

DNVGL-DS-HC202

STANDARD, INTERPRETIVE GUIDELINES AND SURVEYOR GUIDANCE

INTERNATIONAL ACCREDITATION REQUIREMENTS FOR:

PRIMARY CARE PROVIDERS

NOVEMBER 2014, VERSION 2.0

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FOREWORD

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

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

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

These Standards, Interpretive Guidelines and Surveyor Guidance document are based upon the NIAHO® accreditation Standard for Hospitals that has been approved by the US Government's Centers for Medicare and Medicaid (CMS).. When new or revised requirements are introduced to the international requirements these will be published together with a time frame that will indicate when Outpatient Specialist Centres are expected to be able to demonstrate compliance.

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

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

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Section 1 Scope

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

- 1) provides a first point of contact for community with the healthcare service
- 2) is primarily engaged in providing healthcare and provides:
 - A. preventative care and information on healthy lifestyle choices
 - B. diagnostic and therapeutic services for common medical conditions;
 - C. an assessment of the urgency of medical problems and directs patients to the best place for care, including making referrals where necessary;
- 3) maintains clinical records on all patients;

Section 2 Application

The requirements of this standard are generic and are intended to be applicable to all Primary Care Providers (PCPs) as defined above. Where any requirements of this standard cannot be applied due to the nature of the PCP and its processes, this can be considered for exclusion. Where exclusions are made, claims of conformity to this standard are not acceptable, unless such exclusions do not affect the PCP's ability or responsibility to control the manner required by this standard. Any claims of exclusion shall be detailed and justification provided.

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

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

These Standards rely on a management system approach. This implies that identifying, understanding and managing the system of interrelated processes for quality and safety improves the PCP's effectiveness and efficiency. Application of the management systems approach principle leads to the following actions:

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

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

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

Do: Implementing, including training and operational issues,

Check: Checking, including monitoring and corrective action,

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

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

Section 3 Quality Management System (QM)

QM.1 Quality Management System

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

QM.2 ISO 9001 Quality Management System

- SR.1** Compliance with the ISO 9001 standard shall occur within three (3) years after the initial DNV PCP Accreditation. The PCP shall either demonstrate compliance with the ISO 9001 Quality Management System principles through a DNV PCP Accreditation survey or maintain Certification through an Accredited Certification Body. Only certificates covered by an accreditation by MLA (International Accreditation Forum Multilateral Recognition Agreement) signatory shall be eligible. The PCP shall maintain ISO 9001 compliance or formal Certification in order remain eligible for DNV PCP Accreditation.
- SR.2** The Certification Body shall meet the following requirements:
- it shall be accredited under codes for EAC code 38 or NACE code 85.11 by a national accreditation body that is a member of IAF; and
 - It shall have certified or conducted a pre-assessment at a minimum of twelve (12) organisations that provide primary care.
- SR.3** The PCP shall initiate and continue implementation of the ISO 9001 methodology to achieve compliance or certification as stated in QM.1. At a minimum the PCP shall be able to demonstrate at the time of the DNV PCP Accreditation survey evidence of the following:
- Control of Documents: the PCP's documents (i.e. policies, procedures, forms) are structured in a manner to ensure that only the proper revisions are available for use;

- b) Control of Records: the PCP ensures that suitable records are maintained for the requirements of this standard;
- c) Internal Surveys (Internal Audits): the PCP conducts internal reviews of its processes and that resultant corrective/preventive action measures have been implemented and verified to be effective; and
- d) The PCP has established measurable quality objectives and the results are analyzed and addressed;

Interpretive Guidelines:

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

The organization shall demonstrate that aspects consistent with ISO 9001 methodologies identified in SR.3a-SR.3d (above) are present. This may not be of level of compliance with ISO 9001 but will be in place in some manner. If the survey team is conducting the annual ISO periodic survey during the accreditation survey, the survey team will assess the applicable ISO 9001 requirements and review the status of findings and corrective action(s) taken to validate they have been implemented. A separate ISO 9001 report will be created to indicate any findings as a result of the ISO survey when applicable.

QM.3 Quality Outline/Plan

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

Surveyor Guidance:

The organization will present documentation to the survey team that clearly defines how quality and performance are measured, monitored, analyzed and continually improved. This may be demonstrated in a variety of ways. An example would include a Quality Manual or Performance Improvement / Quality Management Plan. It will be verified that the organization has clearly defined how they measure quality and performance. The monitoring methods, data analysis and effectiveness of action(s) taken will be verified.

QM.4 Management Representative

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

Interpretive Guidelines:

The senior leadership is required to designate an individual as a Management Representative. A requirement of ISO 9001 is to define the Management Representative's responsibilities. The Management Representative is responsible for the process for internal reviews (internal audit) and management

reviews to ensure that corrective and preventive action(s) are carried out and are measured for effectiveness. The role may be assigned to a current practitioner or employee.

Surveyor Guidance:

It will be verified that that the PCP has identified a Management Representative and that there is a defined scope of responsibilities for this individual.

QM.5 Documentation and Management Reviews

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

Interpretive Guidelines:

The organization shall evidence that it has identified, applied and documented nonconformity (non-compliance) throughout the organization and the subsequent corrective/preventive action(s) taken. The organization may demonstrate this in various ways, as appropriate to the organizations size. There should be information present that validates that the organization has corrected the nonconformity and that the action(s) implemented have been effective and sustained. The organization should be able to demonstrate that planned actions were effective by quantifiable measurement.

The PCP shall be able to evidence that a management review, (a formal evaluation by top management of the status, adequacy and effectiveness of the quality management system (QMS)) has taken place.

