SERVICE STANDARD 09E : CLINICAL SERVICES - CARDIOLOGY SERVICES

PREAMBLE
The Cardiology Services shall be organised, directed and coordinated with other services in the Facility to provide a high standard of inpatient and outpatient care to the community and cover the following but not limited to:-
a) appropriateness of clinical care
b) unwarranted variation in care that is not explained by the clinical circumstances or personal choices of the medical practitioners in:-
i) overuse of treatments or procedures that do not help patients get better;
ii) underuse of care;
iii) misuse (or errors) of doing something incorrectly and harming patients.

TOPIC TOPIC 9E.1
ORGANISATION AND MANAGEMENT

STANDARD STANDARD 9E.1.1
The Cardiology Services shall be organised, directed and coordinated with other services in the Facility to provide a high standard of inpatient and outpatient care to the community in a safe, efficient, effective, evidence based and caring manner with due regard for the needs, dignity and privacy of patients and confidentiality of their personal information. The Cardiology Services shall be easily accessible and continuity of care assured.

CRITERION NO.	CRITERIA FOR COMPLIANCE	SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
				AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
9E.1.1.1	Vision, Mission and values statements of the Facility are accessible. Goals and objectives that suit the scope of the Cardiology Services are clearly documented and measurable that indicates safety, quality and patient centred care. These reflect the roles and aspirations of the service and the needs of the community. These statements are monitored, reviewed and revised as required accordingly and communicated to all staff.	NA			NA	

EVIDENCE OF COMPLIANCE		
1.	Vision, Mission and values statements of the Facility are available, endorsed and dated by the Governing Body.	NA
2.	Goals and objectives of the Cardiology Services in line with the Facility statements are available, endorsed and dated.	NA
3.	Evidence of planned reviews of the above statements.	NA

	4.	These statements are communicated to all staff (orientation programme, minutes of meeting, etc)	NA				
	5.	Achievement of goals and objectives are monitored, reviewed and revised accordingly.	NA				
9E.1.1.2 CORE	There is an organisation chart which: a) provides a clear representation of the structure, functions and reporting relationships between the Person In Charge (PIC), Head of Cardiology Services, consultants, medical practitioners and staff of the Cardiology Services; b) is accessible to all staff and clients; c) is revised when there is a major change in any of the following: i) organisation; ii) functions; iii) reporting relationships; iv) staffing patterns.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Clearly delineated current organisation chart with line of functions and reporting relationships between the Person In Charge (PIC), Head of Cardiology Services, consultants, medical practitioners and staff of the Cardiology Services.	NA				
	2.	Organisation chart of the service is endorsed, dated and accessible.	NA				
	3.	The organisation chart is revised when there is a major change in any of the items (c)(i) to (iv).	NA				
9E.1.1.3	The Governing Body shall ensure that the Cardiology Services are organised in such a way as to: a) facilitate the provision of cardiology services to patients in the Facility in a safe, efficient, effective, and caring manner and with due regard for the needs, dignity and privacy of patients and confidentiality of their personal information; b) assure continuity of care; c) address the professional needs of the cardiologist; d) ensure that the cardiologists are involved in the formulation of policies and procedures concerning patient care appropriate to the scope of services of the Facility.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Departmental/Service operational policies that address (a) to (d).	NA				

	2.	Medical Staff By-Laws	NA				
	3.	Evidence of involvement of cardiologists in the formulation of policies and procedures concerning patient care.	NA				
	4.	Involvement of Head of the Service in the Medical and Dental Advisory Committee/Medical Advisory Committee and ward meetings.	NA				
	5.	Minutes of meetings	NA				
	6.	Proper and adequate equipment according to current standards.	NA				
9E.1.1.4	There is a mechanism to ensure effective interaction between the Cardiology Services and the Governing Body on all clinical aspects of healthcare and other relevant matters in the Facility. This mechanism is defined in the policies of the Governing Body and may be accomplished through: a) the appointment/assignment of a cardiologist as the Head of Cardiology Services delineating his/her authority, responsibilities and accountabilities in a written document according to the relevant Acts to manage and control the Cardiology Services; b) Medical and Dental Advisory Committee (MDAC) to advise the Governing Body on issues related to clinical governance, i.e. planning, coordinating, implementation, control and to improve activities relating to Cardiology Services.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Letter of appointment/assignment and delineation of duties and responsibilities of the Head of the Service.	NA				
	2.	Letter of appointment and Terms of Reference as member of the Medical and Dental Advisory Committee/Medical Advisory Committee.	NA				
	3.	Minutes of meetings of MDAC/Management	NA				
9E.1.1.5 CORE	The Head of Cardiology Services has: a) representation of the Service in committees and subcommittees where relevant; b) representation of the Service in clinical staff liaison meetings; c) involvement and provide regular input to the Senior Management Team.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Letter of representation of the Head of Service in committees and subcommittees where relevant, e.g. Blood Transfusion Committee,	NA				

		Medical Records Committee, Hospital Infection and Antibiotic Control Committee, etc.					
	2.	Minutes of meetings of committees	NA				
	3.	Minutes of meeting of Senior Management Team.	NA				
9E.1.1.6	The assessment, planning, direction, evaluation and continuity of clinical care are the responsibility of cardiologists managing their patients, thus ensuring clinical independence.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Documentation of departmental policy and procedures	NA				
	2.	Medical Staff By-Laws; clause indicate clinical care responsibility of cardiologist.	NA				
	3.	Documented evidence of clinical notes in the patient's medical record; e.g. documentation on assessment, planning, direction, evaluation and continuity of clinical care, as well as patient care plan including the results of diagnostic tests, valid name stamp of cardiologists/medical practitioners.	NA				
9E.1.1.7	The Head of Cardiology Services shall be involved for the following aspects of management of the services: a) the preparation of budget and ensuring that expenditure remains within the budget allocated; b) human resource management and development including maintaining credentialing and experience of all staff – cardiologists/medical practitioners, nurses and technologists; c) development of policies and procedures and ensuring compliance to them; d) facility and equipment management; e) safety and performance improvement activities and risk management.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Evidence of (a) to (e) in the minutes of meetings of Cardiology Services indicate the involvement of Head of Service.	NA				
	2.	Request for allocation of budget and staffing	NA				
	3.	Credentialing and privileging process for staff	NA				
	4.	Endorsement of policies and procedures	NA				
	5.	Implementation of performance improvement activities	NA				

