“Zero Harm”

HR.5 The hospital has a process for proper credentialing of staff members licensed to provide patient care.	
Intent	Physicians, dentists, and others who are licensed to provide patient care independently represent those primarily responsible for patient care and care outcomes. Applicable laws, regulations, and the organization identify those permitted to work independently. The organization is responsible for ensuring that these individuals are qualified to provide patient care independently as per applicable laws and regulations. Organizations are also responsible for specifying the types of care they are permitted to provide at their facilities. The organization needs to ensure that it has qualified staff that appropriately matches its mission, resources, and patient needs. To ensure this match, the organization must evaluate staff members' credentials at appointment of the staff. An individual credentials consist of an appropriate current license, completion of medical education and any specialty education, and any additional training and experience. The organization develops a process to gather this information, verify its accuracy from the original source, and evaluate it in relation to the need of the organization and its patients. This process can be carried out by the organization or by an external agency. The process applies to all types and levels of staff (employed, honorary, contract, and private community staff members). 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. 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. 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). If no response received after three (3) trials (phone calls or emails), these trials including; name of the person who tried to contact the other institution; time; and phone number should be documented in the personnel file. The credentialing will be accepted for any staff if they are working under the same governing body. (e.g. if a doctor is working in one MOH hospital, s/he can work in another MOH hospitals with the same credentials. However, it is not the same for the privileges because this may be changed according to the scope of services of different facilities).

HR.5.1	Document Review	• Review credentialing policy that should include a process for credential verification for all healthcare professionals providing patient care. This includes: Saudis and Non-Saudis, Medical, Nursing and Allied Healthcare staff. • 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 specify the procedure for verification of credentials and should be signed by the process owner (e.g. HR).
HR.5.2	Personnel File Review	This substandard consist of three (3) elements; gathering, verification and evaluation. ▪ Gathering; having copy of all credentials in personal file. ▪ Verification; having primary source verification for credentials (license, education, training and experience). Primary source verification can either be from a third party such as dataflow or done directly by the hospital. ▪ Evaluation; having documented evidence in personnel file or meeting minutes that credentials were evaluated (signed by credentialing committee for medical staff, and a relevant entity for nursing and allied health staff. An entity could be a committee, a group or an area manager).
HR.5.3	Personnel File Review	• Qualification needs to be verified from the original source, • If staff experience (in current position) exceeding the required years of experience as per job description (JD), experience verification is not required, • Training should be based on JD. • Verification is not required for life support certificates such as BLS, ACLS, PALS.
HR.5.4	Personnel File Review	• All personal files of healthcare professionals should include copy of current job description. Additionally, privileges should be included for medical staff. • If the hospital does not conduct primary source verification or staff is assigned out of his/her profession (e.g., nurse working as anesthesia technician), then the score will be affected.
HR.5.5	Personnel File Review	Files of medical, nursing, pharmacy, laboratory, social work, and other healthcare providers contain valid and current license from the Saudi Commission for Health Specialties (i.e., SCFHS card is valid).
HR.5.6	Personnel File Review	This substandard requires hospital to have a valid copy of Ministry of Health (MOH) license in the personnel file. Thus, this will be scored in private hospitals accordingly and scored as NA in governmental hospitals.

HR.5.7	Personnel File Review	Files of medical, nursing and allied healthcare staff providing patient care shall contain credentialing documents (valid license from SCFHS; education, training, certification and experience).
HR.5.8	Personnel File Review	• Confirmatory documents supporting the process of verification of credentials by the third party if applicable. • This can be scored NA if a hospital doesn't conduct any verification through third party and all verification for license, experience, training and education conducted internally. • Payment receipt from third party is not considered as confirmatory documentation.
HR.5.9	Personnel File Review	• Review samples of part-time, visitor, and locum clinical staff (e.g., in OR, OPD) files to ensure they contain credentialing documents (valid and current license from SCFHS; education, training, certification and experience verified from original source). • Note: use HR.5.3 to score Full time and HR.5.9 to score part time, visitor and locum (The scores are independent of each other).

MS.7 Medical staff members have current delineated clinical privileges.		
Intent	Mandatory that medical staff members are only allowed to practice within the privileges granted by the credentialing and privileging committee after verifying their relevant credentials. Medical staff clinical privileges are reviewed and updated every two years and as needed. The circumstances under which temporary or emergency privileges (not more than 90 days) are granted must be clearly defined. When a new privilege is requested by a medical staff member, the relevant credentials are verified and evaluated prior to approval	
MS.7.1	Document Evidence	• In visited units such as ICU, OR, ER and Radiology, it is required to verify the availability and accessibility of valid copy of privileges for the physicians working in these areas (hard copy or controlled electronic copy). • Note: Although the validity of privileges will be assessed by MS.7.2, such finding needs to be verified as part of MS.7.1 too since both sub-standards are linked.
MS.7.2	Personnel File Review	Review Sample of physician's personnel files to make sure that clinical privileging is reviewed and updated every two years and as needed. Updated privileges imply both upgrading/downgrading.
MS.7.3	Document Review	Privileging policy should include; 1) definition of temporary and emergency privileges 2) the circumstances and process of granting temporary and emergency privileges.
MS.7.3	Personnel File Review	• Review physician personnel file to check the implementation of the hospital policy on granting temporary or emergency privileges. • Although emergency privilege can be scored NA if it is not used, temporary privilege cannot be scored NA as it's the initial step in granting privileges for newly hired staff.
MS.7.4	Document Review	Review the hospital policy on granting temporary or emergency privileging. Both elements (not granted more than 90 days and not renewable) should be written in the policy.
MS.7.5	Personnel File Review	• Review sample of physicians' files to assess the implementation of privileging process in case of requesting new privileges. • Review the last 3 meeting minutes for the privileging committee to check if there were medical staff requesting new privileges.

