnosis.

OR.9.1.2 The name of the surgeon and assistants.

OR.9.1.3 The operation/procedure performed.

OR.9.1.4 Description of the surgery/procedure and findings.

OR.9.1.5 Presence or absence of intra-operative complications.

OR.9.1.6 Surgical specimens removed and sent to histopathology.

OR.9.1.7 Amount of blood loss.

OR.9.2 The operative report is documented before the patient leaves the recovery room to support the continuity of patient care.

OR.9.3 The operative report is signed/authenticated by the surgeon performing the procedure.

Standard Intent:

Operating room should have a policy that control pre, intra, and post procedure documentation. An operative report should be completed before the patient transferred from the room in order to ensure that patient information, surgeon name, samples taken and purpose for it, any complication that occurred during operation are documented elements of substandard OR.9.1.1 through OR.9.1.7). The operative report can be completed by the surgeon or his assistant. If the assistant surgeon is the one who wrote the operative report the principle surgeon (MRP) should review the report and co-sign it in order to ensure that all information included is correct.

OR.10 Tissues removed during surgery are sent for pathologic examination.

OR.10.1 Tissues or specimens removed during surgery have pathological examination unless exempted by a hospital policy.

OR.10.2 Surgical specimens are accurately identified.

OR.10.3 The report of the examination is signed by the pathologist and made part of the medical record.

Standard Intent:

The operative room has a policy that controls all surgical specimen that taken during operation, how to label these specimens and by whom, what type of pathological examination requested, and if a report generated for this examination is should be signed by the authorized pathologist. This specimen must be correctly identified to ensure sending the right specimen for the right patient.

OR.11 Each patient has a post-operative plan of care.

OR.11.1 A post-operative plan of care is written by the responsible surgeon.

OR.11.2 The post-operative plan of care includes:

OR.11.2.1 Post-operative monitoring parameters and its frequency.

OR.11.2.2 Wound care.

OR.11.2.3 Care of drains and catheters.

OR.11.2.4 Special patient positioning requirements.

OR.11.2.5 Nutritional instructions.

OR.11.2.6 When to start mobilization.

OR.11.2.7 Special referrals (e.g. physical therapy, respiratory therapy)

OR.11.2.8 A new order for all required medications.

OR.11.2.9 Any other post-operative care needed including required follow up.

OR.11.3 The post-operative plan of care is available in the patient's medical record before discharge from recovery.

OR.11.4 Each patient is assessed after surgery and reassessed at intervals appropriate to the patient's condition.

OR.11.5 Medical, nursing, and other care plans are documented in the patient's medical record.

Standard Intent:

A postoperative plan should be written by the surgeon immediately after the surgery and before discharging the patient from the recovery unit. The plan should include the elements of the substandard OR.11.2.1 through OR.11.2.9. Patients' reassessment after surgery by all disciplines should follow the standards of practice, in line with the postoperative plan written by the surgeon

OR.12 Adequate pain relief is provided for patients after surgery.

OR.12.1 Pain is assessed by the most responsible physician or his designee after surgery.

OR.12.2 Pain medications are adjusted according to the patients' response.

Standard Intent:

Pain assessment/ reassessment should be implemented post-surgery and the MRP or assistance surgeon should be notified in order to prescribe pain killer and adjust dose according to the findings.

OR.13 The hospital has appropriate measures against fires in the operating room.

OR.13.1 The operating room has a fire safety plan.

OR.13.2 The operating room staff are aware of the fire triangle: ignition sources, oxidizers, and fuels.

OR.13.3 The operating room staff are trained on the identification and location of medical gases, ventilation and electrical systems and controls, as well as when, where and how to shut off these systems.

OR.13.4 There are proper methods for rescue and escape.

OR.13.5 Staff participate in fire drills.

OR.13.6 There are fire-fighting equipment.

OR.13.7 Anesthesia staff determine the safe concentration of oxygen for open delivery during facial surgery.

OR.13.8 Patients are not draped until all flammable preps have dried.

OR.13.9 When performing electro-surgery, electro-cautery or laser surgery, electro-surgical instruments are placed in a holster or another location off the patient when not in active use and lasers are placed in standby when not in active use.

Standard Intent:

Operative room has special work environment as most of the patient in under anesthesia, connected to mechanical ventilator which prevents fast evacuation of them in case of fire adding to that all the rooms have medical gas connection. Operative room should have special fire safety plan and all staff are trained based on this plan which ensure that they know how to act in case of fire for closing of medical gas valves' evacuating patient and rescue any victim. The staff should be trained to deal with electrical surgical instrument used inside operative room.

OR.14 Infection prevention and control standards are strictly implemented and supervised in the operating room.

OR.14.1 The operating room environment is maintained clean at all times.

OR.14.2 The use of storage cabinets in operating rooms is minimized.

OR.14.3 There is a policy for traffic control in the operating room.

OR.14.4 The operating room is maintained at positive pressure with respect to corridors.

OR.14.5 Records of pressure monitoring should be available in the operating rooms.

OR.14.6 More than (15) air changes per hour are maintained in the operating rooms.

OR.14.7 Air is introduced near the ceiling and exhausted near the floor.

OR.14.8 All re-circulated or fresh air should be filtered through High-Efficiency Particulate Air (HEPA) filters that are maintained and frequently replaced as per the manufacturer recommendation.

OR.14.9 Only operating room scrub clothing is allowed inside the restricted areas of the operating room.

OR.14.10 Scrubbing sinks are available at the entry of the operating room.

OR.14.11 Standard precautions are strictly implemented in the operating room with special emphasis on hand hygiene and the appropriate use of gloves, gowns, masks, and other barriers.

OR.14.12 There are clear procedures for cleansing and disinfecting operating rooms by housekeeping after surgical procedures.

OR.14.13 There are clear procedures for cleaning and disinfecting anesthesia machines after each case and toward the end of working hours by anesthesia technicians.

OR.14.14 The storage area of the operating room is well maintained with respect to the infection prevention and control standards.

OR.14.15 The waste management maintains safety of patients and healthcare workers.

OR.14.16 Patients with transmissible diseases are handled properly inside the operating rooms.

OR.14.16.1 Infected cases are scheduled towards the end of the operating list.

OR.14.16.2 There is an implemented policy to handle patients with air-borne transmitted disease inside the operating room.

OR.14.16.3 There is an implemented policy for contact and droplet transmission-based precaution in the recovery room.

Standard Intent:

Operative theatre staff should have special training on infection prevention and control. The aseptic nature of operative theatre urges the staff to monitor and implement all infection control standards inside the unit and not allowing any violence because this will reflect negatively on the patients' health status post-surgery. Operative room mangers with infection control should monitor infection control practice and correct any violations.

Adult Intensive Care Unit Standard Intents

ICU.1 Qualified physician is responsible for managing the adult intensive care unit.

ICU.1.1 The adult intensive care unit is directed by a physician qualified in critical care medicine by education, training, and experience.

ICU.1.2 The unit head takes the overall responsibility for the operation of the unit.

Standard Intent:

The clinical care, patient outcomes, and overall management of the ICU require a person who is qualified in critical care by education, training and experience. The director takes the overall responsibility of the unit.

ICU.2 The adult intensive care unit nurse manager is a qualified registered nurse.

ICU.2.1 The nurse manager is a registered nurse qualified by education, training and, experience in managing critically-ill patients.

ICU.2.2 The nurse manager develops and collaborates with other departments as needed for developing policies and procedures for the unit (e.g., policies and practices related to infection control).

Standard Intent:

The clinical care, patient outcomes, and overall management of a hospital are only as good as the clinical and managerial activities of each individual department or service. Good departmental or service performance requires clear leadership from a qualified individual by education, training and experience.

ICU.3 The adult intensive care unit is covered by qualified medical and nursing staff.

ICU.3.1 The intensive care unit is covered by physicians qualified in managing critically ill patients twenty-four hours a day, seven days a week.

ICU.3.2 Medical staff working in the adult intensive care unit are certified in advanced cardiac life support (ACLS) and are trained on fundamental critical care support.

ICU.3.3 Nursing staff working in the adult intensive care unit are certified in advanced cardiac life support (ACLS).

Standard Intent:

There are qualified staff members (physician and nurses) in ICU to provide safe and effective care and treatment to patients in ICU all the times during the day. Education, background, experience, training, and/or certification must be consistent with the scope of services in ICU, the population served, with the needs of patients.

ICU.4 The adult intensive care unit has admission and discharge criteria.

ICU.4.1 The adult intensive care unit identifies its own population based on age and diagnosis related groups.

ICU.4.2 The admission and discharge criteria are defined in writing.

ICU.4.3 The criteria for admission are based on physiological parameters.

ICU.4.4 The criteria are developed collaboratively between relevant staff.

ICU.4.5 In an open ICU setting, the Most Responsible Physician (MRP) is the admitting consultant whereas in a closed ICU setting, the MRP is a member of the medical staff in the ICU.

Standard Intent:

Managing the patient in intensive care units are costly and usually are limited in space and staffing, hospitals may restrict admission to only those patients with reversible medical conditions. To ensure consistency, the criteria should be physiologic-based and developed collaboratively between the relevant ICU staff. The criteria are used to determine direct entry to the unit; for example, directly from the emergency department. The criteria are also used to determine admission into the unit from within the hospital or from outside the hospital (such as when a patient is transferred from another hospital).

ICU.5 The adult intensive care unit has an effective handover process.

ICU.5.1 There is a documented evidence of handover between physicians at change of shift.

ICU.5.2 There is a documented evidence of handover between nurses at change of shift.

ICU.5.3 There is a documented evidence of handover between intensive care nurse and the unit/ward nurse at the time of transfer to a lower acuity of care.

Standard Intent:

Effective communication, which is timely, accurate, complete, unambiguous, and understood by the recipient, reduces errors and results in improved patient safety. Breakdowns in communication can occur during any handover of patient care and can result in adverse events, background noises, interruptions, and other distractions from unit activities can inhibit clear communication of important patient information. Standardized, critical content for communication between the patient, family, caregiver, and health care providers can significantly improve the outcomes related to handovers of patient care. Handovers of patient care within a hospital occur

- Between health care providers, such as between physicians and other physicians or health care providers, or from one provider to another provider during shift changes;
- Between different levels of care in the same hospital such as when the patient is moved from an intensive care unit to a medical unit or from an emergency department to the operating theatre; and

From inpatient units to diagnostic or other treatment departments, such as radiology or physical therapy.

ICU.6 Patient care in the adult intensive care unit is provided using a multidisciplinary approach.

ICU.6.1 The multidisciplinary team includes both ICU as well as non ICU members. This includes but is not limited to: ICU physician, ICU nurse, clinical pharmacist, respiratory therapist, dietitian, social worker, physiotherapist, and the consultant of the primary service under which the patient was first admitted.

ICU.6.2 Medically necessary services are readily available and accessible at all times.

ICU.6.3 Care is provided equally to all critical care patients whether inside the unit or those in other areas of the hospital (e.g., ventilated patients in emergency department).

ICU.6.4 Care is coordinated amongst the multidisciplinary team members and documented in the patient's medical record.

Standard Intent:

The patient care process in ICU is dynamic and involves many health care practitioners and can involve multiple care settings and departments and services. The integration and coordination of patient care activities are goals that result in efficient care processes, more effective use of human and other resources, and the likelihood of better patient outcomes.

ICU.7 The admission and discharge processes in the adult intensive care unit are coordinated.

ICU.7.1 The ICU physician and the primary physician jointly make the decision to admit and discharge patients from the unit.

ICU.7.2 A summary of the intensive care stay is written by the ICU physician and made available at the time of discharge from intensive care to a lower acuity level.

ICU.7.3 There is a documented evidence of handover between the intensive care unit physician and the unit/ward physician at the time of transfer to a lower acuity of care.

ICU.7.4 When the patient is discharged from the unit, the intensive care unit physician ensures that the receiving team on the floor is well informed about the patient's status and ongoing patient needs.

ICU.7.4.1 The patient's plan of care and medications are written in detail by the physician including how to continue them in the floor.

ICU.7.4.2 Any special care requirements are documented (e.g., to watch for drainage tubes, tracheotomy care, and wound care) in the patient's medical record.

Standard Intent:

To maintain continuity of care throughout the patient's stay in ICU setting, the care which is provided to ICU patients is will coordinated between the primary physician and the ICU physician. The decision of admission and discharge the patient from ICU are discussed between the primary team and the ICU physician.

ICU.8 Nursing staffing plans are available in the adult intensive care unit.

ICU.8.1 The nursing staffing plans demonstrate an evidence based nursing to patient ratio.

ICU.8.2 The nursing staffing plans are matching the patient volume and patient acuity.

Standard Intent:

Appropriate and adequate nursing staffing is critical to patient care in ICU. The planning process uses recognized methods for determining levels of staffing. The plan is written and identifies the number and types of required staff, the skills, the knowledge that must match the patient volume and patient acuity.

ICU.9 Nursing staff in the adult intensive care unit receive continuous training with competency assessment.

ICU.9.1 Nursing staff in the adult intensive care unit receive training and education on the following general and intensive care related needs:

- ICU.9.1.1 Fundamental critical care support.
- ICU.9.1.2 Infection control principles.
- ICU.9.1.3 Blood transfusion.
- ICU.9.1.4 Use of the defibrillator.
- ICU.9.1.5 Care of patients with tracheostomies.
- ICU.9.1.6 IV therapy.
- ICU.9.1.7 Pressure ulcer prevention and care.
- ICU.9.1.8 Knowledge of dosage range, side effects and complications of commonly used high alert medications in critical care including vasopressors, narcotics and controlled medications.
- ICU.9.1.9 Recognizing critical ECG changes including arrhythmias.
- ICU.9.1.10 Using pulse oximetry.
- ICU.9.1.11 Assisting physician in placing central lines or arterial lines.
- ICU.9.1.12 Assessing Glasgow Coma Scale (GCS).
- ICU.9.1.13 Obtaining arterial blood gas samples.
- ICU.9.1.14 Care of patients on ventilators.
- ICU.9.1.15 Reading central venous pressure (CVP) and swan Ganz monitoring.
- ICU.9.1.16 Care of endo-tracheal tube (ETT).

ICU.9.2 There is ongoing competency assessment for the nursing staff (e.g., written test, return demonstration).

ICU.9.3 The competency assessment of the nursing staff is documented.

Standard Intent:

To maintain acceptable ICU Nursing staff performance, to teach new skills, and to provide training on new medical technology and procedures, the hospital provides or arranges

for facilities, educators, and time for ongoing in-service and other education for nursing staff in ICU. The hospital must ensure that nurses are qualified to provide nursing care for ICU patients through training and competency assessment at least on the procedures mentioned in substandard ICU 9.1.1 through 9.1.16. There is documentation of training and competencies assessment in staff file.

ICU.10 The adult intensive care unit has adequate equipment and supplies.

ICU.10.1 There are isolation rooms with at least one negative pressure room.

ICU.10.2 The following equipment are available:

ICU.10.2.1 Ventilators.

ICU.10.2.2 Suction apparatus.

ICU.10.2.3 Airway sets.

ICU.10.2.4 Crash cart that includes defibrillator and all emergency supplies and medications.

ICU.10.2.5 ECG monitor, pulse oximetry and vital signs monitoring devices.

ICU.10.2.6 Automated blood pressure monitoring machine.

ICU.10.2.7 Intravenous infusion and blood transfusion pumps.

ICU.10.2.8 Portable monitoring equipment for patient transfer.

ICU.10.3 The availability and functionality of all tools and equipment are checked daily.

ICU.10.4 Equipment are cleaned and disinfected daily and as needed.

ICU.10.5 Laboratory and imaging services are available to meet the needs of patients receiving intensive care.

Standard Intent:

Risks in clinical care processes are significantly reduced when appropriate and well-functioning equipment is used to provide the planned services. Adequate supplies and medications are also available and appropriate for planned use and emergent situations (substandard ICU.10.2.1 through ICU.10.2.8). Each organization understands the required or recommended equipment, supplies, laboratory and imaging services as well as the medications necessary to provide the planned services to its patient population. The equipment should have a process of daily checking to ensure availability and adequate functionality and should be disinfected regularly after and before use.

ICU.11 Policies and procedures are available to guide the work in the adult intensive care unit.

ICU.11.1 There are policies and procedures for medical and nursing initial assessment and re-assessment requirements, including time frames for completion of initial assessments and frequency of re-assessments.

ICU.11.2 There are policies and procedures for monitoring of patient circulation, respiration, and oxygenation.

ICU.11.3 There are evidence-based criteria for intubation, weaning off ventilator and extubating.

ICU.11.4 There are policies and procedures for handover procedure between staff in between shifts and at discharge to a lower acuity of care.

ICU.11.5 There are policies and procedures for infection control practices including isolation.

ICU.11.6 There are policies and procedures for dealing with ethical issues (e.g., No Code policy, end of life issues and organ donation).

ICU.11.7 Policies are collaboratively developed by the appropriate staff.

Standard Intent:

Policies and procedures are important tools for staff to understand the population served and services, and to respond in a thorough, competent, and uniform manner. Policies and procedures must be tailored to the particular ICU population to be appropriate and effective in reducing the related risk. Substandard ICU.11.2 through ICU.11.6 constitute the essential required policies.

ICU.12 The adult intensive care unit has a process for detection and notification of potential deceased organ donors.

ICU.12.1 The intensive care unit establishes an effective communication and works collaboratively with the Saudi Center for Organ Transplantation (SCOT).

ICU.12.2 The intensive care unit uses criteria to identify, notify, document, and manage potential donors based on the registry of organ donation and transplantation in Saudi Arabia.

ICU.12.3 The intensive care unit reports all cases of potential deceased Donors after Brain Death (DBD) to SCOT on a timely manner.

ICU.12.4 The intensive care unit reports all cases of potential deceased Donors after Circulatory Death (DCD) to SCOT on a timely manner.

ICU.12.5 The hospital establishes and uses criteria that support the effectiveness of the donation process (e.g., patient factors, time since perfusion of the tissue stopped, maintenance of viability by appropriate care of the body between death and donation).

Standard Intent:

In ICU many patients who suffer from irreversible total damage to the brain stem, usually as a result of conditions such as road traffic accidents, cerebral hemorrhage, cerebral anoxia or primary brain tumors, organization should recognize the major contribution of organ transplantation for the good of human health and relief of human suffering , therefor staff within the Intensive Care Unit are responsible for identifying potentially deceased donor patients with clear process of communication and notification of other parties in the community involved in the organ transplant.

ICU.13 Infection control standards are strictly implemented and supervised in the adult intensive care unit.

ICU.13.1 The intensive care unit environment is maintained clean and neat at all times.

ICU.13.2 Infection control standards are strictly applied in the intensive care unit (e.g., hand hygiene and use of personal protective equipment).

ICU.13.3 Intensive care unit staff members adopt and implement care bundle for prevention of epidemiologically significant healthcare associated infections.

Standard Intent:

Patients and staff in ICU are at risk of infection, the goal of infection prevention and control program in ICU is to identify and to reduce the risks of acquiring and transmitting infections among patients, staff, health care professionals, contract workers, volunteers, students, and visitors. Infection risk is minimized with proper cleaning, disinfection, and sterilization processes, in ICU setting all infection control standards and guidelines must be implemented and monitored to reduce the risk of infection.

Pediatric Intensive Care Unit Standard Intents

PICU.1 Qualified physician is responsible for managing the pediatric intensive care unit.

PICU.1.1 The pediatric intensive care unit is directed by a physician qualified in pediatric critical care by education, training and, experience.

PICU.1.2 The unit head takes the overall responsibility for the operation of the unit.

Standard Intent:

Only qualified physician permitted by licensure, applicable laws and regulations, or certification manages the pediatric intensive care unit.

PICU.2 The pediatric intensive care unit nurse manager is a qualified registered nurse.

PICU.2.1 The nurse manager is a registered nurse qualified by education, training, and experience in pediatric critical care.

PICU.2.2 The nurse manager develops and collaborates with other departments as needed for developing policies and procedures for the pediatric intensive care unit (e.g., policies and practices related to infection control).

Standard Intent:

Only qualified Nurse permitted by licensure, applicable laws and regulations, or certification manages the pediatric intensive care unit.

PICU.3 Medical and nursing staff working in the pediatric intensive care unit have appropriate cardiac life support training.

PICU.3.1 Medical staff working in pediatric intensive care unit are certified in pediatric advanced life support (PALS).

PICU.3.2 Nursing staff working in pediatric intensive care unit are certified in pediatric advanced life support (PALS).

Standard Intent:

Medical and nursing staff working in the PICU must be certified in PALS.

PICU.4 The pediatric intensive care unit is covered by qualified physicians.

PICU.4.1 The pediatric intensive care unit is covered twenty four hours a day, seven days a week by qualified pediatric intensive care physicians.

Standard Intent:

Only qualified pediatric intensive care physicians permitted by licensure, applicable laws and regulations, or certification can work in the pediatric intensive care unit.

PICU.5 The pediatric intensive care unit has admission and discharge criteria.

PICU.5.1 The pediatric intensive care unit identifies its own population based on age, weight, and diagnosis related groups.

PICU.5.2 The admission and discharge criteria are defined in writing.

PICU.5.3 The criteria for admission are based on physiological parameters.

PICU.5.4 The criteria are developed collaboratively between relevant staff.

PICU.5.5 In an open pediatric intensive care unit, the Most Responsible Physician (MRP) is the admitting consultant whereas in a closed pediatric intensive care unit setting, the MRP is a member of the medical staff in the PICU.

Standard Intent:

PICU services must establish an admission and discharge criteria for determining those patients who require the level of care provided in such unit. These criteria will guide the staff when to admit and discharge patients from pediatric intensive care unit. To ensure consistency, the criteria should be physiologic based and utilize prioritization and diagnostic and/or objective parameters.

PICU.6 The pediatric intensive care unit has an effective handover process.

PICU.6.1 There is a documented evidence of handover between physicians at change of shift.

PICU.6.2 There is a documented evidence of handover between nurses at change of shift.

PICU.6.3 There is a documented evidence of handover between pediatric intensive care nurse and the unit/ward nurse at the time of transfer to a lower acuity of care.

Standard Intent:

For unifying the patient care within the pediatric intensive care unit and in relation to other (lower acuity of care) units, the hospital needs to design a handover policy and to implement processes for continuity and coordination of care among physicians, nurses, and other health care practitioners.

PICU.7 Patient care in pediatric intensive care unit is provided using a multidisciplinary approach.

PICU.7.1 The multidisciplinary team includes both Pediatric ICU as well as non-ICU members. This includes but is not limited to: Pediatric ICU physician, Pediatric ICU nurse, clinical pharmacist, respiratory therapist, dietitian, social worker, physiotherapist, and the consultant of the primary service under which the patient was first admitted.

PICU.7.2 Medically necessary services are readily available and accessible at all times.

PICU.7.3 Care is provided equally to all Pediatric ICU patients whether inside the unit or those in other areas of the hospital (e.g., ventilated patients in the emergency department).

PICU.7.4 Care is coordinated amongst the multidisciplinary team members and documented in the patient's medical record.

Standard Intent:

The patient care in the PICU should be coordinated among physicians, nurses, and other health care practitioners using a multidisciplinary approach. Staff need to have access to medical support services 24/7 all year round. Same level of care is provided to pediatric cases requiring intensive care but admitted in other units due to lack of bed space in PICU.

PICU.8 The admission and discharge processes in the pediatric intensive care unit are coordinated.

PICU.8.1 The PICU physician and the primary physician jointly make the decision to admit and discharge patients from the unit.

PICU.8.2 A summary of the intensive care stay is written by the pediatric ICU physician and made available at the time of discharge from pediatric intensive care to a lower acuity level.

PICU.8.3 There is a documented evidence of handover between the pediatric intensive care unit physician and the unit/ward physician at the time of transfer to a lower acuity of care.

PICU.8.4 When the patient is discharged from the PICU, the pediatric intensive care unit physician ensures that the receiving team on the floor is well informed about the patient's status and ongoing patient needs.

PICU.8.4.1 The patient's plan of care and medications are written in detail by the physician including how to continue them on the floor.

PICU.8.4.2 Any special care requirements are documented (e.g., to watch for drainage tubes, tracheostomy care, and wound care) in the patient's medical record.

Standard Intent:

The admission and discharge processes should be coordinated among physicians, nurses, and other health care practitioners in the pediatric intensive care unit.

PICU.9 Nursing staffing plans are available in the pediatric intensive care unit.

PICU.9.1 The nursing staffing plans demonstrate an evidence based nursing to patient ratio.

PICU.9.2 The nursing staffing plans are matching the patient volume and patient acuity.

Standard Intent:

Nursing staffing plan should be available in pediatric intensive care unit to support nurse's assignments. The hospital must be consistent with any applicable laws and regulations regarding nursing responsibilities and clinical care.

PICU.10 Nursing staff in the pediatric intensive care unit receive continuous training with competency assessment.

PICU.10.1 Nursing staff in the pediatric intensive care unit receive training and education on the following general and intensive care related needs:

- PICU.10.1.1 Pediatric fundamental critical care support.
- PICU.10.1.2 Infection control principles.
- PICU.10.1.3 Blood transfusion.
- PICU.10.1.4 Use of the defibrillator.
- PICU.10.1.5 Care of patients with tracheostomies.
- PICU.10.1.6 Knowledge of dosage range, side effects and complications of commonly used high alert medications in pediatric critical care including vasopressors, narcotics, and controlled medications.
- PICU.10.1.7 Recognizing critical ECG changes including arrhythmias.
- PICU.10.1.8 Using pulse oximetry.
- PICU.10.1.9 Assisting physician in placing central lines or arterial lines.
- PICU.10.1.10 Assessing Glasgow Coma Scale (GCS).
- PICU.10.1.11 Obtaining arterial blood gas samples.
- PICU.10.1.12 Care of patients on ventilators.
- PICU.10.1.13 Reading central venous pressure (CVP) and swan Ganz monitoring.
- PICU.10.1.14 Care of endo-tracheal tube (ETT).
- PICU.10.1.15 Pressure ulcer prevention and care
- PICU.10.1.16 Guidelines for Monitoring & Management of IV Infiltration, Phlebitis & Extravasations
- PICU.10.1.17 Pain assessment and management based on patient's age and condition (e.g., ventilated & non-ventilated patients).

PICU.10.2 There is ongoing competency assessment for the nursing staff (e.g., written test, return demonstration).

PICU.10.3 The competency assessment of the nursing staff is documented.

Standard Intent:

Qualified nursing staff members are hired by the hospital through a process that matches the requirements of the position with the qualifications of the prospective staff member. This process also ensures that nursing staff member's skills are initially and over time consistent with the needs of patients. Ongoing evaluation and competency assessment ensures that training occurs when needed and that the staff member is able to assume new or changed responsibilities. Training and competency

assessment should be undertaken for the procedures mentioned in substandard PICU 10.1.1 through PICU.10.1.17

PICU.11 The pediatric intensive care unit has adequate equipment and supplies.

PICU.11.1 There are isolation rooms with at least one negative pressure room.

PICU.11.2 The following equipment are available:

PICU.11.2.1 Ventilators.

PICU.11.2.2 Suction apparatus.

PICU.11.2.3 Airway sets.

PICU.11.2.4 Crash cart that includes defibrillator and all emergency supplies and medications.

PICU.11.2.5 ECG monitor, pulse oximetry, and vital signs monitor.

PICU.11.2.6 Automated blood pressure monitoring machine.

PICU.11.2.7 Intravenous infusion and blood transfusion pumps.

PICU.11.2.8 Portable monitoring equipment for patient transfer.

PICU.11.3 The availability and functionality of all tools and equipment are checked daily.

PICU.11.4 Equipment are cleaned and disinfected daily and as needed.

PICU.11.5 Laboratory and imaging services are available to meet the needs of patients receiving pediatric intensive care.

Standard Intent:

Qualified nursing staff members are hired by the hospital through a process that matches the requirements of the position with the qualifications of the prospective staff member. This process also ensures that nursing staff member's skills are initially and over time consistent with the needs of patients. Ongoing evaluation and competency assessment ensures that training occurs when needed and that the staff member is able to assume new or changed responsibilities. Training and competency assessment should be undertaken for the procedures mentioned in substandard PICU 10.1.1 through PICU.10.1.17

PICU.12 Policies and procedures are available to guide the work in the pediatric intensive care unit.

PICU.12.1 There are policies and procedures for medical and nursing initial assessment and re-assessment requirements, including time frames for completion of initial assessments and frequency of re-assessments.

PICU.12.2 There are policies and procedures for monitoring of patient circulation, respiration, and oxygenation.

PICU.12.3 There are evidence-based criteria for intubation, weaning off ventilator and extubation.

PICU.12.4 There are policies and procedures for handover procedure between staff in between shifts and at discharge to a lower acuity of care.

PICU.12.5 There are policies and procedures for infection control practices including isolation.

PICU.12.6 There are policies and procedures for dealing with ethical issues (e.g., end of life issues and organ donation).

PICU.12.7 Policies are collaboratively developed by the appropriate staff.

Standard Intent:

Policies and procedures are important tools for staff to understand the population served and services, and to respond in a thorough, competent, and uniform manner. Policies and procedures must be tailored to the particular ICU population to be appropriate and effective in reducing the related risk. Substandard PICU.11.2 through PICU.11.6 constitute the essential required policies.

PICU.13 The pediatric intensive care unit has a process for detection and notification of potential deceased organ donors.

PICU.13.1 The pediatric intensive care unit establishes an effective communication and works collaboratively with the Saudi Center for Organ Transplantation (SCOT).

PICU.13.2 The pediatric intensive care unit uses criteria to identify, notify, document, and manage potential donors based on the registry of organ donation and transplantation in Saudi Arabia.

PICU.13.3 The pediatric intensive care unit reports all cases of potential deceased Donors after Brain Death (DBD) to SCOT on a timely manner.

PICU.13.4 The pediatric intensive care unit reports all cases of potential deceased Donors after Circulatory Death (DCD) to SCOT on a timely manner.

PICU.13.5 The hospital establishes and uses criteria that support the effectiveness of the donation process (e.g., patient factors, time since perfusion of the tissue stopped, maintenance of viability by appropriate care of the body between death and donation).

Standard Intent:

Pediatric Intensive care unit should have a process to detect and notify involved individuals and departments of potential deceased organ donors. This process should write as policy or guideline to direct health care providers what to do if they have potential deceased organ donor. The faster you report have potential deceased organ donor the better prognosis you have in the transplant program.

PICU.14 Infection control standards are strictly implemented and supervised in the pediatric intensive care unit.

PICU.14.1 The pediatric intensive care unit environment is maintained clean and neat at all times.

PICU.14.2 Infection control standards are strictly applied in the pediatric intensive care unit (e.g., hand hygiene and use of personal protective equipment).

PICU.14.3 Pediatric intensive care unit staff members adopt and implement care bundle for prevention of epidemiologically significant healthcare associated infections.

Standard Intent:

All infection control standards must be implemented in the pediatric intensive care unit such as care of the patient in isolation room, handling body fluid. The standards should by supervised and evaluated, for example (Infection control rounds, infection control report, and head nurse rounds).

Neonatal Intensive Care Unit Standard Intents

NICU.1 Qualified physician is responsible for managing the neonatal intensive care unit.

NICU.1.1 The department head is a qualified Pediatrician with experience in neonatology (for level 1 and 2 NICU) and certified neonatologist (for level3 NICU).

NICU.1.2 The department head takes the overall responsibility for the operation of the unit.

Standard Intent:

Only qualified physician permitted by licensure, applicable laws and regulations, or certification manages the neonatal intensive care unit.

NICU.2 The neonatal intensive care unit nurse manager is a qualified registered nurse.

NICU.2.1 The nurse manager is qualified by education, training, and experience in neonatal intensive care.

NICU.2.2 The nurse manager develops and collaborates with NICU physicians and other departments as needed for developing policies and procedures for the unit (e.g., policies and practices related to infection control).

Standard Intent:

Only qualified Nurse permitted by licensure, applicable laws and regulations, or certification manages the neonatal intensive care unit.

NICU.3 Medical and nursing staff working in the neonatal intensive care unit have the appropriate cardiac life support training.

NICU.3.1 Medical staff working in neonatal intensive care unit are certified in Neonatal Resuscitation Program (NRP).

NICU.3.2 Nursing staff working in the neonatal intensive care unit are certified in Neonatal Resuscitation Program (NRP).

Standard Intent:

Medical and nursing staff working in the neonatal intensive care unit must have NRP.

NICU.4 The neonatal intensive care unit is covered by qualified physicians.

NICU.4.1 The neonatal intensive care unit is covered twenty-four hours a day, seven days a week by qualified neonatal intensive care physicians.

NICU.4.2 For a Level 3 unit, there is certified neonatologist to cover the unit during the on call hours.

Standard Intent:

Only qualified physicians permitted by licensure, applicable laws and regulations, or certification can work in the neonatal intensive care unit.

NICU.5 The neonatal intensive care unit has admission and discharge criteria.

NICU.5.1 The neonatal intensive care unit identifies its own population based on age and diagnosis related groups.

NICU.5.2 The admission and discharge criteria are defined in writing.

NICU.5.3 Criteria for admission are based on physiological parameters.

NICU.5.4 The criteria are developed collaboratively between relevant staff.

Standard Intent:

The NICU must establish an admission and discharge criteria for determining those patients who require the level of care provided in such unit. These criteria will guide the staff when to admit and discharge patients from NICU. To ensure consistency, the criteria should utilize prioritization and diagnostic and/or objective parameters.

NICU.6 Patient care in the neonatal intensive care unit is coordinated.

NICU.6.1 There is a documented evidence of handover between physicians at change of shift.

NICU.6.2 There is a documented evidence of handover between nurses at change of shift.

NICU.6.3 There is a documented evidence of handover between neonatal intensive care nurse and unit nurse at the time of transfer to a lower acuity of care.

Standard Intent:

For unifying the patient care in the NICU, the hospital needs to design and to implement processes for continuity and coordination of care among physicians, nurses, and other healthcare practitioners.

NICU.7 Patient care in the neonatal intensive care unit is provided using a multidisciplinary approach.

NICU.7.1 The multidisciplinary team includes both NICU as well as non NICU members. This includes but not is limited to: NICU physician, NICU nurse, clinical pharmacist, respiratory therapist, and dietitian.

NICU.7.2 Medically necessary services are readily available and accessible at all times.

NICU.7.3 Care is coordinated amongst the multidisciplinary team members and documented in the patient's medical record.

Standard Intent:

The patient care in the NICU should be coordinated among physicians, nurses, and other health care practitioners using a multidisciplinary approach. Staff need to have access to medical support services 24/7 all year round.

NICU.8 The admission and discharge processes in the neonatal intensive care unit are coordinated.

NICU.8.1 A summary of the neonatal intensive care stay is written by the NICU physician and made available at the time of discharge from critical care to a lower acuity level.

NICU.8.2 There is documented evidence of handover between the neonatal intensive care physician and the unit physician at the time of transfer to a lower acuity of care.

NICU.8.3 When the patient is discharged from the unit, the neonatal intensive care unit physician ensures that the receiving team is well informed about the patient's status and ongoing patient needs.

NICU.8.3.1 The patient's plan of care and medications are written in detail by the physician including how to continue them on the floor.

NICU.8.3.2 Any special care requirements are documented in the medical record.

Standard Intent:

The admission and discharge process should be coordinated among physicians, nurses, and other health care practitioners to unifying these processes in the NICU.

NICU.9 Nursing staffing plans are available in the neonatal intensive care unit.

NICU.9.1 The nursing staffing plans demonstrate an evidence based nursing to patient ratio.

NICU.9.2 The nursing staffing plans are matching the patient volume and patient acuity.

Standard Intent:

Nursing staffing plan should be available in NICU to support nurse's assignments. The hospital must make sure that the workforce in the NICU is consistent with any applicable laws and regulations.

NICU.10 Nursing staff in the neonatal intensive care unit receive continuous training with competency assessment.

NICU.10.1 Nursing staff in the NICU intensive care unit receive training and education on the following general and NICU intensive care related needs:

NICU.10.1.1 Assisting physicians in the different procedures performed in the neonatal intensive care unit including securing central lines access.

NICU.10.1.2 Using pulse oximetry.

NICU.10.1.3 Recognizing critical ECG changes including arrhythmias.

NICU.10.1.4 Assisting physician in placing central lines or arterial lines and /or umbilical arterial/venous lines.

NICU.10.1.5 Obtaining arterial blood gas samples and blood drawing from umbilical catheters.

NICU.10.1.6 Knowledge of dosage range, side effects and complications of commonly used medications such as surfactant and high alert medications used in neonatal care including vasopressors, narcotics, and controlled medications.

NICU.10.1.7 Infection control principles.

NICU.10.1.8 Blood transfusion and exchange transfusion.

NICU.10.1.9 Sarnat and Thompson Scoring.

NICU.10.1.10 Use of the defibrillator.

NICU.10.1.11 Care of patients on ventilators.

NICU.10.1.12 Care of endo-tracheal tube (ETT).

NICU.10.1.13 Care of patients with tracheostomies.

NICU.10.1.14 Care of the terminally ill and end of life patients.

NICU.10.1.15 Care of patient in incubator.

NICU.10.2 There is ongoing competency assessment for the nursing staff (e.g., written test, return demonstration).

NICU.10.3 The competency assessment of the nursing staff is documented.

Standard Intent:

Qualified nursing staff members are hired by the hospital through a process that matches the requirements of the position with the qualifications of the prospective staff member. This process also ensures that nursing staff member's skills are initially and over time consistent with the needs of patients. Ongoing evaluation and competency assessment ensures that training occurs when needed and that the staff member is able to assume new or changed responsibilities. Training and competency assessment should be undertaken for the procedures mentioned in substandard NICU 10.1.1 through NICU.10.1.15.

NICU.11 The neonatal intensive care unit has adequate equipment, supplies, and diagnostic services.

NICU.11.1 There are isolation rooms with at least one negative pressure room.

NICU.11.2 The following equipment are available:

NICU.11.2.1 Ventilators.

NICU.11.2.2 Suction apparatus.

NICU.11.2.3 Airway sets.

NICU.11.2.4 Crash cart that includes defibrillator, all emergency supplies, and medications as appropriate to neonates.

NICU.11.2.5 Infant resuscitator.

NICU.11.2.6 Incubators.

NICU.11.2.7 Portable incubator with portable ventilator.

NICU.11.2.8 ECG monitor, pulse oximetry, and vital signs monitor.

NICU.11.2.9 Automated blood pressure monitoring machine.

NICU.11.2.10 Intravenous infusion and blood transfusion pumps.

NICU.11.3 The availability and functionality of all tools and equipment are checked daily.

NICU.11.4 Equipment are cleaned and disinfected daily and as needed.

NICU.11.5 Portable equipment for safe patient transports are available.

NICU.11.6 Laboratory and imaging services are available to meet the needs of patients receiving neonatal intensive care.

Standard Intent:

Risks in clinical care processes are significantly reduced when appropriate and well-functioning equipment is used to provide the planned services. Adequate supplies and medications are also available and appropriate for planned use and emergent situations (substandard NICU.11.2.1 through NICU.11.2.10). Each organization understands the required or recommended equipment, supplies, laboratory and imaging services as well as the medications necessary to provide the planned services to its patient population. The equipment should have a process of daily checking to ensure availability and adequate functionality and should be disinfected regularly after and before use.

NICU.12 Policies and procedures are available to guide the work in the neonatal intensive care unit.

NICU.12.1 There are policies and procedures for medical and nursing initial assessment and re-assessment requirements, including time frames for completion of initial assessments and frequency of re-assessments.

NICU.12.2 There are policies and procedures for monitoring of patient circulation, respiration, and oxygenation.

NICU.12.3 There are evidence-based criteria for intubation, weaning off ventilator and extubating.

NICU.12.4 There are policies and procedures for handover procedure between staff in between shifts and at discharge to a lower acuity of care.

NICU.12.5 There are policies and procedures for infection control practices including isolation.

NICU.12.6 There are policies and procedures for the use of neonatal Total Parenteral Nutrition (TPN) for more sick patients.

NICU.12.7 There are policies and procedures for dealing with ethical issues (e.g., No Code policy, end of life issues, and organ donation).

NICU.12.8 Policies are collaboratively developed by the appropriate staff.

Standard Intent:

Policies and procedures are important tools for staff to understand the population served and services, and to respond in a thorough, competent, and uniform manner. Policies and procedures must be tailored to the particular ICU population to be appropriate and effective in reducing the related risk. Substandard NICU.11.2 through NICU.11.6 constitute the essential required policies.

NICU.13 Infection control standards are strictly implemented and supervised in the neonatal intensive care unit.

NICU.13.1 The neonatal intensive care unit environment is maintained clean and neat at all times.

NICU.13.2 Infection control standards are strictly applied in the neonatal intensive care unit (e.g., hand hygiene and use of personal protective equipment).

NICU.13.3 Neonatal intensive care unit staff members adopt and implement care bundle for prevention of epidemiologically significant healthcare associated infections.

Standard Intent:

All infection control standards must be implemented in NICU such as care of the patient in isolation room, handling body fluid. Those standards should by supervised and evaluated, for example (Infection control rounds, infection control report, and head nurse rounds.

Coronary Care Unit Standard Intents

CCU.1 Qualified physician is responsible for managing the coronary care unit.

CCU.1.1 The department head is a physician qualified by appropriate education, training, and experience in managing intensive cardiac care patients/units.

CCU.1.2 The department head takes overall responsibility for the operation of the unit.

Standard Intent:

The Physician managing Coronary care unit is responsible for ensuring that the measurement activities provide the opportunity for the evaluation of staff as well as the processes of care. The department's head must be qualified by appropriate education, training, and experience in managing CCU care patients/units.

CCU.2 The coronary care unit nurse manager is a qualified registered nurse.

CCU.2.1 The nurse manager is qualified by education, training, and experience in coronary care units.

CCU.2.2 The nurse manager develops policies and procedures for the unit and collaborates with other departments as needed (e.g., policies and practices related to infection control).

Standard Intent:

The coronary care unit nurse manager is a person who has the clinical and managerial skills that enable him/ her to monitor nursing activities in the department and evaluate the staff activities; participate in initiate improvement activities within the unit such as quality improvement projects; establishing multidisciplinary policies and procedures collaboratively with other health disciplines. The nurse manager must be qualified by education, training, and experience in coronary care units.

CCU.3 Medical and nursing staff working in the coronary care unit have appropriate cardiac life support training.

CCU.3.1 Medical staff working in coronary care unit are ACLS-certified.

CCU.3.2 Nursing staff working in the coronary care unit are ACLS-certified.

Standard Intent:

Medical and nursing staff working in CCU must have valid ACLS certificate to ensure that they have the knowledge and skills to manage any cardiac emergency.

CCU.4 The coronary care unit is covered by qualified physicians.

CCU.4.1 The coronary care unit is covered twenty-four hours a day, seven days a week by physicians qualified in managing cardiac patients requiring intensive care.

Standard Intent:

The Coronary Care unit must be covered by qualified physicians twenty-four hours a day, seven days a week.

CCU.5 The coronary care unit has admission and discharge criteria.

CCU.5.1 The coronary care unit identifies its own population based on age and diagnosis related groups.

CCU.5.2 The admission and discharge criteria are defined in writing.

CCU.5.3 Criteria for admission are based on physiological parameters.

CCU.5.4 The criteria are developed collaboratively between relevant staff.

CCU.5.5 In an open CCU setting, the Most Responsible Physician (MRP) is the admitting consultant, whereas in a closed CCU setting the MRP is the CCU physician/intensivist.

Standard Intent:

The decision of admitting any patient in the coronary care unit should base on comprehensive criteria that identified physiological parameters that reviewed by a qualified physician, Similarly the discharge from the unit should have comprehensive criteria to ensure that the patient is no longer need to be in the CCU. All medical staff should be familiar with these criteria as the CCU physician will be the MRP for all the cases admitting to the unit.

CCU.6 The coronary care unit has an effective handover process.

CCU.6.1 There is a documented evidence of handover between physicians at change of shift.

CCU.6.2 There is a documented evidence of handover between nurses at change of shift.

CCU.6.3 There is a documented evidence of handover between the CCU nurse and the unit nurse at the time of transfer to a lower acuity of care.

Standard Intent:

The effective communication is very important part in medical treatment of all patient, and as all the cases admitting to the CCU should have continuous monitoring and adjusting of treatment protocols where no place for any mistake, the CCU should adapt handover process that implemented by the physician at the end of the shift to ensure that all patients information mentioned to the coming shift. Handover should be documented properly for any future reference in case of legal issue occurs. Similarly, the nursing staff should have documented handover within the unit and whenever patient transfer to lower acuity unit to ensure the continuity of care for the patient.

CCU.7 Patient care in coronary care unit is provided using a multidisciplinary approach.

CCU.7.1 There is a multidisciplinary team that includes both CCU as well as non CCU members (CCU physician, CCU nurse, clinical pharmacist, respiratory therapist, dietitian, social worker, physiotherapist, and the consultant of the primary service under which the patient was first admitted).

CCU.7.2 Medically necessary services are readily available and accessible at all times.

CCU.7.3 Care is provided equally to all CCU patients whether inside the unit or those in other areas of the hospital (e.g., ventilated patients in emergency department).

CCU.7.4 Care is coordinated amongst the multidisciplinary team members and documented in the patient's medical record.

Standard Intent:

The patient admitted to the coronary care unit considered some special patients with special need that required multidisciplinary team to identify the needs and work to fulfill these needs. The team should include all concerned hospital personnel and should not limit the service to the patients who required such service all over the hospital.

CCU.8 The admission and discharge processes in the coronary care unit are coordinated.

CCU.8.1 The physician in charge of the coronary care unit together with the most responsible physician jointly make the decision to admit and discharge patients from the unit.

CCU.8.2 A summary of the coronary care stay is written by the physician and made available at the time of discharge from critical care to a lower acuity level.

CCU.8.3 There is a documented evidence of handover between the coronary care physician and the unit physician at the time of transfer to a lower acuity of care.

CCU.8.4 When the patient is discharged from the unit, the coronary care unit physician ensures that the receiving team on the floor is well informed about the patient's status and ongoing patient needs.

CCU.8.4.1 The patient's plan of care and medications are written in detail by the physician including how to continue them on the floor.

CCU.8.4.2 Any special care requirements are documented in the patient's medical record.

Standard Intent:

The continuity of care is one of the most vital aspect in health care institutes and the patient who admitted to the CCU may has another problem that affects cardiovascular problem, therefore, the CCC physician with the primary MRP should jointly discussed patient condition and rational to admit or discharge the patient to CCU. The CCU physician should document all medical management activities and patient progress notes and keep it available for reference at any time to ensure that all health care team have update of the patient's condition. When the discharge from CCU decision taken a comprehensive plan of care should be prepared and endorsed to the unit that the patient will be transferred to. The CCU staff should document and endorsed all of these information to the low acuity unit that the patient is going to as there are some needs that should be monitored and fulfilled for this type of patient as part of their treatment protocol.

CCU.9 Nursing staffing plans are available in the coronary care unit.

CCU.9.1 The nursing staffing plans demonstrate an evidence based nursing to patient ratio.

CCU.9.2 The nursing staffing plans are matching the patient volume and patient acuity.

Standard Intent:

Patient population of the CCU need special treatment and should have adequate number of nursing staff available in the unit. Nursing management should have nurse: patient ratio for the CCU unit and base on this ration a comprehensive nursing staff policy should initiate and maintained all the time. Nursing management should have identified different categories of acuity that may admitted in the unit and considered it when establish staffing plan.

CCU.10 Nursing staff in the coronary care unit receive continuous training with competency assessment.

CCU.10.1 Nursing staff in the coronary care unit receive training and education on the following general and intensive care related needs:

CCU.10.1.1 Assisting physicians in the different procedures performed in the coronary care unit including securing central line access.

CCU.10.1.2 Using pulse oximetry.

CCU.10.1.3 Recognizing critical ECG changes including arrhythmias.

CCU.10.1.4 Obtaining arterial blood gas samples and blood drawing from umbilical catheters.

CCU.10.1.5 Reading central venous pressure (CVP) and swan Ganz monitoring.

CCU.10.1.6 Knowledge of dosage range, side effects and complications of commonly used medications such as high alert medications used in coronary care including vasopressors, narcotics, and controlled medications.

CCU.10.1.7 Infection control principles.

CCU.10.1.8 Blood transfusions.

CCU.10.1.9 Assessing Glasgow Coma Scale (GSC).

CCU.10.1.10 Use of defibrillator.

CCU.10.1.11 Care of patients on ventilators.

CCU.10.1.12 Care of Endo-tracheal tube (ETT).

CCU.10.1.13 Care of patients with tracheostomies.

CCU.10.1.14 Care of the terminally ill and end of life patients.

CCU.10.2 There is ongoing competency assessment for the nursing staff (e.g., written test, return demonstration).

CCU.10.3 The competency assessment of the nursing staff is documented.

Standard Intent:

Qualified nursing staff members are hired by the hospital through a process that matches the requirements of the position with the qualifications of the prospective staff member. This process also ensures that nursing staff member's skills are initially and over time consistent with the needs of patients. Ongoing evaluation and competency assessment ensures that training occurs when needed and that the staff member is able to assume new or changed responsibilities. Training and competency assessment should be undertaken for the procedures mentioned in substandard CCU 10.1.1 through CCU.10.1.14

CCU.11 The coronary care unit has adequate equipment, supplies, and diagnostic services.

CCU.11.1 There are isolation rooms with at least one negative pressure room.

CCU.11.2 The following equipment are available:

CCU.11.2.1 Ventilators.

CCU.11.2.2 Suction apparatus.

CCU.11.2.3 Airway sets.

CCU.11.2.4 Crash cart that includes defibrillator, all emergency supplies and medications as appropriate to the age of the patients.

CCU.11.2.5 ECG monitor, pulse oximetry, and vital signs monitor.

CCU.11.2.6 Automated blood pressure monitoring machine.

CCU.11.2.7 Intravenous infusion and blood transfusion pumps.

CCU.11.2.8 At least one invasive monitor.

CCU.11.3 The availability and functionality of all tools and equipment are checked daily.

CCU.11.4 Equipment are cleaned and disinfected daily and as needed.

CCU.11.5 Portable equipment for safe patient transports are available.

CCU.11.6 Laboratory and imaging services are available to meet the needs of patients in coronary care unit.

Standard Intent:

Risks in clinical care processes are significantly reduced when appropriate and well-functioning equipment is used to provide the planned services. Adequate supplies and medications are also available and appropriate for planned use and emergent situations (substandard CCU.11.2.1 throughCCU.11.2.8). Each organization understands the required or recommended equipment, supplies, laboratory and imaging services as well as the medications necessary to provide the planned services to its patient population. The equipment should have a process of daily checking to ensure availability and adequate functionality and should be disinfected regularly after and before use.

CCU.12 Policies and procedures are available to guide the work in the coronary care unit.

CCU.12.1 There are policies and procedures for medical and nursing initial assessment and re-assessment requirements, including time frames for completion of initial assessments and frequency of re-assessments.

CCU.12.2 There are policies and procedures for monitoring of patient circulation, respiration, and oxygenation.

CCU.12.3 There are evidence-based criteria for intubation, weaning off ventilator and extubation.

CCU.12.4 There are policies and procedures for handover procedure between staff in between shifts and at discharge to a lower acuity of care.

CCU.12.5 There are policies and procedures for common and high risk procedures that include, but are not limited to, the following:

CCU.12.5.1 Coronary Angiogram.

CCU.12.5.2 Temporary pace maker.

CCU.12.5.3 Permanent pace maker.

CCU.12.5.4 Moderate or deep sedation.

CCU.12.6 There are policies and procedures for infection control practices including isolation.

CCU.12.7 Policies are collaboratively developed by the appropriate staff.

Standard Intent:

Policies and procedures are important tools for staff to understand the population served and services, and to respond in a thorough, competent, and uniform manner. Policies and procedures must be tailored to the particular ICU population to be appropriate and effective in reducing the related risk. Substandard CCU.12.2 through CCU.12.6 constitute the essential required policies.

CCU.13 The coronary care unit has a process for detection and notification of potential deceased organ donors.

CCU.13.1 The CCU establishes an effective communication and works collaboratively with the Saudi Center for Organ Transplantation (SCOT).

CCU.13.2 The CCU uses criteria to identify potential donors based on Saudi Center for Organ Transplantation (SCOT) guidelines.

CCU.13.3 The CCU reports all cases of potential Donation after Circulatory Death (DCD) to SCOT in appropriate time.

CCU.13.4 The CCU reports all cases of potential Donation after Brain Death (DBD) to SCOT in appropriate time.

CCU.13.5 The hospital establishes and uses criteria that support the effectiveness of the donation process (e.g., patient factors, time since perfusion of the tissue stopped, maintenance of viability by appropriate care of the body between death and donation).

Standard Intent:

Based on the national standards for organ transplantation availability of organ donation policies ensure that all staff are following same method of notifying concerned section of any possible organ donation case and fill documents that approved by the SCOT, this considered vital issues as organ transplantation helps saving other patients life. In addition, the CCU to report all cases of potential donation in appropriate time to SCOT. It is also essential that hospitals establish and use criteria to support the effectiveness of donation process.

CCU.14 Infection control standards are strictly implemented and supervised in the coronary care unit.

CCU.14.1 The coronary care unit environment is maintained clean and neat at all times.

CCU.14.2 Infection control standards are strictly applied in the coronary care unit (e.g., hand hygiene and using of personal protective equipment).

CCU.14.3 Coronary care unit staff members adopt and implement care bundle for prevention of epidemiologically significant healthcare associated infections.

Standard Intent:

Infection control practice is a mandatory aspect in any health care facility as it decreases infectious rate in the hospital and prevent spread of infection, Coronary Care unit Staff should strictly apply all infection control standards as their patients are

susceptible and may acquire any infection easily, the staff also should follow bundles that imitated by infection control department that help in promote best outcomes with a greater impact.

Labor & Delivery Standard Intents

L&D.1 Qualified physician is responsible for managing the obstetrics department.

L&D.1.1 The head of the obstetrics department is an obstetrician qualified by education, training, and experience.

L&D.1.2 The head of the obstetrics department supervises the development and implementation of policies and procedures related to gynecology and obstetrics practices.

L&D.1.3 The head of the obstetrics department enforces the implementation of infection control guidelines inside the operating and recovery rooms.

Standard Intent:

The head of obstetric department is a qualified obstetrician holding Saudi board or equivalent by education, training, and experience. He is responsible also for drafting the department services policies and procedures related to obstetrics and gynecology and its implementation throughout the hospital including infection control guidelines inside the operating and recovery rooms.

L&D.2 The obstetrics department has adequate medical coverage by qualified medical staff.

L&D.2.1 A qualified obstetrician is physically present in the delivery room twenty-four hours a day, seven days a week.

L&D.2.2 Obstetricians are certified in advanced life support in obstetrics (ALSO) or at least one certified obstetrician is assigned on every shift.

L&D.2.3 A qualified pediatrician/neonatologist attends all caesarean section deliveries.

L&D.2.4 Pediatricians' rosters identify the physician to be called in emergencies.

L&D.2.5 Pediatricians are certified in neonatal resuscitation program (NRP).

Standard Intent:

The obstetric services are provided to patients around the clock by adequate, qualified and experienced staff present physically. The obstetrician should be certified in ALSO or a certified one should be present in each shift at least. All caesarean section deliveries should be attended by a qualified pediatrician/neonatologist who is certified in NRP and roasters should clearly identify the pediatrician on call during emergencies.

L&D.3 Qualified nurse manager supervises midwifery and nursing services in the obstetrics department.

L&D.3.1 The nurse manager in charge of the obstetrics department is a qualified registered nurse with education, training and experience in obstetrics.

L&D.3.2 The nurse manager ensures the competency of the midwives and nursing staff.

