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FOREWARD

This Bhutan Standard was adopted by the Bhutan Standards Bureau after it was finalized by the Pharmaceuticals and Traditional Medicines Technical Committee (TC-05) and endorsed by Bhutan Standards Bureau Board.

INTRODUCTION

Standards can be explicit (written) or implicit (understood). Implicit health care standards are those practices which are based on guidance of experienced professionals in a specific environment without written policies and procedures. Converting implicit standards to explicit standards provides consensus on a way to provide quality care reduces variation between health care providers and allows a baseline measure for monitoring quality and safety. The primary aim of the standard is to provide quality healthcare services and to meet the expectations of the public service. Therefore, this standard is intended to outline the minimum requirements for providing quality healthcare services by a Healthcare centre. The standard requirements may vary from one health center to another depending on the range of services delivered. It will be the responsibility of every healthcare provider to adhere to the standards to ensure quality and safety of the patients. The compliance to the specific requirements of the standards will be monitored using key performance indicators (KPI). HCC shall record and report the KPIs on regular intervals as defined in BHSQA.

1. Scope

The BHSQA applies to following Healthcare service standards: Access, Assessment and Continuity of Care (ACC), Care of Patients (COP), Patients Right and Education (PRE), Management of Medication (MOM), Patient Rights and Education (PRE), HCC Infection Control (HIC), Continuous Quality Infection (CQI), Responsibilities of Management (ROM), Facility Management and Safety (FMS), Human Resource Management (HRM), Information Management System (IMS) for Referral HCCs, District HCCs and BHU-Is and BHU-IIs.

2. Objectives

a) To develop quality culture in all the healthcare centers by establishing quality assurance and management system.
b) To ensure safety, equity, accessibility and uniformity of the healthcare services.
c) To enhance effectiveness and efficiency of the existing healthcare services.
d) To promote team work and ownership for quality and safety of the services being provided.
e) To encourage the environment of continuous quality improvement efforts.

3. Normative References

There are no normative references for this document.

4. Definitions

For the purposes of this standard, the following definitions shall apply. The commonly-used terminologies in the standards are briefly described and explained herein to remove any ambiguity regarding their comprehension. The definitions narrated have been taken from various authentic sources as stated, wherever possible. Notwithstanding the accuracy of the explanations given, in the event of any discrepancy with a legal requirement enshrined in the law of the land, the provisions of the latter shall apply.

4.1 Accreditation

4.1.1 A process of external review of the quality of the health care being provided by a HCC. This is generally carried out by a non-governmental HCC.

4.1.2 It also represents the outcome of the review and the decision than an eligible HCC meets and applicable set of standards.

4.2 Accreditation assessment

The evaluation process for assessing the compliance of a HCC with the applicable standards for determining its accreditation status.

4.3 Advance life support

Emergency medical care for sustaining life, including defibrillation, airway management, and drugs and medications.

4.4 Adverse drug event

Adverse event: Any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have causal relationship with this treatment.
Adverse Drug Reaction (ADR): A response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function.
Therefore ADR = adverse event with a causal link to a drug
Adverse drug event: The FAD recognizes the term adverse drug event to be a synonym for adverse event.
In the patient-safety literature, the terms adverse drug event and adverse event usually denote a causal association between the drug and the event, but there is a wide spectrum of definitions for these terms, including harm caused by a

a) Drug
b) Harm caused by drug use, and
c) A medication error with or without harm

Institute of Medicine: —An injury resulting from medical intervention related to a drugǁ, which has been simplified to "an injury resulting from the use of a drug". Adverse drug events extend beyond adverse drug reactions to include harm from overdoses and under-doses usually related to medication errors. A minority of adverse drug events is medication errors, and medication errors rarely result in adverse drug events.

4.5 Adverse event

An injury related to medical management, in contrast to complications of disease. Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non-preventable. (WHO Draft Guidelines for Adverse Event Reporting and Learning Systems)

4.6 Ambulance

A patient carrying vehicle having facilities to provide unless otherwise indicated at least basic life-support during the process of transportation of patient. There are various types of ambulances that provide special services viz. coronary care ambulance, trauma ambulance, air ambulance, etc.

4.7 Anaesthesia

It consists of general anaesthesia and spinal or major regional anaesthesia and does not include local anaesthesia. Anaesthesia is a drug-induced loss of consciousness during which patient cannot be aroused even by painful stimulation. The ability to independently maintain ventilator function is often impaired.

4.8 Assessment

All activities including history taking, physical examination, laboratory investigations that contribute towards determining the prevailing clinical status of the patient.

4.9 Autopsy

4.9.1 An examination of a cadaver in order to determine the cause of death or to study pathologic changes.
4.9.2 A surgical procedure performed after death to examine body tissues and determine the cause of death

4.10 Barrier nursing

The nursing of patients with infectious diseases in isolation to prevent the spread of infection. As the name implies, the aim is to erect a barrier to the passage of infectious pathogenic organisms between the contagious patient and other patients and staff in the HCC, and thence to the outside world. The nurses wear towns, masks, and gloves, and they observe strict rules that minimize the risk of passing on infectious agents.

4.11 Basic life support

Basic life support (BLS) is the level of medical care which is used for patients with life- threatening illnesses or injuries until the patient can be given full medical care.

4.12 Breakdown maintenance

Activities which are associated with the repair and servicing of site infrastructure, gildings, plant or equipment within the site's agreed building capacity allocation which have become inoperable or unusable because of the failure of component parts.

4.13 Bylaws

A rule governing the internal management of HCC. It can supplement or complement the government law but cannot countermand it, e.g. municipal bylaws for construction of HCCs/nursing homes, for disposal of hazardous and/or infectious waste.

4.14 Clinical audit

A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. (Principles for Best Practice in Clinical Audit 2002, NICE/CHI).

4.15 Clinical practice guidelines

Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. (Field and Lohr 1990. Page 38).

4.16 Competence

Demonstrated ability to apply knowledge and skills (Clause 3.10.4 of ISO 9000:2015).

4.17 Confidentiality

Restricted access to information to individuals who have a need, a reason and permission for such access. It also includes an individual's right to personal privacy as well as privacy of information related to his/her healthcare records.

4.18 Consent

4.18.1 Willingness of a party to undergo examination/procedure/treatment by a healthcare provider. It may be implied (e.g. patient registering in OPD), expressed which may be written or verbal. Informed consent is a type of consent in which the healthcare provider has a duty to inform his/her patient about the procedure, its potential risk and benefits, alternative procedure with their risk and benefits so as to enable the patient to take an informed decision

of his/her health care.

4.18.2 In law, it means active acquiescence or silent compliance by a person legally capable of consenting. In India, legal age of consent is 18 years. It may be evidenced by words or acts or by silence when silence implies concurrence. Actual or implied consent is necessarily an element in every contract and every agreement.