PC.25 Policies and procedures guide the handling, use, and administration of blood and blood products.		
Intent	The use of blood in the organization is supervised and closely monitored by the blood utilization committee. Blood must be handled and used in accordance with standards of practice and in a consistent manner to ensure the safety of the recipient. Policies and procedures are developed and approved by the blood utilization committee covering the administration of blood (including patients' identification, accepted practices, monitoring during and after the transfusion and reporting of transfusion errors) and when to administer blood without a consent. Only physicians can order blood for transfusion. Patients are informed for the reason for transfusion and sign an informed consent for blood transfusion that must include the elements in the substandard PC.25.3.1 through PC.25.3.5. All transfusion reactions are immediately reported to the blood bank and investigated by the appropriate blood bank staff to avoid its recurrence. A report is given to the blood utilization committee for review. This standard is Not Applicable in mental health, rehabilitation, and convalescent hospitals if it is clearly written that blood transfusion is out of their scope of service. Such hospitals need to have a clear written policy specify the process of transferring patients who require blood transfusion after stabilizing to another facility.	
PC.25.1	Document Review	Policy on blood handling/administration should be reviewed and signed/approved by the Blood Utilization Committee and include clear process for handling, use and administration of blood and blood products.
PC.25.1	Staff Interview	Interview clinical staff (e.g., physicians and nurses) in different areas to confirm their competency and awareness of blood administration policies and procedures.
PC.25.2	Document Review	Review the hospital policies and procedures on handling, use, and administration of blood and blood products to confirm the clear identification of medical staff authorized to order blood transfusion.
	Closed Medical Record Review	• Check the record of a patient who received blood to make sure that the blood order is only made by physician and in accordance with hospital policy. • Electronic or handwritten orders are accepted. • Open and closed medical record may be reviewed, if open medical record is breached, this should be reflected in the score.
PC.25.3	Document Review	Review the hospital policies and procedures on handling, use, and administration of blood and blood products. The policy mandate documenting informed consent and identify the elements of proper consent.

PC.25.3	Closed Medical Record Review	Check the record of a patient who received blood to make sure that the patient appropriately consented for the transfusion after being educated by a physician.
PC.25.4	Document Review	• Review the hospital policies and procedures on handling, use, and administration of blood and blood products. The implemented system mandate two staff members verify the patient's identity prior to specimen collection and prior to blood transfusion. • If the hospital mandates taking two (2) samples to verify cross match and that clearly written in the policy, it is accepted.
	Closed Medical Record Review	Check the medical record of a patient who received blood to make sure the patient identity has been verified by two staff members prior to blood drawing and transfusion.
PC.25.5	Document Review	Review policy to confirm consent mandate for "transfusion without NAT testing" in emergencies, (a) hospital has donation area and conduct NAT testing internally, policy should mandate consent for transfusion without NAT. (b) hospital has donation area & NAT testing is outsourced, policy should mandate consent for transfusion without NAT. (c) hospital does not have donation area and receiving tested blood from outsource facility (based on written agreement), PC.25.5 will be NA.
PC.25.6	Document Review	Review hospital policies that developed collaboratively by the blood utilization committee to confirm that blood transfusion guidelines adopted from recognized professional organizations and best practice (e.g., blood transfusion process, blood monitoring, and duration of transfusion in congruent with the best practices). • Accepted references used in developing transfusion policy should be based on recognized professional organization.
	Closed Medical Record Review	Check medical record of patients who received blood to make sure that Blood is transfused according to hospital policy and using accepted transfusion practices from recognized professional organizations (e.g., blood transfusion process, blood monitoring, and duration of transfusion in congruent with the best practices)
PC.25.7	Observation	Observe the accessibility and availability of blood transfusion policy in the visited areas (such as ICU, ER or Surgical Ward).
PC.25.8	Document Review	Review hospital policies and procedures to confirm that the policy mandate close monitoring of the patient during the transfusion and the policy specify monitoring intervals and procedure.

PC.25.8	Closed Medical Record Review	Check the medical record of a patient who received blood to make sure that the patient was closely monitored during transfusion.
PC.25.9	Document Review	• Review the hospital policies and procedures on recognizing, handling and reporting of adverse transfusion events. • It's acceptable to have transfusion reaction policy as part of the blood administration policy.
	Closed Medical Record Review	• Check the medical record of a patient who experienced adverse transfusion event to confirm proper reporting, investigation and actions. • This substandard can be scored as NA, if the rate of transfusion is confirmed to be too low.

PC.26 Patients at risk for developing venous thromboembolism are identified and managed.		
Intent	The hospital must develop a risk assessment tool to identify patients for risk of venous thromboembolism and to start appropriate prophylaxis either mechanical, pharmacological or both according to risk severity and to reassess whenever patient's condition changed. The hospital must adopt an international guideline and policy of venous thromboembolism prophylaxis. This standard is Not Applicable in Pediatric Hospitals.	
PC.26.1	Open Medical Record Review	• Review medical record to check if patients are screened for the risk of developing venous thromboembolism. Form used for VTE screening should include all identified risk factors according to patients' categories (medical/surgical, antenatal, and postnatal) and the calculation of these risks result in adequate treatment. • 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.
PC.26.2	Open Medical Record Review	Review medical record to check if patients at risk of developing venous thromboembolism receive prophylaxis according to current evidence-based practice. Ensure that prophylaxis given according to risk factors identified in PC.26.1. Observe the availability of mechanical prophylaxis.

QM.17 The hospital has a process to ensure correct identification of patients.

Intent	To assure correct patient identification and eliminate errors that can have fatal consequences, there should be a standard process for patient identification throughout the healthcare institution. The identification process should include at least two identifiers (e.g., patient full name and medical record number). The identification process is required in any circumstance involving patient interventions e.g., performing procedures (such as inserting a catheter or performing lumbar puncture), before providing treatment (such as administering medication, or blood and blood products) and before any diagnostic procedures (such as taking blood samples or radiological investigations). When possible, patients are required to be involved in the identification process (This is not applicable in Mental Health Hospitals).	
QM.17.1	Staff Interview	• 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. • Although the activity required for QM.17.1 is staff interview, identification policy/protocol needs to be reviewed to ensure consistency of practice.
QM.17.2	Observation	• 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 and its content is visible, readable and clear, observe staff administering medications without verification against medication records, observe newborn identification, observe to make sure NOT using room number as identifier in medication drawers)
QM.17.3	Staff Interview	• Interview staff and patients to assess implementation. • Most common areas to assess: outpatient pharmacy, phlebotomy area, patient pre-procedure. • This substandard is not applicable (NA) in mental health hospitals.

