STANDARDS/ BEST PRACTICES GUIDELINES 2017

FOR

CARDIAC CATHETERIZATION LABORATORY (CCL)

Islamabad Healthcare Regulatory Authority (IHRA) is an autonomous health regulatory body enacted under the Islamabad Health Regulation Act, 2018. IHRA aims to improve the quality, efficiency and safety of healthcare services delivery by adopting evidence-based regulatory standards for registration and licensing of healthcare establishments, health professionals & equipment, and developing and enforcing minimum standards of safety for patients, healthcare professionals and other staff in healthcare establishments in the Islamabad Capital Territory.

IHRA is responsible for maintaining a register of all healthcare establishments, setting standards for registration and licensing of healthcare establishments, registering all healthcare establishments, health professionals and equipment, and issuing licenses for defining the scope and extent of healthcare services to be provided by healthcare establishments. IHRA is also responsible for regulating healthcare establishments in accordance with minimum service delivery standards and notified practices, prepare and issue notified practices as a guiding document for service provision in healthcare establishments, and inquire and investigate into violation of any of the provisions of the Law by any healthcare facility. Healthcare establishments under IHR Act 2018 are required to get registered with IHRA and implement minimum services delivery standards to acquire license to render health services in the Islamabad Capital Territory.

The following is a list of all functional areas from the *Islamabad Healthcare Regulatory Authority (IHRA)* for CCL Standards/ Best Practices Guidelines 2017 Standards

STANDARDS AND INDICATORS

The IHRA Standard for CCL comprises of, 10 Standards and 33 Indicators, out of which 31 indicators require 100% compliance (ascribed red), while 02 (ascribed yellow) are acceptable even with partial compliance at least to the extent of 80%.

Standard 1: Standard 1. Portrayed Invasive Cardiology services, are provided as per the statutes/ prescribed standards

Indicator 1: Invasive Cardiology / Cardiac Catheterization Laboratory staff is aware of the relevant laws, prescribed rules, regulations and service specific standards.

Assessment Process:

The essence of this indicator is that the Invasive Cardiology/Cardiac Catheterization Laboratory Services, provided by the HCE, should comply with all legal, regulatory and safety requirements. Surveyors should look for availability of the evidence in terms of documents as well as infrastructure that reflects compliance of the regulatory requirements. Key staff should have copies or at least access to the statutes, standards & SOPs and should be aware of the pertinent regulatory requirements

Compliance Requirements:

i. Key staff should have copies / access to the statutes, standards and SOPs.
ii. Key staff is aware of the regulatory requirements.

Rating:

- If the above requirements are complied. Then, rate as **met.**
- If any of the above requirements are not complied. Then, rate as **not met.**

Indicator 2: Level of the Cardiac Catheterization Laboratory is displayed and the CCL is registered with the PSIC.

Assessment Process:

This indicator requires that the particular Cardiac Catheterization Laboratory should be ascribed a Level as provided in the CCL Standards prescribed by the PSIC/NICB as Level-I, Level-II or Level-III according to its infrastructure/HR availability and the range of procedures performed.

Compliance Requirements:

i. Level of the particular Cath Lab, as classified in the CCL Guidelines (Level-I, Level-II or Level-III) is displayed in a way that it is clearly understandable for the patients/clients.
ii. Key staff is aware of the basis of classification of the Cath Labs in to various levels.
iii. Document/s defining the procedures performed and excluded in the CCL is available.
iv. Documentary evidence in respect of registration of the CCL with PSIC.

Rating:

- If the above requirements are complied. Then, rate as **met.**
- If any of the above requirements are not complied. Then, rate as **not met.**

Indicator 3: Registration standards / regulations for the Cardiac stents, LSMDs and disposable used for provision of interventional cardiology services and implanting Cardiac stents as notified by the regulatory authority /competent forum from time to time are followed

Assessment Process:

The SCP decision on HRC Case No. 623-P/2017 in the matter of imbedding substandard cardiac stents are relevant in this regard. DRAP, a federal authority for registration as well as pricing of all drugs and medical devices including stents, vide its notification No. F. NO. l-l/2017-DD/LA dated 22/3/2017 issued an advisory for taking measures to check the quality of cardiac stents. The indicator also mandates that only the Cardiac stents registered with the national registry of DRAP/NMDR are used by the Cath Lab. The purpose of this indicator is to ensure that patients requiring cardiac intervention and cardiac catheterization can avail the services of good quality.