4.19 Control charts

Statistical tool used in quality control to (a) analyze and understand process variables, (b) determine process capabilities, and to (c) monitor effects of the variables on the difference between target and actual performance. Control charges indicate upper and lower control limits, and often include a central (average) line, to help detect trend of plotted values. If all data points are within the control limits, variations in the values may be due to a common cause and process is said to be in control'. If data points fall outside the control limits, variations may be due to a special cause and the process is said to be out of control.

4.20 Credentialing

The process of obtaining, verifying and assessing the qualification of a healthcare provider.

4.21 Critical path method (CPM)

The critical part method (CPM) is a step-by-step technique for process planning that defines critical and non-critical tasks with the goal of preventing time-frame problems and process bottlenecks. The CPM is ideally suited to projects consisting of numerous activities that interact in a complex manner.
In applying the CPM, there are several steps that can be summarized as follows:

a) Define the required tasks and put them down in an ordered (sequenced) list.
b) Create a flowchart or other diagram showing each task in relation to the others.
c) Identify the critical and non-critical relationships (paths) among tasks.
d) Determine the expected completion or execution time for each task.
e) Locate or devise alternatives (backups) for the most critical paths.

4.22 Data

Raw facts, clinical observations, or measurements collected during an assessment activity.

4.23 Discharge summary

A part of a patient record that summarizes the reasons for admission, significant clinical findings, procedures performed, treatment rendered, patient's condition on discharge and any specific instructions given to the patient or family (for example follow-up medications).

4.24 Disciplinary proceedings

Sequence of activities to be carried out when staff does not conform to the laid-down norms, rules and regulations of the HCC.

4.25 Employees

All members of the HCC who are employed full item and are paid suitable remuneration for their services as per the laid-down policy.

4.26 End of life

Period of time marked by disability or disease that is progressively worse until death.

4.27 Ethics

Medical ethics is the discipline of evaluating the merits, risks, and social concerns of activities in the field of medicine. (en.wikipeida.org/wiki/Medical ethics)

4.28 Evidence-based medicine

Evidence-based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.

4.29 Family

The person(s) with a significant role in the patient's life. It mainly includes spouse, children and parents. It may also include a person not legally related to the patient but can make healthcare decisions for a patient if the patient loses decision-making ability.

4.30 Failure Mode and Effect Analysis (FMEA)

A common process use dot prospectively identifies error risk within a particular process. FMEA begins with a complete process mapping that identifies all the steps that must occur for a given process to occur (e.g., programming an infusion pump or preparing an intravenous medication in the pharmacy). With the process mapped out, the FMEA then continues by identifying the ways in which each step can go wrong (i.e., the failure modes for each step), the probability that each error will be detected (i.e., so that it can be corrected before causing harm), and the consequences or impact of the error not being detected. The estimates of the likelihood of a particular process failure, the chance of detecting such failure, and its impact are combined numerically to produce a criticality index.

This criticality index provides a rough quantitative estimate of the magnitude of hazard posed by each step in a high-risk process. Assigning a criticality index to each step allows prioritization of targets for improvement. For instance, an FMEA analysis of the medication-dispensing process on a general HCC word might break down all steps from receipt of orders in the central pharmacy to filling automated dispensing machines by pharmacy technicians. Each step in this process would be assigned probability of failure and an impact score, so that all steps could be ranked according to the product of these tow numbers. Steps ranked at the top (i.e., those with the highest criticality indices) would be prioritized for error proofing.

4.31 Formulary

An approved list of drugs. Drugs contained on the formulary are generally those that are determined to be cost effective and medically effective.
The list is compiled by professionals and physicians in the field and is updated at regular intervals. Changes may be made

depending on availability or market.

4.32 Goal

A broad statement describing a desired future condition or achievement without being specific about how much and when. The term —goals refers to a future condition or performance level that one intends to attain. Goals can be both short- and longer term. Goals are ends that guide actions. (MBNQA)

4.33 Grievance-handling

Sequence of activities carried out to address the grievances of patients, visitors, relatives and staff.

4.34 Hazardous materials

Substances dangerous to human and other living organisms. They include radioactive or chemical materials

4.35 Hazardous waste

Waste materials dangerous to living organisms. Such materials require special precautions for disposal. They include biologic waste that can transmit disease (for example, blood, tissues) radioactive materials, and toxic chemicals. Other examples are infectious waste such as used needles, used bandages and fluid soaked items.

4.36 Healthcare-associated infection

Healthcare-associated infections (HAIs) are infections caused by a wide variety of common and unusual bacteria, fungi, and viruses during the course of receiving medical care. (CDC)This was earlier referred to as Nosocomial/HCC-acquired/HCC-associated infection(s).

4.37 HCC

Generic term is used to describe the various types of HCC that provide healthcare services. This includes ambulatory care Centers, HCCs, laboratories, etc.

4.38 High-dependency unit

A high-dependency unit (HDU) is an area for patients who require more intensive observation, treatment and nursing care than are usually provided for in a ward. It is a standard of care between the work and full intensive care.

4.39 In service education/training

Organized education/training usually provided in the workplace for enhancing the skills of staff members or for teaching them new skills relevant to their jobs/tasks.

4.40 Indicator

A statistical measure of the performance of functions, systems or processes overtime. For example, HCC acquired infection rate, mortality rate, caesarean section rate, absence rate, etc.

4.41 Information

Processed data which lends meaning to the raw data.

4.42 Intent

A brief explanation of the rational, meaning and significance of the standards laid down in a particular standard.

4.43 Inventory control

The method of supervising the intake, use and disposal of various goods in hands. It relates to supervision of the supply, storage and accessibility of items in order to ensure adequate supply without stock-outs/excessive storage. It is also the process of balancing ordering costs against carrying costs of the inventory so as to minimize total costs

4.44 Isolation

Separation of an ill person who has a communicable disease (e.g., measles, chickenpox, mumps, SARS) from those who are healthy. Isolation prevents transmission of infection to others and also allows the focused delivery of specialized health care to ill patients. The period of isolation varies from disease-to-disease. Isolation facilities can also be extended to patients for fulfilling their individual, unique needs.

4.45 Job description

a) It entails an explanation pertaining to duties, responsibilities and conditions required to perform a job.
b) A summary of the most important features of a job, including the general nature of the work performed (duties and responsibilities) and level (i.e., skill, effort, responsibility and working conditions) of the work performed. It typically includes job specifications that include employee characteristics required for competent performance of the job. A job description should describe and focus on the job itself and not on any specific individual who might fill the job.

4.46 Job specification

a) The qualifications/physical requirements, experience and skills required to perform a particular job/task.
b) A statement of the minimum acceptable qualifications that an incumbent must possess to perform a given job successfully.