QM.18 The hospital has a process to prevent wrong patient, wrong site, and wrong surgery/procedure.		
Intent	Preventing medical errors is an essential component of patient safety and surgery is an area of health care in which preventable medical errors and near misses can occur. Clinicians must be aware of the surgery-associated injuries, deaths, and near misses and the process to prevent them. An important aspect in this regard is the process to prevent wrong-site surgery, which encompasses surgery performed on the wrong side or site of the body, a wrong surgical procedure performed, and surgery performed on the wrong patient. This process also includes any invasive procedure performed in settings other than the operating room. Hence, all health care facilities should develop and implement policy and procedure to include the three phases of this process (verification, site marking, and time out.) and to ensure its timely documentation in the patient medical record.	
QM.18.1	Staff Interview	• Interview staff to verify adherence to surgical safety protocol. • Although QM.18.1 activity is staff interview, policy on preventing wrong patient, wrong site, and wrong surgery needs to be reviewed to ensure practice consistency. Process should include invasive procedures (intraoperative and outside OR e.g., endoscopy, radiology…etc.). • QM.18 is NA in Mental Health Hospitals, unless they are conducting ECT procedure.
QM.18.2	Closed Medical Record Review	• 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	Closed Medical Record Review	Review medical records of patients went for invasive procedure to make sure that the pre-procedure verification is documented in the chart.
QM.18.4	Closed Medical Record Review	• Review medical records of patients went for intraoperative surgical procedures to make sure that the pre-procedure verification, site marking, and time out are documented in the chart. • In mental health hospitals, site marking for ECT is Not Applicable.

QM.18.5	Observation	• Hospitals need to have a clear documented evidence in medical records for conducting time-out (prior to skin incision). • Observation activity can be replaced by staff interview (e.g., in recovery room or surgical wards) if there are no cases of invasive procedures to observe during the visit to ensure staff awareness of time-out process.
	Staff Interview	Assess awareness of concerned staff regarding the time out process
QM.18.6	Open Medical Record Review	Review medical records of patients went for invasive procedure/surgical operation to make sure that the pre-procedure verification, site marking, and time out are documented in the chart.

AN.2 Anesthesia staff members have the appropriate qualifications.		
Intent	Anesthesia staff is qualified by documented training and experience, consistent with applicable laws and regulations. Anesthesia consultant administers and supervises anesthesia for major/specialized operations or high-risk patients, including; Pediatric operations, cardio-pulmonary operations, neurosurgery operations, and transplant operations.	
AN.2.1	Personnel File Review	Review random sample of anesthetist's personnel files for qualification and Privileges. Qualified anesthesiologist could be specialist, senior specialist or consultant.
AN.2.2	Closed Medical Record Review	• Review medical records to verify having a documented evidence that anesthesiologist is present in OR throughout the operation. • Discharge recovery sheet, intraoperative anesthesia operation sheet, coupled with adequate match between number of available anesthesiologist (using anesthesia Rota) can be used to verify the availability of anesthesiologist in OR throughout operation time.
AN.2.3	Closed Medical Record Review	Review medical record of patient who had major or high-risk surgery (Pediatric operations, cardio-pulmonary operations, neurosurgery operations, and transplant operations) to make sure that anesthesia consultant administers and supervises anesthesia.
AN.2.4	Personnel File Review	Review sample of anesthesia medical staff personal files to verify having an evidence of advanced life support training as appropriate to the patient's age (e.g., if anesthesiologist participating in pediatric operations, PALS certificate should be checked).

AN.15 Qualified staff perform moderate and deep sedation/analgesia.		
Intent	The physician or dentist responsible for the patient receiving moderate and deep sedation must be qualified and have competency-based privileges if they participate in conducting moderate and deep sedation They must be certified in advanced life support as appropriate to the patient age and successfully complete education/training on moderate and deep sedation.	
AN.15.1	Personnel File Review	• All physicians (non-anesthesiologist) who perform moderate/deep sedation must have evidence of training or specific privileges on moderate sedation in their personal files. ICU Intensivist and ER Physicians classified by SCFHS do not require such training. • If moderate/deep sedation given by anesthesia staff inside and outside operating room, this will satisfy the requirement of this sub-standard.
AN.15.2	Personnel File Review	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 evidence of advanced life support training (and PALS if they serve pediatric group) in their personal files.
AN.15.3	Personnel File Review	• 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 that conducted by a qualified anesthesiologist and kept in their personal files. • Anesthesia physicians and technicians do not require training on moderate/deep sedation as it is already part of their study.

IPC.4 There is a designated multidisciplinary committee that provides oversight of the infection prevention and control program.		
Intent	The activities of the Infection Prevention and Control unit should be supervised and overseen by a multidisciplinary body that is chaired by hospital director or the medical director. This would empower Infection Prevention and Control Committee decisions and recommendations Infection prevention and control activities should reach to every part of a health care hospital and involve individuals from multiple departments and services via multidisciplinary committee. Coordination involves communicating with all parts of the hospital to ensure that the program is continuous and proactive; physicians and nurses are represented and engaged in the activities with the infection prevention and control professionals. Others may be included as determined by the hospitals size and complexity of services (for example, clinical epidemiologist, central sterilization manager, microbiologist, pharmacist, housekeeping services, environmental or facilities services, operating theatre supervisor). Responsibilities include, for example, setting criteria to define healthcare associated infections, establishing data collection (surveillance) methods, designing strategies to address infection prevention and control risks, and reporting processes. Infection Control committee formation order and Term of References should reflect its membership and functions.	
IPC.4.1	Infection Prevention and Control Committee	Review Infection Prevention and Control Committee term of reference (TOR) and meeting minutes to verify that the committee is chaired by hospital director or medical director (i.e., committee's chairman name should be reflected in TOR and meeting minutes). If IPC Committee is reporting to the corporate IPC Committee, it is still necessary that the Chairman be the Medical Director or Hospital Director at the hospital level.
IPC.4.2	Infection Prevention and Control Committee	• Review Infection Prevention and Control Committee term of reference (TOR) and meeting minutes to verify multidisciplinary involvement. • Medical staff involvement should include a representative from critical care areas (adults and pediatrics) depending on the scope of service. • Issues discussed in IPC committee meetings are assigned to concerned representatives and should be traceable and timely closed.

