DNV·GL

DNVGL-DS-HC302

# STANDARD, INTERPRETIVE GUIDELINES AND SURVEYOR GUIDANCE

INTERNATIONAL ACCREDITATION REQUIREMENTS FOR

# Outpatient Specialist Centres

NOVEMBER 2014, VERSION 1.0

**The electronic pdf version of this document found through http://www.dnvba.com/healthcare is the officially binding version**

# 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

# Contents

# Section 1 Scope

The requirements of this Standard are designed to support the development and continual improvement of healthcare quality and patient safety in outpatient specialist centers (OSC). It also addresses general safety for workers, patients and other visitors within these centers. For the purposes of this standard an "OSC" means an institution which is engaged in providing specialty outpatient healthcare by or under the supervision of qualified healthcare workers (For example, Diabetic, Cardiac, Obstetric Clinics). There is no requirement to provide 24 hr care (cf our Hospital Standards) nor is the clinic the likely first point of contact for the patient with the healthcare system (cf our Primary Care Provider Standards).

The OSC will be required to demonstrate compliance to different groups of Standards depending on the services that it offers. The table below provides some guidance as to which Standards would be applied for three different types of Specialist Clinics: Those that perform invasive procedures, those that do not and free standing Dental Clinics (i.e. free standing dental clinics not attached to organizations providing other types of care). Exactly which Standards shall apply need to be confirmed with DNV GL prior to the initial accreditation survey.

Invasive procedures are defined as any procedure or treatment that is performed for the purpose of structurally altering the human body by the incision or destruction of tissues. This would include any diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles.

Such procedures may include but not be limited to:

- tissue being cut, burned, vaporized, frozen, sutured, probed
- manipulation by closed reductions for major dislocations or fractures
- alterations by mechanical, thermal, light-based, electromagnetic, or chemical means.
- Injections of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system

| Section | | **Outpatient** with invasive procedures | **Outpatient** no invasive procedures | **Dental Clinics** |
|---|---|---|---|---|
| SECTION 3 | QUALITY MANAGEMENT SYSTEM (QM) | All | All | All |
| SECTION 4 | SAFETY RISK MANAGEMENT (RM) | All | All | All |
| SECTION 5 | GOVERNING BODY (GB) | All | All | All |
| SECTION 6 | TOP MANAGEMENT (TM) | All | All | All |
| SECTION 7 | STAFFING MANAGEMENT (SM) | All | All | All |
| SECTION 8 | PATIENT CENTRED CARE (PC) | All | All | All |
| SECTION 9 | MEDICATION MANAGEMENT (MM) | All | If Pharmacy on-site then all, if not then MM.1, MM.3 & MM.7 | MM.1, MM.3 & MM.7 |

| | | | | |
|---|---|---|---|---|
| SECTION 10 | DIAGNOSTICS AND SCREENING (DS) | All | All | All |
| SECTION 11 | OPERATING THEATRES (OT) | N/A | All | If provided then OT1, OT.3 & OT.4 |
| SECTION 12 | ANESTHESIA (AS) | N/A | All | If provided then all |
| SECTION 13 | OBSTETRICS (OB) | If provided then all | N/A | N/A |
| SECTION 14 | LABORATORY SERVICES (LS) | All | All | All |
| SECTION 15 | BLOOD SUPPLY AND MANAGEMENT (BM) | If provided then all | If provided then all | N/A |
| SECTION 16 | MEDICAL IMAGING (MI) | If provided then all | If provided then all | If provided then all |
| SECTION 17 | NUCLEAR MEDICINE SERVICES (NM) | If provided then all | If provided then all | N/A |
| SECTION 18 | REHABILITATION SERVICES (RS) | If provided then all | If provided then all | N/A |
| SECTION 19 | EMERGENCY DEPARTMENT (ED) | If provided then all | N/A | N/A |
| SECTION 20 | INFECTION CONTROL (IC) | All | All | All |
| SECTION 21 | MEDICAL RECORDS SERVICE (MR) | All | All | All |
| SECTION 22 | UTILIZATION REVIEW (UR) | All | All | All |
| SECTION 23 | PHYSICAL ENVIRONMENT (PE) | All | All | All |

# Section 2 Application

The requirements of this standard are generic and are intended to be applicable to all Primary Care Providers (OSCs) as defined above. Where any requirements of this standard cannot be applied due to the nature of the OSC 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 OSC'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 OSC. 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 OSC'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 OSC 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 OSC), medical staff, and administrative officials are responsible and accountable for ensuring that the OSC implements and maintains an effective quality management system. This quality management system shall ensure that corrective and preventive actions taken by the OSC are implemented, measured and monitored.