4.47 Laws

Legal document setting forth the rules of governing a particular kind of activity, e.g. organ transplantation act, which governs the rules for undertaking organ transplantation.

4.48 Maintenance

The combination of all technical and administrative actions, including supervision actions, intended to retain an item in, or restore it to, a state in which it can perform a required function (British Standard 3811:1993).

4.49 Medical equipment

Any fixed or portable non-drug item or apparatus used for diagnosis, treatment, monitoring and direct care of patient.

4.50 Medication error

a) A medication error is any preventable event that may cause or lead to inappropriate medication use or harm to a patient. (FDA)
b) Medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing, order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use. (NCC MERP)

4.51 Mission

A HCC's purpose (ASQ).This refers to the overall function of a HCC. The mission answers the question, —What is this HCC attempting to accomplish?‖ The mission might define patients, stakeholders, or markets served, distinctive or core competencies, or technologies used. (MBNDQA)

4.52 Monitoring

The performance and analysis of routine measurements aimed at identifying and detecting changes in the health status or the environment, e.g. monitoring of growth and nutritional status, air quality in operation theatre. It requires careful planning and use of standardized procedures and methods of data collection.

4.53 Multi-disciplinary

A generic term which includes representatives from various disciplines, professions or service areas.

4.54 Near-miss

A near-miss is an unplanned event that did not result in injury, illness, or damage—but had the potential to do so. (Wikipedia) Errors that did not result in patient harm, but could have, can be categorized as near-misses.

4.55 No harm

This is used synonymously with near miss. However, some authors draw a distinction between these tows phrases. A near-miss is defined when an error is realized just in the nick of time and abortive action is instituted to cut short its translation. In no harm scenario, the error is not recognized and the deed is done but fortunately or the healthcare professional, the expected adverse event does not occur. The distinction between the tow is important and is best exemplified by reactions to administered drugs in allergic patients. A prophylactic injection of cephalosporin may be stopped in time because it suddenly transpires that the patient is known to be allergic to penicillin (near-miss). If this vital piece of information is overlooked and the cephalosporin administered, the patient may fortunately not develop and anaphylactic reaction (no harm event).

4.56 Notifiable disease

Certain specified diseases, which are required by law to be, notified to the public health authorities. Under the international health regulation (WHO's International Health Regulations 2005) the following diseases are notifiable to WHO:

a)Smallpox

b)Poliomyelitis due to wild-type poliovirus
c)Human influenza caused by a new subtype
d)Serve acute respiratory syndrome (SARS)

E4The notifiable diseases are: Polio, Influenza, Malaria, Rabies, HIV/AIDS, Louse-borne typhus, Tuberculosis, Leprosy, Leptospirosis, Viral hepatitis etc. The various diseases notifiable under the factories act lead poisoning, byssinosis, anthrax, asbestosis and silicosis

4.57 Objective

A specific statement of a desired short-term condition or achievement includes measurable end-results to be accomplished by specific teams or individuals within time limits (ASQ).

4.58 Objective element

It is that component of standard which can be measured objectively on a rating scale. The acceptable compliance with the measureable elements will determine the overall compliance with the standard.

4.59 Occupational health hazard

The hazards to which an individual is exposed during the course of performance of his job. These include physical, chemical, biological, mechanical and psychosocial hazards

4.60 Operational plan

Operational plan is the part of your strategic plan. It defines how you will operate in practice to implement your action and monitoring plans—what your capacity needs are, how you will engage resources, how you will deal with risks, and how you will ensure sustainability of the HCC's achievements.

4.61 Organogram

A graphic representation of reporting relationship in HCC

4.62 Outsourcing

Hiring of services and facilities from other HCC based upon one's own requirement in areas where such facilities are either not available or else are not cost-effective. For example, outsourcing of house-keeping, security, laboratory/certain special diagnostic facilities with other institutions after drawing a memorandum of understanding that clearly lays down the obligations of both HCCs: the one which is outsourcing and the one which is providing the outsourced facility. It also addresses the quality-related aspects.

4.63 Patient-care setting

The location where a patient is provided health care as per his needs, e.g. ICU, speciality ward, private ward and general ward.

4.64 Patient record/medical record/clinical record

A document which contains the chronological sequence of events that a patient undergoes during his stay in the HCC. It includes demographic data of the patient, assessment findings, diagnosis, consultations, procedures undergone, progress notes and discharge summary. (Death certificate, where required)

4.65 Performance appraisal

It is the process of evaluating the performance of employees during a defined period of time with the aim of ascertaining their suitability for the job, potential for growth as well as determining training needs.

4.66 Plan of care

A plan that identifies patient care needs, lists the strategy to meet those needs, documents treatment goals and objectives, outlines the criteria for ending interventions, and documents the individual's progress in meeting specified goals and objectives. The format of the plan may be guided by specific policies and procedures, protocols, practice guidelines or a combination of these. It includes preventive, promotive, curative and rehabilitative aspects of care.

4.67 Policies

They are the guidelines for decision-making, e.g. admission, discharge policies, antibiotic policy, etc.

4.68 Preventive maintenance

It is a set of activities that are performed on plant equipment, machinery, and systems before the occurrence of a failure in order to protect them and to prevent or eliminate any degradation in their operating conditions.
The maintenance carried out at predetermined intervals or according to prescribed criteria and intended to reduce the probability of failure or the degradation of the functioning of an item. (British Standard 3811:1993)

4.69 Privileging

It is the process for authorizing all medical professionals to admit and treat patients and provide other clinical services commensurate with their qualifications and skills.

4.70 Procedure

a) A specified way to carry out an activity or a process (Clause 3.4.5. of ISO 9000:2015
b) A series of activities for carrying out work which when observed by all help to ensure the maximum use of resources and efforts to achieve the desired output.

4.71 Process

A set of interrelated or interacting activities which transforms inputs into outputs (Clause 3.4.1 of ISO 9000:2015).

4.72 Program

A sequence of activities designed to implement policies and accomplish objectives.

4.73 Project evaluation and Review Technique (PERT)

PERT is a method to analyze the involved tasks in completing a given project, especially the time needed to complete each task, and to identify the minimum time needed to complete the total project.

PERT breaks down the project into events and activities, and lays down their proper sequence, relationships, and duration in the form of a network. Lines connecting the events are called paths, and the longest path resulting from connecting all events are called critical path. The length (duration) of the critical path is the duration of the project, and any delay occurring along it delays the whole project. PERT is a scheduling tool, and does not help in finding the best or the shortest way to complete a project.

4.74 Protocol

A plan or a set of steps to be followed in a study, an investigation or an intervention.

4.75 Quality

a) Degree to which a set of inherent characteristics fulfill requirements (Clause 3.6.2 of ISO 9000:2015).
Characteristics imply a distinguishing feature (Clause 3.10.1 of ISO 9000: 2015).
Requirements are a need or expectation that is stated, generally implied or obligatory (Clause 3.6.4 of ISO 9000:2015).

b) Degree of adherence to pre-established criteria or standards.