IPC.4.3	Infection Prevention and Control Committee	Review Infection Prevention and Control Committee term of reference (TOR) and meeting minutes to verify that the committee is meeting on regular basis. Also, make sure they have been discussing critical issues related to infection control as applicable (e.g. outbreaks).
IPC.4.4	Infection Prevention and Control Committee	Review Infection Prevention and Control Committee term of reference (TOR) and meeting minutes to ensure incorporating IPC.4.4.1-IPC.4.4.6.

IPC.15 Facility design and available supplies support isolation practices.		
Intent	This is to ensure proper implementation of the appropriate type of isolation precautions. The hospital preparedness of isolation precaution includes: the availability of negative pressure airborne isolation room which meets the measurable elements requirements, the availability of required supplies particularly respirator (high filtration mask e.g. N95) in patient care areas, and the availability of isolation card indicating the type of isolation precautions. In certain hospitals (e.g., mental health, rehabilitation, eye hospitals), one negative pressure isolation room in ER and one in inpatient wards is acceptable regardless of hospital's bed capacity. In addition, they should have clearly written agreement with comprehensive transfer plan for referral of infectious cases. The following should be considered in engineering control record; 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. HEPA filter should be changed every 6 months unless the hospital has a cleaning system for the filter with documented evidence on the quality of differential pressure. Portable HEPA filter doesn't ensure enough air changes per hour. Acceptable air changes per hour is 12 or more. Acceptable temperature is 20-24 and humidity between 20-60	
IPC.15.1	Observation	• Hospitals are expected to have at least one negative pressure room in ER and one for every 25-30 beds in general hospitals (In certain hospitals (e.g., mental health, rehabilitation, eye hospitals), one negative pressure isolation room in ER and one in inpatient wards is acceptable regardless of hospital's bed capacity. In addition, they should have clearly written agreement with comprehensive transfer plan for referral of infectious cases. • Having adequate number of negative pressure isolation rooms for inpatient, with no isolation room in ER will partially meet IPC.15.1 requirement.
IPC.15.3	Staff Interview	Interview infection control staff and hospital staff to verify their awareness of negative pressure isolation rooms' engineering control records.
	Document Evidence	Review completeness of engineering control records for air changes per hour, HEPA filter, negativity, humidity, and temperature; (review standard's intent to understand engineering records requirements)
IPC.15.5	Observation	Observe the availability of hand washing facilities, toilets, and shower in negative pressure isolation rooms (note: shower and toilet in ICU isolation room are not mandatory).

IPC.15.6	Document Review	Review isolation precautions policy that should include the specification of isolation precaution cards.
	Observation	Observe the availability of transmission-based precaution card that should be consistent with diagnosis, posted in both Arabic and English, color coded, contain short statements, contain figures, and include transportation instructions.
IPC.15.7	Observation	Observe the availability and appropriate use of N95 by staff when dealing with patient with airborne diseases and 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.
	Staff Interview	Interview the staff to assess their knowledge about the use of appropriate PPEs for airborne cases and fit test
IPC.15.8	Document Review	Review hospital's policy on single use or re-use of N95 masks: - If policy stated single use of N95, document review (DR) and staff interview (SI) activities will be scored "Not Applicable". - If policy does not decide on single or reuse of N95, DR and SI activities will be scored "Not Met". - If policy stated reuse of N95, it should specify the reuse criteria; for the same patient, reuse duration, and way to store used masks… Then DR and SI activities will be scored accordingly. The policy should mention that "If any other precaution added in top of airborne isolation (e.g. MERsCov, chicken pox etc..), N95 mask re use is prohibited".
	Staff Interview	Assess staff knowledge about the policy of re-suing high filtration masks.

MM. 5 The hospital has a system for the safety of high-alert medications		
Intent	High-alert medications are drugs that bear a heightened risk of causing significant patient harm when used in error. Errors may not be more common with these than with other medications, but the consequences of errors may be devastating. Several worldwide organizations had identified a list of High Alert medications such as WHO and ISMP. Hospitals shall have a plan for the safe use of these medications and develop their own annually updated list of high alert medications with the related safety strategies to minimize errors and harm from these medications and other hazardous pharmaceutical chemicals as much as possible.	
MM.5.1	Document Review	Review the multidisciplinary plan/policy for managing high-alert medications and hazardous pharmaceutical chemicals. Policy should be signed by the process owners (Pharmacy Director, Nursing Director, Medical Director). It should include high-alert medications and hazardous pharmaceutical chemicals, and specify the process of identification, location, labeling, storage, dispensing and administration of these medications.
MM.5.2	Document Review	• Review the updated list (annually) of high-alert medications and hazardous pharmaceutical chemicals. • MM.5.2.1 to MM.5.2.9 are examples that need to be part of the list along with other intra-hospital frequently used high alert medications. ▪ The list needs to be approved by Pharmacy and Therapeutics Committee; otherwise it would partially meet the standard. ▪ List must be from within the hospital's formulary ▪ Covers to a minimum the list mentioned in the standard, as applicable ▪ List should include the specific drug names, not just categories.
MM.5.3	Observation	Observe for evidence of implementation of high alert plan (from MM.5.3.1 to MM.5.3.5). MM.5.3.2 does not mean having all high alert medications in a locked cabinet, but we need to ensure limiting access to these high alert medications.
	Staff Interview	Staff interview to verify awareness of strategies to prevent errors associated with using of high-alert medications and hazardous pharmaceutical chemicals. Independent double check should be carried out in both dispensing and administration. In addition, improving access to drug information on high alert medications include having access to dosing, storage, precautions, adverse reactions, etc.