Compliance Requirements:

i. The staff/ Cath Lab operators are aware of the registration / regulations notified by the DRAP in respect of cardiac stents as well as LSMDs and the negative List regarding the stents and LSMDs.
ii. Only the Cardiac stents, LSMDs and other disposables registered with the national registry of DRAP/NMDR are used by the Cath lab.
iii. No cardiac stent, other devices or disposables placed in the 'Negative List' by the NICB and published by DRAP for enforcement are imported or used by the CCL.

Rating:

- If the above requirements are complied. Then, rate as **met.**
- If any of the above requirements are not complied. Then, rate as **not met.**

Indicator 4: Pricing policy for provision of interventional cardiology services, implanting Cardiac stents and other LSMDs, as notified / fixed by the regulatory authority or the CCL/HCE from time to time, is followed

Assessment Process:

The DRAP, a federal authority established under the DRAP Act 2012, is mandated, for registration as well as fixing pricing of all drugs and medical devices including stents. Further, pursuant to the orders of the Supreme Court of Pakistan, the DRAP issued an advisory for taking measures to check the quality as well as prices of cardiac stents. This indicator requires that pricing of the stents and medical devices if fixed by the regulatory authority are followed and also made known to the patients and families. In the case of devices and services for which the DRAP has not notified prices, the HCE/ CCL need to notify cost of the procedures/ interventions and make available for information of the patients.

Compliance Requirements:

i. The staff/ Cath Lab operators are aware of the prices fixed by the DRAP or notified by the CCL/HCE in respect of provision of interventional cardiology including implanting cardiac stents as well as LSMDs and other interventional procedures.
ii. Pricing policy based on the regulatory directions is adopted by the service providers/ CCLs/HCEs and made known to the patients/ families.
iii. The cost of the entire process of interventional cardiology treatment is divided into following four components and prominently displayed for information of the patients;

a) Cost of stents, LSMDs and other necessary devices and disposables.
b) Professional Fee of the operator/ Interventionist.
c) Charges of Cath Lab.
d) Room/ Ward & others costs charged by Hospital.

(Pricing as above, to be applicable for Level I & Level II Cath Labs, Level III Labs to only specify Rates for diagnostic procedures & services offered at the Lab / facility)

Rating:

- If the above requirements are complied. Then, rate as **met.**
- If any of the above requirements are not complied. Then, rate as **not met.**

Indicator 5: Cardiac Catheterization Laboratory has all the facilities available according to its portrayed scope of Services

Assessment Process:

Interventional cardiology/CCL involves extremely sensitive procedures which are lifesaving and also potentially life threatening. Therefore, it is mandatory that all the relevant facilities/ services should be provided depending on the level of the Cath Lab. The on-site availability of any of the required services has an edge to that of the services available on-call only. All level I Cath labs need to have on-site facilities for Cardiovascular Surgery, Anesthesia, ICU and Blood Bank. The Level II Cath Labs are required to have a documented arrangement in the form of an MOU signed with such HCE/s having arrangements for timely availability of Cardiac

Surgery, Anesthesia and Blood bank etc. in case of emergency. All the documents including MOU/ agreements between the CCL facility and the consultants needs to be thoroughly reviewed.

Compliance Requirements:

Level I Cath labs need to have the following facilities on site while the Level II CCLs are required to have a documented arrangement in the form of an MOU signed with such HCE having arrangements for timely availability of Cardiovascular Surgery and Anesthesia services.

i. Cardiovascular Surgery
ii. Cardiovascular Anesthetists
iii. Intensive Care Unit
iv. Coronary Care Unit
v. Echocardiography (TTE &TOE) and Doppler
vi. In case of Pediatric Catheterization Laboratory, similar services for pediatric age patients are available.

Level II Cath Labs should ensure the provision of the following facilities:

i. A working relationship between the interventional cardiologists and cardiac surgery service at the receiving hospital documented by a letter of support from the surgical group to accept cases.
ii. A mechanism whereby a cardiac surgeon has the ability to review coronary angiograms before elective procedures and provide comments to the cardiologist and, if necessary, patients.
iii. Surgical backup available at all hours for urgent cases and for elective cases at mutually agreeable times.
iv. Confirmed availability of cardiac sur and a next available Operating Room before elective procedures begin per written agreement.
v. Mechanism for direct discussion between the Cardiologist and cardiac surgeon should urgent transfer be necessary.
vi. A written transfer agreement endorsed by both facilities and documentation of a rehearsed plan for the transport of patients to a facility with cardiac surgery and the ability to have patients on cardiopulmonary bypass within 90 minutes of the onset of the emergency.
vii. A transport provider able to begin transfer within 20 minutes.