9E.1.1.8	Regular staff meetings are held between the Head of Service and staff with sufficient regularity to discuss issues and matters pertaining to the operations of the Cardiology Services. Minutes are kept; decisions and resolutions made during meetings shall be accessible, communicated to all staff of the service and implemented. EVIDENCE OF COMPLIANCE 1. Minutes are accessible, disseminated and acknowledged by the staff. NA 2. Attendance list of members with adequate representatives of the service. NA 3. Frequency of meetings as scheduled. NA 4. Discussion and resolutions are implemented. (Problems not solved to be brought forward in the next meeting until resolved). NA	NA			NA	
9E.1.1.9	Where there are medical practitioners, nurses and paramedics in cardiology training, there is evidence that: a) their responsibilities for patient care are documented; b) their training needs are identified; c) appropriate supervision and training are given to the medical practitioners, nurses and paramedics concerned. EVIDENCE OF COMPLIANCE 1. Structured training programmes for medical practitioners, nurses and paramedics are in place. NA 2. Training timetable, continuing medical education and attendances list NA 3. Assessment reports NA 4. Log books NA	NA			NA	
9E.1.1.10	Appropriate statistics and records shall be maintained in relation to the provision of Cardiology Services and used for managing the services and patient care purposes. EVIDENCE OF COMPLIANCE 1. Records are available but not limited to the following:	NA			NA	

	a)	monthly submission of all Acute Coronary Syndrome (ACS) and Percutaneous Coronary Intervention (PCI) cases to National Cardiovascular Disease Database (NCVD) Registry;	NA					
	b)	yearly volume of Percutaneous Coronary Interventions (PCIs) and other interventional procedures for the Facility;	NA					
	c)	yearly volume of PCIs and other interventional procedures for individuals;	NA					
	d)	outcomes of PCIs and other interventional procedures for Facility/individuals based on statistics of services and patient care are managed accordingly;	NA					
	e)	accident/incident reports;	NA					
	f)	staffing number and staff profile;	NA					
	g)	staff training records;	NA					
	h)	data on performance improvement activities, including performance indicators	NA					

TOPIC TOPIC 9E.2
HUMAN RESOURCE DEVELOPMENT AND MANAGEMENT

STANDARD STANDARD 9E.2.1
CREDENTIALING AND PRIVILEGING
The Cardiology Services shall be directed by a qualified and competent Cardiologist and staffed by suitably qualified and competent clinical staff to achieve the goals and objectives of the services.

<table>
<tr><th rowspan="2">CRITERION NO.</th><th rowspan="2">CRITERIA FOR COMPLIANCE</th><th rowspan="2">SELF RATING</th><th rowspan="2">FACILITY COMMENTS</th><th colspan="3">SURVEYOR FINDINGS</th></tr>
<tr><th>AREAS FOR IMPROVEMENT / RECOMMENDATIONS</th><th>SURVEYOR RATING</th><th>RISK</th></tr>
<tr><td>9E.2.1.1
CORE</td><td>There is documented evidence of appropriate training and competency for the granting
of clinical privileging. The criteria for determining privileges are specified and documented. There is a structured process to ensure the stated criteria are uniformly
applied to all applicants. These include:
a) the criteria are designed to assure that patients will receive safe and quality care;
b) the criteria for individual procedures are documented in detail; e.g. competency records/log books, application from the individual practitioner, recommendations from peer/referee and minutes of meeting;
c) competency for each performance is dated, verified and signed by the supervisors;
d) the period of time for which the privileges are to be granted is specified;
e) current registration with the local professional registration bodies, e.g. Malaysian Medical Council, National Specialist Register (NSR);
f) peer recommendations are taken into account when privileges are being considered;
g) the recommendations of the relevant department and/or major professional services for privileges to be granted are taken into consideration.

EVIDENCE OF COMPLIANCE
1. Documented policies and procedures are established to govern the credentialing and privileging processes which include items (a) to (g). — NA
2. Compliance with policy and criteria for credentialing and privileging — NA
3. Annual Practising Certificate (APC), National Specialist Register (NSR) certificate and privileging certificate. — NA
4. Recommendations from peer/referee — NA</td><td>NA</td><td></td><td></td><td>NA</td><td></td></tr>
</table>

	5.	Availability of the list of procedures requiring privileging	NA				
	6.	Availability of list of procedures to include core procedures specific to the disciplines performed by medical officers; competency records/log books	NA				
9E.2.1.2 CORE	For Facility identified as Cardiology Training Centre There is documented evidence of appropriate training and competency for certification. The criteria for determining for certification are specified and documented. There is a structured process to ensure the stated criteria are uniformly applied. These include: a) the criteria are designed to assure that patients will receive safe and quality care; b) the criteria for individual procedures are documented in detail; e.g. competency records/log books, application from the individual practitioner, recommendations from peer/referee and minutes of meeting; c) competency for each performance is dated, verified and signed by the supervisors; d) the period of time for which the privileges are to be granted is specified; e) current registration with the local professional registration bodies, e.g. Malaysian Medical Council, National Specialist Register (NSR); f) peer recommendations are taken into account when privileges are being considered; g) the recommendations of the relevant department and/or major professional services for privileges to be granted are taken into consideration.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Documented policies and procedures are established to govern the credentialing and privileging processes which include items (a) to (g).	NA				
	2.	Compliance with policy and criteria for credentialing and privileging	NA				
	3.	Recommendations from peer/referee	NA				
	4.	Competency records/log books	NA				
	5.	Annual Practising Certificate (APC) and privileging certificate	NA				
	6.	Availability of the list of procedures requiring privileging.	NA				
	7.	Availability of list of procedures to include core procedures specific to the disciplines performed by medical officers.	NA				

9E.2.1.3 CORE	Documented evidence of privileges conferred by the Governing Body is available and accessible to relevant staff at point of care. EVIDENCE OF COMPLIANCE 1. Formal letter of assignment or certificate of privileging with stipulated timeline are issued and reviewed accordingly. — NA 2. Updated list of staff with privileges conferred is made accessible at point of care. — NA	NA			NA	
9E.2.1.4	Clinical staff performs procedures within the privileges conferred. EVIDENCE OF COMPLIANCE 1. Verification of procedures performed by individuals at point of care within the awarded privileging rights with evidence of: a) list of procedures privileged; — NA b) clinical notes. — NA	NA			NA	
9E.2.1.5	There are written and dated specific job descriptions for all categories of staff that include: a) qualifications, training, experience and certification required for the position; b) lines of authority; c) accountability, functions, and responsibilities; d) reviewed when required and when there is a major change in any of the following: i) nature and scope of work; ii) duties and responsibilities; iii) general and specific accountabilities; iv) qualifications required and privileges granted; v) staffing patterns; vi) Statutory Regulations. e) administrative and clinical functions. EVIDENCE OF COMPLIANCE 1. Updated specific job description is available for each staff that includes but not limited to as listed in (a) to (e). — NA 2. Job description includes specialisation skills — NA 3. Relevant privileges granted where applicable — NA	NA			NA	

	4.	The job description is acknowledged by the staff and signed by the Head of Service and dated.	NA				

STANDARD STANDARD 9E.2.2

STAFF TRAINING, EDUCATION, APPRAISAL AND RESEARCH

The Facility and all staff shall demonstrate an ongoing commitment to continuing medical education.