MM.5.4	Staff Interview	Interview staff (nurses, physicians, and pharmacists) for evidence of implementation of standard concentrations of all high alert medications administered by intravenous infusion.
	Document Evidence	Review the hospital approved standard concentration for all high alert medications administered by intravenous infusion. (Note: this substandard 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.		
Intent	Medication errors related to look-alike and/or sound-alike medication names and/or packages are common in the healthcare setting throughout the medication use process Look-alike, Sound-alike medications account for an estimated 25- 30% of medication errors. With tens of thousands of medications currently on the market, the potential for serious error due to confusing medication names is significant. Contributing to this confusion are incomplete knowledge of drug names; newly available products; similar packaging or labeling; similar clinical use; illegible prescriptions or misunderstanding during issuing of verbal orders. Several organizations worldwide such as the WHO and the ISMP had identified, published and periodically updated several lists of look-alike and sound-alike medications. Hospitals shall initiate and then annually update their own list of LASA medication names. They should establish scientific based safety strategies to prevent or minimize errors with these confusing medications.	
MM.6.1	Document Review	Review the multidisciplinary plan/policy on handling LASA. Policy should be signed by process owners (Pharmacy Director, Nursing Director, Medical Director). It should include both look alike and sound alike medications (in separate tables or lists), and specify the process of identification, location, labeling, storage, dispensing and administration of LASA medications.
MM.6.2	Document Review	Review the updated list (annually) of confusing drug names including look alike and sound alike medications. Hospitals need to have annually updated list for LASA medications. The list must be: ▪ Approved by Pharmacy and Therapeutics Committee ▪ From within the hospital's formulary ▪ Updated Annually
MM.6.3	Observation	Observe for evidence of error prevention due to LASA medications (from MM.6.3.2 to MM.6.3.8)
	Staff Interview	Interview staff for evidence of implementation of error prevention strategies due to LASA medications (from MM.6.3.1 to MM.6.3.8)
	Document Evidence	Ensure having evidence (material and attendance record) that adequate number of relevant staff members were educated on 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.		
Intent	The fundamental purpose of medication error reporting system is to learn how to improve the medication use and prevent errors recurrence. Reporting of medication errors must become culturally accepted throughout health care. A major investment of resources will be required in the health care system to apply the lessons derived from the reporting of medication errors. Medication error reporting system should include near misses, hazardous conditions, and at-risk behaviors.	
MM.41.1	Document Review	Review the multidisciplinary policy on handling medication errors. Policy should be signed by process owners (Pharmacy Director, Nursing Director, Medical Director). It should highlight the following: ▪ Reference to the reporting form ▪ Notification of provider about the error ▪ Feedback to reporters ▪ Timeframe for reporting and notification of provider ▪ Documenting medical errors and who should document and where
MM.41.2	Document Review	Review the multidisciplinary policy on handling medication errors. Policy should include clear and acceptable definition of significant medication error, near misses, and hazardous situations.
MM.41.3	Staff Interview	Interview physicians (treating/attending/most responsible) on how they get to know/informed about a medication error and when.
MM.41.4	Staff Interview	Interview healthcare providers on when they report medication errors. Match the timeframe in the policy with staff awareness
MM.41.5	Document Evidence	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 Interview	Interview healthcare providers on the process and importance of medication error reporting. If a 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	Document Evidence	• Review medication errors, near misses, and hazardous situations reports • Active reporting means reporting different types of errors by different stakeholders (medical, nursing, pharmacist) and number of reported events should be relevant to the size and scope of service.
MM.41.8	Document Evidence	• Review root-cause analysis of all significant or potentially significant medication errors. • This substandard is linked with MM.41.7, if the hospital doesn't have an active reporting system.
MM.41.9	Open Medical Record Review	Review medical records for selected cases of reported medication errors (reached the patient). Inserting a copy of the report in the medical record is NOT ACCEPTABLE
MM.41.10	Pharmacy and Therapeutics Committee	Interview members of pharmacy and therapeutics committee and review the Committee's meeting minutes to ensure that hospital is analyzing the reported event to take corrective and preventive actions to improve the patient safety. A sub-committee reporting to P&T or any other equivalent committee is acceptable to be responsible for the analysis.
MM.41.11	Staff Interview	Interview healthcare provider who previously reported medication error to verify if and how they received a feedback regarding the analysis of the reported event and the action taken to prevent reoccurrence of the event or not. If the reporter is known, then he or she should get feedback based on the hospital's process in providing feedback. If the reporter is anonymous then the unit/section/department should get feedback.
MM.41.12	Document Evidence	Review documents supporting the fact that the hospital reports sentinel events related to serious medication errors to the relevant authorities.
	Pharmacy and Therapeutics Committee	Interview members of pharmacy and therapeutics committee on reporting sentinel events related to serious medication errors to the relevant authorities. (note: hospitals need to report all sentinel events to CBAHI if they are accredited). This activity CANNOT be NA

LB.51 The blood bank develops a process to prevent disease transmission by blood/platelet transfusion		
Intent	Hospitals need to have written process/policy to prevent disease transmission by blood/platelet transfusion. This process mandate that a sample of blood obtained from the donor during blood/ blood component collection is subjected to the following infectious diseases testing; HBsAg, Anti-HBc, Anti-HCV, Anti-HIV-1/2, Anti-HTLV-I/II, HIV-1 RNA, HCV RNA, HBV DNA, Serological test for syphilis, and other additional or supplemental tests as mandated by relevant health authorities. If hospital does not have donation service and used to receive blood from another facilities/ central blood banks, a written agreement should ensure conducting such tests by providing facility and this agreement should be signed by both parties, include agreement conditions, specify the role of involved party in looking back to monitor how they release blood and blood component, include infectious diseases testing conducted, dated with valid date, and includes the process of resolving disputes. Moreover, if a hospital has donation service but outsourcing the transfusion transmission disease testing (TTDT), written agreement is needed too. Bacterial contamination of blood components (mainly platelets) is a major cause of transfusion-related fatalities. To limit blood component contamination by bacteria from donor skin, two elements of the blood collection process are critical. Before venipuncture, the donor skin must be carefully disinfected using a method with demonstrated efficacy. Second, diversion of the first 10 to 40 mL of donor blood away from the collection container. Furthermore, the blood bank needs to use a method sensitive enough to detect significant bacterial contamination in platelet components. Insensitive methods including pH, glucose and microscopy are no longer acceptable. This standard is not applicable 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	Document Review	• Review the laboratory policies and procedures on Transfusion Transmitted Disease Testing (TTDT) of donor specimen to confirm its comprehensive cover of the requirement. • If a hospital does not have donation service, written agreement is needed (review standard's intent to understand agreement requirements)
	Observation	• Observe TTDT process to confirm compliance. • If a hospital does not have donation service, written agreement is needed (review standard's intent to understand agreement requirements)
	Staff Interview	• Interview personnel to assess their competence with TTDT procedures. • If a hospital does not have donation service, written agreement is needed (review standard's intent to understand agreement requirements)