QM.6 System Requirements

SR.1 A group or individual shall oversee the Quality Management System that includes representatives from management, the healthcare team and service users, as appropriate to the size and complexity of the PCP. This group or individual shall conduct Management Reviews;

SR.2 Written document defining the Quality Management System, to include all clinical and non-clinical services, as appropriate to the size and complexity of the PCP;

SR.3 Statement of the Quality Policy;

SR.4 Measurable Quality Objectives; and

SR.5 Measurement / Prioritization of activities shall:

- a) Focus on high-risk, problem-prone areas, processes or functions;
- b) Consider the incidence, prevalence and severity of problems in these areas, processes or functions; and
- c) Affect health outcomes, improve patient safety and quality of care.

Interpretive Guidelines:

The Management Representative supports and facilitates the Quality Management System; however, it is the responsibility of senior leadership to review these activities and see that appropriate actions are taken for continual improvement. The Quality Manual or other similar document outlines the process that the organization has in place. This Quality Manual will include or reference the policies and procedures for the Quality Management System, Quality Policy, and Quality Objectives. The organization must demonstrate that Management Reviews are undertaken which encompass review of corrective/preventive actions taken, results from internal reviews (internal audits), customer (patient) satisfaction, data analysis (including litigation where applicable) and other performance improvement activities. The Management Review Process is to be carried out by senior leadership throughout the organization.

QM.7 Measurement, Monitoring, Analysis

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

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

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

- a) Threats to patient safety
- b) Patient Centered Care;
- c) Medication therapy/medication use; to include medication reconciliation, look alike-sound alike medications and the use of dangerous abbreviations;
- d) Effectiveness of pain management system;
- e) Infection control system, including healthcare acquired infections (HAI) and antimicrobial resistance;
- f) Customer satisfaction;
- g) Completeness and accuracy of healthcare/medical records;
- h) Physical Environment Management Systems;
- i) Infrastructure (including staffing, facilities, environment);
- j) Staff training and competence (knowledge, skills and attitude); and
- k) Coordination within and in-between services.

Interpretive Guidelines:

In order for the organization to continually improve its Quality Management System, the services and processes must be measured to determine their effectiveness. The PCP shall be able to evidence that through an internal review (internal audit), the organization has determined where corrective/preventive action(s) are to be taken and has processes in place to determine the effectiveness of these action(s).

As a minimum measurements of the elements listed in SR.1 – Sr.11 must be included within the PCP's internal review(s).

Section 4 Safety Risk Management (RM)

RM.1 Planning and Resources

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

Interpretive Guidelines:

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

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

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

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

The scope of the Safety Risk Management System shall include clinical and support activities as well as the physical environment. Facilities, supplies, and equipment should be maintained and ensure an

acceptable level of safety and quality, including the proper ventilation, light and temperature controls in pharmaceutical, food preparation, and other appropriate areas.

RM.2 Risk Assessment

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

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

Interpretive Guidelines:

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

The PCP shall provide evidence that they have undertaken risk assessments in accordance with PCP accepted practice. A variety of risk assessments from all services shall be provided as evidence.

RM.3 Risk Management

SR.1 The organization shall identify, document and implement suitable methodologies for the allocation of actions resulting from risk assessments. This shall include time lines, responsible persons and associated reporting and approval mechanisms being identified, implemented and maintained.

SR.2 Management shall establish the controls and put in place documented procedures for monitoring the effectiveness of the controls being applied to reduce or eliminate the hazards identified in the risk assessment process.

Interpretive Guidelines:

The PCP shall provide evidence that following risk assessment corrective actions are agreed, implemented and monitored in accordance with the PCP's approved document

Actions as a result of a variety of risk assessments from all services shall be provided as evidence.

RM.4 Reporting

SR.1 The PCP shall have documented procedures to define, record, analyze and learn from incidents that impact safety. This shall include medical errors and adverse patient events.

SR.2 The PCP shall have a policy and procedure for informing patients and/or their families about unexpected adverse events.

Interpretive Guidelines:

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

- I. Roles and responsibilities for the management of risk throughout the PCP;*

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

Surveyor Guidance:

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

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

Evidence of implementation of the above shall be available.

Section 5 Governing Body (GB)

GB.1 Legal Responsibility

SR.1 The PCP shall have an effective governing body legally, (or organized group or individual(s) who assumes full legal authority and responsibility for operations of the PCP), responsible for the conduct of the PCP as an institution. The governing body is responsible for all services provided in the PCP including all contracted services. If a PCP does not have an organized governing body, the persons legally responsible for the conduct of the PCP shall carry out the functions specified.

SR.2 The governing body (or organized group or individual(s) who assumes full legal authority and responsibility for operations of the PCP), healthcare team, and administrative officials (to include the chief executive officer and chief financial officer) are responsible and accountable for ensuring the following:

- a) The PCP is in compliance with all applicable national and local legislation and regulations regarding the health and safety of its patients;
- b) The PCP is licensed by the appropriate bodies; and
- c) Personnel working in the PCP are properly licensed / registered.

Interpretive Guidelines:

The PCP shall be able to demonstrate that it has an organized governing body and/or has written documentation that identifies the individual or individuals that are legally responsible for the conduct of the organization operations.

GB.2 Contracted Services

SR.1 The governing body or legally responsible individual(s) is/are responsible for services provided by the PCP whether or not they are provided under contract. The PCP shall evaluate and select contracted services entities/individuals based on their ability to supply products and/or services in accordance with the PCP's requirements.

SR.2 Criteria for selection, evaluation, and re-evaluation shall be established. The criteria for selection shall include the requirement that the contracted entity or individual to provide the products/services in a safe and effective manner and comply with the requirements of this document.

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

SR.4 The governing body or legally responsible individual(s) shall require annual management reviews of selected indicators to ensure that all contracted services, (including all joint ventures or shared services), provide services that are safe and effective and that comply with the requirements of this document.

Interpretive Guidelines:

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

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

The PCP shall determine the services that are carried out by a contracted entity and the scope of their responsibilities. A sample of these contracts will be reviewed to establish that they address the criteria for selection and the evaluation processes. Evidence will be provided verifying that the organization has reviewed the contract and performance of each entity no less than annually.

