CBAHI

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

Essential Safety Requirements 2018

ESR Survey Ground Rules

- Three (3) policies and one (1) report need to be reviewed, although it doesn't have a scorable element (i.e., document review activity) in the scoring application;

  Patient Identification (QM.17), Policy on preventing wrong patient, wrong site, wrong surgery (QM.18), Policy on VTE Prophylaxis (PC.26), and Civil Defense Report.

  These documents need to be reviewed to ensure consistency of practice. If policies are not available, score these sub-standards as per indicated activities on scoring application and recommend for them to have these policies.

- Compliance of four (4) months prior to the survey day is needed.

- If a substandard requires observation activity and there were no cases to observe during the visit, observation can be replaced by staff interview.

- If a substandard requires open medical record review activity and there was no patient present during the visit to verify the implementation, activity can be replaced by closed medical record review during the compliance period and should be scored accordingly.

  - If no Open or Closed Medical Record Review found in the compliance period, it can be scored as Not Applicable.

Report Writing Ground Rules

- Comments should be in **past tense** form of sentences.
- State the number of sample used to verify the evidence *(e.g., Medical Record, Personnel File, Interviewed staff)*
- For Observation, need to specify the location
- Any substandard scored Not Applicable require justification to be indicated in the comments
- Selection of Personnel Files and Medical Records need to be RANDOMLY.
- Policy Scoring; If no policy, the score will be Zero and all other activities under the same substandard will be scored Zero and other sub-standards will be scored separately.
- If the policy is not implementable (e.g., medication error reporting policy indicate having an electronic reporting system, however, no such system was available in the hospital), then Document Review Activity will be scored “0” and all activities under it will have the same score “0”.

HR.5

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

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

- HR.5 standard is applied for any new staff hired after January 1, 2016
- The policy of credentialing verification should include the elements mentioned in standard HR.5 *(such as HR.5.2, 5.3, 5.8, 5.9)*
- The policy should have a process for credential verification for all healthcare professionals providing patient care. This includes: Saudis and Non Saudis, Medical, Nursing and Allied Healthcare.
- If the hospital has a credentialing policy but the policy did not specify the procedure for verification of credentials, the score will be “Not Met”.
- If policy is not signed by HR Department then score will be “Partially Met”.
- If the hospital use Third Party verification process, it should be clearly indicated in the policy and should specify if this Third Party covers all credentials (education, license, training, experience).

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

- Credentials for any position specified as per job description and SCFHS classification.

- This substandard consist of three (3) elements; gathering, verifying and evaluating.
  - **Gathering;** having copy of all credentials in personal file.
  - **Evaluation;** having documented evidence in personnel file that credentials were evaluated (signed by credentialing committee) or review previous three (3) meeting minutes of credentialing committee to ensure that evaluation was taken.
  - **Verification;** having primary source verification for credentials (license, education, training and experience).

Note: If a hospital gathers and evaluate credentials, with no verification from the primary source, score will be Partially Met.

Note: If a hospital gathers and evaluate credentials, but verification found only for 2 or 3 out of 4 credentials, this substandard can still be scored as Fully Met.

HR.5.3 Credentials are verified from the original source

Education Verification

- Required qualification certificate *(based on job description)* needs to be verified from the original source *(Saudi and Non-Saudi)*.

License Verification

- No primary source verification is required for original country license.
- SCHFS license verification is not required if the hospital is responsible for registration process in SCFHS *(name of working place on the card similar to the surveyed hospital).* If SCFHS license issued under another employer, SCFHS verification is required.

Experience Verification

- Experience verification should be as per job description (JD). If a staff has an experience in the current hospital exceeding the required years of experience as per JD, experience verification is not required (e.g., JD requires 3 years of experience and the staff working in the current surveyed hospital since 5 years). However, if staff is newly hired, then verification is required as per the JD.

Training Verification

- Training verification should be as per the job description.

HR.5.3 Credentials are verified from the original source

- Credentials verification can be conducted through letter, secure website, email, documented phone call (internally or through third party). However, an evidence should be kept in staff personnel file.

- CBAHI does not mandate having a verification through a third party. It can be conducted internally by the hospital. For credentials that verified through third party, a confirmation letter should be kept in staff personnel file.

- Verification is not required for life support certificates such as BLS, ACLS and PALS.

- If verification conducted via phone call, contact information (names and position, signature, date, institution and the verification result) of the person who made the phone call and the contacted person should be included in the personnel file stamped, signed and documented.
  - If no response received after 3 trials, the contact details (name, position, signature, institution and contact date & time) of the person trying to call should be included in the personnel file.

- **Verification using more than one method in one personnel file is acceptable (e.g., education verified by third party, license by secure website, training by email).**

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

- If there is no job description and privilege in the personnel file, the score will be 0.
- If no verification but job description and privilege are present in the personnel file, the score will be Partially Met.
- If the staff is assigned out of his profession (e.g., nurse working as anesthesia technician), then the score will be affected.

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

- This substandard requires a valid license from SCFHS (i.e., SCFHS card is valid).

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

- This substandard requires hospital to have a valid copy of MOH license in the personnel file. Thus, this will be scored in private hospitals accordingly and scored as NA in all governmental hospitals.