**SR.2** In addition to any other Quality Management System standard, the OSC is required to comply with QM.1 at all times as a part of its Quality Management System. Until the OSC achieves ISO 9001 Compliance/ Certification, the OSC shall follow at a minimum the ISO 9001 methodology specified in QM.2, SR.3 (below).

**SR.3** The OSC shall develop, implement and maintain an on-going system for managing quality and patient safety.

**SR.4** The OSC shall implement OSC-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 OSC shall assure that adequate resources are allocated for measuring, assessing, improving, and sustaining the OSC'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 GL OSC Accreditation. The OSC shall either demonstrate compliance with the ISO 9001 Quality Management System principles through a DNV GL OSC 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 OSC shall maintain ISO 9001 compliance or formal Certification in order remain eligible for DNV GL OSC Accreditation.

**SR.2** The Certification Body shall meet the following requirements:

a) 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

b) It shall have certified or conducted a pre-assessment at a minimum of twelve (12) organisations that provide primary care.

**SR.3** The OSC shall initiate and continue implementation of the ISO 9001 methodology to achieve compliance or certification as stated in QM.1. At a minimum the OSC shall be able to demonstrate at the time of the DNV GL OSC Accreditation survey evidence of the following:

a) Control of Documents: the OSC’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 OSC ensures that suitable records are maintained for the requirements of this standard;

c) Internal Surveys (Internal Audits): the OSC conducts internal reviews of its processes and that resultant corrective/preventive action measures have been implemented and verified to be effective; and

d) The OSC 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 OSC 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 OSC 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 OSC shall be addressed by the OSC. 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 OSC 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 OSC. 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 OSC;

**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 OSC 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 OSC 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 OSC 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 OSC 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 OSC's internal review(s).*

# Section 4 Safety Risk Management (RM)

## RM.1 Planning and Resources

**SR.1** The OSC 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 OSC. 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 OSC 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 OSC 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 in 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 OSC shall provide evidence that they have undertaken risk assessments in accordance with OSC 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 OSC shall provide evidence that following risk assessment corrective actions are agreed, implemented and monitored in accordance with the OSC'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 OSC 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 OSC shall have a policy and procedure for informing patients and/or their families about unexpected adverse events.

***Interpretive Guidelines:***
*The OSC shall be able to demonstrate that they have a OSC wide approved document which as a minimum shall include:*

*I. Roles and responsibilities for the management of risk throughout the OSC;*
*II. Training requirements related to risk management and adverse event reporting;*
*III. Processes for assessing all risks throughout the OSC;*
*IV. Process for ensuring systematic management of all identified risks throughout the OSC;*
*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 OSC wide approved document which as a minimum shall include:*

VII. *Roles and responsibilities for the management of risk throughout the OSC*
VIII. *Processes for assessing all risks throughout the OSC*
IX. *Process for ensuring systematic management of all identified risks throughout the OSC*
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 OSC shall have an effective governing body legally, (or organized group or individual(s) who assumes full legal authority and responsibility for operations of the OSC), responsible for the conduct of the OSC as an institution. The governing body is responsible for all services provided in the OSC including all contracted services. If a OSC does not have an organized governing body, the persons legally responsible for the conduct of the OSC 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 OSC), 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 OSC is in compliance with all applicable national and local legislation and regulations regarding the health and safety of its patients;

b) The OSC is licensed by the appropriate bodies; and

c) Personnel working in the OSC are properly licensed / registered.

***Interpretive Guidelines:***
*The OSC 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 OSC whether or not they are provided under contract. The OSC shall evaluate and select contracted services entities/individuals based on their ability to supply products and/or services in accordance with the OSC'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 OSC 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 OSC.

## TM.2 Responsibilities

**SR.1** Top Management are responsible for operating the OSC, 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) OSC mission or purpose;

b) OSC values;

c) ethics or code of behaviour;

d) strategic objectives for the OSC 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 OSC informs the public of:

a) the services they provide; and

b) the quality and performance of the services they provide.