4.76 Quality Assurance

Part of quality management focused on providing confidence that quality requirements will be fulfilled (Clause 3.3.6 of ISO 9000:2015).

4.77 Quality improvement

Ongoing response to quality assessment data about a service in ways that improve the process by which services are provided to consumers/patients.

4.78 Re-assessment

It implies continuous and ongoing assessment of the patient which is recorded in the medical records as progress notes

4.79 Resources

It implies all inputs in terms of men, material, money machines, minutes (time), methods, meters (space), skills, knowledge and information that are needed for efficient and effective functioning of an HCC.

4.80 Restraints

Devices used to ensure safety by restricting and controlling a person's movement. Many facilities are —restraint freell or use alternative methods to help modify behaviour. www.alz.org/Resources/Glossalry.asp. Restraint may be physical or chemical (by use of sedatives).

4.81 Risk assessment

Risk assessment is the determination of quantitative or qualitative value of risk related to a concrete situation and a recognized threat (also called hazard). Risk assessment is a step in a risk management procedure.

4.82 Risk management

Clinical and administrative activities to identify evaluate and reduce the risk of injury.

4.83 Risk reduction

The conceptual framework of elements considered with the possibilities to minimize vulnerabilities and disaster risks throughout a society to avoid (prevention) or to limit (mitigation and preparedness) the adverse impacts of hazards, within the board context of sustainable development (source: http://www.preventionweb.net/english/professional/terminology/).
It is the decrease in the risk of a healthcare facility, given activity, and treatment process with respect to patient, staff, visitors and community.

4.84 Root Cause Analysis (RCA)

Root Cause Analysis (RCA) is a structured process that uncovers the physical, human, and latent causes of any undesirable event in the workplace. Root cause analysis (RCA) is a method of problem solving that tries to identify the root causes of faults or problem solving that tries to identify the root causes of faults or problems that cause operating events. RCA practice tries to solve problems by attempting to identify and correct the root causes of events, as opposed to simply addressing their symptoms. By focusing correction on root causes, problem recurrence can be prevented. The process involves data collection; cause charting, root cause identification and recommendation generation and implementation.

4.85 Safety

The degree to which the risk of an intervention/procedure, in the care environment is reduced for a patient, visitors and healthcare providers.

4.86 Safety program

A program focused on patient, staff and visitor safety.

4.87 Scope of services

Range of clinical and supportive activities that are provided by a healthcare HCC.

4.88 Security

Protection from loss, destruction, tampering, and unauthorized access or use.

4.89 Sedation

The administration to an individual, in any setting for any purpose, by any route, moderate or deep sedation. There are three levels of sedation: Minimal sedation (anxiolysis)--A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilator and cardiovascular functions

are not affected. Moderate sedation/analgesia (conscious sedation)—A drug-induced depression of consciousness during which patients respond purposefully to verbal commands either alone or accompanied by light tactile stimulation. No interventions are needed to maintain a patent airway. Deep Sedation/analgesia – A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully after repeated or painful stimulation. Patients may need help in maintaining a patent airway.

4.90 Sentinel events

A relatively infrequent, unexpected incident, related to system or process deficiencies, which leads to death or major and enduring loss of function for a recipient of healthcare services. Major and enduring loss of function refers to sensory, motor, physiological, or psychological impairment not present at the time services were sought or begun. The impairment lasts for a minimum period of two weeks and is not related to an underlying condition.

4.91 Social responsibility

A balanced approach for HCC to address economic, social and environmental issues in a way that aims to benefit people, communities and society, e.g. adoption of villages for providing health care, holding of medical camps and proper disposal of HCC wastes.

4.92 Staff

All personnel working in the HCC including employees, –fee-for-service‖ medical professionals, part-time workers, contractual personnel and volunteers.

4.93 Standard precautions

a) A method of infection control in which all human blood and other bodily fluids are considered infectious for HIV, HBV and other blood-borne pathogens, regardless of patient history. It encompasses a variety of practices to prevent occupational exposure, such as the use of personal protective equipment (PPE), disposal of sharps and safe housekeeping.
b) A set of guidelines protecting first aiders or healthcare professionals from pathogens. The main message is: —Don't touch or use anything that has the victim's body fluid on it without a barrier. It also assumes that all body fluid of a patient is infectious, and must be treated accordingly.

Standard Precautions apply to blood, all body fluids, secretions, and exertions (except sweat) regardless of whether or not they contain visible blood, non-intact skin an mucous membranes

4.94 Standards

A statement of expectation that defines the structures and process that must be substantially in place in HCC to enhance the quality of care.

4.95 Sterilization

It is the process of killing or removing microorganisms including their spores by thermal, chemical or irradiation means.

4.96 Strategic plan

Strategic planning is HCC's process of defining its strategy or direction and making decisions on allocating its resources to pursue this strategy, including its capital and people. Various business analysis techniques can be used in strategic planning; including SWOT analysis (Strengths, Weaknesses, Opportunities and Threats) e.g. HCC can have a strategic plan to become market leader in provision of cardiothoracic and vascular services. The resource allocation will have to follow the pattern to achieve the target. The process by which HCC envisions its future and develops strategies, goals, objectives and action plans to achieve that future. (ASQ)

4.97 Surveillance

The continuous scrutiny of factors that determines the occurrence and distribution of diseases and other conditions of ill health. It implies watching over with great attention, authority and often with suspicion. It requires professional analysis and sophisticated interpretation of data leading to recommendations for control activities.

4.98 Transfusion reaction

A transfusion reaction is a problem that occurs after a patient receives a transfusion of blood.

4.99 Triage

Triage is a process of prioritizing patients based on the severity for their condition so as to treat as many as possible when resources are insufficient for all to be treated immediately.

4.100 Unstable patient

A patient whose vital parameters need external assistance for their maintenance

4.101 Validation

a) Confirmation through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled (Clause 3.8.13 of ISO 9000:2015).

   Objective Evidence –Data supporting the existence or variety of something (Clause 3.8.3 of ISO 9000:2015).

b) The checking of data for correction or for compliance with applicable standards, rules or conventions. These are the tests to determine whether an implemented system fulfils its requirements. It also refers to what extent does a test accurately measure what it purports to measure.

4.102 Vision

The fundamental beliefs that drive HCC behavior and decision-making, (ASQ). This refers to the guiding principles and behaviors that embody how HCC and its people are expected to operate. Values reflect and reinforce the desired culture of HCC. (MBNQA).

4.103 Vulnerable patient

Those patients who are prone to injury and disease by virtue of their age, sex, physical, mental and immunological status,

e.g. infants, elderly, physically- and mentally- challenged, those on immunosuppressive and/ chemotherapeutic agents.

