

MSDS

Minimum Service
Delivery Standards



Indicators
for Hospitals



PUNJAB HEALTHCARE COMMISSION

Striving for quality healthcare in Punjab

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List of Acronyms and Abbreviations

AAC	Access, Assessment and Continuity of care
ASA	American Society of Anaesthesiologists
COP	Care of Patients
CQI	Continuous Quality Improvement
DFID	Department for International Development
FGD	Focus Group Discussion
FMS	Facility Management and Safety
HIC	Hospital Infection Control
HRM	Human Resource Management
ICU	Intensive Care Unit
IMS	Information Management Systems
IND	Indicator
JCAH	Joint Commission for Accreditation of Hospitals
JCI	Joint Commission International
KCl	Potassium Chloride
MOM	Management of Medication
MSDS	Minimum Service Delivery Standards
OH&S	Occupational Health and Safety
PHC	Punjab Healthcare Commission
PNAC	Pakistan National Accreditation Council
PNRA	Pakistan Nuclear Regulatory Authority
PRE	Patient Rights and Education
QA	Quality Assurance
QHA	Quality Holistic Accreditation
ROM	Rules of Management
SEPP	Society of Emergency Physicians Pakistan
SOPs	Standard Operating Procedures
TAC	Technical Advisory Committee
TAMA	Technical Assistance Management Agency

Foreword

The Punjab Healthcare Commission (PHC) is an autonomous health regulatory body established under the PHC Act 2010 for the standardization of healthcare service delivery in Punjab. Under this mandate, the PHC has developed the Minimum Service Delivery Standards (MSDS) and associated Indicators for Hospitals to introduce a culture of Clinical Governance grounded in the principles of responsibility and accountability so that the quality, safety and efficiency of healthcare service delivery in Punjab could subsequently be improved.

A product of collaborative deliberations between international and local health experts, and extensive consultations with the relevant stakeholders, these standards have been reviewed and endorsed by the Technical Advisory Committee (TAC), and approved by the Board of Commissioners (BOC) of the PHC and the Government of Punjab.

A total of 30 Standards and 162 indicators are prescribed in the MSDS covering all vital aspects of healthcare service delivery, ranging from Care of Patients and Management of Medication to Continuous Quality Improvement, Infection Control and Information Management Systems, among others. Each indicator is accompanied by a scoring matrix to assess compliance with the Standards and to facilitate their implementation.

I would like to thank the international consultants from the DFID and the Pakistani experts for their valuable inputs in the compilation of this document. My thanks are also due to all the stakeholders who made extremely beneficial suggestions for making the MSDS practically applicable in the Pakistani context. I am also indebted to the TAC for a highly professional critical appraisal of the final document. My special appreciation also goes to the team of the PHC under the leadership of the Chief Operating Officer for their diligence and hard work in achieving this crucial milestone. Lastly, I am grateful to my fellow Commissioners of the Board for their guidance and support in the development of this document.

I sincerely hope that these MSDS, developed by the PHC, would mark its first step towards achieving its purpose of providing quality healthcare services to the people of Punjab.

Justice (R) Aamer Raza Khan

Chairman

Punjab Healthcare Commission

1. Introduction

The Government of the Punjab, charged with the role of protecting its citizens, promulgated the Punjab Healthcare Commission (PHC) Act 2010. The vision of the PHC is 'to promote high quality and safe healthcare delivery for all' and the mission is 'to continually raise standards of healthcare delivery' throughout Punjab. A reputable team of Pakistani practitioners with international collaboration derived these standards. The origin of the standards can be found in the 1500+ Joint Commission International (JCI) Indicators and in the review of Australian, New Zealand, Indian, UK, and Canadian standards. They have been considerably reduced in number, and the scope has been adapted for the local context to ensure a realistic approach in the foundation years for their introduction.

Minimum Service Delivery Standards (MSDS) and indicators include the fundamental elements that should be present in all healthcare establishments in order to deliver safe health services. They are consistent with the Pakistani national indicators currently being developed. This is to promote consistency and down-stream comparison. They recognize that some establishments are starting from a low base, and cover (i) Patient and (ii) Organization centered standards. They have been developed by Pakistani Experts working in the field of healthcare provision and management and include advice on the surveillance process and scoring.

Health Standards and Indicators are dynamic, reflecting the constant development of healthcare treatments, practices and protocols. They are driven by evidence-based research and are designed to promote a safe environment with managed risks. This benefits both patients and healthcare establishments and contributes to the social objectives of Punjab and the Nation. Over time, it is anticipated that the range and scope of standards and their indicators will increase and develop with the collaboration of Health Sector Leaders, Councils, Colleges, Boards and Associations.

The PHC is pleased to adopt these 30 professionally developed "Foundation Standards" and 162 associated Indicators for Secondary and Tertiary Hospitals on behalf of the citizens of Punjab.

1.1 Service Delivery Standards

Setting service delivery standards and indicators is an established practice for continuously improving the provision of quality services in the health sector. Joint Commission International (JCI) in the USA is one such organisation that sets standards to improve the quality of health services against such standards. Likewise, the Quality Care Commission in the UK ensures clinical governance with the help of a system of standard setting and facilitating compliance. The 'Indian Public Health Standards' were introduced in 2005 and since then the Quality Council of India expanded their scope with the launching of 'Standards for the Health and Wellness Industry' in 2008. The Australian Council on Healthcare Standards was initiated in 1974 that has facilitated the development of the New Zealand and Singapore Councils. La Haute Autorite de Sante is the French equivalent. Accreditation Canada (formally the Canadian Council on Health Services Accreditation) became independent from the Joint Commission for Accreditation of Hospitals (JCAH) in 1953. The Quality Holistic Accreditation (QHA) Trent Accreditation Scheme is based in the UK and Europe and has serviced hospitals in Asia.

Regional Internationally accredited hospitals can be found in Pakistan, India, Bangladesh, Kazakhstan, China and Iran.

1.2 Focus Group Discussions and Consultation

In order to discuss the standards and indicators with a wider group of professionals, a Focus Group Discussion (FGD) was held on 31st May 2011 in the office of the Technical Assistance Management Agency (TAMA). The key objectives of the discussion were to:

1. Review the draft MSDS Foundation Standards and Indicators and amend as required.

2. Confirm readiness for circulation as part of the pending licensing process.
3. Discuss the process of ongoing standards development.

Participants included renowned medical practitioners from key public and private hospitals who have also been actively involved in the PHC Stakeholder Workshop held in January 2011 and in the Licensing, Accreditation and Regulation Workshop in March 2011. The FGDs were part of a series of consultative meetings that TAMA's consultants for the PHC project undertook with relevant stakeholders and health professionals in order to ensure their involvement and engagement with the PHC.

The PHC's Technical Advisory Committee (TAC) reviewed, amended and endorsed the MSDS in August 2012 prior to adoption by the Board of Commissioners.

2. Standards

2.1 Access, Assessment, and Continuity of Care (AAC)

Standard 1. AAC-1: Laboratory services are provided as per the requirements of patients.

Indicators (1-6):

Ind 1. *Scope of the laboratory services is commensurate to the clinical services provided by the organization.*

Survey Process:

This will require an understanding of the full scope of services provided at the healthcare establishment and observation of the diagnostic facilities provided both on and off site. Check on the external reference testing arrangements and validate.¹

Scoring:

- If the healthcare establishment's laboratory and any qualified outsourced services² support the scope of services and are validated with external reference testing, then score as fully met.
- If there is an insufficient scope of laboratory diagnostic procedures to support the services provided by the hospital³ or by an accredited laboratory with adequate service support⁴, and no external validation exists, then score as not met.

Ind 2. *Adequately qualified and trained personnel perform and/or supervise the investigations.*

Survey Process:

Each laboratory personnel should have a job description equivalent to the specifications for laboratory staff in the *Job Descriptions and Performance Evaluation Criteria for Medical, Nursing and Paramedical Staff, Punjab Devolved Social Services Programme, Govt. of the Punjab, 2008-09* that defines the required level of training and experience. Review a sample (3 files or 25% of the staff – whichever is the greater) of human resource files for laboratory technical and supervisory staff to determine if their qualifications, experience and training match the requirements in the job description and to operate the equipment that is being used. A system of Continuous Professional Development⁵ should be active.

Scoring:

- If the sampled individuals' qualifications match the requirements in the job description, or if there are only minor variances (such as only 4 years of experience instead of 5), then score as fully met.
- If only one technician does not have the qualifications required by the job description, then score as partially met, provided that there is evidence of enhanced supervision or training of this individual.
- If two or more technicians do not have the required qualifications (in the job description), then score as not met.

¹Patients should be informed about laboratory tests that are outsourced.

² Independently accredited by a Government of Punjab recognized laboratory standards agency

³ A future date to be determined for all laboratories which will be required to be externally accredited

⁴Adequate communication, specimen pick up and timely provision of results

⁵A recognized program administered by a professional college/council or equivalent

Ind 3. Policies and procedures guide the: 1. Collection, 2. Identification, 3. Handling, 4. Safe transportation, 5. Processing and 6. Disposal of specimens.

Survey Process:

Review the laboratory policy and procedure manual to validate that it covers ALL the 6 requirements. Then, by observation check for example, how a patient whose blood is being drawn was positively identified and how the specimen was labelled. It is always important to verify that the policy or procedure is not just written, but is actually implemented and followed. Ask operational staff about the 6 policy requirements to establish if they are aware of the policies and procedures and have received appropriate orientation and training.

Scoring:

- If there are policies and procedures for ALL the 6 requirements, and evidence that the manual is clearly present at the work place, that documented training has been delivered and that the policies and procedures are followed, then score as fully met.
- Since this is significant for patient safety (misidentified patient and mislabelled specimens are a common source of laboratory errors), if there are no implemented policies and procedures for ALL 6 requirements, then score as not met.

Ind 4. Laboratory results are available within a defined time frame.

Survey Process:

While visiting the laboratory, review their written definition of time frames for test results to be available. Then, see if the laboratory has data to show that the times are being met. If the surveyor needs further validation, while on an inpatient unit, review 3-5 medical records. Look for the time of the physician order for the test, and compare with when the result was available.

Scoring:

- If there are defined times for results to be available and these times are met with only occasional delays (less than 5 percent), then score as fully met.
- If there are defined time frames, but they met between 85-95 percent of the time, then score as partially met.
- If there are no defined time frames or they are met less than 85 percent of the time, then score as not met.

Ind 5. Critical results are reported immediately to the concerned personnel.

Survey Process:

The laboratory should have defined critical values for ALL relevant tests and should have documentation (such as a log book) that the critical results were reported as soon as available. This is a significant patient safety issue.

Scoring:

- If there are defined critical values and there is documentation that they are reported as soon as available, then score as fully met.
- If there are no critical values or if there is no consistent and defined process to report them as soon as available, then score as not met.

Ind 6. Laboratory tests not available in the organization are outsourced to organization(s) based on their quality assurance system and independent accreditation.

Survey Process:

Determine which laboratory or laboratories the hospital uses and then look for documentation that the laboratory or laboratories have demonstrated quality (for example by being accredited by the Pakistan National Accreditation Council (PNAC) or any other evidence of quality). If the hospital has used a referral laboratory for some time and is comfortable that the results are

accurate and timely, this experience can be sufficient. The arrangements including quality Indicators and turnaround times should be specified in a formal contractual arrangement.

Scoring:

- If there is documented evidence that the referral laboratory or laboratories deliver quality indicators (even if only by the hospital's experience in the first year), then score as fully met.
- If there is no or limited evidence that the referral laboratory demonstrates quality, then score as not met.

Standard 2. AAC-2: Imaging services are provided as per the clinical requirements of the patients.

Indicators (7-14):

Ind 7. *Imaging services comply with legal and other requirements*⁶.

Survey Process:

There should be documentation in the Radiology Department of its compliance with ALL legal and regulatory requirements. Key staff should be aware of the regulatory requirements.

Scoring:

- If supporting documents are present in the department and staff is aware of the content and clearly applying the requirements, then score as fully met.
- If the legal and regulatory requirements are present and understood but not fully applied, then score as partially met.
- If there are no regulatory requirements present and most staff members are unaware of their compliance obligations, then score as not met.

Ind 8. *Scope of the imaging services is commensurate to the clinical services provided by the organization.*

Survey Process:

This requires an understanding of the full scope of services provided at the establishment and observation of the diagnostic facilities provided both on and off site. A full complement of imaging services should also be provided to cater for emergency situations that may arise from the services delivered by the hospital. Where invasive imaging services are provided there must be adequate support service in the event of an emergency. This involves resuscitation, and in some cases, emergency surgery when cardiac procedures are involved.