***Interpretive Guidelines:***
*The OSC shall have clear lines of accountability and management throughout the organsiation. Everyone involved in quality and patient safety within the OSC 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 OSC 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 OSC 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 OSCs 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 OSC 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 OSC'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 OSC 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 OSC's approved documented procedure shall be reviewed to verify that the OSC 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 OSC.*

*The OSC 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 OSC should have a description of the scope of services provided for each department. For smaller OSCs 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 OSC 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 OSC and national and regulatory requirements.

**SR.3** The OSC 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 OSC 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 OSC. 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 OSC 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 OSC.

**SR.2** The OSC 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 OSC shall share results of individual performance/evaluations/competence assessment with staff members that allows for staff feedback within a timeframe defined by the OSC.

**SR.5** The OSC 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 OSC 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 OSC.*

*The OSC 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 OSC shall require each staff member, including contract staff, to participate in continuing education as required by individual registration, licensure or certification, or OSC policy.*

*The OSC 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 OSC. 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 OSC 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 OSC 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 OSC 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 OSC 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 OSC 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 OSC 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 OSC will be required to provide evidence of the criteria developed and examples of where this has been implemented.*

## SM.9 History and Physical

**SR.1** The OSC shall ensure that a medical history and physical examination (HP) for each patient shall be done prior to surgery or other procedure requiring anesthesia services, and placed in the patient's medical record within twenty four (24) hours after registration. The HP shall be in the medical record prior to any high-risk procedure.

a) A HP completed within 30 days prior to registration shall include an entry in the medical record documenting an examination for any change in the patient's current medical

condition completed by a medical physician or other qualified individual who has been granted these privileges by the medical staff in accordance with National and local legislation and regulations.

b) This examination and update of the patient's current medical condition shall be completed and placed in the medical record within twenty four (24) hours after registration, but prior to surgery or other procedure requiring anesthesia services.

**SR.2** A physician's assistant or advance practice nurse may perform parts or the whole history and physical within the scope of their license and allowed/privileged by the OSC. The responsible physician shall review and approve the history and physical as specified by the medical staff.

**SR.3** The content of the HP examination shall be determined by an assessment of the patient's condition and any co-morbidities in relation to the reason for surgery.

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

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

## SM.10 Consultation

**SR.1** The OSC 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 OSCs agreed process.*

# Section 8 Patient Centred Care (PC)

## PC.1 Specific Rights

**SR.1** The OSC 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 OSC 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 OSC shall demonstrate that they have mechanisms in place to ensure meaningful communication with service users in relation to the requirements in SR.1. The OSC 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 OSC informs each patient and/or legal representative of the patient's rights in advance of providing or discontinuing care. The OSC will inform both inpatients and outpatients of their rights.*

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

***Interpretive Guidelines:***
*The OSC shall evidence that it provides for interpretation for individuals who speak languages other than the predominant language of the organization. In addition the OSC 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.5 Grievance Procedure

**SR.1** The OSC 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) OSC 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 OSC 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 OSC 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 OSC, the organization shall have written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.

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

*The OSC 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 OSC, 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 OSC 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 OSC 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 OSC 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 OSC has systems in place to ensure that all patients can access the services they need in a timely and coordinated manner. The OSC shall provide evidence of the range of appointment systems it has in place across all care settings. The OSC 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 OSC 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 OSC shall outline how all patient assessments shall be documented.

***Interpretive Guidelines:***
*A patient assessment shall be considered for everyone who receives care from the OSC. The OSC shall identify the assessments required for each patient and as minimum will consider those assessments listed a-i above.*

*Patient healthcare records shall demonstrate conformity with the OSCs agreed process.*

## PC.10 Resuscitation Equipment and DNAR

**SR.1** The OSC 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 OSCs 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 OSC shall demonstrate the processes in place for checking equipment in all care settings.*

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

*Patient healthcare records shall demonstrate conformity with the OSCs agreed process.*

## PC.11 Blood Transfusion

**SR.1** The OSC 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 OSC 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 OSCs 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 primary care providers, other specialist care providers and social services), shall be agreed and implemented throughout the OSC 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 OSC. 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 OSCs agreed process.*

# Section 9 Medication Management (MM)

## MM.1 Management Practices

**SR.1** OSC 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 OSC 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 OSC documented process.