Standard Intent:

The nursing and midwifery services in the obstetric department are supervised by a qualified, registered nursing manager through education, training, and experience, she is also responsible for ensuring that midwifery and nursing staff are competent.

L&D.4 The obstetrics department has adequate coverage by qualified midwifery and nursing staff.

L&D.4.1 Nursing staffing plan is based on patient volume and patient acuity and ensures adequate coverage twenty-four hours a day, seven days a week.

L&D.4.2 Nurses working in the obstetrics department have adequate experience in obstetrics.

L&D.4.3 Nurses working in the obstetrics department are certified in neonatal resuscitation program or at least one certified nurse is assigned on every shift.

L&D.4.4 Midwives are registered and are qualified by education, training, and experience in labor and delivery.

Standard Intent:

The nursing and midwifery services in the obstetric department are offered by a sufficient number and experienced midwifery and nursing staff matching patient's volume and acuity around the clock. Nurses should be certified in neonatal resuscitation program or a certified one should be present in each shift, also midwives should be qualified by education, training, and experience in labor and delivery and have valid SCFHS registration.

L&D.5 The obstetrics department has admission and discharge criteria.

L&D.5.1 The obstetrics department implements specific criteria for admission and discharge.

L&D.5.2 The criteria are collaboratively developed by obstetricians and other relevant departments.

L&D.5.3 The criteria are based on the gestational age of mothers, department's design, and available resources.

Standard Intent:

There must be an admission and discharge criteria for the obstetrics department. The criteria are collaboratively developed by obstetricians and other relevant departments and are based on the gestational age of mothers, department's design, and available resources.

L&D.6 Policies and procedures guide the care of women in labor.

L&D.6.1 There are policies and procedures to guide the care of women in labor including, but are not limited to, the following:

L&D.6.1.1 Assessment and re-assessment of women in labor, including immediate postpartum care and criteria for discharge from delivery room.

L&D.6.1.2 Management of Ante-partum and post-partum hemorrhage.

L&D.6.1.3 Augmentation of labor and the use of oxytocin.

L&D.6.1.4 Use of partogram for woman in labor.

L&D.6.1.5 Caesarian section, repeated caesarian section, and emergency hysterectomy.

L&D.6.1.6 Management of fetal distress.

L&D.6.1.7 The use of sedation.

L&D.6.1.8 The use of cardio-tocography.

L&D.6.1.9 The use of episiotomy.

L&D.6.1.10 Induction of labor.

L&D.6.1.11 Pain relief and regional anesthesia.

L&D.6.1.12 Management of hypertensive disorders of pregnancy.

L&D.6.1.13 Management of the diabetic patient in labor and postpartum.

L&D.6.1.14 Suppression of pre-term labor.

L&D.6.1.15 Management of multiple births.

L&D.6.1.16 Management of abnormal positions and presentations.

L&D.6.1.17 Instrumental vaginal delivery.

L&D.6.1.18 Management of premature rupture of membranes.

L&D.6.1.19 Management of un-booked deliveries.

L&D.6.1.20 Neonatal identification and the immediate assessment and resuscitation of the new born.

L&D.6.1.21 Infection control measures in labor and postpartum.

L&D.6.1.22 Breast feeding.

L&D.6.2 The policies and procedures are collaboratively developed by obstetricians, pediatricians, anesthesiologists, delivery room nurses and midwives, and other staff as needed.

Standard Intent:

There must be policies and procedures to guide the care of women in labor including, but are not limited to all elements in sub-standards L&D.6.1.1- L&D.6.1.22. The policies and procedures are collaboratively developed by obstetricians, pediatricians, anesthesiologists, delivery room nurses and midwives, and other staff as needed.?

L&D.7 The obstetrics department has adequate resources that support the provision of safe care.

L&D.7.1 The obstetrics department has equipment, medications, and tools that meet the needs of patients, including:

L&D.7.1.1 Cardio-tocography machines (at least one capable of simultaneous recording of twin fetal hearts).

L&D.7.1.2 Automated blood pressure monitoring machines.

L&D.7.1.3 Pulse oximetry.

L&D.7.1.4 Appropriate delivery bed.

L&D.7.1.5 Intravenous infusion pumps.

L&D.7.1.6 Adequate light source appropriate for surgical care.

L&D.7.1.7 Specific obstetric instruments such as amnihooks, vacuum extractor and obstetric forceps.

L&D.7.1.8 Infant resuscitation equipment and supplies.

L&D.7.1.9 Emergency obstetric medications (e.g., oxytocics).

Standard Intent:

Adequate resources as equipment, medication and tools are adequately available in obstetric department to meet the patient care needs and provision of department services including; Cardio-tocography machines (at least one capable of simultaneous recording of twin fetal hearts), automated blood pressure monitoring machines, pulse oximetry, appropriate delivery bed, intravenous infusion pumps, adequate light source appropriate for surgical care, specific obstetric instruments such as amnihooks, vacuum extractor and obstetric forceps, infant resuscitation equipment and supplies and emergency obstetric medications (e.g., oxytocics and other medications used for controlling postpartum hemorrhage).

L&D.8 Newborns receive the proper care by qualified nurses.

L&D.8.1 There is a qualified and competent nurse to receive the newborn during delivery.

L&D.8.2 The attending nurse is qualified to perform the following for each newborn:

L&D.8.2.1 Suction.

L&D.8.2.2 Placing an identity band with the medical record number and other identifier(s) according to the hospital policy.

L&D.8.2.3 Finding and documenting the APGAR score.

L&D.8.2.4 Obtaining the footprint of the newborn and the thumbprint of the mother.

Standard Intent:

Qualified and competent nurses must be adequately available in obstetric department in general and in delivery room in specific to carry the newborn care during delivery as immediate suction, complete identification of the newborn by placing identity band/s with medical record number and other identifiers according to hospital policy, finding and documenting APGAR score, obtaining the footprint of the newborn and the thumbprint of the mother. Neonatal identification with reference to the mother should be done in the room where the delivery took place whether a delivery room or

operating room. The neonate should not leave the place of delivery without the proper identification.

L&D.9 The medical records of the obstetrics department are properly completed.

L&D.9.1 The following information must be available in patients' records before discharge from the delivery room:

L&D.9.1.1 Completed assessment and reassessment.

L&D.9.1.2 Completed partogram.

L&D.9.1.3 Secured cardio-tocography.

L&D.9.1.4 Initial neonatal assessment.

L&D.9.1.5 Delivery summary including method of delivery, date and time of delivery, name and designation of the healthcare professional who conducted the delivery and any assistants, type of anesthesia or sedation used during delivery, neonatal outcome, status of placenta and membranes, any postpartum instructions, and postpartum observations and discharge criteria.

Standard Intent:

Care of patients in the obstetric department should be fully documented and medical records should be completed before patient discharge from the delivery room. The Medical records should contain the followings; completed assessment and reassessment, completed partogram, secured cardiotocography, initial neonatal assessment, delivery summary including method of delivery, date and time of delivery, name and designation of the healthcare professional who conducted the delivery and any assistants, type of anesthesia or sedation used during delivery, neonatal outcome, status of placenta and membranes, any postpartum instructions, and postpartum observations and evidence of the patient meeting the discharge from labor room criteria.

Hemodialysis Standard Intents

HM.1 Qualified nephrologist is responsible for managing the clinical services in the hemodialysis unit.

HM.1.1 Clinical services in the hemodialysis unit are led by a qualified nephrologist with experience in managing end stage renal disease (ESRD) patients.

Standard Intent:

The head of the hemodialysis unit should be a qualified nephrologist with experience in managing end-stage renal disease (ESRD) patients.

HM.2 Qualified nurse is responsible for supervising nursing services in the hemodialysis unit.

HM.2.1 The nurse in charge of the hemodialysis unit is a qualified registered nurse with training, education or experience in hemodialysis.

HM.2.2 Nursing staff members are registered nurses qualified to care for ESRD patients by education, training or experience.

Standard Intent:

The hemodialysis head nurse must be qualified with education, training, experience, and the staff members are registered nurses qualified to care for ESRD patients by education, training or experience.

HM.3 Each patient's hemodialysis care is planned and documented in the patient's medical record.

HM.3.1 Hemodialysis procedures are ordered by a qualified nephrologist.

HM.3.2 Comprehensive assessment and reassessment is performed for each patient in the hemodialysis unit.

HM.3.3 The need for dialysis and choice of modality are based on sound clinical principles and a thorough clinical evaluation of the clinical condition and any associated co-morbidities.

HM.3.4 Informed consent is obtained for all dialysis patients after providing adequate information about the different modalities and the modality that is most appropriate for the patient's needs. The consent is updated regularly (e.g., yearly) and when the risk level is changing.

HM.3.5 Multi-disciplinary plan of care is developed for each patient in coordination with other relevant health professionals (e.g., physician, nurse, dietitian, pharmacist, and social worker).

HM.3.6 There is an appropriate multi-disciplinary patient education plan.

HM.3.7 Patients are properly monitored during and after dialysis.

HM.3.8 Plan of care is documented in the patient's medical record.

HM.3.9 Emergency medical care is available when needed.

HM.3.10 Clinical staff who participate in caring for patients on dialysis are certified in advanced life support as appropriate to the different age groups of patients, or at least one certified individual is assigned on every shift.

Standard Intent:

The hemodialysis care plan must be documented in the patient medical record to include all elements in sub-standards HM.3.1- HM.3.10.

HM.4 The hemodialysis unit has admission and discharge criteria.

HM.4.1 The hemodialysis unit has admission and discharge criteria consistent with evidence-based practice.

HM.4.2 The criteria are collaboratively developed by nephrologists, nursing staff and other relevant departments.

Standard Intent:

The hemodialysis unit must have an admission and discharge criteria consistent with evidence-based practice and are collaboratively developed by nephrologists, nursing staff, and other relevant departments.

HM.5 Policies and procedures guide the care of patients requiring hemodialysis.

HM.5.1 Care of patients in hemodialysis unit is guided by policies and procedures that include, but are not limited to, the following:

- HM.5.1.1 Assessment and reassessment of patients.
- HM.5.1.2 Assessment of volume status.
- HM.5.1.3 Care and monitoring of patients with arterio-venous fistula/graft.
- HM.5.1.4 Care and monitoring of tunneled/non-tunneled catheters.
- HM.5.1.5 Management of clotted access.
- HM.5.1.6 Preparation of hemodialysis machines.
- HM.5.1.7 Dialysis procedures.
- HM.5.1.8 Peritoneal dialysis.
- HM.5.1.9 Anticoagulation.
- HM.5.1.10 Management of electrolytes imbalance.
- HM.5.1.11 Management of dialysis-induced complications.
- HM.5.1.12 Management of cardiopulmonary collapse and urgent medical conditions.
- HM.5.1.13 Emergency transfer of patients.

HM.5.2 Policies and procedures are implemented as evidenced in the daily practice and the patient's medical record.

Standard Intent:

The hemodialysis unit must have policies and procedures to guide the care of patients requiring hemodialysis and include all elements in sub-standards HM. 5.1.1- HM.5.1.13. In addition, the policies and procedures should be implemented as evidenced in the daily practice and the patient's medical record.

HM.6 Equipment and machines in the hemodialysis unit are in good working conditions.

HM.6.1 All equipment and machines are operated within manufacturer's specifications.

HM.6.2 The preventive maintenance program -for equipment related to patient care- is developed and implemented in accordance with manufacturer's instructions.

HM.6.3 The preventive maintenance program is performed by qualified staff/entities.

HM.6.4 All records for maintenance and repair are kept on file for future reference and inspection.

HM.6.5 Staff are oriented to equipment in use.

HM.6.6 Staff are trained to identify malfunctioning equipment or machines and to report to appropriate staff for repair.

HM.6.7 Each dialysis machine is equipped with monitors and an alarm system.

HM.6.8 The preventive maintenance program includes the water treatment and distribution system.

Standard Intent:

Hemodialysis unit has specialized medical equipment and machine, to ensure that medical equipment is available for use and functioning properly, the hospital performs and documents

* Regular inspections of medical equipment including the water treatment and alarm system;
* Testing of medical equipment according to its use and manufacturers' requirements; and
* Performance of preventive maintenance.

Qualified individuals provide these services. Inspections, testing results, and any maintenance are documented and kept for future reference. Staff responsible for operating or maintaining medical equipment receive special training. The training can be from the hospital, the manufacturer of the equipment, or some other knowledgeable source. The hospital plans a program designed to periodically test staff knowledge on emergency procedures, including the use and failure of medical equipment that poses a risk to patients and staff.

HM.7 Infection control guidelines specific to the dialysis services are developed and implemented.

HM.7.1 Infection control guidelines are developed or adopted from authoritative sources or relevant professional organizations.

HM.7.2 Infection control guidelines include, but are not limited to, the following:

HM.7.2.1 Adequate space (1.2 -1.5 meters) between patients to prevent transmission of infection.

HM.7.2.2 Separation between patient care (contaminated) and office/supply areas (clean).

HM.7.2.3 Standard precautions are strictly implemented in the unit with special emphasis on hand hygiene and the appropriate use of gloves, gowns, masks, and other barriers.

HM.7.2.4 Adequate supply of personal protective equipment is available and readily accessible.

HM.7.2.5 Hand disinfectants for waterless hand hygiene should be available at every chair/bed. Hands are washed before and after contact with each patient.

HM.7.2.6 Sinks are available in adequate number (preferably one for every 2-4 chair/beds) and are conveniently located.

HM.7.2.7 Staff members have the required knowledge for safe practices to avoid cross contamination.

HM.7.2.8 Sharp disposal containers are available at each chair/bed and elsewhere as needed within the unit. Needles and sharps are disposed appropriately.

HM.7.2.9 Infectious wastes are disposed in accordance with hospital's waste disposal policies.

HM.7.2.10 Surfaces of machines including the control panels, blood pressure cuffs and chairs/beds are disinfected after use with an approved disinfectant.

HM.7.2.11 Blood spills are cleaned properly.

HM.7.2.12 Equipment such as blood pressure cuffs, stethoscopes, clamps, scissors and thermometers are allocated to a single patient and are disinfected at the conclusion of each patient treatment session.

HM.7.2.13 Supplies and equipment are properly handled in a way that prevents contamination.

HM.7.2.14 A process is in place to ensure multi-dose vials are adequately labeled and used for single patient only.

HM.7.2.15 A process is in place for infection control procedures for dialysis machines between patients.

HM.7.2.16 A process is in place for appropriate cleaning and disinfection of the water treatment and distribution system.

Standard Intent:

Hemodialysis patients are uniquely vulnerable to the development of healthcare-associated infections because of multiple factors including exposure to invasive devices, immunosuppression, the lack of physical barriers between patients in the outpatient hemodialysis environment, and frequent contact with healthcare workers during procedures and care. Evidence-based Infection control guidelines specific to the dialysis unit are established and implemented (Substandard HM.7.2.1 through HM.7.2.16).

HM.8 Patients and staff are protected from blood borne pathogens during hemodialysis.

HM.8.1 All patients are screened for Hepatitis B, Hepatitis C and HIV at the beginning of dialysis.

HM.8.2 Patient whose laboratory tests for HBsAg, anti HBs, HCV, or HIV are negative should be re-screened every 3-6 months.

HM.8.3 Patients susceptible to hepatitis B are immunized with Hepatitis B vaccine.

HM.8.4 Machines used for blood-borne infectious diseases (such as hepatitis and HIV/AIDS patients) are separated. Patients infected with Hepatitis B are strictly segregated in a separate room and treated on a separate machine used exclusively for Hepatitis B.

HM.8.5 Staff and employees have checkups for Hepatitis B, Hepatitis C, and HIV upon hiring and annually.

HM.8.6 Staff and employees susceptible to Hepatitis B are immunized with Hepatitis B vaccine and tested for antibodies to evaluate response, and all non-responders are given a second series of the HBV vaccine.

HM.8.7 Records for staff screening and hepatitis immunization are available and maintained for future reference.

Standard Intent:

Transmission of infectious diseases is a potential risk in hemodialysis unit, therefore, patients and staff evaluation and screening to identify those who have a higher risk for infection with a potentially harmful pathogen. Initial screening at the beginning of dialysis for patients for communicable diseases can significantly reduce the incidence of transmission of disease , testing should include tests for HIV, hepatitis B, hepatitis C, and other recommended tests, screening should be repeated at least every three months for patients whose laboratory test are negative and those susceptible to hepatitis B are immunized with Hepatitis B Vaccine, separate machines should be used for blood-borne infectious diseases, and patient with hepatitis B are strictly segregated in a separate room and treated on a separate machine used exclusively for Hepatitis B. As staff working in hemodialysis unit are also at high risk for exposure to and possible transmission of infection, implementing screening and prevention programs (such as immunizations, vaccinations, and prophylaxis) can significantly reduce the incidence of infectious disease transmission, staff and employees should be screened upon hiring and annually thereafter, preventive immunizations should be implemented. Records for staff screening and immunization should be available for each staff.

HM.9 Water quality is checked on a periodic basis.

HM.9.1 There is a written policy defining the periodic checking of water quality.

HM.9.2 The policy is based upon manufacturer's recommendations, regulations, and local experience.

HM.9.3 Hardness and chlorine content of feeding water are monitored on a regular basis by designated staff or authorities.

HM.9.4 Microbiologic monitoring of treated water and dialysate should be performed at least monthly and more frequently if a problem is identified.

HM.9.5 Bacteriology testing of Reverse Osmosis (RO) water as well as endotoxin assay should be performed and documented at least once per month.

HM.9.6 Chemical testing of water is performed at least once per year.

HM.9.7 Reverse Osmosis (RO) system including the feeding pipelines into the hospital is disinfected at least once per month, preferably by heat as well as by chemical disinfection.

HM.9.8 All physical and monitoring checks are verified and signed off by the nephrologist with recording of any corrective actions taken (e.g., out of range results for tests of water or dialysate).

HM.9.9 Written record and results of microbiological and chemical testing of water are in place and reviewed.

Standard Intent:

Water quality is critical factor in renal dialysis. Thus, the hospital establishes a process to monitor water quality, chemically and microbiologically, including biological testing of water. A policy should be established and implemented, the policy should define the testing frequency based on the manufacturer's recommendations, and risk levels, and hospital experience. Actions are implemented when water quality is found to be unsafe.

HM.10 The nurse in charge of the hemodialysis unit ensures the competency of the nursing staff.

HM.10.1 The nursing staff receive ongoing training and education on all relevant policies including, but are not limited to, the following:

- HM.10.1.1 Care of patients with AV fistula/AV graft.
- HM.10.1.2 Dialysis procedures.
- HM.10.1.3 Care of tunneled/non-tunneled catheters.
- HM.10.1.4 Peritoneal dialysis.
- HM.10.1.5 Assessment of patient’s volume status.
- HM.10.1.6 Anticoagulation.
- HM.10.1.7 Management of clotted access.
- HM.10.1.8 Hyperkalemia.
- HM.10.1.9 Pulse oximetry.
- HM.10.1.10 Blood transfusion.
- HM.10.1.11 Use of defibrillator.
- HM.10.1.12 Infection control.

HM.10.2 The nursing staff competencies are assessed by using different methods (e.g., written test, return demonstration) and results are documented.

Standard Intent:

The nurse in charge of the hemodialysis unit ensures the competency of the nursing staff and all nursing staff receive ongoing training and education on all relevant patient care issues as in substandard HM.1.1 through HM.10.1.12. In addition, nursing, staff competencies are assessed by using different methods (e.g., written test, return demonstration) and results are documented.

Emergency Care Standard Intents

ER.1 Qualified physician is responsible for managing the emergency department.

ER.1.1 The head of the emergency department is a physician qualified by education, training, and experience in managing emergency patients.

ER.1.2 The head of the emergency department supervises the development and implementation of policies and procedures related to managing emergency patients.

Standard Intent:

The clinical care, patient outcomes, and overall management of a hospital are only as good as the clinical and managerial activities of each individual department or service. The head of the emergency department is a physician qualified by education, training, and experience in managing emergency patients. The head of ER shall ensure the implementation of policies and procedures related to managing emergency patients.

ER.2 Emergency department staff members have the appropriate qualifications.

ER.2.1 The emergency department is covered twenty-four hours a day, seven days a week by qualified emergency physicians.

ER.2.2 On call rosters for all specialties are available and posted in the emergency department.

ER.2.3 There is an established policy on how to call consultants for opinions.

ER.2.4 All staff members are qualified and experienced in emergency care.

ER.2.5 Clinical staff who participate in caring for patients in the emergency department are certified in advanced life support as appropriate to the ages of the patients served (including Advanced Trauma Life Support) and are present on site or at least one certified individual is assigned on every shift.

Standard Intent:

There are qualified staff members (physician and nurses) in ER to provide safe and effective care and treatment to patients in ER twenty-four hours a day, seven days a week. This must be reflected by a posted roster. All clinical staff working in ER must have ATLS or at least one in each shift. There must be a clear policy on how to call consultants for opinion.

ER.3 Qualified nurse manager supervises nursing services in the emergency department.

ER.3.1 The nurse manager in charge of the emergency department is a qualified registered nurse with bachelor degree in nursing and appropriate education, training, and experience in emergency care.

Standard Intent:

The clinical care, patient outcomes, and overall management of a hospital are only as good as the clinical and managerial activities of each individual department or service. It is essential that the nurse manger in ER is qualified individual.

ER.4 The emergency department has adequate nursing coverage by qualified staff.

ER.4.1 Nursing staffing plan is based on patient volume and patient acuity and ensures adequate coverage twenty-four hours a day, seven days a week.

Standard Intent:

Appropriate and adequate staffing is critical to patient care in ER. Staff planning is carried out by department/service leaders. The planning process uses recognized methods for determining levels of staffing. The plan is written and identifies the number and types of required staff and the skills, knowledge, and other requirements needed in each department and service. Planned and actual staffing is monitored on an ongoing basis, and the plan is updated as necessary.

ER.5 Nursing staff in the emergency department receive continuous training with competency assessment.

ER.5.1 Nursing staff in the emergency department receive training and education as relevant to the scope of services.

ER.5.2 There is ongoing competency assessment for the nursing staff.

ER.5.3 The competency assessment of the nursing staff is documented.

Standard Intent:

To maintain acceptable Emergency Nursing staff performance, to teach new skills, and to provide training on new medical technology and procedures, the hospital provides or arranges for facilities, educators, and time for ongoing in-service and other education for nursing staff in Emergency department. The hospital must ensure that nurses are qualified to provide nursing care for Emergency patient through training and competencies assessment program that should be documented in staff file.

ER.6 The emergency department has adequate resources that support the provision of safe care.

ER.6.1 The emergency department has the necessary equipment, supplies, and medications as appropriate to the scope of services.

ER.6.2 There is a documented process to check equipment and stock refill on a regular basis or when needed.

ER.6.3 Resuscitation/trauma rooms have adequate space to perform resuscitation.

ER.6.4 The medical bag contains all essential resuscitation medications.

ER.6.5 The medical bag is checked daily and refilled after use.

ER.6.6 Waiting areas are available and are visually accessible to the medical staff.

ER.6.7 Registration clerk is available to register emergency patients.

ER.6.8 Security measures and trained personnel are planned for protection of emergency department patients and staff.

Standard Intent:

Risks in clinical care processes are significantly reduced when appropriate and well-functioning equipment is used to provide the planned services. Adequate supplies and medications must be as well available and appropriate for planned use and emergent situations. Each organization understands the required or recommended equipment, supplies, and medications necessary to provide the planned services to its patient population.

ER.7 The clinical records of the emergency department are properly completed.

ER.7.1 There is an emergency department record form that is completed for every patient presenting for care in the emergency room.

ER.7.2 The emergency record is kept in the patient's medical record.

Standard Intent:

The record of each patient receiving emergency care should be completed including but not limited to the arrival time, initial Assessment, treatment provided and departure times. This information is captured for all emergency department patients, including those who are discharged from the hospital, transferred to another facility, or admitted as inpatients. Departure time may be when the patient physically leaves the emergency department to go home or to another facility, or the time at which the patient is moved to another unit as an inpatient. For patients who are discharged from the emergency department, the clinical record includes the conclusions at termination of treatment, the patient's condition at discharge, and follow-up care instructions.

ER.8 There is an effective triage process to prioritize emergency patients.

ER.8.1 There is a process to identify patients with urgent or emergent care needs.

ER.8.2 Patients with urgent or emergent needs are given priority for assessment and appropriate and timely care.

ER.8.3 Re-triage is performed when appropriate (e.g., change of medical condition, long waiting time).

Standard Intent:

Patients with emergent, urgent, or immediate needs (such as trauma patients and patients with severe chest pain) are identified by an evidence-based triage process. Once identified as emergent, urgent, or requiring immediate needs, these patients are assessed and receive care as quickly as necessary. Such patients may be assessed by a physician or other qualified individual before other patients, receive diagnostic services as rapidly as possible, and begin treatment to meet their needs. The triage process may include physiologic-based criteria, where possible and appropriate. The hospital trains staff to determine which patients need immediate care and how their care is given priority.

ER.9 Policies, procedures, pathways and guidelines guide the care of patients in the emergency department.

ER.9.1 There are policies and procedures that are consistent with the hospital scope of services as well as the hospital wide policies and procedures.

ER.9.2 The policies and procedures include, but are not limited to, the following:

- ER.9.2.1 Management of medico-legal cases such as alcohol and narcotic abuse and criminal acts.
- ER.9.2.2 Management of suspected victims of abuse, neglect, and domestic violence.
- ER.9.2.3 Management of suicidal patients.
- ER.9.2.4 Care of trauma patients.
- ER.9.2.5 Care of patients not competent to care for themselves.
- ER.9.2.6 Care of minors.
- ER.9.2.7 Patient transfer from emergency department to inpatient areas or to another organization.
- ER.9.2.8 Patients who leave against medical advice.
- ER.9.2.9 Patients who leave without being seen.

ER.9.3 There are clinical practice guidelines developed as guided by the most common emergencies and the top emergency diagnoses.

ER.9.4 The policies, procedures, and guidelines are developed by the emergency department head, the nurse manager, and staff in collaboration with other relevant department heads.

Standard Intent:

Policies and procedures are important tools for staff to understand the population served and services, and to respond in a thorough, competent, and uniform manner. Policies and procedures must be tailored to the particular ER population to be appropriate and effective in reducing the related risk. Policies mentioned in substandard ER.9.2.1 through 9.2.9 are the minimum acceptable.

ER.10 The hospital implements a policy that defines the responsibility for patients in the emergency department.

ER.10.1 The policy defines the physician responsible for the care of patients in the emergency department including patients under observation, patients waiting for admission, patients waiting for admission with no bed available (boarding patients) and patients waiting for transfer to another organization.

ER.10.2 Boarding patients receive the same care as inpatients.

ER.10.3 The transfer of responsibility is documented at times of shifts, handovers, referral and admission.

Standard Intent:

To maintain continuity of care throughout the patient's stay in Emergency Department, the individual with overall responsibility for coordination and continuity of the patient's care or particular phase of the patient's care is clearly identified. This individual may be a physician or other qualified individual. The responsible individual is identified in the patient's record or in another manner made known to the organization's staff. The responsible individual is expected to provide documentation related to the patient's plan of care. This individual would need to collaborate and to communicate with the other health care practitioners. When a patient moves from one phase of care to another (for example, from emergency to surgical), the individual responsible for the patient's care may change or the same individual may continue overseeing all the patient's care.

ER.11 Emergency diagnostic tests are performed and results communicated on a timely manner.

ER.11.1 Laboratory and radiological diagnostic investigations required for a safe patient care are available twenty-four hours a day, seven days a week.

ER.11.2 The hospital has a process to provide all investigations that are essential but not available.

ER.11.3 Results of investigations are available to the emergency staff within a defined time frame.

Standard Intent:

The hospital defines the time period for performing and result of emergency diagnostic tests. Results are reported within a time frame based on patient needs, services offered, and clinical staff needs. Emergency tests and after-hours and weekend testing needs are included. Results from urgent tests, such as those from the emergency department, operating theatres, and intensive care units, are given special attention in the quality measurement process. In addition, when diagnostic tests are not available, in the hospital, hospital must have a process to provide those diagnostic tests including the time frame.

ER.12 The emergency department has a channel of communication with the designated regional drug and poison information center when needed.

ER.12.1 The contact details of the regional drug and poison information center are available and accessible to the staff in the emergency department.

ER.12.2 The hospital communicates with regional poison center when a need arises.

ER.12.3 The emergency department is equipped to deal with the most common and/or risky poisonous injuries in the community it serves.

Standard Intent:

In some occasions, patient's needs in ER is not expected and need different experts which might be not available in the hospital, and due to the critical of patient conditions, hospital must have a process of communicating with outside information center such as poison center to provide the evidence based care for the patients.

ER.13 There is an efficient process for emergency consultations.

ER.13.1 The hospital implements a clear policy and procedure that regulates consultation requests coming from the emergency department.

ER.13.2 Levels of consultations are identified including Immediate (life, limb, or function threatening) and emergent consultations.

ER.13.3 Level of consulted physicians and the ways of communications are included.

ER.13.4 Timelines of phone response and physical presence to different types of consultations are included.

ER.13.5 If a consultation from outside the hospital is needed, the process is included in the policy (e.g., admit and consult, patient transfer, city wide on call specialty).

Standard Intent:

The Emergency department must have a process of requesting other specialties to assess the patient when needed. When the specialty service is not available, arrangements should be made with other centers either to provide either a consultant to visit the patient in the referring organization or to transfer the patient to the referred organization.

ER.14 Emergency department quality indicators are monitored and reported.

ER.14.1 The Emergency department selects and monitors key quality indicators that are monitored and reported on a regular basis.

ER.14.2 The selected emergency department indicators may include, but are not limited to, the following:

ER.14.2.1 Time to ECG in chest pain patients.

ER.14.2.2 Time to antibiotics in sepsis patients.

ER.14.2.3 Triage to physician time.

Standard Intent:

The leaders of the department or service implement the selection and monitoring of measures specific to the department or service. The measures priorities to reduce variation, improve the safety of high-risk procedures/treatments, improve patient satisfaction, or improve efficiency. The head of ER is responsible for ensuring that the measurement activities provide the opportunity for the evaluation of staff as well as the processes of care. Thus, measurement includes, over time, all of the services provided. The resulting data and information are important to the department's or service's improvement efforts.

ER.15 The hospital maintains effective ambulance services.

ER.15.1 Emergency department has appropriate channels of communication with Red Crescent services upon receiving or transferring patients.

ER.15.2 The ambulance services are supervised by emergency department director or emergency department nursing manager.

ER.15.3 The ambulances have adequate equipment and supplies to be ready for transfer of patients twenty-four hours a day, seven days a week.

ER.15.4 Equipment and supplies are based on Trauma/resuscitation area preparation to transfer critically ill patients.

ER.15.5 A documented daily check is conducted on both medical and mechanical functions of ambulances.

ER.15.6 Maintenance of ambulance equipment is regularly conducted and documented.

Standard Intent:

The hospital's process for referring, transferring, or discharging patients includes an understanding of the transportation needs of patients. Upon completion of the service, the patient may require assistance with transportation back to his or her home or another facility. Assessing the patient's transportation needs and ensuring that the patient has safe transportation is the hospital's responsibility, the type of transportation will vary and may be by ambulance or other vehicles owned by the hospital or by a source designated by the family, the transportation selected will depend on the patient's condition and status. When the transport vehicles are owned by the hospital, they need to be in compliance with all applicable laws and regulations related to their operation, condition, and maintenance. The required drugs, medications, and other supplies needed within the vehicle are based on the types of patients transported. If the hospital contracts for transport services, the hospital must be assured that the contractor meets similar standards for patient and vehicle safety. In all cases, the hospital evaluates the quality and safety of the transportation services.

Radiology Services Standard Intents

RD.1 Qualified radiologist is responsible for managing the radiology department.

RD.1.1 The head of the radiology department is a radiologist qualified by education, training, and experience.

RD.1.2 The head of the radiology department supervises the development and implementation of policies and procedures related to radiology services throughout the hospital.

Standard Intent:

The head of radiology department is a qualified radiologist holding Saudi board or equivalent by education, training and experience. He is responsible also for drafting the radiology services policies and procedures and its implementation throughout the hospital.

RD.2 The radiology department has adequate qualified staff.

RD.2.1 The radiology department has adequate staff, including:

RD.2.1.1 Technical director.

RD.2.1.2 Medical physicists.

RD.2.1.3 Radiation safety officer and supervisor (for radiotherapy nuclear medicine and diagnostics).

RD.2.1.4 Quality officer.

RD.2.1.5 PACS administrator, when applicable.

RD.2.2 Staff working in the department are trained and qualified in their field.

RD.2.3 There is twenty-four-hour coverage by a radiologist and a technologist.

Standard Intent:

The radiology services are provided to patients around the clock by variety of qualified and experienced staff in their field as technical director, medical physicists, radiation safety officer and supervisor (for both oncology /radiotherapy services and diagnostic radiology), PACS administrator and Quality officer. The staff should be sufficient in number to match patient volume and have valid SCFHS registration.

RD.3 The radiology department has policies and procedures that guide all radiological activities.

RD.3.1 The radiology department has policies and procedures to address all important radiological investigations and procedures, including:

RD.3.1.1 X-rays.

RD.3.1.2 Ultrasonography.

RD.3.1.3 Computed Tomography.

RD.3.1.4 Magnetic Resonance Imaging.

RD.3.1.5 Angiogram.

RD.3.1.6 Interventional radiological procedures.

RD.3.1.7 Fluoroscopy.

RD.3.1.8 Contrast agent reactions.

RD.3.1.9 Nuclear medicine imaging.

RD.3.1.10 Molecular Imaging (Positron Emission Tomography –PET scanning).

RD.3.1.11 Bedside and critical care radiography.

RD.3.1.12 Radiopharmaceuticals calibration and quality control.

RD.3.1.13 Portable radiological machines.

RD.3.1.14 Mammography.

Standard Intent:

The radiology department services are guided by policies and procedures for the following investigations and procedures: X-rays, ultrasonography, computed tomography, magnetic resonance imaging, angiogram, interventional radiological procedures, fluoroscopy, nuclear medicine imaging and reactions, molecular imaging (Positron Emission Tomography –PET scanning), bedside and critical care radiography, mammography, radiopharmaceuticals calibration and quality control and portable radiological machines (substandard RD.3.1.1 through RD.3.1.13)

RD.4 Requests for radiological investigations utilize a standardized method throughout the hospital.

RD.4.1 There is a special request form utilized by the medical staff for all requests related to radiology department.

RD.4.2 Relevant information, including a brief case description and rationale for the investigation, are documented on the radiology request form for all diagnostic and/or interventional imaging procedures.

Standard Intent:

A standardized radiological service requisition process is followed throughout the hospital utilizing a unified request form including relevant information, brief description

of the patient condition and reason/s for the investigation for diagnostic and/or interventional imaging procedures.

RD.5 The radiology department implements a policy and procedure that defines the process and time limits of results reporting for all radiological studies.

RD.5.1 The radiology department defines and implements the format and content of radiology reports (paper or electronic). Essential elements of the report include:

RD.5.1.1 Patient identification.

RD.5.1.2 Type of the procedure.

RD.5.1.3 Identification of the ordering physician.

RD.5.1.4 Reporting date and time.

RD.5.1.5 Identification of the reporting radiologist.

RD.5.2 The radiological studies are reported by the radiologist within defined time limits.

RD.5.2.1 Immediate reporting for emergency cases.

RD.5.2.2 Urgent cases are reported within twenty-four hours.

RD.5.2.3 Routine cases are reported within forty-eight hours.

Standard Intent:

A standardized radiological service reporting process is followed throughout the hospital utilizing a unified report format (paper o electronic) and defined time frames for report production. The essential elements of the report are; patient identification, type of the procedure, identification of the ordering physician, reporting date and time and identification of the reporting radiologist. The time frames for report generation should be preciously identified; for emergency cases immediately, for urgent cases within 24 hours and for routine cases within 48 hours.

RD.6 The radiology department implements a policy and procedure for reporting of critical results.

RD.6.1 There is a policy and procedure for reporting of critical results developed in consultation with clinical departments.

RD.6.2 The policy defines the notified party and mean of communication.

RD.6.3 The policy defines the “read- back “sequence of reporting of critical results.

RD.6.4 The policy defines the proper documentation of a notification event, which includes:

RD.6.4.1 Date and time of notification.

RD.6.4.2 Patient identification.

RD.6.4.3 The critical result.

RD.6.4.4 Documentation of read-back.

RD.6.4.5 Identification of the notifying person.

RD.6.4.6 Identification of the notified person.

Standard Intent:

The critical test results are reported following a policy and procedure developed by radiology and clinical departments, the policy clearly defines the notified parties, means of communication, read-back sequence and elements required for documenting the event (date, time, patient identification, critical test result, read-back documentation, identifying both the notifying and the notified person).

RD.7 Previous radiological studies can always be accessed.

RD.7.1 There is a master X-ray jacket or an access to all archived previous radiological studies (Picture Archiving and Communication System-PACS) for every patient.

Standard Intent:

All radiological studies done previously for every patient are easily accessed and retrieved either through master X-ray jacket or picture archiving and communication system (PACS).

RD.8 The radiology department has a documented and implemented safety plan.

RD.8.1 There is a safety plan that indicates the periodic inspection, maintenance, and calibration of all equipment.

RD.8.2 The safety plan involves the management of radioactive materials used for therapeutic and diagnostic purposes, particularly with regard to handling, storing, and transportation.

RD.8.3 The safety plan involves posting of safety warnings on the doors.

RD.8.4 The safety plan involves checking female patients for pregnancy before exposure.

RD.8.5 The safety plan indicates monitoring of the staff for radiation exposure, at least quarterly.

RD.8.6 The safety plan involves the provision and regular testing of radiation protection aprons and thyroid and gonad shields for staff and patients.

RD.8.7 Records are available indicating the radiation dosimetry tools and staff radiation exposure for the past twelve months.

RD.8.8 The safety plan is implemented as evidenced by the daily practice.

Standard Intent:

One of the essential documents that should be in place and fully implemented to ensure patient safety is the radiology safety plan that include how to perform PPM periodic inspection, maintenance and calibration of equipment, management of radioactive materials used for diagnostic and therapeutic modalities especially handling, storing, transportation, posting safety warnings on doors and walls, checking female patients for pregnancy before exposure, monitoring of staff for radiation exposure (dosimetry) minimum quarterly for the past 12 months, regular inspection of radiation protection aprons and The safety plan is implemented as evidenced by practice and documentation, its effectiveness should be evaluated through periodic audits (e.g. six monthly).

RD.9 The radiology department has a documented and implemented protocol for interventional radiological procedures.

RD.9.1 There is a documented protocol for interventional radiological procedures, which indicates pre-procedural assessments (patient and procedure verification, rationale for the procedure, past history and history of allergic reactions, coagulation profile, informed consent with explanation of risks and benefits).

RD.9.2 The protocol indicates monitoring requirements during and after the procedure.

RD.9.3 Findings of patient assessment and monitoring are documented in the patient's medical record.

Standard Intent:

Interventional radiological procedures are performed following a written protocol clearly identifying pre-procedural patient assessments (patient and procedure verification, rationale for the procedure, past history and history of allergic reactions, coagulation profile, informed consent with explanation of risks and benefits), monitoring required during and after the procedure and documenting all in patient's medical records.

RD.10 The radiology department ensures the safety of diagnostic imaging equipment.

RD.10.1 The radiology department ensures the following tests are conducted at least annually:

RD.10.1.1 Automatic Exposure Control (AEC) test.

RD.10.1.2 Kvp reproducibility and repeatability.

RD.10.1.3 Half Value Layer test.

RD.10.1.4 Alignment of collimator and x-ray field.

RD.10.1.5 Mean glandular dose test (for mammography).

RD.10.2 The radiology department implements corrective actions accordingly.

Standard Intent:

The safety of diagnostic imaging equipment is ensured through performing the necessary tests that done minimally annual with the corrective actions accordingly, those test are: Automatic Exposure Control (AEC) test, Kvp reproducibility and repeatability, Half Value Layer test, Alignment of collimator and x-ray field, Mean glandular dose test (for mammography).

Burn Care Standard Intents

BC.1 Qualified director is responsible for managing the clinical services in the burn care unit.

BC.1.1 The clinical services in the burn care unit are led by a qualified plastic surgeon with interest/experience in burn care.

Standard Intent:

Bun services, provided must be under the direction of an individual who is qualified plastic surgeon, by documented education, training, expertise, and experience, and licensed from the Saudi Commission for healthcare specialties. This individual assumes professional responsibility for the Burn unit and the services provided.

BC.2 The burn unit is covered by qualified medical staff.

BC.2.1 The care is provided by consultant burn care five days a week during working hours.

BC.2.2 The care is supplemented by sufficient qualified surgeons twenty-four hours a day, seven days a week (plastic surgeon or general surgeon who has completed initial stage training in plastic surgery).

BC.2.3 The unit has access to consultant burn care twenty-four hours a day, seven days a week.

Standard Intent:

The burn unit must be covered by a qualified consultant who provides care five days a week during working hours and is supplemented by sufficient qualified surgeons twenty-four hours a day, seven days a week (plastic surgeon or general surgeon who has completed initial stage training in plastic surgery). The burn unit must have access to consultant burn care twenty-four hours a day, seven days a week.

BC.3 Clinical staff members have appropriate qualifications.

BC.3.1 Clinical staff members in the burn care unit are qualified in the care of burn patients.

BC.3.2 Clinical staff who participate in providing care for burn patients are certified in advanced life support for the different age groups.

BC.3.3 On every shift, clinical staff are present on site or at least one certified professional is assigned for the burn unit.

Standard Intent:

The clinical staff in the burn unit must be qualified in the care of burn patients and are certified in advanced life support for the different age groups. On every shift, clinical

staff must be present on site or at least one certified professional is assigned for the burn unit.

BC.4 Qualified nurse manager is responsible for supervising nursing services in the burn unit.

BC.4.1 The nurse manager in charge of the burn unit is a qualified registered nurse with training, education, or experience in burn care.

Standard Intent:

The Burn Care Service must have a nominated Nurse Manager who is supervising and take overall responsibility for the services; the nurse manager is qualified by experience, training, education and licensed by the Saudi Commission for health care specialties.

BC.5 The burn unit has adequate nursing coverage.

BC.5.1 Nursing staffing plan is based on patient volume and patient acuity and ensures adequate coverage twenty-four hours a day, seven days a week.

Standard Intent:

Burn unit should have sufficient appropriately qualified registered nurses to provide critical care to burns patients, staffing plan is developed to ensure adequate staffing.

BC.6 The burn unit has admission and discharge criteria.

BC.6.1 The burn unit has admission and discharge criteria consistent with evidence-based practice.

BC.6.2 The criteria are collaboratively developed by the unit medical and nursing staff.

BC.6.3 The admission and discharge criteria are implemented.

Standard Intent:

The burn unit must have an admission and discharge criteria consistent with an evidence-based practice that are collaboratively developed by the unit medical and nursing staff. The criteria should implement.

BC.7 Services provided in the burn unit are coordinated with other services to meet the needs of patients.

BC.7.1 Medical services are readily available and accessible including, but are not limited to:

BC.7.1.1 Critical care services.

BC.7.1.2 Anesthesia services.

BC.7.1.3 Social services.

BC.7.1.4 Pharmaceutical care.

BC.7.1.5 Physiotherapy services.

BC.7.2 Care is coordinated with the different disciplines participating in the plan of care.

Standard Intent:

The services provided in the burn unit must be **coordinated with other services to meet the needs of patients** and are readily available and accessible including all elements in sub-standards BC.7.1.1- BC.71.5.

BC.8 Policies, procedures, guidelines, and protocols guide the care in the burn unit.

BC.8.1 There are policies, procedures, protocols and guidelines covering, but are not limited to:

BC.8.1.1 Inhalation injury.

BC.8.1.2 Varying degrees/types of burns.

BC.8.1.3 Infections.

BC.8.1.4 Use of skin or synthetic grafts.

Standard Intent:

The burn unit must have policies, procedures, protocols and guidelines covering that include inhalation injury, varying degrees/types of burns, infections and the use of skin or synthetic grafts.?

BC.9 Policies and procedures guide all practices relating to infection control in the burn unit.

BC.9.1 There are policies and procedures to guide all practices relating to infection control and this includes, but is not limited to:

BC.9.1.1 Separation of cases.

BC.9.1.2 Use of masks, gowns and gloves.

BC.9.1.3 Cleaning and disinfecting all equipment and tools.

BC.9.1.4 Visitor restrictions.

BC.9.1.5 Aseptic dressing change.

BC.9.1.6 Care of skin graft.

BC.9.1.7 Transport of patients into and out of the unit.

BC.9.1.8 Burn bath management.

BC.9.2 The burn care unit is under positive pressure with High Efficiency Particulate Air (HEPA) filters.

BC.9.3 Policies and procedures relating to infection control are implemented as evidenced in the daily practice and the patient's medical record.

Standard Intent:

Infection is a major complication of burn injury. Infection is linked to impaired resistance from disruption of the skin's mechanical integrity and generalized immune suppression. The burn unit must have effective means of isolation that are consistent with principles

of standard precautions and barrier techniques to decrease the risk of cross-infection and cross-contamination. Positive pressure room with HEPA filter should be available because of low immunity patient. Policies and procedures related to infection control should be established and implemented within the Burn Care Service. Policies mentioned in substandard BC.9.1.1 through BC.9.1.8 are the minimum required. There should be evidence of policies' implementation through monitoring of the daily practices and medical records documentation.

BC.10 The burn care unit has all necessary equipment and supplies for the provision of safe care.

BC.10.1 The burn care unit has the necessary equipment, supplies, and medications including, but are not limited to:

BC.10.1.1 Crash Cart.

BC.10.1.2 Automated blood pressure monitoring machines.

BC.10.1.3 Cardiac monitors.

BC.10.1.4 Suction machines.

BC.10.1.5 Pulse oximeters.

BC.10.1.6 Intravenous infusion pumps and syringes.

BC.10.1.7 Ventilators.

BC.10.1.8 Blood warmers.

BC.10.1.9 Glucometers.

Standard Intent:

Burn unit should have adequate equipment, supplies and medications to safely provide care to patients. Equipment and supplies mentioned in substandard BC.10.1 through BC.10.1.9 are the minimum required.

BC.11 Nursing staff in the burn care unit receive continuous training with competency assessment.

BC.11.1 Nursing staff in the burn care unit receive training and education that include, but is not limited to the following:

BC.11.1.1 Use of pulse oximetry.

BC.11.1.2 Principles of infection control.

BC.11.1.3 Use of the defibrillator.

BC.11.1.4 Knowledge of the dosage, side effects, and complications of commonly used high alert medications.

BC.11.2 There is ongoing competency assessment for the nursing staff (e.g., written test, return demonstration).

BC.11.3 The competency assessment of the nursing staff is documented.

Standard Intent:

Nursing department develop policies that details the competencies required to care for a burn injured patient, and should take account of the age and injury severity of the patients admitted to the service. Annual appraisals, supported by a training and development program, should ensure that all staff have, and are maintaining, the competences expected for their role. Training and competency assessment should be undertaken for the procedures mentioned in substandard BC 11.1.1 through BC.10.1.4. The competency and training assessments should be documented.

Oncology & Radiotherapy Standard Intents

ORT.1 Qualified physician is responsible for managing the oncology and radiotherapy services.

ORT.1.1 The individual(s) responsible for the oncology and radiotherapy services is qualified by education, training, and experience in the fields of oncology/radiation oncology.

Standard Intent:

The individual responsible for the oncology and radiotherapy services must be qualified by education, training, and experience in the fields of oncology/radiation oncology.

ORT.2 The hospital ensures full compliance with the relevant regulations on radiation.

ORT.2.1 The hospital has a valid license for the provision of radiotherapy services from relevant authorities (King Abdulaziz City for Science and Technology).

Standard Intent:

The hospital should be in full compliance with the Saudi regulations for oncology and radiotherapy services stipulated by King A. Aziz medical city for science and technology, facilities are not allowed to render such services unless they have valid licensure.

ORT.3 Oncology and radiotherapy services are provided by qualified staff.

ORT.3.1 Oncology and radiotherapy services are adequately staffed as follows:

- ORT.3.1.1 Oncologists/Radiation oncologists.
- ORT.3.1.2 Medical physicists.
- ORT.3.1.3 Radiation therapists.
- ORT.3.1.4 Mould room technicians.
- ORT.3.1.5 Radiation safety officer and supervisor.
- ORT.3.1.6 Quality officer.

ORT.3.2 Staff are trained and qualified in their fields.

ORT.3.3 Clinical staff maintain registration with the Saudi Commission for Health Specialties.

Standard Intent:

The oncology and radiotherapy unit must be adequately staffed including oncologists/radiation oncologists, medical physicists, radiation therapists, mold room technicians, radiation safety officer and supervisor and quality officer. The staff must be trained and qualified in their fields. In addition, all clinical staff should maintain registration with the Saudi Commission for Health Specialties.

ORT.4 Qualified nurse manager(s) supervises nursing practices in the oncology and radiotherapy services.

ORT.4.1 The nurse manager is a registered nurse qualified by education, training, and experience in the field of oncology/radiotherapy.

ORT.4.2 The nurse manager develops and collaborates with other disciplines for developing all relevant policies and procedures including, but are not limited to:

- ORT.4.2.1 Chemotherapy administration, side effects, and safety precautions.
- ORT.4.2.2 Radiation therapy administration, side effects, and safety precautions.
- ORT.4.2.3 Targeted therapy, immunotherapy and contrast media administration and education.
- ORT.4.2.4 Spill management.
- ORT.4.2.5 Special radiation techniques (brachytherapy, stereotactic radiotherapy, unsealed sources, other techniques), including preparation and delivery guidelines.
- ORT.4.2.6 Extravasations and anaphylaxis management guidelines.
- ORT.4.2.7 Radioactive iodine management.
- ORT.4.2.8 Dying and end of life care management.
- ORT.4.2.9 Bone marrow and stem cell transplant management.
- ORT.4.2.10 Management of neutropenia and other related complications of chemo/radiation therapy.

Standard Intent:

The nursing services in the oncology and radiotherapy department is supervised by a qualified, registered nursing manager (educated, trained and experienced) to enable her to collaborate with other disciplines within the organization to develop the required policies and procedures and guidelines relevant to the department practice, these policies are not limited to the following (Chemotherapy and radiation administration, side effects, and safety precautions, Targeted therapy, immunotherapy and contrast media administration and education, Spill management, Special radiation techniques (brachytherapy, stereotactic radiotherapy, unsealed sources, other techniques), preparation and delivery guidelines, extravasations and anaphylaxis management guidelines, radioactive iodine management, dying and end of life care management, bone marrow and stem cell transplant management, management of neutropenia and other related complications of chemo/radiation therapy).

ORT.5 Oncology and radiotherapy services are guided and overseen by a multidisciplinary committee.

ORT.5.1 There is a multidisciplinary committee to guide and oversee oncology and radiotherapy services.

ORT.5.2 The committee meets at least four times a year. The record of the minutes of meetings is maintained.

ORT.5.3 The committee assists in developing and reviewing policies, procedures, safety plan, guidelines and protocols for the provision of a safe patient care.

ORT.5.4 The committee ensures implementation of policies and procedures.

Standard Intent:

The oncology and radiotherapy services must have a multidisciplinary committee to guide and oversee oncology and radiotherapy services. The committee meets at least four times a year. The record of the minutes of meetings is maintained. The committee assists in developing and reviewing policies, procedures, safety plan, guidelines and protocols for the provision of a safe patient care. The committee ensures implementation of policies and procedures.

ORT.6 Oncology and radiotherapy services include a palliative care unit/service.

ORT.6.1 The unit has policies and procedures, guidelines and protocols for the palliative care including pain management and management of illness/treatment-related symptoms.

ORT.6.2 Staff are well trained on palliative care practices.

Standard Intent:

The oncology and radiotherapy unit must have policies and procedures, guidelines and protocols for the palliative care including pain management and management of illness/treatment-related symptoms. The hospital should ensure that staff are well trained on palliative care practices.

ORT.7 There is a safety plan to ensure the safety of oncology and radiotherapy services.

ORT.7.1 There is a written safety plan that includes:

ORT.7.1.1 Periodic inspection, maintenance and calibration of the linear accelerator and other radiation equipment.

ORT.7.1.2 Guidelines on how to inspect and monitor the medical equipment.

ORT.7.1.3 Management of nuclear material used for therapeutic and diagnostic purposes, especially in regard to its handling, storing, and transportation.

ORT.7.2 The safety plan is implemented and audited for effectiveness.

Standard Intent:

One of the essential documents that should be in place and fully implemented to ensure patient safety is the oncology and radiotherapy services safety plan that include how to perform PPM and calibration of linear accelerator and other radiation equipment, guidelines on how to inspect and monitor medical equipment,

management of nuclear materials used for diagnostic and therapeutic modalities especially handling, storing, transportation, usage and disposal. The safety plan effectiveness should be evaluated through periodic audits (e.g. six monthly).

ORT.8 Oncology and radiotherapy services implement admission and discharge criteria.

ORT.8.1 There are admission and discharge criteria for patients receiving oncology and radiotherapy services.

ORT.8.2 The criteria are collaboratively developed by physicians and nursing staff.

Standard Intent:

The hospital must have an admission and discharge criteria for patients receiving oncology and radiotherapy services that collaboratively developed by physicians and nursing staff.

ORT.9 The nurse manager ensures the competency of the nursing staff.

ORT.9.1 The nursing staff receive training and education that are necessary for the provision of effective and safe care including, but are not limited to:

- ORT.9.1.1 Central and peripheral venous access device.
- ORT.9.1.2 Care of tracheostomies.
- ORT.9.1.3 Chest tube management.
- ORT.9.1.4 Advanced medication administration, including targeted therapy, chemotherapy, immunotherapy, and hormonal therapy.
- ORT.9.1.5 Line management including extravasations.
- ORT.9.1.6 Radiation side effects management.
- ORT.9.1.7 Assisting and preparing for lumber puncture.
- ORT.9.1.8 Assisting in intrathecal administration of chemotherapy.
- ORT.9.1.9 Infection control, including hazardous material and blood spill.
- ORT.9.1.10 Blood transfusion.
- ORT.9.1.11 Use of defibrillator.

ORT.9.2 Nursing staff competencies are assessed and are documented.

Standard Intent:

The nurse manager ensures that all nurses working in oncology and radiotherapy department are competent in all aspects required to deal with patients in their provision by education and training, the nurses competencies are regularly assessed and documented. Those competencies are not limited to the following: central and peripheral venous access device, care of tracheostomies, chest tube management, advanced medication administration, including targeted therapy, chemotherapy,

immunotherapy, and hormonal therapy, line management including extravasations, radiation side effects management, Assisting and preparing for lumber puncture, assisting in intrathecal administration of chemotherapy, Infection control, including hazardous material and blood spill, Blood transfusion, Use of defibrillator and nursing staff competencies are assessed and are documented.

ORT.10 Appropriate documentation is maintained for quality control activities of the oncology and radiotherapy services.

ORT.10.1 Quality records are maintained, which include:

ORT.10.1.1 Periodic inspection, maintenance and calibration of the linear accelerator and other radiation equipment.

ORT.10.1.2 Records of the isotopes used in treatment that include its energy, calibration, and disposal.

ORT.10.1.3 Records of the radiation dosimetry and staff radiation exposure for the past twelve months.

Standard Intent:

Necessary records and documents of oncology and radiotherapy department activities are maintained for quality control activities which include records related to equipment used (periodic inspection, maintenance, and calibration), radioactive materials used (energy, calibration, and disposal), radiation dosimetry and staff exposure to radiation for the past 12 months.

Respiratory Care Services Standard Intents

RS.1 The hospital provides respiratory care services.

RS.1.1 Respiratory care services are provided twenty-four hours a day, seven days a week.