Scoring:

- If there is access to a full array of imaging services commensurate with the scope of hospital services, then score as fully met.
- If there is insufficient scope and number of imaging services to support the services within the hospital, then score as not met.

Ind 9. *Adequately qualified and trained personnel perform, supervise and interpret the investigations.*

Survey Process:

Each member of the Radiology Department should have a job description that defines the required level of training and experience equivalent to the specifications for imaging and diagnostic staff described in the *Job Descriptions and Performance Evaluation Criteria for Medical, Nursing and Paramedical Staff, Punjab Devolved Social Services Programme, Govt. of the Punjab, 2008-09*. Review a sample (3-5 or 25% of staff whichever is greater) of human resource files for radiology technical and supervisory staff to determine if their qualifications, training and experience match the requirements in the job description and to operate the equipment that is being used. Continuous professional development⁷ should be active.

Scoring:

- If the sampled individuals' qualifications match the requirements in the job description, or if there are only minor variances (such as only 4 years of experience instead of 5), then score as fully met.

⁶Building Code of Pakistan and management of ionising radiation

⁷A recognized program administered by a professional college/council or equivalent

- If only one technician does not have the qualifications required by the job description, then score as partially met, provided that there is evidence of enhanced supervision or training of this individual.
- If two or more technicians do not have the required qualifications (in the job description), then score as not met.

Ind 10. Policies and procedures guide identification and safe transportation of patients to imaging services.

Survey Process:

Review the policies and procedures. Specifically look for how the patient is positively identified and it is ensured that the correct imaging procedure is done. Look for evidence that specific medical attendance or equipment is available and provided if needed to accompany the patient to the department and that there is a clear process to ensure this happens. Specifically look for evidence (by observation and interview of staff) that the patient is positively identified.

Scoring:

- If there are implemented policies and procedures for patient identification and safe transport, then score as fully met.
- If either there are no policies or that there is no evidence that they have been implemented and is being followed, then score as not met.

Ind 11. Imaging results are available within a defined time frame.

Survey Process:

While visiting the Radiology Department, review their written definition of time frames both for the availability of the procedure and the availability of the report. Then, see if the department has data to show that the times are being met. If the surveyor needs further validation, while on an in-patient unit, review 3-5 medical records. Look for the time of the physician order for the procedure, and compare with when the result was available.

Scoring:

- If there are defined times for the procedure to be available and the results to be available and these times are met with only occasional delays (less than 5 percent), then score as fully met.
- If there are defined time frames, but they are met between 85-95 percent of the time, then score as partially met.
- If there are no defined time frames or when they are met is less than 85 percent of the time, then score as not met.

Ind 12. Critical results are intimated immediately to the concerned personnel.

Survey Process:

Unlike the laboratory, critical findings on images depend to a great extent on the clinical judgment of the radiologist. However, the department should at least have some general guidelines and a way to document that the findings were reported as soon as possible. This is a significant patient safety issue.

Scoring:

- If there are guidelines to manage critical findings and there is documentation that they are reported as soon as available, then score as fully met.
- If there is no understanding of what constitutes a critical imaging finding, or if there is no consistent and defined process to report them as soon as available, then score as not met.

Ind 13. Quality Assurance activities are evident in the Imaging Department.**Survey Process:**

There should be documented evidence that a Quality Assurance (QA) plan is active in the department. This should include observation of activities such as a register of repeat images due to image quality related reasons and recording of adverse occurrences.

Scoring:

- If a copy of the QA plan is available along with evidence that 80% of staff is aware of its contents and the associated activities, then score as fully met.
- If there is no copy of evidence of a QA plan or less than 80% of staff are aware of its contents, then score as not met.

Ind 14. Imaging tests not available in the organization are outsourced to organization(s) based on their quality assurance system and compliance with applicable laws and regulations.**Survey Process:**

There should be documented evidence that the radiology services to which patients are referred have been approved by the Pakistan Nuclear Regulatory Authority (PNRA) and that the hospital has a history of receiving timely and accurate reports from the referral radiology service commensurate with the clinical needs of the patient.

Scoring:

- If the PNRA approves the referral imaging services and the hospital demonstrates sufficient experience to know that reports are timely and accurate, then score as fully met.
- This should only be scored as not met if a majority of the survey team agrees that there are significant problems with the referral radiology services.

2.2 Care of Patients (COP)

Standard 3. COP-1: Emergency services are guided by policies, procedures and applicable laws and regulations.

Indicators (15-20):

Ind 15. Policies and procedures for emergency care are documented.

Survey Process:

Review the policies and procedures, which should cover the administration of the emergency area (triage, waiting times, admission/registration, legal reporting requirements, discharge and patient transfer). There should be observation of the policy and procedure manual and evidence that staff members are aware of its existence. There should be evidence by observation and interview with staff that the policies and procedures have been implemented.

Scoring:

- If there are policies and procedures, that staff members are aware of, and there is evidence that they are followed by ALL staff, then score as fully met.
- If there are policies and procedures and only 1-2 staff members are not aware of them, or if only 1-2 policies and procedures have not yet been implemented, then score as partially met.
- If there are no policies and procedures, or if none have been implemented, then score as not met.

Ind 16. Policies also address handling of medico-legal cases.

Survey Process:

The policy should define what types of cases should be reported and to whom (what agency) they should be reported to. The surveyor should review the record of reported cases and assess how they have been managed in terms of analysis and consequential changes, if required.

Scoring:

- If there are policies that define what types of cases are “medico-legal” and to whom and how to report such cases, then score as fully met.
- Since this is a legal requirement, if there are no policies, then score as not met.

Ind 17. The patients receive care in consonance with the policies.

Survey Process:

This will need to be surveyed by observation and interview with staff members. The policies should be readily available and understood by staff and embrace ALL the aspects of care being received by patients. There should be evidence of a process where the staff is made aware of and receive training regarding the policies and associated procedures.

Scoring:

- If agreed by the team that there is sufficient evidence that policies are being followed by staff, then score as fully met.
- If a majority of the survey team agrees that there is evidence that one or more policies are not being followed, then score as not met.

Ind 18. Policies and procedures guide the triage of patients for initiation of appropriate care.

Survey Process:

Look for a formal triage process, ideally based on a written algorithm. The most important issue is to validate that triage is based on an evaluation of the patient’s presenting complaint and/or condition (clinical need) and NOT on time of arrival (first come, first served) or mode of arrival (ambulance versus walk-in). A walk-in patient may well have more emergent needs than the

patient who arrived by ambulance. Existing standards on emergency management and disaster response should be observed.⁸

Scoring:

- If there is: 1. A triage process and 2. It is based on actual clinical evaluation⁹ 3. By appropriately trained staff 4. Using appropriate facilities and 5. Staff members are aware and 6. Applying the process, then score as fully met.
- If there is a triage process, but it is not consistently based on at least a brief clinical evaluation of the patient using appropriate facilities, then score as partially met. Surveyor judgment is required since some presenting complaints (chest pain and acute respiratory distress) should trigger immediate attention even without a brief clinical evaluation.
- If there is no triage process or if it is only on a first come, first served basis, then score as not met.

Ind 19. Staff members are familiar with the policies and trained on the procedures for care of emergency patients.

Survey Process:

This is surveyed by observation and interview with staff members. Training and orientation should be documented in terms of content and participation.

Scoring:

- This should be scored the same as for **Ind 15**.

Ind 20. Admission or discharge to home or transfer to another organization is documented.

Survey Process:

Review a sample of at least 10 medical records, files or other documentation (emergency services log book) of patients who were treated in the Emergency Department. Observe the records and determine the discharge process. Review the advice and information provided to the patient or other clinician or treatment facility and determine if it is adequate to ensure support, recovery, on going treatment and follow-up that is clinically required.

Scoring:

- If this is 100 percent documented, then score as fully met.
- If only 1-2 cases fail to meet this requirement, then score as partially met.
- If 3 or more of the cases reviewed do not document this, then score as not met.

⁸In keeping with the National Disaster Management Agency and Government of Punjab hospital requirements for the management of disasters. – The Society of Emergency Physicians Pakistan (SEPP)

⁹Commensurate with the triage process of initial assessment

Standard 4. COP-2: Policies and procedures define rational use of blood and blood products.

Indicators (21-25):

Ind 21. Documented policies and procedures are used to guide rational use of blood and blood products.

Survey Process:

Review the policies and procedures. Policies should at least cover: 1. donor screening, 2. processing of blood, 3. storage of blood, 4. administration of blood, 5. use of blood products, 6. identification and analysis of real or suspected transfusion reactions and 7. disposal of blood and related products. This is a significant patient safety issue.

Scoring:

- If there are policies and procedures and they include at least these 7 requirements (relevant to the scope of services available for the hospital's blood service), then score as fully met.
- Since blood services are such a critical patient safety issue, if any of the 7 requirements (relevant to the scope of service for the hospital's blood service) are not present, then score as not met.

Ind 22. The transfusion services are governed by the applicable laws and regulations.

Survey Process:

The surveyors will need to be aware of the applicable laws and regulations. This is surveyed by reviewing documentation (such as an external official inspection, copies of the legislation and compliance requirements), interviews, and observation. This includes an observable mechanism to ensure that only blood and blood products derived employing recognized Indicators¹⁰ is provided to patients. This is a significant patient safety issue.

Scoring:

- If the laws and regulations are present and being employed by all staff, then score as fully met.
- Considering the critical nature and risk with blood services, if there are any examples of non-compliance that compromise the safety of patients, then score as not met.

Ind 23. Informed consent is obtained for donation and transfusion of blood and blood products.

Survey Process:

While visiting the blood bank identify the names of at least 10 patients who have received blood. Then review the medical records of these patients to determine if there is documented 'informed consent' and if the consent adequately informs the patient. If the hospital processes donors, also review a sample of at least 5 people to determine if the donor gave informed consent and this was appropriate for the individuals concerned. It is important to note that evidence of informed consent can be either a signed form or a note by the physician that the patient's verbal consent was obtained. Informed consent must be designed to ensure that people of ALL backgrounds truly understand the risks and options involved and the evidence provided must clearly support this. This includes information and education of the patient and their family, when present.

Scoring:

- If informed consent is obtained for 100 percent of cases, then score as fully met.¹¹

¹⁰See Standards and Guidelines for Blood transfusion Services, Pakistan Ministry of Health, 1999

¹¹There are exceptions when the recipient is an emergency unconscious patient without family or guardians present at the time.

- Since this is a significant medico-legal issue, if ANY case does not have a documented informed consent, then score as not met.

Ind 24. *Staff members are trained to implement the policies.*

Survey Process:

While visiting the blood bank, identify the policy and procedure manual in the work area. Look for compliance with the documented policies and procedures and discuss with staff. Review the staff training records.

Scoring:

- If the policies and procedures are present in the blood bank and staff has been trained to apply them, then score as fully met.
- If the survey team cannot identify the policy and procedure manual and there are critical gaps in either knowledge or practice, then score as not met.

Ind 25. *Transfusion reactions are analyzed for preventive and corrective actions.*

Survey Process:

Ask for documentation that reports transfusion reactions. Evaluate whether the documentation demonstrates adequate analysis and remedial actions. In the case where no reactions are reported as occurring¹², the surveyors should evaluate whether there are adequate clearly written procedures for analysis and remedial action if a reaction does occur. Check that staff members are aware of the reporting process.

Scoring:

- If there had been a transfusion reaction and it was fully analyzed and remedial action proposed or if the survey team is comfortable that there are written procedures to follow if one occurs, then score as fully met.
- If there had been a transfusion reaction and there is no documented evidence of how it was analyzed, or if there had been no transfusion reaction and the blood bank also does not have any written procedure for analysis, then score as not met.

¹²This would be highly unlikely.

Standard 5. COP-3: Policies and procedures guide the care of high risk obstetrical patients

Indicators (26-30):

Ind 26. *The organization defines and displays whether high-risk obstetric cases can be cared for or not.*

Survey Process:

Since many patients will not know if they are high risk or not, it is important that the hospital has informed its obstetrical patients of the definition of high risk and its capability to provide services for these women. The second important issue is that the hospital has informed those practitioners and facilities that might refer such patients of the hospital's capability to provide care to high-risk obstetric cases.