Note:

Level II Lab: On site availability of Cardiac Surgery &Cardiovascular Anesthesia not applicable; however, these services are to be accessible within prescribed limits as per CCL Guidelines, 2017
Level III Lab: parameters for availability of CCU, Hematology service, Echocardiography, Doppler, Mechanical support devices and formal patient transfer agreement applicable only

Rating:

- If the above requirements are complied. Then, rate as **met.**
- If any of the above requirements are not complied. Then, rate as **not met.**

Indicator 6: Cardiac Catheterization Laboratory has all the services available according to its portrayed scope of work.

Assessment Process:

The cardiac patients undergoing Cardiac Catheterization Intervention frequently need consultation for opinion of this nephrologists, hematological and Neuro Physicians. They might also need to undergo CT scanning or MRI for diagnostic purposes. The on-site availability of any of the following services has an edge to that of the services available on-call only. The indicator requires thorough review of all the documents including MOU/ agreements between the CCL facility and the consultants or the HCEs providing such services.

Compliance Requirements:

For LEVEL-I CCLs:

i. Nephrology consultative services and dialysis.
On-site
On-call

ii. Neurology Consultative Services
On-site
On-call

iii. Hematologic Consultative Services & Blood Bank
On-site
On-call

iv. MRI and CT (optional)
On-site

*(If all the above services are available on-site, then score as fully met
If all or any one of the above consultative services are available on call only, then score as partially met
If any of the above requirements are neither available on site nor on call, then score as not met)

For LEVEL-II CCLs:

i. Hematologic Consultative Services & Blood Bank Services
On-site
On-call

Rating:

- If all the above services are available on-site. Then, rate as **met.**
- If all the above consultative services are available on call only. Then, rate as **partially met.**
- If any of the above requirements are neither available on-site nor on call. Then, rate as **not met.**

Indicator 7: Specialized care services are available on 24/7 basis or on call to handle emergencies.

Assessment Process:

This indicator aims to ensure, 24/7 availability of specialized care services in the HCE/ CCL on-call.

Compliance Requirements:

i. There is an established mechanism (duty roster) for provision of specialized care services on 24/7 basis as well as on call.
ii. Evidence that such services were made available in case of emergency.

Rating:

- If the above requirements are complied. Then, rate as **met.**

- If any of the above requirements are not complied. Then, rate as **not met.**

Indicator 8: There is an established process for the introduction of new procedures into the lab setting.

Assessment Process:

This indicator aims at reviewing the policy of introduction of new procedures in the Cath Lab. The SOPs/protocols followed to inform the staff about the new procedures and availability of the equipment required, should be assessed.

Compliance Requirements:

i. Document defining the process for the introduction of new procedures into the Cath laboratory setting.
ii. SOPs/protocols to inform the staff about the new procedures are implemented.

Rating:

- If the above requirements are complied. Then, rate as **met.**
- If any of the above requirements are not complied. Then, rate as **not met.**

Standard 2: Cardiac Catheterization Laboratory has a program for management of support services equipment

Indicator 9: Cardiac Catheterization Laboratory has all the general equipment according to its portrayed scope of service/level.

Assessment Process:

Interventional Cardiology/CCL involves extremely sensitive procedures while using advanced technology which may prove to be life threatening. Therefore, having all the required equipment and supplies which are of approved standard and well maintained, is of utmost importance. It is mandatory for all CCLs to have the required equipment/consumables and disposables which is essential for their level/scope of service in addition to other essential general equipment for all support functions.

Compliance Requirements:

In order to comply with this indicator:

i. Digital fluoroscopy
ii. Angiography with multiple image intensifier /flat panel sizes (preferably)
iii. On-line image storage and retrieval capabilities(preferably)
iv. Physiologic monitoring with pressure, pulse oximetry & ECG channels
v. Appropriate inventory/stock of disposable supplies for:
a. Vascular access management
b. Diagnostic coronary angiography
c. Ventriculography
vi. Varied inventory/ stock of:
a. Coronary guiding catheters
b. Coronary guide wires

c. Angioplasty balloons
d. Coronary stents
e. Other treatment devices commensurate with the scope of services provided by the Cath lab.
vii. Expiry date in respect of cardiac stents as well as LSMDs and disposables is monitored and followed.