Section 6 Top Management (TM)

TM.1 Organisation and Qualifications

SR.1 The Governing Body shall ensure that the roles and responsibilities of top management have been defined and that top management is qualified through education and experience to be responsible for managing the PCP.

TM.2 Responsibilities

SR.1 Top Management are responsible for operating the PCP, according to the authority conferred by the governing body or legally responsible individual(s). The Top Management shall ensure;

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

SR.2 The Top Management shall ensure that the organization has defined and communicated the following:

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

SR.3 Top Management shall ensure that input from service users, their families, local communities as well as knowledgeable staff is gathered during the ongoing development and provision of services.

SR.4 Top Management shall ensure that the hospital informs the public of:

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

Interpretive Guidelines:

The PCP shall have clear lines of accountability and management throughout the organisation. Everyone involved in quality and patient safety within the PCP should understand the organizational leadership arrangements. The management/reporting structures should be clearly documented as should the lines of reporting and communication between key committees/groups/sub-committees.

Responsibilities of Top Management shall include ensuring that the hospital identifies and is compliant with applicable national and local legislation and regulations and that it identifies and responds to relevant health policy documents where appropriate. Top Management shall also have overall responsibility for ensuring that care provided throughout the hospital is based on "recognized standards" where these exist. Recognized standards should be based on current scientific knowledge (evidence based clinical guidelines). Tasks to ensure that care given is based on recognized standards may be delegated

through the organization provided that they are passed to competent individuals with adequate resources to perform the activities effectively.

Surveyor Guidance:

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

Verify that the governing body or legally responsible individual(s) for the organization has appointed Top Management and that they have met the requirement for this role within the organization and that they are responsible for managing the entire organization.

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

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

Section 7 Staffing Management (SM)

SM.1 Licensure, Registration and Certification

SR.1 The PCP shall have a policy and practice for outlining and verifying that all professionally registered staff possesses a valid and current license, registration or certification. This written policy shall be strictly enforced and compliance data reported to Quality Management oversight.

Interpretive Guidelines:

The PCP's policy and practice for performing initial and ongoing verification of the current licensure, registration and/or certification of all staff members as required by the organization, and national and regulatory requirements shall be reviewed and verified.

The PCP shall provide evidence that it ensures compliance and that data regarding verification and expirations is shared with Quality Management oversight.

SM.2 Professional Scope

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

Interpretive Guidelines:

The PCP's approved documented procedure shall be reviewed to verify that the PCP has a means of ensuring that all staff, including contract staff, students and volunteers are functioning within the limits of their scope of service as it has been defined by the PCP.

The PCP shall provide evidence that it ensures compliance and that data regarding variations is reported to the Quality Management oversight.

SM.3 Department Scope of Service

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

- a) the hours of operation;
- b) patient populations served;
- c) skill mix;
- d) core staffing and methods for determining and modifying staffing to meet patient or process needs;

Interpretive Guidelines:

The PCP should have a description of the scope of services provided for each department. For smaller PCPs this may be replaced by a scope of service for the entire organisation..

SM.3 Orientation

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

SR.2 All staff shall receive a documented orientation to specific job duties and responsibilities and their work environment both on initial appointment, when transferring from one area of the PCP to another or when there is a significant change in individual duties. As a minimum the orientation shall include the following areas:

- a) organizational structure;
- b) patient confidentiality and ethics;
- c) document control, retrieval and verification (specific to policies, procedures, and work instructions/protocols);
- d) internal reporting requirements for adverse patient events;
- e) patient safety;
- f) general safety (work environment);
- g) emergency procedures;
- h) infection control and universal precautions; and,
- i) other issues as required by the PCP and national and regulatory requirements.

SR.3 The PCP shall have a policy for ensuring staff competence following orientation. This should be implemented for all staff.

Interpretive Guidelines:

The purpose of orientation is to ensure that all staff are provided with the key information they require to help them to integrate into their role within the organization quickly, safely and effectively.

The PCP shall provide evidence that all staff, including contract staff, students and volunteers receive an orientation prior to working independently in their respective roles for the PCP. Orientation to specific job duties may be addressed within the department or service where the employee is assigned, but shall be completed prior to the employee working independently.

SM.4 Job Description

SR.1 All staff, whether clinical or supportive, including contract staff, students and volunteers shall have a current job description, (or job responsibilities), available that contains the experience,

educational and physical requirements, supervision, (as indicated), and performance expectations for that position.

Interpretive Guidelines:

A variety of job descriptions shall be provided to verify that the PCP has identified the appropriate experience, educational and physical requirements and performance expectations for the positions reviewed. This shall include contracted staff.

SM.5 Staff Performance Review

SR.1 The performance/competency evaluation of all staff shall be undertaken at least annually and shall contain indicators that objectively measure the ability of staff to perform their role. Variations shall be reported to Quality Management oversight. The following indicators should be considered:

- a) customer satisfaction feedback;
- b) training outcomes;
- c) competency evaluations;
- d) staff feedback;
- e) use of new technology/equipment/processes; and
- f) other indicators as determined by the PCP.

SR.2 The PCP shall aggregate objective performance data from sources that may include individual evaluations, incident reports, risk management, staff and patient feedback, and/or data analysis to identify variations for further training, coaching, and mentoring.

SR.3 The outcomes of this aggregated data shall be reported to Quality Management oversight as required to monitor staff performance improvement.

SR.4 The PCP shall share results of individual performance/evaluations/competence assessment with staff members that allows for staff feedback within a timeframe defined by the PCP.

SR.5 The PCP shall require each staff member, including contract staff, to participate in continuing education as required by individual licensing, registration or certification. Compliance with this standard shall be reported to Quality Management oversight.