There must be documentation of this information (such as letters to referring doctors and facilities plus information available to give to its own obstetric patients).

Scoring:

- If the hospital has informed its own obstetric patients and its referring practitioners and other facilities of its capability to care for high-risk obstetric cases, then score as fully met.
- If the hospital has informed its own patients, but not referring providers or facilities, then score as partially met.
- If the hospital has neither informed its own patients or referring providers or facilities, then score as not met.

Ind 27. *Persons caring for high-risk obstetric cases are competent.*

Survey Process:

Surveyors should look for the availability of at least four¹³ specialists (so that there is 24 hours/day, 7 days/week coverage) who are fully qualified in obstetrics and who have advanced training in high-risk obstetrics and documented experience. In addition, there should be evidence that members of the nursing staff who care for such patients have advanced qualifications and documented experience¹⁴.

Scoring:

- This standard should default to a score of fully met unless a majority of the survey team agrees that there is lack of evidence that ALL personnel who participate in the care of high-risk obstetric patients have appropriate qualifications.

Ind 28. *High-risk obstetric patient's assessment also includes maternal nutrition.*

Survey Process:

This will be surveyed by review of a sample of at least 5 medical records of high-risk obstetric patients.

Scoring:

- If ALL records document assessment of the patient's nutritional status (including corrective measures if needed), then score as fully met.

¹³This is the absolute minimum to provide 24hrs, 7 days per week service based on 3 shifts per day and 270 productive workdays per employee per year.

¹⁴As per the specifications for ALL clinical staff in the Job Descriptions and Performance Evaluation Criteria for Medical, Nursing and Paramedical Staff, Punjab Devolved Social Services Programme, Govt. of the Punjab, 2008-09

- If only one medical record does not document this but it is clinically obvious that the patient had good nutritional status, then score as partially met.
- If more than one record fails to document the patient's nutritional status, then score as not met.

Ind 29. *The organization caring for high risk obstetric cases has the facilities and technically competent staff to take care of neonates of such cases.*

Survey Process:

Although this may require some surveyor judgment, the following minimum should be present (and in working order): 1. Emergency resuscitation drugs, 2. Ambu bag with 3. Appropriate neonatal size facemasks, 4. Laryngoscope with neonatal size blades, 5. A selection of neonatal size endo-tracheal tubes, 6. An oxygen and suction source, 7. A warmer work station, 8. Incubators, 9. Trays to allow cannulation of an umbilical artery, 10. Exchange transfusion trays, 11. Infusion pumps to assure no volume overload of the neonate and 12. Neonatal resuscitation drugs.

Scoring:

- If ALL the equipment listed above is present and in good working order, then score as fully met.
- If ALL the required equipment and supplies defined above are not present, but the survey team agrees that the hospital has safely defined alternatives, then score as partially met.
- If the survey team agrees that any critical equipment or supplies are not available, then score as not met.

Ind 30. *No treatment should be administered unless the identity of the patient can be guaranteed.*

Survey Process:

The surveyor should identify a form of safe patient identification system¹⁵ and confirm that the administration of ALL treatments and therapies are preceded by confirming the identity of the patient.

Scoring:

- If the identification of the patient is clearly observable and fail safe for ALL patients and staff confirm identity, then score as fully met.
- If a fail-safe method of identification is present and staff does not consistently check the identity before treatment, then score as partially met.
- If there is no fail-safe system of identification, then score as not met.

¹⁵For ALL patients the system employed must be permanently with the patient and fail-safe.

Standard 6. COP-4: Policies and procedures guide the administration of anaesthesia.

Indicators (31-40):

Ind 31. *There is a documented policy and procedure for the administration of anaesthesia.*

Survey Process:

The surveyor should look for at least the following policies: 1. Pre-anaesthesia evaluation, 2. Assignment of an anaesthesia risk then score (such as an ASA¹⁶ then score), 3. Documentation requirements during anaesthesia, 4. Recording of any complications, 5. Post-anaesthesia monitoring requirements, and 5. Discharge from anaesthesia care criteria.

Scoring:

- If there are policies and procedures that are implemented that cover ALL the 6 requirements, then score as fully met.
- If there are policies and procedures for ALL the 6 requirements, but only 5 of the 6 have been implemented, then score as partially met.
- If either there are no policies and procedures, or if only 5 of the 6 exist or if less than 5 have been implemented, then score as not met.

Ind 32. *ALL patients for anaesthesia have a pre-anaesthetic assessment by a qualified individual.*

Survey Process:

Review a sample of at least 10 records of patients who underwent anaesthesia. Determine if there is a documented pre-anaesthetic assessment. An anaesthetist should do the assessment unless the hospital has identified another specialty that is qualified to do the pre-anaesthesia assessment.

Scoring:

- If there is a pre-anaesthesia assessment by an anaesthetist or qualified doctor with documented appropriate training for ALL patients, then score as fully met.
- Since this is an important patient safety issue, if ANY medical record does not include a documented pre-anaesthesia assessment, then score as not met.

Ind 33. *The pre-anaesthesia assessment results in formulation of an anaesthetic plan for each patient, which is documented.*

Survey Process:

This standard is intended to validate that the pre-anaesthesia assessment identifies any risks and determines the appropriate anaesthetic approach (for example, a patient with multiple back injuries or surgeries might not be a safe candidate for a spinal anaesthesia or a patient with chronic obstructive pulmonary disease might not be a safe candidate for inhalation anaesthesia). Review a selection of at least 10 medical records of patients who underwent anaesthesia to determine if the anaesthetic plan matches the pre-anaesthesia assessment.

Scoring:

- If the anaesthetic plan reflects the findings of the pre-anaesthesia assessment, then score as fully met.
- If a majority of the survey team agrees that there are significant discrepancies between the pre-anaesthesia assessment and the anaesthetic administered, then score as not met.

¹⁶ Physical Status Classification and Scoring by the American Society of Anaesthesiologists.

Ind 34. An immediate pre-operative (pre-induction) re-evaluation is documented.**Survey Process:**

The intent of this standard is to compare the findings and management plan in the formal pre-anaesthesia assessment with the immediate pre-operative anaesthetic assessment and to see if the management of the patient is changed if required. The immediate pre-anaesthesia repeat evaluation should be documented on the anaesthesia record that becomes part of the patient's medical record.

Scoring:

- If the immediate pre-induction re-evaluation is documented in ALL records, then score as fully met.
- If the immediate pre-induction re-evaluation is NOT documented in ALL records, then score as not met.

Ind 35. Informed consent for administration of anaesthesia is obtained by a qualified member of the anaesthetic team.**Survey Process:**

Reviewing the same records as in **Ind 34**, determine if ALL patients who underwent anaesthesia have a documented informed consent¹⁷. This documentation can either be a signed consent form or written note by the responsible physician that contextually accommodates ALL patient levels of understanding.

Scoring:

- If ALL records contain documentation of informed consent, then score as fully met.
- Since this is a significant medico-legal issue, if ANY record does not contain documentation of informed consent, then score as not met.

Ind 36. During anaesthesia, monitoring includes regular and periodic recording of heart rate, cardiac rhythm, respiratory rate, blood pressure, oxygen saturation, airway security and patency, and level of anaesthesia.**Survey Process:**

This standard is surveyed by observation. While visiting the operating theatre look for the presence (and full functionality) of equipment that supports ALL the requirements in this standard.

Scoring:

- This should default to a score of fully met unless a majority of the survey team agrees that there are significant deficiencies in the hospital's ability to monitor patients during anaesthesia (for example, only one monitor for two or more rooms such that some patients are not monitored).

Ind 37. No anaesthetic should be administered unless the identity of the patient can be guaranteed.**Survey Process:**

The surveyor should identify a form of safe patient ID system¹⁸ and confirm that the administration of anaesthesia is preceded by confirming the identity of the patient.

Scoring:

- If the identification of the patient is clearly observable and fail safe for ALL patients and staff confirm identity prior to induction, then score as fully met.

¹⁷ Informed consent must truly be appropriate for each patient and include reference to the associated risks involved

¹⁸ For ALL patients the system employed must be permanently with the patient and fail-safe.

- If there is no fail safe system of identification or any patient's identity is not confirmed, then score as not met.

Ind 38. *Each patient's post-anaesthetic status is monitored and documented.*

Survey Process:

Review medical records of at least 10 patients in the recovery area or who have been there previously. There should be documented evidence of post-anaesthetic monitoring that includes at least: 1. Blood pressure, 2. Pulse rate, 3. Respiratory status, 4. Level of consciousness, and 5. Pain.

Scoring:

- If ALL records document the requirements above, then score as fully met.
- If only one record does not document ALL the requirements, then score as partially met.
- If more than one record does not document ALL the requirements, then score as not met.

Ind 39. *A qualified individual applies defined criteria to transfer the patient from the recovery area.*

Survey Process:

Look first for the written criteria for discharge from the recovery area. Then while reviewing the records as in **Ind 38**, determine if an anaesthetist or other qualified person with appropriate training¹⁹ has done so.

Scoring:

- If there is an observable documented process that ensures the safe transfer of post anaesthetic patients, then score as fully met.
- If the staff is unaware of criteria for the safe transfer of post anaesthetic patients, then score as not met.

Ind 40. *ALL adverse anaesthesia events are recorded and monitored.*

Survey Process:

Ask for the report(s) of any anaesthesia related adverse events. Review the analysis and any corrective action that is specified. If there have been no adverse events, which is unlikely unless a new service, validate that there is a process to identify the event and to intensively analyze it, including recommended corrective actions.

Scoring:

- If there has been an adverse anaesthesia event and there is evidence of meaningful evaluation and appropriate action if warranted, then score as fully met.
- If there has been no adverse anaesthesia event but the survey team is comfortable that the hospital has a process to identify such events and also has a process to analyze them, then score as fully met.
- If there was an anaesthetic related adverse occurrence and it was not either reported or analyzed, or if there is no process to analyze an adverse event if it were to occur, then score as not met.

¹⁹ This may include nurses who have received documented training

Standard 7. COP-5: Policies and procedures guide the care of patients undergoing surgical procedures.

Indicators (41-50):

Ind 41. *The surgery-related policies and procedures are documented.*

Survey Process:

There are written policies that include pre-operative, intra-operative and postoperative care. Staff members are aware of the policies and procedures and there is observable evidence that they are being applied.

Scoring:

- If there are written (and implemented) policies for pre-operative, intra-operative and postoperative care, then score as fully met.
- If there are policies, but at least one has not been implemented yet, then score as partially met.
- If there are no, or insufficient policies, then score as not met.

Ind 42. *Surgical patients have a pre-operative assessment and a provisional diagnosis documented prior to surgery.*

Survey Process:

Review a sample (10) of medical records of patients who underwent surgery to determine if a pre-operative assessment (surgeon's history and physical examination or pre-operative note) is present and that a pre-operative provisional diagnosis was documented.

Scoring:

- If there is a pre-operative history and physical examination or a pre-operative note by the surgeon that includes a provisional pre-operative diagnosis, then score as fully met.
- If there is a pre-operative history and physical examination or surgeon's note, but no pre-operative provisional diagnosis, then score as partially met.
- If there is no pre-operative history and physical examination or surgeon's note, then score as not met.

Ind 43. *An informed consent is obtained by a qualified medical member of the surgical team prior to the procedure.*

Survey Process:

Review the same 10 records to determine if an informed consent was obtained and documented in the medical record. The informed consent must include evidence that the patient was educated/informed. This is surveyed in the same way as policies and procedures guide for the administration of anaesthesia.

Scoring:

- If ALL the medical record documents an informed consent (a signed form or a note by the physician, then score as fully met.
- Since this is a significant medico-legal issue, if ANY record does not have documentation of informed consent, then score as not met.

Ind 44. *Documented policies and procedures exist to prevent adverse events like wrong site, wrong patient and wrong surgery.*

Survey Process:

This is a critically important patient safety issue. In at least 10 medical records of patients who had surgery look for the following implemented and documented processes: marking of the surgical site when there is the possibility of bilateral confusion, a pre-operative checklist to ensure that ALL documents (X-rays, medical records, etc.) and needed equipment is available, and a "time out" prior to induction of anaesthesia to ensure that ALL members of the surgical

team are in agreement that this is the correct patient; this is the correct procedure for this patient, and that this is (if relevant) the correct side.

Scoring:

- If ALL 3 requirements (marking when relevant, use of a checklist, and a “time-out” recorded) are used and documented in the medical record, then score as fully met.
- If ANY of the three requirements are not documented in the medical record, then score as not met.