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

- This is a reflection of HR.5.2 and HR.5.5. Hospitals should have a personnel file for each employee includes; credentials, valid SCFHS certificate, and valid MOH license.

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

- If verification for any credential is conducted through a third party, confirmatory documentation is required in staff personnel file.
- This can be scored NA if hospital doesn't conduct any verification through third party and all verification for license, experience, training and education conducted internally.
- Payment receipt from third part is not considered as confirmatory documentation.

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

- CBAHI requires healthcare facilitates to have personnel file with all verified credentials for all part time, visitor and locum staff.
- This substandard used only to evaluate verification process for part time, visitor and locum staff.
- Use HR.5.3 to score Full time and HR.5.9 to score part time, visitor and locum.
- Score of HR.5.9 should not affect and should not be affected by the score of HR.5.3.

- During unit visit, areas to be surveyed may include Operating Room and Outpatient Department as both are the highest possible areas for part time, visitors and locum staff.

MS.7

Medical staff members have current delineated clinical privileges.

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

- This substandard requires having valid copy of privileges for physician practitioner in clinical areas. It can be found as hard copy or electronic… either acceptable.

- In visited units such as ICU, OR, ER and Radiology, it is required to verify the **availability and accessibility** of the privileges for the physicians working in these areas.
- Score should be based on the availability and accessibility. If privileges are not accessible, the score will be 0.
- If electronic privileges used, it should be through controlled system. Having a scanned uncontrolled copy on desktop is not accepted.

- Although the validity of privileges will be assessed by MS.7.2, such finding need to be verified as part of MS.7.1 too since both sub-standards are linked.

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

- This requires having a valid clinical privileges in reviewed personal files.
- Although the activity of MS.7.2 is Personnel File, if privileges form found in personnel files are outdated, it is required to validate finding in clinical departments as part of MS.7.1.

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

- Privileging policy should include; definition of temporary and emergency privilege, the circumstances and process of granting temporary and emergency privileges.
- Although emergency privilege can be scored NA if it is not used, temporary privilege cannot be scored NA as it's the first step in granting privilege for newly hired staff.

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

- This substandard consist of two (2) elements; having temporary privileges not granted more than 90 days and not renewable. If these two statements *(both)* are not written in the policy, the score will be "Not Met" for MS.7.4.

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

- This substandard is limited only for newly requested privileges after granting the permanent privilege.
- During survey visit, it is required to request the last 3 meeting minutes for the privileging committee to ensure that if there are any medical staff requesting new privilege.
- If no staff requested for new privilege, this substandard can be scored Not Applicable.

PC.25

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

- This standard can be Not Applicable in specialized hospitals that does not have operating room or have no trauma cases in ER. As well, in mental health and convalescent hospitals if it is clearly written that blood transfusion is out of their scope of service.
  - *In such scenarios, the hospital should provide a clear written policy specify the process of transferring patients after stabilizing to another facility.*

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

- Policy on blood handling/administration should be reviewed and signed by the Blood Utilization Committee and include clear process for handling, use and administration of blood and blood products.

- If policy is not signed by the Blood Utilization Committee, both activities (Document Review and Staff Interview) will be scored “Not Met”.

- If policy is scored “Fully Met”, it is required to interview physicians and nurses in different areas such as ER, ICU, laboratory and surgical wards to ensure the implementation and awareness of this policy.

- CBAHI does not mandate a stand-alone Blood Utilization Committee in small or specialized hospitals. It can be merged in another committee.

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

- Policy should have a clear written mandate that only physicians are allowed to order blood and blood products.

- Medical Record Review;
  - Verify if physician order is complete (type of the blood, number of units, transfusion duration, and order authentication)
  - Electronic or handwritten orders are accepted.
  - Select randomly a representative sample *(e.g., select randomly from dispensed blood units in laboratory logbook)*…. sample of five (5) medical records is required *(as applicable & depends of the number of transfused units)*.
  - Similar to other medical record review sub-standards, if discrepancies found, it is necessary to enlarge the sample size.
  - Open and closed medical record may be reviewed, if open medical record is breached, this should be reflected in the score.

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

PC.25.3.1 Description of the transfusion process.
PC.25.3.2 Identification of the risks and benefits of the transfusion.
PC.25.3.3 Identification of alternatives including the consequences of refusing the treatment.
PC.25.3.4 Giving the opportunity to ask questions.
PC.25.3.5 Giving the right to accept or refuse the transfusion.

- Policy needs to include the process and element of informed consent.
- Random selection of five (5) medical records to verify that consents include all sub-sub-standard elements PC.25.3.1 – 25.3.5.

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

- This substandard includes two (2) parts; identification prior to cross matching and prior to blood administration.
- If one (1) element is present (out of 2), the score will be "Partially Met".
- If the hospital mandates taking two (2) samples to verify cross match and that clearly written in the policy, this can replace double identifications prior to cross matching.

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

In this sub standards, we have 3 scenarios:

(a) hospitals has donation area and conduct NAT testing internally, policy should clearly require informed consent in case of transfusion without NAT testing.
(b) hospital has donation area and testing is done outside the facility, policy should clearly require informed consent in case of transfusion without NAT testing.
(c) hospital does not have donation area and receiving tested blood from outsource facility, the score of PC.25.5 will be NA.