CRITERION NO.	CRITERIA FOR COMPLIANCE	SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
				AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
9E.2.2.1	There are continuing education activities for staff including cardiologists to pursue professional interests and to prepare for current and future changes in practice. **EVIDENCE OF COMPLIANCE** 1. Training calendar includes in-house/external courses/ workshop/conferences — NA 2. Contents of training programme — NA 3. Training records on continuing education activities are kept and maintained for each staff including training in life support. — NA 4. Certificate of attendance/degree/post basic training — NA	NA			NA	
9E.2.2.2	The educational needs of staff and the Facility, as evidenced by the results of medicalcare evaluation such as incident reports, performance improvement studies and complaints, are taken into consideration when the content and structure of educational activities are planned and implemented. **EVIDENCE OF COMPLIANCE** 1. Evidence of inclusion of results of audit activities, e.g. mortality and morbidity reviews, incident reporting, etc in educational activities. — NA 2. Evidence of improvement made from corrective or preventive measures from incident reports. — NA	NA			NA	
9E.2.2.3	In a Facility where undergraduate medical, nursing and allied health training programmes are conducted, the Facility shall ensure that there are sufficient skilled trained staff to provide clinical supervision of students. **EVIDENCE OF COMPLIANCE** 1. Sufficient skilled trained staff to provide clinical supervision as per terms of Memorandum of Understanding. — NA	NA			NA	

9E.2.2.4	There is evidence of training needs assessment and staff development plan which provides the knowledge and skills required for staff to maintain competency in their current positions and future advancement. **EVIDENCE OF COMPLIANCE** 1. Training needs assessment is carried out and gaps identified. — NA 2. A staff development plan based on training needs assessment is available. — NA 3. Training schedule/calendar is in place. — NA 4. Training module — NA	NA			NA	
9E.2.2.5	Staff including cardiologists receive written evaluation of their performance at the completion of the probationary period and annually thereafter, or as defined by the Facility. **EVIDENCE OF COMPLIANCE** 1. Performance appraisal for staff including cardiologists is completed upon probationary period and as an annual exercise. — NA	NA			NA	
9E.2.2.6	Where appropriate the Facility shall endeavour to undertake clinical research using available resources. **EVIDENCE OF COMPLIANCE** 1. Documented evidence of research activities e.g. protocol, policies, consent etc. — NA	NA			NA	

STANDARD STANDARD 9E.2.3

STAFFING LEVEL AND STAFF COMPETENCY

The Head and staff of the Cardiology Services including cardiologists are individuals qualified by education, training and experience commensurate with the requirements of the various positions and relevant laws.

CRITERION NO.	CRITERIA FOR COMPLIANCE		SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
					AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
9E.2.3.1	Deployment of all service providers for the Cardiology Services takes the following factors into consideration: a) the number of persons deployed is proportional to the number of patients being cared for as in regulatory requirements and also the intensity of care provided; b) the categories of service providers based on qualifications and experience providing care reflect the complexity of clinical problems being managed; c) staffing needs shall take into consideration absences due to leave or illness; double shift duties by clinical staff shall be documented and monitored; d) adequate staffing levels of appropriate competency shall be maintained throughout the hours the services are in operation. Where services need to be provided on a 24-hour basis, staffing level reflects the intensity of activities during each shift; e) where it is not possible to have service providers on duty on site, e.g. after working hours, provision is made for relevant staff to be available on call.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Documentation and planning on deployment of staff that includes but not limited to (a) to (e) with evidence of:					
	a)	deployment based on staff to patient ratio, bed occupancy rate and complexity of cases;	NA				
	b)	special skills/training of staff;	NA				
	c)	contingency plan during acute shortage;	NA				
	d)	duty roster.	NA				

STANDARD STANDARD 9E.2.4

STAFF ORIENTATION

A structured orientation programme introduces new staff to their services, operational policies and relevant aspects of the Facility to prepare them for their roles and responsibilities.

<table>
<tr><th rowspan="2">CRITERION NO.</th><th rowspan="2">CRITERIA FOR COMPLIANCE</th><th rowspan="2">SELF RATING</th><th rowspan="2">FACILITY COMMENTS</th><th colspan="3">SURVEYOR FINDINGS</th></tr>
<tr><th>AREAS FOR IMPROVEMENT / RECOMMENDATIONS</th><th>SURVEYOR RATING</th><th>RISK</th></tr>
<tr><td>9E.2.4.1</td><td>There is a structured orientation programme for all newly appointed staff to the Cardiology Services, including cardiologists, and for those new to specific areas that include the following:
a) explanation of the goals, objectives, policies, and procedures of the Facility and those of the Cardiology Services;
b) lines of authority and areas of responsibility;
c) explanation of particular duties and functions;
d) explanation of the methods of assigning clinical care and the standards of clinical practice;
e) handover communication;
f) processes for resolving practice dilemmas in a timely manner;
g) information about safety procedures;
h) training in basic/advanced life support techniques;
i) methods of obtaining appropriate resource materials;
j) staff appraisal procedures for the Cardiology Services;
k) education on Patient and Family Rights;
l) education on MSQH Standards requirements.

EVIDENCE OF COMPLIANCE
1. Policy requiring all new staff to attend a structured orientation programme. — NA
2. There is Cardiology Services orientation programme with relevant topics not limited to topics covered from (a) to (l). — NA
3. Attendance list — NA</td><td>NA</td><td></td><td></td><td>NA</td><td></td></tr>
</table>

TOPIC TOPIC 9E.3
POLICIES AND PROCEDURES

STANDARD STANDARD 9E.3.1
DEVELOPMENT, DERIVATION AND DOCUMENTATION
There are written and dated policies and procedures for all activities of the Cardiology Services. These policies and procedures reflect current standards of medical practice, relevant regulations, statutory requirements, and the purposes of the services. These policies and procedures, terms of reference, by-laws, rules or regulations, state how the clinical staff and cardiologists regulate themselves and provide patient care. There should be a list of procedures requiring informed consent specific to cardiology. Possible risks and complications arising from procedures should be documented either in specific consent forms or in patient's records.

CRITERION NO.	CRITERIA FOR COMPLIANCE	SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
				AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
9E.3.1.1 CORE	There are written policies and procedures for the Cardiology Services which are consistent with the overall policies of the Facility, regulatory requirements and current standard practices. These policies and procedures are signed, authorised and dated. There is a mechanism for and evidence of a periodic review at least once in every three years.	NA			NA	
	EVIDENCE OF COMPLIANCE					
	1. Documented policies and procedures for the service. — NA					
	2. Policies and procedures are consistent with the regulatory requirements and current standard practices. — NA					
	3. Evidence of periodic review of policies and procedures. — NA					
	4. The policies and procedures are endorsed and dated. — NA					
9E.3.1.2	Policies and procedures are developed by a committee in collaboration with staff, cardiologists, Management and where required with other external service providers and with reference to relevant sources involved. Cross departmental collaboration is practised in developing relevant policies and procedures where applicable.	NA			NA	
	EVIDENCE OF COMPLIANCE					
	1. Minutes of committee meetings on development and revision on policies and procedures. — NA					

	2.	Minutes of meeting with evidence of cross reference with other departments	NA				
	3.	Documented cross departmental policies	NA				
9E.3.1.3 CORE	The policy and procedure documentation shall cover at least the following topics and any others required by law: a) description of the organisation structure of the Cardiology Services; b) clinical practice guidelines; c) clinical documentation includes pain as the 5th vital sign where appropriate; d) handover communication; e) drug prescription, dispensing and administration; f) blood transfusion; g) continuing of care including regular review of patient, review of investigation results, discharge (planned or At Own Risk), referrals and escort as necessary; h) pain management; i) management of patients under police custody/prisoner; j) management of cases with an infectious disease including notification of notifiable diseases; k) the responsibilities of the staff including cardiologist in relation to internal and external disasters are documented, and known to the staff (contingency plan); l) incident reports shall be compiled, investigated, discussed, and recorded and action plans implemented; m) transfer protocol for patients who require emergency surgery at facility without onsite cardiothoracic surgery backup; n) end of life care; o) management of a death.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Documented policies and procedures that address but not limited to (a) to (o).	NA				
9E.3.1.4	Current policies and procedures are communicated to all staff.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Training and briefing on the current policies and procedures/Minutes of meetings	NA				
	2.	Circulation list and acknowledgement	NA				
9E.3.1.5	There is evidence of compliance with policies and procedures.		NA			NA	