Ind 45. *Persons qualified by law are permitted to perform the procedures that they are entitled to perform.*

Survey Process:

The surveyors should look for documents that demonstrate a process to validate the qualifications, experience and registration status of physicians to ensure that they are legally permitted, and competent to perform specific procedures. The scope of clinical practice shall be defined and documented for all surgeons and performance monitored through the recording of adverse outcomes and peer review.

Scoring:

- If there is a recognized process to validate that the physician is authorized (currently registered) and competent (based on academic credentials, experience, training and internal recognition) to perform the procedure he/she is conducting, then score as fully met.
- If there is no process to validate the authorization or competence to perform the procedure(s), then score as not met.

Ind 46. *A brief operative note is documented by the surgeon or a doctor in the surgical team prior to transferring the patient out of the recovery area.*

Survey Process:

Review the same 10 medical records as noted for **Ind 44**. Determine if there is a documented operative note that was recorded prior to the patient being transferred from the recovery area. Also, while in the recovery area, review the medical records of patients who are about to be transferred out of the recovery area to determine if an operative note is in the medical record.

Scoring:

- If there is an operative note and it was documented in the medical record prior to transfer from the recovery area, then score as fully met.
- If there is either no operative note, or it was completed after the patient was transferred out of the recovery area, then score as not met.

Ind 47. *The operating surgeon or their surgical assistant²⁰ documents the post-operative plan of care.*

Survey Process:

Review the 10 medical records as noted for **Ind 44** and validate that the surgeon (or their representative such as a surgical assistant) has written post-operative orders.

Scoring:

- If there are post-operative orders, then score as fully met.
- If there are no post-operative orders, then score as not met.

²⁰ Medical practitioner directly involved with the surgical procedure

Ind 48. A quality assurance program is followed for the surgical services.**Survey Process:**

Review any documentation (such as minutes of a quality improvement committee or Surgical Department meeting minutes or research projects) that demonstrates there are quality indicators of surgical care that are being monitored.

Scoring:

- If there is documented evidence that some aspects of the quality of surgical care are being monitored, then score as fully met.
- If there are aspects of surgical care that are being monitored, but they do not relate to the quality of care, then score as partially met.
- If there is no monitoring of surgical care, then score as not met.

Ind 49. The surgical quality assurance program includes surveillance of the operation theatre environment.**Survey Process:**

The following evidence should be reviewed: 1. Infection control surveillance, 2. Medical equipment maintenance, and 3. Cleaning of the theatres between cases. The results of these surveillance activities should be documented (perhaps tabled at the relevant committee meetings and minuted).

Scoring:

- If there is evidence that the safety and cleanliness of the operation theatre environment is evaluated, then score as fully met.
- If there is no surveillance of the operating theatre, then score as not met. _____

Ind 50. The plan also includes monitoring of surgical site infection rates.**Survey Process:**

This should be found in the minutes of an Infection Control Committee. Specifically look for evidence that the infection rates are physician, procedure, and room specific. (Global rates without organizing the data into categories are of little use.) Determine the action that arises from the reports and determine if this is able to influence the rate of infection.

Scoring:

- If there is data about surgical site infections and it is segregated into individual physicians, procedures, and rooms, with evidence that remedial management has been initiated, then score as fully met.
- If there is data about surgical site infections, but only in the aggregate without specific analysis, then score as partially met.
- If there is no data about surgical site infections, then score as not met.

2.3 Management of Medication (MOM)

Standard 8. MOM-1: Policies and procedures exist for the prescription of medications.

Indicators (51-57):

Ind 51. Documented policies and procedures exist for the prescription of medications.

Survey Process:

Review pharmacy and medication policies that relate to prescribing staff, administering staff and pharmacy staff. The important issue is that the policies explicitly define 1. How medication orders/prescriptions must be written, including where in the in-patient record or on an outpatient form, 2. **Which staff can prescribe** and which staff can administer. The policy should also inform what is done when the order or prescription is not accepted because of confusion about the order²¹.

Scoring:

- If there are policies for prescription/ordering of medications and the policy explicitly defines what is done when the prescription or order is not clear, then score as fully met.
- If there are policies for prescription/ordering of medication, but the policy does not define what is to be done when the prescription/order is not clear, then score as partially met.
- If there are no observable policies, then score as not met.

Ind 52. The organization formally determines who can write orders.

Survey Process:

There should be a policy that identifies practitioners who may write medication orders in the medical record or on a prescription. However, determine if any other professionals (such as midwives, anaesthetic nurses, emergency nurses, dentists, optometrists, podiatrists and psychologists) are permitted to write prescriptions or order medication. The policy should delineate which practitioners can prescribe restricted classes of drugs²².

Scoring:

- If the clinical staff members are fully aware of who may write orders and this is supported by evidence in the medication chart, then score as fully met.
- If the survey team finds evidence that there is any confusion about who (which professionals) is permitted to order or prescribe medication, then score as not met.

Ind 53. Orders are written in a uniform location in the medical records.

Survey Process:

While reviewing medical records determine if medication orders are uniformly written in the same location in the record across the various wards in the establishment.

Scoring:

- If ALL of the medication orders are in the specified area of the medical record, then score as fully met.
- Since this is a common source of “oversight” errors, if any orders are not in the designated location, then score as not met.

²¹Example – contraindicated due to other drugs prescribed or allergy, adult dose for child or restricted; wrong patient name or illegible

²²Example – chemotherapy or very expensive drugs or unlicensed drugs administered as part of a research program

Ind 54. Medication orders are clear, legible, dated, timed, named and signed.**Survey Process:**

Determine what is done if a medication order is not legible. While reviewing medical records, determine if ALL medication orders are legible, dated, timed, named, and signed. The score is based on the cumulative findings of ALL the records reviewed.

Scoring:

- If ALL orders are legible, dated, timed, named, and signed, then score as fully met.
- If only 1-2 orders are not timed, then score as partially met.
- If 3 or more orders are not legible, dated, timed, named, and signed, then score as not met.

Ind 55. Policy on verbal orders is documented and implemented.**Survey Process:**

Interview nurses and other personnel who receive verbal orders. Observe a staff member receiving a verbal order. The policy and practice should clearly describe the process including writing down the verbal order and reading it back to ensure that it was clearly understood by both, the person who gave the order and the person who received the order.

Scoring:

- If there is a clear policy and practice for verbal orders, then score as fully met.
- If the survey team agrees that the process is not consistently followed, then score as partially or not met.

Ind 56. The organization defines a list of high-risk medication.**Survey Process:**

Review the list which must be readily available to staff. The list of high-risk medications must include at least: concentrated electrolytes such as KCl, chemotherapy, very high cost drugs, look alike medications, sound alike medications and psychotropics.

Scoring:

- If the hospital has a written list of high-risk medications, then score as fully met.
- If the hospital has a list of high-risk medications, but it does not include both look alike or sound alike medications, then score as partially met.
- If there is no list of high-risk medications, then score as not met.

Ind 57. High-risk medication orders are verified prior to dispensing.**Survey Process:**

Interview both pharmacy and nursing staff since the safety issue is not just dispensing, but also administration.

Scoring:

- If there is a clear practice (based on interviews with pharmacy and nursing personnel) of verifying the order for high-risk medications, then score as fully met.
- If there is no formally defined process, or if there is no list of high-risk medications (**Ind 56**), then score as not met.

Standard 9. MOM-2: Policies and procedures guide the safe dispensing of medications.

Indicators (58-61):

Ind 58. Documented policies and procedures guide the safe storage and dispensing of medications.

Survey Process:

The policies should include at least: matching the order with the correct patient and medication, confirming look alike drugs, and labelling.

Scoring:

- If there are policies and procedures and evidence that they are implemented, then score as fully met.
- If there are policies and procedures, but implementation is inconsistent, then score as partially met.
- If there are no policies and procedures or if none have been implemented, then score as not met.

Ind 59. The policies include a procedure for medication recall.

Survey Process:

While visiting the pharmacy, review the procedure for medication recall. If there had been a recall, review the documentation of how it was done.

Scoring:

- If there is a procedure for medication recall, then score as fully met.
- If there is no procedure, then score as not met.

Ind 60. Expiry dates are checked and documented prior to dispensing.

Survey Process:

This is best surveyed by observation. While on a patient unit, check a sample of medications for their expiration date. Check the procedure where stock bottles are used to ensure that stock is rotated.

Scoring:

- If no expired medications are found, then score as fully met.
- If there is any expired medication found, then score as not met.

Ind 61. Labelling requirements are documented and implemented by the organization.

Survey Process:

The hospital should have defined what is to be included on the label or prescription. When being dispensed directly to the patient this should include at least: 1. Patient's name, 2. Generic and proprietary name of medication, 3. Concentration (dose), 4. Directions for use, 5. Prescribing practitioner and 6. Date of dispensing. When dispensed to a patient care unit the label should include ALL the above information. Check a sample (10-15) of dispensed medications to determine how they are labelled.²³

Scoring:

- If ALL medications are appropriately labelled, then score as fully met.
- Since this is an important patient safety issue, if any are not completely labelled, then score as not met.

²³It is recognized that the establishment of appropriate systems may require a negotiated implementation time frame in some institutions

Standard 10. MOM-3: There are defined procedures for medication administration.

Indicators (62-71):

Ind 62. Medications are administered (dispensed) by those who are permitted by law to do so.

Survey Process:

Review the law and then review a sample of 10 medical records to validate that only those permitted by law have administered medication.

Scoring:

- If all drugs are administered by authorized staff, then score as fully met.
- If the survey team finds an example of medication administered by someone not authorized to do so, then score as not met

Ind 63. Prepared medications are labelled prior to preparation of a second drug.

Survey Process:

Observe a nurse or an anaesthetist preparing medication. Verify that each medication is labelled prior to preparing the next one.

Scoring:

- If the survey team finds that all drugs were labelled prior to preparing subsequent medications, then score as fully met.
- If the survey team finds one or more violations of this requirement, then score as not met.

Ind 64. Patient is identified prior to administration.

Survey Process:

Review the policy and procedure. It should include the requirement for at least 2 separate ways of positively identifying the patient. Then interview a nurse to find out what is done in practice when administering medication and observe how the nurse identifies the patient. Patients should have a form of identification that is reliable with them at all times.²⁴

Scoring:

- If 2 identifiers are routinely used, then score as fully met.
- If this practice is not uniformly followed (1 or more examples where there is failure to follow the procedure), then score as not met.

Ind 65. Medication is verified from the order prior to administration.

Survey Process:

Observe nurses or doctors preparing medication and verify that the medication order was readily available and the type of medication was checked prior to preparing the medication.

Scoring:

- If there is clear evidence that the order was checked by name, then score as fully met.
- If ANY example is seen of medication not being checked against the order, then score as not met.

Ind 66. Dosage is verified from the order prior to administration.

Survey Process:

Observe nurses or doctors preparing medication and verify that the medication order was readily available and the dose was checked prior to preparing the medication.

²⁴For ALL patients the system employed must be permanently with the patient and fail-safe.

Scoring:

- If there is clear evidence that the order was checked for dose, then score as fully met.
- If ANY example is seen of medication not being checked against the order, then score as not met.

Ind 67. Route is verified from the order prior to administration.**Survey Process:**

Observe nurses or doctors preparing medication and verify that the medication order was readily available and was checked for route of administration prior to preparing the medication.

Scoring:

- If there is clear evidence that the order was checked for route of administration, then score as fully met.
- If ANY example is seen of medication not being checked against the order, then score as not met.

Ind 68. Timing is verified from the order prior to administration.**Survey Process:**

Observe nurses or doctors preparing medication and verify that the medication order was readily available and was checked for timing prior to preparing the medication.

Scoring:

- If there is clear evidence that the order was checked for timing, then score as fully met.
- If ANY example is seen of medication not being checked against the order, then score as not met.

Ind 69. Medication administration is documented.**Survey Process:**

On the same 10 medical records in **Ind 68**, review the physician order then verify that ALL administered medications are documented in the record.

Scoring:

- If ALL administered medications are documented, then score as fully met.
- If only 1-2 (cumulative from findings in ALL 10 records) examples of failure to document administration are observed, then score as partially met.
- If more than 3 documentation failures are observed, then score as not met.

Ind 70. Policies and procedures govern patient's self-administration of medications.**Survey Process:**

Review the policy on self-administration. Interview a nurse to see if the policy is understood and speak with a patient to determine if they understand the instructions they have been given.