RS.1.2 A qualified respiratory therapist with a minimum of bachelors of science in respiratory care directs the work of the respiratory care therapists and provides the general administration of the respiratory care services department/unit.

RS.1.3 A qualified physician (e.g., pulmonologist, anesthesiologist, or intensivist) provides the medical supervision on the clinical activities of the respiratory care services department/unit.

RS.1.4 Personnel providing respiratory services are trained professionals in respiratory care.

RS.1.5 Clinical staff providing respiratory care services are certified in advanced life support as appropriate to the age of the patients served and are present on site or at least one certified individual is assigned on every shift.

Standard Intent:

The respiratory service is mandatory in each hospital. Hospitals must make sure that they provide 24 hour respiratory services that is directed by a qualified respiratory therapist and that all personnel providing respiratory services are trained professional in respiratory care. All clinical staff providing respiratory care service must be certified in advance life support as appropriate to the age of the patient served and are present on site or at least one of them is assigned on every shift.

RS.2 Policies and procedures guide respiratory care services.

RS.2.1 There are policies and procedures to guide respiratory care services including, but are not limited to, the following:

- RS.2.1.1 Use of equipment.
- RS.2.1.2 Pulmonary function testing.
- RS.2.1.3 Coughing and breathing exercise.
- RS.2.1.4 Obtaining arterial blood gasses.
- RS.2.1.5 Mechanical ventilator support.
- RS.2.1.6 Dealing with open cases of Tuberculosis.

RS.2.2 Policies and procedures are implemented.

Standard Intent:

The respiratory care service should have an implemented policy and procedure including but not limited to the use of equipment, pulmonary function testing, coughing and breathing exercise, obtaining blood gasses, mechanical ventilator support and dealing with

open cases of tuberculosis. Policies should be implemented as evidenced from clinical practice and medical records documentation reviews.

RS.3 All equipment and machines in the respiratory care services are operated within manufacturers' specifications and maintained free of defects.

RS.3.1 All equipment and machines are operated within manufacturers' specifications.

RS.3.2 The periodical preventive maintenance is developed and implemented in accordance with manufacturers' instructions.

RS.3.3 All maintenance and repair records are maintained for future reference and inspection.

Standard Intent:

Hospital must make sure that all equipment and machines used in the respiratory care service are operated within manufacturers' specifications and that periodical preventive maintenance is developed and implemented in accordance with manufacturers' instructions. All maintenance and repair records are maintained for future reference and inspection.

RS.4 Each patient's respiratory care is planned and documented in the medical record.

RS.4.1 The plan of care is developed through an evidence-based and collaborative approach among the team members involved.

RS.4.2 Comprehensive assessment and reassessment are performed for each patient.

RS.4.3 The plan of care and the response to treatment are documented in the patient's medical record.

Standard Intent:

Hospitals must make sure that the plan of respiratory care is developed through an evidence-based and collaborative approach among the team members involved after a comprehensive assessment is performed for each patient. Assessment and reassessment of patient, the plan of care and the response to treatment must be documented in the patient's medical record.

RS.5 There is an ongoing competency assessment of the respiratory care staff.

RS.5.1 Staff members receive ongoing training and education, as applicable, on the unit's protocols, policies and procedures.

RS.5.2 Competencies are assessed and results are documented.

Standard Intent:

Hospitals must make sure that there is an ongoing competency assessment on the respiratory care unit`s protocols, policies, and procedures. The planned competencies must be assessed and its results are documented.

Dietary Services Standard Intents

DT.1 Dietary services are provided by qualified dietitians.

DT.1.1 A qualified dietitian supervises all aspects of dietary services in the hospital.

DT.1.2 Services provided by the dietitian include, but are not limited to:

DT.1.2.1 Nutritional screening, assessment and reassessment of patients.

DT.1.2.2 Development of nutritional plan of care.

DT.1.2.3 Highlighting “food-drug interaction” to clinical staff.

DT.1.2.4 Making recommendations related to patient dietary needs.

DT.1.2.5 Nil Per Os (NPO) monitoring.

DT.1.2.6 Education of other health staff, patients, and families.

DT.1.2.7 Reviewing and updating the dietary manual.

DT.1.3 Activities conducted by the dietician as part of the process of care is documented in the patient’s medical record.

Standard Intent:

Only qualified dietitians permitted by licensure, applicable laws, and regulations or certification provided the dietary services. Dietitians who will supply the recommended dietary intervention, and nutritionists able to integrate nutritional needs with the other needs of the patient. The minimum services that should be provided by the dietician areas mentioned in the substandard DT.1.2.1 through DT.1.2.7.

DT.2 Patients identified to be at nutritional risk undergo comprehensive nutritional assessment.

DT.2.1 Nutritional screening is conducted by qualified hospital staff (e.g., registered nurse) to determine the patient’s need for comprehensive nutritional assessment by a licensed dietitian.

DT.2.2 The criteria used for nutritional screening during the initial assessment of patients are developed and approved by a qualified dietitian.

DT.2.3 Comprehensive nutritional assessment is performed by a qualified dietitian for:

DT.2.3.1 All patients identified at nutritional risk during the initial screening or assessment.

DT.2.3.2 All patients identified at nutritional risk during the course of treatment.

DT.2.3.3 All patients prescribed for a therapeutic diet.

DT.2.4 Patients identified at nutritional risk are referred to a licensed dietitian for comprehensive nutritional assessment.

DT.2.5 Nutritional assessment is preferably completed within twenty-four hours of referral.

DT.2.6 The comprehensive nutritional assessment is described in a policy and procedure that includes, but is not limited to, the following:

DT.2.6.1 Height and weight chart for children.

DT.2.6.2 Body mass index (BMI) for adults.

DT.2.6.3 Eating habits.

DT.2.6.4 Food allergies.

DT.2.6.5 Need for therapeutic diet.

DT.2.6.6 Physical difficulties with eating and drinking and the need for any assisting devices.

DT.2.7 The nutritional screening and assessment findings are documented in the patient's medical record.

Standard Intent:

The most effective way to identify patients with nutritional needs is through screening criteria. Screening generally involves performing a very simple, high-level evaluation of a patient to determine if the patient exhibits a risk that might indicate the need for a more in-depth assessment. For example, the initial nursing assessment form may contain basic criteria for a nutritional screen, such as five or six simple questions with a numerical score relating to recent decline in food intake, weight loss during the past three months, mobility, and the like. The patient's total score would then identify a patient at nutritional risk requiring a more in-depth nutritional assessment. The comprehensive nutritional assessment should follow a policy based on the elements of the substandard DT.2.6.1 through DT.2.6.6.

DT.3 Patients with nutritional disorders have the appropriate nutritional plans that meet their medical needs.

DT.3.1 The dietitian, in collaboration with other clinical staff, develops an appropriate nutritional plan of care for patients with nutritional disorders.

DT.3.2 Patients cultural and food preferences are respected to the extent possible.

DT.3.3 The nutritional plan allows for consideration of:

DT.3.3.1 Enteral tube feeding for malnourished or patients at risk of malnutrition and have inadequate oral intake and a functioning gastrointestinal tract.

DT.3.3.2 Parenteral nutrition for patients with a non-functioning gastrointestinal tract.

DT.3.3.3 Therapeutic diet prescribed for specific health conditions.

DT.3.4 Patients are reassessed for response by the dietitian at regular intervals and adjustments are made accordingly.

DT.3.5 The nutritional plan is documented in the patient's medical record.

Standard Intent:

The diet plan for patients with nutritional disorders should be specific to meet their needs this required collaboration between all involved healthcare providers such as primary physician, primary nurse and the dietitian. The plan should be documented in the patient medical

record. The nutritional plan should consider the elements mentioned in the substandard DT.3.3.1 through DT.3.3.3

DT.4 The hospital has a current dietary manual.

DT.4.1 There is a current dietary manual that is developed by the dietitian and other relevant staff.

DT.4.2 The dietary manual is approved by the medical staff.

DT.4.3 The dietary manual is used as the basis for diet orders and for planning therapeutic diets.

DT.4.4 The dietary manual includes the following items:

DT.4.4.1 Different types of diets used in the hospital.

DT.4.4.2 Nutritional supplements used and how to use them.

DT.4.4.3 Appropriate storage method for snacks and beverages.

DT.4.4.4 Mealtimes and working hours of the kitchen.

DT.4.5 The dietary manual is reviewed, revised, and updated at least every two years.

DT.4.6 Copies of the dietary manual are readily available to all medical, nursing, and food services personnel.

Standard Intent:

Dietary manual should be a comprehensive resource and guide for dietary process in the hospital and available for all involved healthcare providers. The manual should include but not limited to the elements mentioned in the substandard DT.4.4.1 through DT.4.4.4. The manual should have the approval of the medical staff.

DT.5 Therapeutic diets are provided when ordered.

DT.5.1 Therapeutic diets are prescribed by the most responsible physician based on the patient's needs.

DT.5.2 Therapeutic diets are planned, prepared, and served with supervision or consultation from the dietitian.

DT.5.3 The plan for a therapeutic diet must emphasize:

DT.5.3.1 Total calories required.

DT.5.3.2 Any restrictions.

DT.5.3.3 The route and frequency of feeds.

DT.5.3.4 When required, education about nutritional needs is provided to the patient and family upon discharge.

DT.5.4 Discharge diets are prescribed by the most responsible physician in collaboration with the supervising dietitian.

DT.5.5 Patients are educated on their nutritional needs upon discharge.

DT.5.6 Education is documented in the patient's medical record.

Standard Intent:

Appropriate therapeutic diets are important to patients' well-being and recovery. Food choices take into consideration the patient's age, dietary preferences, and planned care, which may include special dietary needs such as low cholesterol, diabetic diet, and clear liquids, depending on the patient's diagnosis. This required a qualified individual to order the appropriate diet and availability of therapeutic diet. For continuity of care, patients requiring to continue therapeutic diet at home should have the diet prescribed and the patient or family educated on it. The process should be documented in the medical records to ensure continuity of care.

DT.6 The hospital provides safe food services.

DT.6.1 Food preparation, handling, storage, and distribution is safe and guided by professional organizations standards and management systems (e.g., Hazard Analysis and Critical Control Points, HACCP).

DT.6.2 Food preparation, handling, storage, and distribution comply with laws and regulations.

Standard Intent:

Improperly stored and prepared food can cause illnesses, such as food poisoning or food infections. Food illnesses can be particularly dangerous and even life-threatening to hospitalized patients whose conditions are already compromised due to illness, disease, or injury. The hospital must provide for the safe and accurate provision of food and nutrition products by ensuring that the food is stored and prepared at temperatures that prevent the risk of bacterial growth. Cross contamination, particularly from raw foods to cooked foods, is another source of food infections. Cross contamination can result from contaminated hands, countertops, cutting boards, or cloths used to wipe countertops or dry dishes. In addition, the surfaces on which the food is prepared; the utensils, appliances, pots, and pans used for preparing food; and the trays, dishes, and utensils used for serving food can also be a risk for infection if not properly cleaned and sanitized.

Social Care Services Standard Intents

SC.1 The hospital provides social care services.

SC.1.1 A qualified social worker directs social care services provided by the hospital.

SC.1.2 Social care services are adequately staffed and have all other required resources according to the hospital's size and scope of services.

Standard Intent:

Social Care Service provided is a very essential part of patient management. The service should be directed by a qualified social worker and is adequately staffed. All other required resources according to the hospital`s size and scope of service should be available.

SC.2 Patients identified at psychosocial risk undergo comprehensive psychosocial assessment.

SC.2.1 Psychosocial screening is conducted by qualified hospital staff (e.g., registered nurse) to determine the patient's need for comprehensive psychosocial assessment by a licensed social worker.

SC.2.2 The criteria used for psychosocial screening during the initial assessment of patients are developed and approved by a qualified social worker.

SC.2.3 Psychosocial assessment is preferably completed by a qualified social worker within twenty-four hours of referral.

SC.2.4 The psychosocial assessment is described in a policy and procedure that defines factors facilitating/impeding healthcare progress, including:

SC.2.4.1 Emotional, social, and psychological factors.

SC.2.4.2 Home situation.

SC.2.4.3 Financial factors.

SC.2.4.4 Noncompliance to treatment

SC.2.4.5 Physical/mental disabilities.

SC.2.5 The psychosocial screening and assessment findings are documented in the patient's medical record.

Standard Intent:

Psychosocial screening is conducted by qualified hospital staff (e.g., registered nurse) to determine the patient's need for comprehensive psychosocial assessment by a licensed social worker using a criterion that has been developed by a qualified social worker. The assessment is preferably completed within 24 hours of referral. Assessment include emotional, social and psychological factors, the home situation, the financial factors, the noncompliance to treatment and the physical/mental disability. The screening and assessment should be documented in the patient`s medical record.

SC.3 Patients with psychosocial risk have an appropriate plan that meets their needs.

SC.3.1 The social worker works collaboratively with clinical staff (physicians, nurses, and other clinical staff) to develop a suitable plan of care that meets the psychosocial needs of the patient and ensures the continuity of care.

SC.3.2 Patients are reassessed by social worker at regular intervals, their response to the plan of care is monitored, and adjustments are made accordingly.

SC.3.3 The plan of care is documented in the patient's medical record as part of multidisciplinary team planning.

Standard Intent:

The social worker works collaboratively with clinical staff (physicians, nurses, and other clinical staff) to develop a suitable plan of care that meets the psychosocial needs of the patient and ensures the continuity of care with regular reassessment to monitor their response to plan. The plan of care must be documented in the patient`s medical record.

SC.4 The hospital ensures the provision of effective social care services for inpatients and outpatients.

SC.4.1 Social worker helps patients cope with illness, treatment, and recovery.

SC.4.2 Social worker helps patients subjected to abuse, neglect, or violence.

SC.4.3 Social worker assists patients and families communicating meaningfully with healthcare teams.

SC.4.4 Social worker assists patients and families during grief and bereavement.

SC.4.5 Social worker assists patients in job-related and school concerns.

SC.4.6 Social worker assists patients to gain access to hospital and other community-based services including home health care and financial assistance.

SC.4.7 Social worker participates with the treating team in discharge planning.

Standard Intent:

The hospital ensures the provision of effective social care services for inpatients and outpatients including all mentioned sub-elements.

SC.5 The social worker documents all relevant patient information in the medical record.

SC.5.1 The social worker documents relevant information in the patient's medical record, which include:

SC.5.1.1 Reason for referral.

SC.5.1.2 Patient/family assessment and reassessment findings.

SC.5.1.3 Plan of care including goals and interventions such as counseling, education, and facilitation of resources.

SC.5.1.4 Evaluation of the plan of care.

SC.5.1.5 Regular progress notes that include the patient/family understanding, care progress, and needs for different or additional services.

Standard Intent:

The social worker documents relevant information in the patient's medical record, which include the reason for referral, patient/family assessment and reassessment findings and the evaluation of the plan of care. In addition, regular progress notes that include the patient/family understanding, care progress, and needs for different or additional services.

Physiotherapy Services Standard Intents

PT.1 Physiotherapy services are provided by qualified therapists.

PT.1.1 A physiotherapist qualified by education, training, and experience manages the physiotherapy department.

PT.1.1.1 The department head supervises all aspects of physiotherapy services in the hospital.

PT.1.1.2 The department head develops a written scope of services of the physiotherapy department.

PT.1.1.3 The department head recommends space and equipment to meet the scope of services.

PT.1.2 Staff members are qualified by appropriate education, training, and experience in physical rehabilitation.

Standard Intent:

Hospital ensure that physiotherapy services is provided by a qualified therapist. The physiotherapy head supervises all aspects of physiotherapy service in the hospital, develop a written scope of services and recommend space and needed equipment. All members of physiotherapy service must be qualified by appropriate education, training and experience.

PT.2 Policies, procedures and protocols guide the care of patients undergoing physiotherapy in the hospital.

PT.2.1 Policies, procedures, and protocols include, but are not limited to, the following:

PT.2.1.1 Management of strokes.

PT.2.1.2 Management of hip replacements.

PT.2.1.3 Management of knee replacements.

PT.2.1.4 Management of back pain.

PT.2.1.5 Safety measures.

PT.2.1.6 Communication with the physicians.

PT.2.2 Policies are collaboratively developed with the medical staff, nursing staff, and other relevant departments.

Standard Intent:

Hospital ensure the availability of policies, procedures and protocols that guide the care of patient receiving physiotherapy. The policies and procedures include all sub-elements mentioned (PT.2.1.1 through PT2.1.6.) and are developed collaboratively with the medical, nursing and other relevant staff.

PT.3 Patients identified to be at functional risk have comprehensive functional assessment performed.

PT.3.1 Functional screening is conducted by qualified hospital staff (e.g., registered nurse) to determine the patient's need for a comprehensive functional assessment by a licensed therapist.

PT.3.2 The criteria used for functional screening during the initial assessment of patients are developed and approved by qualified therapists

PT.3.3 Comprehensive functional assessment is performed by a qualified therapist for each patient identified at functional risk during the initial screening or assessment.

PT.3.4 Functional assessment is completed within twenty-four hours of referral.

PT.3.5 The comprehensive functional assessment is described in a policy and procedure.

PT.3.6 Functional screening and assessment findings are documented in the patient's medical record.

Standard Intent:

Hospital ensure that patient identified at functional risk should have comprehensive functional assessment that must be clearly defined in a policy ~~and procedures~~. The functional assessment should be completed within 24 hours from referral.

PT.4 Patients with functional disorder(s) have an appropriate plan of care that meets their needs.

PT.4.1 The physiotherapist, in collaboration with other clinical staff, develops a suitable plan of care for patients with functional disorders.

PT.4.2 The plan of care meets the medical needs of the patient.

PT.4.3 The plan of care has measurable goals.

PT.4.4 Patients are educated about the plan of care and the procedures and rehabilitative exercises.

PT.4.5 Patients are reassessed by a physiotherapist at regular intervals, their response to the plan of care is monitored, and adjustments are made accordingly.

PT.4.6 The plan of care is documented in the patient's medical record as part of multidisciplinary team planning, whenever applicable.

Standard Intent:

Hospital ensure that patients with functional disorder(s) have an appropriate plan of care that meets their needs. The physiotherapist, in collaboration with other clinical staff, develops a suitable plan of care for patients with functional disorders and that the plan of care meets the medical needs of the patient and has a measurable element. Patients receiving physiotherapy service must be educated about the plan and are reassessed at a regular interval. The plan of care and the patient education is documented in the patient`s record.

Dental Care Standard Intents

DN.1 Qualified dentist directs the dental services.

DN.1.1 The head of the dental department is a dentist qualified by education, training, and experience.

Standard Intent:

There should be senior, qualified and will trained dentist direct the dental unit. The person must have a current job description that defines his/her role to ensure proper medical staff performance and high quality of care.

DN.2 Dental department staff members have appropriate qualifications.

DN.2.1 Dentists perform dental treatments and procedures within their approved privileges.

DN.2.2 Qualified dental technicians are available as needed.

DN.2.3 There is one dental assistant per chair.

Standard Intent:

Dental department staff members are qualified by documented training, expertise, and experience, consistent with applicable laws and regulations. There is one dental assistant per chair.

DN.3 Education is provided to the patient and family.

DN.3.1 Patients are educated and informed about the nature of the problem.

DN.3.2 Patients are educated and informed about treatments and procedures required.

DN.3.3 Patients are educated and informed about time needed to complete the course of treatment.

DN.3.4 Where applicable, patients are educated and informed about cost of services.

Standard Intent:

The Patients dental care planning process includes educating the patient, his or her family, or decision maker on the risks, benefits, and alternatives related to the planned care so that they have the knowledge and skills to participate in the care processes and care decisions. This discussion Where applicable, include information about cost of services.

DN.4 Each patient's dental care is planned and documented in the medical record.

DN.4.1 Comprehensive assessment is performed for each patient to include:

DN.4.1.1 History of allergic reactions.

DN.4.1.2 Chronic illnesses (e.g., congenital heart disease, rheumatic heart and diabetes).

DN.4.1.3 Infectious diseases.

DN.4.1.4 Hematological diseases (e.g., hemophilia).

DN.4.1.5 Chief complaints.

DN.4.1.6 The need for antibiotic prophylaxis.

DN.4.1.7 Radiological procedures needed.

DN.4.1.8 Treatment plan including procedure(s) to be performed.

DN.4.1.9 Dose of local anesthesia, the tooth treated and the material used.

DN.4.2 The assessment findings and the treatment plan are documented in the patient's medical record.

Standard Intent:

When a dental patient has been registered or admitted to an organization for inpatient or outpatient care/treatment, a complete assessment needs to be performed related to the reason the patient has come for care. The elements of the comprehensive assessment mentioned in the substandard DN.4.1.1 through DN.4.1.9 are the minimum required. The assessment findings must be documented in the patient's medical record.

DN.5 The dental department adopts the hospital wide policies and procedures as applicable.

DN.5.1 Informed consent is obtained for all high-risk procedures.

DN.5.2 General anesthesia and moderate or deep sedation are performed safely and according to the hospital's related policies and procedures.

Standard Intent:

The dental department adopts written policies and procedures that support compliance with applicable standards and regulations regarding Informed consent and General anesthesia and moderate or deep sedation.

DN.6 Infection control guidelines are strictly implemented in the dental department.

DN.6.1 There are infection control guidelines that include, but are not limited to:

DN.6.1.1 Using gloves and masks for each case.

DN.6.1.2 Wearing protective eyewear.

DN.6.1.3 Providing eye protection for patients.

DN.6.1.4 Cleaning surfaces of working area between patients.

DN.6.1.5 Maintaining updated evidence-based disinfection and sterilization practices.

DN.6.1.6 Implementing the hospital infection control plan, policies and procedures as outlined in the "Infection Control" chapter of this manual.

DN.6.2 The infection control guidelines are strictly implemented.

Standard Intent:

For an infection prevention and control program to be effective, it must be comprehensive, encompassing both patient care and employee health. The guidelines of infection control in the dental department must be guided by a plan that identifies and addresses the infection issues that are epidemiologically important to the organization. In addition, it must be appropriate to the organization's size and geographic location, services, and patients and includes systems to identify infections and to investigate outbreaks of infectious diseases (elements of the substandard DN.6.1.1 through DN.6.1.6). The implementation of the program should be monitored.

DN.7 Safety rules are applied in the dental laboratory.

DN.7.1 Fire detection and abatement equipment are available.

DN.7.2 Fire blankets are available.

DN.7.3 Cautionary signs are posted.

DN.7.4 A hooded exhaust is available in the casting area.

DN.7.5 Oxygen cylinders are safely stored.

DN.7.6 Fumes are safely evacuated.

DN.7.7 Eye wash station is available.

Standard Intent:

If dental laboratory is available in the hospital safety rules must be applicable such as:

- Fire detection and abatement equipment are available.
- Fire blankets are available.
- Cautionary signs are posted.
- A hooded exhaust is available in the casting area.
- Oxygen cylinders are safely stored.
- Fumes are safely evacuated.
- Eye wash station is available.

Management of Information Standard Intents

MOI.1 Hospital leaders ensure the conduction of needs assessment related to information management in the hospital.

MOI.1.1 The hospital conducts a needs assessment related to information management based on the hospital's scope of services, complexity of care and affordable resources including technology.

MOI.1.2 The needs assessment involves both clinical and managerial staff.

MOI.1.3 The needs assessment identifies the needs/ requirements of external organizations (e.g., Ministry of Health, accrediting bodies, national research and databases).

MOI.1.4 Information technology needs are identified and integrated with existing information management processes.

MOI.1.5 Relevant clinical and managerial staff participate in selecting, integrating, and using information management technology.

Standard Intent:

Information and data management processes are complex and are of multi-level and categories. In order to have information managed, thorough assessment of users' needs is essential to be conducted.

The information needs assessment should address all possible users, those involved in clinical, managerial, financial and administrative processes. Furthermore, though most facilities have moved to advanced computerized and electronic information management tools and capabilities, manual data and paper-based information dissemination and handling still exist and should not be missed when conducting assessment of the stakeholders needs.

Prior to transforming hospital operations from manual and paper-based information process into an electronic system, documented assessment of users' needs expected to be in place. It is a lengthy and an interactive activity that addresses all steps and levels of data and information procurement to access and sharing of informative reports useful for decision making.

Areas to be explored during information needs assessment and management process may include but not limited to:

- Automation capabilities and streamlining work,
- Using technology to reduce risks and enhance patient safety such as automated medications management, use of bar-coding for patient identification.
- Testing and evaluation strategies prior to full implementation.
- Integration with a hospital's existing technology and processes.

- Interaction of proposed information technology with external providers and customers.

MOI.2 The hospital maintains an effective information management system to serve its internal and external users and stakeholders.

MOI.2.1 The hospital provides adequate resources for an effective information management system.

MOI.2.2 The hospital describes the categorization of the needed information into manual and computerized.

MOI.2.3 Data elements are defined and forms are developed for designated staff to enter the necessary data.

MOI.2.4 Data are collected within predetermined time frames and frequency.

MOI.2.5 There is a process for secure storage of data and information with easy retrieval.

MOI.2.6 Data and information are accurately and timely disseminated to the targeted internal and external users.

MOI.2.7 Data and information are disseminated in a format useful for decision making.

Standard Intent:

Following the thorough analysis of information needs, a comprehensive planning process should take place. The hospital must develop a comprehensive information management system which focuses on dealing with information systems to provide efficiency and effectiveness of strategic decision making. The hospital information management system should describe all types of manual and computerized information coming or generated in the hospital. Also data collection, storage, and dissemination must be detailed for the data collectors and the end users. This will ensure that allocation of resources, redesigning of operational functions and provision of the new technologies are within hospital defined timeframe and means. It also ensures that hospital mission and goals are supported and met.

The information management process makes it possible to combine information from various sources and generate reports to support decision making.

Specifically, the amalgamation of clinical and managerial information helps department/service leaders to plan collaboratively. The information management process supports department/service leaders with cohesive longitudinal data and comparative data. The format and methods of disseminating data and information to the intended user are designed to meet the user's expectations.

Distribution and sharing approaches include providing only the data and information the user requests or needs; formatting the report to aid use in the decision process; providing reports with the frequency needed by the user; linking sources of data and information; and providing interpretation or clarification of data.

MOI.3 The hospital develops a process for the information management system modifications, updates, and validation.

MOI.3.1 There is process for documentation, approval, and validation of any modification or update related to the information management system.

Standard Intent:

The information management process should clarify follow up responsibilities of new or modified technologies and considering stakeholders' feedback as well as the operators input on different aspects of the technology, such as effectiveness, accuracy, meeting its objectives, possible gaps and flaws, and ease of use.

MOI.4 Data collected are transformed into information that is used to support patient care and management decisions.

MOI.4.1 Aggregate data and information include information requirements for key functions as specified in this manual (e.g., facility management and safety, infection control, clinical data and information, identified hospital-wide indicators, department-specific indicators, physician-specific information).

MOI.4.2 Aggregate data and information are used for self-comparison over time and benchmarking against similar hospitals as well as best practices.

MOI.4.3 The hospital uses the information to make decisions, strategically plan, identify and prioritize quality improvement projects.

Standard Intent:

Availability of numerous data and statistical reports without analysis will result in data overload without making use of it. It is important that data gathered and projected based on the hospital complexity in order to have it useful for the different users and stakeholders. Leaders plan and are able to access informative reports from the different departments and units in order to reflect on the status of the hospital operations, risks and areas for improvement.

MOI.5 Hospital leaders as well as users and other staff receive education and training on data management relevant to their roles and responsibilities.

MOI.5.1 There is an education/training process for decision makers and other relevant staff on the principles of data management.

MOI.5.2 The data management education/training is appropriate to the staff roles and responsibilities within the hospital.

MOI.5.3 The data management education/training includes, but is not limited to, the following:

MOI.5.3.1 Selection and use of indicators (measures) in assessment and improvement of work processes.

MOI.5.3.2 Data collection and analysis.

MOI.5.3.3 Use of data and information for decision-making.

MOI.5.3.4 Data/information confidentiality and security.

Standard Intent:

Individuals in the hospital, who generate, collect, analyze, and use data and information should be educated and trained to effectively participate in using and managing information. The education program should include the following: interpreting data; use data and information to help in decision making; support the participation of patients and families in care processes; and use measures to assess and to improve care and work processes. Individuals are educated and trained according to their responsibilities, job descriptions, and data and information needs.

MOI.6 The hospital has a policy and procedures on how confidentiality, security, and integrity of data and information including the medical records are maintained.

MOI.6.1 The policy defines data and information confidentiality, security, and integrity.

MOI.6.2 The policy is in compliance with laws and regulations.

MOI.6.3 The hospital defines appropriate levels of security and confidentiality for data and information and provides appropriate confidentiality measures accordingly.

MOI.6.4 Staff access to different categories of information is restricted on a need to know basis.

MOI.6.5 There is an appropriate mechanism for response to requests for access to information.

MOI.6.6 Data and information are safeguarded against loss, destruction, tampering, damage, and unauthorized access or use.

MOI.6.7 There are measures for protecting data and information in the event of a disaster such as flood, fire, loss of power, and abnormal temperature conditions.

MOI.6.8 Staff responsibilities to maintain confidentiality of data and information are defined (e.g., signing a confidentiality agreement).

MOI.6.9 Information confidentiality and security incidents are reported and acted upon.

Standard Intent:

The hospital maintains the privacy and confidentiality of data and information and is protecting the confidentiality of sensitive data and information. The balance between data sharing and data confidentiality is addressed. The hospital decides the level of privacy and confidentiality maintained for different categories of information. Maintaining data integrity is an important aspect of information management. The information contained in a database must be accurate in order to assure the reliable interpretation of results from data analysis.

Policies and procedures address security procedures that allow only authorized staff to gain access to data and information. Access to different categories of information is based on need and defined by job title and function, including those conducting research/studies. An effective process defines who has access to data and information; the information to which an individual has access; the user's responsibility to retain information confidential; the process for maintaining data integrity; and the process followed when confidentiality, security, or data integrity are violated.

MOI.7 The hospital uses a standardized definition, abbreviations, and symbols.

MOI.7.1 The hospital uses standardized and approved definitions.

MOI.7.2 The hospital implements a list of approved and prohibited abbreviations and symbols.

MOI.7.3 The lists are consistent with national standards and professional organizations concerned with patient safety.

MOI.7.4 The lists are developed and approved by the medical staff and other relevant structures (e.g., medical records review committee, pharmacy and therapeutics committee).

MOI.7.5 The lists are revised periodically (e.g., annually).

Standard Intent:

Standardized terminology, definitions, vocabulary, and nomenclature facilitate comparison of data and information within and among hospitals. Standardization prevents miscommunication and potential errors. The uniform use of diagnosis and procedure codes supports data aggregation and analysis.

Abbreviations can be problematic and at times even dangerous, particularly in the context of prescribing medications. In addition, when one abbreviation is used for multiple medical terms, confusion as to what the author means may result in medical

errors. Abbreviations and symbols are also standardized and include a do-not-use listing. Such standardization is consistent with recognized local and national standards.

MOI.8 The hospital has a policy on the retention of data and information.

MOI.8.1 There is a policy on the retention of data and information that is consistent with relevant laws and regulations.

MOI.8.2 The policy defines the length of time required to retain the data and information.

MOI.8.3 The policy addresses how confidentiality, integrity, and security of the data and information will be maintained during retention.

Standard Intent:

Different types of data and information are present within a hospital to enable smooth flow of its operations. Therefore, data storage must be in accordance with specified policies. However, data cannot be stored indefinitely. Hospitals are expected to specify the types of information and the duration each category should be maintained within reach in accordance with laws and regulations of the country.

MOI.9 The hospital maintains sufficient provisions that ensure the operation of the information system during scheduled or unscheduled (unexpected) downtime.

MOI.9.1 There are procedures and forms to be used during scheduled or unscheduled (unexpected) downtime.

MOI.9.2 End-users are trained on procedures to follow during interruptions of the information system.

MOI.9.3 Patient information is documented and reported during the downtime (e.g., reporting laboratory results).

MOI.9.4 The integrity of the system and data entry is verified after the downtime.

MOI.9.5 There is review of the downtime assessment report.

MOI.9.6 The downtime system is regularly tested for effectiveness.

Standard Intent:

Despite advances in infrastructure robustness, many organizations still face database, hardware, and software downtime, lasting short periods to shutting down the work for days.

In order to maintain completeness of data as well as comprehensiveness, adequate data capturing during downtimes process is highly critical. Gaps in patient data may result in gaps in patient care. Complete manual system must be prepared to be used during the downtime period including both managerial and clinical activities to prevent

interruption of care processes. End-users involved in providing hospital services should be trained on the planned manual system and know how to shift once the electronic system is down.
Downtime system must be assessed for effectiveness regularly and after actual downtime incidents. Documented reports of this assessment should be available and actions are taken in response to any deficiencies.

MOI.10 The hospital implements a process for data backup.

MOI.10.1 The hospital has a process in place for regular information system data backup and retrieval.

Standard Intent:

Even though organizations may treat their storage media with care, they can be damaged accidentally or on purpose and files can be unconsciously changed or erased. Therefore, making backup copies limits the amount of information that is lost. Backup media should be safely stored in a different location, preferably a different building than the original.

As part of information and data integrity, organizations are expected to have a clear mechanism to backup data in order to ensure ease of retrieval. The backup process is regularly implemented to avoid any data loss or gaps in information which may affect gaps in the care and service provided as well as to avoid misinformed decision making by leaders.

MOI.11 The hospital uses and contributes to comparative reference databases in accordance with national guidelines.

MOI.11.1 The hospital contributes to external databases in accordance with national laws and regulations.

MOI.11.2 The hospital uses external reference databases for comparative purposes to identify areas in which performance deviates from expected patterns.

Standard Intent:

Where nationally required, the hospital contribution to a comparative database will provide for its positioning in relation to other care providers in the country. National databases help project the national healthcare status of both communities and service providers. Without providers, accurate data and the informed plans and decisions will not be reflective or comprehensive.

MOI.12 There is a process for the clinical and administrative staff to obtain information that support safe patient care.

MOI.12.1 Information resources are available to address clinical and administrative staff needs and support them to maintain and improve their competencies.

MOI.12.2 Information resources support patient care, patient safety, patient education, performance improvement, educational functions for hospital and medical staff, research, and other appropriate functions.

MOI.12.3 Information resources are accessible when needed (e.g., books and journals).

Standard Intent:

Many questions and queries are generated during the daily work of the clinical and managerial staff dealing with patients. Reliable evidence based resources must be available to answer these queries in proper, easy, and timely manner. These resources should be available 24 hours and can be in a manual or electronic format. Hospital library with updated books and journals, internet access, subscription to international evidence-based clinical websites are examples of how this service can be provided.

Medical Records Standard Intents

MR.1 The Health Information Management (Medical Records) department has adequate qualified staff.

MR.1.1 The health information management (Medical Records) department is directed by individual qualified by education (bachelor in health information management) and experience.

MR.1.2 The department director is credentialed in health information management through formal training as per the national/international guidelines.

MR.1.3 The department has adequate staff to carry out its functions.

MR.1.4 Staff working in the department are credentialed in health information management through formal training as per the national/international guidelines.

MR.1.5 Clinical coding staff working in the department are credentialed/certified in clinical coding through formal training as per the national/international guidelines.

MR.1.6 The department has one or more staff members who are credentialed in Clinical Documentation Improvement (CDI) through formal training as per the national/international guidelines.

Standard Intent:

Patient clinical records are the backbone for communicating care processes, tracking patients' status and progress and ensuring patient safety. Having qualified and adequately staffed department ensures these patient and providers needs are met. Mishandling of patient information and gaps in documentation may lead to risks for the patient and the hospital such as medication errors (omission, overdose, allergies), and breaches in patient information confidentiality. So, formal training in Clinical Documentation Improvement (CDI) should be given to one or more of medical record staff to monitor and improve medical records' documentation deficiencies.

MR.2 A medical record is initiated for every patient.

MR.2.1 The hospital initiates a medical record for each patient on his first contact with the hospital, whether it is for an admission, emergency department or outpatient clinic visit.

MR.2.2 Each medical record is assigned a unique identification number.

MR.2.3 The hospital keeps only one medical record for each patient.

MR.2.4 There is patient identification on each page of the medical record.

Standard Intent:

Every patient assessed or treated in a hospital as an inpatient, outpatient, or emergency care patient has a clinical record. Accurate identification of a patient's record is the backbone of an effective and efficient medical record system. Correct identification is

needed to positively identify the patient and ensure that each patient has one medical record number and one medical record. The record is assigned an identifier unique to the patient, or some other mechanism is used to link the patient with his or her clinical record. A single record and a single identifier enable the hospital to easily locate patient clinical records and to document the care of patients over time as well as eliminate risks result from misidentified information.

MR.3 The hospital maintains a master patient index (either manual or computerized) of all patients who have ever been admitted to or treated by the hospital.

MR.3.1 The master patient index is used to identify a patient's medical record number.

MR.3.2 The master patient index provides basic patient demographic information (identification information collected during the registration process) as well as patient activity (visit) information:

MR.3.2.1 The patient demographic information (identification information) includes: medical record number, patient's full name, date of birth, sex, marital status, address, national identification number, next of kin (and his contacts) and/or a person that the patient wishes to be contacted in an emergency, or authorized representative/designee.

MR.3.2.2 The patient activity (visit) information includes: admission and discharge/transfer dates for inpatient hospitalizations, date of death when a death occurs, encounter date or date of service for outpatient visits, most responsible physician, and mother's name for newborns.

MR.3.3 The patient demographic information (identification information) of the master patient index is recorded on the front sheet of the medical record.

MR.3.4 The master patient index is updated for each new episode of care for any change in information.

MR.3.5 The master patient index is retained permanently to provide historical access to basic patient information and dates of stay in the hospital.

Standard Intent:

The MPI is the key to locating the patient record in a numeric identification system. It identifies all patients who have been treated by the facility and lists the number associated with name. The index can be maintained manually or as part of a computerized system.

The hospital captures and maintains essential demographic and outcome data of all its patients. These data are updated whenever change occurs such as change in address, contact details or next of kin information during new care/visit episodes. This aims at

accuracy of patient data and the ability to reach him/her or their next of kin in cases of emergency such as drug recall or deterioration of patient status.

MR.4 Medical records contain sufficient information to promote continuity and coordination of care and communication among care providers.

MR.4.1 The medical record contains sufficient information to identify the patient and his care provider, support the diagnosis, justify the treatment, and document the results of care provided.

Standard Intent:

The information contained in the medical record allows healthcare providers to determine the patient's medical history and provide informed care. The medical record serves as the central source for planning patient care and documenting communication among patient and healthcare provider and professionals participating in the patient's care. Medical records also ensure documentation of compliance with organizational, professional or governmental regulation.

The hospital determines the specific data and information recorded in the clinical record of each patient assessed or treated on an inpatient, outpatient, or emergency basis. The clinical record needs to present sufficient information to support the diagnosis, to justify the treatment provided, to document the course and results of the treatment, and to facilitate the continuity of care among health care practitioners.

MR.5 The hospital has a complete and accurate medical record for every patient.

MR.5.1 The hospital identifies in a policy all staff members authorized to make entries in medical records.

MR.5.2 All entries in the medical records must be legible, indelibly verified, dated, and authenticated.

MR.5.3 Clinical staff authorized to make entries in the medical record receive formal training in clinical documentation improvement as per the national/international guidelines.

MR.5.5 Medical record completion is a requirement within thirty days of patient discharge and before any elective vacation or period of absence of the staff member entering the notes in the medical record.

MR.5.6 The hospital has a policy to deal with delinquent medical records.

MR.5.7 The most responsible physician is responsible for the completion of his own records.

MR.5.4 The author of each entry must be identified and authenticated by official stamp, signature, written initials, or computer entry.

Standard Intent:

One aspect of maintaining security of patient information is to determine who is authorized to obtain a patient clinical record and make entries into the patient clinical record.

The hospital identifies a list of healthcare professionals allowed to make entries in the patients' medical records. Identified professionals must receive formal training about clinical documentation improvement. Then, the documentation in the medical records must be reviewed and monitored to detect deficiencies and to endure completion of records before next episode of care.

MR.6 The hospital maintains the medical records in one central place.

MR.6.1 The hospital has a medical records department that accommodates all medical records.

MR.6.2 The hospital has processes to manage the different parts of the medical records.

MR.6.2.1 The different parts of multiple records are cross referenced to the patient's unique identifier to enable records linkage.

MR.6.2.2 The different parts can be easily located when not stored together.

MR.6.2.3 The hospital ensures that all information is available and accessible when needed.

MR.6.3 The processes include, but are not limited to, the following:

MR.6.3.1 Records that are partly paper-based and partly electronic.

MR.6.3.2 Records that include items requiring incompatible storage systems such as videos and audio recordings.

Standard Intent:

As part of maintaining integrated and controlled medical records, it is essential that all patient records are stored in a one central place. This aims to prevent missed data pertinent to patient care interventions and their outcomes and to eliminate risks that result of disintegrated documentation of care process which may lead to medical errors.

Having medical records in one central location under one central department enables staff to monitor the availability and timeliness of the records presence in the requesting department such as emergency room and the outpatient department.

MR.7 A discharge summary is completed for all discharged patients.

MR.7.1 There is a discharge summary for all discharged patients.

MR.7.2 The discharge summary is complete and includes:

MR.7.2.1 The reason for the patient's admission.

MR.7.2.2 The patient's diagnosis.

MR.7.2.3 Brief summary of hospitalization (therapies, consultations, interventions and results of any important diagnostic testing).

MR.7.2.4 A list of medications used.

MR.7.2.5 Any surgery or procedures performed and their outcome.

MR.7.2.6 The patient's condition at discharge.

MR.7.2.7 All medications to be taken by the patient after discharge.

MR.7.2.8 Any special care the patient requires after discharge.

Standard Intent:

A discharge summary is a summary of the patient's stay in hospital written by the attending doctor. The minimum detail provided in a discharge summary is described in the standard. A discharge summary may be written on a pre-printed form or on plain paper and typed or word-processed in the Medical Record Department. The attending doctor writes a discharge summary in duplicate when the patient is discharged. The original is kept in the medical record and the copy given to the patient to take to their local doctor to enable continuing care.

MR.8 The hospital uses nationally recognized standardized diagnosis and procedure codes.

MR.8.1 The hospital uses the International Statistical Classification of Diseases and Related Health Problems, 10th Revision, Australian Modification (ICD-10-AM) for diagnosis coding.

MR.8.2 The hospital uses Australian Classification of Health Interventions (ACHI) for procedure coding.

Standard Intent:

Hospitals are expected to meet national laws and regulations including the use of standardized diagnosis and procedure codes. Clinical coding is the translation of diseases, health related problems and procedural concepts from text to alphabetic/numeric codes for storage, retrieval and analysis of health care data. Staff responsible for coding should be formally trained by attending clinical coding courses offered at a local or regional level.

Coded data are used to collect statistics on the types and incidence of diseases and injuries. This information is used at a national level for planning health care facilities, for

determining the number of health care personnel required, and for educating the population on health risks within the country. It is used at an international level to compare health status of countries in a region or globally.

MR.9 There is a process to ensure availability of the medical records in a timely manner.

MR.9.1 The hospital determines in a policy all disciplines who may have access to the medical records.

MR.9.2 Care providers have access to current and past medical records.

MR.9.3 Medical records are readily retrievable for each patient encounter.

MR.9.4 Medical records are available within thirty minutes of being requested.

MR.9.5 Medical records can be retrieved any time of the day.

Standard Intent:

Doctors, nurses and other health care professionals write up medical records so that previous medical information is available when the patient returns to the hospital. The medical record must therefore be available. This is the job of the medical record staff. If a medical record cannot be located, the patient may suffer because information, which could be vital for their continuing care, is not available. If the medical record cannot be produced when needed for patient care, the medical record system is not working properly and confidence in the overall work of the medical record service is affected.

MR.10 Medical records are consistently organized.

MR.10.1 Individual medical records are securely compiled.

MR.10.2 Medical records are organized into sections. (e.g., a section for test results, operative reports, consultations, discharge summary).

MR.10.3 The different sections of the medical record are organized chronologically (e.g., the physician orders start with the initial set written when the patient was admitted to the hospital and end with the discharge order).

MR.10.4 During each hospitalization episode, both in-patient and outpatient medical records are separated into different sections in the patients' medical record (e.g., for doctors' orders, nursing notes, progress notes).

Standard Intent:

To ensure security of medical record's forms and to prevent loss of patient information, forms should be securely held in the medical record either by a clip or fastener. A two-

pronged clip can be threaded through clip holes in the folder or can be attached to the folder by the adhesive backing.

Each section of the medical record must be separated by a divider; the divider will be slightly wider than the forms in the medical record and have a tab on which to write “test results”, “operative reports”, etc. In addition, if combined with the inpatient notes, all outpatient notes can be stored behind an outpatient divider.

MR.11 The hospital has a system to manage voluminous medical records.

MR.11.1 There is a system that enables medical record linkage.

MR.11.2 When the medical record is divided into volumes, the number of each volume should be clearly visible on the folder and on the sign-out slip (e.g., "Volume 1 of 2", "Volume 2 of 2,").

MR.11.3 When the hospital practices thinning of voluminous medical records:

MR.11.3.1 The hospital develops thinning guidelines that remain consistent for the type of documentation contained.

MR.11.3.2 The hospital retains documentation in the medical record that reflects the current plan of care and services provided.

MR.11.3.3 The hospital removes parts of the medical record older than a certain date and moves them into a secondary record (the overflow record).

Standard Intent:

Hospitals need to have a process based on which voluminous medical records are handled. When a second volume is initiated, what is the essential information that needs to be accessible to care providers at all care intervals and the storage of those records should be clearly defined. This is part of ensuring integrity and completeness of patient records which influence continuity of the care provided as well as informed care plans and interventions.

MR.12 The hospital has a system for the retention of medical records in accordance with laws and regulations.

MR.12.1 The hospital has a policy on the retention of medical records.

MR.12.2 The policy is consistent with laws and regulations.

MR.12.2.1 The medical records are retained for a minimum of five years after the patient was last seen unless otherwise specified by laws and regulations. For minors, records shall be kept until he/she is eighteen years of age, and then for a minimum additional five years.

MR.12.2.2 The policy addresses the retention period of the different types of the medical records as well as the permanent types (e.g., records of medico-legal cases).

MR.12.2.3 The policy addresses the retention period of the different parts of the medical records as well as the permanent parts (master patient index, admission and discharge dates, name of the most responsible physician, diseases treated and operations performed; and a discharge summary for each admission).

MR.12.3 The method used for medical records destruction, when the retention period is complete, renders the information unreadable.

MR.12.4 When the hospital discontinues operation, it stores the medical records in a facility offering retrieval services for the specified retention periods. Patients or their representatives are informed.

Standard Intent:

The hospital determines the retention time of patient clinical records and other data and information. Patient clinical records and other data and information are retained for sufficient periods to comply with laws and regulations and to support patient care, management, legal documentation, research, and education.

The retention of records, data, and information is consistent with the confidentiality and security of such information. When the retention period is complete, patient clinical records and other records, data, and information are destroyed in a manner that does not compromise confidentiality and security.

MR.13 There is a policy that outlines how the medical records are stored.

MR.13.1 The policy addresses how the medical records are protected from loss, theft and deliberate alterations or destruction.

MR.13.2 The procedures for protection of medical records are implemented.

MR.13.3 The policy addresses how confidentiality, integrity, and security of the records will be maintained during storage.

Standard Intent:

Patient records and other data and information are secure and protected at all times. For instance, active patient records are kept in areas where only authorized health professional staff members have access, and records are stored in locations where heat, water, fire, or other damage is not likely to occur.

MR.14 The hospital develops and implements a policy for the release of medical records from the medical records department.

MR.14.1 There is a policy that describes the process for the release of medical records for patient care encounters (inpatient, outpatient, and emergency department).

MR.14.2 The hospital determines when to release medical records for reasons not related to direct patient care (e.g., research, utilization management, quality improvement, morbidity and mortality, and governmental requests).

MR.14.3 The hospital has an approval mechanism for the release of medical records for reasons not related to patient care. The approval mechanism is implemented.

Standard Intent:

The hospital implements processes to prevent unauthorized access to electronically or manually stored information. The medical records department should follow a hospital approved policy that manages the release of patient records and how their locations are tracked to avoid delays as well as misplacement or loss of these records. The policy should fulfill requirements to maintain confidentiality of patient information and situations when records are released for non-care purposes (committee reviews and improvement activities).

MR.15 The hospital has a system for tracking of medical records.

MR.15.1 There is a medical records tracking system to identify the location of any record not in the medical records department and its date and time of movement as well as subsequent movements, when applicable.

MR.15.2 The medical records tracking system includes all components of the medical records.

Standard Intent:

Regardless of how records are filled within facility, one of the biggest concerns is knowing where the record is when it is needed. For a record management system to be efficient, there must be some method of tracking the current location of a patient record.

The hospital must use manual or electronic record tracking systems or both. With such a system, the location of a medical record can be readily found. In addition, a list of previous places where the medical record was sent can be printed, e.g.; clinics including the date when the record was sent to that location. Some hospitals use a bar code system as seen in department stores and super markets while other enter details via a computer terminal in the Medical Record Department.

MR.16 The hospital uses standardized forms in medical records.

MR.16.1 The hospital uses standardized forms in medical records, generated based on hospital needs and the needs of healthcare professionals.

MR.16.2 The hospital assigns a structure to control the development of medical records forms (e.g., a forms committee or the medical records review committee).

Standard Intent:

The content, format, and location of entries for a patient's clinical record are standardized to help support the integration and continuity of care among the various practitioners of care to the patient.

Some important points to be considered about forms in the medical record

- Forms should all be the same size, usually A4.
- The patient's name and medical record number, and the name of the form should be in the same place on EVERY form.
- Only official forms approved by the administration or forms committee or the medical records review committee (if there is one) should be included in the medical record.

Additionally, forms are reviewed and approved by the committee to prevent duplication of entries, involve the concerned parties, and to ensure compliance with regulatory and accreditation standards.

MR.17 The hospital has a system in place for monitoring completion of medical records.

MR.17.1 The medical records are reviewed on an ongoing basis (e.g., monthly or quarterly).

MR.17.2 The review includes a representative sample.

MR.17.3 The review is conducted by care providers authorized to make entries in medical records.

MR.17.4 The review process focuses on the appropriate and comprehensive documentation, timeliness, and legibility.

MR.17.5 Data collected are analyzed and corrective actions are taken.

Standard Intent:

Each hospital determines the content and format of the patient clinical record and has a process to assess record content and the completeness of records. That process is a part of the hospital's performance improvement activities and is carried out regularly.

Patient clinical record review is based on a sample representing the practitioners providing care and the types of care provided.

The review process is conducted by the medical staff, nursing staff, and other relevant clinical professionals who are authorized to make entries in the patient record. The review focuses on the timeliness, completeness, legibility, and so forth of the record and clinical information. Clinical record content required by laws or regulations is included in the review process. The hospital's clinical record review process includes records of patients currently receiving care as well as records of discharged patients.

Home Healthcare Services Standard Intents

HHC.1 A qualified individual directs the home healthcare services.

HHC.1.1 The home healthcare unit is directed by a qualified individual preferably with experience in home healthcare services.

HHC.1.2 The unit head develops the scope of services of the unit.

HHC.1.3 A qualified individual (e.g., registered nurse) is available at all times during working hours and participate in all activities relevant to the professional home healthcare services provided.

HHC.1.4 Emergency care is available to meet the patient's needs in a timely manner outside normal working hours.

HHC.2 Home healthcare services are provided by qualified individuals.

HHC.2.1 Qualified individuals provide home healthcare services in accordance with laws and regulations.

HHC.2.2 Home healthcare staff receive the appropriate training on relevant tasks and procedures to be performed for patients at home.

HHC.3 The home healthcare services have admission and discharge criteria.

HHC.3.1 The home healthcare services have admission and discharge criteria.

HHC.3.2 Criteria are collaboratively developed by physicians, nursing and other relevant staff.

HHC.3.3 Criteria are based upon the patient's needs and the ability of the hospital to meet the medical, nursing, social, nutritional and other needs of the patient in the patient's residence.

HHC.4 Policies and procedures guide the provision of home healthcare services.

HHC.4.1 The unit head develops policies and procedures in collaboration with other relevant departments.

HHC.4.2 Policies and procedures address the requirements of relevant standards specified in the different chapters of this manual and are tailored to the home healthcare setting (examples include, but are not limited to, facility management and safety, infection control, medical records, patient and family rights and education, provision of care, medical staff and nursing).

HHC.5 There are policies and procedures for initiation, implementation, review and revision of plans of care.

HHC.5.1 Each home healthcare service episode is ordered by a most responsible physician.

HHC.5.2 Comprehensive initial assessment is performed for each patient.

HHC.5.3 The need for home healthcare and choice of modality are based on sound clinical principles and a thorough clinical evaluation of medical condition and co-morbidities.

HHC.5.4 Patients are reassessed at regular intervals (as defined in policies and procedures), their response to the plan of care is monitored and adjustments are made accordingly.

HHC.5.5 The assessment, reassessment, plan of care and the response to treatment are documented in the patient's medical record as part of multidisciplinary team planning.

HHC.5.6 The completion of an episode of home healthcare service is considered by a discharge order by the most responsible physician with documentation in the patient's medical record.

HHC.6 The hospital ensures coordination and integration of home healthcare services.

HHC.6.1 The hospital assigns an individual (e.g., registered nurse) responsible for coordination and integration of care of each patient.

HHC.6.1.1 The assigned individual provides a link in the continuum of care between different staff members, caregivers and the patient.

HHC.6.1.2 The assigned individual communicates all relevant information to relevant staff and care givers on a timely manner.

HHC.6.2 The hospital provides the most responsible physician with information about the patient in defined time frames.

HHC.6.3 Changes in the patient's condition are reported to the most responsible physician.

HHC.6.4 Each patient/family can identify and contact the individual responsible for the coordination of his care.

HHC.6.5 The patient/family is educated about how and when to contact the individual responsible for coordinating his care.

HHC.6.6 Care is provided by the same healthcare provider whenever possible.

HHC.7 Policies and procedures govern the use of laboratory investigations in the home healthcare setting.

HHC.7.1 Point of care testing is performed by trained and competent individuals.

HHC.7.2 Quality control of point of care testing is performed and reviewed regularly by a qualified individual.

HHC.8 The hospital provides appropriate education to patient/family/caregiver to ensure safe care delivery and participation of patent/family in the care process.

HHC.8.1 Patient/family/caregiver education includes, but is not limited to, the following:

HHC.8.1.1 Safe use of medications.

HHC.8.1.2 Safe use of medical equipment.

HHC.8.1.3 Interaction between patient medications and food.

HHC.8.1.4 Pain management.

HHC.8.1.5 Nutritional counseling.

HHC.8.1.6 Infection control practices including hand hygiene.

HHC.8.1.7 Handling and disposing hazardous waste.

HHC.8.1.8 Home safety instructions.

HHC.8.1.9 Storage and handling of medical gases and related supplies.

HHC.8.2 Patient/family/caregiver education is documented in the patient's medical record.

HHC.9 The hospital ensures a safe home healthcare environment for patient, family, and staff.

HHC.9.1 Safety rounds are conducted to identify safety issues and safety concerns.

HHC.9.2 Patients/families are informed about the identified risks and recommendations to address them. (e.g., use of assistive equipment and devices like canes, walkers and bath benches, changes made to the home environment like adding ramps and lowering cabinets, and having smoke detectors in case oxygen therapy is used).

HHC.9.3 There is a fire safety plan that clarifies the response to fires and handling of potential fire hazards in the home care setting.

HHC.9.4 Utility systems are assessed to determine its appropriateness.

HHC.9.5 There is a process for the identification, handling, storage and disposal of hazardous materials and waste.

HHC.10 The hospital ensures the availability and safety of medical equipment.