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

- Policy needs to include details on blood transfusion process, blood monitoring, and duration of transfusion in congruent with the best practices from a recognized professional organization.
- References used in developing transfusion policy should be based on recognized professional organization.

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

- Observe the accessibility and availability of transfusion policy in the visited areas (such as ICU, ER or Surgical Ward), ask the staff if they have access to.

PC.25.8 Patients receiving blood are closely monitored.

- Policy should specify the monitoring intervals and procedure. This as well need to be reflected in medical records.
- Sample of medical records should be selected to verify the monitoring procedures.

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

- Transfusion reaction policy should indicate the process of **reporting** and **analyzing** the transfusion reaction.
  - If the policy includes only the process of reporting (nothing regarding analysis), the score will be “Partially Met”.
  - It’s acceptable to have transfusion reaction policy as part of the blood administration policy.

- If a hospital stated not having any reactions or complication in the last four (4) months, this will depend on the number of transfused units. We may need to interview staff to assess their competence in recognizing adverse transfusion reaction.

- This substandard can be scored as NA, if the rate of transfusion is too low and the staff stated not having any reaction during the last four (4) months.

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

- The difference between PC.25.9 and PC.25.10:
  - *PC.25.9 is related to transfusion reaction.*
  - *PC.25.10 is related to side effects or complications of transfusion such as hematoma, extravasation, air embolism and other complications.*

- Policy should clearly state that such complications need to be reported to medical staff **and** blood bank as well.

- Policy should also indicate the process of dealing with blood unit after the complication *(e.g., returning the blood bag to blood bank for further investigations).*

PC.26

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

- This standard is Not Applicable in Pediatric Hospitals *(pediatric group)*.
- Although the activity required for PC.26.1 and PC.26.2 is medical record review, VTE prophylaxis policy needs to be reviewed to ensure consistency of practice. If policy is not available, score these sub-standards based on medical records finding and recommend for them to have written policy.

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

- Form used for VTE screening should includes all identified risk factors and the calculation of these risks result in adequate treatment.

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

- Ensure that prophylaxis given according to risk factors identified in PC.26.1
- Ensure that prophylaxis given according to the evidence based.
- Check the evidence based guidelines used in providing VTE prophylaxis.

QM.17

The hospital has a process to ensure correct identification of patients.

- Although this standard does not include “document review” activity, we need to review identification policy/protocol to ensure consistency of practice. If policy is not available, score QM.17.1-QM.17.3 using observation and interview and recommend for them to have written policy.

QM.17.1 At least two patient identifiers (e.g., patient full name and medical record number) are required whenever taking blood samples, administering medications or blood products, or performing procedures.

- Interview staff to ensure that they are aware of the policy and using at least 2 patient identifiers before procedures, blood sampling, medications administration… etc.

QM.17.2 The hospital has a standardized approach to patient identification (e.g., use of ID bands with standardized information).

- Visit and observe different location to ensure consistency and standardization of patient identification process.
- Suggested areas for observation:
  - Observe if patients in ER having ID bands specially in observation room,
  - Observe that ID bands include visible, readable and clear information,
  - Observe staff administering medications without verification against medication records,
  - Observe if pediatric patients having ID bands,
  - Observe using room number as identifier in medication drawers.

QM.17.3 Patients are actively involved in the process of patient identification.

- Interview staff and patients and observe the implementation.
- Most common areas to observe: outpatient pharmacy, phlebotomy area, patient pre-procedure.
- This substandard is NA in mental health hospitals.

QM.18

The hospital has a process to prevent wrong patient, wrong site, and wrong surgery/procedure.

- Although this standard does not include “document review” activity, we need to review the policy on preventing wrong patient, wrong site, and wrong surgery to ensure consistency of practice. If policy is not available, score QM.18.1-QM.18.6 using other activities and recommend for them to have written policy.

QM.18.1 There is a process implemented to prevent wrong patient, wrong site, and wrong surgery/procedure during all invasive interventions performed in operating rooms or other locations.

- This substandard have 2 parts; surgical operations in operating room (50%) and invasive procedures outside operating room (50%).

- Interview staff (medical, nursing, anesthesia, technicians) to ensure their awareness of sign-in, sign-out and time-out processes.
- Interview staff (medical, nursing) to ensure having list identify all invasive procedures that require time-out process.
- Suggested areas to verify invasive procedures practices are; surgical wards, ICU, ER, endoscopy, radiology.
- For Mental Health Hospitals, this substandard is applicable only if they are conducting ECT procedure.

QM.18.2 The process consists of three phases: verification, site marking, and time out.

- This substandard consists of 3 elements; verification, site marking, & time- out.
- Review medical records to ensure a proper timely documentation of verification, site marking, & time- out (e.g., in recovery room).
- Verification and time-out need to be reviewed in surgical operations and invasive procedures too, to ensure compliance.

QM.18.3 A pre-procedure verification of the patient information is carried out including the patient's identity, consent, full details of the procedure, laboratory tests and images, and any implant or prosthesis.

- For surgical operations, review documented pre-procedure verification (e.g., in OR holding area or in surgical ward if no cases present in OR).
- For invasive procedure, review time-out documentation to ensure verification.

QM.18.4 The surgical/procedural site is marked before conducting the surgery/procedure.