LB.51.1	Document Evidence	• Review randomly-selected records to confirm the laboratory compliance with TTDT policy. • If a hospital does not have donation service, written agreement is needed (review standard's intent to understand agreement requirements)
LB.51.2	Document Review	Review the laboratory policies and procedures on limiting and detecting bacterial contamination in bacterial contamination.
LB.51.2	Observation	Observe practices to confirm implementation of strategies to limit bacterial contamination in platelet components. Make sure to observe a demonstration for proper site preparation and the use of diversion pouch.
LB.51.2	Staff Interview	Interview personnel to assess their competence with bacterial contamination prevention and detection procedures.
LB.51.2	Document Evidence	• Review randomly-selected records of platelets units to confirm the laboratory compliance with bacterial detection policy. • Review the validation documents of the employed bacterial detection method to confirm that the employed method is sensitivity in detecting significant bacterial contamination.

FMS.9 The hospital ensures that all its occupants are safe from radiation hazards.		
Intent	To ensure that hospital staff, patients and visitors are safe from un-necessary radiation hazards (ionizing/non-ionizing), the hospital should implement a radiation safety program, complying with national regulations and provide the necessary radiation protection equipment.	
FMS.9.1	Document Review	Review the radiation safety policy and procedure to ensure having the following; - Testing of lead aprons, thyroid and gonad shields - Monitoring personnel TLD badges (quarterly) - Annual testing/calibration of radiology equipment. - Procedure for pregnant radiology staff - Permissible Exposure limits for staff - Radiation emergencies (spills). In case the hospital has radio-active materials, then the policy should also include safe handling/storing of radio-active materials and radioactive waste disposal
FMS.9.2	Observation	Observe all radio-active materials are clearly labeled and safely and securely stored.
FMS.9.3	Document Review	Review the validity of the hospital's license from the National Authorities (i.e. K.A. CARE, KACST, ….) for dealing with radio-active materials.
FMS.9.4	Staff Interview	Interview staff handling radio-active materials and evaluate the implementation of the radiation safety policy. If the hospital has radio-active materials, there must be a certified Radiation Safety Officer (RSO).
	Personnel File Review	Review RSO's personal file to see certificate from the national authorities (i.e. K.A. CARE, KACST …).
FMS.9.5	Staff Interview	Interview relevant staff (e.g. medical physicist, RSO in charge) on how he/she regularly tests concerned areas for permissible radiation levels.
	Document Evidence	Review the validity of shielding certificate/radiation survey (leak test) of the X-ray (mammography, CT, fluoroscopy, conventional x-ray and dental panorama x-ray) room(s) and ensure it is carried out by a company certified by national authorities (i.e. K.A. CARE). In addition, shielding certificate/leak test is required with every renewal of license for these rooms or whenever there are constructions/renovations

FMS.9.6	Observation	Make sure that lead aprons and gonad and thyroid shields are available to cover patients and staff needs and are regularly tested according to a hospital-wide inventory. Also, make sure that identified defective aprons and shields are not returned to service.
	Document Evidence	Make sure that all lead aprons, gonad, and thyroid shields are tested annually according to a hospital-wide inventory; not only those available at the radiology department (e.g., OR, ER and Cath Lab)
FMS.9.7	Observation	Make sure that personal radiation dosimeters (TLD cards) are available to cover staff needs and staff are provided with replacement TLDs during the testing period. Also make sure that all staff working in radiation areas are wearing TLD cards during procedures.
	Document Evidence	Personal radiation dosimeters (TLD cards) are tested quarterly and the results are reviewed by a radiation physicist or radiation safety officer to ensure staff safety and cumulative results are interpreted.

FMS.21 The hospital has an effective fire alarm system.		
Intent	To ensure proper functionality of hospitals' fire detection and alarm systems, it is important to conduct routine inspections, testing, and maintenance as required. It includes the following: • Date • Test frequency • Name and address of property • Name and signature of the individual performing inspection, maintenance, tests, or combination thereof, and affiliation • Designation of the detector(s) tested • Functional test of detectors • Functional test of required sequence of operations • Check of all smoke detectors • Loop resistance for all fixed-temperature, line-type heat detectors • Other tests as required by equipment manufacturers and authorities. • Disposition of problems identified during test (e.g., owner notified, problem corrected/successfully retested, device abandoned in place) - Testing Frequency. Testing shall be performed in accordance with an approved schedule.	
FMS.21.1	Document Evidence	• Review the fire alarm inspection schedule and reports. (The inspection can be done by the hospital technical staff). The checklist and records should include; list of devices of zones to be inspected, inspection points and criteria for each zone, inspection date, technician's name and signature, and comments that are resolved. • This sub-standard is linked to FMS.21.3 and its score can't be higher than FMS.21.3.
	Observation	Observe fire alarm control panels and make sure that they work properly with no alarms or errors. Observe random smoke detectors, make sure they are operational, have number tags, and not obstructed. This sub-standard is linked to FMS.21.3 and its score can't be higher than FMS.21.3.
FMS.21.2	Document Evidence	• Review the fire alarm testing schedule and reports. (The weekly or monthly testing can be done the hospital own technical staff). The checklists and records should include; list of devices in zones to be tested, testing points and criteria for each device or zone, testing date, technician's name and signature, and comments that are resolved. • This sub-standard is linked to FMS.21.3 and its score can't be higher than FMS.21.3.