Interpretive Guidelines:

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

- I. Customer satisfaction feedback;*
- II. Training outcomes;*
- III. Competency evaluations;*
- IV. Staff feedback;*

- V. *Use of new technology/equipment/processes; and*
- VI. *Other indicators as determined by the PCP.*

The PCP shall have an approved documented procedure outlining the process for sharing results of individual performance evaluations/competence assessment with staff members. This shall include processes for staff feedback within a timeframe defined by the organization.

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

In order to continually improve the fulfillment of their job responsibilities, the PCP shall require each staff member, including contract staff, to participate in continuing education as required by individual registration, licensure or certification, or PCP policy.

The PCP will provide a sample of aggregated data and staff records to verify compliance with all of the above.

SM.6 Clinical Performance Review

SR.1 Practitioner specific performance data is required to be evaluated, analysed and appropriate action taken as necessary when variation is present and/or standard of care has not been met as determined by the PCP. The following indicators should be considered:

- a) prescribing/administration of medications: Prescribing patterns, trends, errors and appropriateness of prescribing/administration;
- b) significant deviations from established standards of practice;
- c) poor clinical outcomes;
- d) timely and legible completion of patients' healthcare records; and
- e) any variant should be analyzed for statistical significance.

Interpretive Guidelines:

The PCP shall define and measure the respective elements within this standard to generate a quality profile for each practitioner, (professionally registered staff member), to be used for evaluation. A sample of profiles will be reviewed for verification of this standard requirement.

SM.7 Continuing Education

SR.1 All staff shall participate in continuing education that is related to their duties.

SR.2 The PCP shall undertake an annual documented training needs analysis, (TNA), identifying the training needs of all staff.

SR.3 The training needs analysis shall include which staff groups require training and the frequency of training updates. A risk based approach to determining the training needs and frequency shall be used and documented.

SR.4 Compliance with this standard shall be reported to Quality Management oversight.

Interpretive Guidelines:

A lack of training can be a contributory factor in poor quality care and patient safety related incidents. The PCP must therefore ensure that all staff have been trained appropriately to undertake their duties to reduce the risk of an error or omission occurring.

The PCP shall provide evidence that it has undertaken an annual documented training needs analysis and that staff have been trained accordingly. As a minimum the TNA should include:

- I. Infection, prevention and control;*
- II. Fire safety;*
- III. Risk management;*
- IV. Orientation;*
- V. Healthcare record keeping;*
- VI. Grievances;*
- VII. Resuscitation; and*
- VIII. Medicines management;*

SM.8 Clinical Authority and Responsibility

SR.1 There shall be a process for determining the authority to be granted to individual professionally registered staff and a procedure for applying the criteria to those individuals that request authority.

SR.2 There shall be a process in place to ensure that all individuals with clinical authority provide services only within the scope of the authority granted.

SR.3 The PCP shall define and document under what circumstances clinical authority will be suspended. This shall include;

- a) concerns in relation to individuals performance and competence;
- b) failure to maintain or have a restriction of professional license, registration or certification;
- c) failure to maintain the specified amount of professional liability insurance, if applicable; and
- d) non-compliance with written medical record completion or deficiency requirements.

Interpretive Guidelines:

Criteria shall be developed by the PCP for determining the authority to be granted to individual professionally registered staff. This should also include the criteria for consideration of automatic suspension of clinical authority of professionally registered staff. The PCP will be required to provide evidence of the criteria developed and examples of where this has been implemented.

SM.9 Consultation

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

Interpretive Guidelines:

Evidence will be reviewed to verify the circumstances and criteria which require consultation or management by a physician or other qualified licensed independent practitioner.

Patient healthcare records shall demonstrate conformity with the PCPs agreed process.

Section 8 Patient Centred Care (PC)

PC.1 Specific Rights

SR.1 The PCP shall have approved documented processes that address the following as a minimum:

- a) patient participation and means for making informed decisions regarding his/her plan of care;
- b) personal privacy;
- c) provision of care in a safe setting;
- d) freedom from all forms of abuse or harassment;
- e) confidentiality of clinical records;
- f) patient access to clinical records as quickly as record keeping system permits the PCP shall not impede the legitimate efforts of individuals to gain access to their own clinical records;
- g) procedure for submission of a written or verbal grievance. (See PR.3- Grievance Procedure); and
- h) when unexpected events occur, patients and/or their families can expect to receive an apology and explanation.

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

Interpretive Guidelines:

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

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

PC.2 Consent

SR.1 The PCP shall have approved documented processes for the taking of consent across all services provided.

SR.2 A process for the provision of patient information shall be integral to the consent taking process. As a minimum all patient information, whether verbal or written, shall contain:

- a) risks associated with the treatment/procedure;
- b) benefits associated with the treatment/procedure; and
- c) alternatives available, if any.

SR.3 The PCP shall identify which treatments/procedures require written consent. The approved document shall outline how this shall be documented.

Interpretive Guidelines:

Patients have a fundamental ethical right to determine what treatments they receive. Valid consent to treatment is fundamental in all forms of healthcare from providing personal care to undertaking surgical procedures. Such consent shall be considered valid when it is demonstrated that it is made:

- I. voluntarily;*
- II. with reasonable information to make an informed, purposeful decision;*
- III. by a mentally competent person.*

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

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

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

The procedures/treatments which will require the hospital to obtain patient written consent will include as a minimum;

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

PC.3 Language and Communication

SR.1 The PCP shall ensure that it has access to competent individuals to interpret for patients' who do not speak the predominant language of the organization.

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

Interpretive Guidelines:

The PCP shall evidence that it provides for interpretation for individuals who speak languages other than the predominant language of the organization. In addition the PCP shall evidence that it also provides alternative communication techniques or aides for those who are hearing impaired, vision impaired or have other specific needs, or take other steps as needed to effectively communicate with the patient.

PC.4 Safeguarding Children and Adults

SR.3 The PCP shall have local systems in place to ensure that vulnerable people are cared for and managed appropriately.

SR.4 Mechanisms shall be in place for referral to additional support services and for ongoing continuation of care.