QM.18.4.1 The site is marked especially in bilateral organs and multiple structures (e.g. fingers, toes, and spine).
QM.18.4.2 The site is marked by the individual who will perform the procedure.
QM.18.4.3 The patient is involved in the marking process.
QM.18.4.4 The marking method is consistent throughout the hospital.
QM.18.4.5 The mark is visible after the patient is prepped and draped.

- The specification of site marking from QM.18.4.1 – QM.18.4.5 should be documented in reviewed medical records *(used only for surgical operations)*

- CBAHI does not mandate hospitals to have drawing for body diagram to indicate the site marking. It is acceptable to have it written in the surgical site checklist but should indicate the body part used for site marking.

- In mental health hospitals, site marking for ECT is Not Applicable.

QM.18.5 A final check (time-out) is conducted before the procedure is initiated.

QM.18.5.1 The time-out is conducted in the location where the procedure will be done, just before starting.

QM.18.5.2 The time-out is initiated by a designated member of the team and involves the members of the team, including the individual performing the procedure, the anesthesia providers, and the nurse(s) involved.

QM.18.5.3 The entire procedure team uses active communication during the time out.

QM.18.5.4 During the time-out, the team members agree on the correct patient identity, the correct procedure to be performed, the correct site, and when applicable, the availability of the correct implant or equipment

- Hospitals need to have a clear documented evidence in medical records for conducting time-out.
- Although QM.18.5, need to be verified using observation and interview activities, observation can be replaced by staff interview (e.g., in recovery room or surgical wards) if there are no cases of invasive procedure to observe during the visit to ensure staff awareness of time-out process.
- If time-out is conducted prior to induction, the score will be “Partially Met” as it should be t should be immediately prior incision.

QM.18.6 The hospital documents its processes for preventing wrong patient, wrong site, and wrong surgery/procedure.

- All processes from QM.18.2 to QM.18.5 should be documented in medical record. Open medical record may be replaced by closed, if no available cases to review.

AN.2

Anesthesia staff members have the appropriate qualifications

AN.2.1 Qualified anesthesiologists provide anesthesia services.

- Qualified anesthesiologist could be specialist, senior specialist or consultant.
- Personnel files for review can be selected randomly from Anesthesia Rota.

AN.2.2 Qualified anesthesiologist is present inside the operating room throughout the operation.

- hospitals need to have a documented evidence in medical records that anesthesiologist is present in OR throughout the operation.
- Surveyors need to check the Discharge Recovery Sheet and Intraoperative Anesthesia Operation coupled with adequate match between number of available anesthesiologist (using anesthesia rota) and active operation room that can be obtained from the daily OR list. Compare it with the number of anesthesiologist that can indicate the availability of anesthesiologist in OR throughout operation time.
- ***Suggestion as applicable***, select operations done in a specific date to ensure that not having anesthesiologist supervising two operations at the same time.

AN.2.3 Anesthesia consultant administers and supervises anesthesia for major/specialized operations or high risk patients, including:

AN.2.3.1 Pediatric operations.
AN.2.3.2 Cardio-pulmonary operations.
AN.2.3.3 Neurosurgery operations.
AN.2.3.4 Transplant operations.

- Anesthesia consultant needs to be present inside OR during high risk surgeries.
- Pediatric group consider high risk. Thus, all pediatric operations require having anesthesia consultant.

AN.2.4 Anesthesia staff are certified in advanced life support as appropriate to the patient's age.

- Hospitals need to have an evidence of advanced life support training in anesthesiologists personal files.
- If an anesthesiologist participating in pediatric operations, we need to pay attention of having PALS certificate as well.

AN.15

Qualified staff perform moderate and deep sedation/analgesia

AN.15.1 Physicians who perform moderate and deep sedation/analgesia have competency based privileges granted to perform moderate and deep sedation/analgesia.

- If moderate sedation given by anesthesia staff, the score will be “Fully Met”.
- All physicians *(non-anesthesiologist)* who perform moderate/deep sedation must have training or specific privileges on moderate sedation. ICU Intensivist and ER Physicians who classified from SCFHS as ER, doesn’t require such training.

AN.15.2 Clinical staff who participate in caring for patients receiving moderate or deep sedation are certified in advanced life support as appropriate to the age of the patients served.

- Clinical staff such as nurses, anesthesia technicians, radiology technicians, labor and delivery staff who participate in caring of patients received moderate sedation are required to have advanced life support training (and PALS if they serve pediatric group).

AN.15.3 Clinical staff who participate in conducting sedation must successfully complete a proper education/training on moderate and deep sedation.

- Clinical staff such as nurses, radiology technicians, labor and delivery staff who participate and conduct sedation must complete adequate training in moderate and deep sedation.
- Training should be conducted by a qualified anesthesiologist and should not be too short 1 - 2 hours *(at least one day)*.

- Anesthesia physicians and technicians do not require training on moderate/deep sedation as it is already part of their study.

IPC.4

IPC.4.1 The infection prevention and control committee is chaired by the hospital director or the medical director.

- Infection Prevention and Control Committee need to be chaired by hospital director or medical director. If the committee chaired by IPC department head, the score will be “Not Met”.

- The committee chairman name should be reflected in the Terms of Reference (TOR) and meeting minutes. If meetings are conducted quarterly, reviewing the latest meeting minutes is needed and if conducted monthly, reviewing the last four (4) meeting minutes is needed to verify signature and involvement of the committee chairman.