FMS.21.3	Document Evidence	• Review the fire alarm maintenance schedule and preventive maintenance work orders (Maintenance must be performed by company certified by civil defense). The preventive maintenance checklists and records should include; list of devices in zones to be maintained, maintenance points and criteria for each device or zone, and maintenance date, technician's name and signature, and comments that are resolved. • Review corrective action plans for identified findings.
FMS.21.4	Document Review	Check fire alarm system distribution drawings to ensure that elevators are connected to the fire alarm system or certificates from a certified contractor.
	Observation	Check availability of functional fire alarms in the elevator mechanical room. Inspect for physical connection between fire alarm and elevator control panel. Test one elevator to ensure it lands on the assigned floor level

FMS.22 The hospital has a fire suppression system available in the required area(s).		
Intent	In a wide range of applications where human lives, and assets need to be protected against the effects of fires, reliable fire extinguishing systems need to be properly installed and maintained. Hospitals need to endure that such systems (sprinklers, clean agent suppression, wet chemical, stand pipes and hose systems) are properly installed (depending on room functions). The system's functions are not interrupted by surrounding practices (improper storage, adjacent construction activities), and their functions are regularly inspected and maintained.	
FMS.22.1	Observation	Visit Fire Pump area, make sure that the jockey, electrical and diesel pumps are set to auto mode. Check the sprinkler system test valve/drain valve. Sprinkler heads should not be obstructed nor painted and distance between each in ordinary risk area should not be more than 5 meters. Check if the hospital has a fire water tank or a 2-level general tank. x-ray rooms can have sprinkler system with preauction valve.
	Document Evidence	• Review sprinkler system inspection schedule and inspection reports. All corrective actions are performed. • Review sprinkler system preventive maintenance schedule and reports. All corrective actions are performed. • This activity is linked to observation and cannot be scored higher. Monthly inspection and PPM for the sprinkler system can be done by the hospital maintenance department while the quarterly maintenance schedule and preventive maintenance work orders must be performed by company certified by civil defense. Preventive maintenance checklists and records should include; list of devices / components to be maintained, maintenance points and criteria for each device, maintenance date, technician's name and signature, and comments that are resolved.
FMS.22.2	Observation	• Make sure that hospital has clean agent suppression system installed at the medical records department, the servers' room (data center), electrical rooms, and generators' rooms • Check clean agent suppression system inspection tag to verify that inspection performed. Some clean agent systems (e.g. Novec, FM200, or Fire pro) can be installed in public areas. CO2 suppression system can be installed in none occupied areas such as generators or electrical rooms. Small electrical rooms (dry electrical room with no combustible material stored within) that has fire rated doors and walls and sealed opening with fire stop materials do not require clean agent systems, only CO2 fire extinguishers located by the room door.

FMS.22.2	Document Evidence	• Review clean agent system inspection schedule and inspection reports. All corrective actions are performed. • Review clean agent system preventive maintenance schedule and reports. All corrective actions are performed. • This activity is linked to observation and cannot be scored higher. Monthly inspection and PPM for the clean agent system can be done by the hospital maintenance department while the quarterly maintenance schedule and preventive maintenance work orders must be performed by company certified by civil defense. Preventive maintenance checklists and records should include; list of devices and components to be maintained, maintenance points and criteria for each device, maintenance date, technician's name and signature, and comments that are resolved.
FMS.22.3	Observation	• Inspect hospital wet chemical system in the kitchen during building tour to ensure that its function is not jeopardized by adjacent installations. • Check wet chemical system inspection tag to verify that inspection is not due.
	Document Evidence	• Monthly inspection and PPM for the wet chemical system can be done by the hospital maintenance department while the quarterly maintenance schedule and preventive maintenance work orders must be performed by company or personnel certified by civil defense. Preventive maintenance checklists and records should include; list of devices and components to be maintained, maintenance points and criteria for each device, maintenance date, technician's name and signature, and comments that are resolved. • Review corrective action plans for identified findings. • This activity is linked to observation and cannot be scored higher.
FMS.22.4	Observation	• Inspect hospital's stand pipes and hose system during building tour to ensure that its function is not jeopardized by adjacent installations. • Check the pressure in at least one hose reel to ensure that it's functioning automatically, and the pressure is adequate.
	Document Evidence	• Monthly inspection and PPM for the stand pipes and hose reel system can be done by the hospital technical staff, while the quarterly maintenance schedule and preventive maintenance work orders must be performed by company or personnel certified by civil defense. Preventive maintenance checklists and records should include; list of components to be maintained and tested, maintenance points and criteria for each component, maintenance date, technician's name and signature, and comments that are resolved. • Review corrective action plans for identified findings. • This activity is linked to observation activity and cannot be scored higher.

FMS.23 The hospital has a fire suppression system available in the required area(s).		
Intent	To ensure safe evacuation during emergencies, hospitals must maintain the integrity of its fire exits (including exit routes, exit doors, exit stares and landing to a safe public area) through the following: Fire exits are available, properly located, not locked, not obstructed, have panic hard ware, fire resistant, and clearly marked with illuminated exit sign.	
FMS.23.1	Observation	• Observe fire exits are available, properly located in the hospital. (It is not mandatory to have 2 exits for each room/area, it depends on the number of occupants, travel distance, area and type of materials stored). Please refer to Saudi Building Code (SBC) for specific cases. • This sub-standard will affect the score of sub-standards FMS.23.2, FMS.23.3, FMS.23.4, and FMS.23.6. If fire exits are not available, then these sub-standards will not meet the requirements.
FMS.23.2	Observation	• Test three to five fire exits and make sure that they are not locked by any means (chains, access control, keys, local lock…). If doors are locked by access control or keys, assess proper signage and that the hospital has taken proper action to reduce risks (key boxes, manual exit press buttons) to ensure smooth evacuation. • The score of this sub-standard can't be higher than FMS.23.1.
FMS.23.3	Observation	• Observe fire exits and make sure that there are no obstructions from both ends (furniture, project debris, cartoons...etc.) • The score of this sub-standard can't be higher than FMS.23.1.
FMS.23.4	Observation	• Check escape exits to ensure they have necessary panic hardware to allow opening in the direction of evacuation. • The score of this sub-standard can't be higher than FMS.23.1.
FMS.23.6	Observation	• Observe fire exits are clearly marked with illuminated exit signs. • The score of this sub-standard can't be higher than FMS.23.1.