Interpretive Guidelines:

The PCP must ensure that processes are in place for protecting all vulnerable people. The process shall consider both the proactive measures that the organization should implement as well as the procedures to follow once a safeguarding issue has been either identified or suspected. The PCP shall provide evidence to verify that appropriate arrangements are in place.

PC.5 Grievance Procedure

SR.1 The PCP shall develop and implement a formal grievance procedure that provides for the following:

- a) A list of whom to contact;
- b) The governing body's review and resolution of grievances or the written delegation of this function to an appropriate person or committee;
- c) A referral process for quality of care issues to the Quality Management oversight; and
- d) Specification of reasonable timeframes for review and response to grievances.

SR.2 Grievance resolutions shall be in writing and directed to the patient. The grievance resolution shall include the following:

- a) PCP contact person;
- b) Steps taken to investigate;
- c) Results of the grievance process;
- d) Process for escalation if unresolved; and
- e) Date of completion.

Interpretive Guidelines:

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

The PCP shall provide a selection of cases to demonstrate that it is implementing the approved grievance procedures.

PC.6 Emergency Services not provided

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

Interpretive Guidelines:

It is important that even if the PCP does not provide emergency services it should have systems and processes in place to manage any clinical emergencies.

The PCP shall have documented policies and procedures for appraisal of all emergencies, initial treatment, and referral when appropriate.

PC.7 Positive Patient Identification

SR.1 There shall be a process in place, throughout all services provided by the PCP, for the positive identification of all patients.

SR.2 Positive identification of all patients shall be considered on initial contact and throughout on-going care where applicable.

SR.3 The PCP shall have a process for the reporting and management of patient misidentification.

Interpretive Guidelines:

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

PC.8 Appointments and Recall

SR.1 The PCP shall have an appointment system(s) to facilitate the provision of timely care for all patients within all care settings.

SR.2 There shall be processes in place for ensuring that any patients who fail to attend an appointment are followed up in a timely manner. This shall include the management of persistent non-attendance.

Interpretive Guidelines:

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

PC.9 Patient Needs Assessment

SR.1 The PCP shall identify where the following patient assessments should be undertaken:

- a) General needs assessment;
- b) VTE;
- c) Moving and handling;
- d) Falls;
- e) Pain management;
- f) Pressure area care;
- g) Nutrition and hydration;
- h) Control and restraint; and
- i) DNAR.

These assessments shall take place upon admission or transfer into a service, where relevant.

SR.2 The PCP shall outline how all patient assessments shall be documented.

Interpretive Guidelines:

A patient assessment shall be considered for everyone who receives care from services within the PCP. The PCP shall identify the assessments required for each patient and as minimum will consider those assessments listed i – ix above.

Patient healthcare records shall demonstrate conformity with the PCPs agreed process.

PC.10 Resuscitation Equipment and DNAR

SR.1 The PCP shall have processes in place to ensure the continual availability of resuscitation/emergency equipment in all care settings.

SR.2 The equipment shall be checked to ensure that it is both available and in good working order at all times and in all care settings. Timescales and responsibilities for checking the equipment will be determined.

SR.3 Any patient identified as requiring a DNAR shall be managed in accordance with the PCPs approved documented process.

Interpretive Guidelines:

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

The PCP shall have an agreed documented process for invoking DNAR's when clinically necessary.

Patient healthcare records shall demonstrate conformity with the PCPs agreed process.

PC.11 Blood Transfusion

SR.1 The PCP shall have processes in place for the administration of blood and blood products. This shall include:

- a) Request of blood samples for pre-transfusion compatibility testing;
- b) Prescribing of blood and blood products;
- c) Collection, transport and storage of blood and blood products ;
- d) Administration of blood and blood products;
- e) Care of the patient receiving the blood and blood products; and
- f) Documentation requirement in relation to all of the requirements above.

Interpretive Guidelines:

To ensure the right patient receives the right blood and blood products the PCP shall have in place approved and documented checking procedures and process which shall be followed throughout pre-transfusion and administration of any blood and blood product.

Patient healthcare records shall demonstrate conformity with the PCPs agreed process.

PC.12 Transfer of Care

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

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

Interpretive Guidelines:

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

Patient healthcare records shall demonstrate conformity with the PCPs agreed process.

Section 10 Obstetrics (OB)

OB.1 Home Births

SR.1 The PCP shall have an approved documented process for the management of home births.

SR.2 Emergency transfer requirements of the woman/baby shall be determined and documented.

SR.3 Systems shall be in place for the management of any obstetric emergency. As a minimum these shall include:

- a) shoulder dystocia;
- b) breech;
- c) severe/major haemorrhage;
- d) fetal distress; and
- e) maternal collapse; and
- f) neonatal resuscitation.

Interpretive Guidelines:

Managing the risks associated with homebirths is essential for both the safety of the mother and unborn child. Where the PCP provides care for mothers who choose to have a home birth they shall have approved documented processes for management of the home birth, emergency transfer arrangements for the women/ baby and the management of obstetric emergencies which as a minimum should include requirements a - f, as above.

Section 11 Anesthesia (AS)

AS.1 Anaesthesia

- SR.1** The PCP shall identify which services administer anaesthesia.
- SR.2** Anesthesia services shall be appropriate to the scope of the services offered. Anesthesia services shall be provided in an organized manner, and function under the direction of a qualified healthcare professional.
- SR.3** Anesthesia shall only be administered by an anesthesiologist or a suitably qualified healthcare professional.
- SR.4** There shall be an approved and implemented document for the administration and care of the patient receiving general anesthesia.
- SR.5** For inpatient and outpatient surgery, a pre-anesthesia assessment and post-anesthesia evaluation is completed and documented by the individual who administers the anaesthesia or by any qualified healthcare professional.