CORE							
	EVIDENCE OF COMPLIANCE						
	1.	Compliance with policies and procedures through:					
	a)	interview of staff on practices;	NA				
	b)	verify with observation on practices;	NA				
	c)	results of audit on practices;	NA				
	d)	practices in line with established policies and procedures.	NA				
9E.3.1.6	Copies of policies and procedures, protocols, guidelines, relevant Acts, Regulations, By-Laws and statutory requirements are accessible to staff.			NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Copies of relevant policies and procedures, protocols, guidelines, relevant Acts, Regulations, By-Laws and statutory requirements are accessible on-site for staff reference.	NA				
9E.3.1.7	The Cardiology Services shall operate on a 24-hour basis providing a level of care appropriate to the activities of the patients in the Facility. Where treatment facilities are not available on a 24-hour basis, there is a written policy for referral of patients to the nearest facilities where such facilities exist to render optimum treatment to the patient.			NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Operational policy on 24-hour services	NA				
	2.	Staffing level reflects good mix of experienced staff and the intensity of activities during each shift.	NA				
	3.	On-call roster is dated and authorised.	NA				

TOPIC TOPIC 9E.4
FACILITIES AND EQUIPMENT

STANDARD STANDARD 9E.4.1
The Head of Cardiology Services shall ensure adequate facilities and equipment that are safe and appropriate are available for the staff to function effectively and to meet the goals and objectives of the Cardiology Services.

CRITERION NO.	CRITERIA FOR COMPLIANCE		SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
					AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
9E.4.1.1	There are adequate and appropriate facilities and equipment with proper utilisation of space to enable staff to carry out their professional, teaching and administrative functions.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Adequate and proper utilisation of space.	NA				
	2.	Appropriate type of equipment to match the complexity of services.	NA				
	3.	Adequate facilities and equipment at each patient care area for safe care. (e.g. defibrillators, emergency cart, hand washing facilities etc)	NA				
	4.	Easy access and clear exit routes	NA				
	5.	Absence of overcrowding	NA				
9E.4.1.2	Existing facilities shall take cognisance of the safety of staff and patients.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Design and layout of the unit, e.g. wards, treatment rooms, dirty and clean utility rooms, access, lighting, signage, etc address the safety aspects of patients and staff.	NA				
	2.	Adequate equipment and supplies for Cardiology Services, e.g. emergency trolley, functioning patient call bell, etc.	NA				
	3.	Equipment should have scheduled planned preventive maintenance (PPM).	NA				
9E.4.1.3	Suitable and adequate forms of communication and intercommunication systems and equipment are provided to enable clinical staff to communicate among themselves and		NA			NA	

	with the other members of the healthcare team.						
	EVIDENCE OF COMPLIANCE						
	1.	Appropriate telecommunication modalities available for daily operation and during emergencies.	NA				

STANDARD STANDARD 9E.4.2

FACILITIES AND EQUIPMENT FOR PATIENT CARE

Adequate facilities and equipment shall be available to provide safe and effective patient care.

CRITERION NO.	CRITERIA FOR COMPLIANCE		SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
					AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
9E.4.2.1	Facilities are suitably located to facilitate easy access and to provide an atmosphere of user, environmental and 'disabled' friendly.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Floor plan indicates accessibility and patient and user friendly.	NA				
	2.	Feedback from patient satisfaction survey	NA				
	3.	Incident reporting relating to facilities if any.	NA				
9E.4.2.2	Equipment, both for emergency and non-emergency usage, shall be appropriate to the level of care.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Availability of emergency and non-emergency equipment appropriate to level of care, such as defibrillator, emergency trolley, suction machine, electrocardiogram (ECG) machine, infusion or syringe pump, vital sign monitor, etc.	NA				
	2.	Scheduled checking of items in emergency trolley	NA				
9E.4.2.3	There is documented evidence that equipment complies with relevant national/international standards and current statutory requirements.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Testing, commissioning and calibration records (certificates or stickers)	NA				
	2.	Certification of equipment from certified bodies, e.g. Standards and Industrial Research Institute of Malaysia (SIRIM), etc as evidence of compliance to the relevant standards and Acts.	NA				
9E.4.2.4 CORE	There is evidence that the facility has a comprehensive maintenance programme such as predictive maintenance, planned preventive maintenance and calibration activities,to ensure the facilities and equipment are in good working order.		NA			NA	

	EVIDENCE OF COMPLIANCE						
	1.	Planned Preventive Maintenance records such as schedule, stickers, etc.	NA				
	2.	Planned Replacement Programme where applicable.	NA				
	3.	Complaint records	NA				
	4.	Asset inventory	NA				
9E.4.2.5	Where specialised equipment is used, there is evidence that only staff who are trained and authorised by the Facility operate such equipment.			NA			NA
	EVIDENCE OF COMPLIANCE						
	1.	User training records	NA				
	2.	Competency assessment record	NA				
	3.	Letter of authorisation	NA				
	4.	List of staff trained and authorised to operate specialised equipment	NA				
9E.4.2.6	Equipment is upgraded (based on evidence) from time to time so as to keep pace with advancement in operative and diagnostic techniques and technology.			NA			NA
	EVIDENCE OF COMPLIANCE						
	1.	Equipment are being replaced and upgraded to meet current standard of care and advancement in technology in a planned and systematic manner.	NA				

STANDARD STANDARD 9E.4.3

FACILITIES FOR CARDIOLOGY OUTPATIENT SERVICES

Where specialist outpatient services are provided, there are adequate outpatient clinics to enable the provision of safe and effective patient care; and patient privacy and confidentiality are assured.