5. Acronyms

ABG	Arterial blood gas
ACLS	Advanced Cardiac Life Support
AERB	Atomic Energy Regulation Board
BHSQA	Bhutan Healthcare Standard for Quality Assurance
BID	"Bis In Die" which in Latin means twice a day
BLS	Basic Life Support
BMHC	Bhutan Medical and Health Council
CAPD	Continuous Ambulatory Peritoneal Dialysis
CDC	Centre for Disease Control
CID	Citizenship Identity Card
CPM	Critical Path Method
CPR	Cardiac Pulmonary Resuscitation
CQI	Continuous Quality Improvement
CSSD	Central sterile services Department
CT	Computerized Topography
DRA	Drug Regularity Authority
EMOC	Emergency Medical and Obsteritic Care
EPR	Electronic Patient Record
EPRE	Electronic patient records
EQA	External Quality Assessment
EQAP	External quality Assessment Program
EQAS	External quality Assessment Scheme
FIFO	First In First Out
FMEA	Failure Mode and Effects Analysis
GCP	Good Clinical Practice
HCC	Healthcare Center
HIRA	Hazard Identification and Risk Analysis
ICD	International Code for Diseases
ICMR	International Center for Materials Research
ICU	Intensive Care Unit
IPD	Inpatient Department
IQC	Internal Quality Control
ISMO	Isosorbide Mononitrate
IV	Intra Venous
LAMA	Left Against Medical Advice
MCI	Mild Cognitive Impairment
MLC	Medico-Legal Cases
MRD	Medical Record Division

MRI	Magnetic Resonance Image
MSDS	Material Safety and Data Sheets
MTP	Medical Termination of Pregnancy
NALS	Neonate advanced Life Support
NEQAS	Neonate advanced Life Support
OPD	Outpatient Department
PALS	Paediatric Advanced Life Support
PERT	Project Evaluation and Review Technique
PNDT	Prenatal Diagnostic Techniques
RBS	Random Blood Sugar
RTI	Right to Information Act
SOP	Standard Operating Procedure
SSCL	Surgical Safety Check List
TID	Thrice a Day (Latin)

6. Access, Assessment and Continuity of Care (AAC)

Preamble

Patients should be well informed of the services that a healthcare centre (HCC) provides. Patients that match the HCC resources are admitted using a defined process. Patients who do not match the HCC"s resources are referred to higher centre that has the matching resources. Patients cared for by the HCC undergo an established initial assessment and periodic and regular reassessments. Assessments include planning for utilization of laboratory and imaging services. The laboratory and imaging services are provided by competent staff in safe environment both for patients and staff. Continuity of health care is provided through well-defined transfer and discharge protocols which include transfer of adequate information along with the patient.

Summary of Standards

Std. No.	Standards
AAC 6.1	The HCC defines and displays the services that it can provide.
AAC 6.2	The HCC has a well-defined registration and admission process.
AAC 6.3	There is an appropriate mechanism for transfer (in and out) or referral of patients.
AAC 6.4	Patients cared for by the HCC undergo an established initial assessment.
AAC 6.5	Patients cared for by the HCC undergo a regular reassessment.
AAC 6.6	Laboratory services are provided as per the scope of services of the HCC and adhering to best practices.
AAC 6.7	There is an established laboratory quality assurance program.
AAC 6.8	There is an established laboratory-safety protocol
AAC 6.9	Radiological services are provided as per the scope of services of the HCC and adhering to the best practices.
AAC 6.10	There is an established quality assurance program for Radiological services.
AAC 6.11	There is an established radiation safety protocol.

AAC 6.12	Patient care is continuous and multidisciplinary in nature.
AAC 6.13	The HCC has a documented discharge process
AAC 6.14	HCC defines the content of the discharge summary
AAC 6.15	Services in the Departments/Units are provided as per the scope of services of the HCC and adhering to the best practices.
AAC 6.16	The Quality Assurance Program in the Departments/Units is documented.
AAC 6.17	There is an established Safety protocols in the Departments/Units

Standards and Objective Elements

Standard

AAC 6.1: The HCC defines and displays the services that it can provide.

Objective Elements

6.1.1 The services being provided are clearly defined and are in consonance with the needs of the community.

Interpretation/Remarks:

a) The HCC shall define this keeping in mind the scope of services applied for.

b) The needs of the community should be considered especially when planning a new HCC or adding new services.

c) The same could be recorded through the feedback mechanism.

6.1.2 The defined services are prominently displayed.

Interpretation/Remarks:

a) The services so defined should be numbered and displayed prominently in an area visible to all patients entering the HCC.

b) The display could be of permanent nature in the form of boards, etc.

c) Display should be at least bi-lingual (Dzongkha and English/local language).

6.1.3 The staff are oriented to these services.

Interpretation/Remarks:

a) All the staff in the HCC mainly in the reception/registration, OPD, IPD are oriented to these facts through regular training program or through manuals.

b) Records of all such training shall be documented and available.

Standard

AAC 6.2: The HCC has a well-defined registration and admission process.

Objective elements

6.2.1 Documented policies and procedures are used for registering and admitting patients.

Interpretation/Remarks:

a) HCC shall prepare documents(s) detailing procedures for registration and admission of patients which should also include unidentified patients.
b) All patients who are assessed in the HCC shall be registered.
c) All admission must be authorized by an authorized prescriber.

6.2.2 The documented procedures address out-patients, in-patients and emergency patients.

Interpretation/Remarks:

a) It is preferable if each one of these is separately addressed (Out-patients, In-patients & emergency patients).

6.2.3 A unique identification number (CID/HCC Registration Number) is generated at the end of registration.

Interpretation/Remarks:

a) The HCC shall ensure that every patient gets a unique number (CID/HCC Registration Number) which is generated at the end of registration of the first interaction that the patient has with the HCC.
b) This number shall be used for identification of the patient across the HCCs and to ensure continuity of care across the HCCs.
c) All HCC records of the patient shall have this number.
d) "Unique" implies that this is a one-time affair.
e) Please note that a particular patient can have only one unique number. However, in case of multiple visits (OP/IP) a different number could be generated in addition to the above- mentioned unique number each time.
f) To ensure continuity of care, these numbers shall be linked to the unique number.

6.2.4 Patients are accepted only if the required services are available at the HCC.

Interpretation/Remarks:

a) The staff handling admission and registration needs to be aware of the services that the HCC can provide.
b) It is also advisable to have a system wherein the staff are aware as to who to contact if they need any clarification on the services provided.
c) Patients are referred immediately to the higher healthcare centre if the required services are not available.

6.2.5 The documented policies and procedures also address managing patient when it surpasses the total capacity of the bed strength.