- The applicable activity for this substandard in ESR visits is Documented Evidence.

IPC.4.2 The membership of the infection prevention and control committee includes representatives from the medical staff, nursing staff, microbiology, operating room, central sterilization service, pharmaceutical care, dietary services, housekeeping, infection prevention and control staff, and other departments as needed.

- This substandard requests nine (9) members as part of infection control committee, in addition to other departments as involvement. If the membership list lack any of those members, the score will be “Not Met”.
- In large hospitals, medical staff involvement should include a representative from all critical care areas (PICU, NICU, AICU, CCU) in IPC Committee.
- Surveyor needs to review the meeting minutes to ensure that issues discussed in the meeting are assigned to concerned representatives (e.g., if the discussion in the meeting is regarding antibiogram, the issue should be assigned to microbiology representative in this committee).

IPC.4.3 The infection prevention and control committee meets on a regular basis (at least quarterly).

- Hospitals need to show evidence for regular basis meeting.

IPC.4.4 Functions of the infection prevention and control committee include, but are not limited to, the following:

IPC.4.4.1 Review of the hospital infection prevention and control policies and procedures.
IPC.4.4.2 Review of the reports of healthcare-associated infections surveillance submitted regularly by the infection prevention and control team and suggestion of appropriate actions.
IPC.4.4.3 Revision of the yearly plan submitted by infection prevention and control team and suggestion of additions/changes if necessary.
IPC.4.4.4 Evaluates and revises on a continuous basis the procedures & the mechanisms developed by the infection prevention & control team to serve established standards and goals.
IPC.4.4.5 Brings to the attention of the infection prevention & control team new infection control issues arising in different departments of the hospital & suggests solutions.
IPC.4.4.6 Each member of the committee acts as an advocate of infection prevention & control in his department, trying to promote its principles, and ensures application of its rules.

- Hospitals need to ensure incorporating these six (6) functions in the terms of reference.
- Score will be according to percentage of having these 6 functions *(e.g., if 1 out of 6 functions is missing, this can be scored "Fully Met" and the missing function can be added as recommendation in surveyor's comment).*
- Infection prevention and control **annual plan** need to reviewed and signed by the committee (IPC.4.4.3).

IPC.15

Facility design and available supplies support isolation practices.

IPC.15.1 There is at least one negative pressure airborne isolation room in the emergency room and one in patient care areas (one negative pressure room for every 25-30 beds in general hospitals).

- Hospitals are expected to have;
  - At least one negative pressure room in ER.
  - At least one negative pressure room for every 25-30 beds in general hospitals.
  - Log sheet for negative pressure monitoring at least daily if room is equipped with a patient who require airborne isolation and weekly monitoring if room is vacant.

- Engineering control record should be completed and reviewed for air changes per hour, HEPA filter, negativity, humidity, & temperature as illustrated under IPC.15.3.

- If hospital has adequate number of negative pressure isolation rooms for inpatient, with **no** isolation room in ER, observation and documented evidence activities will be scored “Partially Met”.

- If observation activity scored “Not Met”, the documented evidence activity must also be scored “Not Met”.

IPC.15.2 The infection prevention and control team decides the need for more airborne isolation rooms depending on the volume of patients in need for airborne isolation admitted to the hospital.

- Hospitals need to have an evidence indicate that the team of IPC discuss and decide the need for more isolation rooms regardless if the hospital have isolation rooms or not. This can be found in;
  - Infection prevention and control annual plan
  - Risk Assessment Plan
  - Infection prevention and control committee meeting minutes

- The score of this substandard will not depend on IPC.15.1. Thus, the hospital could have no negative pressure isolation room and get “Fully Met” in IPC.15.2.

IPC.15.3 The ventilation system serving airborne isolation facilities provides pressure patterns that prevent airborne pathogens from being distributed to other areas of the hospital.

IPC.15.3.1 Rooms designed for airborne isolation patients are under negative pressure.
IPC.15.3.2 Air is exhausted to the outside and is not re-circulated unless it is filtered through High -Efficiency Particulate Air (HEPA) Filter.
IPC.15.3.3 There is evidence of daily air exchange monitoring (12 air changes per hour) when a patient is isolated. Weekly monitoring of the air exchange is needed when no patient is isolated.

- Engineering control record should be completed and reviewed for air changes per hour, HEPA filter, negativity, humidity, and temperature;
  - HEPA filter should be changed every 6 months, unless if the hospital has cleaning system for filter with documented evidence on the quality of differential pressure
  - Portable HEPA filter is not accepted (it doesn't ensure sufficient air changes per hour)
  - Acceptable air changes per hour is 12 or more (in OR, 15 or more)
  - Acceptable temperature is 20-24
  - Acceptable humidity is 20-60

- The score of IPC.15.3 is linked with IPC.15.1;
  - If the score of IPC.15.1 is “Not Met”, IPC.15.3 will be scored “Not Met” too.
  - If the score of IPC.15.1 is “Partially Met” and there is any missing element from (IPC.15.3.1 to IPC.15.3.3), IPC.15.3 will be scored “Not Met”.

IPC.15.4 The entry of the isolation room is through a work area or ante-room that serves as a site for hand washing, gowning and storage of protective clothing (gloves, aprons, masks).