CRITERION NO.	CRITERIA FOR COMPLIANCE			SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
						AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
9E.4.3.1	The Specialist Outpatient Services shall have the following features: a) the organisation and management of the clinics are planned so as to ensure prompt attention to patients, minimal of waiting time, and avoidance of unnecessary visits by the patients; b) record keeping shall be efficient; c) an appointment or queuing system is used to manage patient consultations; d) the clinic is easily accessible including for non-ambulant patients and is easily identified through adequate signage; e) the clinic is located close to other facilities, e.g. radiology, laboratories and pharmacy. f) adequate provision is made for patient comfort.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	The Specialist Outpatient Services address (a) to (f) with evidence of but not limited to the following:						
	a)	list of services available and offered to patients;	NA					
	b)	flow chart on work process;	NA					
	c)	safe keeping of medical records;	NA					
	d)	security of data in Health Information System;	NA					
	e)	clinic appointment system;	NA					
	f)	monitoring of waiting time;	NA					
	g)	adequate and appropriate signage;	NA					
	h)	floor plan indicates accessibility to supporting services and optimisation of space;	NA					
	i)	adequate patient personal use items, e.g. wheelchair, etc;	NA					
	j)	adequate waiting area, rest rooms, refreshments, reading material and parking space.	NA					

9E.4.3.2	Adequate numbers of rooms are provided to ensure patient privacy and confidentiality for various patient care activities including: a) consultation (only one patient in a room at any time); b) conduct of minor procedures and nursing procedures; maintain a register of procedures performed, e.g. electrocardiogram (ECG); c) performance of various tests where applicable.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Adequate facilities for consultation and patient care activities that address (a) to (c) with evidence of but not limited to the following:						
	a)	privacy of patient is ensured;	NA					
	b)	procedure room appropriately equipped;	NA					
	c)	patient monitoring device is available where required;	NA					
	d)	list of procedures done.	NA					

TOPIC TOPIC 9E.5
SAFETY AND PERFORMANCE IMPROVEMENT ACTIVITIES

STANDARD STANDARD 9E.5.1
The Head of Cardiology Services shall ensure the provision of quality performance with staff involvement in the continuous safety and performance improvement activities of the Cardiology Services. The Head of Cardiology Services shall ensure compliance to monitoring of specific performance indicators.

CRITERION NO.	CRITERIA FOR COMPLIANCE	SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
				AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
9E.5.1.1	There are planned and systematic safety and performance improvement activities to monitor and evaluate the performance of the Cardiology Services. The process includes: a) Planned activities b) Data collection c) Monitoring and evaluation of the performance d) Action plan for improvement e) Implementation of action plan f) Re-evaluation for improvement Innovation is advocated.	NA			NA	
	EVIDENCE OF COMPLIANCE					
	1. Planned performance improvement activities include (a) to (f) — NA 2. Records on performance improvement activities — NA 3. Minutes of performance improvement meetings — NA 4. Performance improvement studies — NA 5. Mortality and morbidity audits with remedial actions — NA 6. Records on innovation if available. — NA					
9E.5.1.2	The Head of Cardiology Services has assigned the responsibilities for planning, monitoring and managing safety and performance improvement activities to appropriate individual/personnel within the respective services.	NA			NA	
	EVIDENCE OF COMPLIANCE					
	1. Minutes of meetings — NA					

	2.	Letter of assignment of responsibilities	NA				
	3.	Job description	NA				
9E.5.1.3	The Head of the Cardiology Safety Services shall ensure that the staff are trained and complete incident reports which are promptly reported, investigated, discussed by the staff with learning objectives and forwarded to the Person In Charge (PIC) of the Facility. Incidents reported have had Root Cause Analysis done and action taken within the agreed time frame to prevent recurrence.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	System for incident reporting is in place, which include:					
	a)	Training of staff	NA				
	b)	Policy on incident reporting	NA				
	c)	Methodology of incident reporting	NA				
	d)	Register/records of incidents	NA				
	2.	Completed incident reports	NA				
	3.	Root Cause Analysis	NA				
	4.	Corrective and preventive action plans	NA				
	5.	Remedial measure	NA				
	6.	Minutes of meetings	NA				
	7.	Acknowledgment by Head of Service and PIC/Hospital Director	NA				
	8.	Feedback given to staff regarding incident reporting.	NA				
9E.5.1.4 CORE	The staff including cardiologist provide an appropriate peer group structure for performing the safety and performance improvement activities to accomplish clinical care evaluation. a) The cardiologists undertake clinical reviews of all risk assessments, incident reports, audits and safety and performance improvement activities: i) as a single committee for all safety and performance improvement activities; ii) in multidisciplinary committees within the service; iii) in a variety of purpose-specific committees, such as mortality and morbidity, infection control, blood transfusion, etc.		NA			NA	

	b) Whatever structure is utilised, provision is made for review and analysis of the clinical work of each individual clinical service, department, unit or function. EVIDENCE OF COMPLIANCE 1. Performance improvement activities — NA 2. Minutes of meetings — NA 3. Relevant reports and documents, e.g. clinical audit reports, incident reports, mortality and morbidity review reports, etc. — NA					
9E.5.1.5 CORE	There is tracking and trending of specific performance indicators of the following where appropriate: a) electrocardiogram taken within 10 minutes after triaging as possible Acute Coronary Syndrome patients (Target: 100%) b) mortality and morbidity review of patients with acute myocardial infarction (Target: Mortality review - 100%; Morbidity discussion based on the department's discretion) c) Thrombolytic Therapy within 30 minutes after hospital arrival in patient with acute myocardial infarction "Door to Needle" Time (Target: 90%) d) percentage of patient who received Thrombolytic Therapy (TT) in patients admitted for acute myocardial infarction (Target: 90%) e) percentage of "Normal" Diagnostic Angiogram (Target: <5%) f) major complication rate during Diagnostic Coronary Angiogram (Death, acute myocardial infarction, stroke) (Target: <1%) g) major complication rate during Percutaneous Coronary Intervention (Death, acute myocardial infarction, stroke) (Target: ≤1%) h) Percutaneous Coronary Intervention (PCI) within 90 minutes after diagnosed as acute myocardial infarction "Door to Balloon" Time (Target: 90%) i) Percentage of high risk Acute Coronary Syndrome (ACS) cases undergoing Cardiac Catheterisation during the index admission (Target: > 90%)	NA			NA	

	j) Percentage of Heart Failure Mortality Rate during index hospitalisation (Target: ≤ 10%) k) Percentage of Heart Failure Readmission Rate at 1-month (Target: ≤ 15%) EVIDENCE OF COMPLIANCE 1. Specific performance indicators monitored. NA 2. Records on tracking and trending analysis. NA 3. Minutes of mortality/morbidity audits meetings NA 4. Remedial measures taken where appropriate NA					
9E.5.1.6	Feedback on results of safety and performance improvement activities are regularly communicated to the staff. EVIDENCE OF COMPLIANCE 1. Results on safety and performance improvement activities are accessible to staff. NA 2. Evidence of feedback via communication on results of performance improvement activities through continuing medical education/meetings. NA 3. Minutes of service/unit/committee meetings NA	NA			NA	
9E.5.1.7	Appropriate documentation of safety and performance improvement activities is kept and confidentiality of medical practitioners, staff and patients is preserved. EVIDENCE OF COMPLIANCE 1. Documentation on performance improvement activities and performance indicators. NA 2. Policy statement on anonymity on patients and providers involved in performance improvement activities. NA	NA			NA	

TOPIC TOPIC 9E.6
SPECIAL REQUIREMENTS

STANDARD STANDARD 9E.6.1
INVASIVE CARDIAC LABORATORY SERVICES

STANDARD 9E.6.1.1: STAFFING, PROCESS AND SAFETY REQUIREMENTS
The Invasive Cardiac Laboratory is constructed, equipped, operated, and maintained in a manner that enable adequate investigations and treatment of cardiac patients taking into consideration the safety of patients and staff, and in accordance to relevant regulatory requirements.