HHC.10.1 The hospital ensures availability of the medical equipment required for plan of care in the patient home.

HHC.10.2 The medical equipment in the patient home are inspected, tested and maintained by qualified staff.

HHC.11 Policies and procedures ensure safe management of medications in the home healthcare setting.

HHC.11.1 There is a policy and procedure to ensure stability and potency of medications and nutritional therapy solutions delivered to the patient's home.

HHC.11.2 There are policies and procedures for the preparation, storage, administration and monitoring effects of medications.

HHC.11.3 New medication orders are reviewed by a pharmacist as outlined in the "Medication Management" chapter in this manual.

HHC.11.4 The medication regimen of the patient is reviewed at least once a month by a licensed pharmacist.

HHC.11.5 The pharmacist reports any irregularities to the most responsible physician and/or nurse. Appropriate actions are taken accordingly.

HHC.11.6 Patient and/or caregiver are trained on the storage, proper preparation, administration, and monitoring of medications at home.

HHC.12 Infection control policies and procedures are applied in the home healthcare setting.

HHC.12.1 The infection control program provides a safe, sanitary and comfortable environment and helps prevent the development and transmission of disease and infection.

HHC.12.2 Home healthcare services follow and implement an evidence-based immunization program.

HHC.12.3 Home healthcare services identify the patient care processes associated with the risk of infection and implement interventions to reduce that risk.

HHC.13 The hospital promotes patient safety and quality care for patients requiring home healthcare.

HHC.13.1 The hospital uses evidence based practices that promote hand hygiene.

HHC.13.2 The hospital uses evidence based practices for prediction, prevention and management of pressure ulcers and other wounds.

HHC.13.3 The hospital uses evidence based practices for assessment of risk for fall and for risk reduction interventions.

HHC.13.4 The hospital uses evidence based practices for diabetic foot care.

HHC.13.5 The hospital uses evidence based practices for ensuring medication compliance.

HHC.14 The hospital has a standardized and effective transfer process to external home healthcare organizations.

HHC.14.1 The hospital maintains a list of licensed home healthcare organizations located in the geographical area where its patient population resides.

HHC.14.2 The list is provided to patients as indicated in the patient's discharge plan.

HHC.14.3 There is a policy and procedure in place that defines an effective process for transferring patients to outside home health care organizations.

HHC.14.3.1 The policy identifies an individual responsible for communication with the home healthcare organization performing the transfer process (e.g., social worker).

HHC.14.3.2 The policy defines the criteria for transfer to home health care organizations.

HHC.14.3.3 The policy is collaboratively developed by different disciplines (e.g., physicians, nurses, and social workers).

HHC.14.4 There is a physician order for transfer to a home health care organization.

HHC.15 When patients are transferred to external home health care organization, the hospital provides all relevant patient information to support the continuity of care.

HHC.15.1 The hospital provides the home health care organization with a copy of completed discharge summary including diagnosis, services provided at the hospital and discharge medications.

HHC.15.2 The hospital uses a special form for transfer to home health care organizations.

HHC.15.3 The form includes, but is not limited to, the following information:

HHC.15.3.1 Problem list (e.g., dementia, incontinence).

HHC.15.3.2 Equipment needed at home (e.g., suction machine, ventilator, oxygen cylinder, oxygen regulator).

HHC.15.3.3 Required home care services (e.g., dietary, rehabilitative, respiratory, diabetes monitoring).

HHC.15.3.4 Reason for transfer (e.g., help for self-care, relapse prevention, others).

~~HHC.15.4 The transfer process is documented in the patient's medical record.~~

Infection Prevention and Control Standard Intents

IPC.1 Hospital leaders support an infection prevention and control program.

IPC.1.1 Hospital leaders allocate adequate resources such as equipment and supplies for the support of the infection prevention and control program.

IPC.1.2 Information management system supports the infection prevention and control program.

IPC.1.3 When some infection prevention and control functions are outsourced (e.g., sterilization or laundry), the hospital provides oversight and management of the contract through the process described in the "Leadership" chapter in this manual.

Standard Intent:

Effective implementation of an infection prevention and control program requires the leaders of the hospital to ensure that the program has adequate resources to be effectively carried out. The program must be managed by adequate staff to meet the program goals and the needs of the hospital. The infection prevention and control program requires resources to provide education to all staff, equipment, and supplies, such as alcohol hand rubs for hand hygiene, surface disinfectant, availability of internet…etc. Information management systems are important resources to support the tracking of risks, rates, and trends in health care–associated infections. Information management functions support data analysis, interpretation, and presentation of findings. The hospital leaders should provide evidence for oversight and management of outsourced service contract.

IPC.2 There is a qualified professional responsible for directing the infection prevention and control program.

IPC.2.1 The infection prevention and control Program is supervised by a healthcare professional qualified by education, training and experience.

IPC.2.2 The supervisor of the infection prevention and control program reports to the hospital leadership.

IPC.2.3 The supervisor of the infection prevention and control program is responsible for managing and strategizing the infection prevention and control program, including:

IPC.2.3.1 Developing the annual infection prevention and control plan and assuring its implementation.

IPC.2.3.2 Reviewing the daily activities of the structure responsible for infection prevention and control (e.g., infection prevention and control department or team).

IPC.2.3.3 Ensuring coordination of all aspects of the infection prevention and control activities.

IPC.2.3.4 Ensuring effective implementation of infection prevention and control policies.

IPC.2.3.5 Ensuring that healthcare associated infection surveillance is conducted in a systematic manner.

IPC.2.3.6 Providing ongoing consultation to all hospital departments.

Standard Intent:

Infection prevention and control activities should be overseen by one or more persons who should be qualified in infection prevention and control practices through education, training, experience, or certification. This qualified staff should directly report to higher administrative authority to ensure the presence of an independent administrative unit that oversees IC issues in the whole institution. The person fulfills program oversight responsibilities as per standard requirements that should be described within the job description.

IPC.3 The hospital has an infection prevention and control structure (e.g., department, team) with adequate qualified staff, based on its size, level of risks, and program scope and complexity.

IPC.3.1 At least one full time infection prevention and control practitioner is assigned per hundred beds (including emergency beds, dental chairs, day case, dialysis and others).

IPC.3.1.1 An additional ratio of one infection prevention and control practitioner per thirty intensive care beds is considered where ventilation and hemodynamic monitoring are routinely performed.

IPC.3.1.2 An additional ratio of one infection prevention and control practitioner per one hundred twenty patients dialyzed per day.

IPC.3.2 The infection prevention and control practitioners are qualified in infection prevention and control practices by education (physician, registered nurse, or certified professional in infection prevention and control), training or experience.

IPC.3.3 The infection prevention and control practitioners acquire and maintain current knowledge and skills in the field of infection prevention and control and epidemiology.

Standard Intent:

The infection prevention and control program should be appropriate to the hospital's size, level of risks, complexity of activities, and the program's scope. One or more Infection Prevention and Control Practitioner (s), working on a full-time basis as per standard requirements, should oversee the infection control program as part of their assigned responsibilities in the job descriptions. Their qualifications depend on the activities they will carry out and should be met through education; training; experience; and certification. The hospital should provide a continuous medical education program

to update the knowledge and skills of Infection Prevention and Control Practitioner (s).

IPC.4 There is a designated multidisciplinary committee that provides oversight of the infection prevention and control program.

IPC.4.1 The infection prevention and control committee is chaired by the hospital director or the medical director.

IPC.4.2 The membership of the infection prevention and control committee includes representatives from the medical staff, nursing staff, microbiology, operating room, central sterilization service, pharmaceutical care, dietary services, housekeeping, infection prevention and control staff, and other departments as needed.

IPC.4.3 The infection prevention and control committee meets on a regular basis (at least quarterly).

IPC.4.4 Functions of the infection prevention and control committee include, but are not limited to, the following:

IPC.4.4.1 Review of the hospital infection prevention and control policies and procedures.

IPC.4.4.2 Review of the reports of healthcare-associated infections surveillance submitted regularly by the infection prevention and control team and suggestion of appropriate actions.

IPC.4.4.3 Revision of the yearly plan submitted by infection prevention and control team and suggestion of additions/changes if necessary.

IPC.4.4.4 Evaluates and revises on a continuous basis the procedures & the mechanisms developed by the infection prevention & control team to serve established standards and goals.

IPC.4.4.5 Brings to the attention of the infection prevention & control team new infection control issues arising in different departments of the hospital & suggests solutions.

IPC.4.4.6 Each member of the committee acts as an advocate of infection prevention & control in his department, trying to promote its principles, and ensures application of its rules.

Standard Intent:

The activities of the Infection Prevention and Control unit should be supervised and be overseen by a multidisciplinary body that is chaired by a designee of the higher administration. Infection prevention and control activities should reach to every part of a health care hospital and involve individuals from multiple departments and services via multidisciplinary committee. Coordination involves communicating with all parts of the hospital to ensure that the program is continuous and proactive; physicians and nurses are represented and engaged in the activities with the infection prevention and

control professionals. Others may be included as determined by the hospital's size and complexity of services (for example, clinical epidemiologist, central sterilization manager, microbiologist, pharmacist, housekeeping services, environmental or facilities services, operating theatre supervisor). Responsibilities include, for example, setting criteria to define healthcare–associated infections, establishing data collection (surveillance) methods, designing strategies to address infection prevention and control risks, and reporting processes. Infection Control committee formation order and Term of References should reflect its membership and functions.

IPC.5 The hospital designs and implements a coordinated program to reduce the risk of healthcare-associated infections (HAIs) in patients, visitors, and healthcare workers.

IPC.5.1 There is a program to reduce the risk of healthcare-associated infections which involves patients, families, staff, volunteers, trainees and visitors.

IPC.5.2 The program applies to all areas of the hospital.

IPC.5.3 The program is guided by an annual infection prevention and control plan.

IPC.5.4 The program addresses the unique situations of the hospital and its community such as patient populations, complexity of care provided, climate, and location.

IPC.5.5 The infection prevention and control program is based on:

IPC.5.5.1 Risk assessment.

IPC.5.5.2 Current scientific knowledge.

IPC.5.5.3 Referenced practice guidelines.

IPC.5.5.4 Applicable laws and regulations.

Standard Intent:

For an infection prevention and control program to be effective, it must be comprehensive, encompassing both patient care and employee health. The program is guided by an annual plan that identifies and addresses the infection issues that are epidemiologically important to the hospital. The program and plan are appropriate to the hospital's size, services provided, and patients' volume. The program should be based on periodic assessment of risk and setting of risk-reduction goals that guide the program. In addition, updated scientific information of national and international references is required to understand and to implement effective infection and control activities. Practice guidelines provide information on preventive practices and infections associated with clinical and support services. Applicable laws and regulations define elements of the basic program, the response to infectious disease outbreaks, and any reporting requirements.

IPC.6 The hospital has an infection prevention and control annual plan.

IPC.6.1 The hospital has infection prevention and control annual plan that addresses the epidemiologically important infections, processes, and devices that are associated with risk of healthcare-associated infections as identified by the hospital.

IPC.6.2 The plan includes measures for patient safety (standard precautions, transmission based isolation, different care bundles).

IPC.6.3 The plan includes measures for staff safety (e.g., staff immunization and post exposure management).

IPC.6.4 The plan includes measures for staff, and patient/family education.

IPC.6.5 The plan is evaluated and approved annually by the infection prevention and control committee.

IPC.6.6 The plan includes metrics of required changes in targets and goals to reduce hospital acquired infections.

Standard Intent:

The hospital should develop an annual infection prevention and control plan that supports the hospital Infection Prevention and Control Program. The plan should include audit activity and identify areas associated with infection risks within the organization. The plan should be approved by the infection control committee and should be periodically reviewed and evaluated to targeted goals and required improvement.

IPC.7 Policies and procedures guide the infection prevention and control program.

IPC.7.1 Infection prevention and control policies and procedures are developed by the infection prevention and control staff and approved by the infection prevention and control committee.

IPC.7.2 Infection prevention and control policies and procedures are collaboratively developed with medical staff, nursing staff, and other internal and external relevant stakeholders.

IPC.7.3 Infection prevention and control policies and procedures are organized in one manual.

IPC.7.4 The infection prevention and control manual is readily available to all relevant staff and in all patient care areas.

Standard Intent:

To ensure proper practices of infection prevention and control principles within the hospital, the program should be guided by policies and procedures which are all gathered in a manual that is available in all patient care areas. The Infection control policies should be relevant to the Hospital scope of services and approved by the Infection Prevention and control committee.

IPC.8 The hospital provides continuing education on infection prevention and control practices to staff, patients, families, and other caregivers as indicated by their involvement in the care process.

IPC.8.1 The hospital provides continuing education for relevant staff on:

IPC.8.1.1 Hospital wide policies, procedures, and practices of the infection prevention and control program.

IPC.8.1.2 Departmental policies, procedures, and practices of the infection prevention and control program based on the service provided.

IPC.8.2 The hospital provides education on infection prevention and control to patients, families, and other caregivers as appropriate.

IPC.8.3 New staff receive an orientation to the hospital's infection prevention and control policies and procedures upon hiring. Training records are maintained in their files.

Standard Intent:

For the hospital to have an effective infection prevention and control program, it must educate staff members about the program when upon hiring and regularly thereafter. The education program includes professional staff, clinical and nonclinical support staff, patients & families, students, volunteers, trade people and other visitors. Patients and families are encouraged to participate in the implementation and comply with infection prevention and control practices in the hospital. The education is provided as part of the orientation of all new staff and is refreshed periodically, or at least when there is a change in the policies, procedures, and practices that guide the hospital's infection prevention and control program. The education also includes the findings and trends from the measurement activities.

IPC.9 There is a continuous surveillance of healthcare-associated infections.

IPC.9.1 There are policies and procedures which define the types of surveillance to be carried out with regard to healthcare-associated infections.

IPC.9.2 There are written standardized definitions for identification of healthcare-associated infections.

IPC.9.3 The policies and procedures define how data will be collected, analyzed, and used.

IPC.9.4 The monitoring process includes using indicators related to infection issues that are epidemiologically important to the hospital.

Standard Intent:

Surveillance is an important component of infection control program to assess the effectiveness of prevention and control measures. Surveillance assists the hospitals to identify risks from practices and infections on which they should focus their programs to control and minimize them. Each hospital should identify those epidemiologically important infections, infection sites, and associated devices, procedures, and practices

that will provide the focus of efforts to prevent and to reduce the risk and incidence of health care–associated infections. Identification of HAIs should be done according to Standardized Criteria. Data Collection & analysis should be done according to hospital surveillance policy. The hospital should adopt outcome indicators for monitoring HAIs rates.

IPC.10 Results of healthcare-associated infections surveillance are integrated into the hospital's quality improvement program.

IPC.10.1 The hospital selects indicators based on the projected use of data (internal and external benchmarking).

IPC.10.2 The hospital defines the data collection methods and sources (e.g., hospital information system, verbal and written communication, medical record review, direct observation and review of clinical indicators).

IPC.10.3 The results of infection monitoring in the hospital are regularly communicated to staff, physicians, and management.

IPC.10.4 The hospital uses risk, rate, and trend information to design or modify processes to reduce healthcare-associated infections to the lowest possible level.

IPC.10.5 The hospital makes the necessary improvements for the identified epidemiologically important infections, processes, and devices that are associated with risk of healthcare-associated infections.

Standard Intent:

To ensure that the surveillance data (calculated HAI rates) are properly utilized by the hospital to improve the clinical services and safety within the hospital. The calculated HAIs rates should be trended, benchmarked and communicated regularly with concerned departmental/unit leaders, higher administration authority and integrated with quality improvement projects.

IPC.11 The hospital designs and implements a comprehensive system for investigation and management of outbreaks of infectious diseases.

IPC.11.1 There is a policy and procedure that guides staff for investigation and control of outbreaks of infectious diseases.

IPC.11.2 The policy defines how an outbreak is determined.

IPC.11.3 The infection prevention and control team leads the investigation and control of outbreaks of infectious diseases.

IPC.11.4 The results of investigation of an outbreak are used to prevent recurrence.

Standard Intent:

Providing a management protocol of an outbreak in health care facilities assists in early detection of an outbreak and initiates immediate control measures that prevent further

disease transmission. For proper management of outbreak, the hospital should consider the following:

1. Develop policy and procedure for investigation and management of outbreak
2. Formation of an outbreak team that is led by IPC Team.
3. Identification of outbreak, establish a case definition and search for additional cases.
4. Determining the steps of an outbreak investigation and implement of infection prevention & control measures.
5. Monitor and evaluate the control measures.
6. Documentation of all activities of outbreak team in ICC meetings minutes.

IPC.12 The hospital implements a comprehensive program for preventing and managing sharp injuries.

IPC.12.1 There is a policy and procedure that addresses handling of sharps.

IPC.12.2 Needles are not bent, broken, or recapped except in special and approved circumstances (if recapping is necessary, the "scoop method" is used).

Standard Intent:

To prevent sharp injuries with healthcare workers' exposure to blood borne infections, the hospital should have a defined system to prevent sharp injuries and ensure proper handling of sharps. Handling sharps, their use and disposal within the hospital should be practiced according to written policy and procedure. Hospital staff should have the knowledge and skills on handling sharps (needles are not bent or broken, scoop method for necessary recapping).

IPC.13 Sharps are discarded in appropriate containers.

IPC.13.1 Sharp boxes used are puncture-proof, leak-proof, and present no risk to staff or patients.

IPC.13.2 Sufficient number of sharp boxes is available in patient care areas (ideally one per patient's room or at least one per procedure trolley).

IPC.13.3 Sharp boxes are available in appropriate size according to the size of sharps used.

IPC.13.4 Sharp boxes are properly used: not overfilled, not opened to transfer sharps into other containers, and mounted at or below eyes level.

IPC.13.5 Sharp boxes are disposed in accordance to laws and regulations when their contents are 3/4 of their sizes and/or when an odor arises.

Standard Intent:

To ensure that the hospital provides the necessary resources to implement a comprehensive program for preventing sharps injuries. The hospital should ensure that the type of sharps box used is puncture-resistant and leak-proof and presents no risks to

staff or patients, availability of a sufficient number of appropriate sharp containers, sharp boxes are properly located and used, and sharp boxes disposal in accordance with national laws and regulation.

IPC.14 There is a system that separates patients with communicable diseases and those who are colonized or infected with epidemiologically important organisms.

IPC.14.1 There are policies and procedures that address standard and transmission-based precautions.

IPC.14.1.1 The policies and procedures address separating patients with communicable diseases and those who are colonized or infected with epidemiologically important organisms from other patients, staff, and visitors.

IPC.14.2 The transfer of patient outbound or inbound should secure the prevention of spread of Methicillin-resistant staphylococcus aureus (MRSA) or other epidemiologically significant organisms.

IPC.14.2.1 All patients for transfer outbound known to have MRSA or other epidemiologically significant organisms must be reported upon requesting the transfer with the supporting document.

IPC.14.2.2 All patients transferred to the hospital must be kept under contact transmission-based precaution unless proving otherwise.

Standard Intent:

Isolation precautions should be applied for patients with suspected or confirmed communicable diseases or epidemiologically important organisms to provide safe healthy environment for other patients, health care workers, and visitors. The hospital should have strategy for early identification of patients with possible infectious risks to others to implement the appropriate type of isolation precautions. This strategy must be guided by policies and procedures that establish the isolation procedures based on the mood of disease transmission and address individual patients with contagious infections, provide clear instructions during patient transfer either outbound or inbound. The policy must be implemented by the hospital and the staff should be fully oriented to it.

IPC.15 Facility design and available supplies support isolation practices.

IPC.15.1 There is at least one negative pressure airborne isolation room in the emergency room and one in patient care areas (one negative pressure room for every 25-30 beds in general hospitals).

IPC.15.2 The infection prevention and control team decides the need for more airborne isolation rooms depending on the volume of patients in need for airborne isolation admitted to the hospital.

IPC.15.3 The ventilation system serving airborne isolation facilities provides pressure patterns that prevent airborne pathogens from being distributed to other areas of the hospital.

IPC.15.3.1 Rooms designed for airborne isolation patients are under negative pressure.

IPC.15.3.2 Air is exhausted to the outside and is not re-circulated unless it is filtered through High-Efficiency Particulate Air (HEPA) Filter.

IPC.15.3.3 The negative pressure for the isolation room should be validated on daily basis when patient is isolated (admitted in the room). Weekly validation is done when the room has no patients. A minimum of 12 air changes per hour should be maintained by testing and documentation as per manufacturer's recommendation/hospital's policy

IPC.15.4 The entry of the isolation room is through a work area or ante-room that serves as a site for hand washing, gowning and storage of protective clothing (gloves, aprons, masks).

IPC.15.5 Toilet, shower, or tub and hand washing facilities are provided for each isolation room.

IPC.15.6 Transmission-based precaution cards (isolation signs) are consistent with the patient diagnosis and are posted in Arabic and English and indicate the type of precautions required.

IPC.15.6.1 Transmission-based precaution cards (isolation signs) are color coded for isolation of different categories (e.g., contact: green, airborne: blue, droplet: pink or red).

IPC.15.6.2 Transmission-based precaution cards (isolation signs) should contain short statements and supported with the required figures.

IPC.15.6.3 Isolation instructions must highlight the transmission-based precaution cards (isolation signs) needed while transporting the patients under transmission-based precautions to other department (e.g., radiology).

IPC.15.7 Respirator (high filtration) masks (N-95, N-99) are used by staff during direct care of patients on airborne precautions and are available on all units likely to admit patients on airborne precautions.

IPC.15.8 Respirator (high filtration) masks (N95, N-99) can be reused by the same patient care giver as per the period specified by the manufacturer.

Standard Intent:

This is to ensure proper implementation of appropriate type of isolation precautions. The hospital preparedness of isolation precaution includes: the availability of negative

pressure airborne isolation room which meets the measurable elements requirements, the availability of required supplies particularly respirator (high filtration mask e.g. N95) in patient care areas, and the availability of isolation card indicating the type of isolation precautions.

IPC.16 Disinfectants use is supervised by the infection prevention and control team.

IPC.16.1 The purchase of equipment and supplies used for sterilization and disinfection is reviewed by the infection prevention and control team.

IPC.16.2 Antiseptics and disinfectants are used in accordance with current scientific guidelines and recommended practice (e.g., approved by recognized professional organizations such as the Food and Drug Administration and Environmental Protection Agency).

Standard Intent:

Disinfectants are frequently used in hospital to kill infectious organisms. The choice of disinfectant to be used depends on many factors. Some disinfectants have a wide spectrum (kill many different types of microorganisms), while others kill a narrower range of disease-causing organisms but are preferred for other properties (they may be non-corrosive, non-toxic, or inexpensive). To ensure proper use of disinfection, selection and indication for uses must be based on scientific references and national laws and regulations, reviewed and supervised by infection control personnel.

IPC.17 The hospital ensures environmental safety when disinfectants are used outside the central sterilization service.

IPC.17.1 In endoscopy units, a proper approved disinfectant is used in a way to protect the patient, the staff and the environment from possible infectious hazard.

IPC.17.1.1 The procedure room and the decontamination room are physically separated and the decontamination room has infection control requirements to prevent spread of infection to healthcare workers and to patients.

IPC.17.1.2 Appropriate personal protective equipment (respirator, gloves: nitrile or butyl rubber, goggles and gowns) are used.

IPC.17.1.3 Unauthorized persons are not allowed in the processing area.

IPC.17.1.4 Well closed containers are used to keep the disinfectant solution.

IPC.17.1.5 A policy and procedure is implemented on how the endoscope is processed (cleaning, decontamination, and disinfection) between patients.

IPC.17.1.6 Endoscopes are cleaned with disposable brushes or with reusable brushes that are sterilized after every use. Heat-stable parts and accessories of the endoscopes such as biopsy forceps are cleaned by mechanical cleaners and stabilized after use.

IPC.17.1.7 Quality tests (strips or other method) used to confirm the stability of the disinfectant are performed every day and records are maintained.

IPC.17.2 For bronchoscopy, the following is applied:

IPC.17.2.1 Bronchoscopy is performed in a room with negative air pressure and at least twelve air changes per hour. Personal protective equipment is available including N-95/N-99 masks.

IPC.17.2.2 Cleaning of the bronchoscopes begins immediately after the procedure to prevent drying or hardening of organic debris.

IPC.17.2.3 Bronchoscopes are disinfected as per manufacturer's recommendation.

Standard Intent:

Disinfection process should take place in a centralized sterilization area or, with proper supervision, in other areas of the hospital, such as an endoscopy unit. Cleaning and disinfection process should maintain the same standards wherever they are performed in the hospital**.** All reprocessing should be carried out by trained staff, in a disinfection designated area with traffic control in place and using approved disinfectant. Cleaning and disinfection should be done according to hospital policy and procedures considering manufacture's recommendations. The hospital should ensure that the adequate facilities for reprocessing of contaminated items are available.

IPC.18 The hospital ensures efficient and quality sterilization service.

IPC.18.1 The hospital provides central sterilization service.

IPC.18.2 There are policies and procedures for the central sterilization service.

IPC.18.2.1 The policies and procedures are consistent with scientific guidelines.

IPC.18.2.2 The policies and procedures are reviewed and approved by the infection prevention and control committee.

IPC.18.2.3 There are policies and procedures on transportation, cleansing, decontamination, disinfection, sterilization, storage, and recall of sterile items.

IPC.18.3 Contaminated items are transported in safe closed containers with biohazards sign from the outside to prevent spills or aerosolization of infectious fluids.

Standard Intent:

Infection risk is minimized with proper cleaning, disinfection, and sterilization processes, of surgical supplies and other invasive or noninvasive patient care equipment. To ensure the proper method of collections, decontamination, cleaning and sterilization, these services must be centralized and maintained the same standards wherever they are

performed within the hospital. CSSD staff must set clearly written policies & procedures that guide collections and transportation, decontamination and disinfection, cleaning and sterilization, storage of sterile items and mechanism for recall of sterile items in case of failure of sterilization process. The policy must be scientifically sound, reviewed and approved by the infection prevention and control committee. All hospital concerned staff must be acknowledged by CSSD policies and procedures and the hospital must ensure proper implementation of the approved policies.

IPC.19 Central sterilization service staff are qualified by education, certification, or training in the field of sterilization and disinfection.

IPC.19.1 The supervisor of the central sterilization service has experience, knowledge, and certification in sterilization practice and is registered with the Saudi Commission for Health Specialties as a central sterilization service technician.

IPC.19.2 Central sterilization service staff are qualified by education, certification, or training in the field of sterilization and disinfection.

IPC.19.3 Staff are able to explain the sterilizers' operation and to name the main parameters to be followed: sterilization time, temperature, and pressure.

IPC.19.4 Proper sterilization parameters are recorded.

IPC.19.4.1 Records include load list, daily function test, spore test results, lot number, and name of operator.

IPC.19.4.2 Sterilization records are kept for one year to allow inspection.

IPC.19.5 Sterilization time and temperature cycles used are in accordance with the manufacturer's guidelines.

Standard Intent:

To ensure efficient and quality sterilization services, the process should be conducted by qualified CSSD Staff either by experience, knowledge and certification in the field. This information should be documented in CSSD staff personnel file and assessed during CSSD staff interview. The hospital must strictly have monitored the sterilization process using, physical, chemical and biological indicator and the results of monitoring should be recorded and kept to be supervised by infection control team.

IPC.20 The central sterilization service design supports its functions.

IPC.20.1 There is a uni-directional flow of traffic from dirty to clean areas (i.e. decontamination area, packing, sterilization, storage areas).

IPC.20.2 Traffic control signs are in place.

IPC.20.3 The decontamination area is under negative pressure with exhaust to the outside; the clean area is under positive pressure with at least ten air cycles/hour.

IPC.20.4 There is complete physical separation between the decontamination area, the area where clean items are packaged and sterilized, and the area were sterilized items are stored.

Standard Intent:

To ensure proper implementation of infection control practices and to minimize the risk of infection, CSSD construction design must have a complete separation between decontamination (should be kept under negative pressure) and clean areas (should be kept under positive pressure with at least 10 air cycle/hr), considering CSSD work flow started at decontamination area to ensure unidirectional flow of traffic with traffic control signs in place.

IPC.21 The central sterilization service has measures to ensure staff safety and proper function.

IPC.21.1 Personal protective equipment are available and used during decontamination (heavy-duty gloves, waterproof aprons, facemask, plastic durable boots and goggles or face shield).

IPC.21.2 If manual cleaning is performed, at least two sinks are used, one for soaking and cleaning and one for rinsing before the final wash.

IPC.21.3 The cleansing brushes are disposable. When the cleansing brushes are auto-clavable, the manufacturer's instructions are followed and the brushes are replaced when needed.

IPC.21.4 Staff inspect instrument after cleansing to ensure that they are in good practical condition and fit to be used.

IPC.21.5 Sterilizers are in good working order. Instructions on sterilizers' use are available.

IPC.21.6 Preventive maintenance records for sterilizers are available and clearly show the maintenance history of the sterilizers.

IPC.21.7 Chemical indicators are used in every package. Biological indicators are used at least weekly. Records of results are kept for one year.

IPC.21.8 Use of flash steam sterilizer is limited to urgent situations which preclude use of other sterilizer methods. This use is closely monitored and recorded. Policies in this regard are reviewed by central sterilization service staff.

IPC.21.9 Where ethylene oxide is used, safety and health hazards are addressed.

Standard Intent:

To ensure CSSD staff safety, to minimize CSSD occupational risk, and to ensure that the CSSD function comprehensively monitored, the sterilization process should be monitored and tested at different steps, the process should also document and can be presented (sterilization records, spore and results, biological indicator results, others records). All required types of personnel protective equipment must be available and appropriately used considering the type of work area. Hospital must ensure proper functioning of autoclaves and regularly maintained PPM. The use of flash sterilizer by the hospital should be limited to clearly written policy and regularly monitored process by OR and CSSD staff.

IPC.22 The hospital ensures safe reprocessing of single use items.

IPC.22.1 The hospital implements a policy and procedure regarding reprocessing of single use items. The policy defines the following:

IPC.22.1.1 The items that can be reused.

IPC.22.1.2 Patients and conditions for reuse of single-use items.

IPC.22.1.3 Measures taken to ensure safety and integrity including testing and maintenance by biomedical engineering.

IPC.22.1.4 Manufacturer approval as a prerequisite, whenever applicable.

IPC.22.2 The policy is approved by the infection prevention and control committee and hospital director.

IPC.22.3 Justification of reprocessing is provided by the head(s) of the concerned department(s).

Standard Intent:

In order to reduce the risks associated with reprocessing of single use items for instance, increase the risk of infection and increase the risk of inadequate performance of the device post it is reprocessing. When single-use devices are reused, the hospital must have clearly written policy that guides the process of reusing single use items to meet the standard requirements, to clarify the responsibility for justification of reprocessing, to be consistent with the national laws and regulations, approved by hospital director and Infection Control Committee and concerned staff must be fully aware about it.

IPC.23 The hospital has policies and procedures for housekeeping.

IPC.23.1 The housekeeping has policies and procedures that describe the areas to be cleaned, the schedule for cleaning, and the procedures to be used for cleaning different environmental surfaces.

IPC.23.2 Policies and procedures, schedules, and agents utilized are reviewed by infection prevention and control staff.

IPC.23.3 All units have a cleaning/ disinfection schedule which lists all environmental surfaces to be cleaned.

Standard Intent:

Environmental cleaning is a fundamental principle of infection prevention and control in healthcare settings. To ensure appropriate decontamination of hospital surfaces that could play an important role in the transmission of dangerous pathogens, including *Clostridium difficile*, and antibiotic-resistant organisms such as methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant enterococci (VRE).The hospital must implement clearly written housekeeping policies and procedures that reviewed by

infection control staff, must have detailed cleaning schedules listed hospital environmental surfaces, prepared and implemented by housekeeping staff and monitored by Infection Control staff.

IPC.24 The hospital environment is kept clean.

IPC.24.1 Hospital environment, lockers, and cabinets are clean.

IPC.24.2 Food is stored under sanitary conditions and is consumed in designated places.

IPC.24.3 Food refrigerators are clean and are used only for food storage.

IPC.24.4 There are separate clean and dirty utility areas in each patient care area.

IPC.24.5 There are policies and procedures on pest control that address the regular schedule for pest control, chemical list, and time and place of exposure.

IPC.24.6 Routine environmental microbiological cultures are not performed unless recommended by the infection prevention and control team.

Standard Intent:

To provide safe and supportive environment for healthcare workers, patient and visitors, regular hospital wide cleaning and decontamination must be maintained by the hospital. Pest Control process should be conducted as per written hospital policy with a fixed schedule for different hospital areas, the hospital must have separate dirty and clean utility rooms in each patient care area that used for its designated purposes.

IPC.25 There is a system to handle blood/body fluids spills.

IPC.25.1 The hospital implements a policy on blood/body fluids spill kit use.

IPC.25.2 Blood spill kits are available in all patient care units, including all necessary components. Hospital staff working in patient care areas are capable of cleaning of blood/body fluids spills.

Standard Intent:

To minimize the risk of spread of infection and the risk of potential blood borne pathogens exposure, all blood and body substances should be treated as potentially infectious. The hospital must have a defined system on how to handle blood and body fluid spills. Managing exposure to blood or other body substances required availability of blood spill kit in every patient care unit that contains all necessary equipment and properly used by the hospital staff, written policies and procedures on spills management.

IPC.26 The hospital implements a program that is consistent with laws and regulations for safe disposal of medical waste.

IPC.26.1 There is a policy and procedure for safe disposal of medical waste.

IPC.26.2 Medical waste is disposed by specialized company and includes all types of medical waste.

IPC.26.3 Medical waste segregation, collection, and storing is conducted as per applicable laws and regulations.

IPC.26.4 Yellow bags are used for all non-sharp disposable materials contaminated with patient's blood and/or body fluids.

IPC.26.5 Yellow bags are distributed in the hospital in sufficient number and location.

IPC.26.6 Red bags are used for tissues, body parts, and amputated parts to be saved and then collected by the municipality to be buried.

IPC.26.7 Medical waste containers are cleaned and maintained regularly.

IPC.26.8 Hazard signs are fixed on all medical waste containers.

IPC.26.9 Medical waste collection points are cleaned and maintained regularly.

IPC.26.10 Labor working in medical disposal are well trained and vaccinated against blood borne pathogens.

Standard Intent:

To protect the public and the environment from potentially infectious disease and to provide safe healthy environment to patient, healthcare worker and visitors, the hospital should implement Medical Waste Management Program that regulates the segregation, handling, storage, and disposal of medical waste and providing oversight for its implementation as per hospital policy. The program should be implemented within national laws and regulation. The hospital should ensure the availability of required supplies (yellow bags, red bags, medical waste containers…etc.). Medical waste workers should be vaccinated and trained on safe handling of medical waste as reflected in their employee health records.

IPC.27 The mortuary and postmortem area are supervised by infection prevention and control.

IPC.27.1 There are written policies on how to handle bodies post mortem especially bodies that have multiple open wounds.

IPC.27.2 The temperature of the morgue is kept at 2-4°C and logged daily.

IPC.27.3 For long term preservation of dead bodies, the facility must provide a deep freezing compartment (temp < -15°C).

IPC.27.4 The morgue is regularly cleaned and disinfected.

Standard Intent:

To ensure that there is proper handling of dead patients' bodies in compliance with infection control precautions. The hospital should develop comprehensive policy and procedure covering post mortem functions. Morgue temperature should meet standard requirement; temperature is logged on daily basis. The hospital should ensure that mortuary and postmortem area are regularly cleaned, disinfected and supervised by Infection Control Team.

IPC.28 Kitchen environment and functions are supervised by infection prevention and control.

IPC.28.1 Kitchen design supports its function.

IPC.28.2 Kitchen areas are separated based on assigned function. (Separate area for vegetables, meat, desert preparation, etc.).

IPC.28.3 Adequate number of hand washing facilities are present in each area.

IPC.28.4 Food containers are properly labeled and expiry dates noted.

IPC.28.5 Temperature requirements are met during storage, preparation, and transportation.

IPC.28.6 Food is protected from environment during storage, preparation, display, and transportation.

IPC.28.7 Garbage containers or receptacles are adequate in number, insect and rodent proof, and are covered.

IPC.28.8 Refrigerator temperatures are checked daily and documented on log sheets.

IPC.28.9 Kitchen environment is clean.

IPC.28.10 The kitchen environment and functions are addressed in policies and procedures that are reviewed by the infection prevention and control team.

IPC.28.11 Food delivery to the receiving area must be checked for quality and temperature.

IPC.28.12 Fruits and vegetables are washed and disinfected thoroughly.

IPC.28.13 Food containers are washed immediately after being emptied from food.

IPC.28.14 Boards used to cut meat, poultry, chicken, or vegetables are identifiably separated and immediately washed after use.

Standard Intent:

The organization should reduce the risk of infections in the facility associated with operations of the food service. Kitchen design should support its function. Kitchen environment and functions must be supervised by Infection Control Team. The hospital must provide evidence of comprehensive food hygiene for all steps of food preparation, adequate resources that ensure proper kitchen function and clean environment

(including adequate hand hygiene facilities, identified cutting board, adequate and proper garbage containers, no stagnant water on floors).

IPC.29 Kitchen staff hygiene and health are supervised by infection prevention and control.

IPC.29.1 There are policies and procedures that address staff hygiene and health in the kitchen and are reviewed by infection prevention and control team.

IPC.29.2 While handling food, hands are washed, hair is covered, and gloves are worn.

IPC.29.3 Personnel with respiratory infections or gastroenteritis are restricted from handling food.

IPC.29.4 Stool tests and cultures are performed routinely upon hiring, every six months, and after returning back from vacation.

IPC.29.5 Results of stool analysis and cultures are reviewed by the infection prevention and control practitioner.

Standard Intent:

To ensure that kitchen staff practices during food handling are in compliance with Infection Control principles. Kitchen staff hygiene and health should be supervised by Infection Control Team according to written policies and procedures. The kitchen staff hygiene should be practiced properly through utilizing the required resources (hair cover, gloves, hand washing facilities, others). The kitchen staff health should be regularly monitored with availability of supported documents.

IPC.30 Laundry functions are supervised by infection prevention and control team.

IPC.30.1 There are policies and procedures on linen management that cover all steps starting from collecting linen from patients' rooms until completion of the cleaning process.

IPC.30.2 Clean linen is transported, handled, and stored in a way that keeps it protected from contamination and dust.

IPC.30.3 Clean and used linen are separated during storage and transport.

IPC.30.4 Linen carts used for clean and used linen are clearly identified.

IPC.30.5 Loose (un-bagged) linen is not to be put down a laundry chute.

IPC.30.6 Hand washing facilities are located in all areas where un-bagged linen is handled.

IPC.30.7 Soiled linen (contaminated with patient's blood, excreta, or other body fluids) and linen from patients under isolation precautions are contained and transported in accordance with current professional standards:

IPC.30.7.1 Soiled linen must be handled as little as possible and with minimal agitation.

IPC.30.7.2 Appropriate barriers (gloves, gowns, and masks) should be used when handling soiled linen.

IPC.30.7.3 Linen is bagged at the location where it is used and is not stored or pre-rinsed in patient's care areas.

IPC.30.7.4 Linen is put into special color-coded and water-proof laundry bags.

IPC.30.8 Laundry functions are supervised by the infection prevention and control team.

Standard Intent:

To ensure that there is a defined system that guarantees proper practices are done when handling linen. The hospital should have written policies and procedures on linen management that cover all steps starting from collecting linen from patients' rooms through safe transporting of linen to completion of the cleaning process and storage. Laundry functions should be supervised by Infection Control Team as per hospital policy. The hospital should ensure proper linen handling, transportation, and storage using the required resources, in a way to protect staff and environment. The laundry should be properly structured and adequately function with respect to all infection control standard measures.

IPC.31 The infection prevention and control team reviews and supervises construction projects in the hospital.

IPC.31.1 There are policies that address infection prevention and control considerations during demolition, renovation, and construction projects.

IPC.31.2 There is a mechanism to ensure involvement of infection prevention and control team prior to any demolition, renovation, and construction projects.

IPC.31.3 Accepted infection prevention & control measures are followed during any demolition, renovation & construction projects e.g. infection control risk assessment (ICRA).

Standard Intent:

When planning demolition, construction, or renovation, the organization should use risk criteria that assess the impact of the renovation or new construction on air-quality requirements, infection prevention and control, utility requirements, noise, vibration, and emergency procedures according to the hospital policy. Construction or renovation projects in patient care areas will be evaluated prior to starting them based on ICRA,

reviewed during construction and after completion of work by infection prevention and control team.

IPC.32 Personal protective equipment use is supervised by infection prevention and control team.

IPC.32.1 Personal protective equipment (gown, gloves, masks, and protective eyewear) are readily available in all patient care areas.

IPC.32.2 Policies and procedures are available on the appropriate use of gloves, gowns, facemasks, protective eyewear, and high filtration respirator masks (N-95, N-99).

IPC.32.3 Proper training for the use of personal protective equipment is conducted.

Standard Intent:

Personnel protective equipment (PPEs) are fundamental tools for proper infection prevention and control practices. The hospital identifies those situations in which masks, eye protection, gowns, or gloves are required in written policy, with providing of enough supply of PPEs and training in their proper use.

IPC.33 The hospital supports appropriate hand hygiene practices.

IPC.33.1 The hospital develops policies and procedures on the proper hand hygiene practices.

IPC.33.2 Hand hygiene is practiced according to the relevant policies.

IPC.33.3 Compliance with hand hygiene is regularly monitored.

Standard Intent:

Hand hygiene is the most effective simple method to reduce the risk of Healthcare Associated Infections (HAIs) to achieve patient safety. The organization must adopt hand-hygiene guidelines from an authoritative source, identifies those situations for which hand hygiene required, the staff are educated in hand hygiene proper practice hospital wide, and the compliance rate regularly monitored for performance improvement.

IPC.34 The hospital provides sufficient hand hygiene facilities.

IPC.34.1 Toilets, hand washing, and bathing facilities meet the needs of the hospital and are clean and in good repair.

IPC.34.2 Hand washing sinks are available in all patients' rooms (including clinics and emergency rooms) and nursing stations.

IPC.34.3 Hand washing sinks and bathing facilities are supplied with hot and cold water under pressure.

IPC.34.4 Hand washing sinks are conveniently accessible to staff.

IPC.34.5 Antiseptic soap and towels are available for hand washing.

IPC.34.6 Hand disinfectants are available in adequate number (one dispenser per patients' room in general wards and clinics, one per bed in critical care areas and emergency rooms, and one in every nursing station).

Standard Intent:

To achieve best practice in hand hygiene, the required facilities such as toilets and hand washing sinks should be conveniently allocated and regularly maintained. The required supplies such as soap, alcohol hand rub sanitizers, and towels or other means of drying should be provided in adequate quantities in areas where proper hand hygiene practices are required.

IPC.35 The hospital reports communicable diseases to the relevant authorities.

IPC.35.1 Communicable diseases are timely reported internally to the infection prevention and control team by the treating team.

IPC.35.2 The hospital reports communicable diseases to the Ministry of Health in accordance with laws and regulations and to other authorities whenever required.

Standard Intent:

To ensure that the hospital in compliance with the Ministry of health requirements on reporting of notifiable communicable diseases, the hospital should have an evidence of reporting of communicable diseases to MOH as per the hospital policy and evidence of staff awareness of hospital reporting system.

IPC.36 There are policies and procedures that address employees' immunization and post exposure management.

IPC.36.1 There is a structure (e.g., staff health clinic) that provides pre-employment counseling and medical services related to screening, immunization, and post exposure management.

IPC.36.2 Employees' immunization and post exposure management are addressed in written policies and procedures.

IPC.36.3 Employees' immunization and post exposure management are consistent with laws and regulations and recommendations of professional organizations.

IPC.36.4 All employees have baseline screening for hepatitis B, C, HIV, and tuberculosis.

IPC.36.5 The immune status of newly hired staff against hepatitis B, measles, mumps, rubella, and varicella is determined by serological testing. Appropriate vaccine(s) is administered to those who are susceptible.

IPC.36.6 Response to hepatitis B vaccination is monitored in vaccinated employees four weeks after completing vaccine series. Non-responders to hepatitis B vaccine are offered at least a second series of the vaccine.

IPC.36.7 Newly hired staff are screened for tuberculosis upon contracting with PPD test, and the test is repeated annually for those who are non-reactive.

IPC.36.8 PPD conversion rates are calculated and monitored.

IPC.36.9 There is a system for reporting, follow up and management of exposure to open pulmonary TB and vaccine-preventable viruses: chickenpox, measles, mumps, and rubella.

IPC.36.10 There is a system for reporting, follow up, and management of needle prick and sharp injuries.

IPC.36.11 The infection prevention and control team regularly monitors exposure of staff to pathogens and take corrective actions to prevent recurrence.

IPC.36.12 The screening, immunization, and post exposure management data are kept in staff medical records.

Standard Intent:

To ensure that the hospital has a defined system that guarantees all staff is screened, immunized and offered post exposure prophylaxis as recommended by Infection Prevention and Control principles. Employee health services should be provided via Staff Health Clinic, its scope of services should include counseling and medical services related to screening, immunization, and post exposure management. Employee health services should be guided by hospital policy which addresses staff screening, immunizations and exposure to blood/body fluid and exposure to infectious diseases. Employees' medical records reflect required staff screening, immunization and post exposure measures. The hospital should evaluate the Infection Control risks on hospital staff by measuring PPD conversion rates, and sharp injuries rate.

IPC.37 The hospital develops an anti-biogram that is regularly reviewed.

IPC.37.1 The anti-biogram is prepared at least once yearly.

IPC.37.2 The anti-biogram is regularly discussed by infection prevention and control committee.

Standard Intent:

Current evidences clearly demonstrate that the inappropriate use of broad-spectrum antibiotics is associated with the development of antibiotic resistant bacteria. Availability of anti-biogram helps in organizing a systematic approach to optimize the utilization of antimicrobials that subsequently improves patient's outcomes, ensures cost effective therapy, and minimizes adverse consequences, including antimicrobial resistance, toxicity, morbidity and mortality. Each hospital must have antimicrobial sensitivity pattern (Anti-biogram Report) that is produced at least yearly and based on high quality diagnostic microbiology services and discussed regularly during Infection Control Committee meetings. Organizational antimicrobial prescribing guidelines should be updated based on anti-biogram.

IPC.38 The hospital adopts safe injection practices that minimize or prevent transmission of infection.

IPC.38.1 Staff use aseptic technique for injections preparation.

IPC.38.2 Staff use sterile syringes and needles.

IPC.38.3 Staff use single-dose vials as appropriate.

IPC.38.4 Staff use mask during injecting a medicine or placing a catheter into a spinal place.

Standard Intent:

Injected medications are commonly used in healthcare settings for the prevention, diagnosis, and treatment of various illnesses. Unsafe injection practices increase the patients and healthcare providers' risk to be exposed to infectious and non-infectious adverse events. Unsafe injection practices have been associated with a wide variety of procedures in different hospital settings. Safe injection practices should be implemented by the hospital as a part of the standard precautions and guided by written policies and procedures that address required aseptic techniques, appropriate use of single-dose vials and infection control practices for special lumbar puncture procedures.

IPC.39 The hospital implements evidence-based interventions to prevent ventilator–associated pneumonia.

IPC.39.1 The hospital adopts and implements care bundle for prevention of ventilator-associated pneumonia (VAP) consistent with recognized professional practices

IPC.39.2 Data on the care bundle for prevention of ventilator-associated pneumonia are regularly collected, analyzed, and evaluated. Improvement interventions are taken accordingly.

Standard Intent:

To optimize the outcome of the mechanical ventilation procedure in critical care areas, the hospital should have a clear policy and procedure to minimize the risk of developing ventilator associated pneumonia (VAP). To be able to verify patient safety and demonstrate quality for mechanically ventilated patients, the hospital should also have a policy for VAP prevention & care bundle; all concerned hospital staff must be fully oriented about the elements of adopted care bundle. The hospital should regularly collect and analyze the data and assess bundle compliance rate for performance improvement.

IPC.40 The hospital implements evidence-based interventions to prevent surgical site infection.

IPC.40.1 The hospital adopts and implements care bundle for prevention of surgical site infection consistent with recognized professional practices.

IPC.40.2 Data on the care bundle for prevention of surgical site infection are regularly collected, analyzed, and evaluated. Improvement interventions are taken accordingly

Standard Intent:

To optimize perioperative, intraoperative and post-operative care, the risk of surgical site infections (SSI) should be reduced to the minimum. To be able to verify patient safety and demonstrate the quality of operative care among surgical patients, the hospital should have a policy for SSI prevention & care bundle, the concerned hospital staff must be fully educated by the elements of adopted care bundle. The hospital should regularly collect and analyze the data and assess bundle compliance rate for performance improvement.

IPC.41 The hospital implements evidence-based interventions to prevent catheter-associated urinary tract infection.

IPC.41.1 The hospital adopts and implements care bundle for prevention of catheter-associated urinary tract infection consistent with recognized professional practices.

IPC.41.2 Data on the care bundle for prevention of catheter-associated urinary tract infection are regularly collected, analyzed, and evaluated. Improvement interventions are taken accordingly.

Standard Intent:

To optimize urinary catheter (UC) insertion and maintenance procedures in patient care areas and thereby minimize the risk of catheter-associated urinary tract infections (CAUTI). To be able to verify patient safety and demonstrate quality UC cares. The hospital should have a policy for CAUTI prevention & care bundle, the concerned hospital staff must be fully educated about the elements of adopted care bundle. The hospital should regularly collect and analyze the data and assess bundle compliance rate for performance improvement.

IPC.42 The hospital implements evidence-based interventions to prevent central intravascular catheter-associated blood stream infection. scular catheter-associated blood stream infection are regularly collected, analyzed, and evaluated. Improvement interventions are taken accordingly.

IPC.42.1 The hospital adopts and implements care bundle for prevention of central intravascular catheter-associated blood stream infection consistent with recognized professional practices.

IPC.42.2 Data on the care bundle for prevention of central intravascular catheter-associated blood stream infection are regularly collected, analyzed, and evaluated. Improvement interventions are taken accordingly.

Standard Intent:

To ensure the Central Venous Catheter insertion and maintenance procedure in patient care areas and critical care areas are optimal, evidence-based and minimize the risk of harm to the patient. To be able to verify patient safety and demonstrate qualities central line care. The hospital should have a policy for CLABSI prevention & care bundle; the concerned hospital staff must be fully educated about the elements of adopted care bundle. The hospital should regularly collect and analyze the data and assess bundle compliance rate for performance improvement.

IPC.43 The hospital implements evidence-based interventions to reduce the burden of epidemiologically significant organisms.

IPC.43.1 The hospital adopts and implements care bundle for prevention of Multidrug Resistant Organisms (MDROs) consistent with recognized professional practices.

IPC.43.2 Data on the care bundle for prevention of Multidrug Resistant Organisms (MDROs) are regularly collected, analyzed, and evaluated. Improvement interventions are taken accordingly.

Standard Intent:

To prevent and control the transmission of epidemiologically significant organisms such as Multidrug Resistant Organisms (MDROs), the hospital should have a policy for MDROs

prevention & care bundle; the concerned hospital staff must be fully educated about the elements of adopted care bundle. The hospital should regularly collect and analyzed the data and assess bundle compliance rate for performance improvement.

IPC.44 Staff accommodation is healthy.

IPC.44.1 Staff accommodation is clean, well ventilated, not overcrowded, well maintained, and free from pets.

IPC.44.2 Staff accommodation provides facilities for staff isolated or restricted from work due to infection issues.

Standard Intent:

Provision of healthy staff accommodation is crucial to maintain staff health, satisfaction, and productivity. The organization should ensure that staff is protected from acquiring infection by providing them a clean, well maintained accommodation with facilities to isolate staff suffering from communicable diseases.

Medication Management Standard Intents

MM.1 Patient specific information is readily accessible to all healthcare professionals involved in the medication management system.

MM.1.1 The hospital has a multidisciplinary policy and procedure on patient specific information to be readily accessible to all healthcare professionals. The information includes, but is not limited to, the following:

MM.1.1.1 Patient's age and sex.

MM.1.1.2 Current medications.

MM.1.1.3 Diagnoses, co-morbidities.

MM.1.1.4 Laboratory values.

MM.1.1.5 Allergies.

MM.1.1.6 Body weight and height.

MM.1.1.7 Pregnancy and lactation status.

MM.1.2 Except in emergency situations, patient specific information is accessible when needed to all healthcare professionals involved in the medication management system.

Standard Intent:

Medication management in hospitals is a complex system and requires the collaboration of all healthcare providers. In order to ensure utmost medication safety, patient specific relevant information should be captured and documented in the patient's medical record so it remains available and accessible to all healthcare providers caring for the patient. The information includes patient's demographics, weight and height, current medications, known allergies to medications or to other allergens, diagnoses and co-morbidities, laboratory values and pregnancy and lactation status for women. Rarely, such information may not be fully accessible-as in dire emergencies, but all efforts must be made, to ensure its availability.

MM.2 The pharmaceutical care department has a clear organizational structure and is directed by a qualified pharmacist.

MM.2.1 The pharmaceutical care department has a clear organizational structure.

MM.2.2 The head of pharmaceutical care is a licensed pharmacist, qualified by education, training, and experience.

MM.2.3 The head of pharmaceutical care has a valid professional registration with the Saudi Commission of Health Specialties and Ministry of Health practice license in Saudi Arabia, as applicable.

MM.2.4 The authorities and accountabilities of the head of the pharmaceutical care is clearly delineated in a job description and updated every three years.

Standard Intent:

The hierarchical arrangement of lines of authority, communications, rights and duties of pharmacy are clearly illustrated. A clear organization structure defines how pharmacy activities such as task allocation, coordination and supervision are directed towards the achievement of pharmaceutical care. The structure shall determine the mode in which the pharmacy operates and perform. Effective leadership is essential for the department to be able to operate efficiently and to fulfill its mission. The head of pharmaceutical care is certified, trained, licensed pharmacist who has valid registration with the Saudi Commission of Health Specialties. The essential functions, duties and responsibilities and accountabilities of the head of pharmaceutical care is clearly written in a job description that must be updated every three years.

MM.3 The pharmaceutical care department has adequate number of qualified staff.

MM.3.1 The pharmaceutical care department has adequate number of staff qualified by education, training, and experience.

MM.3.2 There is a current staffing plan based on work load statistics that ensures availability of sufficient staff resources to deliver the service.

MM.3.3 The staff responsible for intravenous admixtures, parenteral nutrition, chemotherapy, and drug information services have appropriate training and competency assessment.

MM.3.4 The quality coordinator has appropriate certification/training.

MM.3.5 There is a structured orientation program where new staff are briefed on pharmaceutical care and relevant aspects of the facility to prepare them for their roles and responsibilities.

MM.3.6 There is a process to ensure that the new employee's competency is evaluated before allowed to work independently.

MM.3.7 There are continuing professional development activities for all pharmaceutical care staff.

Standard Intent:

Appropriate and adequate staffing is critical to patient care. Staffing plan is a systematic process to ensure that the pharmaceutical care department has the right number of staff with the right qualifications to fulfill service needs. Staffing plan depends on the department mission, functions and services provided. Staffing plan should take in consideration, the job description, job requirements such as skills, knowledge, and qualifications needed for the job. Gathering statistics of productivity of your current workforce help determines how much the average person can do in each working hour. Such statistics should be examined to evaluate the staffing needs during the busiest periods. Due to the critical nature of the service, special training and

competencies are required for pharmacy staff working in intravenous admixture, total parenteral nutrition, chemotherapy, drug information services, and quality coordination activities. Staff orientation, competency assessment and continuous professional activities are essential for provision of safe and quality services.

MM.4 The pharmaceutical care and medication use in the hospital are well planned and comply with laws and regulations of relevant authorities and the Saudi Food and Drug Authority (SFDA).