**SR.4** Prescriptions shall only be made following assessment of patient needs and in accordance with approved OSC 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 OSC 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 OSC, only personnel authorized by the OSC and described within the OSC 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 OSC shall not be available for patient use.

***Interpretive Guidelines:***
*The OSC 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 OSC agreed processes. All medications must be kept in locked areas/secured environments. Only personnel authorized by the OSC shall have access to medications and/or secured environments.*

*Patient healthcare records and site visits shall demonstrate conformity with the OSCs 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 OSC shall implement a system to record and maintain current and accurate records of the receipt and disposal of all controlled drugs.*

*The OSC 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.*

*OSC 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 OSC 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 OSC's agreed process.*

## MM.5 Medication Oversight

**SR.1** The OSC 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 OSC 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 OSC 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 OSC 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 OSC 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 dichotomyof hours).

***Interpretive Guidelines:***
*The OSC 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 OSCs agreed process.*

## DS.2 Laboratory Services

**SR.1** The OSC 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 OSC 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 OSC.

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

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

# Section 11 Operating Theatres (OT)

## OT.1 Organization

**SR.1** For OSCs that provide services in an operating theatre, the services shall be well organized, appropriate to the scope of the services offered, and provided in accordance with acceptable standards of practice.

**SR.2** Operating theatres and the work within them shall be designed to assure the provision of high quality patient care that meets recognized standards of medical practice.

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

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

*As a minimum the OSC policies and procedures shall include:*

*I.* *Aseptic and sterile surveillance and practice, including scrub techniques*

*II.* *Infection Prevention and Control to include;*

*a)* *Identification of infected and non-infected cases;*
*b)* *Sterilization and Disinfection Procedures*
*c)* *Handling Infectious and Biomedical/Medical Waste*
*d)* *Air Quality Testing*

*III.* *Housekeeping requirements/procedures;*

*IV.* *Duties of surgical assistants, scrub and circulating staff. These may be defined within job descriptions, but may vary depending on the cases for which these staff members are involved;*

*V.* *Conducting surgical counts in accordance with recognized standards of practice. The OSC will have a process in place to ensure that no foreign bodies are retained in patients following surgical procedures;*

*VI.* *The scheduling of patients for surgery;*

*VII.* *Patient care requirements including:*

*a)* *Pre-operative testing*
*b)* *Clinical procedures*
*c)* *Patient identification procedure and site verification process*
*d)* *Tissue viability*

*VIII.* *Resuscitative techniques;*

*IX.* *Care of surgical specimens;*

*X.* *Malignant hyperthermia;*

*XI.* *Procedure-specific protocols that identify requirements against all applicable surgical procedures performed. This will include a list of equipment, materials, and supplies necessary to properly carry out the surgical services provided;*

*XII.* *Monitoring of temperature and humidity*

*XIII. Safety practices*

*XIV. Acceptable operating room attire*

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

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

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

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

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

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

## OT.2 Staffing and Supervision

**SR.1** The OSC of the operating theatres shall be supervised by either a registered nurse with appropriate experience, or by a physician.

**SR.2** Staff working within operating theatres shall have relevant and specialized training. Individuals under training or observing shall be appropriately supervised.

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

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

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

***Surveyor Guidance:***
*Review the OSC's organizational chart regarding surgical services to confirm that there are lines of authority and delegation of responsibility indicated within surgical services.*

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

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

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

## OT.3 Available Equipment

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

a) emergency call system;

a) cardiac monitor;

b) resuscitator/AMBU-bag;

c) defibrillator;

d) suction equipment; and,

e) provisions for emergency airway intervention.

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

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

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

## OT.4 Operating Room Register

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

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

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

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

## OT.5 Post-Operative Care

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

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

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

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

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

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

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

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

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

**SR.1** The OSC shall ensure continuity of care between the operating theatre, recovery unit and other care providers or the social services. Relevant information shall be documented prior to any transfer.

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

a) name, date of birth and OSC identification number of the patient;

b) date and times of the surgery;

c) name(s) of the surgeon(s)

d) type of anaesthesia administered;

e) complications, if any;

f) pre-op and post-op diagnosis;

g) procedures performed;

h) specimens removed;

i) blood administered;

j) grafts or implants; and

k) medications administered.