CRITERION NO.	CRITERIA FOR COMPLIANCE	SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
				AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
9E.6.1.1.1 CORE	*The Invasive Cardiac Laboratory is constructed, equipped, operated, and maintained in a manner that enable adequate investigations and treatment of cardiac patients taking into consideration the safety of patients and staff, and in accordance to relevant regulatory requirements.* EVIDENCE OF COMPLIANCE 1. 1. Cardiologists registered with National Specialist Register (NSR) — NA 2. Letter of appointment/assignment — NA 3. Staff are credentialed and certified by approved institutions. — NA	NA			NA	
9E.6.1.1.2 CORE	Personnel working with radiation equipment shall wear appropriate monitoring devices. These devices shall be assessed periodically in an appropriate agency/laboratory. The results are reported to the relevant authority. Records are kept for constant monitoring and proactive action taken to improve the safety of the services. EVIDENCE OF COMPLIANCE 1. Monthly monitoring of dosimetry by the licensed agency/laboratory approved by Atomic Energy Licensing Board (AELB), Malaysia. — NA	NA			NA	
9E.6.1.1.3 CORE	Invasive Cardiac Laboratory Services staff and cardiologist are represented on interdepartmental committees and involved in decision making on issues related to the provision of invasive cardiac laboratory services. EVIDENCE OF COMPLIANCE 1. Documented evidence on involvement in interdepartmental committees, e.g. letters of appointment, etc. — NA	NA			NA	

	2.	Minutes of meetings	NA				
9E.6.1.1.4 CORE	Written policies and procedures shall include the following: a) scheduling; b) investigative procedures using imaging in the Invasive Cardiac Laboratory Services; c) the administration of diagnostic agents; d) the role of technical and paramedical personnel; e) the care of patients having special needs including those who are critically ill and those needing isolation facilities; f) response time for interpretations and reporting; g) patient identification, with verification of the nature of investigation and signed informed consent documents. Consent shall include disclosure if the centre is without on-site surgical backup and its potential implications; h) infection control procedures, including aseptic technique, routine and terminal cleaning and procedures for infectious patients; i) patient management during recovery from anaesthesia and investigative procedure; j) priorities for using the Invasive Cardiac Laboratory Services time and space; k) the role of the Invasive Cardiac Laboratory staff in the fire and disaster plans of the Facility.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Policies and procedures address (a) to (k).	NA				
	2.	For centres without on-site cardiothoracic surgery, written agreements for full- time coverage and emergency transfer of patients to a facility with cardiothoracic surgery service.	NA				
	3.	All PCI cases are done only when cardiothoracic surgeon and referral centre are available to accept urgent transfer if required.	NA				
	4.	Regular testing of transfer protocols: capability for rapid response, use of intra-aortic balloon pump and intensive monitoring.	NA				
	5.	Checklists are available:-					
	a)	Patient's name and Medical Record Number (MRN);	NA				
	b)	Content of patient records;					
	i)	issues regarding sedation and analgesia;	NA				

	ii)	medication records;	NA				
	iii)	laboratory results;	NA				
	iv)	electrocardiogram (ECG);	NA				
	v)	assessment of bleeding risks especially for those who may receive a stent and maybe facing upcoming surgery;	NA				
	vi)	drug allergies;	NA				
	vii)	informed consent which includes disclosure if the centre is without on-site surgical backup and the potential complications.	NA				
	c)	documentation in the patients' records to include:					
	i)	All potential risks and benefits to the patient, including the possible need for unplanned coronary intervention. Information should include placement of a stent and other invasive techniques used for evaluation, including the need for additional contrast use and radiation exposure.	NA				
	6.	Where it is not possible to have service providers on duty on site, e.g. after working hours provision is made to facilitate staff to be available to meet the door to balloon time of 90 minutes.	NA				
9E.6.1.1.5 CORE	There is evidence of compliance with guidelines to ensure patient and staff safety, which include: a) radiation hazards; b) handling of catheters, monitoring equipment and other items; c) a manual of Technical Procedures and Routines shall be provided for radiographic and relevant staff. Equipment shall include: i) guide catheters, balloons and stents in multiple sizes; ii) covered stents; iii) temporary pacemakers; iv) pericardiocentesis sets; v) access to other diagnostic modalities such as intravascular ultrasound (IVUS) and fractional flow reserve (FFR); vi) thromboaspiration device and distal protection devices (highly recommended for centres WITHOUT on-site surgical backup) vii) rotational or other atherectomy shall not be done in centres WITHOUT on- site surgical backup. EVIDENCE OF COMPLIANCE		NA			NA	

	1.	Documentation of guidelines to address (a) to (c).	NA				
	2.	Verify compliance to guidelines during survey.	NA				
9E.6.1.1.6 CORE	Invasive Cardiac Laboratory Services records are adequate for clinical, medicolegal, and evaluation purposes and these include the following: a) a register of interventional procedure is maintained within the Invasive Cardiac Laboratory; b) standard anaesthetic and drug administration records are maintained, and statutory regulations relating to the control of drugs are followed; c) a record of the investigative procedure performed is written into the patients' medical records and signed by the operator. Each record contains the following: i) indication for procedure; ii) time and dose of all medications; iii) details of the procedure performed; iv) pertinent haemodynamic data obtained; v) description of angiographic findings; vi) proposed care plan; vii) personnel involved; viii) post-investigative orders; ix) reports of all investigative findings shall be signed by cardiologist.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Invasive Cardiac Laboratory Services records which include items listed (a) to (c).	NA				
	2.	Patient care plan including the results of diagnostic tests	NA				
9E.6.1.1.7 CORE	Support services such as Critical Care Services (ICU/CCU) and blood bank are available and a cardiothoracic surgeon is on standby. Effective communication and relationships with these services are maintained.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	On-site ICU/CCU and blood bank services available.	NA				
	2.	Cardiothoracic surgeon on-site or agreement with other facility providing cardiothoracic surgery support.	NA				
9E.6.1.1.8 CORE	Anaesthetic services, where required, in the Invasive Cardiac Laboratory are consistent with standards in the operating suite.		NA			NA	
	EVIDENCE OF COMPLIANCE						

	1.	Facilities for anaesthetic services are maintained at same standard as the operating suite.	NA				
9E.6.1.1.9 CORE	Safety instruction and safety precautions are implemented according to recommendations of the International Commission of Radiation Protection (ICRP) for the protection of both patients and staff in view of the presence of hazardous equipment. EVIDENCE OF COMPLIANCE			NA			NA	
	1.	Verify compliance with recommendations of the International Commission of Radiation Protection (ICRP) on-site.	NA				
9E.6.1.1.10 CORE	Safety precautions against radiation hazards and other health hazards shall be developed and supervised by designated personnel of the Invasive Cardiac Laboratory Services. Such measures shall include instructions, signage, policies and procedures against the following hazards: a) electrical and mechanical hazards; b) fire and explosion; c) radiation hazard. EVIDENCE OF COMPLIANCE			NA			NA	
	1.	Documentation on safety precautions is signed by designated personnel.	NA				
	2.	Compliance with safety precautions against radiation hazards and other hazards are monitored and documented.	NA				
9E.6.1.1.11 CORE	Rooms and equipment shall be assessed for safety at yearly intervals by independent radiation experts (Class H license holders certified by Engineering Services Division Ministry of Health). Records on such assessment are kept. EVIDENCE OF COMPLIANCE			NA			NA	
	1.	Valid licence is available.	NA				
	2.	Records on yearly inspection of records on rooms and equipment.	NA				
9E.6.1.1.12 CORE	Multilingual signs warning women of childbearing age about radiation dangers shall be prominently displayed. EVIDENCE OF COMPLIANCE			NA			NA	
	1.	Availability of multilingual signs warning women of childbearing age about radiation dangers	NA				

STANDARD STANDARD 9E.6.1
INVASIVE CARDIAC LABORATORY SERVICES

STANDARD 9E.6.1.2: FACILITIES FOR INVASIVE CARDIAC LABORATORY
There are appropriate and adequate physical facilities and equipment for the safe and efficient functioning of the Invasive Cardiac Laboratory Services.