Rating:

- If the above requirements are complied. Then, rate as **met.**
- If any of the above requirements are not complied. Then, rate as **not met.**

Indicator 10: All the emergency management equipment to cater for the claimed scope of service/ level is installed.

Assessment Process:

This indicator requires ensuring availability of emergency management equipment apart from the presence of general equipment. Inventory should be checked for availability and reporting of nonfunctional equipment and corrective action for the repair of the same.

Compliance Requirements:

i. Presence of following emergency management equipment:
a. Resuscitation Equipment
b. A biphasic Defibrillator and back up
c. Vasoactive and Antiarrhythmic Drugs
d. Endotracheal intubation
e. Temporary trans-venous pacemaker
f. Pericardiocentesis equipment
ii. Mechanical support Devices*:
a. Intra-aortic Balloon pump
b. Impella Catheters
iii. Expiry date in respect of drugs and disposables is monitored and followed.
iv. Personnel trained on their indications and use of the emergency management equipment

Rating:

- If all the above requirements including the IAoBP and Impellla Catheters, both, are available. Then, rate as **met.**
- If all the above requirement and either IAoBP or Impellla Catheters are available. Then, rate as **partially met.**
- If any of the above requirements, and neither IAoBP nor Impellla Catheters, are available. Then, rate as **not met.**

Indicator 11: Cardiac Catheterization Laboratory has the radiographic equipment according to its claimed scope of service/level.

Assessment Process:

This indicator pertains to assessing the availability, functioning and quality of results of radiographic equipment required and used at the CCL.

Compliance Requirements:

i. The radiographic equipment is capable to ensure/ provide for the following:

a. Image quality
b. Dynamic range
c. Modulation transfer function(preferably)
d. Fluoroscopic spatial resolution
e. Fluoroscopic field of view size accuracy
f. Low contrast resolution
g. Record fluoroscopic mode
h. Automatic exposure control under standard conditions and at maximum output

ii. Calibration of integrated radiation Dosimeter.

iii. Qualified and trained staff to operate the radiographic equipment

Rating:

- If the above requirements are complied. Then, rate as **met.**
- If any of the above requirements are not complied. Then, rate as **not met.**

Indicator 12: The Preventive maintenance and calibration Program for all equipment is documented and implemented

Assessment Process:

This indicator aims at validating that the equipment used at CCL, meet the recommended manufacturers' standards and they are performing at the required level to provide safe and effective care. Periodic preventive maintenance and calibration extends equipment life and allows its use to be at peak efficiency to deliver accurate results.

Compliance Requirements:

i. A process documenting routine preventive maintenance and testing calibration of Cath Laboratory equipment based on vendor recommendations/ OEM guidelines is established and implemented.

ii. The operational efficiency of infrequently used equipment is ensured through regular assessment of their functions with logs kept that also include personnel training updates.

iii. Functional UPS/Generator

Rating:

- If the above requirements are complied. Then, rate as **met.**
- If any of the above requirements are not complied. Then, rate as **not met.**

Indicator 13: The CCL has a valid license issued by the PNRA

Assessment Process:

The angiography equipment used at the CCLs emit radiations and as such all the CCLs are required to have a valid license from Pakistan Nuclear Regulatory Authority (PNRA) ensuring radiation safety for the patients and the staff. Surveyors are required to check the validity of the

license, compliance with the licensing requirements and any observations by the PNRA. The surveyors also need to assess and observe that the CCL staff radiation uses radiation safety measure e.g. lead aprons etc.

Compliance Requirements:

i. The CCL is licensed by PNRA and the license is valid.
ii. The comprehensive radiation safety programme is documented and implemented.
iii. The CCL staff uses radiation protection equipment e.g. Lead aprons, neck shields and dosimeter etc

Rating:

- If the above requirements are complied. Then, rate as **met.**
- If any of the above requirements are not complied. Then, rate as **not met.**

Standard 3: A Credentialing Committee is established with defined and notified TORs

Indicator 14: CCL credentialing committee reviews the individual physician`s credentials to authorize/ grant privileges to CCL operators to carry out defined procedures

Assessment Process:

This indicator is to ensure that appointment of all the staff/operators of the CCL is in accordance with the eligibility criteria defined for the assigned job. The Credentialing Committee must include the senior management, senior interventional cardiologist/s and Director/Head of HR in addition to any other member/s as specified in the CCL Guidelines 2017.