Scoring:

- If there is a policy and it is understood, then score as fully met.
- If there is no policy or if nurses are unaware of the policy and procedure, then score as not met.

Ind 71. Policies and procedures govern patient's medications brought from outside the organization.**Survey Process:**

Review the policy and procedure. Usually this requires the pharmacy to verify specifically what the medication is. Also, it is common that the hospital retains the medication but does not use it during the patient's stay in the hospital.

Scoring:

- If there is an implemented policy on medication brought from the outside, then score as fully met.
- If there is no policy or it is not implemented, then score as not met.

2.4 Patient Rights and Education (PRE)

Standard 11. PRE-1: A documented process for obtaining patient and/or family consent exists for informed decision making about their care.

Indicators (72-75):

Ind 72. General consent for treatment is obtained when the patient enters the organization. Patient and/or their family members are informed of the scope of such general consent.

Survey Process:

Review 10 medical records (this can be done simultaneously with review for other reasons). Determine if ALL records document a general consent. Also determine if the content of the general consent is made clear to the patient and/or family.

Scoring:

- If ALL records have a documented general consent, then score as fully met.
- Since this is a medico-legal issue, if ANY record does not have a general consent, then score as not met.

Ind 73. The organization has listed those situations where specific informed consent is required.

Survey Process:

Review any written policy or list. Then review 10 medical records of patients who should have (by hospital policy) a specific informed consent to validate that it is documented in the record. This would include consent related to procedures and therapies with particular concern for anaesthesia, surgery, sterilization, termination of pregnancy and high-risk medications.

Scoring:

- If ALL records document an informed consent, then score as fully met.
- Since this is also a medico-legal issue, if ANY records do not document consent, then score as not met.

Ind 74. Informed consent includes information on risks, benefits, and alternatives and as to who will perform the requisite procedure in a language that they can understand.

Survey Process:

This standard relates to the “informed” part of informed consent. Review the same 10 records as for **Ind 73** above to verify if the required information is included and documented.

Scoring:

- If ALL records document informed consent, then score as fully met.
- Since this is also a medico-legal issue, if ANY records do not document informed consent, then score as not met.

Ind 75. The policy describes who can give consent when patient is incapable of independent decision-making.

Survey Process:

Review the policy to determine who is identified as being able to give consent in addition to the patient.

Scoring:

- If there is a policy describing who, other than the patient, may give informed consent, then score as fully met.
- If there is no policy, then score as not met.

Standard 12. PRE-2: Patient and families have a right to information on expected costs.

Indicators (76-79):

Ind 76. *There is uniform pricing policy in a given setting (out-patient and ward category).*

Survey Process:

Visit the finance or billing office. Review the policy and verify that it is uniformly applied.

Scoring:

- If the policy is uniformly applied, then score as fully met.
- If the survey team finds evidence that it is not uniformly applied, then score as not met.

Ind 77. *The tariff list is available to patients.*

Survey Process:

Review the tariff list and then ask how it is made available to a patient. Customarily this is only upon the patient's request however, frequently the tariff list is posted in the outpatient areas. Patients should be made aware that the tariff list is available.

Scoring:

- If there is evidence that the tariff list is readily available to patients, then score as fully met.
- If there is no procedure to make it available to patients, then score as not met.

Ind 78. *Patients and family are educated about the estimated costs of treatment.*

Survey Process:

Review the process used to inform/educate the patient and/or family about the estimated costs. Also determine if this is done by someone who is knowledgeable (surveyor judgment).

Scoring:

- If there is a process to inform patients and/or families about the estimated costs and it is done by a knowledgeable person, then score as fully met.
- If there is a process to inform patients and/or families about the estimated costs but it is not done by a knowledgeable person, then score as partially met.
- If there is no process, then score as not met.

Ind 79. *Patients and family are informed about the financial implications when there is a change in the patient condition or treatment setting.*

Survey Process:

Review the process. Determine what prompts the patient and/or family to be informed, including who makes the decision and who provides the information.

Scoring:

- If there is a consistent process, including when it is done, who makes the decision, and who provides the information, then score as fully met.
- If there is a process, but there are no clear guidelines of when it is done, then score as partially met.
- If there is no process, then score as not met.

Standard 13. PRE-3: Patient Rights for Appeals and Complaints**Indicators (80-83):**

Ind 80. *The organization informs the patient of his/her right to express his/her concern or complain either verbally or in writing.*

Survey Process:

Review the process and determine how policies are implemented.

Scoring:

- If there are policies to handle appeals and the files substantiate dealing of the appeals according to the policies, then score as fully met.
- If there are policies to handle appeals but no record available how the policies are implemented, then score as partially met.
- If there is no appeal process, then score as not met.

Ind 81. *There is a documented process for collecting, prioritizing, reporting and investigating complaints, which is fair and timely.*

Survey Process:

Review the process and determine through records how the policies are implemented.

Scoring:

- If there are policies for collecting, prioritizing, reporting and investigating complaints and records that the policies are implemented, then score as fully met.
- If there are policies for collecting, prioritizing, reporting and investigating complaints but no record available on how the policies are implemented, then score as partially met.
- If no policies for collecting, prioritizing, reporting and investigating complaints, then score as not met.

Ind 82. *The organization informs the patient of the progress of the investigation at regular intervals and informs about the outcome.*

Survey Process:

Review the process and determine how the policies are implemented. Review files that include all the elements associated with managing a complaint and demonstrate the progressive follow-up with complainants.

Scoring:

- If there are policies to inform the patients about the progress of the investigation and the outcome, and records reflect that the policies are implemented, then score as fully met.
- If there are policies to inform the patients about the progress of the investigation and about the outcomes but no record available on how the policies are implemented, then score as partially met.
- If there are no policies to inform the patients about the progress of the investigation and about the outcome, then score as not met.

Ind 83. *The organization uses the results of complaints investigations as part of the quality improvement process.*

Survey Process:

Review the process and documentation. Identify and observe actual examples of policy and procedure changes that have been made as a result of complaints analysis.

Scoring:

- If there is a quality improvement process to use complaint-handling data and reports are available, then score as fully met.
- If there is a quality improvement process to use complaint handling data and no evidence available how that data was used for improvement, then score as partially met.
- If no quality improvement process about using complaint-handling data, then score as not met.

2.5 Hospital Infection Control (HIC)

Standard 14. HIC-1: The organization has a well-designed, comprehensive and coordinated infection control programme aimed at reducing/eliminating risks to patients, visitors and providers of care.

Indicators (84-89):

Ind 84. *The hospital infection control programme is documented which aims at preventing and reducing risk of nosocomial infections.*

Survey Process:

There should be a written hospital infection control plan. The plan should identify at least: 1. The surveillance activities, 2. Hand hygiene procedures, 3. Isolation procedures, and 4. The responsibilities and authorities of an Infection Control Committee.

Scoring:

- If there is a documented infection control plan that includes at least surveillance activities, hand hygiene procedures, isolation procedures, and the responsibilities and authorities of an Infection Control Committee, then score as fully met.
- If there is a documented plan but it does not define the authority of the committee, then score as partially met.
- If there is either no written plan, or it does not include at least 3 of the 4 requirements above, then score as not met.

Ind 85. *The hospital has a multi-disciplinary Infection Control Committee.*

Survey Process:

Review the plan and the minutes of the committee. The membership should include at least doctors and nurses.

Scoring:

- If there is a committee with minuted meetings and it includes at least doctors and nurses, then score as fully met.
- If there is no committee, or it only includes doctors, then score as not met.

Ind 86. *The hospital has an infection control team.*

Survey Process:

Customarily the team consists of a doctor, a nurse, a laboratory scientist/technician, someone from housekeeping, and a safety officer. However, the appropriate membership of an infection control team will require surveyor judgment. The role of the team is to respond to, and inform, the findings of the Infection Control Committee (**Ind 85**) and make periodic infection control rounds in the hospital to verify that infection control policies and procedures are effectively followed. These should be documented.

Scoring:

- If there is a team that meets regularly and its membership is reasonable (surveyor judgment), then score as fully met.
- If there is a team but it consists of only one discipline (nurse, doctor, etc.) or it meets rarely, then score as partially met.
- If there is no team or no meeting has taken place, then score as not met.

Ind 87. *The hospital has designated a qualified infection control nurse(s) for this activity.*

Survey Process:

Review the job description of the infection control nurse or nurses to determine the required qualifications. Then review the human resource file for this individual(s) to validate if their qualifications match the requirements of the job description.

Scoring:

- If the qualifications of the individual(s) match the requirements in the job description, or if there are only minor variances (such as a little less experience than noted in the job description, then score as fully met.
- This standard should be scored as not met with the agreement of the entire survey team, if the job description and qualifications of the infection control personnel do not match.

Ind 88. *The establishment has appropriate consumables, collection and handling systems, equipment and facilities to manage the control of infection.*

Survey Process:

Observe the clinical areas and check for the presence and use of hand washing facilities in ALL care and treatment areas. Determine if there is 1. Hand washing soap/liquid, 2. Gloves, 3. Masks, 4. Sharps collection containers, 5. Single use syringes and 6. A full system of waste management from the point of generation to the point of destruction. Adequate cleaning equipment and appropriate consumables should be readily available and the staff trained to use it effectively.

Scoring:

- If there are fully resourced hand-washing and sharps disposal facilities to service all care and treatment areas, and trained cleaning staff with appropriate facilities, then score as fully met.
- If there are fully resourced facilities, cleaning staff and facilities in some areas, then score as partially met.
- If there are areas without facilities or appropriate supplies of consumables, cleaning staff and facilities, then score as not met.

Ind 89. *ALL staff involved in the creation, handling and disposal of medical waste shall receive regular training and ongoing education in the safe handling of medical waste.*

Survey Process:

Identify the staff that conduct training in infection control and review the training manual. Speak with a range of staff involved with the generation, handling and management of medical waste to determine their level of training and applied knowledge. This should include the situation for temporary or short-term staff. The system employed by the healthcare establishment should encompass the full process on site and include what happens once the waste leaves the site. Adequate systems, facilities, safety equipment/consumables and training should be observable.

Scoring:

- If there is evidence that training takes place at induction, when new waste management systems are introduced, or when new consumables or equipment are employed related to medical waste, then score as fully met.
- If training takes place when some of the above factors prevail, then score as partially met.
- If no training takes places, then score as not met.

Standard 15. HIC-2: There are documented procedures for sterilization activities in the organization.

Indicators (90-92):

Ind 90. *There is adequate space available for sterilization activities.*

Survey Process:

The definition of “adequate” includes enough space (or at least physical barriers) to ensure separation of ‘clean’ and ‘dirty’.

Scoring:

- If there is adequate space including clear separation with adequate barriers, then score as fully met.
- If there is inadequate separation, then score as partially met.
- If there is no separation, then score as not met.

Ind 91. *Regular validation tests for sterilization are carried out and documented.*

Survey Process:

This is an important patient safety issue. Review the process/procedure to validate that complete sterilization has occurred. This should be uniformly done on each “batch” that is sterilized. There are several methods that can be used (such as colour change strips). Whatever method is used, it must be effective and documented. Observe that the date of sterilization and expiry are clearly indicated on the packaging.

Scoring:

- If there is a process/procedure to verify that complete sterilization has occurred, it is used for ALL “batches” that are sterilized, and it is documented, and production and expiry dates are indicated, then score as fully met.
- If it is only done on a random sample, and dates are not fully indicated, then score as partially met.
- If there is no process/procedure, or if it is rarely (once a day) used, or if it is not documented, or dates are not indicated, then score as not met.

Ind 92. *There is an established recall procedure when breakdown in the sterilization system is identified.*

Survey Process:

Review any written recall procedure. If an actual breakdown had occurred, review how the recall was implemented. Check to see if staff members receive training in the procedure.

Scoring:

- If there is a written recall procedure that staff members are aware of, then score as fully met.
- If there is no written procedure, then score as not met.

2.6 Continuous Quality Improvement (CQI)

Standard 16. CQI-1: There is a structured quality improvement and continuous monitoring programme in the organization.

Indicators (93-98):

Ind 93. *The quality improvement programme is developed, implemented and maintained by a multi-disciplinary committee.*

Survey Process:

There should be a written CQI plan. Review the plan that should include at least the following: 1. A committee with terms of reference, 2. The CQI methodology to be used, 3. Reporting structure of CQI results, 4. The requirement for minutes of the committee meetings, and 5. The responsibilities and authorities of the committee. It should demonstrate that it is regularly updated and that a process of staff induction to the program is in place.