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

***Interpretive Guidelines:***
*An operative report shall be written or dictated and signed by the surgeon immediately following surgery and before the patient is transferred. The operative report will contain at least the following:*

*I.* *Name, date of birth and OSC identification number of the patient;*

*II.* *Date and times of the surgery;*

*III.* *Name(s) of the surgeon(s) and assistants or other practitioners who performed surgical tasks (even when performing those tasks under supervision);*

*IV.* *Pre-operative and post-operative diagnosis;*

*V.* *Name of the specific surgical procedure(s) performed;*

*VI.* *Type of anesthesia administered;*

*VII.* *Complications;*

*VIII.* *A description of techniques, findings, and tissues removed or altered;*

*IX.* *Surgeons or practitioners name(s) and a description of the specific significant surgical tasks that were conducted by practitioners other than the primary surgeon/practitioner (significant surgical procedures include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues); and,*

*X.* *Prosthetic devices, grafts, tissues, transplants, or devices implanted*

*XI.* *Immediate postoperative care required*

*In the event there is a delay in dictation turnaround regarding the operative report, an immediate written postoperative note is required to include the elements as described in SR.2a – l (above). This information shall be available in the medical record, and, as applicable, authenticated as accurate by the attending surgeon.*

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

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

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

# Section 12 Anesthesia (AS)

## AS.1 Anesthesia

**SR.1** The OSC shall identify which services administer anesthesia.

**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 anesthesia or by any qualified healthcare professional.

***Interpretive Guidelines:***
*The OSC 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 OSC shall provide evidence to demonstrate that either an anesthesiologist or a suitably qualified healthcare professional administers all anesthetics.*

*The OSC shall have an approved documented process for the administration of 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 OSCs agreed process.*

# Section 13 Obstetrics (OB)

## OB.1 Home Births

**SR.1** The OSC 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 hemorrhage;

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 OSC 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 14 Laboratory Services (LS)

## LS.1 Organization

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

**SR.2** The OSC shall ensure that all laboratory services provided to its patients are performed in a certified laboratory.

**SR.3** A documented scope of laboratory services shall be available to the medical staff.

**SR.4** The laboratory and OSC shall have policies and practices for proper receipt and reporting of tissue specimens.

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

*The OSC will a documented scope describing the laboratory services available. The OSC shall have a current license appropriate to the level of services performed.*

*There will be documented policies and practices for proper receipt and reporting of tissue specimens.*

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

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

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

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

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

*Review a sampling of records and determine if reporting has followed the documented policies and policies.*

# Section 15 Blood Supply and Management (BM)

## BM.1 Organization

**SR.1** The OSC shall have a blood use policy based on current scientific knowledge and that reduces unnecessary transfusions and minimizes the risks associated with transfusion. The policy shall describe the appropriate use of alternatives to transfusion where possible.

**SR.2** The preparation of blood and blood products used for patient care shall be prepared:

a) in units that have effective quality systems, including quality management in place

b) using quality standards

c) in units that have effective documentation systems in place

d) using appropriately trained staff

e) subject to regular quality assessment.

**SR.3** Blood and blood products used for patient care shall be subject to quality-assured screening for transfusion transmissible infections, including HIV, hepatitis B, hepatitis C, Treponema pallidum (syphilis) and, where relevant, other infections that pose a risk to the safety of the blood supply, such as Trypanosomacruzi (Chagas disease) and Plasmodium species (malaria); as well as testing for blood groups and compatibility.

**SR.4** If an organization uses the services of an external blood bank, it shall have an agreement with the blood bank that governs the procurement, transfer, and availability of blood and blood products and that ensures blood and blood products comply with the requirements in SR.1, SR.2 and SR.3.

**SR.5** The OSC shall maintain adequate records which identify the source and disposition of all units of blood and blood components for no less than ten (10) years from the date of disposition and they shall be stored in such a manner that they are available for prompt retrieval.