CRITERION NO.	CRITERIA FOR COMPLIANCE	SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
				AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
9E.6.1.2.1 CORE	The design of the Invasive Cardiac Laboratory Services supports efficient systems for the management of invasive cardiac procedures. This includes: a) suitable area in reception of patients awaiting procedure; b) recovery area; c) adequate space for patient movement within the laboratory; d) adequate storage space for equipment, surgical supplies, linen, housekeeping equipment and pharmaceutical supplies including dangerous drugs; e) separate areas for collection and separate area for disposal of used equipment and waste; f) staff change and scrub rooms. EVIDENCE OF COMPLIANCE 1. Services as approved in the current Facility's licence. — NA 2. Design of the Invasive Cardiac Laboratory Services include (a) to (f). — NA 3. Space area complies with requirements from Radiation Safety Section, Engineering Services Division, Ministry of Health Malaysia. — NA	NA		NA		
9E.6.1.2.2 CORE	The design of the Invasive Cardiac Laboratory Services complies with fire safety requirements which include: a) fire detection, alarm and suppression systems; firefighting equipment and appropriate sign posting; b) adequate means of egress from the laboratory in the event of fire; c) ready access for routing emergency patients; d) free movement of patient trolleys throughout the laboratory with minimum cross traffic. EVIDENCE OF COMPLIANCE 1. Design of the Invasive Cardiac Laboratory Services complies with fire safety requirements which include (a) to (d). — NA	NA		NA		

	2.	Complies with requirements from Radiation Safety Section, Engineering Services Division, Ministry of Health Malaysia.	NA				
9E.6.1.2.3 CORE	Other systems include: a) adequate numbers of general power outlets distributed according to needs of each area; b) suitable lighting and at least one procedure light with uninterrupted power supply (UPS); c) environmental control of temperature and humidity within safe limits especially in procedure rooms; d) adequate provision for emergency electrical supply and suction of an appropriate nature complying with current Malaysian Standards; e) adequate numbers of various medical gas outlets and wall suction outlets and gadgets complying with current Malaysian Standards; f) fluoroscopy units shall have image intensifiers.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Invasive Cardiac Laboratory equipped with features listed (a) to (f).	NA				
	2.	Compliance with requirements from Radiation Safety Section, Engineering Services Division, Ministry of Health Malaysia.	NA				
9E.6.1.2.4 CORE	Safety features include: a) compliance with electrical standards for cardiac-protected or body-protected electrical areas, where required; b) electrical equipment complying with Malaysian Standards/Standards and Industrial Research Institute of Malaysia (SIRIM); c) appropriate shielding and protective clothing are provided in the presence of biohazards or radiographic equipment; d) schedule for regular maintenance and monitoring of mechanical and electrical facilities and biomedical equipment, and system of repair and replacement. Notes/Explanations Body protection means basically that every power point needs to be protected by 10 milliamp R.C.D's or a Safety Switch which is the same as in most houses but more sensitive to Earth Leakage Currents.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Safety features as stated in (a) to (d) are addressed in Invasive Cardiac Laboratory	NA				
	2.	Safety features complies with requirement from Radiation Safety Section, Engineering Services Division, Ministry of Health Malaysia.	NA				

9E.6.1.2.5 CORE	There is documented evidence that equipment complies with relevant national/international standards and current statutory requirements. EVIDENCE OF COMPLIANCE 1. Testing, commissioning and calibration records (certificates or stickers) — NA 2. Certification of equipment from certified bodies, e.g. Standards and Industrial Research Institute of Malaysia (SIRIM), etc as evidence of compliance to the relevant standards and Acts. — NA	NA			NA	
9E.6.1.2.6 CORE	There is evidence that the facility has a comprehensive maintenance programme such as predictive maintenance, planned preventive maintenance and calibration activities, to ensure the facilities and equipment are in good working order. Notes/Explanations a) Scheduled planned preventive maintenance applies to electric services, medical gases, air conditioning, major equipment, emergency and resuscitation equipment. b) Emergency biomedical equipment is thoroughly tested as a routine, e.g. defibrillator is discharged and output checked every day or after each use and the result is recorded. EVIDENCE OF COMPLIANCE 1. Planned Preventive Maintenance records, such as schedule, stickers, etc. — NA 2. Planned Replacement Programme where applicable — NA 3. Complaint records — NA 4. Asset inventory — NA	NA			NA	
9E.6.1.2.7 CORE	Where specialised equipment is used, there is evidence that only staff who are trained and authorised by the Facility operate such equipment. EVIDENCE OF COMPLIANCE 1. User training records — NA 2. Competency assessment record — NA 3. Letter of authorisation — NA 4. List of staff trained and authorised to operate specialised equipment — NA	NA			NA	

STANDARD STANDARD 9E.6.2
NON-INVASIVE CARDIAC LABORATORY SERVICES

STANDARD 9E.6.2.1: STAFFING, PROCESS AND SAFETY REQUIREMENTS
The Non-Invasive Cardiac Laboratory is constructed, equipped, operated, and maintained in a manner that enable adequate investigations of cardiac patients taking into consideration the safety of patients and staff, and in accordance to relevant regulatory requirements. Investigations requiring the use of radioactive substances shall not be carried out in this laboratory but in an area specially equipped to handle such substances to ensure safety of patients and staff.

CRITERION NO.	CRITERIA FOR COMPLIANCE	SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
				AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
9E.6.2.1.1 CORE	The Non-Invasive Cardiac Laboratory Services shall be under the appointed Head of Cardiology Services, and staffed by cardiologists, qualified technical, nursing and clerical staff. The number of staff shall commensurate with the number of investigations and treatment performed. EVIDENCE OF COMPLIANCE 1. Cardiologists registered with National Specialist Register (NSR) — NA 2. Letter of appointment/assignment — NA 3. Staff are credentialed and certified by approved institutions. — NA	NA			NA	
9E.6.2.1.2 CORE	Personnel working in non-invasive cardiac laboratory shall be assessed periodically with regards to competency in the operation of the equipment. In the operation of certain specific equipment, e.g. echocardiography, the personnel shall be credentialed and privileged to operate the machine. EVIDENCE OF COMPLIANCE 1. Credentialing and privileging process in place. — NA 2. List of personnel privileged and for specific procedures. — NA	NA			NA	
9E.6.2.1.3 CORE	The results of tests shall be reported and signed by the cardiologist/physician with adequate training. EVIDENCE OF COMPLIANCE 1. Results of tests are reported and signed by the cardiologist/physician with adequate training. — NA	NA			NA	