- Hospitals should utilize ante-room as working area for hand washing, gowning, and storage of PPEs. Having PPEs/gowning outside ante-room is not acceptable.
- Shared ante-room is not acceptable.
- IPC.15.4 scored separately regardless if there are negative pressure isolation rooms or not. The score depends on the number of isolation rooms that having ante-room meeting the criteria. If ER isolation room doesn't have ante-room, this is enough to score IPC.15.4 as "Partially Met", even if the remaining inpatients isolation rooms meeting the criteria.

IPC.15.5 Toilet, shower, or tub and hand washing facilities are provided for each isolation room.

- IPC.15.4 scored separately regardless if there are negative pressure isolation rooms or not. The score depends on the number of isolation rooms that having Toilet, shower, or tub.
- Shower and toilet in ICU isolation room is not mandatory.
- Toilet and shower should **not** be opened to ante-room.

IPC.15.6 Transmission-based precaution cards (isolation signs) are consistent with the patient diagnosis and are posted in Arabic and English and indicate the type of precautions required.

IPC.15.6.1 Transmission-based precaution cards (isolation signs) are color coded for isolation of different categories (e.g., contact: green, airborne: blue, droplet: pink or red).

IPC.15.6.2 Transmission-based precaution cards (isolation signs) should contain short statements and supported with the required figures.

IPC.15.6.3 Isolation instructions must highlight the transmission-based precaution cards (isolation signs) needed while transporting the patients under transmission-based precautions to other department (e.g., radiology).

- Hospital's policy need to include the specification of isolation precaution cards.
- The transmission based precaution card should be consistent with diagnosis, posted in both Arabic and English, color coded, contain short statements, contain figures, and include transportation instructions.
  - *If cards are not consistent with diagnosis and not in both languages (Ar & En), score is "Not Met" regardless IPC.15.6.1 – IPC.15.6.3 findings.*
  - *If cards are not posted in both languages (Ar & En), and all other elements available, score is "Partially Met"*
  - *If cards are not consistent and all other elements available, score is "Partially Met"*
  - *If cards are consistent with diagnosis and posted in both languages (Ar & En), assess IPC.15.6.1 – IPC.15.6.3, if missing one element, score it "Partially Met" and if more than one element missing, score it "Not Met".*
- The color coding card written in IPC.15.6.1 is an example. If hospital uses different color code, known to all staff, and written in the policy, it's accepted.

IPC.15.7 Respirator (high filtration) masks (N-95, N-99) are used by staff during direct care of patients on airborne precautions and are available on all units likely to admit patients on airborne precautions.

- Surveyors need to ensure; 1) the availability of different sizes of N95 masks, 2) having fitting test and staff are aware about their results, 3) observe donning and removing of N95.

IPC.15.8 Respirator (high filtration) masks (N95, N-99) can be reused by the same patient care giver as per the period specified by the manufacturer.

- This sub-standard may have 3 different scenarios:
  - If hospital policy stated single use of N95, document review and interview activities will be scored “Not Applicable”.
  - If hospital policy does not decide on single or reuse of N95, document review and interview activities will be scored “Not Met”.
  - If hospital policy stated reuse of N95, it should specify the reuse criteria; reuse for the same patient, reuse duration, and way to store used masks… Then document review and interview activities will be scored accordingly.

MM.5

The hospital has a system for the safety of high-alert medications.

MM.5.1 There is a written multidisciplinary plan for managing high-alert medications and hazardous pharmaceutical chemicals. It includes identification, location, labeling, storage, dispensing, and administration of high-alert medications.

- Policy should be multidisciplinary, includes high-alert medications and hazardous pharmaceutical chemicals, and specify the process of identification, location, labeling, storage, dispensing and administration.
- If policy does not specify the process of identification, location, labeling, storage, dispensing and administration, the score will be “Not Met”.
- If policy is not signed by pharmacy director, the score will be “Not Met”.
- If policy is not multidisciplinary *(e.g., not signed by nursing)*, the score will be “Partially Met”.
- If policy includes only high alert medications (doesn’t include hazardous pharmaceutical chemical), the score will be “Partially Met”.

Note: Surveyors need to ensure that chemotherapy is not the only example of hazardous pharmaceutical chemical. Handling of hazardous pharmaceutical chemical should be stated clearly in the policy.

MM.5.2 The hospital identifies an annually updated list of high-alert medications and hazardous pharmaceutical chemicals based on its own data and national and international recognized organizations (e.g., Institute of Safe Medication Practice, World Health Organization). The list contains, but is not limited to, the following:

MM.5.2.1 Controlled and narcotics medications.
MM.5.2.2 Neuromuscular blockers.
MM.5.2.3 Chemotherapeutic agents.
MM.5.2.4 Concentrated electrolytes (e.g., hypertonic sodium chloride, concentrated potassium salts).
MM.5.2.5 Antithrombotic medications (e.g., heparin, warfarin).
MM.5.2.6 Insulins.
MM.5.2.7 Anesthetic medications (e.g., propofol, ketamine).
MM.5.2.8 Investigational (research) drugs, as applicable.
MM.5.2.9 Other medications as identified by the hospital.