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

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

*If the OSC regularly uses the services of an outside blood bank, it shall have an agreement with the blood bank to govern the procurement, transfer, and availability of blood and blood products. This applies to OSCs that receive blood and blood products from an outside source and only performs compatibility (cross match) testing in preparation for transfusion to patients.*

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

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

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

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

***Surveyor Guidance:***
*Verify that the OSC has policies and procedures in place to ensure the sate transfusion of blood and blood products and addresses all elements covered in SR.1 – SR.5.*

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

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

*Verify that the OSC maintains adequate records which identify the source and disposition of all units of blood and blood components for no less than ten (10) years from the date of disposition in in such a manner they are available for prompt retrieval.*

# Section 16 Medical Imaging (MI)

## MI.1 Organization

**SR.1** If medical imaging is provided, the OSC 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 OSC must ensure that systems are in place to verify the contracted entity and that its employees are properly qualified.

***Interpretive Guidelines:***
*The OSC shall demonstrate that is has available, diagnostic radiology services for the population it serves. The OSC 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 OSC 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 OSC;

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

*The OSC 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 OSC 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 OSC 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 OSCs agreed process.*

# Section 17 Nuclear Medicine Services (NM)

## NM.1 Organization

**SR.1** If the OSC provides nuclear medicine services; those services shall meet the needs of the patients in accordance with acceptable standards of practice as defined by the OSC. The nuclear medicine services shall be free from hazards for patients and personnel.

**SR.2** The organization of the nuclear medicine service shall be appropriate to the scope and complexity of the services offered.

**SR.3** There shall be a director who is a physician qualified in nuclear medicine.

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

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

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

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

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

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

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

## NM.2 Radioactive Materials

**SR.1** Radioactive materials shall be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice as defined by the OSC.

**SR.2** The OSC shall maintain records of the receipt and disposition of radiopharmaceuticals.

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

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

*I. Handling of equipment and radioactive materials;*

*II. Protection of patients and personnel from radiation hazards;*

*III. Labeling of radioactive materials, waste and hazardous areas;*

*IV. Transportation of radioactive materials between locations within the OSC;*

*V. Security of radioactive materials, including determining who may have access to radioactive materials and controlling access to radioactive materials;*

*VI. Testing of equipment for radiation hazards;*

*VII. Maintenance of personal radiation monitoring devices;*

*VIII. Storage of radionuclides and radiopharmaceuticals as well as radioactive waste; and*

*IX. Disposal of radionuclides, unused radiopharmaceuticals, and radioactive waste.*

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

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

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

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

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

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

## NM.3 Equipment and Supplies

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

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

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

***Interpretive Guidelines:***
*The OSC shall develop and implement a preventive maintenance process to ensure that nuclear medicine equipment is maintained in safe operating condition to ensure accurate results and patient, staff, and public safety.*

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

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

## NM.4 Interpretation

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

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

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

***Interpretive Guidelines:***
*Only practitioners approved by the organization may interpret and sign the interpretation of diagnostic procedures and tests as defined within OSC policy.*

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

***Surveyor Guidance:***
*Review and verify that only practitioners approved by the organization to interpret diagnostic procedures.*

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

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

# Section 18 Rehabilitation Services (RS)

## RS.1 Organization

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

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

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

***Surveyor Guidance:***
*Review the extent of rehabilitation services and if these services are provided directly by the OSC or through a contractual arrangement.*

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

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

## RS.2 Management and Support

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

a) a director/manager who has the responsibility and accountability for these services

b) the director/manager shall have the qualifications, experience and/or training defined by the OSC

c) services shall be provided by qualified physical therapists, physical therapists assistants, occupational therapists, occupational therapist assistants, speech-language therapists, or audiologists as defined by the OSC and consistent with National and local legislation and regulations.

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

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

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

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

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

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

## RS.3 Treatment Plan / Orders

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

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

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

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

*I. The order from the practitioner for the service(s) in collaboration with individuals qualified to provide the service(s);*

*II. The type, amount, frequency and duration of services;*

*III. Measurable short-term and long-term goals, results and notes; and,*

*IV. Reviews and revisions, as necessary, to account for changes in the patient's response to therapeutic intervention.*

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

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

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

# Section 19 Emergency Department (ED)

## ED.1 Organisation

**SR.1** Emergency Services shall be coordinated with other departments and/or other local care providers to meet the emergency needs of its patients

**SR.2** The emergency department shall be appropriately staffed at all times by medical and nursing staff qualified in emergency care, as outlined within the written scope of service.

**SR.3** A qualified professional as defined by the OSC shall perform patient triage upon presentation to the emergency department.