Interpretive Guidelines:

The PCP shall identify which services administer anesthesia (whether local, regional or general anesthesia). Where these services are provided it must be done so in an organized and structured manner. The anesthetic services will be offered under the direction of a qualified healthcare professional. This individual will be responsible for all anesthetic administered throughout the organization.

The PCP shall provide evidence to demonstrate that either an anesthesiologist or a suitably qualified healthcare professional administers all anesthetics.

The PCP shall have an approved documented process for the administration off all anesthesia and for the care of the patient receiving an anesthetic. This shall include the process and responsibilities for both pre-anesthesia assessment and post-anesthesia evaluation.

Patient healthcare records shall demonstrate conformity with the PCPs agreed process.

Section 9 Medication Management (MM)

MM.1 Management Practices

- SR.1** PCP shall have a medication management program that meets the needs of the patients. Medications shall be prescribed and administered in accordance with accepted professional principles. A senior pharmacist will be responsible for developing, supervising, and coordinating all the activities of the medication management program.
- SR.2** The PCP shall have a documented process for the preparation, prescription, administration, reconciliation, storage and disposal of all medications.
- SR.3** All prescription only medication shall only be dispensed and administered on receipt of a properly constituted prescription in accordance with approved PCP documented process.
- SR.4** Prescriptions shall only be made following assessment of patient needs and in accordance with approved PCP documented process and agreed standards of practice.
- SR.5** All compounding, packaging, and dispensing of medication shall be performed under the supervision of an approved pharmacist or licensed dispenser in accordance with approved PCP documented process.
- SR.6** All drugs and biologicals shall be controlled, secured and distributed in accordance with applicable standards at all times.
- SR.7** Where medication is under the ownership and/or control of the PCP, only personnel authorized by the PCP and described within the PCP approved documented process shall have access to medications and/or locked areas/secured environments.
- SR.8** Outdated, mislabelled, or otherwise unusable medications owned and controlled by the PCP shall not be available for patient use.

Interpretive Guidelines:

The PCP shall have a medication management program administered in accordance with accepted professional principles and shall be led by a senior pharmacist.

All medication management practices, including preparation, prescribing, administration, reconciliation, storage and disposal shall be in accordance with PCP agreed processes. All medications must be kept in locked areas/secured environments. Only personnel authorized by the PCP shall have access to medications and/or secured environments.

Patient healthcare records and site visits shall demonstrate conformity with the PCPs agreed process.

MM.2 Controlled Medications

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

SR.2 Abuses and losses of controlled medications shall be reported within one working day to the individual responsible for the medications management programme or to the chief executive officer. Abuses and losses shall also be reported to external parties as appropriate.

Interpretive Guidelines:

The PCP shall implement a system to record and maintain current and accurate records of the receipt and disposal of all controlled drugs.

The PCP must develop and implement approved processes to minimize abuses and losses of controlled substances. These procedures must outline the reporting process to the individual responsible for the medications management programme, and to the chief executive officer, as appropriate.

PCP records shall demonstrate conformity.

MM.3 Medication Prescription

SR.1 All prescriptions shall be legible and include:

- a) Name of patient;
- b) Age, date of birth and weight of patient, when appropriate;
- c) Date and time of the order;
- d) Drug name;
- e) Dosage form (e.g., tablets, capsules, inhalants);
- f) Frequency, and route;
- g) Quantity and/or duration; and
- h) Name and signature of prescriber.

Interpretive Guidelines:

All of the above requirements, a-h, shall be included in any prescriptions.

Patient healthcare records shall demonstrate conformity.

MM.4 Medication Use Reviews

SR.1 All prescriptions shall be reviewed prior to administration of the first dose. Review shall be performed by qualified and competent personnel according to recognized standards of practice.

SR.2 The PCP shall have in place a process for ongoing review of individual patient medication use to ensure continued appropriateness and safety. This should include:

- a) What medication the patient is currently taking including over the counter and complimentary therapies (dosage, form and strength)

- b) Does the patient use the medicine as prescribed?
- c) Does the patient know why they are using the medicine?
- d) Is the formulation appropriate?
- e) Are they experiencing any side-effects?
- f) Has advice been given on use, side-effects, contraindications and interactions?

Interpretive Guidelines:

All medication orders, (except in emergency situations), should be reviewed for appropriateness by a qualified and competent personnel according to recognized standards of practice, before the first dose is dispensed.

All patient medication use shall be reviewed on an ongoing basis and shall include requirements, a-f, as above.

Patient healthcare records shall demonstrate conformity with the PCP's agreed process.

MM.5 Medication Oversight

- SR.1** The PCP is responsible for developing policies and procedures that minimize medication errors.
- SR.2** There shall be procedures for reporting adverse drug reactions, and errors in preparing, prescribing and administering medications.
- SR.3** There shall be procedures for the aggregation, trending and analysis of prescribing data, adverse drug reactions, and errors in preparing, prescribing, and administering medications.
- SR.4** Drug preparation, administration, and prescribing errors, adverse medication reactions, and incompatibilities shall be reported to the prescriber responsible for care and to the Quality Management oversight.

Interpretive Guidelines:

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

The PCP shall develop and implement approved documented procedures for reporting adverse drug reactions, and errors in preparing, prescribing, and administering medications. These errors and reactions must be promptly reported to an appropriate healthcare professional. The PCP will document the information obtained from the errors and reactions reported and demonstrate that there is a process for aggregating this information and reporting to the Quality Management oversight.

Section 10 Diagnostics and Screening (DS)

DS.1 Diagnostics and Screening

SR.1 The PCP shall identify the diagnostics and screening tests provided by the organization. Identification of these tests shall involve:

- a) In-house;
- b) By contractor; and
- c) As a service to others.

SR.2 For all of the tests identified in SR.1, the PCP shall document processes, with timescales, that address the following issues:

- a) Patient need;
- b) Requesting;
- c) Collecting;
- d) Labelling and tracking;
- e) Transport;
- f) Storage;
- g) Testing;
- h) Reporting (to other healthcare professionals including out of hours);
- i) Communication (to the patient);
- j) Documentation; and
- k) Action where there are significant results (including out of hours).