- Hospitals need to have annually updated list for high-alert medications and hazardous pharmaceutical chemical.
- Examples mentioned in MM.5.2.1 to MM.5.2.9 are examples that need to be part of the list along with other high alert medications that not listed above.
- If the list is outdated or not dated (i.e., no evidence of update), the score will be “Not Met”.
- If the updated list does not include hazardous pharmaceutical chemicals, the score will be “Partially Met”.

MM.5.3 The hospital plan for managing high-alert medications and hazardous pharmaceutical chemicals is implemented. This includes, but is not limited to, the following:

MM.5.3.1 Improving access to information about high-alert medications.
MM.5.3.2 Limiting access to high-alert medications.
MM.5.3.3 Using auxiliary labels or computerized alerts if available.
MM.5.3.4 Standardizing the ordering, transcribing, preparation, dispensing, administration, and monitoring of high-alert medications.
MM.5.3.5 Employing independent double checks.

- The hospital plan for high-alert medications and hazardous pharmaceutical chemicals should include all the sub substandard MM.5.3.1 to MM.5.3.5, then the score will depend on the percentage of compliance with these sub substandard.
- MM.5.3.2 does not mean having high alert medication in a locked cabinet, but we need to ensure limiting access to these high alert medications.

MM.5.4 The hospital develops and implements standard concentrations for all medications administered by intravenous infusion.

- Hospital need to have a list of medications administered by IV infusion with dilution details. Moreover, staff *(nursing, medical and pharmacist)* should be aware about it.
- MM.5.4 cannot be scored NA in any hospital setting.

MM.6

The hospital has a system for the safety of look-alike and sound-alike (LASA) medications

MM.6.1 There is a multidisciplinary policy and procedure on handling look- alike/sound-alike (LASA) medications.

- Hospital's policy should be multidisciplinary and should include the process of handling LASA. That includes; identification, location, labeling, storage, dispensing and administration of LASA medications.
- If policy does not specify the process of identification, location, labeling, storage, dispensing and administration, the score will be "Not Met".
- If policy is not signed by pharmacy director, the score will be "Not Met".
- If policy is not multidisciplinary *(e.g., not signed by nursing)*, the score will be "Partially Met".

MM.6.2 The hospital reviews and revises annually its list of confusing drug names, which include LASA medication name pairs that the hospital stores, dispenses, and administers.

- Hospitals need to have annually updated list for LASA medications.
- If hospital's list include only Look Alike medications, the score will be "Partially Met".
- If the list is outdated or not dated (i.e., no evidence of update), the score will be "Not Met".

MM.6.3 The hospital takes actions to prevent errors involving LASA medications including the following, as applicable:

MM.6.3.1 Providing education on LASA medications to healthcare professionals at orientation and as part of continuing education.
MM.6.3.2 Using both the brand and generic names for prescribing LASA medications.
MM.6.3.3 Writing the diagnosis/ indication of the LASA medication on the prescription.
MM.6.3.4 Changing the appearance of look-alike product package.
MM.6.3.5 Reading carefully the label each time a medication is accessed, and/or prior to administration.
MM.6.3.6 Minimizing the use of verbal and telephone orders.
MM.6.3.7 Checking the purpose/indication of the medication on the prescription prior to dispensing and administering.
MM.6.3.8 Placing LASA medications in locations separate from each other or in nonalphabetical order.

- The hospital plan for preventing error involving LASA medications should include all the sub substandard MM.6.3.1 to MM.5.3.8, then the score will depend on the percentage of compliance with these sub substandard.

- For MM.6.3.1 ensure having evidence that adequate number of staff were educated about LASA medications.

MM.41

The hospital has a process for monitoring, identifying, and reporting significant medication errors, including near misses, hazardous conditions, and at-risk behaviors that have the potential to cause patient harm.

MM.41.1 There is a multidisciplinary policy and procedure on handling medication errors, near misses, and hazardous situations (e.g., confusion over look-alike/sound-alike drugs or similar packaging).

- This substandard includes three (3) elements; medication errors, near misses, and hazardous situations.
- If policy is not signed by pharmacy director, the score will be “Not Met”.
- If policy is not multidisciplinary *(e.g., not signed by nursing)*, the score will be “Partially Met”.

MM.41.2 The policy has a clear and acceptable definition of significant medication error, near misses, and hazardous situations.

- Medication errors reporting policy should include three (3) definitions; significant medication error, near misses, hazardous situation.
- Definitions should be written in the policy in a clear and acceptable manner.
- **Suggestion:** use the definition as per the Saudi Patient Safety Center Taxonomy.

MM.41.3 The treating physician is notified of the medication error at the appropriate time.

- Hospital policy should define appropriate time of medication error reporting to treating physician. Use this policy as reference in interviewing medical and nursing staff then score accordingly.

MM.41.4 Medication error reporting is completed within the specified time frame after discovery of the error.

- Hospital policy should define the timeframe of incident reporting realted to medication errors. Then interview staff (pharmacist, physicians and nurses) to ensure reporting of incident report completed within specified timeframe as per the policy.

MM.41.5 The hospital has a standard format for reporting medication errors.

- Ensure that pharmacist, physicians, and nurses in different areas (clinical areas and pharmacy) are using the same standardized format for reporting medication errors.

MM.41.6 Staff are educated on the process and importance of medication error reporting.