Interpretation/Remarks:

a) The HCC is aware of the availability of alternate arrangement where the patients may be directed in case of non-availability of beds in the desired bed category or unit.
b) In case the admitted patients is in a temporary holding area, it shall ensure that there is adequate infrastructure to take care of these patients and shall define as to how long patients are kept on temporary beds before a decision to transfer out is taken.
c) The documented procedure also addresses managing patients when bed space is not available in the desired bed category or unit.

6.2.6 The staff are aware of these processes.

Interpretation/Remarks:

a) All the staff handling these activities should be oriented to these policies and procedures.
b) Orientation can be provided by documentation/training.

Standard

AAC 6.3: There is an appropriate mechanism for transfer (in and out) or referral of patients. Objective Elements

6.3.1 Documented procedures guide the transfer-in of patients to the HCC.

Interpretation/Remarks:

a) This shall address both planned and unplanned transfers.

b) For unplanned transfers and in case of suspected unstable patients, the HCC could send a staff trained in basic life support with the ambulance. However, this shall be guided by the information received and policy of the HCC.

6.3.2 Documented procedures guide the transfer-out/referral of unstable patients to next higher centre in an appropriate manner.

Interpretation/Remarks:

a) The HCC shall at the outset define the unstable patient as per the National Standards for Emergency Services.

b) This shall be defined based on physiological criteria.

c) The documented procedure should address the methodology of safe transfer of the patient in a life-threatening situation (like those who are on ventilator) to another higher centre.

d) There should be availability of an appropriate ambulance fitted with-life support facilities and accompanied by trained personnel.

e) These patients include those who have come to the emergency but need to be transferred to another higher HCC or those already admitted but who now require care in higher HCC.

f) It also includes patients being shifted for diagnostic tests.

6.3.3 Documented procedures guide the transfer-out/referral of stable patients to another facility in an appropriate manner.

Interpretation/Remarks:

a) Patients not in a life threatening situation (stable) should also be transported in a safe manner.

6.3.4 The documented procedures identify staff responsible during transfer/referral.

Interpretation/Remarks:

a) The staff accompanying shall at least be a trained trauma/emergency technicians or nurses. He/she shall have undergone training as per National Standards for Emergency Services. Further, the procedure shall identify the responsible staff for various steps of the procedure.

b) A competent health professional should accompany an unstable patient and criteria for the unstable patient should be defined.

6.3.5 The HCC gives a summary of patient's condition and the treatment given.

Interpretation/Remarks:

a) The HCC gives a case summary mentioning the significant findings and treatment given in case of patients who are being transferred from emergency. A copy of the same shall be retained by the HCC. For admitted patients a discharge summary has to be given (refer AAC 6.14).

b) This shall include patients being transferred both for diagnostic and/or therapeutic purposes.

c) Patient under critical condition should be escorted by at least two competent health professionals.

Standard

AAC 6.4: Patients cared for by the HCC undergo an established initial assessment.

Objective Elements

6.4.1 The HCC defines and documents the content of the initial assessment for the out-patients, in- patients and emergency patients.

Interpretation/Remarks:

a) The HCC shall have a format using which a standardized initial assessment of patients is done in the OPD, emergency and in-patients. The initial assessment could be standardized across the HCC or could be modified depending on the need of the department. However, it shall be the same in that particular, e.g. in pediatric OPD the weight and height may be a must, whereas it may not be so for orthopedics OPD. In emergency department, this shall include recording the vital parameters.

b) Every initial assessment shall contain the presenting complaints, vital signs (temperature, pulse, BP and respiratory rate) and salient examination findings (especially of the system concerned).

c) This shall incorporate initial assessment by doctors and nursing staff in case of in-patients.

6.4.2 The HCC determines who can perform the initial assessment.

Interpretation/Remarks:

a) The HCC determines who can do what assessment and it should be the same across the HCC. Assessments are performed by each discipline within its scope of practice as per the regulations of the BMHC.

b) Refer to HRM 9.1

6.4.3 The HCC defines the time frame within which the initial assessment is completed based on patient's needs.

Interpretation/Remarks:

a) The HCC has defined and documented the time frame within which the initial assessment is to be completed with respect to OPD/emergency/ indoor patients. The time frame shall be from the time that the patient has registered (or in case of emergency: come to the emergency) till the time that the initial assessment is documented by the treating doctor/consultant.

b) The time frame shall be reasonable and match with the HCC resources and patient load. In case of out-patients there could be a separate timeframe for patients coming with appointment and for "walk-in" patients. Patient's needs mean the condition of the patient.

6.4.4 The initial assessment for in-patients is documented within 24 hours or earlier as per the patient's condition as defined in the HCC"s policy/protocol.

Interpretation/Remarks:

a) This should cover history, examination including vital signs and documentation of any drug allergies. It should mention the provisional diagnosis.

b) For an admitted patient, if a detailed assessment has been done earlier (either in OPD within the past seven days or emergency), it need not be written in detail again.

c) Please note that the maximum time allowed for documentation is 24 hours. However, the Healthcare Centre shall define and document the appropriate time depending on the patient's condition and the scope of its services.

6.4.5 Initial assessment of in-patients includes nursing assessment which is done at the time of admission and documented.

Interpretation/Remarks:

a) This shall identify the nursing needs and also help identify any special needs of the patient. It shall be completed within a defined time frame. This assessment shall help in identifying the nursing needs of the patient. It may be in form of a Nursing process/note.

b) A checklist or template could be used for the same.
c) Nursing process/note

6.4.6 Initial assessment includes screening for nutritional needs.

Interpretation/Remarks:

a) The protocol for patient's initial assessment should cover his/her nutritional needs, height and weight.
b) This is only a screening for nutritional needs and not a complete assessment.
c) A detailed nutritional assessment shall be done wherever necessary.
d) This could be done by the treating doctor/nurse/dietician.
e) Questionnaires could be used for the same.
f) Nutritional screening shall be done for all stable patients including OP and IP.
g) Where appropriate, the HCC should consider providing a nutritional assessment for out- patients too.

6.4.7 The initial assessment results in a documented plan of care.

Interpretation/Remarks:

a) This shall be documented by the treating doctor or by a member of his team in the patient record.
b) For definition of "plan of care" refer to glossary. This is applicable only for day-care and in-patients.

6.4.8 The plan of care also includes preventive aspects of the care where appropriate.

Interpretation/Remarks:

a) The documented plan of care should cover preventive actions as necessary in the case and could include diet, drugs etc. In condition where it is not possible to incorporate this at the time of assessment (e.g. diagnosis not made/unclear) the same shall be done as soon as a definite diagnosis is arrived at.
b) This could also be done through booklets/patient information leaflets etc. e.g. diabetes, hypertension.

6.4.9 The plan of care is countersigned by the clinician in-charge of the patient within 24 hours

Interpretation/Remarks:

a) The treatment of the patient could be initiated by a junior doctor but the same should be countersigned and authorized by the treating doctor within 24 hours. The clinician in charge implies the treating doctor.