Compliance Requirements:

i. Established/notified Credentialing Committee with defined role/ TORs
ii. The Credentialing Committee includes the senior managers, senior Interventional Cardiologists/ Director/ head of HR, as members
iii. The credentialing committee reviews the credentials of the Cath Lab Operators to authorize / grant privileges as per the defined eligibility criteria

Rating:

- If the above requirements are complied. Then, rate as **met.**
- If any of the above requirements are not complied. Then, rate as **not met.**

Indicator 15: Eligibility criteria for Cath Lab Director is defined and followed as per the CCL Guidelines

Assessment Process:

This indicator requires the Cardiac Catheterization Laboratory to define the eligibility criteria for the Cath-Lab Director in accordance with the guidelines provided in the CCL Standards and appointment of the CCL Director is made in accordance with the defined criteria i.e. a senior Interventional Cardiologists with five or more years' experience. The Organogram and the staff appointed in the Cath lab is in accordance with the Guidelines/ Standards

Compliance Requirements:

i. Eligibility criteria of the Cath Lab Director is defined

ii. Appointment of the CCL Director is as per eligibility criteria i.e. Interventional Cardiologist with five or more years of experience

Rating:

- If the above requirements are complied. Then, rate as **met.**
- If any of the above requirements are not complied. Then, rate as **not met.**

Indicator 16: The eligibility criteria of all Cath Lab Operators based on Practice and Training pathways, as defined in the CCL Standards and Best Practices Guidelines is followed

Assessment Process:

The essence of this indicator is that every CCL operator is allowed to perform procedures in accordance with the defined eligibility criteria. All operators should have prescribed qualification registered with relevant regulatory authority e.g. PMC, the registration should be valid and have certificate/s issued by the PSIC certifying that the operator is eligible to perform as interventional cardiologist. The prescribed qualification includes:

i. FCPS in Interventional Cardiology
ii. Diplomate American board of Interventional Cardiology
iii. MRCP with specialized cardiology training
iv. FCPS Cardiology with specialized training in Interventional cardiology
v. Performed at least 75 procedures/ year as primary operator

Compliance Requirements:

i. Eligibility Criteria for the CCL operators is defined as per CCL Standards
ii. Evidence that the eligibility criteria is followed

Rating:

- If the above requirements are complied. Then, rate as **met.**
- If any of the above requirements are not complied. Then, rate as **not met.**

Indicator 17: The Physician Extenders and Cardiology Fellows are allowed to work as primary operators for training purpose only.

Assessment Process:

The Cardiology fellows are enrolled in the recognized Institutions for training purpose. The SOPs for working and training of such professionals should be defined specifying that the Physician Extenders and Cardiology Fellows are authorized as primary operators for training purpose only. There should be evidence that the practice/ SOPs is followed. Further the Non-Physician extenders need to be appropriately trained and credentialed by the CCL. The documented policy of the Cath Lab should define the supervisory role of the Primary Operating Physician / CCL Operator.

Compliance Requirements:

i. SOPs defining that Interventional Fellows/ Residents are recognized as primary operators for training purpose only.
ii. Evidence that the physician extenders and non-physician extenders are proficient.
iii. The Physician Extenders are appropriately trained and credentialed

iv. Presence of documented policy regarding the supervisory role of the Primary Operating Physician / CCL Operator

Rating:

- If the above requirements are complied. Then, rate as **met.**
- If any of the above requirements are not complied. Then, rate as **not met.**

Indicator 18: The nursing personnel in the CCL is qualified and have specific experience and well-defined role/ JDs

Assessment Process:

This indicator entails assessment of Nursing personnel deputed in the CCL in terms of their qualification, training and experience. The nursing staff working in the CCL should be supervised by a senior registered Nurse having relevant experience of working in a Cath Lab and her supervisory role should be defined. The nurses deputed in the Cath Lab should be trained and skilled as per guidelines (preferably include one-year critical care practice, complete knowledge of cardiovascular medications). The nurses working in Cath Labs should have prior working experience of working at such setting and the nursing staff should be supported by nursing assistants.

Compliance Requirements:

i. A registered Nurse with relevant experience functions as Nursing Supervisor for the CCL.
ii. The role of nursing supervisor is defined.
iii. The nurses deputed in the CCL are qualified, trained and skilled.
iv. Nursing assistants are appointed in the CCL as required.

Rating:

- If the above requirements are complied. Then, rate as **met.**
- If any of the above requirements are not complied. Then, rate as **not met.**

Indicator 19: The technologists at the CCL have specific experience and well-defined role/ JD

Assessment Process:

The technologists/ Radiological Technician need to have prescribed qualification and training as well as skilled to work in CCL settings. The surveyors should assess that the technologists are dully qualified and trained as radiological technologists and have experience of working in the Cath Lab.