MM.4.1 Organization and management of medications throughout the hospital (procurement, storage, prescribing, preparing and dispensing, administration, and monitoring) are guided by clear multidisciplinary plan or policy.

MM.4.2 Policies and procedures are developed in collaboration with relevant staff, such as medical, nursing, and management staff.

MM.4.3 Updated policies and procedures manual is readily accessible to all healthcare professionals involved in medication use.

MM.4.4 Appropriate sources of drug information are readily available to all healthcare professionals involved in medication use. (e.g., books, manuals, CDs/DVDs, online subscription to drug information resources).

MM.4.5 The pharmaceutical care services are provided twenty-four hours a day, seven days a week for inpatients and emergency patients.

MM.4.6 There is a pharmacist on-call whenever the inpatient pharmacy is closed.

Standard Intent:

Medications must be organized and managed effectively and efficiently. Medication management is not only the responsibility of the pharmaceutical service alone, but also of managers and health care professionals utilizing multidisciplinary plan and hospital policies and procedures. In addition, compliance with the country related laws and regulations is an essential element for safe and appropriate use of medication in any healthcare organization. These laws and regulations were initially put in place by the health authorities to ensure safe, secure, consistent and efficient use of medication for all patients in the country. All disciplines involved in the medication use process shall be aware of their related Saudi laws that govern their functions and activities. To fulfill their professional obligations, appropriate resources of drug information are made available to healthcare providers at all times.

MM.5 The hospital has a system for the safety of high-alert medications.

MM.5.1 There is a written multidisciplinary plan for managing high-alert medications and hazardous pharmaceutical chemicals. It includes identification, location, labeling, storage, dispensing, and administration of high-alert medications.

MM.5.2 The hospital identifies an annually updated list of high-alert medications and hazardous pharmaceutical chemicals based on its own data and national and international recognized organizations (e.g., Institute of Safe Medication Practice, World Health Organization). The list contains, but is not limited to, the following:

- MM.5.2.1 Controlled and narcotics medications.
- MM.5.2.2 Neuromuscular blockers.
- MM.5.2.3 Chemotherapeutic agents.
- MM.5.2.4 Concentrated electrolytes (e.g., hypertonic sodium chloride, concentrated potassium salts).
- MM.5.2.5 Antithrombotic medications (e.g., heparin, warfarin).
- MM.5.2.6 Insulins.
- MM.5.2.7 Anesthetic medications (e.g., propofol, ketamine).
- MM.5.2.8 Investigational (research) drugs, as applicable.
- MM.5.2.9 Other medications as identified by the hospital.

MM.5.3 The hospital plan for managing high-alert medications and hazardous pharmaceutical chemicals is implemented. This includes, but is not limited to, the following:

- MM.5.3.1 Improving access to information about high-alert medications.
- MM.5.3.2 Limiting access to high-alert medications.
- MM.5.3.3 Using auxiliary labels or computerized alerts if available.
- MM.5.3.4 Standardizing the ordering, transcribing, preparation, dispensing, administration, and monitoring of high-alert medications.
- MM.5.3.5 Employing independent double checks.

MM.5.4 The hospital develops and implements standard concentrations for all medications administered by intravenous infusion.

Standard Intent:

High-alert medications are drugs that bear a heightened risk of causing significant patient harm when used in error. Errors may not be more common with these than with other medications, but the consequences of errors may be devastating. Several worldwide organizations had identified a list of High Alert medications such as WHO and ISMP. Hospitals shall have a plan for the safe use of these medications and develop their own annually updated list of high alert medications with the related safety

strategies to minimize errors and harm from these medications and other hazardous pharmaceutical chemicals as much as possible.

MM.6 The hospital has a system for the safety of look-alike and sound-alike (LASA) medications.

MM.6.1 There is a multidisciplinary policy and procedure on handling look- alike/sound-alike (LASA) medications.

MM.6.2 The hospital reviews and revises annually its list of confusing drug names, which include LASA medication name pairs that the hospital stores, dispenses, and administers.

MM.6.3 The hospital takes actions to prevent errors involving LASA medications including the following, as applicable:

MM.6.3.1 Providing education on LASA medications to healthcare professionals at orientation and as part of continuing education.

MM.6.3.2 Using both the brand and generic names for prescribing LASA medications.

MM.6.3.3 Writing the diagnosis/ indication of the LASA medication on the prescription.

MM.6.3.4 Changing the appearance of look-alike product package.

MM.6.3.5 Reading carefully the label each time a medication is accessed, and/or prior to administration.

MM.6.3.6 Minimizing the use of verbal and telephone orders.

MM.6.3.7 Checking the purpose/indication of the medication on the prescription prior to dispensing and administering.

MM.6.3.8 Placing LASA medications in locations separate from each other or in non-alphabetical order.

Standard Intent:

Medication errors related to look-alike and/or sound-alike medication names and/or packages are common in the healthcare setting throughout the medication use process. Look-alike, Sound-alike medications account for an estimated 25- 30% of medication errors. With tens of thousands of medications currently on the market, the potential for serious error due to confusing medication names is significant. Contributing to this confusion are incomplete knowledge of drug names; newly available products; similar packaging or labeling; similar clinical use; illegible prescriptions or misunderstanding during issuing of verbal orders. Several organizations worldwide such as the WHO and the ISMP had identified, published and periodically updated several lists of look-alike and sound-alike medications. Hospitals shall initiate and then annually update their own list of LASA medication names. They

should establish scientific based safety strategies to prevent or minimize errors with these confusing medications.

MM.7 The hospital establishes a multidisciplinary pharmacy and therapeutics committee or equivalent to provide oversight of the hospital formulary and medication use.

MM.7.1 There is a pharmacy and therapeutics committee chaired by a senior medical or pharmaceutical care staff member.

MM.7.2 There are terms of reference for the pharmacy and therapeutics committee that include committee's functions, membership, quorum, frequency of meetings, approval, and distribution of minutes.

MM.7.3 The pharmacy and therapeutics committee meets on a regular basis (at least quarterly).

MM.7.4 The meeting minutes of the committee reflects the members in attendance, items discussed, decisions reached, lead accountability assigned for action undertaken and subsequent reporting, as well as follow-up data for these activities.

MM.7.5 Functions of the pharmacy and therapeutics committee include, but are not limited to, the following:

MM.7.5.1 Serve in an evaluative, educational, and advisory capacity to the medical staff and hospital management in all matters pertaining to the use of medications.

MM.7.5.2 Develop and approve criteria for selecting medications that include at least indications, effectiveness, risks (potential for medication errors, abuse potential, and sentinel events), or cost.

MM.7.5.3 Develop a formulary of drugs accepted for use in the hospital and provide for its constant revision.

MM.7.5.4 Establish programs and procedures that help ensure safe and effective drug therapy.

MM.7.5.5 Establish programs and procedures that help ensure cost-effective drug therapy.

MM.7.5.6 Establish or plan suitable educational programs for the hospital's professional staff on matters related to drug use.

MM.7.5.7 Participate in quality improvement activities related to distribution, administration, and use of medications.

MM.7.5.8 Monitor and evaluate adverse drug events and make appropriate recommendations to prevent their recurrence.

MM.7.5.9 Establish evidence-based therapeutic guidelines according to the scope of services of the hospital (e.g., intravenous iron,

intravenous immunoglobulin, albumin, heparin, chemo protocols, high alert medications, and electrolyte management guidelines).

MM.7.5.10 Initiate and/or direct drug use evaluation programs and studies, review the results of such activities, and make appropriate recommendations to optimize drug use.

MM.7.5.11 Advise the pharmaceutical care department in the implementation of effective drug distribution and control procedures.

MM.7.5.12 Disseminate information on its actions and approved recommendations to all staff.

MM.7.5.13 The committee conducts an annual review of its hospital formulary based on safety and efficacy information (e.g., Saudi FDA warnings, international medication safety alerts, hospital-based adverse drug reaction reports, and drug utilization evaluation studies).

Standard Intent:

Inappropriate use of medicines wastes resources and seriously undermines the quality of patient care. A pharmacy and therapeutics (P&T) committee can significantly improve drug use and reduce costs in hospitals. The P&T committee is an important medical staff advisory group. As the primary, formal communication link between the pharmacy and medical staff, the P&T committee is of particular importance to the department of pharmacy services. The committee is responsible for managing the formulary system. The evaluation of medications requires significant expertise and time commitment and a rigorous, transparent approach. Documented evidence for the efficacy, safety, quality and cost of all drugs under consideration for inclusion in the formulary list must be examined.

P&T committee is composed of actively practicing physicians, other prescribers, pharmacists, nurses, administrators, quality improvement managers, and other health care professionals and staff who participate in the medication-use process. The P&T committee is responsible for overseeing policies and procedures related to all aspects of medication use within an institution. Other responsibilities of the P&T committee include medication-use evaluation, adverse-drug-event monitoring and reporting, medication-error prevention, and development of clinical care plans and guidelines.

MM.8 The hospital has an updated, structured, and well organized drug formulary.

MM.8.1 The hospital has a structured and well organized formulary that is updated annually.

MM.8.2 Healthcare professionals involved in prescribing, ordering, dispensing, administering, and patient monitoring processes are involved in developing, evaluating, updating and maintaining the hospital formulary.

MM.8.3 The hospital formulary is accessible to all those involved in medication management.

MM.8.4 The hospital formulary is properly indexed (alphabetical index for generics and trade names of drugs), and properly classified using therapeutic classification.

MM.8.5 The hospital formulary includes short drug monographs that illustrate the generic drug name, strength, and dosage form(s), indication(s), adverse drug reactions, and prescribing information.

MM.8.6 The hospital formulary provides guidance on antibiotics use (both prophylactic and therapeutic uses).

MM.8.7 The hospital formulary provides a list of approved prescribing abbreviations.

MM.8.8 The hospital formulary provides a list of prohibited prescribing abbreviations.

MM.8.9 The hospital formulary provides appendixes on important policies, therapeutic guidelines, drug safety in pregnancy and lactation, and dose adjustment in organ failure.

Standard Intent:

The formulary process is the cornerstone of good medication management and rational drug use. It consists of preparing, using and updating a formulary list of essential medications. A hospital formulary manual provides adequate information on all essential medications that should be available all the time in the hospital in a properly indexed, easily accessible format. Formulary medications are selected on the basis of the standard treatment guidelines or protocols that have been developed or adapted for use in the hospital. Periodic review by multidisciplinary healthcare professionals is necessary because of changing costs and indications, new information on safety, and the emergence of new medicines. Hospital formulary supports clinical staff choosing the most appropriate therapies and selecting the most cost-effective good-quality drugs according to the standard treatment guidelines to ensure provision of better quality of care and more efficient, equitable use of resources. Antimicrobials are amongst the most expensive of all drugs, often consuming most of a hospital's drug budget. In addition to the normal hazards of drug use, the use of antimicrobials contributes to the development of antimicrobial resistance, and poor infection control contributes to the spread of resistant pathogens. Therefore, P&T committees should publish antimicrobials use guidelines to ensure its appropriate and safe use. In addition, the formulary shall include important scientific appendixes and important policies and procedures.

MM.9 The hospital has a system for procurement of medications that are not on the hospital's formulary (non-formulary medications).

MM.9.1 There is a policy and procedure for selection, approval, and procurement of non-formulary medications within an acceptable time frame.

MM.9.2 A patient-specific non-formulary drug request form is readily available.

MM.9.3 There is proper handling of non-formulary drug requisition within an acceptable time frame.

MM.9.4 There is a regular review of non-formulary drug requests by the pharmacy and therapeutics committee or an equivalent multidisciplinary body.

Standard Intent:

Occasionally, hospitals may encounter some clinical conditions where formulary medication(s) are ineffective or may be contraindicated. Treating physician may also believe it is appropriate to continue therapy for a patient who had been stabilized on a non-formulary medication before admission to hospital and where changing to another medication is considered detrimental. Hospitals should establish a process for procurement of patient specific non-formulary medications within an acceptable time frame. A register of all non-formulary medication requests should be kept by the pharmacy and periodically reviewed by the pharmacy and therapeutics committee to evaluate prescribers' adherence to the formulary list and to help in deciding whether or not to add drugs onto the formulary.

MM.10 The hospital has a system for handling out of stock, shortage and disaster needs of medications.

MM.10.1 The hospital implements a policy and procedure on proper communication of medication shortage and outage to prescribers and other healthcare professionals involved in medication management and obtaining medications in the event of a disaster.

MM.10.2 The pharmacy and therapeutics committee develops and approves medication substitution protocols in the event of medication shortage or outage.

MM.10.3 There is implementation of the hospital approved medication substitution protocols and staff awareness.

MM.10.4 There is a plan for emergency preparedness to respond to the special and large demand of medications during internal and external disasters. The plan is tested for effectiveness and integrated with the general hospital plan.

Standard Intent:

Hospitals are experiencing a rapidly increasing frequency of drug shortages, which have caused numerous difficulties for clinicians and patients. Drug shortages are caused by many factors and adversely affect patient care. Management strategies need to be developed for handling out-of-stock medications to ensure continuity of patient care. This includes timely communication with clinicians, development and approval of

medication substitution protocols by the pharmacy and therapeutics committee. Any hospital emergency preparedness plan should take in consideration the special and large demand of medications during internal and external disasters.

MM.11 The hospital has a safe and secure system for the storage of regular medications and nutrition products in stores, pharmacies, and patient care areas.

MM.11.1 There is a policy and procedure on proper storage and control of medications, nutrition products, and free medical samples (from the point of receipt until the point of administration).

MM.11.2 There is a policy and procedure to control the access of pharmaceutical care and non-pharmaceutical care staff to stores, pharmacies, and patient care areas including after hours and in case of emergency (e.g., fire, flood).

MM.11.3 There are measures in place to secure medications storage areas including limited access, proper locking procedures, and door keys handling.

MM.11.4 Only authorized individuals have access to stored medications.

MM.11.5 Medications are stored in a way to avoid mixing with labels showing the drug name and expiry date.

MM.11.6 No medications are stored directly on floor (a minimum of ten centimeters is left to manage spills). Medications are not stacked so high to block sprinklers or come in contact with overhead lights or pipes.

MM.11.7 Medications are stored according to manufacturer's recommendations (temperature, light, humidity, sanitation).

MM.11.8 There is an appropriate storage area for regular medications with controlled temperature (between 18 and 25 degrees centigrade), twenty-four hours a day, seven days a week.

MM.11.9 The room air temperature is checked and documented at least once daily on the temperature log sheet.

MM.11.10 Temperature records are kept for at least three years.

MM.11.11 All antiseptics, disinfectants, and medications for external use are stored separately from enteral and injectable medications.

MM.11.12 The "first expiry/ first out" (FEFO) principle is followed.

MM.11.13 All medication storage areas are inspected at least monthly by the pharmaceutical care according to the hospital policy to ensure proper storage of medications. Inspection includes, but is not limited to: availability, stock level, expiry date, and storage conditions.

MM.11.14 Expired and damaged medications are clearly labeled and separated from other drugs until its removal and proper destruction.

MM.11.15 Medication quality issues are reported to the Saudi FDA, as required.

Standard Intent:

People can be harmed if they take out-of-date or damaged pharmaceuticals. Proper storage of pharmaceuticals is extremely important from the time it is received in the hospital until it reaches the patient. The loss of potency during storage may influence the efficacy and safety of pharmaceuticals. Proper environmental control (i.e., proper temperature, light, and humidity, conditions of sanitation, ventilation, and segregation) must be maintained wherever drugs and supplies are stored anywhere in the hospital. Proper labeling and storage in a way to avoid mixing is very crucial for medication safety especially for look-alike and sound-alike pharmaceuticals. Medication security addresses keeping medication in a storage area such that unauthorized personnel are prevented from obtaining access to the medication. Routine inspection of drug storage areas by qualified pharmacy staff is indicated to ensure compliance with given standards. The objectives of drug storage shall be to ensure stock security and the maintenance of the quality of drugs throughout their shelf life.

MM.12 The hospital has a safe and secure system for storage of refrigerated and frozen medications, biologicals, and vaccines in stores, pharmacies, and patient care areas.

MM.12.1 There is a policy and procedure on proper storage and control of refrigerated and frozen medications from the point of receipt until the point of administration.

MM.12.2 There are medication refrigerators and freezers for storing refrigerated and frozen medications, biologicals and vaccines.

MM.12.3 All medication refrigerators and freezers are equipped with appropriate thermometers or equivalent device for temperature recording.

MM.12.4 The refrigerators' temperature is checked and documented at least once daily on the temperature log sheet.

MM.12.5 The refrigerator's temperature is kept between (2-8°C).

MM.12.6 The freezer's temperature is kept between (-10 and -25°C).

MM.12.7 All vaccine refrigerators are connected to emergency power source and electric outlets are marked accordingly.

MM.12.8 Vaccine refrigerator's temperature is continuously recorded around the clock or an equivalent process is in place to monitor temperature around the clock.

MM.12.9 Temperature records are kept for at least three years.

MM.12.10 There is a clear and defined mechanism to deal with electric power outage or out-of-range temperature of the medication refrigerators and freezers to ensure the integrity of the affected medications before its reuse.

MM.12.11 Food, drinks, biological samples, and culture media are not allowed inside any medication refrigerator or freezer.

Standard Intent:

Vaccine storage and handling are key components in maintaining the efficacy of immunization programs. Vaccines are biological substances that may lose their effectiveness quickly if they become too hot or too cold at any time, especially during transport and storage. Storage outside of the recommended temperature range, including during transport and storage, may speed up loss of potency, which cannot be reversed. Inappropriate storage may result in vaccines wastage, or if undetected, failure of the vaccine to protect. Due to the delicate nature of vaccines, continuous monitoring of temperature is indicated. The devastating effect of electric power outage shall be mitigated through connection of vaccine refrigerators to emergency power supply. To avoid contamination, refrigerated medications, biologicals and vaccines shall not be stored with food, drinks, biological samples, and culture media in the same refrigerator.

Refrigerated and frozen pharmaceuticals must be secured and access be limited to authorized personnel only. Routine inspection of refrigerated and frozen pharmaceuticals by qualified pharmacy staff is indicated to ensure compliance with given standards. The objectives of drug storage shall be to ensure stock security and the maintenance of the quality of drugs throughout their shelf life.

MM.13 The hospital has a safe and secure system for the storage and safe management of hazardous medications and pharmaceutical chemicals.

MM.13.1 There is a written policy on proper storage and handling of hazardous medications and pharmaceutical chemicals.

MM.13.2 The hospital has a list of hazardous medications and pharmaceutical chemicals in areas where they are stored or used.

MM.13.3 Hazardous medications and pharmaceutical chemicals are stored separately on low shelves and in the original labeled containers.

MM.13.4 Flammables and volatile substances are stored in appropriate safety cabinets in well ventilated areas.

MM.13.5 Spill kits and personal protective equipment are readily available.

MM.13.6 For staff involved in the handling of chemicals and hazardous medications (such as chemotherapeutic agents) who are attempting to conceive, pregnant, or breast feeding, a structured process is in place to review potential exposure risks and offer alternative work assignment.

MM.13.7 Material safety data sheets (MSDS) for all available hazardous medications and pharmaceutical chemicals are available and accessible to staff.

MM.13.8 Eye wash station and emergency water shower are available where hazardous medications and pharmaceutical chemicals are located.

MM.13.9 The hospital staff are well educated on the proper storage and handling of hazardous medications and pharmaceutical chemicals and spill management.

Standard Intent:

Worker exposure to hazardous drugs has been identified by OSHA as a problem of increasing health concern. Improper storage and handling of hazardous medications and pharmaceutical chemicals may expose healthcare workers to potentially significant levels of these chemicals. Antineoplastic cytotoxic medications, anesthetic agents, anti-viral agents, and others, have been identified as hazardous. These hazardous medications are capable of causing serious effects including cancer, organ toxicity, fertility problems, genetic damage, and birth defects. Hospital should create and keep a current list of drugs considered to be hazardous in their workplace. Use the criteria and sources of information provided by NIOSH, as well as specific information found in each manufacturer's Material Safety Data Sheet (MSDS) to create a list of Hazardous Drugs used in their specific department.

Hazardous drugs are stored in a separate, labelled and secured cabinets away from non-hazardous drugs while flammables require special fire-safety cabinet with proper ventilation. Spill control protocols (e.g. spills kits and use of emergency eyewash stations and showers) should be readily available. A key element of this safety program is the availability of Material Safety Data Sheet (MSDS) for all hazardous agents in the workplace. Personal Protective Equipment (PPE) are essential for handling hazardous drugs. Staff education on safe handling and spill management is of paramount importance.

MM.14 The hospital has a system for ensuring stability of medications available in multi-dose containers.

MM.14.1 The hospital develops and maintains a set of guidelines for ensuring stability of multi-dose vials, vaccines, multi-dose oral liquids, and other multi-dose medications (e.g., eye, ear, and nasal drops, creams, ointments, nebulization solutions).

MM.14.2 The hospital ensures that all open multi-dose containers are labeled with open date, expiry date, initials, and time (if necessary).

MM.14.3 The hospital ensures that no expired open or unlabeled open multi-dose containers are available in patient care areas.

Standard Intent:

Multiple-dose vials (MDVs) are widely used in all healthcare settings. By definition, a MDV contains antibacterial preservatives and, according to manufacturer's recommendations, may be used more than once. It is important to recognize that although common preservatives used in MDVs are effective against most bacteria, they are not antiviral agents. It does not protect against contamination when healthcare personnel fail to follow safe injection practices. In addition, contaminating pathogens are able to survive in MDVs for approximately two hours before the preservative takes full effect. It is possible that endotoxins survive even after the preservative inactivates the organism. The contamination rate of MDVs in published studies has been as low as 0% and as high as 27%.

Multi-dose vials should be dedicated to a single patient whenever possible. If multi-dose vials must be used for more than one patient, they should not be kept or accessed in the immediate patient treatment area. If a multi-dose has been opened or accessed (e.g., needle-punctured) the vial should be dated and discarded within 30 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial. If a multi-dose vial has not been opened or accessed (e.g., needle-punctured), it should be discarded according to the manufacturer's expiration date. The manufacturer's expiration date refers to the date after which an unopened multi-dose vial should not be used.

MM.15 The hospital has a system for ensuring accessibility, availability, monitoring, and security of emergency medications.

MM.15.1 The hospital develops and maintains a standardized set of guidelines for emergency drugs for crash carts and emergency medical bags in accordance with the current Saudi Heart Association recommendations.

MM.15.2 Emergency medications are available in the patient care units and readily accessible to meet emergency needs.

MM.15.3 The emergency medications in the crash carts and emergency medical bags are protected from loss or theft using safety plastic seal.

MM.15.4 Plastic seals of crash carts and emergency bags are stocked in a safe place under supervision of pharmaceutical care or nursing.

MM.15.5 There is a process in place for monitoring emergency medications and replenishing them in a timely manner after use or when expired or damaged.

MM.15.6 The hospital maintains documents of emergency medications inspection on every shift by nursing staff.

MM.15.7 The hospital maintains documents of emergency medications inspection every month by pharmaceutical care staff.

Standard Intent:

When emergency arise, the immediate availability and accessibility of emergency medications becomes very crucial. The hospital should have a process to secure such medications from theft or loss. Medication-loaded crash carts and emergency medical bags are commonly used in hospital setting. Hospitals are expected to ensure availability and security of adequate and valid supply of all emergency medications. Collaboration between nursing and pharmacy is strongly recommended to monitor emergency medication and replenish them in timely fashion after being consumed. The use of tamper-evident plastic seals allows for quick access to the contents of a crash cart or emergency medical bag as they can be easily broken by hand.

MM.16 The hospital has a safe and secure system for managing medications in the patient care areas.

MM.16.1 The hospital implements a multidisciplinary policy and procedure on medications assignment as floor stocks in limited quantities according to the needs of each service unit.

MM.16.2 Anesthesia reversal agents are available in operating rooms and areas where moderate or deep sedation is performed.

MM.16.3 Oxytocics are available in the labor and delivery unit.

MM.16.4 Benzodiazepine and narcotics antagonists are available in all patient care areas where benzodiazepines and narcotics are stocked.

MM.16.5 All medications in the patient care areas are well separated and properly labeled.

MM.16.6 Concentrated electrolytes are not allowed in patient care areas (unless patient safety necessitates their immediate use). All necessary precautions and separate locked cabinet with proper signage are in place to prevent inadvertent administration of concentrated electrolytes.

Standard Intent:

In addition to emergency medication, patient care units in different areas of the hospital should keep limited stock of urgent medications such as anesthesia reversal agents in areas where anesthesia is administered; STAT doses of benzodiazepine and narcotics anti-dotes where benzodiazepine and narcotics are stocked and used; STAT doses of pain killers or antispasmodics or anti-emetics where waiting for pharmacy dispensing would have negative impact on patient management. Cytotocics should be stocked in labor and delivery units. To prevent medication errors, adult doses should not be stocked in pediatric units as much as possible.

Floor stock may include simple pharmaceuticals that do not require immediate and intensive pharmacy intervention such as plain intravenous fluids such as normal saline and dextrose 5% water. Concentrated electrolytes pose a fatal threat to patients. When they are available on a patient care unit, it is far too easy for someone to accidentally administer the concentrated material without first diluting it in solution, especially during an emergency. Concentrated electrolytes shall not be allowed in patient care units unless absolutely necessary to have it in certain nursing units while the pharmacy is closed. In such case all necessary precautions should be taken to prevent serious medication errors secondary to its use. Several reports of medication errors have been linked to floor stock pharmaceuticals. Floor stock pharmaceuticals should not be considered a replacement of pharmacy services.

MM.17 There is a system to identify all medications brought into the hospital by patients or their families.

MM.17.1 The hospital implements a multidisciplinary policy and procedure on handling medications brought into the hospital by patients or their families (patient's own medications).

MM.17.2 Patient's own medications are checked for integrity and properly labeled if permitted for use, by a qualified pharmacist.

MM.17.3 There is proper documentation of patient's own medications in the medical record (ordering, dispensing, and administration records).

MM.17.4 When patient's own medication is not permitted, both patient and prescriber are informed.

Standard Intent:

The medications prescribed for and administered to patients while they are hospitalized are typically provided by the hospital's pharmaceutical care department. However, there are times when it may be necessary for a patient to bring his or her own medications into the hospital to take accurate medication reconciliation. Since the integrity and quality of medications brought from home can't always be guaranteed, it is generally discouraged to utilize such stock during hospital stay. In rare occasion, the prescribed drug may not be on the hospital's formulary and the hospital has no therapeutic alternative, the patients' personal medications may be used to avoid an interruption in therapy. In such case, a qualified pharmacist must evaluate quality and integrity of patient own medication before being approved for use and both patient and treating physician should be informed. All unused (not prescribed) patient's own medications shall be returned to the patient family or kept in the pharmacy until the time of patient discharge. Proper storage condition has direct effect of safety and efficacy of medications.

MM.18 There is a system for storing narcotics, psychotropic and other controlled medications in accordance with relevant laws and regulations.

MM.18.1 The hospital implements a multidisciplinary policy and procedure on proper storage of narcotics, psychotropic and other controlled medications.

MM.18.2 Controlled and narcotics medications are kept behind steel doors with double locks.

MM.18.3 The hospital allows a limited floor stock supply of controlled and narcotics medications to meet patients' needs.

MM.18.4 The hospital maintains proper documentation of drug count, endorsement, and accountability.

MM.18.5 The hospital maintains proper documentation of empty containers of narcotics and proper disposal of unused portions.

Standard Intent:

Narcotic and controlled medicines are those agents either naturally or compounded have been included in the schedule #1 and schedule # 2 in the SFDA regulations manual. The hospital has to implement the related rules and regulations of the SFDA and MOH as stated. Medications are stored and secured behind locked steel doors or inside steel cabinet with double lock and/or double doors all over the hospital. Limited quantities of essential controlled and narcotics medications may be allowed in patient care units according to clinical needs. The documentation process should be maintained for all related steps like requisition, procurement, ordering, dispensing, distribution, endorsement, registration and discarding of unused portion and empty containers.

MM.19 The hospital identifies qualified healthcare professionals permitted to prescribe or order controlled and narcotic medications.

MM.19.1 The hospital has a multidisciplinary policy and procedure on identification of those individuals permitted to prescribe or order controlled and narcotic medications and their prescribing privileges.

MM.19.2 Only individuals permitted by the hospital and relevant laws and regulations prescribe or order controlled and narcotic medications.

MM.19.3 Individuals permitted to prescribe or order controlled and narcotic medications are known to pharmaceutical care staff and nursing staff who dispense medications.

MM.19.4 The hospital implements its policy on prescribing privileges such as those for controlled and narcotic substances, chemotherapy agents, high-alert, radioactive or investigational, and other specialty medications.

Standard Intent:

Prescribing drugs is a standard component of most physicians' practices. It is an important area of practice that requires appropriate knowledge, skill and professional judgment. To improve patient safety when prescribing, the legal requirements of Narcotic and Psychotropic medications by the ministry of health (MOH) and Saudi FDA need to be followed and respected by healthcare institutions. These medications are considered high-alert medications. The main objective of these legal requirements is to protect patient and society from the consequences of misuse and/abuse of these medications. Prescribing privileges and supply quantities are clearly stated in the Saudi FDA narcotic manual. Chemotherapy agents, radioactive pharmaceuticals and other high-alert medications or investigational agents have narrow therapeutic window and error with these medications can lead to devastating consequences. The pharmacy and therapeutics committee should clearly define prescribing privileges for each of these medications in order to improve medication safety. A list of physicians' prescribing privileges shall be made accessible to all healthcare professionals. The list shall be updated as new prescribers join the hospital or when changes of privileges are made.

MM.20 Safe prescribing, ordering, and transcribing of medication orders are guided by a clear policy and procedure.

MM.20.1 There is a multidisciplinary policy and procedure that clearly defines a complete prescription.

MM.20.2 All currently prescribed or ordered medications are written in a uniform location in the patient's medical record.

MM.20.3 Medication reconciliation is conducted at the time of admission and discharge.

MM.20.4 Patient identification, diagnosis, indication, or clinical condition are made available with each medication order.

MM.20.5 Medications are prescribed by generic name except when brand names are acceptable or required.

MM.20.6 Staff comply with the proper use of approved and prohibited prescribing abbreviations.

MM.20.7 The pharmaceutical care team conducts corrective actions when medication order is incomplete, illegible, or unclear.

MM.20.8 All medications are accurately transcribed into the medication administration record (MAR) after being verified against the original physician order or prescription.

Standard Intent:

The medication use process is very complex and safe use process is warranted. Hospital staff need to know what constitute complete prescription. Studies shown that medication errors occur predominantly during the prescribing (39%). Nearly half of all

prescribing errors are intercepted by pharmacists and nurses. Prescribers usually include multiple different abbreviations in their prescription. Abbreviations, symbols, or designations have been shown to cause errors and compromise patient safety and should not be used. Medication reconciliation is a standardized process designed to provide the most complete and accurate list possible of all medications at the time of admission and discharge. Medication orders are written in a unified location in the medical record and in the generic name unless the brand name is recommended (such as combination products) or indicated for safety reasons (such as look-alike and sound-alike drug names). A prescription is not considered complete unless patient name, diagnosis, indication, or clinical condition are made available with each order. Studies shown that medication errors occur during drug administration (38%). Accurate transcription of orders into the medication administration record should be verified by a qualified nurse.

MM.21 The hospital ensures safe prescribing, ordering and transcribing of specific types of medication orders.

MM.21.1 The hospital implements a policy and procedure on specific types of medication orders including as needed (PRN), standing, automatic stop (ASO), titrating, tapering, range, weight-based, body surface area-based medication orders, and discharge or transfer orders.

MM.21.2 The hospital prohibits blanket orders (e.g., resume pre-op medications).

MM.21.3 Prescribing controlled drugs is according to laws and regulations of the Saudi Food and Drug Authority and other relevant authorities.

MM.21.4 The transcription of medication order into the medication administration record (MAR) clearly reflects the type of order.

Standard Intent:

To reduce the variation and improve patient safety, the hospital defines in a policy the required elements for processing specific type of medication orders that include: writing indications for use with any PRN order; standing, automatic stop (ASO), titrating, tapering, range, weight-based, body surface area-based medication orders, and discharge or transfer orders. Blanket order such as resume pre-operative medication should be prohibited in order to improve patient safety. New and complete drug orders post-surgery should be encouraged. The legal requirements of Narcotic and Psychotropic medications by the ministry of health (MOH) and Saudi FDA need to be followed and respected by healthcare institutions. Patient specific medication administration record should have a list of all medications ordered and the dosage, frequency, route, and time the medication was administered. This should include PRN and STAT orders.

MM.22 The hospital has a system for prescribing antibiotics.

MM.22.1 The hospital implements updated and approved multidisciplinary guidelines on the proper prescribing of antibiotics.

MM.22.2 The antibiotics guidelines are updated as recommended by the pharmacy and therapeutics committee utilizing the hospital anti-biogram.

MM.22.3 There is proper implementation of the approved guidelines for antibiotics prophylaxis before surgery and/or dental procedures.

MM.22.4 There is proper implementation of the approved guidelines for empiric and therapeutic use of antibiotics.

MM.22.5 There is proper implementation of the approved prescribing privileges for antibiotics.

Standard Intent:

Antibiotics misuse is a global concern, this misuse of antibiotics has a negative impact on patients and the community safety, increasing antibiotic resistant micro-organisms, and increasing the overall cost of health care. Development and implementation of antibiotic guidelines is scientifically proven to prevent, control, and treat infections. Each hospital should develop and update their own evidence-based guidelines taking in consideration their own anti-bigram and pathogens identified from the surveillance system. Guidelines should include surgical prophylaxis, empiric and therapeutic use of antibiotics. The use of appropriate antibiotics could be challenging nowadays. Hospitals are expected to define prescribing privileges of antibiotics in order to prevent development of resistance.

MM.23 The hospital has a system for managing the use of verbal and telephone orders of medications.

MM.23.1 The hospital has a multidisciplinary policy and procedure that control ordering, verifying, authenticating and limiting the use of verbal and telephone orders of medications. The policy includes a list of medications not allowed to be prescribed by verbal and telephone order.

MM.23.2 The hospital staff understand the proper use of verbal and telephone orders (accepting, documenting, verifying, authenticating, and executing orders).

MM.23.3 Verbal and telephone orders are limited to emergent and urgent situation where immediate written or electronic medication order is not feasible. Clear definition of emergent and urgent situations should be included.

MM.23.4 Time frame for authentication of verbal (as soon as the emergency is over) and telephone orders (within twenty-four hours) is clearly stated and implemented.

Standard Intent:

Verbal and telephone orders of medication are orders given by authorized health care practitioner to other authorized health care practitioner verbally (in case of emergency) and via telephone (in an urgent situation that needs prompt medical attention but is not an immediate threat to the patient). Verbal and telephone orders are proven to be error prone and may result in fatal medical errors due to different accents and pronunciations among healthcare providers. Though it is acknowledged that they may be required in exceptional care delivery situations, however hospitals must ensure that they will be accurate, complete, and mostly understood by the recipient and timely authenticated.

MM.24 The hospital has a system for prescribing non-formulary medications and prescribing formulary medications for off-label (unapproved) indication or investigation.

MM.24.1 The hospital has a multidisciplinary policy and procedure on prescribing non-formulary medications.

MM.24.2 The hospital has a multidisciplinary policy and procedure on prescribing formulary medications for off-label (unapproved) indications.

MM.24.3 There is clear documentation, on a special request form, of every individual case where non-formulary medication is used.

MM.24.4 There is clear documentation, on a special request form, of every individual case where a formulary medication is used for unapproved indication or investigation.

MM.24.5 The department head approves every single case where non-formulary medication is used or where a formulary medication is used for unapproved indication or investigation.

MM.24.6 The pharmacy and therapeutics committee reviews and monitors all cases of using non-formulary medication and all cases of using formulary medication for unapproved indication or investigation.

Standard Intent:

Since not all medications could be made available on the shelf all the time, a limited formulary list is defined by each hospital. When a clinical need arises to obtain a non-formulary drug, a process must be in place to prescribe and obtain the required medication in a reasonable time. Proper documentation and justification of drug request must be maintained on file and regularly reviewed by the pharmacy and therapeutics committee.

Whenever standard therapeutic modalities are tried and failed or when there is no established treatment for a medical illness, the need may arise to try an investigational agent or an approved formulary drug for un-approved indication (Off-label). The ethics committee as well as the pharmacy and therapeutics committee could allow such practice by developing policies and procedures. Clear justification of drug need, dose, duration, and route of administration, therapeutic and toxic monitoring parameters must be clearly documented and approved by the prescriber and department head. Approval of such treatment must be limited to one individual patient at a time. Close monitoring and outcome reporting must be made by the treating physician to the concerned committees.

MM.25 The hospital has a system for reviewing the appropriateness of medication orders before medication is dispensed.

MM.25.1 The hospital maintains an updated and complete medication profile (electronic or paper record) for each patient in the pharmaceutical care department.

MM.25.2 A trained pharmacist reviews all medication orders or prescriptions before dispensing (except in emergencies, lifesaving situations, or diagnostic imaging where the prescriber is physically present).

MM.25.3 All medication orders are reviewed for:

MM.25.3.1 Patient's allergies or sensitivities.

MM.25.3.2 Approved indications for use.

MM.25.3.3 Therapeutic duplications.

MM.25.3.4 Existing or potential interactions (drug-drug and drug-food interactions).

MM.25.3.5 Appropriateness of the medication dose, frequency, and route of administration.

MM.25.3.6 Contraindications.

MM.25.4 All issues, concerns, or questions regarding medication order or prescription are clarified with the prescriber and documented before medication dispensing.

Standard Intent:

Patients are prescribed different medications at different times during their hospital stay. Maintaining and updating the drug profile allows pharmacy to monitor for drug allergy, indications, dosing, and route of administration, therapeutic duplication, drug interactions, adverse drug reactions and contraindications.

Allergy to prescribed medication constitutes a major patient safety issue. It is the responsibility of admitting physician to take drug history for any known allergies and communicate it in writing to the pharmacy. Pharmacy should not dispense any

medication without knowing and documenting drug allergy in the patient drug profile. The pharmacy is authorized to stop dispensing any medication the patient is allergic to until clarification is made with the prescriber. A qualified and licensed pharmacist reviews each prescription or order new to the patient for appropriateness except in emergency situations. This occurs prior to dispensing by a pharmacist or a technician. When questions arise, the individual who prescribed or ordered the medication is contacted for verification. Any changes in medication order shall be documented in patient's medical record. To prevent dispensing errors, dispensed medicine must be double checked by another pharmacist before leaving the pharmacy. As authorized by the pharmacy and therapeutics committee, the pharmacist is allowed to dispense generic substitution without consulting the prescriber unless the prescriber specifies "dispense as written".

MM.26 The hospital has a system for safe preparation of sterile compounded preparations.

MM.26.1 The hospital has a manual for proper aseptic technique and intravenous admixture (e.g., the guidelines of the Saudi Food and Drug Authority, the American Society of Health-System Pharmacists, United States Pharmacopoeia USP).

MM.26.2 Sterile compounded preparations are performed by the pharmaceutical care except during emergency or urgency situations in which a delay could harm the patient or when product stability is short.

MM.26.3 Sterile compounded preparations are performed in the clean room by pharmaceutical care staff, qualified in intravenous admixture and aseptic technique.

MM.26.4 The hospital provides and documents training and competency assessment of non-pharmaceutical care staff involved in compounding sterile preparations outside the pharmaceutical care department during emergency or urgency situations.

MM.26.5 There is full compliance with aseptic technique in all medication preparation areas all over the hospital.

MM.26.6 Visual inspection is performed for all compounded sterile products by a trained individual for particulate, discoloration, or evidence of loss of integrity.

MM.26.7 The pharmaceutical care has a clean room that is a functionally separate facility to maintain product sterility.

MM.26.8 The design of the clean room is guided by the professional organizations' standards (e.g., the American Society of Health-System Pharmacists, United States Pharmacopoeia USP).

MM.26.9 The pharmaceutical care uses ISO Class 5 laminar airflow hood for preparing sterile injectable preparations and all other sterile preparations.

MM.26.10 The laminar airflow hood is tested at least every six months and in accordance with the manufacturer's requirements, the Saudi Food and Drug Authority guidelines and the professional organizations' standards (e.g., American Society of Health-System Pharmacists, United States Pharmacopoeia USP).

MM.26.11 The hospital implements the written and approved guidelines on intravenous drug stability and compatibility.

MM.26.12 Any sterile preparation compounded outside the clean room (e.g., in the patient care area during emergency or urgency situation) is done in an appropriate environment (location, space, cleanliness, traffic, etc.) to prevent contamination.

MM.26.13 The pharmaceutical care regularly (at least once a month) inspects all areas where sterile preparations are compounded outside the pharmaceutical care clean room.

MM.26.14 The pharmaceutical care monitors the performance and qualifications of non-pharmacists permitted to prepare sterile compounded medications outside the pharmaceutical care department.

MM.26.15 There are written guidelines for safe recycling of returned (un-used) sterile preparations.

Standard Intent:

Parenteral medications account for >40% of all medications administered in institutional practice. The intravenous route is the most dangerous route of administration since all natural barriers are bypassed when the drug is given directly into the vein, so the administration of a contaminated solution can have very serious consequences. Contamination occurs when proper control over manipulation is not maintained. Contaminations may be introduced from the environment, equipment, supplies, and personnel, it is essential to control all these different sources at the time aseptic technique is carried out. Giving a patient a contaminated product can cause serious adverse effects including death.

The compounding of medications is a fundamental part of pharmacy practice. Qualified pharmacists and pharmacy technicians are responsible for compounding and dispensing sterile preparations of correct ingredient identity, purity, strength, stability and compatibility, and sterility and for dispensing them in appropriate containers that are labeled accurately and appropriately for the end user. The safety of intravenous admixture product depends on the skills of the operator, compliance with aseptic techniques, and IV room cleanliness. The pharmacy should have updated and reliable information resources for drug stability and compatibilities and establish guidelines for recycling of returned (un-used) sterile drugs.

Clean room design, equipment and cleanliness are pre-requisite for aseptic technique. Proper selection and maintenance of equipment prevent any break-through aseptic procedure. The pharmacy regularly monitors the performance of laminar airflow hood (LAFH) and maintains updated certification. Chemotherapy admixture area is completely separated from regular IV area.

It is the responsibility of pharmacy director to closely monitor nurses' performance, dispensing environment where sterile preparations are compounded outside the clean room (e.g., in the patient care area during emergency or urgency situation), and confirm compliance with given guidelines.

MM.27 The hospital has a system for safe preparation of parenteral nutrition products.

MM.27.1 There is a multidisciplinary policy and procedure on preparation and dispensing of parenteral nutrition products.

MM.27.2 All parenteral nutrition products are compounded in the pharmaceutical care clean room under the laminar air flow hood.

MM.27.3 The hospital permits only pharmaceutical care staff qualified in aseptic technique and parenteral nutrition to prepare parenteral nutrition products.

MM.27.4 Aseptic technique is strictly followed by all staff in the parenteral nutrition compounding area.

MM.27.5 Double check policy is implemented at each stage of compounding and visual inspection of the final parenteral nutrition product.

MM.27.6 All essential macro-and micro-nutrients of parenteral nutrition are available.

MM.27.7 Appropriate membrane filters are available for the different types of parenteral nutrition and different patient-age groups.

MM.27.8 The hospital implements the written and approved guidelines on stability and compatibility of parenteral nutrition products.

MM.27.9 When parenteral nutrition products are compounded by an outside vendor, the pharmaceutical care team maintains a copy of the contract and ensures the compliance of the vendor with quality and safety standards. Contract monitoring is conducted at least annually with corrective actions accordingly.

Standard Intent:

Parenteral nutrition formulations are extremely complex admixtures containing 40 or more components including amino acids, dextrose, fat emulsions, water, electrolytes, trace elements, multivitamins, and others. Serious harm and death have been reported secondary to administration of improperly prepared, and/or contaminated parenteral nutrition formulations. Compounding of such formulation should be performed by qualified staff using aseptic technique in clean room environment with close

monitoring of compliance with national and international practice guidelines. Inclusion of in-line membrane filter of appropriate pore size is very crucial for retaining viable, non-viable particles and toxins.

When the hospital is outsourcing total parenteral nutrition formulations from an outside vendor, the pharmacy team should have copy of the valid contract. In order to ensure compliance of the vendor with CBAHI quality and safety standards, contract monitoring should be conducted at least annually with corrective actions accordingly. CBAHI contract monitoring form for total parenteral nutrition formulations must be used.

MM.28 The hospital has a system for safe preparation of sterile chemotherapy compounded preparations.

MM.28.1 There is a multidisciplinary policy and procedure on preparation and handling of sterile compounded chemotherapy preparations.

MM.28.2 The chemotherapy compounding services is operated and managed by the pharmaceutical care.

MM.28.3 The hospital permits only pharmaceutical care staff qualified in chemotherapy compounding to work in the chemotherapy compounding area.

MM.28.4 Aseptic technique is strictly followed by all staff in the chemotherapy compounding area.

MM.28.5 Visual inspection is performed for all compounded sterile chemotherapy preparations by a trained pharmacist for particulate, discoloration or evidence of loss of integrity.

MM.28.6 The chemotherapy compounding area is physically and functionally separate area to maintain product sterility and prevent cross contamination.

MM.28.7 The design of the chemotherapy compounding area is guided by the professional organizations' standards (e.g., the American Society of Health-System Pharmacists, United States Pharmacopoeia USP).

MM.28.8 The pharmaceutical care uses ISO Class 5 biological safety cabinet with 100% exhaust air outside the building (class II B vertical laminar airflow hood) for preparing chemotherapy.

MM.28.9 The biological safety cabinet is tested at least every six months and in accordance with the manufacturer requirements. the Saudi Food and Drug Authority guidelines, and the professional organizations' standards such as the American Society of Health-System Pharmacists (ASHP) and United States Pharmacopoeia (USP).

MM.28.10 The hospital implements written and approved guidelines on chemotherapy drug stability and compatibility.

MM.28.11 The hospital uses chemotherapy ziploc plastic bags to prevent accidental spills during transportation and storage of compounded chemotherapy preparations.

MM.28.12 Special chemotherapy protective materials such as gloves, gowns, and masks are adequately available and consistently used.

MM.28.13 Chemotherapy spill kits are available in all areas where chemotherapy agents are stored, prepared, dispensed, and/or administered.

MM.28.14 Relevant staff are trained on the proper handling of chemotherapy spills.

MM.28.15 Trash plastic bags for collection and disposal of contaminated materials and articles used for preparation, dispensing and/or administration of chemotherapy are as guided by the Saudi Food and Drug Authority (SFDA) and the international organizations standards such as Occupational Safety & Health Administration (OSHA).

MM.28.16 When chemotherapy products are compounded by an outside vendor, the pharmaceutical care team maintains a copy of the contract and ensures compliance of the vendor with quality and safety standards. Contract monitoring is conducted at least annually with corrective actions accordingly.

Standard Intent:

Many hazardous drugs are designed for parenteral administration, requiring aseptic reconstitution or dilution to yield a final sterile preparation. As such, the compounding of these products is regulated as pharmaceutical compounding by the United States Pharmacopeia (USP), chapter 797 which becomes chapter 800 in late 2015. The intent of the chapter is to ensure the safety of personnel involved according to OSHA guidelines and protect patients from improperly compounded sterile preparations by regulating facilities, equipment, and work practices to ensure the sterility of extemporaneously compounded sterile preparations. Due to the high-risk involved in the handling of chemotherapy, a highly qualified and trained pharmacists in addition to proper design and close monitoring of chemotherapy admixture area are required to reduces the risk of environmental contamination as well as operator risk.

When the hospital is outsourcing chemotherapy formulations from an outside vendor, the pharmacy team should have copy of the valid contract. In order to ensure compliance of the vendor with CBAHI quality and safety standards, contract monitoring should be conducted at least annually with corrective actions accordingly. CBAHI contract monitoring form for chemotherapy formulations must be used.

MM.29 The hospital has a system for safe preparation of non-sterile compounded preparations (extemporaneous compounds).

MM.29.1 There is a multidisciplinary policy and procedure on non-sterile compounding of oral and topical preparations not readily available from manufacturers.

MM.29.2 The pharmaceutical care has proper facilities for non-sterile compounding that include clean work bench with smooth surface, stainless steel sink with water supply, and storage cabinets.

MM.29.3 The pharmaceutical care has essential equipment and glass wares that include sensitive balance, electric heater, mortar and pestle, beakers, flasks, and measuring cylinders.

MM.29.4 The pharmaceutical care has a preparation manual (formulation book) that is properly referenced.

MM.29.5 A log book is maintained for preparation name, strength, prepared quantity, batch number, preparation date and expiration date, prepared by and checked by.

MM.29.6 When non-sterile compounded preparations are compounded by an outside vendor, the pharmaceutical care team maintains a copy of the contract and ensures compliance of the vendor with quality and safety standards. Contract monitoring is conducted at least annually with corrective actions accordingly.

Standard Intent:

Not all pharmaceuticals are readily available from the manufacturer. It is the responsibility of pharmacy to provide a safe pharmaceutical product. Pharmacists are the only health care providers formally trained in the art and science of compounding medications. Therefore, pharmacists are expected, by the medical community and the public, to possess the knowledge and skills necessary to compound extemporaneous preparations. Pharmacists have a responsibility to provide compounding services for patients with unique drug product needs (such as unusual strength or concentration for the very young, the very old, unconscious or those who can’t swallow tablet or capsule). A well-equipped pharmaceutical laboratory must include necessary equipment, glass wares, chemicals, sink, work bench, etc. Formulation manual, work sheet, and log book are maintained for all compounded preparations. An internal batch number should be created and printed on the final product label.

When the hospital is outsourcing extemporaneous preparations from an outside vendor, the pharmacy team should have copy of the valid contract. In order to ensure compliance of the vendor with CBAHI quality and safety standards, contract monitoring should be conducted at least annually with corrective actions accordingly. CBAHI contract monitoring form for extemporaneous preparations must be used.

MM.30 The pharmaceutical care enforces the hospital guidelines for infection prevention and control.

MM.30.1 All areas where medications are stored, compounded, prepared, dispensed, and /or administered are clean, neat and well organized.

MM.30.2 The pharmaceutical care has a separate housekeeping materials dedicated for the clean room.

MM.30.3 A sink, antiseptic soap, and/or antiseptic hand rub are available in the pharmaceutical care department and all other areas where medications are stored, compounded, prepared, dispensed, and /or administered.

MM.30.5 Pharmaceutical care staff observe the hospital approved standard precautions and understand the hospital's isolation policy and procedure to reduce the risk of transmission of infection.

MM.30.6 Food, drinks, or smoking are not allowed in the pharmaceutical care department and all other areas where medications are stored, compounded, prepared, dispensed, and /or administered.

MM.30.7 Laminar air flow hood certification for operational efficiency and maintenance such as checking, cleaning and/or replacing filter are performed regularly and according to the manufacturer's specifications.

MM.30.8 The pharmaceutical care has a schedule for proper cleaning of laminar air flow hood work surface.

MM.30.4 Hand washing technique, and antiseptic soap are in accordance with the hospital's policy and procedures.

Standard Intent:

For infection prevention and control program to be effective, it must be comprehensive involving both patient care and employee health. Pharmacy identifies procedures and processes associated with the risk of infection and implement strategies to reduce infection risk. This includes equipment used in drug transfer and compounding (such as laminar airflow hoods, TPN compounders, repeater pump), pre-packing and/or dispensing, disposal of sharps and needles. Hand washing, gloves, masks, soap, and disinfecting agents are fundamental to infection prevention and control. Staff education and training are crucial to ensure compliance with guidelines.

MM.31 The hospital has a system for safe dispensing of medications.

MM.31.1 The hospital has a uniform system for dispensing and distribution of medications.

MM.31.2 The hospital dispenses medications in the most ready-to-administer form possible (such as repackaged unit-doses) to minimize chance of error during distribution or administration.

MM.31.3 The hospital dispenses quantities of medications consistent with patient needs.

MM.31.4 The hospital dispenses no more than twenty-four hours supply of medications for inpatient at a time except for bulk oral liquids and topical preparations.

MM.31.5 The hospital dispenses medications with time frames defined by the hospital (such as STAT, now, routine).

MM.31.6 The hospital maintains records for all dispensed medications.

MM.31.7 There is implementation of the independent double check during preparation and before dispensing of all high-alert medications.

Standard Intent:

To improve drug safety and minimize opportunities for medication errors, work environment must represent the most comfortable zone for professional service. Documentation of each step in dispensing medication is crucial in identifying what went wrong and how to be fixed. 24 hours supply of unit-dose medication ensures that the right medication in the right dose has been delivered to the right patient. Close monitoring via daily review of patient drug profile and medication administration record guarantee compliance with therapeutic regimen of the treating physician. In order to prevent dispensing errors, pharmacist must dispense medications against physician order and independent double checking before dispensing is necessary for high alert medication. New order, reorder, change order or cancellation of order must be communicated to pharmacy. Orders transcribed by nurses are not acceptable except for verbal/telephone orders.

To meet the urgent needs for medications, the Pharmacy director should develop a mechanism to ensure that Stat orders are easily identified and medications dispensed to patient care area within 30 minutes. Patients are prescribed different medications at different times during their hospital stay. Maintaining and updating the drug profile allows pharmacy to monitor for drug allergy, indications, dosing, therapeutic duplication, drug interactions and adverse drug reactions.

MM.32 The hospital has a system for labeling medications.

MM.32.1 Medications prepared but not intended for immediate administration are labeled. This includes all injectable medications drawn into syringes or mixed with intravenous fluids for use inside the operating rooms or procedure areas.

MM.32.2 Multiple medications for a single patient, such as those in the operating room or emergency room, must be labeled for drug name and dose/concentration.

MM.32.3 All individualized medications prepared for multiple patients are labeled with all necessary information in a standardized format.

MM.32.4 All individualized medications prepared for multiple patients are labeled with:

MM.32.4.1 Patient name and medical record number.

MM.32.4.2 Patient location (ward, unit, room, bed number).

MM.32.4.3 Medication name, dosage form, strength, and amount.

MM.32.4.4 Directions for use.

MM.32.4.5 Relevant cautionary instructions (e.g., refrigerate, shake before use, may cause drowsiness).

MM.32.4.6 Date of preparation, beyond use date, and time (when beyond use date occurs in less than twenty-four hours).

MM.32.5 All compounded intravenous admixture preparations are labeled with diluent name concentration, and its volume.

MM.32.6 All compounded parenteral nutrition solutions are labeled with individual components quantities, and total volume.

MM.32.7 All outpatient medications are labeled with patient name, medical record number, medication name, dosage form, strength, direction and duration for use, and cautions in a language and form the patient can understand.

Standard Intent:

Proper identification of patient's medication is very crucial for patient safety. Drug labeling for ambulatory patients must be in a language understood by the patient. Patient identity, drug identity, directions and instructions for proper use, duration, and storage condition must be made clearly on the label. Necessity for auxiliary instructions should always be entertained to ensure proper drug storage and/or administration. Safety precautions must be taken to avoid mixing and inadvertent dispensing of wrong drug to patients. Physical separation and clear labeling of different categories and formulations serve as safeguard. Unit-dose packaging is aimed at preserving the identity of medicine in a single unit, free from contamination until the time of administration at bedside. Unused unit-doses could be returned to pharmacy for recycling. Studies have shown that proper labeling of unit-dose guarantee drug and patient safety.

To avoid mixing up of medications, all inpatient drug cassettes must be properly labeled with patient name, medical record number and bed number. Colored auxiliary labels are meant to stick out and warn user of particular precautions before drug administration. Final IV admixtures are properly labeled with drug identity, dosing, concentration, diluent type and volume, administration rate, time of preparation and expiration. Medications prepared but not intended for immediate administration must

be labeled. This includes all injectable medications drawn into syringes or mixed with intravenous fluids for use inside the operating rooms or procedure areas.