Interpretive Guidelines:

The PCP shall have clear approved documented processes for all screening and diagnostic testing. As a minimum the approved documented processes shall include requirements, SR.2 a-k, as above.

There shall be clear lines of accountability and systems to ensure that all results can be acted upon in a timely and efficient manner.

Patient healthcare records shall demonstrate conformity with the PCPs agreed process.

DS.2 Laboratory Services

SR.1 The PCP shall maintain, or have available, adequate and safe laboratory services, either directly or through contractual services, to meet the needs of its patients.

SR.2 The PCP shall ensure that all laboratory services provided to its patients are performed in a certified or accredited laboratory.

SR.3 A documented scope of laboratory services shall be available for the PCP.

Interpretive Guidelines:

The PCP shall maintain, or have available, adequate laboratory services and a documented scope of service. The PCP may have laboratory services in-house or through contractual agreement.

The PCP shall provide evidence that all laboratory services are provided in a certified or accredited laboratory.

Section 11 Medical Imaging (MI)

MI.1 Organization

- SR.1** If medical imaging is provided, the PCP shall have readily available, diagnostic radiology services that meet professionally approved standards and national legal and regulatory requirements. The medical imaging services, particularly ionizing medical imaging procedures, shall be free from hazards for patients and personnel.
- SR.2** If radiology services are provided through a contractual agreement the PCP must ensure that systems are in place to verify the contracted entity and that its employees are properly qualified.

Interpretive Guidelines:

The PCP shall demonstrate that it has available, diagnostic radiology services for the population it serves. The PCP shall provide evidence that where the service is provided through a contractual agreement they have ensured that radiology services are provided safely and appropriately by qualified staff.

MI.2 Radiation Protection

- SR.1** Proper radiation safety precautions shall be maintained, including adequate shielding for patients, staff, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.
- SR.2** The PCP shall have approved documented procedures which as a minimum shall include:
- a) Adequate shielding for patients, personnel and facilities;
 - b) Labeling of radioactive materials, waste, and hazardous areas;
 - c) Transportation of radioactive materials between locations within the PCP;
 - d) Securing radioactive materials, including determining limitations of access to radioactive materials;
 - e) Testing and maintenance of equipment for prevention of radiation hazards;
 - f) Maintenance monitoring and measuring devices for equipment;
 - g) Proper storage of radiation monitoring badges when not in use;
 - h) Storage and disposal of radio nuclides and radio pharmaceuticals as well as radioactive waste; and,
 - i) Methods of identifying patients who may be pregnant.
- j) **SR.3** All staff working in radiation areas shall be monitored continually for the amount of radiation exposure by the use of exposure meters or badge dosimeters.
- k) **SR.4** Any high radiation readings shall be investigated and reported to Quality Management oversight.

Interpretive Guidelines:

The PCP shall develop and implement policies and procedures to provide a safe environment for patients and staff. The PCP policies and procedures shall address the safety standards as required in SR.2 a-k, as above.

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

The PCP shall report any high radiation readings to Quality Management oversight.

MI.3 Order

SR.3 Medical imaging services shall be provided only on the order of a physician or other healthcare practitioner consistent with national and regulatory requirements.

Interpretive Guidelines:

The PCP shall provide evidence that medical imaging services are provided only on the order of a physician or other healthcare practitioner consistent with national and regulatory requirements.

Patient healthcare records shall demonstrate conformity with the PCPs agreed process.

Section 12 Infection Prevention and Control (IC)

IC.1 Infection Prevention and Control System

- SR.1** The PCP shall have a process in place to maintain a sanitary environment for PCP patients, staff, and others.
- SR.2** The PCP shall have a documented process, policies and procedures to define how infections and communicable diseases are prevented, controlled and investigated throughout the PCP.
- SR.3** The Infection Prevention and Control system shall be evaluated at least annually. This evaluation shall be reported to Quality Management oversight.
- SR.4** Infections and communicable diseases shall be measured and analyzed to identify any patterns or trends.

Interpretive Guidelines:

The PCP shall maintain an infection control program for the prevention, control, and surveillance of infection, (which includes, but is not limited to PCP acquired infections), and communicable diseases of patients and personnel, (which includes, but is not limited to patient care staff) which shall be evaluated at least annually. Evidence shall be provided to demonstrate that this evaluation has been reported to Quality Management oversight.

Site visits shall demonstrate conformity with the PCPs agreed processes for maintaining sanitary environments.

Section 13 Medical Records Service (MR)

MR.1 Organization

SR.1 The PCP shall identify what healthcare records are utilised in accordance with the scope and complexity of the services it provides.

Interpretive Guidelines:

The PCP shall provide evidence that it has identified all types of healthcare records used within the organization and that the medical record services reflect the scope and complexities of the services offered.

MR.2 Complete Medical Record

SR.1 The PCP shall maintain an accurately written, contemporaneous completed healthcare record for each patient.

SR.2 The PCP shall have an approved documented process for providing services for the completion, filing, retrieval and tracking of the healthcare record. The process for completion of the healthcare record shall address timeframes.

SR.3 The PCP shall have a process for the storage, archiving and destruction of healthcare records. Healthcare records, (original or legally reproduced form), shall be retained for a period of at least five (5) years, or more if required by National or local law.

SR.4 There is a process in place to verify the authenticity of all healthcare record entries.

SR.5 The PCP shall have a process for dealing with healthcare record delinquencies.

SR.6 The PCP shall ensure that SR.1 – SR.5 are subject to audit no less than annually.

Interpretive Guidelines:

The PCP shall maintain a healthcare record for each patient treated or evaluated in any part or location of the PCP. The PCP shall ensure that all healthcare records are accurate and complete.