Compliance Requirements:

i. Presence of technologist/certified Radiological Technologists in the CCL as per requirement.
ii. The technologist are qualified, trained and skilled as per guidelines

Rating:

- If the above requirements are complied. Then, rate as **met.**
- If any of the above requirements are not complied. Then, rate as **not met.**

Standard 4: Pre-procedure good practices are defined and followed

Indicator 20: Informed consent (IC) for performing cardiac procedure is obtained as per guidelines

Assessment Process:

By reviewing the sample records, determine if the medical record of ALL the patients who underwent Interventional procedures have a documented informed consent. The hospital must have a written policy on Informed Consent that describes the process used to obtain consent, including documentation and surrogate decision-maker issues. Each facility must have an approved consent form present in the medical record that includes risks, benefits, and alternatives to the procedure in a form and language that the patient or a layperson can understand. This should include the potential for Adhoc PCI and its risks/benefits, and alternatives when appropriate. The IC should be in the patient's native language and for the consent to be valid, the patient must be competent to voluntarily provide consent.

This documentation can either be a signed consent form or written note by the responsible physician that contextually accommodates ALL patient levels of understanding. The written informed consent may be obtained by trained secondary operators or non-physician providers. Confirmation of consent should be obtained during 'preparation' or 'time out'. Procedures that the patient has not consented to must not be performed unless it is a life-threatening emergency and the reasons for this must be documented by the physician.

Compliance Requirements:

Level- I Cath Labs:

i. Documented policy on taking informed consent.
ii. Each patient's medical record has a documented Informed, valid consent as per guidelines

Level-II Cath Labs:

A PCI consent form that explains that the procedure is being performed without onsite surgery and what will be the way if surgery is necessary

Rating:

- If the above requirements are complied. Then, rate as **met.**
- If any of the above requirements are not complied. Then, rate as **not met.**

Indicator 21: Pre-procedure assessment protocols are complied, and there is documented evidence

Assessment Process:

Pre-procedural assessment requires consideration of ethical issues, any allergies that patient may have, evaluation of lab values and outside reports and the medications etc. The respect for autonomy mandates that patients be given appropriate and un-coerced choices about their health and potential medical care and requires that physicians provide accurate and unbiased information about the patient's medical condition, and disclose all potential avenues of care. The

physician is responsible for documentation of the indication for the procedure and to document review of appropriate data (e.g., noninvasive tests). In addition, the physician must be transparent regarding any and all potential ethical or financial conflicts concerning therapies or devices employed in the patient's care. Many challenges involved in the Cardiac Interventions inter alia, include maintaining high ethical standards, maintenance of proficiency, avoidance of real or perceived financial conflict of interest, disclosure of potential conflicts, and, most importantly, maintaining the patient's best interest at the top.

Compliance Requirements:

i. Documented pre-procedure assessment protocols
ii. The pre-procedure assessment protocols cover:
    a. Review of Ethical concerns
    b. Prior knowledge of allergies
    c. Management of medication
    d. Documentation of allergic reactions
    e. Protocol for preventing Contrast reaction
    f. Review of Lab Values/ Reports
iii. The evidence that pre-procedure assessment protocols are followed

Rating:

- If the above requirements are complied. Then, rate as **met.**
- If any of the above requirements are not complied. Then, rate as **not met.**

Standard 5: Prescribed Intra Procedure Protocols are defined and complied

Indicator 22: Documented intra-procedure protocols are available and practiced by the operators

Assessment Process:

The primary requirement of this indicator is that written Intra-procedural protocols are available in the procedure room for instant reference and to be followed by the operators. These protocols are printed boldly and displayed in such a way that these remain visible and operators can read from their place of procedure. Assessors need to see the documented intra- procedural protocols and the evidence that they are followed

Compliance Requirements:

i. Intra-procedure protocols are followed and documented
    a. Verification of expiry dates of device being inserted
    b. Writing/Pasting of the label (batch no./ manufacture details) of the device used
ii. Intra-procedure monitoring must include:
    a. Noninvasive hemodynamic and oximetric monitoring of patients' vitals.
    b. Defibrillation pads should be attached to all STEMI patients
iii. The technologists are trained and skilled to follow intra procedure protocols as per guidelines.