***Interpretive Guidelines:***
*The OSC shall ensure that a qualified member of the medical staff is on premises and available to supervise the provision of emergency services 24 hours a day.*

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

*The OSC shall staff the emergency department with the appropriate numbers and types of professionals and other staff who possess the skills, education, certifications, specialized training and experience in emergency care when emergency services are provided.*

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

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

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

*Verify that the appropriate numbers and types of professionals and other staff who possess the skills, education, certifications, specialized training and experience in emergency care when emergency services are provided.*

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

# Section 20 Infection Prevention and Control (IC)

## IC.1 Infection Prevention and Control System

**SR.1** The OSC shall have a process in place to maintain a sanitary environment for OSC patients, staff, and others.

**SR.2** The OSC shall have a documented process, policies and procedures to define how infections and communicable diseases are prevented, controlled and investigated throughout the OSC.

**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 OSC shall maintain an infection control program for the prevention, control, and surveillance of infection, (which includes, but is not limited to OSC 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 OSCs agreed processes for maintaining sanitary environments.*

# Section 21 Medical Records Service (MR)

## MR.1 Organization

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

***Interpretive Guidelines:***
*The OSC shall provide evidence that is 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 OSC shall maintain an accurately written, contemporaneous completed healthcare record for each patient.

**SR.2** The OSC 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 OSC 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 OSC shall have a process for dealing with healthcare record delinquencies.

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

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

*The OSC 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 OSC 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 OSCs 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 OSC 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 OSC only in accordance with National or local law, court orders, or subpoenas.

***Interpretive Guidelines:***
*The OSC 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 OSCs 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 OSC approved process.

***Interpretive Guidelines:***
*Authentication may include written signatures. Electronic authentication is permissible*

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

# Section 22 Utilization Review (UR)

## UR.1 Documented Plan

**SR.1** The OSC shall maintain a documented utilization review plan that provides for review of organizational and medical staff services to patients.

**SR.2** The responsibilities and authority for those involved in utilization review activities in a Utilization Review (UR) Committee shall be described by the OSC and shall:

a) Have representation from clinical staff; ;

b) Ensure the committee reviews are not conducted by any individual who:
i. Has a direct financial interest (for example, an ownership interest) in the OSC; or
ii. Was professionally involved in the care of the patient whose case is being reviewed.

**SR.3** Requirement for all review findings in the aggregate to be reported to Quality Management Oversight.

**SR.4** Review shall address at least the following:

a) medical necessity of professional services; and

b) how well the services provided met the needs of the patient and whether they are contributing to increasing the health, quality of life and independence of the population served.

***Interpretive Guidelines:***
*The OSC UR plan should include a delineation of the responsibilities and authority for those involved in the performance of UR activities, define the requirement for all review findings to be reported to the Quality Management Oversight body, and ensure that there is no conflict of interest (financial or otherwise) by those individuals participating in the review.*

***Surveyor Guidance:***
*Verify that the OSC has a utilization review plan for those services furnished by the OSC.*

*Sample records and reports, and supporting documentation that UR activities are being performed as described in the OSC UR plan.*

*Verify the composition of the UR committee.*

*Review for any conflicts of interest.*

*Interview the chairperson of the UR Committee and/or other representative members of the committee to validate their role in carrying out the UR plan.*

# Section 23 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 OSC services appropriate to the needs of the community.

**SR.2** The condition of the OSC facilities and the overall OSC 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 OSC 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 OSC 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 OSC's patients, staff, and others.

**SR.5** The OSC 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 OSC.

**SR.6** The OSC 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 OSC, through its senior leadership shall ensure that the physical environment and associated management systems adequately address issues identified throughout the OSC 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 OSC 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 OSC 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 OSC monitors staff exposure levels in hazardous environments and report the results of the monitoring to the Quality Management System.

## PE.5 Emergency Management System

**SR.1** The OSC shall provide a comprehensive Emergency Management System to respond to emergencies in the OSC or within the community and region that may impact the OSC's ability to provide services.

**SR.2** The OSC 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** The OSC shall have contingency plans in place for the outbreak of communicable disease.

## PE.6 Medical Equipment Management System

**SR.1** The OSC 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 OSC's initial service inspection, the orientation, and the demonstration of use for rental or OSC 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 OSC 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.