6.4.10 The plan of care includes goals or desired results of the treatment, care or service.

Interpretation/Remarks:

a) The indicative goals are curative, preventive and rehabilitative.

Standard

AAC 6.5: Patients cared for by the HCC undergo a regular reassessment.

Objective elements

6.5.1 Patients are reassessed at appropriate intervals

Interpretation/Remarks:

a) After the initial assessment, the patient is reassessed periodically and this is documented in the case sheet. Reassessments shall also be done in response to significant changes in patient's condition.
b) Every patient shall be reassessed at least once every day by the treating doctor. Reassessments shall also be done for day-care patients (before discharging) or patient's waiting for admission/bed.

6.5.2 Out-patients are informed of their next follow-up, where appropriate.

Interpretation/Remarks:

a) The reassessment notes shall reflect the patient's response to treatment and at a minimum capture the symptoms (change or fresh) and vital signs.
b) This would not be applicable in cases where patient has come for just an opinion or the patient's condition does not warrant repeat visits.

6.5.3 For in-patients during reassessment, the plan of care is monitored and modified, where found necessary.

Interpretation/Remarks:

a) The plan of care shall be dynamic and modified where necessary by the treating doctor according to the patient's condition.

6.5.4 Staff involved in direct clinical care document reassessments.

Interpretation/Remarks:

a) Action taken under reassessment is documented and the documentation shall include vitals, findings of the systemic examination and medication orders where necessary.
b) Action taken under reassessment is documented.
c) The staff could be the treating doctor or any member of the team as per their domain of responsibility of care.
d) At a minimum, the documentation shall include vitals, systemic examination findings and medication orders.
e) The nursing staff shall document patient's vitals and other findings.
f) Only phrases like "patient well", "condition better" would not be acceptable.

6.5.5 Patients are reassessed to determine their response to treatment and to plan further treatment or discharge.

Standard

AAC 6.6: Laboratory services are provided as per the scope of services of the HCC and adhering to best practices.

Objective elements

6.6.1 Scope of the laboratory services are commensurate to the services provided by the Healthcare Centre.

Interpretation/Remarks:

a) The HCC should ensure availability of laboratory services round the clock and patient care does not suffer.
b) Test results required for emergency management must be available within its premises.
c) Laboratory services are in consonance with the Standards for Laboratory services 2007.
d) For example, a cardiac care HCC must necessarily have facilities for cardiac enzyme

6.6.2 The infrastructure (physical and manpower) is adequate to provide for its defined scope of services.

Interpretation/Remarks:

a) The available equipment and manpower should be able to effectively deliver its laboratory services.
b) Reports should not get delayed due to lack of adequate equipment or manpower (including people authorized to report results).

6.6.3 Adequately qualified and trained personnel perform, supervise and interpret the investigation.

Interpretation/Remarks:

a) The staff employed in the lab should be suitably qualified and trained to carry out the tests.
b) Competent laboratory staff supervises the staff.

c) Only trained and qualified laboratory staff are recruited who are recognized by BMHC.

6.6.4 Documented procedures guide ordering of test, collection, identification, handling, safe transportation, processing and validation and disposal of specimens.

Interpretation/Remarks:

a) The HCC has documented SOP for ordering, collection, identification, handling, safe transportation, processing, and disposal of specimens, to ensure quality of reports and safety of the specimen till the tests and retests (if required) are completed.

b) In addition unique identification number (CID/HCC Registration Number), laboratory could use appropriate lab number to identify the sample.

c) This should be in line with standard precautions. The disposal of waste shall be as per the rules and regulation requirements (Infection Control and Medical Waste Management Guideline 2006, Waste Management Act 2009 and Waste Management Rules and Regulation 2012).

6.6.5 Laboratory results are available within a defined time frame Results are reported in a standardized manner.

Interpretation/Remarks:

a) The HCC should ensure availability of laboratory results within the defined time frame.

b) The turnaround time could be different for different tests and could be decided based on the nature of test, criticality of test and urgency of test result.

c) At a minimum, the report shall include the name of the HCC, the patient's name and sex, the unique identification number, and reference range of the test (where applicable) and the name and signature of the person reporting the test result.

6.6.6 Critical results are intimated immediately to the personnel concerned.*

Interpretation/Remarks:

a) The laboratory shall establish its biological reference intervals for different tests. The laboratory shall establish and document critical limits for tests which require immediate attention for patient management and the same shall be documented.

b) The critical test results shall be communicated to the personnel concerned and this shall be documented.

c) If it is not practical to establish the biological reference interval for a particular analysis the laboratory should carefully evaluate the published data for its own reference intervals.

6.6.7 Results are reported in a standardized manner.

Interpretation/Remarks:

a) At a minimum, the report shall include the name of the HCC, the patient's name, the unique identification number, and reference range of the test (where applicable) and the name and signature of the person reporting the test result.

Standard

AAC 6.7: There is an established laboratory quality management system (QMS).

Objective Elements

6.7.1 The laboratory quality QMS is documented.

Interpretation/Remarks:

a) The HCC has a documented quality QMS (quality manuals, SOPs, IQC, NEQAS & EQAS – if any for

quality and competence).

b) QMS includes management and organization, internal quality control, external quality assurance, pre-analytic phase, test standardization and post-analytic phase.

c) The laboratory shall participate in external quality assurance program when available. When such programs are not available, the laboratory could exchange samples with another laboratory for purposes of peer comparison.

6.7.2 The QMS addresses verification and/or validation of test methods. Interpretation/Remarks:

a) This holds true for any laboratory-developed methods. Standard methods need verification to ensure that the laboratory is capable of performing the analysis

b) Verification of an analytical procedure is the demonstration that a laboratory is capable of replicating with an acceptable level of performance a standard method.

c) Verification under conditions of use is demonstrated by meeting system-suitability specifications established for the method, as well as a demonstration of accuracy and precision or other method parameters for the type of method.

d) Verification of Standard Method Performance is defined for two situations, (1) for verifying method performance with each analytical batch (EAB) and (2) the first use of a standard method within the laboratory.

e) Non-standard and laboratory-developed methods need method validation.

f) Methods requiring validation are:

1) Modified official methods
2) In-house developed methods
3) Methods extended to a component, analysis or matrix not previously tested or included in validation
4) Changes involving new technology or automation

d) Verification usually includes accuracy, precision and linearity.

e) Validation in addition includes sensitivity and specificity.

6.7.3 The QMS addresses surveillance of test results. Interpretation/Remarks:

a) The head of laboratory department shall periodically assess the test results. This shall be done in a structured manner. The HCC shall specify the frequency and the sample size that it shall use for the surveillance.