The PCP shall demonstrate that they are implementing their approved documented process for completion, filing and retrieval and tracking of the healthcare record. In the event records are stored outside of the medical records office or off-premises through a contractual arrangement, the PCP must ensure there is a process in place to protect and retrieve these records in a timely manner.

Patient healthcare records and site visits shall demonstrate conformity with the PCPs agreed processes.

MR.4 Confidentiality

SR.1 Confidentiality of medical records shall be assured.

- SR.2** Individuals, who are authorized by the patient to receive information from, or copies of records, shall follow the local and national guidance on confidentiality.
- SR.3** The PCP shall also ensure that the medical record that they control cannot be altered or accessed by unauthorized individuals.
- SR.4** Original medical records shall be released by the PCP only in accordance with National or local law, court orders, or subpoenas.

Interpretive Guidelines:

The PCP shall have a means of ensuring that access to all information regarding patient's records is limited to those individuals designated by law, regulation, and policy or duly authorized as having a need to know.

Patient healthcare records and site visits shall demonstrate conformity with the PCPs agreed processes.

MR.5 Record Content

SR.1 The healthcare record shall provide a structured record of care planning and delivery processes including, as a minimum, the following:

- a) Patient needs assessment;
- b) Care planning;
- c) Care delivery; and
- d) Evaluation.

SR.2 All entries shall be:

- a) Legible, complete, dated and timed; and
- b) Authenticated by the person responsible for providing patient care in accordance with PCP approved process.

Interpretive Guidelines:

Authentication may include written signatures. Electronic authentication is permissible

Patient healthcare records shall demonstrate conformity with the PCPs agreed processes as required by SR.1 and SR.2.

Section 14 Physical Environment (PE)

PE.1 Facility

- SR.1** The facility shall be constructed, arranged, and maintained to ensure patient safety, and to provide areas for diagnosis and treatment and for special hospital services appropriate to the needs of the community.
- SR.2** The condition of the PCP facilities and the overall hospital environment shall be developed and maintained in such a manner that the safety and well-being of patients, visitors, and staff are assured.
- SR.3** The hospital shall maintain adequate facilities for its services:
- a) Diagnostic and therapeutic facilities shall be located for the safety of patients.
 - b) Facilities, supplies, and equipment shall be maintained to ensure an acceptable level of safety and quality.
 - c) The extent and complexity of facilities shall be determined by the services offered.
- SR.4** The PCP shall have a process in place, as required and/or recommended by National and local legislation and regulations or related professional organizations, to maintain a safe environment for the PCP's patients, staff, and others.
- SR.5** The PCP shall have a documented process, policies and procedures to define how unfavourable occurrences, incidents, or impairments in the facility's infrastructure, Life Safety, Safety, Security, Hazardous Material/Waste, Emergency, Medical Equipment, and Utilities Management Systems are prevented, controlled investigated, and reported throughout the PCP.
- SR.6** The PCP shall evaluate the facility's physical environment management systems at least annually. This evaluation shall be forwarded to Quality Management oversight.
- SR.7** Occurrences, incidents, or impairments shall be measured and analyzed to identify any patterns or trends.
- SR.8** The PCP, through its senior leadership shall ensure that the physical environment and associated management systems adequately address issues identified throughout the PCP and there are prevention, correction, improvement and training programs to address these issues.
- SR.9** Significant physical environment data/information shall be disseminated regularly to Quality Management oversight.

PE.3 Security Management System

- SR.1** The PCP shall develop a Security Management System that provides for a secure environment.

- SR.2** The Security Management System shall provide for identification of patients, staff and others.
- SR.3** The Security Management System shall address issues related to abduction, elopement, visitors, workplace violence, and investigation of property losses and be proportional to the risk.
- SR.4** The Security Management System shall establish emergency security procedures to include all hazard events and be proportional to the risk.
- SR.5** The Security Management System shall require vehicular access to emergency service areas.
- SR.6** The Security Management System shall require a process for reporting and investigating security related issues.

PE.4 Hazardous Material (HAZMAT) Management System

- SR.1** The PCP shall provide a HAZMAT Management System to manage hazardous materials and waste.
- SR.2** The HAZMAT Management System shall provide processes to manage the environment, selection, handling, storing, transporting, using, and disposing of hazardous materials and waste.
- SR.3** The HAZMAT Management System shall provide processes to manage reporting and investigation of all spills, exposures, and other incidents.
- SR.4** The PCP monitors staff exposure levels in hazardous environments and report the results of the monitoring to the Quality Management System.

PE.5 Management System

- SR.1** The PCP shall provide a comprehensive Emergency Management System to respond to emergencies in the PCP or within the community and region that may impact the PCP's ability to provide services.
- SR.2** SR.2 The PCP shall have policies, procedures, and decision criteria for the determination of protection in place or evacuation of patients in the event of a disaster.
- SR.3** SR.3 The PCP shall have contingency plans in place for the outbreak of communicable disease.

PE.6 Medical Equipment Management System

- SR.1** The PCP shall establish a Medical Equipment Management System that provides processes for the acquisition, safe use, and the appropriate selection of equipment.

- SR.2** The Medical Equipment Management System shall address issues related to the PCP's initial service inspection, the orientation, and the demonstration of use for rental or PCP owned equipment.
- SR.3** The Medical Equipment Management System shall address criteria for the selection of equipment.
- SR.4** The Medical Equipment Management System shall have a process for reporting and investigating equipment management problems, failures, and user errors.
- SR.5** The Medical Equipment Management System shall address a process for determining timing and complexity of medical equipment maintenance.

PE.7 Utility Management System

- SR.1** The PCP shall require a Utility Management System that provides for a safe and efficient facility that reduces the opportunity for healthcare-acquired illnesses.
- SR.2** The Safety Management System shall require proper ventilation, light and temperature controls in pharmaceutical, food preparation, and other appropriate areas.
- SR.3** Emergency power and lighting or battery lamps and flashlights shall be available throughout the facilities.