Scoring:

- If there is a written plan and it includes at least the 5 requirements above, then score as fully met.
- If there is a plan but it lacks defining the responsibilities and authorities of the committee, then score as partially met.
- If there is no plan or it includes 3 or fewer of the requirements above, then score as not met.

Ind 94. *The quality improvement programme is documented.*

Survey Process:

The documentation of issues, activities and outcomes should be in the minutes of the CQI committee. Staff is aware of the document's location and familiar with the contents.

Scoring:

- If the minutes document the activities of the programme, then score as fully met.
- If the minutes only document some activities or are so brief as to not allow full understanding of what activities have occurred, then score as partially met.
- If there are no minutes, or they do not contain any information about the CQI activities, then score as not met.

Ind 95. *There is a designated individual for coordinating and implementing the quality improvement programme.*

Survey Process:

This customarily is a "Quality Improvement Coordinator" and may be either a nurse or a doctor or any other health professional. There should be a job description for this individual that defines the requisite qualifications and the duties. This may be either a full time or a part time position (depending on the size of the hospital and its scope of services). The person has adequate knowledge and authority to undertake the role and hospital staff members are aware of the person and the role they play.

Scoring:

- If there is a designated quality improvement coordinator and a job description for the individual, then score as fully met.
- If there is a designated coordinator but no job description, then score as partially met.
- If there is no designated coordinator, then score as not met.

Ind 96. *The quality improvement programme is comprehensive and covers ALL the major elements related to quality improvement and risk management.*

Survey Process:

The definition of “comprehensive” and “ALL major elements” includes at least the following: 1. All departments participate, and 2. All high-risk areas (blood bank, laboratory, operating theatres, emergency room, and equivalent) 3. Have documented quality improvement activities. This requires some surveyor judgment.

Scoring:

- Unless the survey team agrees that there are significant gaps in the programme’s coverage, then this should default to a score of fully met.

Ind 97. *The designated programme is communicated and coordinated amongst ALL the employees of the organization through a proper training mechanism.*

Survey Process:

There should be documented evidence that ALL the appropriate staff including a minimum of 1. All the senior leaders, 2. All department heads, and 3. All members of the CQI committee have participated in a formal process to ensure they fully understand the program. Interview staff and ask to be shown examples of the impact of the CQI program.

Scoring:

- If there is documented evidence of training of ALL the personnel listed above, then score as fully met.
- If only 1-2 department heads have not been trained, then score as partially met.
- If there has been no training, or it has not included at least the senior leadership, the committee members and “most” of the department heads, then score as not met.

Ind 98. *The quality improvement programme is a continuous process and updated at least once in a year.*

Survey Process:

Review the documented evidence that the program has been reviewed at least once in the past year or at the frequency defined in the hospital’s policy.

Scoring:

- If there is documented evidence that the programme was reviewed at least once in the past year, or more frequently if required by hospital policy, then score as fully met.
- If there has been no review or if the review is more than one year ago, then score as not met.

Standard 17. CQI-2: The organization identifies key indicators to monitor the clinical structures, processes and outcomes which are used as tools for continual improvement.

Indicators (99-105):

Ind 99. Monitoring includes appropriate patient assessment.

Survey Process:

Review the documentation in the committee minutes. When surveying the hospital ask to see examples of the impact of CQI program. Examples should be observable at 1. Admission, 2. Regularly through the course of the treatment pathway and 3. Based on the condition of the patient and 4. Recorded in the medical record. In the initial stages healthcare establishments can set their own benchmarks, which need to be documented. These will eventually be compared across similar institutions and shared with the intent of achieving the right benchmarks for Pakistan.

Scoring:

- If there is documented evidence that this has been monitored and examples can be seen as a result of the CQI program, then score as fully met.
- If not, then score as not met.

Ind 100. Monitoring includes safety and quality control programmes of the diagnostic services.

Survey Process:

Review the documentation in the committee minutes. Check these and the diagnostic service locations to observe the following: 1. Documented Standard Operating Procedures (SOPs), 2. Documented training of staff in SOPs and Occupational Health and Safety (OH&S), 3. Reference testing to ensure validity, 4. External audit of facilities, procedures and protocols, 5. Documented occupational health and safety protocols and 6. Documented staff training.

Scoring:

- If there is documented evidence that these factors are present and related activities are being monitored and reflected in the minutes of the CQI program, then score as fully met.
- If not, then score as not met.

Ind 101. Monitoring includes ALL invasive procedures.

Survey Process:

Review the documentation in the CQI committee minutes. Check to see if indicators such as the reporting of all adverse occurrences²⁵ is included such as return to operating room within 24 hours and re-admissions within 24 hours if related to invasive procedures.

Scoring:

- If there is documented evidence that this has been monitored, then score as fully met.
- If not, then score as not met.

Ind 102. Monitoring includes adverse drug events.

Survey Process:

Review the documentation in the committee minutes and check to see if there are references to adverse drug events such as allergic reactions, wrong dose, wrong drug, wrong patient, contraindications and similar issues and how these events have been managed.

Scoring:

- If there is documented evidence that this has been monitored, then score as fully met.

²⁵ An unplanned event with a negative consequence for the patient

- If not, then score as not met.

Ind 103. Monitoring includes use of anaesthesia.

Survey Process:

Review the documentation in the committee minutes and observe for adverse occurrence reporting and adequate follow up from anaesthetic services.

Scoring:

- If there is documented evidence that this has been monitored and adequate follow up has occurred, then score as fully met.
- If not, then score as not met.

Ind 104. Monitoring includes use of blood and blood products.

Survey Process:

Review the documentation in the committee minutes and observe for adverse occurrence reporting and adequate follow up from the blood services.

Scoring:

- If there is documented evidence that this has been monitored and adequate follow-up has occurred, then score as fully met.
- If not, then score as not met.

Ind 105. Monitoring includes availability and content of medical records.

Survey Process:

Review the documentation in the committee minutes to observe references to the quality of medical records. Records should be standardized across the hospital with specific entries for each specialty service as required and entries for each shift, all procedures, vital signs and the status of the patient. Integrated notes are preferred²⁶.

Scoring:

- If there is documented evidence that this has been monitored, then score as fully met.
- If not, then score as not met.

²⁶Integrated notes involve all careers writing sequentially in the progress notes so that doctors' nurses and paramedics all write in the same section of the notes.

Standard 18. CQI-3: Sentinel events are intensively analysed.**Indicators (106-107):****Ind 106. *The organization has defined sentinel events.*****Survey Process:**

Review the written definition of a sentinel event. At a minimum this should include: 1. All unexpected deaths including infants, mothers and suicide, 2. Serious adverse patient events that caused, or could have caused, harm to the patient including return to the operating room within 24 hours, readmission within 24 hours, wrong-patient, wrong-site, wrong-procedure, medication error, 3. Patient violence against staff, 4. Violence against patients, 5. Infant abduction, and 6. Switching of babies. Although not specifically required, it is good practice to also include “near misses”. Look to see if the system analyses the root cause and associated factors that contributed to the event.

Scoring:

- If there is significant evidence of a rigorous documented process of monitoring, reviewing, responding to and mitigating sentinel events, then score as fully met.
- If there is no list, or if in the surveyors’ judgment it is not adequately comprehensive, then score as not met.

Ind 107. *Sentinel events are intensively analyzed when they occur.***Survey Process:**

Ask for any documentation of intense analysis of any sentinel event that has occurred in the past 12 months. (It is highly *unlikely* that none have occurred. If none were reported, the surveyors should explore the reporting process). Determine the corrective actions taken as a result of the analysis such as a change in policy and operating procedures and training for staff.

Scoring:

- If there was a reported sentinel event and it was intensively analyzed, including corrective action to prevent or reduce the likelihood of reoccurrence, then score as fully met.
- If no sentinel event was reported, but the survey team is comfortable that if one occurred it would be reported and analyzed, then also score as fully met.
- If there was a sentinel event, but there was either no analysis or the analysis was “superficial” such as limited to assigning blame to an individual, then score as not met.

2.7 Responsibilities of Management (ROM)

Standard 19. ROM-1: The responsibilities of the management are defined.

Indicators (108-116):

Ind 108. *Those responsible for governance lay down the organization's mission statement.*

Survey Process:

Review the hospital's mission statement and ask how it was developed. Look for involvement of senior leadership, including those involved with the hospital's governance. See if policies support the mission statement including the effective and efficient allocation of resources. See if the mission is published for the staff and patients to view. Interview staff to determine if they are aware of and support achievement of the mission

Scoring:

- If there is a mission statement and evidence of involvement of the appropriate leaders with policy support, and staff members are aware of the mission, then score as fully met.
- If there is no mission statement, or if there is no evidence that it was developed with the participation of senior leaders, including governance, then score as not met.

Ind 109. *Those responsible for governance lay down the strategic and operational plans.*

Survey Process:

Review the strategic and operational plans. Verify if the plans are commensurate with the hospital's mission and that resources support them. Check to see if staff members are aware of the plans and know where they can access a copy.

Scoring:

- If there are both strategic and operational plans and they are in accord with the hospital's mission and adequately supported by the senior management, then score as fully met.
- If there is a strategic plan but no operational plans yet to define how the strategy will be implemented, then score as partially met.
- If there is no strategic plan, then score as not met.

Ind 110. *Those responsible for governance approve the organization's budget and allocate the resources required to meet the organization's mission.*

Survey Process:

Review the budget formulation process. Determine by review of the budget how it is approved and if it adequately supports the mission with resources.

Scoring:

- If there is a budget process and a clear process for its approval and it supports the organization's mission, then score as fully met.
- If there is no budget process (i.e., it is just handed down from "on high"), then score as not met.

Ind 111. *Those responsible for governance monitor and measure the performance of the organization against the stated mission.*

Survey Process:

Review any documentation (such as meetings of the governing body or the senior leadership of the hospital). There should be objective measures/indicators that allow monitoring of progress toward meeting the hospital's strategic objectives that support its mission.

Scoring:

- If there is documentation of monitoring of the progress toward the hospitals strategic and operational goals, then score as fully met.
- If there is no documentation, then score as not met.

Ind 112. Those responsible for governance establish the organization's organogram.**Survey Process:**

Review the organizational chart that defines the hospital's organizational structure.

Scoring:

- If there is an organizational chart ("organogram"), then score as fully met.
- If there is none, then score as not met.

Ind 113. Those responsible for governance appoint the senior leaders in the organization.**Survey Process:**

Review the process for appointment of the hospital's senior leaders. It must support the appointment of the most appropriate people for all positions in terms of credentials and experience.

Scoring:

- If there is a clearly defined process for appointment of the hospital's senior leaders, then score as fully met.
- If the process is limited to only the hospital director, then score as partially met.
- If there is no formal process, then score as not met.

Ind 114. Those responsible for governance support research activities and quality improvement plans.**Survey Process:**

All research must be formally approved by the hospital. Review any reports to the governing body that document the results of the CQI program or research activities (including the process for approving the research protocols). Ideally, there should be evidence that the governing body asks for more information or directs actions.

Scoring:

- If there is documented evidence that the governing body receives reports about research activities (if applicable) and CQI activities, then score as fully met.
- If there is research of any kind underway and no documented evidence to support this has been received by the governing body, then score as not met.

Ind 115. The organization complies with the laid down and applicable legislations and regulations.**Survey Process:**

The surveyors should be aware of the applicable laws and regulations that relate to hospitals in Punjab²⁷. Ask to view the laws and regulations that apply and determine if appropriate staff members are aware of the legal and regulatory obligations for the hospital.

Scoring:

- Unless the survey team agrees that there are significant deficiencies in compliance with laws and regulations, then score as fully met.

²⁷ Related to finance, building and safety codes, business practice and so forth.

Ind 116. *Those responsible for governance address the organization's social and community responsibilities.*

Survey Process:

Look for documents that demonstrate the hospital has evaluated its community's healthcare needs. Also look for any "out-reach" activities, such as cancer or hypertension screening or home based care.

Scoring:

- Unless the survey team agrees that there is insufficient evidence that the hospital is sensitive to the needs of the community it serves, then score as fully met.

Standard 20. ROM-2: A suitably qualified and experienced individual heads the organization.

Indicator (117):

Ind 117. *The designated individual has requisite and appropriate administrative qualifications and experience.*

Survey Process:

Review the job description of the hospital director and determine if the individual has the appropriate qualifications and experience to manage a complex multidimensional institution²⁸.