9E.6.2.1.4 CORE	Non-Invasive Cardiac Laboratory Services staff are represented on interdepartmental committees and involved in decision making on issues related to the provision of non-invasive cardiac laboratory services. EVIDENCE OF COMPLIANCE 1. Documented evidence on involvement interdepartmental committees, e.g. letters of appointment, etc. — NA 2. Minutes of meetings — NA	NA			NA	
9E.6.2.1.5 CORE	Written policies and procedures shall include the following: a) scheduling; b) the administration of drugs; c) the role of technical and paramedical personnel; d) the care of patients having special needs including those who are critically ill and those needing isolation facilities; e) response time for interpretations and reporting; f) patient identification, with verification of the nature of investigation and signed informed consent documents; g) infection control procedures, including aseptic technique, routine and terminal cleaning and procedures for infectious patients; h) patient management during recovery from investigative procedures; i) priorities for using the Non-Invasive Cardiac Laboratory Services time and space; j) the role of the Non-Invasive Cardiac Laboratory staff in the fire and disaster plans of the Facility. EVIDENCE OF COMPLIANCE 1. Policies and procedures address items (a) to (j). — NA	NA			NA	
9E.6.2.1.6 CORE	A manual of Technical Procedures and Routines shall be provided for relevant staff which include the following: a) electrocardiography (ECG); b) stress test; c) echocardiogram; d) HOLTER monitoring. EVIDENCE OF COMPLIANCE 1. A manual of Technical Procedures and Routines which include investigations listed (a) to (d) are available. — NA	NA			NA	
9E.6.2.1.7 CORE	There is evidence of compliance with guidelines to ensure patient and staff safety in the handling of, monitoring and investigative equipment and other items.	NA			NA	

	EVIDENCE OF COMPLIANCE 1. Observation on compliance with guidelines during survey — NA					
9E.6.2.1.8 CORE	Non-Invasive Cardiac Laboratory Services records are adequate for clinical, medicolegal, and evaluation purposes and these include the following: a) standard drug administration records are maintained, and statutory regulations relating to the control of drugs are followed; b) a record of the investigative procedure performed is written into the patients' medical records. Each record contains the indication for procedure, time and dose of all medications, details of the procedure performed, description of findings, proposed care plan, personnel involved, and post-investigative orders signed by the cardiologist/physician requesting the investigation. EVIDENCE OF COMPLIANCE 1. Non-Invasive Cardiac Laboratory Services records include items listed (a) to (b). — NA	NA			NA	
9E.6.2.1.9 CORE	Support services such as Critical Care Services (ICU/CCU) are available/accessible and where appropriate a cardiologist is on standby. Effective communication and relationships with these services are maintained. EVIDENCE OF COMPLIANCE 1. On-site ICU/CCU services available. — NA 2. Cardiothoracic surgeon on-site or agreement with other facility providing cardiothoracic surgery support. — NA	NA			NA	
9E.6.2.1.10 CORE	Safety instruction and safety precautions are implemented for the protection of both patients and staff. EVIDENCE OF COMPLIANCE 1. Safety instructions and safety precautions are available. — NA 2. Observation on implementation of safety precautions during survey — NA	NA			NA	

STANDARD STANDARD 9E.6.2
NON-INVASIVE CARDIAC LABORATORY SERVICES

STANDARD 9E.6.2.2: FACILITIES FOR NON-INVASIVE CARDIAC LABORATORY
There are appropriate and adequate physical facilities and equipment for the safe and efficient functioning of the Non-Invasive Cardiac Laboratory.

CRITERION NO.	CRITERIA FOR COMPLIANCE	SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
				AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
9E.6.2.2.1 CORE	The design of the Non-Invasive Cardiac Laboratory Services provides adequate space: a) for reception of patient awaiting procedures; b) adequate space and rooms for different investigative procedures to ensure privacy; c) adequate storage space for equipment, surgical supplies, linen, housekeeping equipment and pharmaceutical supplies; d) area for resuscitation. EVIDENCE OF COMPLIANCE 1. Services as approved in the current Facility's licence. — NA 2. Design of the Non-Invasive Cardiac Laboratory Services includes facilities listed (a) to (d). — NA	NA			NA	
9E.6.2.2.2 CORE	The design of the Non-Invasive Cardiac Laboratory Services complies with fire safety requirements which include: a) fire detection, alarm and suppression systems; firefighting equipment and appropriate sign posting; b) adequate means of egress from the laboratory in the event of fire; c) ready access for routing emergency patients; d) free movement of patients throughout the laboratory with minimum cross traffic. EVIDENCE OF COMPLIANCE 1. Design of the Invasive Cardiac Laboratory Services complies with fire safety requirements which include items listed (a) to (d). — NA	NA			NA	
9E.6.2.2.3 CORE	Other systems include: a) adequate numbers of general power outlets distributed according to needs of each area; b) suitable lighting; c) environmental control of temperature and humidity within safe limits especially in procedure rooms;	NA			NA	

	d) adequate numbers of oxygen outlets and wall suction outlets, emergency electric supply in rooms, e.g. where stress tests are performed; e) resuscitation trolley shall be readily available. EVIDENCE OF COMPLIANCE 1. Non-Invasive Cardiac Laboratory equipped with features listed (a) to (e). NA					
9E.6.2.2.4 CORE	Safety features include: a) electrical equipment complying with Malaysian Standards; b) schedule for regular maintenance and monitoring of mechanical and electrical facilities and biomedical equipment, and system of repair and replacement. EVIDENCE OF COMPLIANCE 1. Safety features as listed (a) to (b) are addressed in the Non- Invasive Cardiac Laboratory NA	NA			NA	
9E.6.2.2.5 CORE	There is documented evidence that equipment complies with relevant national/international standards and current statutory requirements. EVIDENCE OF COMPLIANCE 1. Testing, commissioning and calibration records (certificates or stickers) NA 2. Certification of equipment from certified bodies, e.g. Standards and Industrial Research Institute of Malaysia (SIRIM), etc as evidence of compliance to the relevant standards and Acts. NA	NA			NA	
9E.6.2.2.6 CORE	There is evidence that the facility has a comprehensive maintenance programme such as predictive maintenance, planned preventive maintenance and calibration activities, to ensure the facilities and equipment are in good working order. *Notes/Explanations* a) Scheduled planned preventive maintenance applies to electric services, medical gases, air conditioning, major equipment, emergency and resuscitation equipment. b) Emergency biomedical equipment is thoroughly tested as a routine, e.g. defibrillator is discharged and output checked every day or after each use and the result is recorded. EVIDENCE OF COMPLIANCE 1. Planned Preventive Maintenance records, such as schedule, stickers, etc. NA 2. Planned Replacement Programme where applicable NA	NA			NA	

	3.	Complaint records	NA				
	4.	Asset inventory	NA				
9E.6.2.2.7 CORE	Where specialised equipment is used, there is evidence that only staff who are trained and authorised by the Facility operate such equipment.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	User training records	NA					
	2.	Competency assessment record	NA					
	3.	Letter of authorisation	NA					
	4.	List of staff trained and authorised to operate specialised equipment	NA					

SERVICE SUMMARY	
-	
OVERALL RATING :	NA
OVERALL RISK :	-