FMS.24 The hospital and its occupants are safe from fire and smoke.		
Intent	To ensure that hospitals and its occupants are safe from fire hazards, number of measures need to be implemented. This includes: • Adopting a strict No-Smoking policy. • Ensure free access to fire extinguishers, fire alarm boxes, and emergency blankets. • Provision of necessary emergency evacuation lighting • Installing necessary Fire rated doors and having no fire wall penetration according to identified fire zones.	
FMS.24.1	Document Review	Review the "No Smoking" policy to ensure that it includes all types of smoking (e-cigarettes, pipe, water pipe incense...etc.), disciplinary actions against violators.
	Observation	Smoking is totally prohibited on premises of healthcare facilities. Observe any thrown cigarette butts on hospital's premises (e.g. hospital's roof, mechanical rooms, entrances...etc.)
FMS.24.2	Observation	Observe that there are no obstructions to fire extinguishers, fire alarm boxes, and fire blankets.
FMS.24.3	Observation	• Observe that emergency lighting is adequate for safe evacuation of the hospital. (Light batteries are mandated only in OR and generator room). • Perform functional test for emergency lighting to ensure that it is charging/working properly.
FMS.24.4	Observation	Observe storage areas are properly and safely organized (note: pay special attention to the central supplies store). In Central supply store; Test emergency doors, observe exit signage, inspect fire extinguishers, access control and safe storage protocol.
FMS.24.5	Observation	• Observe Fire rated doors are available according to the hospital zones with no separation between walls and ceiling to prevent smoke spread between rooms and areas. • Make sure to remove ceiling tiles on 3 different locations to ensure that the fire wall is intact. • In relations to hospital's identified zones, lack of fire rated doors or having fire wall penetrations between zones would not fulfill the requirement of this substandard.

FMS.32 The hospital ensures proper maintenance of the medical gas system.		
Intent	Medical gas systems are a standard feature of most healthcare facilities, and they require special monitoring and maintenance to ensure they are operating properly. Unlike other medical equipment and systems, their use of gas under pressure makes them vulnerable to a unique set of potential failures, which may not be clear. This makes medical gas preventative maintenance critical to a problem-free working environment. The medical gas source will vary depending on the type of gas and average consumption rate of gas. Compressors are also used to provide medical air, and vacuum pumps are needed for suction. Failing to properly monitor these complex pressurized systems can be costly, both in terms of increased use of consumables and damage to permanent equipment. Piped Medical Gas (PMG) system is mandatory for healthcare facilities with; high consumption rate, active operating theaters, emergency departments which use ventilators or handle trauma cases. PMG system is NOT mandatory for: hospitals that use only local anesthesia, mental health, rehabilitation and convalescent hospitals. Thus, FMS. 32.1, FMS. 32.2, FMS.32.3, FMS.32.5, FMS.32.6, FMS.32.10, FMS.32.11 would be not applicable (NA) in such hospitals.	
FMS.32.1	Document Evidence	Review preventive maintenance schedule and reports for piped medical gas system (manifolds, air compressor, liquid oxygen and suction system).
FMS.32.2	Document Review	Review medical gases policy and procedure to ensure covering the following: 1) Procedure of taking part of the system offline, 2) Procedure of modifying, altering, commissioning, testing any part of PMG, 3) Procedure of ordering/refilling liquid oxygen, 4) Documenting repairs/ alterations/ tests/ filling logs/ consumption.
FMS.32.3	Document Evidence	Review compressed medical air testing reports to include humidity and purity (particles, water =< 0.05mg/L / dewpoint of -46oC, CO =< 5ppm, CO2 =< 500ppm, SO2 =< 1ppm) measurements.
FMS.32.4	Observation	• Observe that medical gases manifold room and compressors rooms are safe and secure (locked, signage, clean, no oil, no exposed wiring…etc.). • In hospitals that use only local anesthesia, mental health, rehabilitation and convalescent hospitals this substandard is applicable to ensure storing medical gas cylinders in safe and secure place.
FMS.32.5	Observation	Observe that all PMG outlets are functioning and unified in label and connection type for each gas.

FMS.32.6	Observation	Medical gas pipes are clearly identified for type and direction as per SBC (Saudi Building Code).
FMS.32.8	Observation	• Compare average consumption rate with the number of standby cylinders to ensure sufficiency for 48 hours. (to change LOX to gas: 1 liquid O2 liter = ~ 855 liters of gas @ 20 Celsius & 1 K size gas cylinder = ~ 6800 liters @ 2000 psi) • Make sure there are no active alarms for low pressure during your visit the medical gas manifold.
	Staff Interview	Utility manager(s)/engineer(s) are aware of the average daily consumption rate of oxygen and medical air.
FMS.32.9	Observation	Observe that the gas cylinders are regularly tested for gas type, amount and any leaks.
FMS.32.10	Observation	Observe availability of labels indicating room numbers served by the gas valve box at wards.
	Staff Interview	Interview clinical staff to ensure their awareness of PMG shutoff valves location and affected rooms. In addition to their ability to demonstrate how to shut-off valves safely.
FMS.32.11	Staff Interview	Interview staff responsible for valve shut off and make sure that he/she is aware of the risk associated with valve shut off, breaking valve box cover, and what rooms are affected by closing the valve.
FMS.32.12	Observation	Observe that the PMG outlets are adequate in-patient care areas and are to be error proof.