MM.33 The hospital has a system for obtaining medications when the pharmacy is closed.

MM.33.1 There is a multidisciplinary policy and procedure on obtaining medications when the pharmacy is closed.

MM.33.2 The hospital permits only trained registered nurses and those authorized to prescribe medications to access pharmacy after working hours.

MM.33.3 The hospital has a limited list of approved medications to be accessible to non-pharmaceutical care staff when the pharmacy is closed.

MM.33.4 A qualified on-call pharmacist is available to answer questions and provide medications other than those accessible to non-pharmacists

Standard Intent:

Continuity of patient care requires the availability of drugs within reasonable time and 24-hours daily. Most pharmacies are providing 24-hour services through inpatient pharmacy. Drug supply for emergency room patients could be met via establishing emergency room pharmacy working 24hours daily or serving through inpatient pharmacy after closure of outpatient pharmacy. Whenever pharmacist is not physically available on site, an on-call service must be established and announced to customers.

Pharmacy is a secure area and access is limited to working staff. Access to pharmacy by non-pharmacy staff after working hour may be allowed in some hospital but it should be very limited to a pre-defined list of medications that may be needed to serve patients. A night cabinet containing such medications have been tried in hospitals. Non-pharmacy staff allowed to access these medications should be known to the pharmacy director.

MM.34 The hospital has a system for handling recalled, discontinued, and damaged medications.

MM.34.1 There is a multidisciplinary policy and procedure on retrieval and handling of recalled, discontinued, and damaged medications within specified time frame for patient safety.

MM.34.2 The hospital recognizes and maintains on file all drug recall memorandums from the Saudi Food and Drug Administration, manufacturer, and/ or other relevant legal bodies.

MM.34.3 The hospital notifies prescribers and individuals involved in prescribing, dispensing and administration of recalled, damaged, and discontinued medications.

MM.34.4 The hospital informs patients that their medication has been recalled or discontinued for safety reasons.

MM.34.5 The hospital complies with handling recalled, discontinued, and damaged medications guidelines.

Standard Intent:

Recalled, discontinued and damaged medications constitute patient safety risk. Hospitals should have a process for identifying, retrieving, and returning or destroying these medications. Medications may be recalled by the manufacturer, local supplier, ministry of health (MOH), or Saudi FDA. It is the responsibility of the pharmacy director to ensure that recalled, discontinued, and damaged medications are not available for dispensing in the pharmacy or any patient care area and the treating physician should always be informed. All related records and memorandums should be maintained. In case recalled medication is dispensed to outpatients, hospitals must have a mechanism to contact and retrieve the recalled medication.

MM.35 The pharmaceutical care department has a system for provision of outpatient education and counseling.

MM.35.1 The pharmaceutical care department has a system for provision of outpatient education and counseling that includes verbal explanation and instructions by a pharmacist to patients and their families on the safe and effective use, administration, and storage condition of medications.

MM.35.2 Written educational information is given in a language and form the patient can understand.

MM.35.3 Patient privacy is maintained during education and counseling.

Standard Intent:

Lack of sufficient knowledge about their health problems and medications is one cause of patients' nonadherence to their therapeutic regimens and monitoring plans. Without adequate knowledge, patients cannot be effective partners in managing their own care. Providing pharmaceutical care entails accepting responsibility for patients' therapeutic outcomes. Pharmacists can contribute to positive outcomes by educating and counseling patients to prepare and motivate them to follow their therapeutic regimens and monitoring plans.

Pharmacists should encourage patients to seek education and counseling and should eliminate barriers to providing it. Patient education and counseling usually occur at the time prescriptions are dispensed. The techniques and the content should be adjusted to meet the specific needs of the patient. Drug counseling must be offered to all patients before going home. This includes all patients seen in the outpatient clinics and emergency room. Patient and family education includes drug indication, dosing,

administration, side effects, proper storage condition, etc. either verbally or utilizing supporting written educational materials. To respect patient rights; patient counseling must be provided in as private environment as possible.

MM.36 The hospital has a safe system for drug administration.

MM.36.1 The hospital defines nurses and other clinical staff authorized to administer medications with or without supervision.

MM.36.2 Qualifications, experiences, and competency assessments of individuals involved in drug administration are available in their personnel files.

MM.36.3 The hospital guidelines for safe administration of intravenous push medications are available, disseminated and implemented in all patient care units. The guidelines include medication name, infusion time, nurse qualification and patient care unit.

MM.36.4 The hospital has approved, disseminated, and implemented guidelines on standard drug administration time.

MM.36.5 The hospital maintains accurate records of the disposal of the unused portion of narcotic drugs and controlled substances.

MM.36.6 The hospital maintains updated and accurate records of drug administration.

MM.36.7 Independent double check of all high alert medications is performed.

MM.36.8 The hospital adopts safe administration and disposal of chemotherapy.

Standard Intent:

Nurses often serve as the final point in the checks-and-balances triad (physicians and other prescribers, pharmacists, and nurses) for the medication use process. Nurses who practice in hospital settings should be familiar with standard medication administration times. Standard drug administration times should be established for the hospital by the P&T committee (or its equivalent). All doses should be administered at scheduled times unless there are questions or problems to be resolved. Medication doses should not be removed from packaging or labeling until immediately before administration. The administration of medication should be documented (in the medication administration record, MAR) as soon as it is completed. Only authorized nurses with the appropriate qualification, experience, and competencies are allowed to administer medications. Special skills and competencies for nursing staff are required for administration of IV push medications, narcotics and controlled medications, chemotherapy and other high alert medications.

MM.37 The hospital has a system to review and verify medications before administration.

MM.37.1 The hospital implements a multidisciplinary policy and procedure on proper verification of dispensed medications before administration (right patient, right medicine, right dose, right frequency, right route, and right time).

MM.37.2 Medications are verified against the medication administration record (MAR) before administration.

MM.37.3 Medications are administered in the prescribed dose and by the correct route.

MM.37.4 Medications are administered at the correct time (the approved hospital standard administration time).

MM.37.5 Medications are administered after verifying the expiry date.

MM.37.6 Medications are administered after visual inspection for discoloration, particulate, or other clues of loss of integrity or instability.

MM.37.7 Medications are administered after verifying that there are no contraindications.

Standard Intent:

All drug orders should be verified before medication administration. Nurses should carefully review original medication orders before administration of the first dose and compare them with medications dispensed. Transcriptions of orders should be avoided to the extent possible and should be recognized as prime opportunities for errors. Doses should not be administered unless the meaning of the original order is clear and unambiguous and there are no questions with respect to the correctness of the prescribed regimen. Nurses should check the drug identity, dose, route, and integrity (e.g., expiration date and general appearance) of the medications dispensed before administering them. When there are discrepancies, the nurse should contact the pharmacy department and determine the appropriate action. Patient identity should be verified before the administration of each prescribed dose. Nurses should make sure that there are no contraindications before administering the prescribed medication.

MM.38 The hospital has a safe system for self-administration of medications.

MM.38.1 The hospital educates patients and families involved in self-administration of medications about:

MM.38.1.1 Medication name, type, and indication.

MM.38.1.2 Time, frequency, route, and dose of medication.

MM.38.1.3 Expected medication effect and potential side effects.

MM.38.1.4 Monitoring and reporting of medication effects.

MM.38.2 The hospital does not allow administration of any medication brought from outside the hospital unless prescribed by the treating physician.

MM.38.3 The hospital does not allow administration of free medical samples.

Standard Intent:

Some hospitals have developed patient self-administration program as an alternative medication administration method for selected patients. The self-administration of medication by patients in the hospital offers many advantages. It allows patients to assume more responsibility for their direct care, to learn how to use medication

properly, and to be able to anticipate potential side effects and other medication-related problems. Healthcare providers must educate patients and families on the safe and proper use of medications. Patients should be encouraged and taught how to report medication errors and near misses that occur as a result of self-administration.

Hospital that allow a patient to self-administer specific medications must have policies and procedures in place that address several issues. One of these issues is assessment of the patient's capacity to self-administer the medications. Patients with stable medication regimens, receiving chronic medications, and good physical and mental health are appropriate candidates for self-administration. Another issue is the security of those medications. Yet another issue is documentation in the medical record of each instance of medication administration by the patient. Nursing should make round to ensure that patients are using their medication appropriately.

Free medical samples of newly manufactured pharmaceuticals are designed for advertisement and not meant for clinical use therefore, free medical samples should not be used in hospitals.

MM.39 The hospital has a system to monitor the patient response to medications.

MM.39.1 There is a multidisciplinary policy and procedure on monitoring the patient response to medications.

MM.39.2 There is an annually updated list of all formulary medications that cause changes in the patient's equilibrium and may raise the risk of falls.

MM.39.3 The hospital has a collaborative process, involving physicians, nurses, and pharmacists, to monitor the patient's response to medications.

MM.39.4 Monitoring includes the following:

MM.39.4.1 The medication's effect on patient's clinical condition, as well as blood count, liver and renal functions and other relevant therapeutic monitoring parameters.

MM.39.4.2 The patient's perception of side effects to the first dose of a new medication.

MM.39.4.3 Unanticipated drug-drug interactions.

MM.39.4.4 Changes in the patient's equilibrium that may raise the risk of falls

MM.39.4.5 Allergic reactions including documentation and flagging of medical records.

Standard Intent:

Monitoring activities are primarily the responsibility of the physician. However, observation and reporting are required from the person who administered the

medication (usually the nurse) and from other members of the healthcare team involved in the patient's therapy. In some settings, a clinical pharmacist monitors medication therapy in the hospital and consults on medication therapy that requires special expertise to ensure safety and efficacy, for example total parenteral nutrition, anticoagulation, or treatment with aminoglycosides antibiotics. Monitoring prescribed medication starts from the moment prescription is received in the pharmacy. A qualified and trained pharmacist evaluates and monitors for drug indications, correct route of administration, administration time, and report drugs that may affect patient equilibrium and increase the risk of fall. Significant drug-drug and drug-food interactions are immediately reported to the treating physician and corrective measures are done accordingly.

When appropriate, the patient should be observed by the nurse after administration of the drug product to ensure that the doses were administered as prescribed and have the intended effect and observe if any adverse reactions occurred. Allergy to prescribed medication constitutes a major patient safety issue. It is the responsibility of admitting physician to take drug history for any known allergies and communicate it in writing to the pharmacy. Pharmacy should not dispense any medication without knowing and documenting drug allergy in the patient drug profile. The pharmacy is authorized to stop dispensing any medication the patient is allergic to until clarification is made with the prescriber.

MM.40 The hospital has a process for detecting, managing and reporting adverse drug reactions (ADRs).

MM.40.1 The hospital has a multidisciplinary policy and procedure on handling Adverse Drug Reaction (ADR) reports.

MM.40.2 The policy has a clear definition of ADR and its severity.

MM.40.3 The treating physician is notified at the appropriate time.

MM.40.4 The patient affected by ADR receives appropriate care at the appropriate time.

MM.40.5 The ADR report forms are readily available and in use.

MM.40.6 All ADRs are documented in the patient's medical record.

MM.40.7 The hospital conducts analysis of all significant and serious ADRs.

MM.40.8 The hospital has a system for improving ADR reporting.

MM.40.9 The hospital reports all serious or unexpected ADRs to the Saudi Food and Drug Authority.

Standard Intent:

Adverse drug reaction (ADR) is a response to a drug which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis or

therapy of disease, or for the modification of physiological function. An unexpected adverse reaction refers to a reaction, the nature or severity of which is not consistent with domestic labelling or market authorization, or expected from characteristics of the drug. A serious adverse reaction is any medical occurrence that at any dose normally used in humans: results in death, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, or is life-threatening.

All new medicines undergo a significant amount of testing and evaluation before marketing to ensure the product is not only effective, but also safe. There are no drugs that are free of side-effects or adverse reactions. One large meta-analysis estimated that ADRs cause 3–4% of all hospital admissions in the USA. Adverse drug reactions may be due to the unknown effects of new (or older) drugs, unknown drug combinations and interactions, or poor drug quality.

Monitoring medication effects includes observing and documenting any adverse effects. The healthcare institution established a mechanism for documenting in patient's medical record, reporting adverse events and the time frame for reporting. Hospitals are responsible for ensuring that patients are treated as safely as possible. Prevention of ADRs is possible, and indeed necessary. Studies have shown that over 50% of adverse drug reactions may be preventable. Most ADRs are related to the prescribing of an incorrect dose or the administration of a drug to a patient with a known allergy. Many ADRs could be avoided if the relevant health worker asked specific questions before prescribing and/or dispensing a drug. Pharmacy and therapeutics committee regularly review reported ADR reports and inform professional staff of the incidence and impact of ADRs.

MM.41 The hospital has a process for monitoring, identifying, and reporting significant medication errors, including near misses, hazardous conditions, and at-risk behaviors that have the potential to cause patient harm.

MM.41.1 There is a multidisciplinary policy and procedure on handling medication errors, near misses, and hazardous situations (e.g., confusion over look-alike/sound-alike drugs or similar packaging).

MM.41.2 The policy has a clear and acceptable definition of significant medication error, near misses, and hazardous situations.

MM.41.3 The treating physician is notified of the medication error at the appropriate time.

MM.41.4 Medication error reporting is completed within the specified time frame after discovery of the error.

MM.41.5 The hospital has a standard format for reporting medication errors.

MM.41.6 Staff are educated on the process and importance of medication error reporting.

MM.41.7 There is active reporting of medication errors, near misses, and hazardous situations.

MM.41.8 The hospital conducts intensive root-cause analysis for all significant or potentially significant medication errors.

MM.41.9 Medication errors, near misses, and hazardous situations are documented in the patient's medical record.

MM.41.10 The hospital utilizes reported data to improve the medication use process, prevent medication errors, and improve patient safety.

MM.41.11 Healthcare professionals are provided with feedback on reported medication errors, near misses, and hazardous situations.

MM.41.12 The hospital reports sentinel events related to serious medication errors to the relevant authorities.

Standard Intent:

In its 1999 landmark paper, "To Err is Human," the U.S. Institute of Medicine stressed the fact that medical errors are the eighth most frequent cause of death in the United States, more frequent than car accidents, breast cancer, or AIDS. On average, every hospital patient is probably subjected to at least one medication error every day. Fortunately, many of these errors do not cause harm. Regardless of numbers, medication errors are common and that they can happen to all of us. We all—from patients to providers to policymakers—need to take this issue more seriously so that we can make medication use as safe as we would like it to be and as safe as it deserves to be. Also, medication errors compromise patient confidence in the health-care system and increase health-care costs. Risk managers are taking a more proactive approach to preventing medication incidents in hospitals.

Medication errors may be committed by both experienced and inexperienced staff. The outcome(s) or clinical significance of many medication errors may be minimal, with few or no consequences that adversely affect a patient. Tragically, however, some medication errors result in serious patient morbidity or mortality. Determination of the causes of medication errors should be coupled with assessment of the severity of the error. Medication error reporting has been shown to improve medication-use systems and aid in conducting a cause analysis of a medication error.

The fundamental purpose of medication error reporting system is to learn how to improve the medication use and prevent errors recurrence. Reporting of medication errors must become culturally accepted throughout health care. A major investment of resources will be required in the health care system to apply the lessons derived from the reporting of medication errors. Medication error reporting system should include near misses, hazardous conditions, and at-risk behaviors.

Laboratory Standard Intents

LB.1 Laboratory services are available to meet patient needs and are in accordance with applicable national standards.

LB.1.1 The laboratory has a clearly defined scope of services.

LB.1.2 The laboratory services are in compliance with applicable national standards.

LB.1.3 Basic laboratory services (e.g., hematology, blood bank and biochemistry) are available twenty-four hours a day, seven days a week.

LB.1.4 When laboratory services are provided through a contract, the hospital provides oversight and management of the contract through the process described in the "Leadership" chapter in this manual.

LB.1.5 The laboratory has a defined organizational chart that displays key positions including the laboratory director, sections' heads and supervisors, quality management officer, facility and safety officer, and, as applicable, infection control officer, point of care testing coordinator, and training and education coordinator.

Standard Intent:

Developing and maintaining current scope of services that meets the needs of patient population, clients, and customers is a sign of commitment to quality and professional practice. The laboratory scope of services should be clearly defined in writing, easily accessible to all staff, as well as internal and external customers.

LB.2 The laboratory has adequate and functional space and facilities that maintain safe and proper working conditions.

LB.2.1 There is a space allocated for the laboratory which provides:

- LB.2.1.1 Proper location and design.
- LB.2.1.2 Adequate patient and donor waiting areas and lavatories.
- LB.2.1.3 Adequate area for each laboratory activity/section.
- LB.2.1.4 Proper, safe, and adequate storage space for reagents, supplies, consumables, samples, records, paraffin blocks, and glass slides.
- LB.2.1.5 Adequate area for administrative and clerical staff.

LB.2.2 The laboratory management ensures the availability of the following facilities:

- LB.2.2.1 Adequate water taps and sinks.
- LB.2.2.2 Adequate electrical outlets and emergency power.
- LB.2.2.3 Adequate temperature and humidity control.
- LB.2.2.4 Adequate ventilation.
- LB.2.2.5 Adequate lighting.
- LB.2.2.6 Adequate emergency exits, access control, and all ways are not obstructed.

LB.2.2.7 Adequate safety signs.

LB.2.2.8 Clean and well maintained floors, walls, ceilings, bench tops, and sinks.

LB.2.2.9 Conveniently located telephones.

LB.2.3 Personnel safety, quality of work, patient care, and donor care are not compromised by the allocated laboratory space.

Standard Intent:

Deficiencies in lab space and design are regarded as minor unless they are so severe as to interfere with the quality of work or safety, in which case they become a major issue.

LB.3 The laboratory services are carried out by qualified staff.

LB.3.1 The laboratory services are provided by staff qualified by education, training, and experience.

LB.3.2 The laboratory director, section heads and supervisors are appropriately qualified according to the complexity of laboratory scope of services.

LB.3.2.1 The laboratory director of a high complexity laboratory (laboratories of tertiary care hospitals/referral facilities or laboratories providing anatomical pathology and/or transfusion medicine services) is a licensed/registered anatomical or clinical pathology consultant (board certified or equivalent).

LB.3.2.2 The laboratory director of a moderate or low complexity laboratory (laboratories with no anatomical pathology and transfusion medicine services) is a licensed/registered clinical scientist or laboratory specialist.

LB.3.2.3 The sections' heads/supervisors are qualified (by education, training and experience) in the discipline of their assigned sections.

LB.3.2.4 The laboratory staff participate in relevant hospital committees.

Standard Intent:

The director of the laboratory must be recognized as the main authorized and responsible person for establishing and maintaining all of the quality and operational policies, processes and procedures. The necessary education, training, skills, experience, certifications, and licensure of the director need to be specified and kept current with the applicable national, professional and accreditation requirements. The director of a high complexity laboratory (laboratories of tertiary care hospitals/referral facilities or laboratories providing anatomical pathology and/or transfusion medicine services) must be an MD licensed to practice medicine and either possess qualifications required for board certification in clinical pathology or have at least one-year training or experience in the discipline he/she serves.

LB.4 The laboratory has a system for personnel audit trail.

LB.4.1 The system allows for the identification of who performed a critical task/step.

LB.4.2 The system allows for the identification of when, where, and why the task/step is performed.

Standard Intent:

An audit trail (also called audit log) is a security-relevant chronological record that provides documentary evidence of the sequence of activities that have affected or contributed to a specific outcome. Laboratory records must be complete and all relevant data available, including results, interpretation, dates, and identity of persons performing the work. A personnel audit trail must be maintained for each significant step in the collection, processing, testing, storage, and distribution of blood and blood components.

LB.5 The laboratory has a comprehensive training and competency assessment program.

LB.5.1 The laboratory implements an orientation, training and competency assessment program that ensures:

LB.5.1.1 Satisfactory completion of training program for all lab personnel in their assigned area.

LB.5.1.2 Training on new equipment or method.

LB.5.1.3 Competency assessment of all laboratory personnel before working independently and annually thereafter.

LB.5.1.4 Corrective action plan and reassessment in the event of unsatisfactory performance.

LB.5.1.5 Utilization of the appropriate competency assessment tools, including technique observation for technical competency, assessment of personnel's knowledge about the contents of the procedures and instruments operation manuals (written/verbal exam), and assessment of personnel's problem solving skills (unknown samples).

LB.5.1.6 Laboratory personnel performing tests or tasks requiring color discrimination undergo a color discrimination test.

Standard Intent:

To ensure that skills are maintained, the laboratory should have regularly scheduled competency evaluations of all staff members whose activities affect the quality of laboratory testing, manufacturing of products, or provision of products or services. Depending on the nature of the job duties and when applicable, the following methods of competency assessment must be employed during the pre-operational period of hiring and annually thereafter:

1. Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing,
2. Monitoring the recording and reporting of test results, including, as applicable, reporting critical results,
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records,
4. Direct observation of performance of instrument maintenance and function checks,
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
6. Evaluation of problem-solving skills.

?Analysis of competency assessment data can be very useful in identifying staff learning needs.

LB.6 The laboratory has a system for the receipt of incoming supplies and services, inventory management, and tracking of critical materials.

LB.6.1 The laboratory implements policies and procedures on documenting the receipt, inspection, and testing (as applicable) of incoming critical material or service.

LB.6.2 The laboratory implements policies and procedures on inventory management and tracking the use of critical materials, supplies, and reagents to ensure the following:

LB.6.2.1 Materials are used within their expiration dates.

LB.6.2.2 New reagents lot numbers are tested against old lots or suitable reference materials before use.

LB.6.2.3 Kit components are used within the kit lot number.

LB.6.2.4 Lot number use is traceable to patient/blood donors or inclusive dates of use.

Standard Intent:

Before acceptance and use of critical materials, reagents, supplies or services, they should be inspected and tested (if necessary) to ensure that they meet specifications for their intended use. It is essential that supplies used in the collection, processing, preservation, testing, storage, distribution, transport, and administration of blood, components meet predefined acceptance criteria. Laboratories must develop procedures to control and prevent inadvertent acceptance and use of materials, reagents and services that do not meet specifications. Corrective action may include returning the material to the vendor or destroying it. Receipt and inspection records provide the

facility with means to trace materials that have been used in a particular process and also provide information for ongoing supplier evaluation.

LB.7 The laboratory has reagents and solutions management system.

LB.7.1 The laboratory implements policies and procedures to ensure that prepared/reconstituted reagents and solutions are labeled, as applicable, with:

LB.7.1.1 Content.

LB.7.1.2 Concentration/titer.

LB.7.1.3 Preparation/reconstitution date.

LB.7.1.4 Expiration Date.

LB.7.1.5 Storage requirements.

LB.7.2 Laboratory supplies and reagents are stored under appropriate conditions.

LB.7.2.1 Critical laboratory supplies and reagents are stored according to the manufacturer's recommendations under controlled conditions or in an appropriate storage device.

LB.7.2.2 Critical supplies and reagents storage conditions are continuously monitored using appropriate temperature monitoring/recording system.

LB.7.2.3 In the event of monitoring systems failure, the storage temperature is monitored and recorded every eight hours using a standardized thermometric device.

LB.7.3 The laboratory defines and specifies water types.

LB.7.3.1 There is definition of the specific type of water required for each of its testing procedures.

LB.7.3.2 Water quality is tested at least annually.

Standard Intent:

The labeling requirements may be recorded in a log or on the containers themselves, providing that all containers are identified so as to be traceable to the appropriate data in the log. While useful for inventory management, labeling with "date received" is not routinely required. There is no requirement to routinely label individual containers with "date opened"; however, a new expiration date must be recorded if opening the container changes the expiration date or storage requirement.

The laboratories should develop an inventory management system to ensure maintenance of adequate supplies on-hand to minimize emergency requisitions and shortages of supplies, adequate accessibility to all critical supplies necessary for operations, storage under monitored conditions as specified by the manufacturer, and maintain sufficient records on:

1. Date received
2. Lot number and expiration date
3. Whether or not acceptance criteria were met and if any follow-up
4. Date placed in service or disposition, if not used.

Grades of water defined in the current edition of CLSI Guideline C3-A4 as:

1. Clinical Laboratory Reagent Water (CLRW) suitable for most laboratory procedures.
2. Special Reagent Water (SRW), defined by a laboratory for procedures that need different specifications.
3. Instrument Feed Water, specified by the manufacturers as suitable for use with their instruments.

The CLSI Guidelines provide testing information for microbial content, and resistivity, as well as total organic carbon. It also addresses the use of purchased water, the effects of storing water, and the monitoring of stored water.
The quality (specifications) of the laboratory's water, whether prepared in-house or purchased, must be checked and documented at least annually. The frequency and extent of checking may vary, according to the quality of source water and specific laboratory needs. Corrective action must be documented if water does not meet acceptability criteria.
For commercial instrument-reagent systems, the laboratory must use a specific type of water recommended by the manufacturer. Although routine commercial methods are typically designed to work with laboratory reagent grade water, higher-quality water systems exist and may be required for specific methods or if analytical imprecision or inaccuracy has been traced to the quality of in-lab water.

LB.8 The laboratory has a process describing its role in equipment management.

LB.8.1 The laboratory has a role in the selection of critical laboratory equipment (equipment that must be operated at defined specifications to ensure the quality of the product or service).

LB.8.2 The laboratory has a role in the receipt, installation and identification of critical laboratory equipment.

Standard Intent:

Critical equipment must operate within defined specifications to ensure the quality of blood components, test results and services. Critical equipment may include instruments, measuring devices, and computer systems (hardware and software). Maintaining a list of all critical equipment helps in the control function of scheduling and performing functional and safety checks, calibrations, preventive maintenance, and repair.

Furthermore, equipment list can be used to ensure that all appropriate actions have been performed and recorded.

The process of critical equipment selection should consider the criteria established by the laboratory and (as applicable) the criteria set by the facility. When selecting new equipment, it is important to consider not only the performance of equipment as it will be used in the facility, but also any supplier issues regarding ongoing service and support. The outcome of the selection process should be acquiring a piece of equipment that is affordable, appropriate and effective for the intended purpose. Also, there should be a mechanism to uniquely identify and track all critical equipment. The unique identifier may be the manufacturer's serial number or a unique identification applied by the laboratory or organization-wide identification system.

Upon receipt of critical equipment, the laboratory should develop a written plan for installation, operational, and performance qualifications;

1. Installation according to the manufacturer's specifications.
2. Verification of the equipment's functionality by ensuring that the criteria established by the manufacturer for its intended use are met.
3. Assurance that the equipment performs as expected in the facility's processes.

After installation, there should be documentation of any problems and the follow-up actions taken.

LB.9 The laboratory has a system for equipment validation.

LB.9.1 The laboratory implements policies and procedures describing the validation of critical laboratory equipment for its intended use, including:

LB.9.1.1 Installation Qualification.

LB.9.1.2 Operational Qualification.

LB.9.1.3 Detailed functional validation study with predefined acceptance criteria.

LB.9.1.4 Critical laboratory equipment are not used before completing the validation studies.

Standard Intent:

Upon receipt of critical equipment, the laboratory should develop a written plan for installation, operational, and performance qualifications;

1. Installation according to the manufacturer's specifications.
2. Verification of the equipment's functionality by ensuring that the criteria established by the manufacturer for its intended use are met.

3. Assurance that the equipment performs as expected in the facility's processes.

After installation, there should be documentation of any problems and the follow-up actions taken.

LB.10 The laboratory develops a process for test method validation.

LB.10.1 The laboratory implements policies and procedures on test method validation including:

LB.10.1.1 Verification of accuracy/precision.

LB.10.1.2 Verification of sensitivity (lower detection limit).

LB.10.1.3 Verification of carryover acceptability.

LB.10.1.4 Verification of the Analytic Measurement Range (AMR).

LB.10.1.5 Approval of the method for clinical use.

Standard Intent:

When the laboratory wishes to implement a test system, validation/verification studies must be performed to confirm the performance specifications, which were established by the manufacturer before approving the method for clinical use.

Validation defined as provision of objective evidence through a defined process that a test performs as intended. While verification defined as an abbreviated validation process to demonstrate that a test performs in substantial compliance to previously established claims.

At a minimum, the laboratory must demonstrate that it can obtain performance specifications comparable to the manufacturer for accuracy, precision, reportable range, and reference intervals (normal values). Although no single format for a validation plan is required, most plans include the following common elements:

1. System description.
2. Purpose or objectives.
3. Risk assessment.
4. Responsibilities.
5. Validation procedures.
6. Acceptance criteria.
7. Approval signatures.
8. Supporting documentation.

When a validation process does not produce the expected outcome, its data and corrective actions must be documented.

LB.11 The laboratory develops a process for establishing or verifying and evaluating reference ranges/intervals and cut off values for each analyte and specimen source.

LB.11.1 The laboratory implements policies and procedures that define:

LB.11.1.1 Circumstances and method for establishing reference ranges.

LB.11.1.2 Circumstances and method for verifying published reference ranges.

LB.11.1.3 Circumstances and method for the re-evaluation of reference ranges.

LB.12 The laboratory has a system for standardizing critical laboratory instruments.

LB.12.1 The laboratory implements policies and procedures defining the calibration, adjustment and/or standardization of critical laboratory instruments. This includes:

LB.12.1.1 Calibrations and adjustment are performed before use, after activities that may alter the calibration and at predefined intervals.

LB.12.1.2 All thermometers used in the laboratory are checked against certified standardized thermometric device before being placed in use and annually thereafter.

LB.12.1.3 All stopwatches and instrument timers are checked against standardized stopwatch before the initial use and every six months thereafter.

LB.12.1.4 All pipettes (fixed volume and/or adjustable) are checked for accuracy and reproducibility before being placed in use and semi-annually thereafter.

LB.12.1.5 Balances are placed on vibration resistance surface and checked against standardized weights before being placed in use and every six months thereafter.

LB.12.1.6 Actions are taken in the event of unsatisfactory results.

LB.12.2 Calibration, adjustment and/or standardization procedures conform to the manufacturer's instructions and best practices.

Standard Intent:

Calibration and adjustment must be performed initially, at regular intervals, after repairs or after activities that may alter the calibration. The frequency of such checks should be based on the manufacturer recommendations, regulatory requirements and historical stability of the device.

LB.13 The laboratory has a system for instruments/methods correlation.

LB.13.1 When the laboratory uses more than one method and/or instruments to test for a given analyte, the laboratory develops and implements policies and procedures on correlation to ensure the following:

LB.13.1.1 The correlation studies are conducted every six months.

LB.13.1.2 There is clear description of the correlation study.

LB.13.1.3 There are clearly defined acceptance criteria.

LB.13.1.4 There is a process for review and approval of the correlation results.

Standard Intent:

This standard applies to tests performed on the same or different instrument makes/models or by different methods. The purpose of correlation studies is to evaluate the relationship between test results using different methodologies, instruments, or testing sites. Quality control data may be used for this comparison for tests performed on the same instrument platform, with both control materials and reagents of the same manufacturer and lot number. Otherwise, the use of human samples, rather than stabilized commercial controls, is preferred to avoid potential effects.

LB.14 The laboratory has a system for controlling the quality of test methods.

LB.14.1 The laboratory implements policies and procedures on quality control of test methods to satisfy the following:

LB.14.1.1 Assignment of performance and review responsibility (control specimens are handled and tested in the same manner and by the same laboratory personnel testing patient samples).

LB.14.1.2 Number and frequency of running controls.

LB.14.1.3 Tolerance limits of controls results.

LB.14.1.4 Corrective action to be taken in the event of unacceptable results.

LB.14.2 The laboratory quality control system conforms to the manufacturer's instructions.

Standard Intent:

Quality control (QC) testing is performed to ensure the proper functioning of materials, equipment, and methods during operations. QC performance expectations and acceptable ranges should be defined and readily available to staff so that they will recognize unacceptable results and trends in order to respond appropriately. The frequency for QC testing is determined by the facility in accordance with the applicable regulatory requirements, accreditation standards and manufacturer instructions. QC results should be documented concurrently with performance and unacceptable QC results must be investigated and corrective action must be taken, if indicated before continuing the operational process. If products or services were provided since the last acceptable QC results were obtained, it may be necessary to evaluate the conformance of these products or services. The review of quality control data must be documented and include follow-up for outliers, trends, or omissions that were not previously addressed.

LB.15 The laboratory has comprehensive work instructions and procedures manuals.

LB.15.1 The laboratory develops work instructions and procedures manuals that fulfill the following:

LB.15.1.1 Conform to the hospital document control/management system.

LB.15.1.2 Readily available at the work areas.

LB.15.1.3 Prepared in accordance with the instrument operating manual, reagent inserts and/or manufacturer's instructions.

Standard Intent:

Procedures have specified ways to carry out an activity (also referred to by ISO as "work instructions"). The procedure manual should be used by personnel at the workbench and must include the following elements, when applicable to the test procedure:

1. Principle of the test and clinical significance.
2. Requirements for specimen collection, labeling, storage, preservation, transportation, processing, and criteria for specimen acceptability and rejection.
3. Step-by-step performance of the procedure, including test calculations and interpretation of results.
4. Preparation of solutions, calibrators, controls, reagents, and other materials used in testing.
5. Calibration and calibration verification procedures.
6. Quality Control procedures.
7. Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability.
8. Limitations in the test methodology, including interfering substances.
9. Reference intervals (normal values).
10. Entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life-threatening (critical) results.

The specific style and format of procedure manuals are at the discretion of the laboratory director.

Reagent inserts or instrument operating manuals provided by the manufacturer are not acceptable in place of a procedure manual. However, such documents may be used as part of a procedure description, if they accurately and precisely describe the procedure as it was performed in the laboratory.

Electronic (computerized) manuals are fully acceptable. There is no requirement for paper copies to be available for the routine operation of the laboratory, so long as the electronic versions are readily available to all personnel. However, procedures

must be available to laboratory personnel when the electronic versions are inaccessible (e.g. during laboratory information system or network downtime); thus, the laboratory must maintain either paper copies or electronic copies on CD or other media that can be accessed via designated computers.

LB.16 The Laboratory develops a process for the control of deviations and exceptions.

LB.16.1 There is a written policy, process, and forms for the control and documentation of deviations and exceptions to policies and procedures.

LB.16.2 Deviations and exceptions warranted by clinical situations or special circumstances are justified, pre-approved, and documented on a case-by-case basis.

LB.16.3 Deviations and exceptions must be approved for only one implementation event by the authorized person who signs the policy or procedure for implementation.

Standard Intent:

Exceptions to policies, processes, and procedures warranted by clinical situations are justified and pre-approved on a case-by-case basis and for one implementation event. A wide variety of routine procedures may, from time to time, require the medical director or designee to authorize an alternative approach because of specific clinical situations.

LB.17 The laboratory has a comprehensive safety and infection control programs.

LB.17.1 The laboratory implements safety and infection control policies and procedures that are in compliance with the national and international laboratory safety standards as well as the hospital safety and infection control plan. Policies define the following:

LB.17.1.1 Chemical hygiene plan.

LB.17.1.2 Mercury reduction/elimination plan.

LB.17.1.3 Mechanism of fumes and vapors monitoring.

LB.17.1.4 Mechanism of compressed and flammable gases control.

LB.17.1.5 Radiation safety plan.

LB.17.1.6 Biological safety procedures and use of standard precautions.

LB.17.1.7 Tuberculosis and other biological hazards exposure plan.

LB.17.1.8 Electrical safety plan.

LB.17.1.9 Fire prevention and control plan.

LB.17.1.10 Provision and use of Personal Protective Equipment (PPE).

LB.17.1.11 Provision and control of negative pressure in sections dealing with highly infectious materials.

LB.17.1.12 Provision, use, and control of fume hoods.

LB.17.1.13 Provision, use, and control of biological safety cabinets.

LB.17.1.14 Provision of safety equipment (eye wash, emergency shower, fire extinguisher, fire blanket, biological and chemical spill kits).

LB.17.1.15 Waste disposal/control plan (chemical, biological and sharps) using prick proof containers and leak proof bags.

LB.17.1.16 Provision and use of first aid kits.

LB.17.1.17 Reporting of infection and safety incidents.

LB.17.2 The laboratory has safety and infection control training program that includes:

LB.17.2.1 Initial training and competency assessment.

LB.17.2.2 Annual training, recertification and competency assessment.

LB.17.3 The laboratory has a system for monitoring the laboratory safety and infection control program.

LB.17.3.1 Documented safety and infection control audits are conducted at regular predefined-intervals (at least twice yearly).

LB.17.3.2 Findings of the audits are reported to the laboratory director, the facility safety officer, the infection control department, and other concerned parties.

LB.17.3.3 Corrective actions, whenever needed, are taken and documented.

Standard Intent:

The laboratory director is the ultimate responsible person for laboratory safety. He/she will be responsible for providing laboratory personnel with a comprehensive safety manual and assigning a safety officer to provide guidance and monitoring. The safety manual outlined above addresses common laboratory risks and hazards. Specialized laboratories might need to develop additional safety requirements to meet specific risk factors.

LB.18 The laboratory has a services/specimen collection manual.

LB.18.1 The laboratory develops a services/specimen collection manual that includes the following:

LB.18.1.1 Available tests and services on and off-site (reference laboratory) and their Turn Around Times (TAT).

LB.18.1.2 Methods of patient preparation.

LB.18.1.3 Procedures for positive patient identification.

LB.18.1.4 Quality and quantity of sample.

LB.18.1.5 Phlebotomy and sample collection procedures.

LB.18.1.6 Recognizing and handling adverse reactions to phlebotomy.

LB.18.1.7 Specimen labeling.

LB.18.1.8 Requisition and required clinical data.

LB.18.1.9 Specimen handling and transportation.

LB.18.1.10 Specimen rejection criteria.

LB.18.2 Laboratory services/specimen collection manual is available to all relevant departments.

Standard Intent:

Because of the importance of clinical information, instructions must be included in a manual and made available at all sites where specimens are collected. Instructions must include procedures and instructions for proper patient preparation, positive patient identification, quality and quantity of sample, phlebotomy, recognizing and handling adverse reactions to phlebotomy, specimen labeling, requisition and required clinical data, specimen handling and transportation and list of specimen rejection reasons. It is acceptable for this information to be electronically available to users.

LB.19 The laboratory establishes Turn Around Times (TAT) for routine and STAT tests.

LB.19.1 Turnaround Times are clearly defined for routine and STAT tests.

LB.19.2 Turnaround Times are established in agreement with relevant clinical departments.

LB.19.3 Turnaround Times are communicated, Implemented, and monitored.

Standard Intent:

TAT needs to be defined clearly; Collection-to-reporting or receipt-in-laboratory-to-reporting. This definition needs to be included in written agreement or memo of understanding with all clinical departments, more importantly, with critical care areas. The agreement needs to include the expectations for TAT, requests for patients with special transfusion needs and the notifications of delays in obtaining suitable products, and transportation of components and products. Agreements should be approved by the medical staff, transfusion service medical director, and hospital administration. Furthermore, TAT needs to be monitored (mean or median TAT, or the percent of specimens TAT that falls within the established limits) and reported at predefined intervals.

LB.20 Requests for laboratory tests or services are complete and legible.

LB.20.1 Requests for laboratory tests or services bear sufficient information, including:

LB.20.1.1 Two patient's identifiers (patient's full name and medical record number).

LB.20.1.2 Patient Age and Sex.

LB.20.1.3 Patient location.

LB.20.1.4 Identification of the authorized ordering physician.

LB.20.1.5 Type of specimen and required test.

LB.20.1.6 Date and time of specimen collection.

LB.20.1.7 Identification of the phlebotomist or the person who collected the specimen.

LB.20.1.8 Additional clinical information, as required.

Standard Intent:

Requests for blood/blood components, tests or services may be submitted in an electronic or written format. Requests must contain sufficient information for accurate patient identification. Two independent patient identifiers are required, ideally including the patient's first full names and an ID number that is unique to the patient. The importance of accurate patient identification is fundamental in patient safety. Other information necessary to process a request for transfusion includes the specific component, the amount, any special requirements such as irradiation, the gender and age of the recipient, and the name of the authorized prescriber ordering the transfusion. The recipient's diagnosis and a history of transfusion and pregnancy may provide useful information to guide testing, product/component selection, or both. Blood banks should have a written policy defining the acceptance criteria for transfusion orders. Verbal requests are acceptable in urgent situations but should be documented in accordance with local policies.

LB.21 The laboratory ensures correct specimen labeling.

LB.21.1 The laboratory implements policies and procedures to ensure correct specimen labeling, including:

LB.21.1.1 Labeling of the specimen containers is conducted immediately after sample collection at the patient side.

LB.21.1.2 Two Patient's identifiers (patient's full name and medical record number).

LB.21.1.3 Date and time of sample collection.

LB.21.1.4 Identification of the person collecting the specimen.

Standard Intent:

Blood specimens collected for lab test or compatibility testing must be positively and completely identified and labeled before leaving the patient side. Acceptable practices for positive identification of patient and blood specimen labels must be defined in the specimen collection manual. Either handwritten or imprinted labels may be used provided that the information on the label is identical to that on the wristband and the lab request form. All tubes must be indelibly labeled and there must be a method to identify the phlebotomist who collected the blood sample and the date of sample collection.

LB.22 The laboratory develops a process for sample handling after collection.

LB.22.1 The laboratory has policies and procedures on proper sample handling, transporting, and tracking. This covers:

LB.22.1.1 Packing instructions (use of biohazard leak-proof containers).

LB.22.1.2 Personnel training (including safety and proper packaging).

LB.22.1.3 Specimen tracking system.

LB.22.2 The laboratory has a system to maintain the identity of laboratory specimen during receipt, processing, examination, and archiving.

Standard Intent:

Proper handling of specimen after collection play an important role in the quality and accuracy of lab results. Personnel who package potentially infectious specimens for shipment must satisfactorily complete certified training in these requirements. The laboratory may send personnel to courses for certified training, or may obtain materials to train its personnel in-house.

LB.23 The laboratory develops a process for specimen receipt.

LB.23.1 The laboratory implements policies and procedures for the receipt and inspection of laboratory specimen to ensure the performance and documentation of:

LB.23.1.1 Date and time of specimen reception.

LB.23.1.2 Check for proper packaging.

LB.23.1.3 Check for quality and quantity of specimen.

LB.23.1.4 Check for adequacy of specimen labeling.

LB.23.1.5 Check for request completion.

LB.23.1.6 Check for label/request discrepancies.

LB.23.1.7 The use of suboptimal specimen is clearly highlighted in the reported results.

LB.23.1.8 Final decision (accept/reject).

Standard Intent:

Because patient/specimen misidentification may cause morbidities or mortalities, the best hope for prevention lies in preventing or detecting errors in every phase of the laboratory processes. When a sample is received in the laboratory, documented checks must be made to confirm that the information on the sample label and the information on the request are identical. If there is any doubt about the identity of the patient or about the labeling of the sample, a new sample must be obtained.

LB.24 The laboratory has a written description for the format and contents of its reports.

LB.24.1 The laboratory has a written description for the format and contents of its reports which include:

LB.24.1.1 Identification of the testing laboratory.

LB.24.1.2 Patient identification (full name and medical record number, age and sex).

LB.24.1.3 Identification of the ordering physician.

LB.24.1.4 Date and time of specimen collection and the source of specimen.

LB.24.1.5 Reporting date and time.

LB.24.1.6 Test results and reference intervals.

LB.24.1.7 Identification of the authorized person releasing the report.

Standard Intent:

As applicable, all of the above elements of a laboratory report must be available in the laboratory information system or in paper records.

LB.25 The laboratory develops a process for critical results reporting.

LB.25.1 The laboratory implements policies, procedures and records in consultation with clinical departments to address the following:

LB.25.1.1 Identification of results that should be reported as critical.

LB.25.1.2 Identification of the notified party.

LB.25.1.3 Identification of the means of communicating critical results.

LB.25.1.4 Description of the sequence of conveying the result and read-back.

LB.25.2 Documentation of critical results notification event includes:

LB.25.2.1 Date and time of notification.

LB.25.2.2 Patient identification.

LB.25.2.3 Test results.

LB.25.2.4 Documentation of read-back.

LB.25.2.5 Identification of the notifying person.

LB.25.2.6 Identification of the notified person.

Standard Intent:

Critical results are those results that may require rapid clinical attention to avert significant patient morbidity or mortality. The medical director of the laboratory needs to define the critical values in consultation with clients and clinical departments served.

Records must be maintained showing prompt notification of the appropriate clinical individual after obtaining results in the critical range. These records should include: date, time, responsible laboratory individual, person notified, test results and documentation of read-back. Any problem encountered in accomplishing this task should be investigated

to prevent recurrence. Allowing clinicians to "opt out" of receiving critical results is strongly discouraged.

LB.26 The laboratory develops a process for amending reported laboratory results.

LB.26.1 The laboratory implements policies and procedures for amending/correcting reported results. This includes:

LB.26.1.1 Definitions of report corrections and amendments.

LB.26.1.2 Format of the corrected report.

LB.26.1.3 Requirement to include the previous result in the corrected report.

LB.26.1.4 Notification of clinical departments.

LB.26.1.5 Application of general reporting requirements.

Standard Intent:

Corrected or revised report means changes to patient results, accompanying reference intervals and interpretations, or patient identifiers, but not to minor typographical errors of no consequence. As clinical decisions or actions may have been based on the previous report, it is important to replicate previous information (test results, interpretations, reference intervals) for comparison with the revised information. The previous information and the revised information must be identified as such, and the original data must be present in the revised report (for paper reports), or linked electronically or logically to the revised information (in electronic reports).

When there are multiple sequential corrections of a previously reported result, it is considered inappropriate to note only the last correction made, as the clinician may have made a clinical decision based upon erroneous data rather than the "true" result. All corrections should be referenced in the patient report.

LB.27 The laboratory has a process for reference laboratory services.

LB.27.1 There is a clearly defined and implemented process describing the laboratory role in selecting and evaluating providers of reference laboratory service, including:

LB.27.1.1 Selection criteria (including accreditation status) for the provider of reference laboratory services.

LB.27.1.2 Inclusive list of send-out tests.

LB.27.1.3 Detailed procedure for specimen transportation and results reporting.

Standard Intent:

Reference laboratory services are one of the critical services that should be properly controlled. Laboratories may outsource services such as infectious disease testing, advanced immunohematology testing, hematology and coagulation for quality control testing. The suppliers of these services may be internal (e.g., other departments within the same organization) or external (outside vendors). Proper control of reference

laboratory services includes:

Selection; Selection of reference laboratories must be based primarily upon the quality of performance of such laboratories. Whenever possible, referral specimens should be sent to an accredited laboratory. The laboratory director should ensure that the reference laboratories provide turnaround times that meet clinical needs.

Scope of service; an inclusive list of outsourced services/tests need to be maintained current.

Specimen requirements; the referring laboratory should follow all requisition, collection and handling instructions specified by the reference laboratory.

Result Reporting; Testing records and patient reports must state the name of the reference lab performing the test and the identification of the person authorizing the release of the results.

Agreement/Service Contract; a signed document specifying the expectations of the two parties involved should be readily available for quick referencing. Essential elements of such a document may include:

1. Scope of Service
2. Agreement conditions (including accreditation status).
3. Sample Requirements
4. Turn Around Time
5. Result Reporting
6. Release of information to third party
7. Solving disputes
8. Validity of the Agreement and Review schedule.

LB.28 The laboratory develops a comprehensive system for Point-of Care-Testing (POCT).

LB.28.1 The laboratory implements policies and procedures to address the following:

LB.28.1.1 Clear definition of POCT.

LB.28.1.2 Assignment of the responsibility of managing the POCT to the laboratory.

LB.28.1.3 Guidelines describing the process of acquiring POCT devices/methods.

LB.28.1.4 Training and competency testing requirements.

LB.28.1.5 Maintenance, quality control, and quality management of the POCT devices/methods.

LB.28.2 The laboratory assigned a qualified individual as POCT coordinator.

Standard Intent:

Point-of-Care Testing (POCT) is defined as tests designed to be used at or near the site where the patient is located, that do not require permanent dedicated space, and that are performed outside the physical facilities of the clinical laboratories. Other standards for quality management, results reporting, and safety are applied. The POCT program should be centrally coordinated in the laboratory, with designated qualified personnel who review testing and quality control procedures, conduct/oversee training and competency assessment of testing personnel. The surveyor will review all centrally maintained records and visit at least three testing sites in order to evaluate compliance.

LB.29 Laboratory records are retained for defined periods.

LB.29.1 The laboratory implements a general laboratory records retention system that ensures the following:

LB.29.1.1 Laboratory test request forms, specimen accessioning logs, instrument printouts, reported results, records of quality control, proficiency testing records, and quality management reports (quality indicators, audits, process improvement projects) are retained for three years.

LB.29.1.2 Method/instrument validation records are retained for the entire period of using the method/instrument and three years after discontinued.

LB.29.1.3 Maintenance records are retained for the life time of the instrument and three years after retirement.

LB.29.1.4 Employee identification records (signature, initials, identification code, and inclusive dates of hiring) are retained for the entire period of hiring and three years after departure.

LB.29.2 The implemented blood bank and transfusion services records retention system ensures the following:

LB.29.2.1 Inspection records (blood, blood components and critical supplies), proficiency testing records, and quality management reports (quality indicators, audits, process improvement projects) are retained for five years.

LB.29.2.2 Whole blood collection, apheresis collection, therapeutic phlebotomy, therapeutic apheresis, component preparation, component modification, quality control, and normal pre-transfusion testing records are retained for ten years.

LB.29.2.3 Donation history, donor testing, donor notification, deferred donors, final disposition of blood/blood components, and look back records are retained permanently.

LB.29.2.4 Abnormal patients testing records (records of patients with antibodies, transfusion reactions or special requirements), patient's transfusion

history, transfusion reaction, and transfusion transmitted diseases investigation records are retained permanently.

LB.29.3 The implemented anatomical pathology records retention system ensures the following:

LB.29.3.1 Surgical pathology reports, outside consultations report and images of studies are retained for ten years.

LB.29.4 Discontinued (retired) blood bank and transfusion controlled documents are retained for five years after the retirement date.

LB.29.5 Discontinued (retired) general laboratory controlled documents are retained for three years after the retirement date.

Standard Intent:

Documentation provides a framework for understanding and communication throughout the organization. Documents describe how processes are intended to work, how they interact, where they must be controlled, what their requirements are, and how to implement them. On the other hand, records provide evidence that the process was performed as intended and provide information needed to assess the quality of products and services. Together, documents and records are used by quality oversight personnel to evaluate the effectiveness of a facility's policies, processes, and procedures.

The laboratory should maintain a log listing all current policies, processes, procedures, forms and labels with the locations of copies. The log contains other information as appropriate, such as dates when documents were placed in service, schedule of review, identity of reviewer(s), and dates when documents were discontinued/superseded.

When forms are used for capturing or recording data, steps, or test results, the forms become records. Data should be recorded in a format that is clear and consistent. Records provide evidence that critical steps in a procedure have been performed appropriately and that products and services conform to specified requirements. Review of records is an important tool to help evaluate the effectiveness of the quality management system. Records should be created concurrently with the performance of each significant step and should clearly indicate the identity of the individuals who performed each step and when it occurred. The process for managing records should address the following items:

1. Creation and identification.
2. Protection from accidental or unauthorized modification or destruction.
3. Verification of completeness, accuracy, and legibility.
4. Storage and retrieval.
5. Retention periods.
6. Confidentiality.

If records are maintained electronically, adequate backups should exist in case of system failure. Electronic records should be readable for the entire length of their retention period.

The length of time that records are retained may vary; however, the records must be retained for that period encompassing a high frequency of requests for retrieval.

LB.30 The laboratory has a system for sample retention.

LB.30.1 There is a sample retention policy to ensure that general laboratory specimens are retained under appropriate conditions for no less than the periods specified below:

LB.30.1.1 Whole blood specimens and urine specimens are retained for twenty-four hours.

LB.30.1.2 Serum, plasma, cerebrospinal fluid and other body fluids specimens are retained for forty-eight hours.

LB.30.1.3 Permanently fixed and stained blood films are retained for seven days.

LB.30.1.4 Permanently fixed and stained microbiology slides are retained for seven days.

LB.30.2 The sample retention policy ensures that donors and patients samples are retained under appropriate conditions for no less than the periods specified below:

LB.30.2.1 Outpatient specimens (not for compatibility testing) are retained for twenty-four hours.

LB.30.2.2 Inpatient specimens are retained for seventy-two hours.

LB.30.2.3 Specimens of patients who receive blood transfusion are retained for seven days after transfusion.

LB.30.2.4 Segment/specimens from transfused RBC are retained for seven days after transfusion.

LB.30.2.5 Specimens for transfusion reaction investigation are retained for seven days.

LB.30.3 The sample retention policy ensures that anatomical pathology specimen is retained under appropriate conditions for no less than the periods specified below:

LB.30.3.1 Gross specimens of wet or fixed tissues are retained for fourteen days after the release of final report.

LB.30.3.2 Paraffin blocks are retained for ten years.

LB.30.3.3 Glass slides are retained for ten years.

Standard Intent:

Retaining both the patient's sample and the donor's sample allows repetition or additional testing if the patient has a transfusion reaction. Appropriate storage conditions (refrigeration, sealed containers) are necessary to prevent specimen degradation and contamination. Testing of stored samples should be based on the sample storage limitations in the reagent manufacturers' package inserts.

LB.31 The laboratory develops a process for internal (self) and external assessment of operations and quality management system.

LB.31.1 The laboratory develops and implements policies and procedures on quality indicators and systems checks.

LB.31.2 The implemented system covers the selection, data collection, reporting, and monitoring of quality indicators.

LB.31.3 The laboratory selects and monitors key quality indicators covering the pre-analytical, analytical, and post-analytical phases of the laboratory operations.

LB.31.4 Selected general laboratory indicators may include, but are not limited to, the following:

LB.31.4.1 Patient identification errors.

LB.31.4.2 Rejected specimens.

LB.31.4.3 Turnaround Time (TAT) of routine, STAT and urgent requests.

LB.31.4.4 Critical value reporting failures.

LB.31.4.5 Customer satisfaction.

LB.31.4.6 Corrected laboratory reports.

LB.31.4.7 Blood culture contamination.

LB.31.5 The selected transfusion services indicators may include, but are not limited to, the following:

LB.31.5.1 Rejected donors.

LB.31.5.2 Rejected units.

LB.31.5.3 Donor satisfaction.

LB.31.5.4 Adverse donor reactions.

LB.31.5.5 Usage and discards.

LB.31.5.6 Ability to meet the patient's needs.

LB.31.5.7 Blood ordering practices (cross matched/transfused ratio).

LB.31.5.8 Blood administration practices.

LB.31.6 The laboratory has a system for process improvement that covers the following activities:

LB.31.6.1 Identification of opportunities for improvement.

LB.31.6.2 Corrective and preventive actions.

LB.31.6.3 Description of the selected quality improvement tool used in the laboratory.

LB.31.7 The laboratory is involved in hospital-wide/multidisciplinary improvement projects. During the current accreditation cycle, the laboratory was engaged in at least four quality improvement projects, including:

LB.31.7.1 Two general laboratory projects.

LB.31.7.2 One blood bank project.

LB.31.7.3 One transfusion services project.

Standard Intent:

Assessments are systematic examinations to determine whether actual activities comply with planned activities, are implemented effectively, and achieve objectives. Assessments can be internal or external and can include quality assessments, peer reviews, self-assessments, and proficiency testing.

The laboratory must establish and maintain a process for internal (self) and external assessments. Results of assessments must be reviewed by the medical director and the organization's executive management to determine the appropriateness and effectiveness of corrective/ preventive actions (if taken).

Quality indicators are specific performance measurements designed to monitor one or more processes during a defined time and are useful for evaluating service demands, production, adequacy of personnel, inventory control, and process stability. The blood bank must regularly compare the performance against available benchmarks.