Scoring:

- Unless the survey team identifies significant deficiencies in the hospital director's qualifications and experience, then score as fully met.

²⁸ This would be tertiary qualifications in the field of management plus considerable experience and continuous professional development in the field of hospital management. A doctor with extensive medical CV and no management credentials would not be considered qualified to run a major hospital.

2.8 Facility Management and Safety (FMS)

Standard 21. FMS-1: The organization is aware of and complies with the relevant rules and regulations, laws and bylaws and facility inspection requirements under the relevant building and associated codes applicable to hospitals.

Indicators (118-121):

Ind 118. *The management is conversant with the relevant laws and regulations and knows their applicability to the organization.*

Survey Process:

Through observation and discussion locate copies of the laws and regulations and ask to be shown examples of compliance. Examples should include fire safety requirements; lifts and elevators and handling of contaminated and nuclear waste. There must be observable compliance with laws for at least clean water supply, sanitation, ventilation, uninterrupted power supply, safe food, procurement of safe pharmaceuticals and fire safety management including effective contingency plans in the event of primary systems failure.

Scoring:

- If there is clear evidence of compliance with fire safety and other building code specifications and operational staff are aware of the requirements and there is strong evidence of compliance, then score as fully met.
- If there is awareness of the requirements of the applicable laws and regulations but incomplete compliance, then score as partially met.
- If there is no evidence of applied knowledge of legal and regulatory requirements, then score as not met.

Ind 119. *The management regularly updates any amendments in the prevailing laws of the land.*

Survey Process:

Directly observe evidence of routinely updated laws and regulations.

Scoring:

- If there is evidence of a process to identify and acknowledge changes in laws and regulations, then score as fully met.
- If there is no evidence of an update process, then score as not met.

Ind 120. *The management ensures implementation of these requirements.*

Survey Process:

Check to see if documentation supports implementation and that this is confirmed with observable examples.

Scoring:

- If there is evidence of compliance with all prevailing laws and regulations, then score as fully met.
- If there is substantial compliance, then score as partially met.
- If there is limited compliance, then score as not met.

Ind 121. *There is a mechanism to regularly update licenses/registrations/certifications.*

Survey Process:

Directly observe and note the validity and currency of the range of compliance documents.

Scoring:

- If there is a full range of current compliance documents, then score as fully met.
- If there is a full range of compliance documents however some are not current, then score as partially met.
- If there is incomplete range of compliance documents, then score as not met.

Standard 22. FMS-2: The organization has a program for clinical and support service equipment management

Indicators (122-125):

Ind 122. *The organization plans for equipment in accordance with its services and strategic plan.*

Survey Process:

Review any written plan that includes at least: 1. Acquisition, 2. Testing, 3. Planned preventive maintenance of medical equipment, and 4. An inventory of ALL medical equipment in the hospital that includes evidence of a formal disposal (write-off) process. While visiting patient care areas, identify 5 pieces of medical equipment. Then ask for documentation that the equipment is listed on the hospital's inventory and that scheduled preventive maintenance has been done on time. Check with the maintenance staff that they have the required training, service manuals and required tools, parts and consumables to deliver the required preventive maintenance and servicing regime. Check for valid sub-contracts to service equipment that is beyond the scope of in-house engineers. Confirm that there is an adequate budget to support implementation of the full maintenance plan.

Scoring:

- If there is a plan (and evidence that it is resourced and being implemented), then score as fully met.
- If there is a plan but it does not include the requirement for testing prior to use, or there are inadequate skills and resources for implementation, then score as partially met.
- If there is no medical equipment plan or if it does not include the requirement for preventive maintenance or if there is no inventory of medical equipment, then score as not met.

Ind 123. *Equipment is selected by a collaborative process.*

Survey Process:

Review the process for assessing needs and prioritizing the requests for new or replacement medical equipment. There should be evidence that the appropriate department heads and 'end-users' participate in determining the best options and procurement priorities. There should preferably be a dedicated team appointed with senior membership from the clinical, financial, engineering and management departments.

Scoring:

- If there is a prioritized process for requesting new or replacement medical equipment and there is input from the appropriate department heads, then score as fully met.
- If there is a process, but no "meaningful" (surveyor judgment) input from the appropriate department heads, then score as partially met.
- If there is no process, or if the decision is left to a single individual, then score as not met.

Ind 124. *Qualified and trained personnel operate and maintain²⁹ the equipment.*

Survey Process:

To determine if appropriate personnel operate the equipment correctly, look for documented training and any data (in the medical equipment department) that identifies "user error"³⁰. Also review the job description of medical equipment maintenance personnel and their human resources file to verify that they have the required qualifications, knowledge and experience.

²⁹Servicing and planned preventive maintenance can be outsourced to appropriately qualified technicians if required – or a combination of in-house and outsourced maintenance and servicing would be fine

³⁰Equipment failures due to incorrect use is common in hospitals

Scoring:

- If staff are adequately qualified and experienced and trained for all equipment within the scope of their ability and other equipment is serviced by reputable contractors, then score as fully met.
- If there is evidence of a system of planned preventive maintenance but concerns with the ability of the staff and service contractors, then score as partially met.
- If there are inadequately qualified staff or sub-contractors, then score as not met.

Ind 125. *Equipment is periodically inspected, serviced and calibrated to ensure their proper function. There is a documented operational and maintenance (preventive breakdown and replacement) plan.*

Survey Process:

There should be a written schedule that is based at least on manufacturer's recommendations. The inspection, calibration (if needed), and maintenance must be documented. The surveyors should review this documentation.

Scoring:

- If ALL the requirements for this standard are documented, then score as fully met.
- Since this is a significant patient safety issue, if any of the requirements are not documented, then score as not met.

Standard 23. FMS-3: The organization has plans for fire and non-fire emergencies within the facilities.

Indicators (126-129):

Ind 126. *The organization has plans and provisions for 1. Early detection, 2. Containment and 3. Abatement of fire and non-fire emergencies.*

Survey Process:

Review the plan to ensure that it addresses ALL 3 requirements. Then, by observation, review of documentation and interview, determine if ALL the requirements have been implemented³¹.

Scoring:

- If the plan includes ALL 3 requirements and there is evidence that ALL are implemented, then score as fully met.
- Since this is such an important patient safety issue, if any of the requirements are not included in the plan, or if any are not clearly implemented, then score as not met.

Ind 127. *The organization has a documented safe exit (evacuation) plan in case of fire and non-fire emergencies.*

Survey Process:

Review the “evacuation” plan. There should also be documented evidence that the plan has been tested. It is not necessary that the hospital has actually evacuated patients, but at least has conducted a “mock” evacuation to verify that the plan would work in an actual emergency. Since it is unlikely that the entire hospital must be evacuated, “mock” drills can be conducted for a single area or department. However, the plan should clearly define a “whole hospital” evacuation (as in an earthquake) plan, including defined alternate sites for the patients and how to transport them. This should be included in the induction program for new staff. The plan should be readily available and visible.

Scoring:

- If there is a written facility evacuation plan, staff is aware of and trained in its use and it has been tested, then score as fully met.
- If there is a written evacuation plan but it has not yet been tested, then score as partially met.
- If there is no plan, then score as not met.

Ind 128. *Mock drills are held at least once in a year.*

Survey Process:

See **Ind 127**. Look for documentation that “mock” drills have been done at least once in the past year. As for fire drills, the “mock” drills should have involved different areas and different shifts. The drills should be fully reported noting the staff involved, major observations and any subsequent changes to the system.

Scoring:

- If there is documented evidence that mock drills have been held at least once in the past year and that they involved different areas or shifts, then score as fully met.
- If no drill has been conducted, then score as not met.

Ind 129. *Staff members are trained for their role in case of such emergencies.*

Survey Process:

Look for documentation of the training. The training should include at least key personnel from every area. They should be able to demonstrate awareness of their own role and the role of others.

³¹A threat matrix employed by SKMT is available at the PHC website as an example of industry standard

Scoring:

- If there is documented evidence of training of key personnel in every area, then score as fully met.
- If only a few (approximately 5) key personnel (surveyor judgment) have not yet been trained, then score as partially met.
- If there has been no training or if more than 5-10 key personnel (surveyor judgment) have not been trained, then score as not met.

2.9 Human Resource Management (HRM)

Standard 24. HRM-1: The staff members joining the organization are oriented to the hospital environment, the institution, respective departments and their individual jobs.

Indicators (130-133):

Ind 130. *Each staff member, employee, student and voluntary worker is appropriately oriented to the organization's mission and goals.*

Survey Process:

The orientation should be in three parts: 1. Orientation to the hospital (such subjects as fire and general safety, infection control, and CQI), 2. Orientation to the assigned department, and 3. Orientation to the specific job within that department. The content of each level of orientation should be written to ensure that whoever provides the orientation always covers the same topics.

Scoring:

- If there are written orientation “guides” and documented participation, then score as fully met.
- If there are the three orientation programs but no written definition of what is to be covered, then score as partially met.
- If there is no orientation program, then score as not met.

Ind 131. *Each staff member is made aware of hospital wide policies and procedures as well as relevant department/unit/service/program policies and procedures.*

Survey Process:

This would be part of the hospital wide and departmental orientation as in **Ind 130** and will be surveyed and then scored as for that standard. Observe the orientation program and evidence of its implementation.

Scoring:

- If there is documented evidence that all staff have participated in an orientation process that includes induction to the policies and procedures for their work area, then score as fully met.
- If there is an adequate orientation program and at least 80% of staff has been inducted, then score as partially met.
- If there is an absence of an orientation program or less than 80% of the staff has been involved in an orientation and induction program, then score as not met.

Ind 132. *Each staff member is made aware of his/her rights and responsibilities.*

Survey Process:

This standard would require that each staff member have a written job description that defines his or her responsibilities. The staff member’s rights should be detailed in the human resources employee manual or other documentation that is shared with the staff member.

Scoring:

- If each staff member has a written job description and there is a document shared with the individual that defines their rights, then score as fully met.
- If every staff member does not have a written job description or if there is no formal way to let the member know of their rights, then score as not met.

Ind 133. *ALL employees are educated with regard to patients' rights and responsibilities.*

Survey Process:

If this is not part of the general hospital orientation, there should be other documentation of how ALL employees are educated about patient rights and responsibilities.

Scoring:

- If there is documented evidence that all employees have been so educated, then score as fully met.
- If only direct caregivers have been educated, then score as partially met.
- If there is no evidence that this education has been given, then score as not met.

Standard 25. HRM-2: An appraisal system for evaluating the performance of an employee exists as an integral part of the human resource management process.

Indicators (134-137):

Ind 134. A well-documented performance appraisal system exists in the organization.

Survey Process:

Review the system. In particular, look for evidence that the appraisal system evaluates actual performance targets and not just administrative factors. Review the human resources files of a sample (10) of employees to determine if the appraisal is documented and includes appraisal of the employees' actual performance and an agreed plan for staff development to address any performance issues.

Scoring:

- If there is a documented appraisal in ALL the human resources files reviewed AND it includes evaluation of the employee's actual performance and a development plan to address any issues, then score as fully met.
- If there is a documented appraisal but it only includes administrative issues and not actual performance evaluation, then score as partially met.
- If there is no documented appraisal in ALL the reviewed human resources files, then score as not met.

Ind 135. The employees are made aware of the system of performance appraisal at the time of induction.

Survey Process:

This should be part of the initial orientation and there should be documented evidence (such as the employee's signature on the job description) that confirms the employee understood how they were to be evaluated.

Scoring:

- If there is a clear system/process for the employee to understand how their performance will be evaluated, then score as fully met.
- If there is no system/process, then score as not met.

Ind 136. The appraisal system is used as a tool for further development.

Survey Process:

There should be documented evidence (when appropriate to the employee's appraisal) that the appraisal system is used as a tool for further development (such as more experience, more training, a different job assignment). This may not be required for every appraisal – only if the appraisal indicated the need.

Scoring:

- When appropriate the appraisal indicates the need for further development and this is documented, then score as fully met.
- If the appraisal indicates the need for further development (surveyor judgment), but there is no documentation of this, then score as not met.

Ind 137. Performance appraisal is carried out at pre-defined intervals and is documented.

Survey Process:

The hospital should have defined the frequency of performance appraisals. Customarily this is within the first 3-4 months for a new employee and at least annually for ALL other employees. The surveyors should evaluate two things: 1. Does the hospital have a definition of how often the appraisal should occur; and 2. What percent of employees have had their appraisal on time.