6.7.4 The QMS includes periodic calibration and maintenance of all equipments. Interpretation/Remarks:

a) Refer to SOPs/manual on calibration/ISO 15189.

b) Traceability certificate(s) of all calibration done shall also be documented and maintained.

6.7.5 The QMS includes the documentation of corrective and preventive action. Interpretation/Remarks:

a) Incident reports are well documented

b) Action plans are documented for prevention

Standard

AAC 6.8 There is an established laboratory-safety protocol

Objective elements

6.8.1 The laboratory-safety protocol is documented.
Interpretation/Remarks:

a) A well-documented laboratory safety manual is available in the lab. This takes care of the safety of the

workforce as well as the equipments available in the lab. It shall be inconsonance with the risks and hazards identified.

b) This program is aligned with the HCC"s safety protocol

c) This could be as per rules & regulation of Occupational Health and Safety of Bhutan 2012.

6.8.2 Written SOPs guide the handling and disposal of infectious and hazardous materials.

Interpretation/Remarks:

a) This could be as per Occupational Health and Safety Management System, Infection Control and Medical Waste Management Guideline 2006, Waste Management Act 2009, and Waste Management Rules and Regulation 2012.

6.8.3 Laboratory personnel are appropriately trained in safe practices.

Interpretation/Remarks:

a) All the lab staff undergoes training regarding safe practices in the lab.

6.8.4 Laboratory personnel are provided with appropriate safety equipment/devices.

Interpretation/Remarks:

a) Adequate safety devices are available in the lab, e.g. fire extinguishers, disinfectants etc. This should be sufficient to address the safety issue. At a minimum, standard precautions are adhered to.

b) All laboratory staff shall be appropriately immunized especially against Hepatitis B.

Standard

AAC 6.9: Radiological and imaging services are provided as per the scope of services of the HCC and adhering to the best practices.

Objective elements

6.9.1 Imaging services comply with legal and other requirements.

Interpretation/Remarks:

a) The HCC is aware of the legal and other requirements of imaging services and the same are documented for information and compliance by all concerned in the HCC and maintains and updates its compliance status of legal and other requirements in regular manner.

b) All the legal requirements are met with such as dosimeters, lead sheets, lead aprons, signage, display etc.

c) The HCC shall have a Radiation Safety Rules & regulation in place.

6.9.2 Scope of the Radiological and imaging services is commensurate to the services provided by the Healthcare Centre

Interpretation/Remarks:

a) For example, a neuro-science Centre shall have CT and MRI.

6.9.3 The infrastructure (physical and manpower) is adequate to provide for its defined scope of services.

Interpretation/Remarks:

a) The equipment available and manpower should be able to effectively deliver its imaging services.

b) Reports should not get delayed due to lack of adequate equipment or manpower (including people authorized to report results).

6.9.4 Adequately qualified and trained personnel perform, supervise and interpret the investigations.

Interpretation/Remarks:

a) As per the guidelines and SOPs.

6.9.5 Documented procedure guide identification and safe transportation of patients to Radiology Department

Interpretation/Remarks:

a) The Healthcare Centre has documented policies and procedures for informing the patients about the radiological activities, their identification and safe transportation to the radiological services. This should also address transfer of unstable patients to imaging services.

b) The patients shall also be transported back in a safe manner.

6.9.6 Imaging results are available within a defined time frame.

Interpretation/Remarks:

a) The HCC shall document turnaround time of imaging results for all modalities.

b) The defined time frame could be different for different types of radiological services and could be decided based on the nature, criticality and urgency of radiological service (as desired by the treating doctor).

6.9.7 Critical results are intimated immediately to the concerned clinicians.

Interpretation/Remarks:

a) Critical results shall be intimated to the treating clinician at the earliest on phone, followed by a written report. Time of communication and the person contacted should be documented.

b) The HCC shall define and document the critical results which require immediate attention of clinician, e.g. ectopic pregnancy.

6.9.8 Results are reported in a standardized manner.

Interpretation/Remarks:

a) At a minimum, the report shall include the name of the HCC, the patient's name, the unique identification number (CID/HCC Registration Number), and the name and signature of the person reporting the test result.

b) In case of tele-radiology, there shall be the name of the reporting doctor and a remark to that effect.

Standard

AAC 6.10: There is an established quality assurance program for Radiological and imaging services.

Objective Elements

6.10.1 The quality assurance program for radiological and imaging services is documented.

Interpretation/Remarks:

a) Some examples include congruence of optical and radiation field, focal sport size, output consistency, leakage rate, etc.

6.10.2 The program addresses verification and/or validation of radiological imaging methods.

Interpretation/Remarks:

a) This holds true for any in-house developed methods.

6.10.3 The program addresses surveillance of radiology results.

Interpretation/Remarks:

a) The head of the radiology department shall periodically assess the radiology results. This shall be done in

a structured manner. The HCC shall specify the frequency and the sample size that is shall use for the surveillance.

6.10.4 The program includes periodic calibration and maintenance of all equipment.
Interpretation/Remarks:

a) Calibration and maintenance of all equipment shall be carried out by competent persons.
b) Traceability certificate(s) of all calibration done by calibrated equipment shall be documented and maintained.

6.10.5 The program includes the documentation of corrective and preventive actions.

Standard

AAC 6.11: There is an established radiation safety protocol.

Objective Elements

6.11.1 The radiation-safety program is documented.
Interpretation/Remarks:

a) Refer to protocol & SOPs
b) HOD and QA focal person shall devise implement and monitor the process.

6.11.2 This program is aligned with the HCC"s safety program
Interpretation/Remarks:

a) Radiology safety program is aligned with, and its broad principles shall be the same as that of the HCC"s safety program.

6.11.3 Handling, usage of disposal of radio-active and hazardous materials is as per legal requirements.
Interpretation/Remarks:

a) Document on safe use of radioactive isotopes for radiology services shall be available and implemented.
b) Radioactive and hazardous materials shall be disposed of as per guidelines laid down by competent bodies (Infection Control and Medical Waste Management Guideline 2006, Waste Management Act 2009 and Waste Management Rules and Regulation 2012).
c) Material safety and data sheets (where applicable) shall be available and staff well versed in the same.

6.11.4 Radiology personnel are provided with appropriate radiation safety devices.
Interpretation/Remarks:

a) This includes lead aprons, shields and dosimeters to name a few.
b) The number of such devices shall be adequate to ensure that all workers have proper protection.

6.11.5 Radiation-safety devices are periodically tested and results documented.
Interpretation/Remarks:

a) Protective devices, e.g. lead aprons, should be expensed to X-ray for verification of cracks and damages.
b) It is preferable that the film of the same be stored (either physical or electronic).
c) Where appropriate corrective and/or preventive action shall be taken and documented.
d) HCC shall ensure availability of safety measures for portable X-Ray.