Process improvement includes determination of root causes, implementation of corrective actions and preventive actions, and evaluation of the effectiveness of these actions. Several process improvement methodologies used in the healthcare systems, including, Plan–Do–Check–Act (PDCA) cycle, Failure Modes and Effects Analysis (FMEA), Define-Measure-Analyze, Improve, and Control (DMAIC) and Lean Six Sigma. These are systematic step-wise approaches for identifying all possible failures within a process, product, or service to improve performance, reduce costs and waste, cut time, and eliminate non-value-added actions.

LB.32 The laboratory has a comprehensive system for Proficiency Testing (PT) sufficient for the extent and complexity of the laboratory scope of services.

LB.32.1 The laboratory implements policies, processes and procedures on Proficiency Testing to ensure the following:

- LB.32.1.1 All laboratory analyses are covered with Proficiency Testing.
- LB.32.1.2 Alternative Proficiency Testing is performed when appropriate.
- LB.32.1.3 Clear instruction for the receipt, processing and reporting of Proficiency Testing results.
- LB.32.1.4 Proficiency Testing samples are tested by the same personnel handling patient/donor samples.
- LB.32.1.5 Proficiency Testing sample are tested by the same method used for testing patient/donor samples.
- LB.32.1.6 Proficiency Testing samples are not referred to other laboratory for testing.
- LB.32.1.7 Proficiency Testing results are not shared with other laboratories.
- LB.32.1.8 Proficiency Testing results are evaluated and compared to the acceptable performance.
- LB.32.1.9 Whenever appropriate, unacceptable performance is investigated and appropriate corrective actions are taken.
- LB.32.1.10 Proficiency Testing records are reviewed and approved by laboratory management.
- LB.32.1.11 Corrective actions are implemented and monitored (if applicable).

Standard Intent:

Assessments are systematic examinations to determine whether actual activities comply with planned activities, are implemented effectively, and achieve objectives. Assessments can be internal or external and can include quality assessments, peer reviews, self-assessments, and proficiency testing.

The laboratory must establish and maintain a process for proficiency testing (external quality assessment). Results of assessments must be reviewed by the medical director and the organization’s executive management to determine the appropriateness and effectiveness of corrective/ preventive actions (if taken).

LB.33 The blood bank has a process for identifying and delivering pre-donation education to prospective blood donors.

LB.33.1 There are policies and procedures to ensure proper donor identification through:

LB.33.1.1 Definition of acceptable form(s) of identification (Saudi national I.D/Iqama).

LB.33.1.2 Linking the donor identification information to existing donor history (records) on each donor encounter.

LB.33.2 The policies and procedures ensure that donors receive appropriate information/education materials, including:

LB.33.2.1 Educational materials regarding the donation process.

LB.33.2.2 Educational materials regarding infectious diseases transmitted by blood transfusion.

LB.33.2.3 Importance of providing accurate information.

LB.33.2.4 Importance of withdrawing themselves from the donation process if they believe that their blood is not suitable for transfusion.

LB.33.2.5 Donors acknowledge that the educational materials have been read and understood.

Standard Intent:

The blood donor should provide an acceptable form of identification, and each donor must be properly identified by the collection staff before each donation. Accurate donation records are essential to link a repeat donor to existing records and to prevent collection from a donor who is not currently qualified, as well as to ensure that the donor can be contacted in the following the donation and informed of test results or other relevant information, if necessary. If the interview and/or the screening findings constitute deferring the donor temporarily or permanently, the donor still need to be registered and formally notified.

?Blood banks must provide all prospective blood donors with educational materials and give the donors an opportunity to ask questions. The prospective donor should be informed about possible risks of whole blood and apheresis procedure and the infectious disease tests that will be performed on his or her donation and the limitations of the tests to detect early infections (testing may not detect all infected persons). Moreover, the donor must be aware of the behavioral risk factors for transmission of blood-borne pathogens, and of the importance of refraining from blood donation if they are at an increased risk of being infected. The donor screening questions must provide an opportunity to obtain an accurate and truthful history of possible infectious exposure to enable the prospective donors of giving informed consent and an accurate health history.

LB.34 The blood bank develops acceptance criteria for blood donors.

LB.34.1 The laboratory implements criteria for accepting blood donors to minimize the risk of harm to them. The criteria include:

LB.34.1.1 Whole blood is not collected from a donor weighing less than fifty Kilograms or under seventeen years of age.

LB.34.1.2 Whole blood is not collected from a donor more frequently than once every eight weeks and not from donors who donated apheresis product less than forty-eight hours ago.

LB.34.1.3 The blood pressure and pulse rate of prospective donor are within normal ranges; Diastolic blood pressure less than 100 mm Hg, Systolic blood pressure less than 180 mm Hg and pulse rate between 50-100 beats/minute.

LB.34.1.4 The hemoglobin level of the prospective donor should be greater than 12.5g/dL or a hematocrit of more than 38%.

LB.34.1.5 The prospective donor has no history of heart or lung disease.

LB.34.1.6 Female donors are not pregnant or have been pregnant within the last six weeks.

LB.34.1.7 Prospective donor's history is evaluated and the donor examined by a qualified person before whole blood collection.

LB.34.2 The policies and procedures minimize the risk of harm to blood recipients by preventing donations by individuals who has:

LB.34.2.1 Evidence of disease transmissible by blood transfusion.

LB.34.2.2 Conditions thought to compromise the suitability of the blood or blood component.

LB.34.2.3 Body temperature exceeding 37.5C.

LB.34.2.4 History of liver diseases, cancer or bleeding tendency.

LB.34.2.5 History of laboratory or clinical evidence for viral hepatitis, HIV, HTLV.

LB.34.2.6 History of laboratory or clinical evidence for malaria within the last three years.

LB.34.2.7 History of syphilis treatment or unconfirmed test result for syphilis within the past twelve months.

LB.34.2.8 Been excluded as per the current recommendations for the prevention of HIV infection.

LB.34.3 The prospective donor's travel history checked against the current travel deferral list for the risk of HIV, vCJD and Malaria.

LB.34.4 The prospective donor's medications checked against current deferral list. Other medications are assessed by the blood bank physician.

LB.34.5 The prospective donor's vaccinations checked against the current vaccination deferral list. Other vaccinations must be assessed by the blood bank physician.

LB.34.6 Prospective donor's arms are free of lesions suggestive of skin disease or parenteral drug abuse.

Standard Intent:

Prospective blood donors must feel healthy and well on the day of donation. The administered donor history questionnaire and physical examination is intended to ensure that the donor is in good general health and will tolerate the collection procedure, moreover, the collected blood will not harm the recipient.

LB.35 The blood bank develops acceptance criteria for platelets pheresis donors.

LB.35.1 The laboratory implements additional acceptance criteria for platelet pheresis donors. The criteria include:

LB.35.1.1 Donation Intervals meet the following conditions: eight weeks after whole blood donations, not more than once every forty-eight hours, not more than twice a week, not more than four times a month, not more than twenty-four times a year, and eight weeks after failure to return the donor red cells during apheresis procedure or the total RBC loss during apheresis procedure exceeds 200 ml.

LB.35.2 Use of medications that inhibit platelet function (such as Aspirin and Piroxicam) defers the platelet apheresis donation for seventy-two hours after the last dose.

LB.35.3 The prospective apheresis donor should have a qualifying platelet count of more than 150,000/µl.

LB.35.4 The acceptance criteria of blood donors outlined in this chapter apply.

Standard Intent:

Platelets collection by apheresis follows many of the same rules and guidelines that apply to whole blood donation, Except, Platelet pheresis donors may donate more frequently than whole blood donors. Additionally, prospective platelet pheresis donors must have platelet count be above 150,000/µL and should not have taken antiplatelet medications that irreversibly inhibit platelet function are deferred for specific intervals. Platelet pheresis donors must be given information so that their consent to donate is informed.

LB.36 The blood bank has a process for consenting blood donors.

LB.36.1 The laboratory implements a process for consenting blood donors to ensure:

LB.36.1.1 Receiving explanation of the donation procedure.

LB.36.1.2 Being informed about the risks of the procedure.

LB.36.1.3 Being informed about the tests performed and the risks of transmission of infectious diseases.

LB.36.1.4 Being informed about the donor confidentiality and the requirement to report test results to health authorities.

LB.36.1.5 Being informed that there are circumstances in which blood/blood components are released for transfusion before the completion of infectious disease testing.

LB.36.1.6 Having read and understood the information presented to him/her

LB.36.1.7 Having the opportunity to ask questions and having them answered.

Standard Intent:

At the time of each donation, the blood bank staff should explain the blood or blood component collection procedure to the donor in terms the donor understands, and document the donor consent process to indicate that the donor has read and understood all of the educational materials presented to him/her and has had an opportunity to ask questions.

LB.37 The blood bank develops a system for donor notification of significant findings detected during donor screening or after performing laboratory testing.

LB.37.1 A policy and procedure defines events requiring official donor notification.

LB.37.2 The policy and procedure mandates the provision of proper education, counseling, and referral for donors with significant findings.

LB.37.3 The policy and procedure mandates that acknowledgment of the notification is documented within eight weeks of donation.

Standard Intent:

Effective donor notification and counseling should achieve the following objectives:

a. Protect the health of the donor, and in a number of cases, prevent secondary transmission of infectious diseases to sexual partners and offsprings;
b. Protect the safety of the blood supply by conveying the message that the individual should refrain from future blood donations;
c. Provide feedback about the effectiveness of donor selection procedures such as pre-donation education, medical history and confidential unit exclusion;
d. Fulfill ethical requirements of disclosure.

Positive test results for Syphilis, HBsAg, HBcAb, HCV, HIV or HTLV should be communicated to the donors in writing. The letter of notification must convey several important messages, including:

a. Name of the test/disease marker.
b. Implication of the test on the donor's health and the need to seek medical attention.
c. Instructing the donor not to attempt to donate in the future (or you may donate after a defined period).

Directing the donor to the source for additional information.

LB.38 The Blood Bank develops a system for the calibration of collected blood volume regulators.

LB.38.1 The laboratory implements a system for calibration/adjustment of blood volume regulators (blood shakers) to ensure that calibration and adjustment are performed at regular intervals, on every day of use, and after activities that may alter the calibration.

LB.38.2 Calibration and adjustment procedures conform to the manufacturer's instructions.

Standard Intent:

Devices such as agitators, balances, and scales must be standardized with a container of known mass or volume. This must be done before initial use and after repairs or adjustments, and checked each day of use to ensure that the correct volume is drawn.

LB.39 The blood bank adopts the appropriate system for providing the necessary care for blood donors before, during, and after the procedure.

LB.39.1 There is a policy and procedure for venipuncture site preparation to reduce the risk of bacterial contamination of the collected blood/blood component that includes:

LB.39.1.1 Detailed and appropriate procedure for the collection site preparation.

LB.39.1.2 Regular assessment of personnel competency on proper venipuncture site preparation.

LB.39.2 The blood bank uses appropriate whole blood and apheresis products collection sets. The collection sets used in the blood bank are:

LB.39.2.1 Sterile and pyrogen-free.

LB.39.2.2 Closed system.

LB.39.2.3 Equipped with diversion pouch.

LB.39.3 The blood bank has sufficient provisions for providing appropriate care for blood donors during and after the procedure.

LB.39.3.1 Donors are given proper written post donation instructions.

LB.39.3.2 Supplies and equipment needed for donors' care are available.

LB.39.3.3 Personnel are trained and competent in recognition and handling of adverse donor reactions.

LB.39.3.4 Personnel have valid basic life support certification.

LB.39.4 The blood bank has a process for confidential self-unit exclusion and handling post donation information.

LB.39.4.1 The policies and procedures describe the receiving and documenting self or third party information about the donor.

LB.39.4.2 The blood/blood product is kept in quarantine for further actions.

LB.39.4.3 The laboratory management review and decision are documented.

Standard Intent:

The specific procedure used for collection site preparation may vary but should include directions for the chemicals to be used, the time and manner that each is applied and the exact sequence of the steps taken so that bacterial contamination of the collect product is minimized. Donor arm preparation should be monitored to assure that the procedure is followed. Although a variety of skin preparation techniques are available, the application of iodine following use of isopropyl alcohol is most effective in reducing skin organisms. Some donors may have allergies that preclude the application of topical iodine; alternatively, effective measures may be used in such cases; the use of chlorhexidine is preferred.

Blood or blood components' collection sets must be pyrogen-free and identified by a lot number. Additionally, collection containers must be equipped with a diversion pouch to allow diversion of the first 30 to 45 mL of blood. The diversion pouches effectively capture the "skin plug" cored by the phlebotomy needle, resulting in decreased bacterial contamination. Blood in the pouch is subsequently used to fill sample tubes for donor testing.

Donor care starts from continuously observing the donor for signs or symptoms of reactions during and after blood collection. If the donor tolerates the procedure, he/she should remain reclining on donor chair for at least five minutes then allowed to sit up under close observation. If the donor condition continues to appear satisfactory, the donor should be walked to the observation/refreshment area and given the post donation instructions. The donor observation should be continued for at least another five minutes during which the donor is encouraged to drink fluids while waiting to be released. If the donor chooses to leave before being released, such an act must be documented in the donor records.

After any collection procedure, blood donors must be given post-donation information which provide another opportunity to educate the donor. The post donation information should include description for the process of confidential-self unit exclusion as a measure to improve the safety of blood inventory. Donors should be instructed to call blood center if they believe that their blood should not be transfused or if they have any concerns about the safety of their blood. The. The provided contact number should be available 24/7.

LB.40 The blood bank develops a system for managing adverse donation events.

LB.40.1 The laboratory has a system for managing adverse donation events that covers:

LB.40.1.1 Recognition and handling of adverse donation events.

LB.40.1.2 Reporting and monitoring of adverse donation events.

Standard Intent:

Adverse reactions are seen at the time of donation or reported later in about 3.5% of donations, on average. The adverse events reporting system of the blood bank should cover detecting, and responding to adverse reactions to donation. Personnel performing whole blood or blood components collection should be trained in recognizing and handling adverse reactions. Also, the blood bank has the provisions to obtain emergency services for treatment of severe adverse donor reactions.

LB.41 The blood bank develops a process for the collection of donor blood specimen.

LB.41.1 The Laboratory implements a process to ensure that donor blood specimens are:

LB.41.1.1 Collected during the donation.

LB.41.1.2 Properly labeled and crosschecked with the collected product label.

LB.41.1.3 Stored under appropriate and controlled conditions.

Standard Intent:

Assignment of blood components and test results to the properly identified donor is critical to ensuring the transfusion recipient's safety. Those elements should match before blood collection can proceed, as well as during and after the collection. Before phlebotomy, the donor is asked to present appropriate identification. Donor identifying information commonly includes the donor's full name and ID number. The donor records and blood sample tubes are similarly labeled. Electronic records of the donation are also assigned the same number.

LB.42 The blood bank develops a system for the preparation, storage, transportation, and quality control of Red Blood Cells (RBC) components.

LB.42.1 RBC components are prepared by separating the RBC from the plasma proteins.

LB.42.2 RBC components are stored under properly controlled conditions between 1 and 6°C.

LB.42.3 RBC components are transported in properly insulated container between 1 and 10°C.

LB.42.4 RBC components are assigned an expiration date according to the manufacturer's recommendations or:

LB.42.4.1 21 Days for RBC in CPD.

LB.42.4.2 35 Days for RBC in CPDA-1.

LB.42.4.3 42 Days for RBC in additive solution.

LB.42.4.4 24 hours' post opening the RBC unit.

LB.42.5 Policies and procedures ensure that 1% of the monthly production- but not less than 4 units every month- are subjected to quality control testing. All tested RBC units have a hematocrit of less than 80% (RBC in additive solution are exempted from quality control requirement).

Standard Intent:

There are two commonly used whole blood collection systems from which two RBC components are derived; RBC preserved in CPDA-1 with a 35 days' shelf life and RBC preserved in CPD- or CP2D and Additive Solutions (AS) with a shelf life of 42 days.

The blood bank must employ a validated technique to ensure that RBC preserved in CPDA-1 have adequate residual plasma to maintain the hematocrit at <80%. As for RBC preserved in CPD- or CP2D and AS, the residual plasma need to be reduced to <50 mL, to which 100 to 110 mL of AS is added within 72 hours of the blood collection. If the AS solution is not added, the RBC have a shelf life of 21 days and should have adequate residual plasma to maintain the hematocrit at <80%.

LB.43 The blood bank develops a system for the preparation, storage, transportation, and quality control of Platelet Concentrates (PC) components.

LB.43.1 PC components are prepared by separating the platelets from whole blood within eight hours of collection.

LB.43.2 PC components are stored under properly controlled conditions between 20 and 24°C with continuous agitation.

LB.43.3 PC components are transported in properly insulated container as close as possible to 20 and 24°C.

LB.43.4 PC components are assigned an expiration date of twenty-four hours to five days from the day of whole blood collection according to the manufacturer's recommendations or four hours of opening PC unit.

LB.43.5 Policies and procedures ensure that 1% of the monthly production but not less than four units every month are subjected to quality control testing. On the expiration date or at issue, 90% of the subjected units have a platelet count of 5.5X1010 platelets/unit or more and a minimum pH of 6.2.

Standard Intent:

Two major methods are used in preparing Platelets from WB. The first is the Platelet Rich Plasma (PRP) method, consisting of a soft spin followed by a hard spin. The second is the Buffy-Coat (BC) method, consists of a hard spin of WB that enables removal of the supernatant Platelet Poor Plasma (PPP) from the top of the container and the RBCs from the bottom into transfer packs. The buffy coat that remains in the primary container is used to harvest platelets.

Platelets must be continuously agitated during storage at a temperature between 20 and 24 C. However, platelets are not necessarily agitated during transport.

LB.44 The blood bank develops a system for the preparation, storage, transportation, and quality control of Fresh Frozen Plasma (FFP).

LB.44.1 FFP components are prepared by separating and freezing the plasma from the whole blood within eight hours of collection and within six hours for plasma collected by apheresis.

LB.44.2 FFP components are stored under properly controlled conditions below -18°C.

LB.44.3 During transportation, FFP units are maintained at frozen state in properly insulated container.

LB.44.4 FFP components are assigned an expiration date of one year from the day of whole blood collection.

LB.44.5 If cryoprecipitate is not prepared, 1% of the quarterly production- but not less than twelve units every three months- are subjected to quality control testing. 75% of the tested units must have minimum factor VIII level of 700 IU/L.

Standard Intent:

Regardless of the anticoagulant/preservative solution used, plasma separated from WB and frozen within 8 hours of collection has the designation of "Fresh Frozen Plasma" (FFP) and a shelf life of one year. The volume of plasma per unit varies according to the method used for collection and components' separation. BC method tends to yield larger plasma units.

LB.45 The blood bank develops a system for the preparation, storage, transportation, and quality control of Cryoprecipitate (CRYO).

LB.45.1 CRYO components are prepared by separating cold insoluble proteins from Fresh Frozen Plasma and re-freezing of the product within one hour of preparation.

LB.45.2 CRYO components are stored under properly controlled conditions below -18°C.

LB.45.3 During transportation, the CRYO units are maintained at frozen state in properly insulated container.

LB.45.4 CRYO components are assigned an expiration date of one year from the day of whole blood collection.

LB.45.5 Policies and procedures ensure that 1% of the quarterly production- but not less than twelve units every three months- are subjected to quality control testing. 75% of the tested units must have minimum factor VIII level of 80 IU/unit and 150mg of fibrinogen/bag.

Standard Intent:

Cryoprecipitate AHF is the cold-insoluble protein that precipitates when FFP is thawed to 1 to 6 C and is collected by centrifugation; supernatant plasma (Plasma cryoprecipitate reduced) is transferred into a satellite container; and the precipitate is re-suspended in 15 to 20 mL of residual plasma, and then it is refrozen within an hour of separation.

LB.46 The blood bank develops a system for the preparation, storage, transportation, and quality control of platelet apheresis units.

LB.46.1 Platelet apheresis units are prepared by separating the platelets from whole blood using apheresis machine.

LB.46.2 Policies and procedures ensure that 1% of the monthly production-but not less than 4 units every month- subjected to quality control testing. On the expiration date or at issue, all of the subjected units must have a platelet count of 3.0X1011 platelets/unit or more, a minimum pH of 6.2, and a residual WBC count of 5X106 WBC/ unit.

LB.46.3 Requirements for PC storage, transport, and expiration apply.

Standard Intent:

Platelet pheresis is the process of removing whole blood from a donor, separating the blood into its components, keeping the platelets, and then returning the remaining blood components to the donor. The collected platelets are of higher numbers than a normal donation and will be equivalent to 6 – 12 whole blood derived platelet, thus the use of apheresis platelets reduces donor exposure.

LB.47 The blood bank and transfusion services develop policies and procedures to ensure that the prepared and/or transfused Leukocyte-Reduced Red Blood Cells (LR-RBC) units are handled in an appropriate manner.

LB.47.1 Policies and procedures ensure that LR-RBC units are prepared by a method known to retain 85% of the RBC in the original product and a residual WBC count of less than 5X106 WBC/ unit.

LB.47.2 Policies and procedures ensure that 1% of the quarterly production -but not less than 12 units every three months- are subjected to quality control testing. All tested LR-RBC units have a RBC recovery rate of more than 85% and a residual WBC count of less than 5X106 WBC/unit in all subjected units.

LB.47.3 Requirements for RBC preparation, storage, transport and expiration apply.

Standard Intent:

Units with lower leukocyte concentrations are associated with decreased febrile transfusion reactions, reduced all immunization potential, reduced cytomegalovirus transmission, and other benefits.

LB.48 The blood bank and transfusion services develop policies and procedures to ensure that the prepared and/or transfused Leukocyte-Reduced Platelet concentrates (LR-PC) units are handled in an appropriate manner.

LB.48.1 Policies and procedures ensure that LR-PC units are prepared by a method known to retain 85% of the platelets in the original product and a residual WBC count of less than 8.3X105 WBC/ unit or 5X106 WBC/pool of six units.

LB.48.2 Policies and procedures ensure that 1% of the quarterly production -but not less than twelve units every three months- are subjected to quality control testing. All

tested LR-PC units have a platelets recovery rate of more than 85% and a residual WBC count of less than 8.3X105 WBC/unit or 5X106 WBC/pool of six units.

LB.48.3 Requirements for PC preparation, storage, transport and expiration apply.

Standard Intent:

Units with lower leukocyte concentrations are associated with decreased febrile transfusion reactions, reduced alloimmunization potential, reduced cytomegalovirus transmission, and other benefits.

LB.49 The blood bank and transfusion services develop policies and procedures to ensure that the prepared and/or transfused irradiated cellular blood products are handled in an appropriate manner.

LB.49.1 Policies and procedures ensure that irradiated cellular blood products are prepared by a method known to ensure that irradiation has occurred at each time of use.

LB.49.2 Policies and procedures ensure that the preparation method used is known to deliver a minimum of 25 GY to the central part of the canister and a minimum of 15 GY at any point. Verification of dose delivered must be performed and evaluated annually.

LB.49.3 Policies and procedures ensure that irradiated RBC components assigned an expiration date not exceeding twenty-eight days from the date of irradiation or the original assigned expiration date (whichever occurs first).

LB.49.4 Policies and procedures ensure that irradiated platelet components retain their original expiration date.

Standard Intent:

Cellular blood components must be irradiated for the prevention of graft-vs-host disease (GVHD). Irradiation of RBCs followed by storage does result in some decrease in percentage of recovery after transfusion. In addition, an increased efflux of potassium from red cells causes the potassium levels to rise approximately twofold compared to non-irradiated units. Platelets are not damaged by an irradiation dose as high as 5000 cGy. Blood irradiators should be validated by measuring the amount of radiation delivered by machine upon installation and after mechanical maintenance, especially those involving the specimen handling apparatus such as the turntable. There should be periodic documentation (annually for Cesium-137 and semi-annually for Cobalt-60) that the procedure delivers a minimum of 2500 cGy targeted to the midplane of the canister if a free-standing irradiator is used, or to the central midplane of an irradiation field if a radiotherapy instrument is used. The minimum dose at any point in the canister or irradiation field should be 1500 cGy. The procedure should define the maximum number of units of blood or blood components that can be irradiated in a batch. There should be a quality control program for the indicator system in use.

LB.50 The blood bank develops a process for initial immune-hematological testing of blood donor samples.

LB.50.1 There are policies and procedures mandating that a sample of blood obtained from the donor during blood/ blood component collection is subjected to the following testing:

LB.50.1.1 Determination of the donor's forward ABO group (RBC grouping).

LB.50.1.2 Determination of the donor's reverse ABO group (serum grouping).

LB.50.1.3 Determination of the donor's Rh-D type (including a test for weak-D).

LB.50.1.4 Detection of unexpected antibodies to red cell antigens (antibody screening).

LB.50.1.5 There is a confirmation of agreement between donor's current and historical group/type.

LB.50.2 Discrepancies are solved before releasing any blood/blood components.

Standard Intent:

The donor's ABO/Rh-D must be established/confirmed on a specimen collected during the Blood/blood component collection; he red cells must be tested for the presence or absence of A and/or B antigens and the serum or plasma must be tested for the presence or absence of anti-A and/or anti-B antibodies.

The presence or absence of the Rh(D) antigen is determined by testing the red blood cells with Anti-D. Patient with weak D antigen that is not detected by D typing reagent will be designated as D-negative. However, donor with negative or week Rh(D) must be confirmed with a test for weak-D.

Plasma from all donors should be tested for unexpected antibodies to red cell antigens. The methods used demonstrate most of the clinically significant red cell antibodies. When such antibodies are found, plasma-containing blood components shall be labeled to indicate the antibody detected. Components containing significant amounts of plasma should be transfused only to patients known to be negative for the corresponding antigen.

Cross-check between the donor's current and historical group/type must be performed and discrepancies should be resolved before issue of the blood for transfusion purposes.

LB.51 The blood bank develops a process to prevent disease transmission by blood/platelet transfusion.

LB.51.1 There are policies and procedures mandating that a sample of blood obtained from the donor during blood/ blood component collection is subjected to the following infectious diseases testing:

- LB.51.1.1 HBsAg.
- LB.51.1.2 Anti-HBc.
- LB.51.1.3 Anti-HCV.
- LB.51.1.4 Anti-HIV-1/2.
- LB.51.1.5 Anti-HTLV-I/II.
- LB.51.1.6 HIV-1 RNA.
- LB.51.1.7 HCV RNA.
- LB.51.1.8 HBV DNA.
- LB.51.1.9 Serological test for syphilis.
- LB.51.1.10 Other additional or supplemental tests as mandated by relevant health authorities.

LB.51.2 The blood bank has a process to limit and detect bacterial contamination in platelet components. The process:

- LB.51.2.1 Describes the blood bank approach to limit bacterial contamination and the investigations of positive cases.
- LB.51.2.2 Ensures the employed detection method is sensitive enough to detect significant bacterial contamination.

Standard Intent:

Bacterial contamination of blood components (mainly platelets) is a major cause of transfusion-related fatalities. To limit blood component contamination by bacteria from donor skin, two elements of the blood collection process are critical. Before venipuncture, the donor skin must be carefully disinfected using a method with demonstrated efficacy. Second, diversion of the first 10 to 40 mL of donor blood away from the collection container. Furthermore, the blood bank needs to use a method sensitive enough to detect significant bacterial contamination in platelet components. Insensitive methods including pH, glucose and microscopy are no longer acceptable.

LB.52 The blood bank establishes a process for the identification and discard of unacceptable blood/blood product.

LB.52.1 The process mandates two qualified staff members to perform and document this activity.

LB.52.2 The process mandates discarding unacceptable components before the initial labeling of blood and blood components.

Standard Intent:

All units of blood collected should be immediately placed in quarantine in a designated area until donor information and donation records have been reviewed, the current donor information has been compared against the previous information, the donor's previous deferrals have been examined, and all laboratory testing has been completed. WB units may be separated into components before all of the earlier processes have been completed. Separated components are quarantined at the appropriate temperature until all the suitability steps have been completed and reviewed.

All blood and blood components that are found unsuitable for transfusion must be stored in a separate quarantine area from blood and components for which testing has not been completed and from blood and components that are suitable for distribution. The blood bank must adopt a system to prevent labeling of components until before all donor information and the current test results are reviewed and found to be acceptable.

Note:

The sequence and the number of staff performing this task is not applicable is the lab use a validated computer system and barcode readers.

LB.53 The blood bank develops a process for initial labeling of blood and blood components.

LB.53.1 There are policies and procedures to ensure that:

LB.53.1.1 Blood and blood components are not labeled before completion of the donor testing.

LB.53.1.2 Blood and blood components are not labeled before the discard of unacceptable units.

LB.53.2 Initial labeling requirements include:

LB.53.2.1 Identification of the collecting facility.

LB.53.2.2 Product name.

LB.53.2.3 Unit number.

LB.53.2.4 ABO/Rh.

LB.53.2.5 Expiration date and time.

Standard Intent:

Blood component labeling should be performed in a quiet area to prevent disruption of the process and errors caused by distraction. A number of items must be reviewed at the time of labeling. Infectious disease tests should be nonreactive or negative; also, group/type should be completed and checked with historical records before labeling occurs. The process of applying labels to the components must include a second

verification step to ensure that the correct labels have been used (both, machine readable (Bar-coded) and eye-readable).

Note:

The sequence of performing this task is not applicable is the lab use a validated computer system and barcode readers.

LB.54 The blood bank has a process to confirm the ABO/Rh-D of donated blood.

LB.54.1 There is a process to confirm the ABO/Rh-D of donated blood which mandates that segment from RBC components is subjected to the following testing:

LB.54.1.1 Determination of the donor's forward ABO group (RBC grouping).

LB.54.1.2 Determination of the donor's Rh-D type.

LB.54.1.3 ABO/Rh-D conformation is performed after initial labeling.

LB.54.2 Discrepancies are solved before releasing any blood/blood components.

Standard Intent:

The blood bank must confirm that the ABO/Rh label affixed is correct by performing ABO/RhD testing using a sample from an attached segment. The documentation must show that the result was acceptable before the unit is made available or before releasing the blood/blood component for transfusion.

Note:

The sequence of performing this task is not applicable is the lab use a validated computer system and barcode readers.

LB.55 The blood bank establishes a process to prevent the release of units that are not suitable for transfusion to the available inventory.

LB.55.1 Policies, processes, and procedures ensure the accuracy and legibility of identification information.

LB.55.2 Policies, processes, and procedures ensure the agreement of the identification information (records and donor units).

LB.55.3 Policies, processes, and procedures ensure the performance of visual inspection for discoloration, clots, hemolysis, and adequacy of seal.

LB.55.4 Policies, processes, and procedures ensure two qualified staff members perform and document this activity.

Standard Intent:

The sequence of performing this task is not applicable is the lab use a validated computer system and barcode readers.

LB.56 The transfusion services establish a process for the release of incompletely tested blood/blood components.

LB.56.1 There are implemented policies, processes and procedures to ensure that incompletely tested blood/blood components can be released under the following circumstances:

LB.56.1.1 For urgent need only.

LB.56.1.2 Upon the discretion of the medical director of the transfusion medicine, the agreement of the attending physician and the consent of the patient or next of kin, when applicable.

LB.56.1.3 Approved only for a particular patient and one transfusion event.

LB.56.1.4 The released blood products are conspicuously labeled to this effect.

LB.56.2 Testing of the blood/blood components must be completed and reported promptly to the attending physician.

LB.56.3 Deviations and exceptions standard in this chapter applies.

Standard Intent:

Some blood components require emergency release because of high demand or very short storage time such is the case for platelet concentrates. Emergency release of untested or incompletely tested blood require blood bank medical director and treating physician approval and a label or tie tag to indicate that testing was incomplete at the time of release.

LB.57 The blood bank has a process for request, approval, and execution of therapeutic procedures.

LB.57.1 The process ensures all therapeutic procedures are ordered and justified by an authorized physician.

LB.57.2 The process ensures the blood bank medical director or designee is responsible for reviewing therapeutic procedures orders for appropriateness and evaluating patient clinical and laboratory data before approving the procedure.

LB.57.3 The process ensures therapeutic procedures are explained to the patient and consented.

LB.57.4 The process ensures that blood/ blood components discarded immediately after collection.

Standard Intent:

The transfusion service's medical director must approve all therapeutic procedures and accept medical responsibility for the patient undergoing this procedure. This involvement is in addition to responsibility for overall management of the therapeutic procedures' program, establishment of eligibility criteria for therapeutic procedures, provision of medical support for reactions, and oversight of quality assurance measures.

The risks of therapeutic procedures must be explained by a knowledgeable, responsible person according to approved policies and procedures. The patient must have the opportunity to ask questions, and should sign a document indicating agreement.

LB.58 The blood bank and transfusion services use appropriate blood and blood components storage devices.

LB.58.1 The blood and blood components storage devices are:

LB.58.1.1 Designed for the intended use.

LB.58.1.2 Equipped with continuous temperature monitoring system (temperature recording).

LB.58.1.3 Equipped with audio/visual alarm systems.

LB.58.2 The device's alarm and monitoring system conforms with the following:

LB.58.2.1 Activates at a temperature that allows for intervention before the contents reaches unacceptable temperature.

LB.58.2.2 Activates at an area staffed 24 hours a day, seven days a week.

LB.58.2.3 Connected to a separate or DC power supply.

LB.58.3 The alarm system is checked weekly.

LB.58.4 Alarm activation temperatures are checked quarterly.

LB.58.5 The inner temperature of blood storage devices is monitored and recorded at least once a day using a standardized thermometric device.

LB.58.6 In the event of failure of continuous temperature monitoring, temperature recording, or alarm systems, the inner temperature is monitored and recorded every four hours.

Standard Intent:

The storage capacity should be large enough to accommodate the optimal inventory of blood and blood components with a margin for expansion, emergencies and other storage device failures**.** Refrigerators, freezers, and platelet incubators for blood component storage are available with continuous temperature monitoring devices that would be able to detect a temperature deviation before blood components might be affected. Automated electronic monitoring devices that are available include:

1. Weekly pen and chart recorder
2. Wireless temperature recording devices
3. Connection to centralized temperature monitoring system.

The blood storage devices must be equipped with audible alarms to alert personnel that temperature ranges are approaching unacceptable levels. Central alarm monitoring

allows facilities that do not have personnel in the vicinity of the equipment to alert the designated staff at another location. Alarm systems must continue to function during a power failure. This may be accomplished by having the alarm on a separate circuit, installing battery power back-up, or having a power failure alarm.

LB.59 The blood bank and transfusion services develop policies and procedures to ensure that the thawed Fresh Frozen Plasma (FFP) units are handled in an appropriate manner.

LB.59.1 Thawed FFP units are prepared by thawing the FFP between 30 and 37°C without direct contact with the water.

LB.59.2 Thawed FFP units are stored under properly controlled conditions between 1 and 6°C.

LB.59.3 Thawed FFP units are transported in properly insulated container between 1 and 10°C.

LB.59.4 Thawed FFP units are assigned an expiration time of twenty-four hours from the thawing time.

LB.59.5 Requirements for FFP preparation, storage, transport and expiration apply.

Standard Intent:

If FFP are thawed in a water bath, an overwrap bag or other similar protection must be used to prevent water from coming in contact with outlet ports and possibly introducing bacterial contamination. FFP, once thawed, has a shelf life of 24 hours. However, at the end of that interval, the plasma can be relabeled as Thawed Plasma, which can be stored for an additional 4 days at 1 to 6°C. Thawed Plasma prepared from FFP and stored for 5 days contains reduced levels of Factor V (>60%) and Factor VIII (>40%).

LB.60 The blood bank and transfusion services develop policies and procedures to ensure that the thawed CRYO units are handled in an appropriate manner.

LB.60.1 Thawed CRYO units are prepared by thawing CRYO units between 30 and 37°C without direct contact with the water.

LB.60.2 Thawed CRYO units are stored and transported at room temperature (between 20 and 24°C).

LB.60.3 Thawed CRYO units are assigned an expiration time of six hours from the thawing time for individual units and four hours from the thawing time of pooled units.

LB.60.4 Requirements for CRYO preparation, storage, transport and expiration apply.

Standard Intent:

If CRYO are thawed in a water bath, an overwrap bag or other similar protection must be used to prevent water from coming in contact with outlet ports and possibly introducing bacterial contamination. Once thawed, CRYO has a shelf life of 6 hours from thawing and only 4 hours from pooling. Thawed CRYO is stored at room temperature (20-24°C), during which the mean rates of decline of Factor VIII levels at 2, 4, and 6 hours are approximately 10%, 20%, and 30%, respectively.

LB.61 The Blood bank and transfusion services develop a system for reagents quality control.

LB.61.1 Policies and procedures ensure performance of reagents quality control on each day of use.

LB.61.2 Policies and procedures ensure anti-sera are checked against known positive and negative cells.

LB.61.3 Policies and procedures ensure reagent Red Blood Cells are checked against known positive and negative anti-sera.

LB.61.4 Policies and procedures ensure results are checked against predefined acceptable results.

LB.61.5 Policies and procedures ensure results are reviewed and reagents are approved before use for patient testing.

LB.61.6 Corrective actions are taken for unacceptable results.

Standard Intent:

Quality control (QC) of blood bank reagents must be performed on each day of use. QC performance expectations and acceptable results should be defined and readily available to staff so that they will recognize unacceptable results and trends in order to respond appropriately. QC results should be documented concurrently with performance, and unacceptable QC results must be investigated and corrective action must be taken, if indicated, before releasing donor or patient results. If products or services were provided since the last acceptable QC results were obtained, it may be necessary to evaluate the conformance of these products or services. The review of quality control data must be documented and include follow-up for outliers, trends, or omissions that were not previously addressed.

Unless manufacturer instructions state otherwise, one vial of each reagent lot each day of testing are subjected to the following:

1. Typing sera (Anti-A, Anti-B, Anti A, B and Anti-D) are checked for reactivity and specificity against known positive and negative cells.
2. Typing cells (A and B cells) are checked for reactivity and specificity against known positive and negative antisera.
3. Each cell used for antibody detection (Screening Cells) are checked for reactivity of at least one antigen using antisera of 1+ or greater avidity.
4. Other typing sera (Anti-K, Anti-Fy(a), Anti- M etc.) are checked at every use for reactivity and specificity against known positive and negative cells.

Anti-IgG (Antiglobulin) reagents reactivity are checked during antibody screening and crossmatching through the use of IgG-coated red blood cells.

LB.62 The blood bank and transfusion services implement a system for receiving or sending blood and blood products to outside facilities.

LB.62.1 There are written blood supply/exchange agreements with outside facilities covering the following:

LB.62.1.1 Agreement conditions (including accreditation status).

LB.62.1.2 Agreement on adequate blood/blood components inventory.

LB.62.1.3 Role of the involved parties in look back and transfusion transmitted diseases investigation.

LB.62.1.4 Release of blood, blood components or information to a third party.

LB.62.1.5 Validity of agreement and agreement review schedule.

LB.62.1.6 Resolving disputes.

LB.62.2 There is a written procedure describing the process for requesting or releasing blood from or to outside facilities.

LB.62.3 Policies and procedures on receipt and inspection of incoming blood/blood components include:

LB.62.3.1 Evaluation and verification of the shipping condition of each blood component.

LB.62.3.2 Checking for meeting predefined acceptance criteria for each blood component received.

LB.62.3.3 Evaluation and verification of the agreement of units' identification information (unit numbers, ABO/Rh-D and Expiration dates).

LB.62.3.4 Conformation of ABO/Rh-D for RBC components.

LB.62.3.5 Actions taken for unsatisfactory consignment.

Standard Intent:

Blood banks should maintain written contracts or agreements with transfusing facilities to define the expectations of the two parties involved and should be approved by the executive management of both facilities. The supplier may be another department within the same facility that is managed independently, or it may be another facility. The contracting facility assumes responsibility for ensuring compliance with all applicable standards and regulations.

Upon receipt of blood component from other facilities, each unit must be inspected for proper labeling and shipping conditions. Red blood cell component must be checked for abnormal appearance, observation for bag integrity, hemolysis, and clots. Comparison of bag and segment color should be performed to aid in detecting bacterially contaminated units.

LB.63 The blood bank and transfusion services implement a system for pre-transfusion testing of the recipient.

LB.63.1 Pre-transfusion testing is performed on a specimen collected from the recipient with every admission and within three days of the scheduled transfusion time.

LB.63.2 There is a consistency between patient's current and historical records (including group/type, antibody screening). Discrepancies are resolved before performing compatibility testing.

LB.63.3 When there is no history for the patient in the transfusion services records or computer system, two determinations of the patients ABO/RhD must be made on two specimens collected during the current admission.

LB.63.4 Pre-transfusion testing includes:

LB.63.4.1 Determination of the patient's forward ABO group (RBC grouping).

LB.63.4.2 Determination of the patient's reverse ABO group (Serum Grouping).

LB.63.4.3 Determination of the patient's Rh-D type.

LB.63.4.4 Detection and Identification (if applicable) of unexpected antibodies to red cell antigens.

Standard Intent:

The blood bank must have a policy defining the maximum interval during which a recipient sample may be used for crossmatching. This may not exceed 3 days in patients who have been transfused or pregnant within the past 3 months, or if relevant medical/transfusion history is unknown or uncertain. The day of sample draw is day 0. The ABO/Rh-D type of the patient's red blood cells must be determined by an appropriate test procedure. Tests on each sample must include forward and reverse grouping. The recipient serum/plasma must be screened for unexpected RBC antibodies including incubation with reagent RBC at 37^0C and read at the antiglobulin phase.

Comparison of records of previous ABO and Rh typing are an essential step. Available laboratory records for each patient must be routinely searched. If no record of the patient's blood type is available from previous determination(s), the transfusion service should be aware that there is an increased probability of an incorrect blood type assignment and, consequently, of a hemolytic transfusion reaction. If a laboratory collects an additional sample for the purpose of verification of patient identity, a repeated antibody screening doesn't need not be performed on this specimen.

LB.64 The transfusion services develop a system for the selection of blood/blood product for transfusion.

LB.64.1 There are policies and procedures for the selection of blood/blood product for transfusion to ensure the following:

LB.64.1.1 The selected red blood cells component is ABO group-specific or ABO group-compatible with the recipient's plasma.

LB.64.1.2 Only Rh-D negative red blood cell components are transfused to Rh-D negative patients.

LB.64.1.3 Identification of the conditions for the release of Rh-D positive red blood cells components to Rh-D negative patients.

LB.64.1.4 If the patient has current or previous history of clinically significant antibodies in the patient serum, the selected red cells must lack the corresponding antigen(s).

LB.64.2 There are policies and procedures for the selection of plasma components for transfusion to ensure the following:

LB.64.2.1 The selected plasma component is ABO group-specific or ABO group-compatible with the recipient's RBC.

LB.64.2.2 Conditions for the release of ABO-incompatible plasma are identified.

LB.64.2.3 In the presence of clinically significant antibody in the donor's plasma, the recipient red cells must lack the corresponding antigen.

LB.64.2.4 If the plasma components are visually contaminated with red blood cells (more than 2 ml of RBC), RBC selection criteria apply.

LB.64.3 There are policies and procedures for the selection of blood/blood components for patients with special requirements that address the following:

LB.64.3.1 The use of leukocyte-reduced cellular blood components.

LB.64.3.2 The use of irradiated-cellular blood components.

LB.64.3.3 Transfusion of known Hemoglobin-S patients.

LB.64.3.4 Massive transfusions.

Standard Intent:

Whenever possible, patients should receive ABO-identical blood; however, it may occasionally be necessary to make alternative selections. If the component to be transfused contains 2 mL or more of red cells, the donor's red cells must be ABO-compatible with the recipient's plasma.

D-positive blood components should routinely be selected for D-positive recipients. D-negative units will be compatible but should be reserved for D-negative recipients. D-negative patients (especially females of childbearing potential) should receive red-cell-containing components that are D negative to avoid immunization to the D antigen and possible HDFN. When ABO-compatible D-negative components are not available for a D-negative recipient, the medical director of the blood bank and the patient's physician should weigh alternative courses of action. Depending on the childbearing potential of the patient and the volume of red cells transfused, it may be desirable to administer Rh Immune Globulin (RhIG) to a D-negative patient who is given D-positive blood.

Antigens other than ABO and D are not routinely considered in the selection of units of blood for nonalloimmunized patients. If the patient has a clinically significant unexpected antibody(ies), blood lacking the corresponding antigen(s) should be selected for crossmatching. When crossmatch-compatible units cannot be found, the medical director of the transfusion service should be involved in the decision on how to manage the patient's transfusion needs.

LB.65 The transfusion services establish a process for compatibility testing.

LB.65.1 There is a process to ensure the detection of ABO incompatibility between the recipient's serum/plasma and the donor's RBC.

LB.65.2 The process ensures the compatibility testing is performed on integrally attached segment from the donor's RBC unit.

LB.65.3 The process ensures the checking for presence, now or in the past, of clinically significant antibody in the patient's serum.

LB.65.4 The process ensures the proper labeling of cross-matched units with patient's name, patient's identification number and patient's ABO /Rh-D.

Standard Intent:

Unless there is an urgent need for blood, a crossmatch must be performed before a red cell transfusion. When clinically significant antibodies are not detected in current antibody detection tests and there is no record of previous detection of such antibodies, then a method is required that at least detects ABO incompatibility, such as an immediate spin (IS) or computer/electronic crossmatch (the antiglobulin test may be omitted).

When a patient has a clinically significant antibody identified currently or historically, even if the antibody is presently nonreactive, RBC lacking relevant antigens should be selected for transfusion and the crossmatch must include incubation at 37 C and the AHG test.

A tag or label indicating the recipient's two independent identifiers, Patient's ABO / Rh-D and the compatibility test interpretation, must be attached securely to the blood container.

LB.66 The transfusion services develop a process for intra-uterine and neonatal testing and transfusion.

LB.66.1 There is a process for intra-uterine and neonatal testing and transfusion that entails determination of the neonate ABO/Rh and conditions for repeat of ABO/Rh testing.

LB.66.2 The process entails performance and interpretation of Direct Anti-globulin Test (DAT).

LB.66.3 The process describes conditions for omitting re-typing and serological cross-match.

LB.66.4 The process considers the clinically significant antibodies of maternal origin.

LB.66.5 The process describes selection of RBC and plasma components for top-up, exchange and intrauterine transfusions.

Standard Intent:

Initial neonatal testing must include ABO and Rh typing of red cells and a screen for red cell antibodies; the antibody detection test may be done on either serum or plasma, from either the infant or the mother.

During any one hospitalization, repeat compatibility testing and ABO/Rh typing may be omitted, provided that the screen for red cell antibodies is negative; that all red cells transfused are group O, ABO-identical or ABO-compatible; and that red cells are either Rh-negative or the same Rh type as the patient.

If an unexpected red cell antibody is detected in the infant's specimen or the mother's serum which contains clinically significant red cell antibodies, the infant should be given either red cell unit that lack the corresponding antigen(s) or units compatible by an antiglobulin crossmatch. This should continue throughout the neonatal admission (≤four months of age) and for as long as maternal antibody persists in the infant's blood.

The selected blood must be fresh (< 14 days old) leukocyte-reduced, irradiated, Sickle screen negative and G6PD screen normal. Neonatal RBC replacement therapy must be given with maximum amount of RBCs per ml of volume. Therefore, the hematocrit of the selected unit must be adjusted to 70 – 80%. If group O RBCs have been transfused, testing for anti-A and/or anti-B must be performed through the antiglobulin phase before switching the newborn back to his/her original blood group.
In the case of HDN, the selected unit must lack the antigen corresponding to the maternal antibody or crossmatch compatible with the mother serum/plasma at the antiglobulin phase.

LB.67 The transfusion services develop a process for the issue of blood/blood component for transfusion.

LB.67.1 There is a process for the issue of blood/blood component to ensure accurate identification of the intended recipient and the required blood components.

LB.67.2 The process ensures the integrity of the donor unit identification label and the recipient identification label.

LB.67.3 The process ensures confirmation that the donor's ABO/Rh is identical with the recipient's, or marked compatible.

LB.67.4 The process ensures proper documentation of the release event.

Standard Intent:

Misidentification of patients or donor units causes the majority of acute hemolytic transfusion reactions. The best hope in preventing such a fatal reaction from occurring lies in detecting technical and clerical errors during the issue of the donor unit. Transfusion services must design a system to detect technical and clerical errors in donor unit identification and to ensure that blood is issued to the correct patient.

Blood and blood components must be visually inspected immediately before issue for transfusion or shipment to other facilities. Pre-issue inspection must be documented; records should include description of any abnormal units, action taken, and the identification of the personnel involved.

LB.68 The transfusion services develop a process for emergency release of uncross-matched or incompletely cross-matched blood.

LB.68.1 There is a process for emergency release of uncross-matched or incompletely cross-matched blood that ensures a proper ordering procedure and required ordering information.

LB.68.2 The process considers age and sex factors.

LB.68.3 The process ensures ABO/Rh-D and labeling of the selected blood.

LB.68.4 The process ensures subsequent compatibility testing and notification of the results.

LB.68.5 The process ensures documentation of the release event (including the ordering physician signature).

Standard Intent:

The intent of emergency blood release system is to establish a mechanism for making blood available in emergency situations with a minimum of delay. The physician requesting blood under this policy assumes full responsibility for administering the uncrossmatched or incompletely crossmatched to the patient. Normal Blood Bank documentation and crossmatching procedures.

LB.69 The medical director of the transfusion services participates (through the blood transfusion committee) in the development of a process for the management of adverse or suspected transfusion events.

LB.69.1 There is a process for the management of adverse transfusion events which covers:

LB.69.1.1 Recognition and handling of adverse transfusion events.

LB.69.1.2 Reporting and monitoring of adverse transfusion events.

LB.69.2 There is a process for management of suspected transfusion reactions which covers:

LB.69.2.1 Clerical check of the identification information and records.

LB.69.2.2 Visual inspection of the blood product, pre and post transfusion samples.

LB.69.2.3 Initial immune-hematological testing and conditions for performing additional testing (minor/major cross-match, urine analysis, biochemistry, microbial culture).

LB.69.2.4 Conclusion and instructions for future transfusion.

LB.69.3 Transfusion reaction reports are reviewed by the transfusion services medical director and the transfusion committee.

Standard Intent:

Hemolytic transfusion reactions (HTR) are primarily caused by an alloantibody in the patient's circulation directed against an antigen on the transfused red blood cells (RBC). HTR following red blood transfusion are of two types: acute (immediate) hemolytic transfusion reactions (AHTR) or delayed hemolytic transfusion reactions (DHTR)

AHTR are life-threatening reactions almost always due to human error in transfusing an ABO incompatible unit. DHTR occurs very rarely as a result of primary immunization but are more frequent following an anamnestic response. When antibodies produced by the primary immune response increase in titer and avidity, they may react with the transfused cells that are still circulating and cause a DHTR. DHTR as the result of primary immunization cannot be prevented because allogenic blood transfusion exposes the recipient to numerous foreign antigens (other than ABO and D, the only antigens matched for transfusion) which are potentially immunogenic. However, DHTR as the result of an anamnestic response can be minimized by keeping accurate records of antibodies produced by the patient and through the use of sensitive techniques for antibody screening.

Some reactions such as febrile and allergic reactions, also known as Non-Hemolytic Transfusion Reactions (NHTR) cannot be eliminated. Although they are not life threatening, they cannot be ignored and they must be distinguished from true HTR because both types of reaction may present with the same symptoms. Therefore, all

transfusion reactions reported must be treated as a STAT procedure. Furthermore, any unexpected investigation results must be reported, expeditiously, to the medical director of the blood bank.

LB.70 The medical director of the transfusion services participates (through the blood transfusion committee) in the development and implementation of a process for the investigation of suspected cases of post-transfusion infection.

LB.70.1 There is a process for the investigation of suspected cases of post-transfusion infection which ensures the following:

LB.70.1.1 Prompt identification of the implicated donors.

LB.70.1.2 Prompt notification of the collecting facility (if applicable).

LB.70.1.3 Prompt quarantine of available components from the implicated donors.

LB.70.1.4 Investigating the implicated donors.

LB.70.1.5 Assigning appropriate deferrals to the implicated donors.

LB.70.1.6 Reporting the investigation results (internally and externally), as applicable.

LB.70.2 The process for investigation of donors subsequently found to have transfusion transmissible disease (Look Back) ensures the following:

LB.70.2.1 Prompt quarantine of available components from the same donor.

LB.70.2.2 Prompt identification of the recipients.

LB.70.2.3 Prompt notification of the facility where the transfusion was conducted (if applicable).

LB.70.2.4 Prompt notification of the patient's physician and/or infection control.

LB.70.2.5 Investigation and follow-up of recipients.

LB.70.2.6 Reporting the investigation results (internally and externally), as applicable.

Standard Intent:

Because the interval between an infected transfusion and onset of disease can be very long, recipients and donors are usually unaware of their infection and may be infectious to others. Also, if a patient develops a Transfusion Transmissible Disease (TTD) after receiving blood or blood component(s), the donor(s) of those units must be traced retested and notified if they show seroconversion.

LB.71 Gross examination of surgical pathology specimens is performed by a qualified pathologist.

LB.71.1 Surgical specimens are subjected to gross examination by a qualified pathologist or another qualified individual under the supervision of a qualified pathologist.

LB.71.2 When gross examination is performed by individuals other than pathologists, the laboratory maintains the following:

LB.71.2.1 Training records.

LB.71.2.2 Extent of their activity.

LB.71.2.3 Scheme of supervision.

Standard Intent:

There must be a written policy for training and assessing professional competency, criteria for the assessment, and records of the assessment must be reviewed by the laboratory medical director. There must be a list of the specific types of specimens for which non-pathologists are permitted to assist in the gross examination.

LB.72 There is a process for daily review by a pathologist of all technical activities in the anatomical pathology laboratory.

LB.72.1 There is a process that mandates a documented daily review of all activities in the anatomical pathology lab, including:

LB.72.1.1 Specimen processing.

LB.72.1.2 Quality of histology and cytology preparation.

LB.72.1.3 Quality of routine and special stains.

Standard Intent:

The documented review applies to routine activities. Quality control for special stains, immunohistochemistry, and other special studies are reviewed by the pathologist with every case and deemed acceptable before reporting patient results.

LB.73 The anatomical pathology develops a process for the provision of intra-operative surgical pathology services.

LB.73.1 There is a process for the provision of intra-operative surgical pathology services which addresses:

LB.73.1.1 Scheduling of cases.

LB.73.1.2 Specimen acceptance, accessioning, processing and testing.

LB.73.1.3 Documentation of direct verbal communication with the surgeon.

LB.73.1.4 Inclusion of the frozen section results with the final surgical pathology report.

Standard Intent:

Intraoperative consultations and frozen sections are intended to assist the surgeon in case management. The pathologist in charge of anatomical pathology through the Tissue Review committee should establish clear policy, validated process and detailed guidelines on the scheduling, request, processing and reporting of surgical pathology results.

LB.74 The anatomical pathology develops a process for intra-departmental and extra-departmental consultations.

LB.74.1 There is a process for intra-departmental and extra-departmental consultations that addresses circumstances for the inclusion of the consultation in the final pathology report.

LB.74.2 The process addresses circumstances for separate filing of the consultation report.

Standard Intent:

Intra-departmental consultations may be included in the patient's final report, or filed separately. The pathologist in charge of the case must decide whether the results of intra-departmental consultations provide relevant information for inclusion in the patient's report.

Extra-departmental consultations must be readily accessible within the pathology department. These consultations must be mentioned with the official surgical pathology reports or filed separately, so long as they can be readily linked.

LB.75 The anatomical pathology develops guidelines for compiling surgical pathology reports.

LB.75.1 There are implemented guidelines for compiling surgical pathology reports, addressing the following elements:

LB.75.1.1 Gross description (type, number, dimensions).

LB.75.1.2 Essential processing information and performed studies.