It is common that a hospital has a schedule for periodic appraisals, but inconsistently follows it. Select a sample (10-15) human resources files and determine if there was a documented periodic appraisal and if it was done “on time”.

Scoring:

- If the hospital has defined the frequency of employee appraisal and there is documentation that greater than 90 percent of employees have received timely appraisals, then score as fully met.
- If the hospital has defined the frequency of employee appraisal, but the documentation shows that only between 75 and 90 percent of employees had their appraisal on time, then scores partially met.
- If either the hospital does not have a schedule for periodic employee appraisal or if less than 75 percent of the employees received their appraisal “on time”, then score as not met.

Standard 26. HRM-3: There is a documented personnel record for each staff member.

Indicators (138-141):

Ind 138. Personnel files are maintained in respect of ALL employees.

Survey Process:

Randomly select 10-15 employees (either from a list of ALL employees, or by name of personnel identified during visits to hospital areas). Then determine if ALL have a human resource/personnel file.

Scoring:

- If ALL have a human resources/personnel file, then score as fully met.
- If ANY do not, then score as not met.

Ind 139. The personnel files contain personal information regarding the employee's qualification, disciplinary background and health status.

Survey Process:

Review the same files as for **Ind 138**.

Scoring:

- If ALL reviewed files have documented information regarding the employee's qualification, disciplinary background and health status, then score as fully met.
- If any do not contain ALL the required information, then score as not met.

Ind 140. ALL records of in-service training and education are contained in the personnel files.

Survey Process:

Review the same files as for indicator **Ind 138**.

Scoring:

- If ALL the reviewed files contain documentation of in-service education (when relevant to the individual – surveyor judgment) and the employee's education, then score as fully met.
- If any file does not document relevant in-service training (surveyor judgment), or does not document the employee's education, then score as not met.

Ind 141. Personal files contain results of ALL employee evaluations.

Survey Process:

This standard relates to both the periodic appraisal and to any "ad hoc" evaluation (such as their involvement in an adverse event).

Scoring:

- If the human resource/personnel file contains at least the documentation of the periodic appraisal, then score as fully met.
- If ANY file does not include the periodic appraisal, then score as not met.

Standard 27. HRM-4: There is a process for collecting, verifying and evaluating the credentials (education, registration, training and experience) of medical professionals including physicians, nurses, pharmacists and others permitted to provide patient care without supervision.

Indicators (142-143):

Ind 142. *Only medical professionals permitted by law, regulation and the hospital are to provide patient care without supervision.*

Survey Process:

Look for documentation of the way the hospital validates that its medical staff has the appropriate and required documents that demonstrate that they are legally permitted to care for patients. There should be a process to validate the accuracy of these documents (there are multiple examples internationally of fraudulent “credentials”). The hospital should have verified the documents with the primary source – such as the university or the training organization. Practitioners should be currently registered with their professional council or body.

Scoring:

- If there is a clearly defined process to validate the “credentials” of ALL staff members, then score as fully met.
- Since this is an important legal issue as well as a patient safety issue, if there is no recognized process to validate the “credentials”, then score as not met.

Ind 143. *The 1. Education, 2. Registration, 3. Training and 4. Experience of the identified health professionals is documented and updated periodically.*

Survey Process:

Randomly select the human resource/personnel files of approximately 10 members of the medical staff and others. Review these files to determine if the 4 required elements are present.

Scoring:

- If ALL reviewed files contain documentation of education, registration, training and experience of the identified medical professional, then score as fully met.
- Since this is an important issue, if ANY file does not include ALL the required information, then score as not met.

2.10 Information Management Systems (IMS)

Standard 28. IMS-1: The organization has a complete and accurate medical record for every patient.

Indicators (144-148):

Ind 144. Every medical record has a unique identifier³².

Survey Process:

Identify that each medical record has a unique identifier. The important issue is whether there may be more than one record for a patient or that there is the possibility that the information such as laboratory or pathology results might be placed into the wrong patient's medical record.

Scoring:

- If there is a clear mechanism to positively identify each patient's medical record, then score as fully met.
- If there is the possibility that an individual patient has more than one record, but there is a system to identify this and consolidate the various records, then also score as fully met.
- If there is evidence that there is more than one record for a patient but no mechanism to consolidate these records, then score as not met.

Ind 145. Organization policy identifies those authorized to make entries in the medical record.

Survey Process:

Review any policy and then during review of medical records for any of the previous reasons for review, confirm that only authorized individuals have made entries into the medical record.

Scoring:

- If ALL entries are by authorized persons, then score as fully met.
- If there are any entries by unauthorized persons, then score not met.

Ind 146. Every medical record entry is dated and timed.

Survey Process:

This is a difficult standard to achieve since the "timing" of ALL entries may be difficult to achieve. Focus attention on timing of medication orders and any entries in ICU's. This can be evaluated during the review of the previously selected records.

Scoring:

- This will require surveyor judgment. If ALL appropriate entries are both dated and TIMED, then score as fully met.
- If the survey team agrees that some appropriate entries are not timed (ALL must be at least dated), then score as partially met.
- If there is inconsistent dating (more than 5 examples) or if there are more than 5 examples of entries that should have been timed but were not, then score as not met.

Ind 147. The author of the entry can be identified.

Survey Process:

During review of the previous medical records verify that ALL entries can be identified by both the individual and their specialty (doctor, nurse, etc.).

Scoring:

- If ALL entries can be identified by name and title, then score as fully met.
- If less than 2 of 10 entries can be so identified, then score as partially met.

³²An alpha/numeric system that gives each patient their own code number

- If 3 or more entries cannot be identified, then score as not met.

Ind 148. *The record provides an up-to-date and chronological account of patient care.*

Survey Process:

Review the record to determine if the record adequately records the care and treatment pathway for all patients. Check the systems of records storage to ensure they are in good order and stored for a period in compliance with the statute of limitations³³.

Scoring:

- This should default to a score of fully met unless the survey team identifies significant deficiencies in the medical records.

³³ The Limitation Act 1908 requires records be stored for 12 years. Some hospitals in Pakistan have electronically stored records with capacity for analytical reporting and research. <http://www.vakilno1.com/saarclaw/pakistan/limitationact/limitationact.htm>

Standard 29. IMS-2: The medical record reflects continuity of care.**Indicators (149-155):**

Ind 149. *The medical record contains information regarding reasons for admission, diagnosis and plan of care.*

Survey Process:

Review 10 medical records (they can be the same record as for previous Indicators) to determine if the reason for 1. Admission, 2. The presumptive diagnosis, and 3. The plan of care is documented. This is then scored on the cumulative findings for ALL the records reviewed.

Scoring:

- If ALL the required 3 elements above are documented in ALL the records, then score as fully met.
- If any of the 3 is missing in any record, then score as not met.

Ind 150. *Operative and other procedures performed are incorporated in the medical record.*

Survey Process:

Review 10 records of patients who underwent surgery or an invasive procedure to verify that the record documents the procedure. The documentation should include at least: 1. The name of the service provider, 2. The procedure undertaken, 3. The findings, 4. Any specimens removed, and 5. The patient's condition at the conclusion of the surgery/procedure.

Scoring:

- If ALL medical records have documentation of the above 5 requirements of the surgery/procedure, then score as fully met.
- If ANY medical records do not have ALL the 5 requirements documented, then score as not met.

Ind 151. *When a patient is transferred to another hospital, the medical record contains the date of transfer, the reason for the transfer and the name of the receiving hospital.*

Survey Process:

Ask for the medical record of 3 or more patients who were transferred to another hospital. Check the forwarded information to determine if it includes the results of any diagnostic investigations and any treatments rendered prior to transfer and the clinical status of the patient.

Scoring:

- If the medical record documents the date of transfer, the reason for transfer, and the name of the receiving hospital, then score as fully met.
- If the medical record fails to document any of these 3 requirements, then score as not met.

Ind 152. *The medical record contains a copy of the discharge note duly signed by appropriate and qualified personnel.*

Survey Process:

Review 10 medical records of discharged patients. The discharge summary should include at least the following: 1. The reason for admission, 2. Significant diagnostic investigation results, 3. Any procedures or other treatments, 4. The patient's response to treatment, 5. Any discharge medications, and 6. Follow-up instructions.

Scoring:

- If ALL discharge summaries include ALL the 6 requirements above, then score as fully met.

- Since this is a significant continuity of care issue, if ANY discharge summary does not include ALL the 6 requirements, then score as not met.

Ind 153. *In the case of death, the medical record contains a copy of the death certificate indicating the cause, date and time of death.*

Survey Process:

Ask for 2-3 records of patients who have died. Review these records to verify that they contain a copy of the death certificate that includes the cause, date and time of death.

Scoring:

- If ALL death records include the cause, date and time of death, then score as fully met.
- If any do not include ALL the requirements (cause, date and time of death), then score as not met.

Ind 154. *Whenever a clinical autopsy is carried out, the medical record contains a copy of the report of the same.*

Survey Process:

Ask for 2-4 medical records of patients who had an autopsy, verify that the final report is in the medical record.

Scoring:

- If ALL the reviewed medical records contain the final autopsy report, then score as fully met.
- If any do not have the final report, then score as not met.

Ind 155. *Care providers have access to current and past medical records.*

Survey Process:

Request the names of 5 patients who were previously discharged. Then request that these records be brought to the surveyor.

Scoring:

- If ALL the requested records are available (brought to the surveyor), then score as fully met.
- If only 4 of the 5 are available, then score as partially met.
- If only 3 are available, then score as not met.

Standard 30. IMS-3: The organization regularly carries out review of medical records.

Indicators (156-162):

Ind 156. *The medical records are reviewed periodically.*

Survey Process:

There should be a policy or other documentation that the hospital has a process for review of medical records and it should define the frequency of this review.

Scoring:

- If the hospital has a medical record review process and a schedule, then score as fully met.
- If the hospital has a medical record review process, but it has only occurred twice in the past 12 months, then score as partially met.
- If the hospital does not have a medical record review process, or it has never been implemented (no meetings or documentation), then score as not met.

Ind 157. *The review uses a representative sample based on statistical principles.*

Survey Process:

Check the documentation of the review to determine if the sample was reflective of the hospital's services and staff. There should be evidence that the hospital defined the sample size.

Scoring:

- If there is evidence that a representative sample (covering the scope of the hospital's services and its staff) is reviewed, then score as fully met.
- If in the collective opinion of the survey team the sample is not statistically representative, then score as partially met.
- If there is no review, then score as not met.

Ind 158. *The review is conducted by identified care providers and health professionals.*

Survey Process:

Look for documented evidence that the review was conducted by professionals from disciplines that are authorized to make entries into the medical record. The review should not be done only by medical records personnel.

Scoring:

- If there is documented evidence that the review was done by members of disciplines that are authorized to make entries into the medical record, then score as fully met.
- If the review does not include representatives of ALL disciplines who are authorized to make entries into the medical record, then score as partially met.
- If the review is done only by medical records personnel, then score as not met.

Ind 159. *The review focuses on the timeliness, legibility and completeness of the medical records.*

Survey Process:

Analyze documentation of the review to verify that it includes timeliness, legibility and completeness of the medical records.

Scoring:

- If the documentation of the review demonstrates evidence of review of timeliness, legibility and completeness of the medical records, then score as fully met.
- If the review process does not include ALL of timeliness, legibility and completeness, then score as not met.

Ind 160. The review process includes records of both active (current) and discharged patients.**Survey Process:**

Consider the documentation of the review process to verify that both “open” and “closed” records were included. An “open” record is that of a patient currently hospitalized. A “closed” record is of a patient who has been discharged.

Scoring:

- If the review includes both “open” and “closed” records, then score as fully met.
- If the review does not include both “open” and “closed” records, then score as not met.

Ind 161. The review identifies, and documents any deficiencies in the record.**Survey Process:**

Review the minutes or other documents that demonstrate the findings of the review, including deficiencies found. It is highly unlikely that the hospital’s review has not identified any problems with medical record documentation.

Scoring:

- If the documentation includes identification of any deficiencies, then score as fully met.
- If not, then score as not met.

Ind 162. Appropriate corrective and preventive measures undertaken are documented.**Survey Process:**

Review the minutes to confirm the response to deficiencies.

Scoring:

- If the minutes document corrective action when indicated (surveyor judgment), then score as fully met.
- If not, then score as not met.

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