- Interview staff and score will be based on the interviewed staff.
- If documented evidence shown (list of trained staff), we need to ensure that education involves the highest possible number of staff and not limited to specific area.

MM.41.7 There is active reporting of medication errors, near misses, and hazardous situations.

- Active reporting means reporting different types of errors by different stakeholders (medical, nursing, pharmacist).
- If hospital reporting only prescription errors, the score will be “Not Met”.

MM.41.8 The hospital conducts intensive root-cause analysis for all significant or potentially significant medication errors.

- Surveyors need to review previous significant and potentially significant medication errors. This substandard could be scored NA based on the number of reported medication errors.
- This substandard is linked with MM.41.7, if the hospital doesn’t have an active reporting system and scored “Not Met”, the score of this MM.41.8 will be affected.

MM.41.10 The hospital utilizes reported data to improve the medication use process, prevent medication errors, and improve patient safety.

- Review Pharmacy and Therapeutic Committee meeting minutes to ensure that hospital is analyzing the reported event to take corrective and preventive actions to improve the patient safety.
- If there is active reporting and potential significant error that was not analyzed and utilized, the score will be “Not Met”.

MM.41.11 Healthcare professionals are provided with feedback on reported medication errors, near misses, and hazardous situations.

- Interview healthcare provider who previously reported medication error to verify if they received a feedback regarding the analysis of the reported event and the action taken to prevent reoccurrence of the event or not.

MM.41.12 The hospital reports sentinel events related to serious medication errors to the relevant authorities.

- There are two (2) activities under this substandard;
  1) Documented Evidence: review previously reported sentinel events and score it accordingly. It can be scored NA, if there is no any reported sentinel event previously.

  2) Pharmacy and Therapeutic Committee: this will be replaced by Staff Interview *(only for ESR visits).* Interview staff regarding their awareness of the process of sentinel event handling, how to report it internally and how to report to relevant authorities.

- Hospitals need to report all sentinel events to CBAHI only if they are accredited.

LB.51

The blood bank develops a process to prevent disease transmission by blood/platelet transfusion

- This standard can be scored NA, if blood transfusion service is out of the hospital scope of services neither by having donation area nor by outsourced blood bank (e.g., mental health hospitals, convalescent hospitals).

LB.51.1 There are policies and procedures mandating that a sample of blood obtained from the donor during blood/ blood component collection is subjected to the following infectious diseases testing:

LB.51.1.1 HBsAg.
LB.51.1.2 Anti-HBc.
LB.51.1.3 Anti-HCV.
LB.51.1.4 Anti-HIV-1/2.
LB.51.1.5 Anti-HTLV-I/II.
LB.51.1.6 HIV-1 RNA.
LB.51.1.7 HCV RNA.
LB.51.1.8 HBV DNA.
LB.51.1.9 Serological test for syphilis.
LB.51.1.10 Other additional or supplemental tests as mandated by relevant health authorities.

- If hospital collects and tests blood, a clear written policy is required. The policy should detail the process/aspects of transfusion transmitted disease testing.
- Hospitals need to have a documented evidence of transfusion transmission disease testing that were conducted.
- Interview staff to ensure awareness and observe the transfusion transmission disease testing to confirm compliance with the policy.
- If hospital has donation area but outsourced infectious disease testing, we need to check the agreement.

LB.51.1 There are policies and procedures mandating that a sample of blood obtained from the donor during blood/ blood component collection is subjected to the following infectious diseases testing:

LB.51.1.1 HBsAg.
LB.51.1.2 Anti-HBc.
LB.51.1.3 Anti-HCV.
LB.51.1.4 Anti-HIV-1/2.
LB.51.1.5 Anti-HTLV-I/II.
LB.51.1.6 HIV-1 RNA.
LB.51.1.7 HCV RNA.
LB.51.1.8 HBV DNA.
LB.51.1.9 Serological test for syphilis.
LB.51.1.10 Other additional or supplemental tests as mandated by relevant health authorities.

- If hospital doesn't have donation area and receives blood and blood products from central blood bank or another hospital, check the agreement.
- **Score LB.51.1 as NA if the agreement includes;**
  - signed by both parties
  - includes agreement conditions
  - specify the role of involved party in looking back to monitor how they release blood and blood component
  - includes infectious diseases testing conducted
  - Dated with valid date
  - Includes the process of resolving disputes

LB.51.2 The blood bank has a process to limit and detect bacterial contamination in platelet components. The process:

LB.51.2.1 Describes the blood bank approach to limit bacterial contamination and the investigations of positive cases.

LB.51.2.2 Ensures the employed detection method is sensitive enough to detect significant bacterial contamination.

- If hospital collects and tests platelet, a clear written policy is required. The policy should detail the process to limit and detect bacterial contamination.
- Hospitals need to have a documented evidence of platelet tested for bacterial contamination or any testing record for the bacterial detection method.
- Interview staff to ensure awareness and observe the process used to limit and detect bacterial contamination.
- If hospital doesn't transfuse platelets or receive outsource platelets as written in blood product agreement and/or hospital's scope of service, score is NA.
- If hospital doesn't have donation area and receives platelets from central blood bank or another hospital, check the agreement. Score LB.51.2 as NA if the agreement is valid and signed by both parties and includes; agreement conditions, monitoring procedure, process used to limit bacterial contamination, and process of resolving disputes