Rating:

- If the above requirements are complied. Then, rate as **met.**
- If any of the above requirements are not complied. Then, rate as **not met.**

Standard 6: Prescribed Post Procedure Protocols are complied

Indicator 23: Patient is communicated his post procedural clinical status by the Physician

Assessment Process:

The indicator requires that the physician should communicate to inform the patient about his clinical condition actually observed during the procedure, procedure actually undertaken and difficulties encountered and/or complication encountered if any and the post-procedural management plan. Discussions with patients should be delayed until cognitive impairment due to sedation has resolved.

Compliance Requirements:

i. Documented post procedural protocols/SOPs and defined mechanism of Physician to Patient communication as per guidelines.
ii. Evidence that the SOPs are complied

Rating:

- If the above requirements are complied. Then, rate as **met.**
- If any of the above requirements are not complied. Then, rate as **not met.**

Indicator 24: Access site is managed as per protocols

Assessment Process:

The requirement is to ensure that the selected access site is properly managed that includes its closure according to the most current and acceptable practices. The surveyors should ensure that following compliance requirements are met.

Compliance Requirements:

i. Choice of Access site is as per Guidelines.
ii. Access site closure/ management is as per guidelines
iii. Procedures Notes including details regarding access site management and closure devices used are recorded

Rating:

- If the above requirements are complied. Then, rate as **met.**
- If any of the above requirements are not complied. Then, rate as **not met.**

Standard 7: Patient outcomes are documented in the interest of patients

Indicator 25: Results of interventional procedures are reported as per protocols and regulatory requirements.

Assessment Process:

There must be enough information documented in the medical record of the patients regarding the procedure, immediately after the procedure is completed. The plan to manage the patient throughout the post-procedure period should also be documented in the medical record. This information could be entered as the preliminary procedure report or as a hand-written operative note immediately after procedure to provide pertinent information for those attending, the patient for post procedure management. It further implies documenting the progress note after completion of the procedure and before the patient is shifted to the next level of care.

Compliance Requirements:

i. Preliminary procedure reports /notes must be written or dictated immediately after the procedure and added in the medical record of the patient.
ii. Procedural notes are documented in the record as per guidelines.
iii. A CD consisting of a video recording of all the procedures is added in the medical record of the patient.
iv. Progress notes are entered in the record as per guidelines before transfer of the patient to the next level of care

Rating:

- If the above requirements are complied. Then, rate as **met.**
- If any of the above requirements are not complied. Then, rate as **not met.**

Indicator 26: Complications and adverse in-hospital outcomes are reviewed for diagnostic interventional procedures

Assessment Process:

Adverse in-hospital patient outcomes (complications) must be reviewed for diagnostic procedures. Participation in the NCDR or CROP-Cath PCI Registry i.e. National database or an International database fulfills the data collection requirements for interventional procedure outcomes/complications.

Compliance Requirements:

i. Documented SOPs to review the adverse in-hospital outcomes/complications.
ii. Evidence that the adverse in-hospital outcomes/ complications are identified and documented in the medical records and are reviewed for diagnostic interventional procedures.
iii. Evidence of participation in NCDR or CROP-Cath PCI Registry.
iv. In case of non-participation in NCDR or CROP Cath PCI Registry, assessment of complications is in accordance with the guidelines as under:
    a. Assessed complications are based on the list provided in the guidelines
    b. System for follow-up of renal functions in high risk patients is established.

Rating:

- If the above requirements are complied. Then, rate as **met.**
- If any of the above requirements are not complied. Then, rate as **not met.**

Standard 8: Radiation exposure safety program is deployed at the CCL

Indicator 27: Results of interventional procedures are reported as per protocols and regulatory requirements.

Assessment Process:

There must be enough information documented in the medical record of the patients regarding the procedure, immediately after the procedure is completed. The plan to manage the patient throughout the post-procedure period should also be documented in the medical record. This information could be entered as the preliminary procedure report or as a hand-written operative note immediately after procedure to provide pertinent information for those attending, the patient for post procedure management. It further implies documenting the progress note after completion of the procedure and before the patient is shifted to the next level of care.

Compliance Requirements:

i. A documented radiation exposure Safety Programme to document radiation exposure.
ii. Established radiation safety Education Programme.
iii. SOPs for monitoring of Staff Radiation dose and evidence of monitoring.
iv. Evidence that procedure are performed with the goal of keeping radiation doses as low as reasonably achievable (ALARA).
v. All related personnel in the room/ Cath Lab wear personal protective equipment including lead aprons, neck shields etc.
vi. Evidence of implementation of strategies to reduce radiation exposure
vii. Patient radiation dose is monitored as per guidelines
viii. Surveillance Programme for radiation safety is documented and implemented.
ix. When radioactive materials are used in the laboratory, processes are developed and implemented for their safe handling, monitoring, use and disposal.