LB.75.1.3 Other relevant report elements necessary for the management of the patient.

Standard Intent:

As applicable, all of the above elements of anatomical pathology report must be available in the laboratory information system or in paper records. General laboratory results reporting requirements (LB.24, LB.25 and LB.26) apply.

LB.76 The anatomical pathology has a process for reviewing the previous cytology and histology material and solving disparities.

LB.76.1 There is a policy mandating the inclusion of review results with the current patient report.

LB.76.2 The policy covers solving and documenting disparities between frozen section/ cytology/ gross examination and the final pathology report.

Standard Intent:

In certain clinical situations, review of previously examined specimens may affect current patient care by determining subsequent management protocols. Retrospective comparison of specimens from multiple body sites within a relatively short time span may be required for comparison of a current specimen with one from the past may distinguish a metastasis from a second primary neoplasm. Results of the review can be incorporated in the current cytology or tissue report or in a separate document. Retrospective reviews are subject to the biasing effect of knowledge of outcome, and this fact should be kept in mind during any such review.

Facility Management and Safety Standard Intents

FMS.1 Hospital Leaders establish and support a facility management and safety program.

FMS.1.1 The facility management and safety program includes the following written and approved plans:

FMS.1.1.1 Safety of the Building.

FMS.1.1.2 Security.

FMS.1.1.3 Hazardous materials and waste disposal.

FMS.1.1.4 External emergency.

FMS.1.1.5 Internal emergency.

FMS.1.1.6 Fire Safety.

FMS.1.1.7 Medical equipment.

FMS.1.1.8 Utility System.

FMS.1.2 Hospital leaders support the facility management and safety program to acquire the necessary equipment.

FMS.1.3 The program includes regular inspection, testing, and maintenance of all the operating components of the program.

FMS.1.4 The program has a budget for the necessary upgrading or replacement as identified by monitoring data or to meet applicable laws and regulations.

FMS.1.5 There is an orientation program conducted for new hires on the facility management and safety plans.

Standard Intent:

To manage the risks within the environment in which patients are treated and staff work requires planning, execution, monitoring and improvement. The hospital develops one master program or individual programs that include the following:

a) **Safety and Security**

Safety—The degree to which the hospital's buildings, grounds, and equipment do not pose a hazard or risk to patients, staff, and visitors

Security—Protection from loss, destruction, tampering, or unauthorized access or use

b) **Hazardous materials**—Handling, storage, and use of radioactive and other materials are controlled, and hazardous waste is safely disposed.

c) **Emergencies**—Response to disasters, and emergencies is planned and effective.

d) **Fire safety**—Property and occupants are protected from fire and smoke.

e) **Medical technology**—Technology is selected, maintained, and used in a manner to reduce risks.

f) **Utility systems**—Electrical, water, and other utility systems are maintained to minimize the risks of operating failures.

Such programs are written and are up to date in that they reflect present or recent conditions within the hospital's environment. There is a process for their review and updating. When the hospital has nonhospital entities within the patient care facilities to be surveyed (such as an independently owned coffee shop or gift shop), the hospital has an obligation to ensure that these independent entities comply with the facility management and safety programs.

To ensure these plans are properly disseminated to hospital newly hired staff an orientation program should be established covering all aspects of the program to ensure their safety and the safety of patients under their care.

To ensure that safety requirements are met with no budgetary concerns, the hospital should be able to establish a systematic approach for necessary safety expenditures (allocated budget) with necessary documentation of purchase orders.

FMS.2 There is a qualified individual(s) responsible for directing and coordinating the facility management and safety program.

FMS.2.1 The hospital has a facility management and safety program director who directs and coordinates all aspects of the facility management and safety program.

FMS.2.2 The program director is qualified by education (e.g., bachelor's degree in engineering science, training, and experience in healthcare facility management and safety.

FMS.2.3 The program director is assisted by qualified staff (e.g., safety officer) as required, according to the size and complexity of the hospital services.

FMS.2.4 The program director provides ongoing consultation to all departments.

FMS.2.5 Each department has an assigned "liaison safety officer" to liaise all safety issues within the department.

Standard Intent:

To ensure that Facility Management and Safety Program is properly coordinated and implemented, one individual should be assigned to provide program oversight alongside the Safety Committee; oversight includes:

Hospital should consider training, experience and qualifications to this individual prior to assignment.

In order to ensure safety, culture is spread through the organization, departmental safety liaison officers should be appointed in a way that ensure that the entire hospital services are covered. These liaison officers should have clear responsibilities and reporting channels for safety matters.

FMS.3 There is a multidisciplinary safety committee that provides oversight of the facility management and safety program.

FMS.3.1 The committee's membership consists of representatives from relevant departments such as safety, security, housekeeping, infection control, risk management, biomedical engineering, laboratory, medical staff (E.R), nursing, radiation safety, maintenance, and quality management.

FMS.3.2 The safety committee provides oversight of the facility management and safety program.

FMS.3.3 Safety committee meets at least ten times per year on a monthly schedule. Minutes are documented to be approved by the hospital leadership.

FMS.3.4 The safety committee, through a multidisciplinary team, conducts quarterly and as needed facility safety tours to identify risks and hazards related to the facility and physical plants as well as evaluation of staff knowledge.

FMS.3.5 The committee uses the resulting information for corrective and preventive actions, planning, and budgeting of long-term upgrading and replacement.

Standard Intent:

In order to act as a Professional Advisory Team to control / eliminate all safety hazards, hospitals should create a multidisciplinary safety committee responsible for Facility Management and Safety Program oversight, oversight includes:

a) planning all aspects of the program, such as development of plans and providing recommendations for space, technology, and resources;

b) implementing the program;

c) educating staff;

d) testing and monitoring the program;

e) periodically reviewing and revising the program; and

f) providing annual reports to the governing body on the effectiveness of the program.

FMS.4 The hospital is in compliance with applicable laws and regulations.

FMS.4.1 The hospital has a valid Saudi Civil Defense license.

FMS.4.2 The hospital has a valid Saudi Civil Defense report and action plan as applicable.

FMS.4.3 Hospital leaders ensure compliance with applicable building and environmental protection standards, laws, and regulations (e.g., MOMRA's hospital building requirements, Saudi building code, discharges to drainage systems, safe disposal of waste).

Standard Intent:

Laws, regulations, and inspections by local authorities determine in large part how a facility is designed, used, and maintained. All hospitals, regardless of size and resources, must comply with these requirements as part of their responsibilities to their patients, families, staff, and visitors. Such requirements may differ depending on the facility's age and location and other factors.

Hospital leadership, including governance and senior management, are responsible for:

a) knowing what national and local laws, regulations, and other requirements apply to the hospital's facilities;

b) implementing the applicable requirements or approved alternative requirements; and

c) planning and budgeting for the necessary upgrading or replacement as identified by monitoring data or to meet applicable requirements and providing evidence of progress toward implementing the improvements.

When the hospital has been cited for not meeting requirements, hospital leadership takes responsibility for planning for and meeting the requirements in the prescribed time frame.

FMS.5 The hospital ensures safety and security of staff and patients during construction, renovation, or demolition projects.

FMS.5.1 The hospital implements a policy for safety and security of patients, staff and visitors during construction, renovation, or demolition that includes:

FMS.5.1.1 Safety and security instructions.

FMS.5.1.2 Education of contractors.

FMS.5.1.3 Proper isolation of construction and renovation sites.

FMS.5.1.4 How to eliminate the risks of fire and spread of dust.

FMS.5.1.5 Penalties incurred on contractors for violating the policy.

FMS.5.1.6 Safety rounds on construction/renovation sites by facility management and safety and infection control staff.

FMS.5.2 A work permit is signed by the construction team and posted in the construction, renovation, or demolition sites.

Standard Intent:

Construction, renovation and demolition pose additional risks to the safety of patients, families, visitors, and staff, and include risk related to infection control, ventilation, traffic flow, garbage/refuse, and other risks.

This standard intends to minimize construction, renovation and demolition risks by establishing and implementing safety policy that covers all standard's elements.

A preconstruction work permit is required in identifying potential risks, as well as the impact of the construction project on services provided. The work permit cover areas of safety, security, infection control and maintenance at least.

Safety inspections should be performed during all phases of construction.

FMS.6 Warning and directive signs are posted inside the hospital as appropriate.

FMS.6.1 There are warning signs posted as appropriate in the hospital and include:

FMS.6.1.1 Signs for the radioactive materials including warning signs for pregnant women.

FMS.6.1.2 Signs for wet floors during cleaning.

FMS.6.1.3 No smoking signs.

FMS.6.1.4 Signs and warning lights for x-ray room(s).

FMS.6.1.5 Signs to restrict cellular phones in sensitive areas as appropriate, e.g. MRI or critical care units.

FMS.6.2 There are directive signs posted as appropriate in the hospital and include:

FMS.6.2.1 Signs indicating the hospital name and main entrances/exits.

FMS.6.2.2 Directional signs.

FMS.6.2.3 Signs to direct staff and patients to the different services in the hospital.

FMS.6.2.4 Fire exit signs.

FMS.6.2.5 Signs to identify floor level at staircases and in front of elevators.

FMS.6.2.6 Signs to instruct staff, patients, and visitors in restricted areas.

FMS.6.2.7 MRI patient safety measures and steel restriction signs.

FMS.6.2.8 Signs for populations with special needs.

Standard Intent:

The hospital should post warning signs (relevant to substandard FMS.6.1.1 through FMS.6.1.6.) this enables the identification of hazards and restriction around the hospital facility. The hospital should also have clear direction signs posted in the appropriate areas in order to ease evacuation during emergencies, assist patients, visitors and staff and reduce unnecessary movement around the facility during normal hospital operation (substandard FMS.6.2.1 through FMS.6.2.8)

FMS.7 The hospital is equipped for vulnerable individuals and others with special needs.

FMS.7.1 The hospital is equipped with special parking spots.

FMS.7.2 The hospital is equipped with wheel chairs and relevant ramps are in all elevated areas.

FMS.7.3 The hospital is equipped with handrails in the corridors and stairs.

FMS.7.4 The hospital is child safe in the public areas (tamper free outlets, no sharp ends).

Standard Intent:

Hospital facilities need to be designed in a way that ensures that it suits the needs of the wide spectra of patients anticipated to benefit from the healthcare services; this includes vulnerable patients and patients with special needs (disabled and children).

Accessibility of doctors' offices, clinics, and other health care providers is essential in providing medical care to people with disabilities. Due to barriers, individuals with disabilities are less likely to get routine preventative medical care than people without disabilities. Accessibility is important medically so that minor problems can be detected and treated before turning into major and possibly life-threatening problems.

Also, areas where pediatric populations are expected to be served (waiting rooms, hospital lounge, playground and kindergartens) need to be assess for any risks and these risks need to be eliminated.

FMS.8 Safety measures and equipment are applied where needed in the hospital to ensure safety of patients and staff.

FMS.8.1 The patients' bathrooms and showers are provided with the following safety measures:

FMS.8.1.1 Non-slipping floors' surfaces.

FMS.8.1.2 Bars to support patients.

FMS.8.1.3 Bell or a system to call for help.

FMS.8.1.4 Lock system that allows opening from outside.

FMS.8.2 The kitchen has safety equipment that include:

FMS.8.2.1 Eye wash stations.

FMS.8.2.2 Fire blankets.

FMS.8.2.3 First aid kit.

FMS.8.2.4 Fire Extinguishers.

FMS.8.2.5 Emergency shut off valve for liquid propane gas.

FMS.8.2.6 Emergency shower.

FMS.8.3 The laundry has safety equipment that include:

FMS.8.3.1 Eye wash stations.

FMS.8.3.2 Fire blankets.

FMS.8.3.3 First aid kit.

FMS.8.3.4 Fire Extinguishers.

FMS.8.3.5 Emergency shower.

FMS.8.4 The Laboratory has safety equipment that include:

FMS.8.4.1 Eye wash stations.

FMS.8.4.2 Fire blankets.

FMS.8.4.3 First aid kit.

FMS.8.4.4 Fire extinguishers.

FMS.8.4.5 Emergency shower.

FMS.8.4.6 Fire resistant safety cabinets for laboratory chemicals.

Standard Intent:

Fall and injury prevention continues to be a considerable challenge across the care continuum. Therefore, patient bathrooms and showers need to comply with the standard requirements (substandard FMS.8.1.1 through FMS.8.1.4). The kitchen should have the safety features as in substandard FMS.8.2.1 thought FMS.8.2.6. The laundry should have the features mentioned in substandard FMS.8.3.1 through FMS.8.3.5 and the laboratory should have the safety features as mentioned in substandard FMS.8.4.1 through FMS.8.4.6.

FMS.9 The hospital ensures that all its occupants are safe from radiation hazards.

FMS.9.1 The hospital has a radiation safety policy and procedure and it is implemented.

FMS.9.2 All radio-active materials are clearly labeled and safely and securely stored.

FMS.9.3 The hospital has the relevant valid license(s) from King Abdulaziz City for Science and Technology.

FMS.9.4 Staff handling nuclear materials are qualified and certified by King Abdul-Aziz City for Science and Technology.

FMS.9.5 There is a valid shielding certificate of the x-ray room(s) including regular test to ensure permissible radiation levels.

FMS.9.6 Lead aprons and gonad/thyroid shields are available to cover patients and staff needs and are annually tested according to a hospital-wide inventory.

FMS.9.7 Personal radiation dosimeters (TLD cards) are available, tested every 3 months, and actions taken when test results exceed permissible levels.

Standard Intent:

To ensure that hospital staff, patients and visitors are safe from unnecessary radiation hazards (ionizing/non-ionizing), the hospital should implement a radiation safety program, complying with national regulations and provide the necessary radiation protection equipment (substandard FMS.9.2 through FMS.9.7.)

FMS.10 Patients and staff are protected from unnecessary exposure to laser beams in areas where it is used.

FMS.10.1 There are laser warning signs at all areas where the laser is used.

FMS.10.2 Laser is performed in rooms that do not have refractive surfaces such as glass and mirrors.

FMS.10.3 Staff working or assisting in laser procedures are provided with protective eye goggles appropriate to the wavelength used.

FMS.10.4 Laser safety manuals are available for the concerned staff.

Standard Intent:

Patients and staff should be protected from injury by laser in areas where it is used. This is accomplished by having posted laser warning signs, avoiding refractive surfaces in laser rooms, having the appropriate protective staff equipment and the availability of laser safety manuals.

FMS.11 The hospital environment is secure for patients, visitors, and staff.

FMS.11.1 There are identification badges for the following staff categories:

- FMS.11.1.1 Hospital staff.
- FMS.11.1.2 Temporary employees.
- FMS.11.1.3 Contractor staff.

FMS.11.2 Security personnel or alternative security systems are utilized to restrict access to sensitive areas that include, but are not limited to, the following:

- FMS.11.2.1 Delivery room.
- FMS.11.2.2 Neonatal intensive care unit.
- FMS.11.2.3 Nursery.
- FMS.11.2.4 Female wards.
- FMS.11.2.5 Operating room.
- FMS.11.2.6 Central sterilization service department.
- FMS.11.2.7 Morgue.
- FMS.11.2.8 Medical records.
- FMS.11.2.9 Hospital roof.
- FMS.11.2.10 Medical equipment and goods stores including pharmacy narcotic vault.

FMS.11.3 There are policies and procedures for the following:

- FMS.11.3.1 Preventing children and neonates abduction.
- FMS.11.3.2 Lost and found items.
- FMS.11.3.3 Safe keeping of patient belongings.
- FMS.11.3.4 Involvement of police in cases of trauma, motor vehicle accidents, and medico-legal incidents.
- FMS.11.3.5 Incidents of violence (violence code).
- FMS.11.3.6 Women and child abuse.

FMS.11.4 Staff are trained on response to all security alerts.

Standard Intent:

Hospital security program must ensure that everyone in the hospital is protected from harm, loss, or damage to property. Staff, vendors, and others identified by the hospital, such as volunteers or contractors, are identified by badges (temporary or permanent) or other form of identification. Others, such as families or visitors in the hospital, may be identified depending on hospital policy and laws and regulations.

Restricted areas such a must be secure and monitored by security personnel and/or security access control systems.

Children, elderly adults, and other vulnerable patients unable to protect themselves or signal for help must be protected from harm. In addition, remote or isolated areas of the facility and grounds may require the use of security cameras

Security program policies and procedures must be disseminated to hospital staff to clarify their roles and responsibilities during different situations.

FMS.12 The hospital has a mechanism to deal with a bomb threat.

FMS.12.1 There is a written policy on how to deal with a bomb threat in the hospital which includes:

- FMS.12.1.1 Defining the code or alert.
- FMS.12.1.2 Defining the role of the person receiving threat alerts.
- FMS.12.1.3 Defining the response team including the individual responsible for announcing the emergency status and contacting the local authorities.
- FMS.12.1.4 Defining the duties and the responsibilities of all staff involved and their action cards.
- FMS.12.1.5 The command center location.
- FMS.12.1.6 Defining the steps to be taken during the bomb threat.

FMS.12.2 Staff are trained on response to bomb threat alerts.

Standard Intent:

Writing the policy and exercising its component will contribute highly in protecting the healthcare facility and its occupants during bomb threat situations. The plan should cover the requirements (12.1.1 to 12.1.6) and documented evidence of staff training on code activation should be available.

The policy should cover all possible sources of threats (telephone, email, suspicious packages) and what steps to be implemented for each scenario.

Facility personnel have to accompany police or military bomb demolition personnel in searching for the suspected bomb, because speed is of the essence and only individuals familiar with a given area can rapidly spot unfamiliar or suspicious objects or condition in the area (this staff individual should be clarified in the policy). This is particularly true in health care facilities. The facility telephone operator has to be provided with a checklist to be kept available at all times, in order to obtain as much information as possible from the caller concerning the location of the supposed bomb, time of detonation, and other essential data, which have to be considered in deciding whether or not to evacuate all or part of the facility.

FMS.13 The hospital has qualified individuals assigned to maintain security.

FMS.13.1 The number of security personnel is proportional to the size of the hospital, number of entrances, and the availability of supporting security systems.

FMS.13.2 The security personnel have written job descriptions.

FMS.13.3 The security personnel receive orientation about:

FMS.13.3.1 Scope of work and job description.

FMS.13.3.2 Emergency codes.

FMS.13.3.3 Fire safety.

FMS.13.4 The security personnel roles are clearly defined for the following:

FMS.13.4.1 External disaster plan.

FMS.13.4.2 Internal disaster plan.

FMS.13.4.3 No smoking policy.

FMS.13.5 The security personnel have a dress code.

FMS.13.6 The security personnel conduct hospital wide security rounds and significant findings are documented.

Standard Intent:

To ensure security coverage of hospital facilities, a security risk-assessment needs to be conducted to determine the necessary number of security personnel needed to cover the hospital's main gates, entrances, and security sensitive areas and to conduct security actives such as hospital-wide security rounds.

It is important for patient's, employees, and visitors to sense the security presence in the hospital. This presence needs to be available throughout hospital's operational shifts.

Security personnel needs to be oriented and familiar with their job descriptions and roles and responsibilities during various security scenarios and emergency cases.

Female security personnel needs to be available as required and security personnel needs to be able to communicate properly with hospital's employees and patients without language barriers.

FMS.14 The hospital ensures safe management of hazardous materials.

FMS.14.1 There is a written hazardous materials plan that includes the following:

FMS.14.1.1 Appropriate handling, storing, transporting, and disposing of hazardous materials.

FMS.14.1.2 Education and training on signs and symptoms of exposure to hazardous materials and the appropriate treatment according to Material Safety Data Sheets (MSDS).

FMS.14.2 Each department has a current list of hazardous materials used in the department. The list covers:

FMS.14.2.1 Purpose of use.

FMS.14.2.2 The responsible person.

FMS.14.2.3 Permitted quantity.

FMS.14.3 Each department dealing with hazardous materials has Material Safety Data Sheets (MSDS) relevant to its current list of hazardous materials.

FMS.14.4 Each department using hazardous materials has proper personal protective equipment (PPE) and spill kits to handle any spill or exposure.

FMS.14.5 All hazardous materials are labeled clearly and this includes:

FMS.14.5.1 Anti-neoplastic drugs.

FMS.14.5.2 Radioactive materials.

FMS.14.5.3 Corrosives, acids, and toxic materials.

FMS.14.5.4 Hazardous gases and vapors.

FMS.14.5.5 Anesthetic gases.

FMS.14.5.6 Flammable liquids.

FMS.14.6 Any leak, spill, or exposure to any hazardous material is reported.

Standard Intent:

A hazardous materials program is in place that includes identifying and safely controlling hazardous materials and waste throughout the facility. A hazardous material is any solid, liquid, or gas that can harm people, other living organisms, property, or the environment.

Hazardous materials Dangerous goods may be radioactive, flammable, explosive, toxic, corrosive, biohazardous, an oxidizer, an asphyxiant, a pathogen, an allergen, or may have other characteristics that render it hazardous in specific circumstances.

The hazardous materials program includes processes for:

1-Inventory of hazardous materials.

2-handling, storage, and use of hazardous materials.

2-proper protective equipment and procedures during use, spill, or exposure.

3-proper labeling of hazardous materials and waste.

4-reporting and investigation of spills, exposures, and other incidents.

5-documentation, including any permits, licenses, or other regulatory requirements.

6- Education and training on signs and symptoms of exposure to hazardous materials and the appropriate treatment according to Material Safety Data Sheets (MSDS).

Information regarding procedures for handling or working with hazardous materials in a safe manner must be immediately available at all times and includes information about the physical data of the material (such as its boiling point, flashpoint, and the like), its toxicity, what effects using the hazardous material may have on health, identification of proper storage and disposal after use, the type of protective equipment required during use, and spill-handling procedures, which include the required first aid for any type of exposure.

FMS.15 The hospital implements a waste management plan.

FMS.15.1 The hospital has a waste management plan that includes handling, storing, transporting, and disposing all kinds of waste (e.g., clinical waste, radioactive waste, and hazardous gases).

FMS.15.2 The plan is implemented.

FMS.15.3 Staff (including contractors' staff) are trained on dealing with hazardous waste.

Standard Intent:

Hospitals produce considerable waste each day. Frequently that waste is or could be infectious.

Thus, the proper handling, segregation and disposal of waste contributes to the reduction of infection risk in the hospital.

A waste management plan is in place that includes identifying and safely controlling waste throughout the facility.

Healthcare waste are categorized as either hazardous waste or non-hazardous waste.

1- Infectious waste including:

a. SPECIMENS (EXCLUDING BODY PARTS)

b. BLOOD & BLOOD COMPONENTS

c. CONTAMINATED PLASTIC INSTRUMENTS

d. OTHERS (DISPOSABLE MATERIALS USED IN CLEANING AND DISINFECTING SPILLS)

e. Contaminated GLOVES

2- Pathological and anatomical waste including Wastes generated by pathological services; such as tissues, organs and body parts removed during surgery, autopsy. Hair, Nails and extracted teeth are excluded

3- Hazardous chemicals waste including:

a) Chemicals

b) Reagents

c) Media

d) Stains

e) Liquid waste (machines)

4- Pharmaceutical waste

5- Pressurized containers

6- Sharps including Syringes (NEEDLES), Slides & Cover slides, Blades, Knives, Glass tubes and Glass fragments

7- Hazardous gases and vapors including biological safety cabinets and scavenging systems waste.

8- Radioactive waste

National rules and regulations must be complied with when management healthcare wastes as applicable.

FMS.16 The hospital ensures preparedness for external disasters.

FMS.16.1 The hospital has a plan to deal with potential external disasters. The plan includes:

FMS.16.1.1 Identification of all potential external emergencies and disasters.

FMS.16.1.2 Names and titles of all staff to be called including their contact numbers and action cards.

FMS.16.1.3 Duties and responsibilities of hospital leaders.

FMS.16.1.4 The triage areas, their locations, and triage action cards.

FMS.16.1.5 The individual responsible for announcing the emergency state and contacting the local authority.

FMS.16.1.6 The control room location and the person in charge.

FMS.16.1.7 The total number of beds that can be evacuated.

FMS.16.1.8 The role of the security personnel.

FMS.16.1.9 The role of each department in the hospital.

FMS.16.2 The hospital conducts an external disaster drill at least annually.

FMS.16.3 The hospital ensures the availability of ambulances and medical supplies and equipment required in case of external disasters (e.g., medical bags, drugs and mobile monitors).

FMS.16.4 There is an orientation on the external disaster plan for new hires with an annual update for all staff.

Standard Intent:

External disasters may directly involve the hospital, such as a major chemical spill incident that cause a flux of casualties to rush to the hospital's emergency department seeking for necessary medical treatment.

It is important to identify the effects of a disaster as well as the types of external disasters that are more likely to occur. This helps in planning the strategies that are needed in the event that a disaster occurs. For example, what is the likelihood that a natural disaster, such as rain floods, will affect water and power.

To respond effectively, the hospital developed a program to manage such emergencies. The program provides processes for:

a) determining the type, likelihood, and consequences of hazards, threats, and events;

b) determining the hospital's role in such events;

c) communication strategies for events;

d) the managing of resources during events, including alternative sources;

f) the identification and assignment of staff roles and responsibilities during an event.

FMS.17 The hospital ensures preparedness for internal disasters.

FMS.17.1 The hospital has a plan to deal with potential internal disasters. The plan includes:

FMS.17.1.1 Names and titles of all staff to be called in case of internal disaster, their contact numbers, and action cards.

FMS.17.1.2 The control room location and the position of the individual in charge.

FMS.17.1.3 The duties and responsibilities of hospital leaders.

FMS.17.1.4 The procedure for relocation of patients.

FMS.17.1.5 The individual responsible for announcing the emergency state and contacting local authority.

FMS.17.1.6 Individual(s) authorized to deal with the electricity supply and medical gas system and to shut them off as needed in case of fire or explosions in the hospital.

FMS.17.1.7 The meeting point for the staff in case of horizontal evacuations (assembly points) inside the building.

FMS.17.1.8 The meeting point for the full evacuation (holding area) outside the building.

FMS.17.1.9 The evacuation procedure for patients, visitors, and employees.

FMS.17.2 Every department has a specific internal disaster plan that addresses departmental actions in case internal disasters.

FMS.17.3 There are evacuation maps posted hospital wide indicating locations of:

FMS.17.3.1 You are here.

FMS.17.3.2 Fire extinguishers.

FMS.17.3.3 Fire hose reel/cabinets.

FMS.17.3.4 Fire blankets.

FMS.17.3.5 Escape routes.

FMS.17.3.6 Assembly points.

FMS.17.3.7 Fire exits.

FMS.17.3.8 Call points break glass/pull station.

FMS.17.3.9 Medical gas isolation valves.

Standard Intent:

Hospitals need to assess the type of internal disasters it is more likely subjected to and determine the type of actions needed to be taken in order to ensure patient and staff safety and continue the medical services provided.

Such disasters might include: fire emergencies, emergencies of hazardous materials spills, and any other emergencies that require evacuation of patients and/or staff.

There must be a clear internal disaster plan with roles and responsibilities for leaders and staff to refer to when needed.

As unique actions need to be considered for certain departments (such as Operating Rooms and Intensive Care Units) due to nature of it occupancy, a department-specific internal disaster plan needs to be created.

FMS.18 The hospital has a system for scheduling and conducting fire drills regularly.

FMS.18.1 Fire drills are scheduled and conducted regularly in all departments.

FMS.18.2 Fire drills are conducted during different shifts to test:

FMS.18.2.1 Using Rescue, Alarm, Confine, Extinguish/Evacuate (RACE) procedure.

FMS.18.2.2 Using Pull, Aim, Squeeze, Sweep (PASS) procedure.

FMS.18.2.3 The ability to contain the fire when it starts.

FMS.18.2.4 Staff performance in the event of fire.

FMS.18.2.5 Evacuation procedures.

FMS.18.2.6 Whether the oxygen and electricity supplies were shut off at the right time.

FMS.18.3 All staff participate in the fire drills.

FMS.18.4 All fire drills' results and corrective actions are documented and integrated into the quality improvement program.

FMS.18.5 A full fire drill is conducted for the internal disaster plan once a year and this drill is evaluated.

Standard Intent:

Fire safety and evacuation plans outline staff duties and responsibilities in time of emergency. On-going training is required to help ensure that staff is aware of those duties and responsibilities. Fire drills serve as an opportunity for staff members to demonstrate under simulated fire conditions that they can perform those duties and responsibilities safely and efficiently. It's also a time for them to show that they are aware of defend-in-place strategies and can take advantage of the facility's fire safety features and egress facilities to protect the people in their care.

Fire drills are more than an exercise designed to evaluate staff response to a simulated emergency. They are also a test of your facility's fire safety/evacuation plans and staff training programs. Not all fire drills run as expected, therefore, staff and management need to learn from them and correct mistakes made. It's important, therefore, that there be a critique of each drill so that any problems encountered can be addressed. Perhaps the problems are due to incomplete or outdated fire safety/evacuation plans. Perhaps there's a need for additional staff training.

It is important to cover all departments and all shifts of a department. It is also important that all department's staff participate and to mix between announced and un-announced drills to test staff readiness.

Drills need to be documented.

FMS.19 The hospital supports fire prevention.

FMS.19.1 The hospital ensures procuring materials like curtains and drapes that are fire retardant.

FMS.19.2 The hospital ensures separating all dangerous materials or flammables from heat generating areas.

FMS.19.3 The hospital ensures installing fire rated walls as appropriate, especially in high risk areas like the laboratory, electrical rooms, and kitchen.

FMS.19.4 The hospital ensures installing fire stop materials to seal penetrations as appropriate (especially in technical rooms, electrical rooms, and escape routes).

FMS.19.5 The hospital ensures developing and scheduling staff training programs on the use of fire extinguishers.

Standard Intent:

Hospital occupants fire safety needs to be ensured through number of facility control measures besides staff training. These measure need to include procurement of fire rated materials such as furniture and curtains (should be proved through materials specs) and establishing fire and smoke compartments specially for high risk areas like the laboratory, electrical rooms, and kitchen. Facility management and safety team should be able to provide floor layouts of such compartments and fire walls should have plate to certify that it is fire rated with required hour-protection. Fire rating should also include windows glass and doors along the compartment.

Whenever penetration is made, approved fire stop materials should be installed for sealing the penetration.

Also, staff training schedule on fire extinguisher usage should be provided considering different types of fire extinguishing systems.

FMS.20 Fire extinguishers are available in the hospital and are properly distributed.

FMS.20.1 The fire extinguishers are adequate in number as per civil defense guidelines.

FMS.20.2 The fire extinguishers are appropriately distributed throughout the hospital.

FMS.20.3 The fire extinguishers are appropriately positioned as per civil defense guidelines.

FMS.20.4 The fire extinguishers are inspected monthly to assess functionality.

Standard Intent:

The selection of fire extinguishers for a given situation shall be determined by the character of the fires anticipated, the construction and occupancy of the individual property, the vehicle or hazard to be protected, ambient-temperature conditions, and other factors. The number, size, placement, and limitations of use of fire extinguishers

required shall meet the requirements of the Civil Defense Guidelines for healthcare occupancies.

To ensure fire extinguishers functionality, documented monthly inspection needs to be documented with inspection tag placed on the extinguisher.

FMS.21 The hospital has an effective fire alarm system.

FMS.21.1 There is a fire alarm system that is functioning and regularly inspected as per civil defense guidelines.

FMS.21.2 The fire alarm system testing results are documented.

FMS.21.3 The fire alarm system has preventive maintenance.

FMS.21.4 The elevators are connected to the fire alarm system.

Standard Intent:

To ensure functionality of hospital's fire detection and alarm system a record of all inspections, testing, and maintenance shall be provided that includes the following information regarding tests and all the applicable information requested in:

(1) Date

(2) Test frequency

(3) Name of property

(4) Address

(5) Name of person performing inspection, maintenance, tests, or combination thereof, and affiliation.

(6) Designation of the detector(s) tested.

(8) Functional test of detectors.

(9) Functional test of required sequence of operations.

(10) Check of all smoke detectors.

(11) Loop resistance for all fixed-temperature, line-type heat detectors.

(12) Other tests as required by equipment manufacturers.

(13) Other tests as required by the authority having jurisdiction.

(14) Signatures of tester and approved authority representative.

(15) Disposition of problems identified during test (e.g., owner notified, problem corrected/successfully retested, device abandoned in place).

Testing Frequency. Testing shall be performed in accordance with an approved schedule.

FMS.22 The hospital has a fire suppression system available in the required area(s).

FMS.22.1 The hospital has a functional sprinkler system.

FMS.22.2 The hospital has clean agent suppression system.

FMS.22.3 The hospital has wet chemical system.

FMS.22.4 The hospital has stand pipes and hose system.

Standard Intent:

In a wide range of applications where human lives and material assets need to be protected against the effects, reliable fire extinguishing systems need to be properly installed and maintained.

Hospitals need to endure that such systems (sprinklers, clean agent suppression, wet chemical, stand pipes and hose systems) are properly installed (depending on room functions), that their functions are by any means not interrupted due surrounding practices (improper storage, adjacent construction activities, and that their functions are regularly inspected and maintained.

FMS.23 There are fire exits that are properly located in the hospital.

FMS.23.1 Fire exits are available and are properly located in the hospital.

FMS.23.2 Fire exits are not locked.

FMS.23.3 Fire exits are not obstructed.

FMS.23.4 Fire exits have panic hard ware.

FMS.23.5 Fire exits are fire resistant.

FMS.23.6 Fire exits are clearly marked with illuminated exit sign.

Standard Intent:

To ensure safe evacuation during emergencies, hospitals must maintain the integrity of its fire exits (including exit routes, exit doors, exit stares and landing to a safe outside public area) through the following:

1. Fire exits are available and are properly located in the hospital.
2. Fire exits are not locked.
3. Fire exits are not obstructed.
4. Fire exits have panic hard ware.
5. Fire exits are fire resistant.
6. Fire exits are clearly marked with illuminated exit sign.

FMS.24 The hospital and its occupants are safe from fire and smoke.

FMS.24.1 The hospital implements a strict "No Smoking" policy.

FMS.24.2 There are no obstructions to exits, fire extinguishers, fire alarm boxes, emergency blankets, safety showers, and eye wash stations.

FMS.24.3 Emergency lighting is adequate for safe evacuation of the hospital.

FMS.24.4 Storage areas are properly and safely organized:

FMS.24.4.1 Shelves and racks are sturdy and in good condition.

FMS.24.4.2 No items stored directly on the floor (a minimum of ten centimeters is left to manage spills).

FMS.24.4.3 Items should be stacked on a flat base.

FMS.24.4.4 Heavier objects are close to the floor and lighter/smaller objects are higher.

FMS.24.4.5 Items are not stacked so high to block sprinklers or come in contact with overhead lights or pipes (a minimum distance of fifty centimeters from ceiling level).

FMS.24.5 Fire rated doors are available according to the hospital zones with no separation between walls and ceiling to prevent smoke spread between rooms and areas.

Standard Intent:

To ensure that hospitals and its occupants are safe from fire hazards, there are number of measures needed to be implemented. This includes:

1. Adopting a strict No-Smoking policy that clearly defines smoking, states the hospital's policy, specify smoking designated areas and any exceptions.

2. Ensure free access to exits, fire extinguishers, fire alarm boxes, emergency blankets, safety showers, and eye wash stations.

3. Provision of necessary emergency evacuation lighting.

4. Follow safe storage practices all-over the organization.

5. Installing necessary Fire rated doors.

FMS.25 The hospital has a biomedical equipment plan to ensure that the medical equipment are regularly monitored, maintained, and ready for use.

FMS.25.1 The hospital has adequate number of qualified biomedical staff.

FMS.25.2 There is a written biomedical equipment plan that covers the following:

- FMS.25.2.1 A comprehensive inventory of medical equipment with their corresponding locations.
- FMS.25.2.2 Preventive maintenance program that conforms with the manufacturer's instructions.
- FMS.25.2.3 The program specifies, for each equipment, the frequency of checks, methods of checks, acceptance criteria, and actions to be taken in the event of unsatisfactory results.
- FMS.25.2.4 The program includes the process for investigation and follow-up of equipment failure that addresses reporting of failure, immediate remedial actions, assessment of the failure effect on reported results and services (needs alignment), and requalification of the equipment.
- FMS.25.2.5 Electrical safety testing for patient related equipment.
- FMS.25.2.6 History record for the maintenance schedule, failure incidence, and repairs done.

FMS.25.3 Technical service manuals for all equipment are available at the biomedical workshops.

FMS.25.4 Operator manuals are available at all departments using the equipment.

FMS.25.5 The hospital ensures that all maintenance works are conducted by qualified and trained staff.

FMS.25.6 Equipment maintenance and repairs are documented to help in the decision making for replacement.

FMS.25.7 Investigation procedures conform to manufacturer's instructions.

FMS.25.8 There is an equipment recall system that is implemented.

FMS.25.9 Each department has a back-up or alternative for each critical equipment to cover for prolonged downtime.

FMS.25.10 Preventative Maintenance data are used for upgrading/replacing of equipment.

Standard Intent:

To ensure that medical equipment are safe to use through regularly inspection, maintenance and testing, a medical equipment management program must be implemented. Such a program needs to include:

1. Availability of a valid medical equipment management plan.

2. Inventory of medical equipment's that covers at least (Equipment name, its manufacturer, model, serial number, location, organization number and maintenance history).

3. Availability of a system for medical equipment's alerts and recalls monitoring through SFDA and manufacturer notifications and reporting medical equipment failures in a death, serious injury or illness to SFDA.

4. Availability of necessary service and operation manual whether hardcopy or softcopy to refer to when needed.

5. Availability of calibrated necessary test and calibration equipment's.

Since medical equipment's failures are expected, the hospital needs to develop a risk-assessment based back up plan for failed medical equipment's through provision of a stand-by medical equipment or shifting to an equal medical intervention alternative.

The program needs to be run by qualified biomedical engineers through education, experience and training.

FMS.26 The hospital has policies and procedures that support the medical equipment management program.

FMS.26.1 There is a policy to perform inspection on all new equipment for conformity before commissioning including those brought for "demos".

FMS.26.2 There is a written policy for tagging medical equipment as follows:

FMS.26.2.1 Preventive maintenance with testing date and due date.

FMS.26.2.2 Inventory number.

FMS.26.2.3 Removal from service.

FMS.26.2.4 Electrical safety check.

FMS.26.3 There is a policy for removal of equipment from service.

FMS.26.4 There is a policy to address agent or contractor repairs.

FMS.26.5 There is a policy to eliminate the use of extension cords.

FMS.26.6 There is a policy to restrict the use of cellular phones in the intensive care units, operating room, and cardiology units, as needed.

Standard Intent:

Medical equipment management program needs to be supported by policies and procedures that mitigate the risks associated with the introduction of new medical equipment into service, tagging of medical equipment, removal of equipment from service, agent/sub-contractors repairs, use of extension cords, and cellular phones.

FMS.27 Hospital staff are trained on safe operation of medical equipment.

FMS.27.1 Hospital staff are trained to operate safely all medical equipment.

FMS.27.2 The training includes physicians, nurses, and paramedics.

FMS.27.3 The training considers the following:

FMS.27.3.1 New equipment.

FMS.27.3.2 Staff transferred from a department to another.

FMS.27.3.3 New staff hired.

FMS.27.3.4 Recurrent misuse of equipment.

Standard Intent:

Staff are the hospital’s primary source of contact with patients, families, and visitors. Thus, they need to be educated and trained to carry out their roles in identifying and reducing risks, protecting others and themselves, and creating a safe and secure facility,

Staff responsible for operating or maintaining medical equipment should receive special training. The training can be from the hospital, the manufacturer of the technology, or some other knowledgeable source.

The training program should be designed in a way that ensures that it covers staff transferred from a department to another, new staff hired, and departments with evidence of recurrent misuse of equipment.

FMS.28 The hospital has a utility system management plan.

FMS.28.1 The hospital has adequate number of qualified staff to manage the utility system.

FMS.28.2 There is a utility system management plan that includes management of failure or interruption of the following utilities:

- FMS.28.2.1 Normal power.
- FMS.28.2.2 Emergency power, cases of no power at sockets at critical areas, and lamp failure at critical areas.
- FMS.28.2.3 Elevators.
- FMS.28.2.4 Water supply.
- FMS.28.2.5 Reverse osmosis plant.
- FMS.28.2.6 Air-conditioning fan coil unit (FCU) at patient rooms.
- FMS.28.2.7 Air-conditioning air handling unit (AHU) at operating rooms.
- FMS.28.2.8 Medical gas system.
- FMS.28.2.9 Sewer lines.
- FMS.28.2.10 Boiler.
- FMS.28.2.11 Telephone service (Public Address Exchange - PABX).
- FMS.28.2.12 Intercom, nurse call, and overhead paging.
- FMS.28.2.13 Fire alarm.

FMS.28.3 The utility system management plan includes description of necessary hospital programs to:

- FMS.28.3.1 Acquire necessary equipment.
- FMS.28.3.2 Upgrade equipment.
- FMS.28.3.3 Upgrade physical condition of the building.

FMS.28.4 Emergency plans are tested in simulation at least once a year and the test results are evaluated.

FMS.28.5 The utility system plan ensures the availability of the following:

FMS.28.5.1 Technical utility drawings that show the distribution lines for all utilities and how to control them centrally and peripherally so that lines can be controlled as required in case of emergency.

FMS.28.5.2 Statistical data produced by the maintenance management system as an indicator to evaluate performance of the systems, suggest improvements and upgrade as required.

Standard Intent:

Utilities can be defined as the systems and equipment that support essential services that provide for a safe health care. Such systems include electrical distribution, water distribution, ventilation and airflow, medical gases, plumbing, heating, waste, and communication, and data systems.

Effective utility management throughout the hospital creates a safe patient care environment.

To ensure 24/7 provision of utility services, the utilities management plan needs to highlight that specifies what corrective actions are going to be taken to restore the functionality of interrupted utilities and what back-up plans are going to be initiated in case repair activities fail.

The plan should identify the areas that pose the highest risk to patients and staff (in case of utility interruptions, for example, it identifies where there is the greatest need for electricity and water supply and assesses and minimizes the risks of utility system failures in these areas.

Hospitals must test it utility failure management plans in simulation at least once a year and the test results are evaluated.

Monitoring each of the facility management programs through data collection and analysis provides information that helps the hospital prevent problems, reduce risks, make decisions on system improvements, and plan for upgrading or replacing.

FMS.29 The hospital implements a preventive maintenance plan.

FMS.29.1 There is a preventive maintenance plan that covers at least the following:

- FMS.29.1.1 Electrical system.
- FMS.29.1.2 Elevators.
- FMS.29.1.3 Refrigerators/Freezers.
- FMS.29.1.4 Air conditioning system.
- FMS.29.1.5 Medical gas system.
- FMS.29.1.6 Medical suction.
- FMS.29.1.7 Domestic water system, including water pumps and fire hydrants.
- FMS.29.1.8 Fire water system, including fire pumps.
- FMS.29.1.9 Boilers.
- FMS.29.1.10 Plumbing.
- FMS.29.1.11 Low current and communication system.
- FMS.29.1.12 Pavement and ground.
- FMS.29.1.13 Hospital building and ancillaries.

FMS.29.2 The hospital ensures all maintenance works are conducted by qualified and trained staff.

Standard Intent:

For the continued safe operation of hospital utilities, a schedule of periodic preventive maintenance should be established. It is the responsibility of the health care facility to ensure that this program is effective.

Hospitals should be able to provide an approved 52-week maintenance schedule for all utilities, supported by documented evidence of maintenance work orders that show what maintenance activities have been conducted along with corrective action and name and signature of the maintenance team.

Because of the complex nature of the utility systems, repairs should be made by qualified service personnel. Service could be provided by a competent internal engineering group, the manufacturer, or other reliable agency.

Personnel concerned with the application and maintenance of electric appliances, including physicians, nurses, nursing assistants, engineers, and technicians, shall be aware of the risks associated with their use.

FMS.30 The hospital ensures electrical safety.

FMS.30.1 The electrical outlets are identified for:

FMS.30.1.1 Voltage (110/220).

FMS.30.1.2 Source (essential/prime).

FMS.30.2 Thermal inspection of circuit breakers is annually conducted for:

FMS.30.2.1 Operating Room.

FMS.30.2.2 Laboratory.

FMS.30.2.3 Critical care units.

FMS.30.2.4 Alarm system.

FMS.30.2.5 Blood storage.

FMS.30.2.6 Medical gas system.

FMS.30.3 There is an earthing system in the roof top and sockets used for medical equipment.

Standard Intent:

To ensure electrical safety:

1- hospital electrical receptacles should have clear labeling of voltage rating (110/220) and power source to differentiate between normal and emergency electrical supplies. Such information is crucial for clinical staff, for example, to ensure that the function of life-support medical equipment's will not be affected during power interruptions.

2-Annual thermal imaging a (technology that utilizes detection of heat signatures to pinpoint critical areas where the circuitry might be damaged) needs to be conducted showing heat signatures and levels.

3-Earthing system in the roof top and sockets used for medical equipment needs to be available to protect handlers of such equipment from leakage electrical currents.

FMS.31 The hospital ensures that emergency power covers the critical areas in case of failure.

FMS.31.1 The hospital has an emergency power that covers at least the following critical areas:

- FMS.31.1.1 Operating room.
- FMS.31.1.2 Labor and delivery.
- FMS.31.1.3 Critical care units.
- FMS.31.1.4 Alarm system.
- FMS.31.1.5 Fire pumps
- FMS.31.1.6 Blood storage.
- FMS.31.1.7 Medical gas system.
- FMS.31.1.8 Refrigerators in the pharmacy, laboratory, medical store, and kitchen.
- FMS.31.1.9 Elevators.
- FMS.31.1.10 Escape routes/corridors.
- FMS.31.1.11 Morgue.
- FMS.31.1.12 Medications stores.
- FMS.31.1.13 Emergency room.

FMS.31.2 The hospital ensures the readiness of its emergency power generator(s).

- FMS.31.2.1 The hospital maintains its generator(s) on a periodic basis. The maintenance results are documented.
- FMS.31.2.2 The hospital performs weekly test without load for ten minutes.
- FMS.31.2.3 The hospital performs monthly on load test for thirty minutes.
- FMS.31.2.4 The hospital performs full load test every three years on external load.
- FMS.31.2.5 The hospital generator starts normally without load for ten minutes.

Standard Intent:

An emergency power system is an independent source of electrical power that supports important electrical systems on loss of normal power supply. A standby power system may include a standby generator, batteries and other apparatus. Emergency power systems are installed to protect life and property from the consequences of loss of primary electric power supply.

Hospitals must ensure the readiness of its emergency power systems through regular maintenance and testing.

FMS.32 The hospital ensures proper maintenance of the medical gas system.

FMS.32.1 The medical gas system is regularly tested for:

- FMS.32.1.1 Pressure.
- FMS.32.1.2 Leaks.
- FMS.32.1.3 Functionality of valves, alarms, pressure gauge, and switches.

FMS.32.2 There is a policy and procedure that ensures effective use of medical gas system. Areas covered include, but are not limited to, the following:

- FMS.32.2.1 The procedures to follow for taking any part of the system offline.
- FMS.32.2.2 Commissioning and testing new branching or modifications.
- FMS.32.2.3 The procedure for ordering and filling liquid oxygen.
- FMS.32.2.4 Documenting all repairs/alterations/tests/filling logs/consumption.

FMS.32.3 Compressed medical air is regularly tested for humidity and purity.

FMS.32.4 The central medical gas station is in a safe and secure place.

FMS.32.5 The outlets of medical gases in patient care areas are clearly marked with the type of gas and have different connections according to the gas type.

FMS.32.6 All medical gas pipes are clearly marked and labeled for the contents and direction of gas flow.

FMS.32.7 In case of gas pipe repairs or new extensions, outlets are tested for the type of gas to ensure the correct type is delivered through the new pipe. Results of testing are recorded and maintained with engineering and the unit manager.

FMS.32.8 The hospital keeps standby oxygen and medical air cylinders enough for forty-eight hours of average consumption.

FMS.32.9 The gas cylinders are regularly tested for gas type, amount, and any leaks.

FMS.32.10 Emergency shut off valves are available in all units and are clearly marked with areas/rooms affected.

FMS.32.11 The hospital dedicates the responsibility of the closure of shut off valves to well-trained individual(s) available in the unit concerned.

FMS.32.12 The hospital has adequate medical gases outlets in the patient care areas as appropriate and these outlets are to be error proof medical gas outlets-preferred to be in accordance with DIN standards related to gases piping, outlets and valves.

Standard Intent:

Medical gas systems are a standard feature of most healthcare facilities, and they require special monitoring and maintenance to ensure they are operating properly. Unlike other medical equipment and systems, their use of gas under pressure makes

them vulnerable to a unique set of potential failures, which may not be readily apparent. This makes medical gas preventative maintenance critical to a problem-free working environment.

The medical gas source equipment used will vary, depending on the type of gas and the size of the institution. For smaller needs, cylinder-only solutions are often adequate. For large hospitals with substantial requirements, large reservoirs of liquid oxygen may be maintained to provide piped gas. Compressors are also used to provide medical air, and vacuum pumps are needed for suction. Failing to properly monitor these complex pressurized systems can be costly, both in terms of increased use of consumables and damage to permanent equipment.

FMS.33 The hospital has a documented system for handling the various types of compressed gasses.

FMS.33.1 There is a policy on how to handle various types of compressed gasses, which includes:

FMS.33.1.1 Storing them in a well-ventilated area.

FMS.33.1.2 Positioning them upright the wall and secured by a chain.

FMS.33.1.3 Separating any flammables from oxidizing gases.

FMS.33.2 Exhausts of the following gases are extended to the roof and identified:

FMS.33.2.1 Laboratory safety cabinet gases of a certain classes.

FMS.33.2.2 Central vacuum gases.

FMS.33.2.3 Scavenger gases of certain types.

FMS.33.2.4 Bone marrow transplantation (BMT) laboratory gases.

Standard Intent:

Due to the nature of gas cylinders, special storage and handling precautions are necessary. The hazards associated with compressed gases include oxygen displacement, explosion hazards, toxic effect of some gases, as well as the physical hazards of a ruptured cylinder. Hospitals need to develop and implement a policy for the on how to handle, store, transport and dispose of various types of compressed gasses.

FMS.34 There is a periodic preventive maintenance plan for heating, ventilating, and air-conditioning.

FMS.34.1 There is a periodic preventive maintenance (PPM) plan for heating, ventilating, and air-conditioning (HVAC) that is supported by trained and specialized staff/contractor.

FMS.34.2 The HVAC maintenance records are maintained.

FMS.34.3 The HVAC is maintained to control the air quality by:

FMS.34.3.1 Cleaning /replacement of filters.

FMS.34.3.2 Cleaning of diffuser.

FMS.34.3.3 Cleaning of ducts.

FMS.34.4 HEPA filters are monitored on a monthly basis and the results are documented.

FMS.34.5 Air change per hour is maintained as per national and international guidelines (e.g., American Society of Heating, Refrigerating & Air-Conditioning Engineers, ASHRAE).

Standard Intent:

The HVAC system functions not only to maintain minimum requirements of comfort and ventilation, but is an essential tool for the control of infection, removal of noxious odors, dilution, and expelling of contaminants, and establishment of special environmental conditions conducive to medical procedures and patient healing. Hospitals must develop and implement a planned preventive maintenance for the hospital's heating, ventilation, and air conditioning system that is supported by the qualified staff.

FMS.35 The hospital ensures proper air flows (positive, negative, balanced) in the required locations.

FMS.35.1 Appropriate air flows (positive, negative, balanced) are established and monitored in operating room(s).

FMS.35.2 Appropriate air flows (positive, negative, balanced) are established and monitored in labor and delivery.

FMS.35.3 Appropriate air flows (positive, negative, balanced) are established and monitored in isolation room(s).

FMS.35.4 Appropriate air flows (positive, negative, balanced) are established and monitored in critical care unit(s).

FMS.35.5 Appropriate air flows (positive, negative, balanced) are established and monitored in clean and dirty utility.

FMS.35.6 Appropriate air flows (positive, negative, balanced) are established and monitored in janitorial closet.

FMS.35.7 Appropriate air flows (positive, negative, balanced) are established and monitored in the laboratory.

FMS.35.8 Appropriate air flows (positive, negative, balanced) are established and monitored in triage and trauma management areas.

FMS.35.9 Appropriate air flows (positive, negative, balanced) are established and monitored in the central sterilization and supply department.

Standard Intent:

Microbiological transmission in healthcare setting is inevitably a very potential risk. The main routes are droplets, contact, and air borne transmissions. Infection control for patients, healthcare providers and visitors is of paramount importance in the healthcare process in medical facilities. Proper air conditioning of medical care facilities is helpful in prevention and treatment of diseases.

Design of the ventilation system shall provide air movement which is generally from clean to less clean areas. Maintaining air differential pressure between areas in critical departments as stated by the standard is crucial for patient and staff safety. Hospitals must ensure that a permanently installed visual mechanism to constantly monitor the pressure status of the rooms when occupied.

FMS.36 The hospital provides appropriate control of temperature and humidity in the required locations.

FMS.36.1 Temperature and humidity are controlled and regularly monitored in operating and recovery room(s).

FMS.36.2 Temperature and humidity are controlled and regularly monitored in nursery.

FMS.36.3 Temperature and humidity are controlled and regularly monitored in critical care unit(s).

FMS.36.4 Temperature and humidity are controlled and regularly monitored in sterile storage supply.

FMS.36.5 Temperature and humidity are controlled and regularly monitored inpatient rooms.

Standard Intent:

Although there are many steps a medical care facility can take to reduce the chance that a patient falls ill for any reason, one of the top ways that not all treatment centers may have considered is through humidity monitoring and control.

Mold, bacteria, and fungi responsible for causing many lung-related medical episodes thrive when the air is especially moist. However, buildings operators should be sure that moisture levels do not drop too much, as overly dry air can aggravate mucus membranes and damage sinuses.

Therefore, hospitals must provide necessary controls of temperature and humidity in the required locations.

FMS.37 The hospital has a periodic preventive maintenance plan for the water system.

FMS.37.1 There is a periodic preventive maintenance plan (PPM) for the water system that is supported by trained and specialized staff/contractor.

FMS.37.2 The PPM records are maintained for the following:

FMS.37.2.1 Water is available twenty-four hours a day, seven days a week.

FMS.37.2.2 The incoming water supply is checked regularly for at least: chemicals (once every six months) and bacteria (monthly), and results are monitored.

Standard Intent:

Water quality can change suddenly from many causes, some of which occur outside of the hospital, such as a break in the supply line to the hospital. When there is a disruption in the usual source of water supplied to the organization, emergency potable water supplies must be immediately available.

Hospitals must develop a maintenance program for its water system with documentation along with necessary testing.

FMS.38 The hospital ensures safe sewage handling and disposal.

FMS.38.1 Sewage handling and disposal is safely conducted in an efficient and sanitary manner according to professional codes of practice.

Standard Intent:

To ensure safe disposal of sewage from different hospital departments (Operating theaters, laboratories, maintenance workshops and kitchen), hospitals must follow national sewage disposal guidelines (Municipality).

FMS.39 The hospital maintains the kitchen and laundry equipment in good working condition.

FMS.39.1 Laundry equipment are regularly inspected and tested.

FMS.39.2 Results of inspection and testing of kitchen equipment are documented as follows:

FMS.39.2.1 Hood fans are in good operating condition and free from grease.

FMS.39.2.2 Hood filters are cleaned weekly and no cooking is done with missing filters.

FMS.39.2.3 Cold room temperature is monitored.

FMS.39.2.4 Kitchen and pantry microwaves, stoves, and ovens are at least annually tested and maintained.

Standard Intent:

Hospital should maintain the kitchen and laundry equipment in good working condition. Maintenance and inspection program should be developed and results documented with proper action taken highlighted.