Rating:

- If the above requirements are complied. Then, rate as **met.**
- If any of the above requirements are not complied. Then, rate as **not met.**

Standard 9: Infection Prevention & Control (IPC)

Indicator 28: CCL has an appropriate waste management plan in place, implements and monitors well.

Assessment Process:

In order to comply with this indicator, HCE has developed a waste management plan in documented form and is available for inspection) Clinical waste management protocol adheres to relevant regulations and guidelines. ii) General waste management protocol available. iii) Chemical waste management protocol adheres to relevant guidelines the Clinical Waste Management Plan ensuring availability of:

a. Single use syringes as required and syringe cutters/auto disposable (AD) syringes

b. Separate containers for HCE waste (for infectious, non-infectious and sharps) Evidence of Waste Management system including the following components in practice;
    a. Segregation
    b. Collection
    c. Disposal

Rating:

- If there is waste management plan available in place and following. Then, rate as **met.**
- If there is no waste management plan available. Then, rate as **not met.**

Indicator 29: CCL has implemented an infection control plan to minimize the occurrence and prevention of nosocomial infections

Assessment Process:

In order to comply with this indicator, the CCL should have a written IPC Plan to verify that it covers the following aspects.

i. SOPs for Infection Prevention & Control.
ii. Arrangement for the Infection Prevention & Control Practices

Rating:

- If there is a documented infection prevention and control plan that includes SOPs for infection control and arrangements of infection control practices. Then, rate as **met.**
- If there is either no written plan, or it does not include any one of the above requirements. Then, rate as **not met.**

Indicator 30: In CCL, there is qualified individual(s) who oversee all infection prevention and control activities. They have the necessary education, training, experience, or certification in infection prevention and control practices.

Assessment Process:

In order to comply with this indicator, The CCL has a qualified person or team responsible for overseeing infection prevention and control activities. These individuals have the necessary education, training, experience, or certification in infection prevention and control practices. Their role is to monitor and manage infection risks, implement preventative measures, and ensure compliance with established protocols. This helps to maintain a safe and healthy environment for patients and healthcare workers.

Rating:

- If there are qualified personnel is available for infection prevention and control activities. Then, rate as **met.**
- If the qualified personnel do not available for infection prevention and control activities. Then, rate as **not met.**

Indicator 31: Gloves, disposable masks and hand sanitizer are available, accessible and ready for use

Assessment Process:

In order to comply with this indicator, In the CCL, it is necessary to have readily available single-use gloves, hand sanitizers and disposable masks. It is essential for the CCL to use these gloves and masks correctly to maintain proper hygiene standards.

Rating:

- If masks and gloves are available in the dental HCE. Then, rate as **met**.
- If masks and gloves are not available in the dental HCE. Then, rate as **not met.**

Standard 10: Facility Management and Safety

Indicator 32: The Laboratory complies with relevant laws, regulations, building and fire safety codes and facility inspection requirements.

Assessment Process:

In order to comply with this indicator:

i. Laboratory leaders plan and provide for sufficient space and resources to support all laboratory areas.
ii. Laboratory storage areas have sufficient space and are maintained under proper conditions for storage.
iii. Records, information, and other patient data are protected from loss, destruction, tampering, unauthorized access, and unsafe storage conditions.

Rating:

- If the above requirements are complied. Then, rate as **met.**
- If any of the above requirements are not complied. Then, rate as **not met.**

Indicator 33: The laboratory establishes and implements a program for fire safety that includes ongoing assessment of risks and compliance with national and local codes, laws, and regulations.

Assessment Process:

In order to comply with this indicator:

i. The fire safety program includes the prevention, early detection, suppression, and containment of fire and smoke, and the safe exit from the facility when fire and nonfire emergencies occur.
ii. All fire safety equipment and systems, including devices related to early detection, alarm notification, and suppression, are inspected, tested, and maintained.
iii. The laboratory involves staff in regular exercises to evaluate fire safety programs. The fire safety program includes limiting smoking by staff and patients to designated non–patient care areas of the facility

Rating:

- If the above requirements are complied. Then, rate as **met.**
- If any of the above requirements are not complied. Then, rate as **not met.**