

## SERVICE STANDARD 11 : OPERATING SUITE SERVICES

### PREAMBLE

*The Operating Suite Services have combined multidisciplinary healthcare personnel, e.g. surgeons, anaesthetists, nurses, theatre technician and other support staff in delivering a high standard of comprehensive patient care to those who require operative procedures during their stay in Healthcare Facility.*

*The multidisciplinary teams working in the operating suite provide operative care, anaesthetic, theatre care and recovery. Each aspect works together to provide a coherent working relationship, which ensures high levels of patient comfort, dignity and safety.*

*The operating suite promotes a culture of safe and evidence based practice that is monitored to meet:*

- a) expectations of patients;
- b) compliance with regulatory and statutory requirements;
- c) WHO Patient Safety Solutions
  - Safe Surgery Saves Lives

### TOPIC TOPIC 11.1

#### ORGANISATION AND MANAGEMENT

#### STANDARD STANDARD 11.1.1

The Operating Suite Services shall be directed and organised to provide safe and efficient perioperative care for patients. The services shall be coordinated with other services of the Facility.

CRITERION NO.	CRITERIA FOR COMPLIANCE		SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS			
					AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK	
11.1.1.1	Vision, Mission and values statements of the Facility are accessible. Goals and objectives that suit the scope of the Operating Suite 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 Operating Suite 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					
11.1.1.2 CORE	<p>There is an organisation chart which:</p> <p>a) provides a clear representation of the structure, functions and reporting relationships between the Person In Charge (PIC), Head of the Operating Suite Services, consultants, medical practitioners and staff of the Operating Suite Services;</p> <p>b) is accessible to all staff and clients;</p> <p>c) includes off-site services if applicable;</p> <p>d) is revised when there is a major change in any of the following:</p> <p>i) organisation;</p> <p>ii) functions;</p> <p>iii) reporting relationships;</p> <p>iv) staffing patterns.</p>			NA			NA	
	<b>EVIDENCE OF COMPLIANCE</b>							
	1.	Clearly delineated current organisation chart with line of functions and reporting relationships between the Person In Charge (PIC), Head of the Operating Suite Services, consultants, medical practitioners and staff of the Operating Suite Services.	NA					
	2.	Organisation chart of the service is endorsed, dated and accessible.	NA					
	3.	The organisation chart shall incorporate off-site Operating Suite Services offered by the facility.	NA					
	4.	The organisation chart is revised when there is a major change in any of the items (d)(i) to (iv).	NA					
11.1.1.3	<p>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 Operating Suite Services. Minutes are kept; decisions and resolutions made during meetings shall be accessible, communicated to all staff of the service and implemented.</p>			NA			NA	
	<b>EVIDENCE OF COMPLIANCE</b>							
	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					
11.1.1.4	The Operating Suite Services shall be guided by an Operating Theatre (OT) Committee (a subcommittee of MDAC) which consists of multidisciplinary users and providers of services.			NA			NA	
	<b>EVIDENCE OF COMPLIANCE</b>							
	1.	Letters of appointment for the Chairman and members of the Operating Theatre Committee.	NA					
	2.	Terms of Reference	NA					
11.1.1.5	The Operating Suite Services staff are represented on interdepartmental committees and involved in decision making on issues related to the provision of operating suite services.			NA			NA	
	<b>EVIDENCE OF COMPLIANCE</b>							
	1.	List of Interdepartmental Committees where OT staff representation is evidenced	NA					
	2.	Minutes of Interdepartmental Committee meetings on issues related to the provision of operating suite services.	NA					
11.1.1.6	The Head of Operating Suite Services is involved in the planning, justification and management of the budget and resource utilisation of the services.			NA			NA	
	<b>EVIDENCE OF COMPLIANCE</b>							
	1.	Minutes of management meeting	NA					
	2.	Documented evidence on request for allocation of budget and resources (staffing, equipment, etc) for the service.	NA					
	3.	Approved budget and resources	NA					
11.1.1.7	The Head of Operating Suite Services is involved in the appointment and/OR assignment of staff.			NA			NA	
	<b>EVIDENCE OF COMPLIANCE</b>							
	1.	Records on staff interview (if applicable)	NA					

	2.	Appointment/assignment letter of Head of Service	NA					
	3.	Job description of Head of Service	NA					
	4.	Records on staff deployment	NA					
	5.	Duty roster	NA					
11.1.1.8 CORE	The surgical and anaesthetic practices in the Operating Suite Services are consistent with the privileges conferred by the Credentialing and Privileging Committee and a copy of such privileges conferred shall be readily available upon request.			NA			NA	
	<b>EVIDENCE OF COMPLIANCE</b>							
	1.	List of privileges conferred to each practitioner for procedures at the operating theatre is available on-site.	NA					
	2.	Records on registration with National Specialist Register (NSR) for all specialists	NA					
11.1.1.9 CORE	The records maintained by the Operating Suite Services are adequate for clinical, medicolegal, and evaluation purposes and include the following: a) consent taken by surgeon and anaesthetist in writing and documented according to guidelines; b) a documented system for tissues/specimens sent for laboratory examination; c) a register of operations performed within the suite; d) standard anaesthetic and drug administration records and regulations relating to the control of drugs; e) a record of the surgical procedure performed which shall also be written into the patient's medical record. Each record contains details of the procedure and personnel involved, the dressings applied and drainage systems inserted, prostheses used, and the postoperative orders. Such entries in the records are signed with designation of the surgeon and dated accordingly.			NA			NA	
	<b>EVIDENCE OF COMPLIANCE</b>							
	1.	Records maintained at the operating suite includes but not limited to items listed (a) to (e).	NA					
	2.	Verification with on-site inspection of:						
	a)	consent taking as per Malaysian Medical Council Guidelines;	NA					
	b)	specimen book;	NA					
	c)	register on all operations done in the operating theatre;	NA					
	d)	drug administration records;	NA					

	e)	documentation on disposal of dangerous drugs as per Dangerous Drug Act (DDA) disposal guidelines;	NA					
	f)	patient medical records on details of procedure and surgeon/personnel involved.	NA					
11.1.1.10	Documented evidence of the counting of accountable (e.g. gauze, instruments etc) items used and a copy of the record is included in the patient's medical record.			NA			NA	
	<b>EVIDENCE OF COMPLIANCE</b>							
	1.	Swab count record in patient medical records	NA					
11.1.1.11	Support services such as radiology, pathology, and blood bank are available. Effective communication and relationships with these services are maintained.			NA			NA	
	<b>EVIDENCE OF COMPLIANCE</b>							
	1.	Cross departmental policies with related support services, i.e. blood bank.	NA					
	2.	Evidence of compliance to such policies as observed on-site.	NA					
11.1.1.12	Appropriate statistics and records shall be maintained in relation to the provision of Operating Suite Services and used for managing the services and patient care purposes.			NA			NA	
	<b>EVIDENCE OF COMPLIANCE</b>							
	1.	Records are available but not limited to the following:						
	a)	workload/census;	NA					
	b)	annual report;	NA					
	c)	accident/incident reports;	NA					
	d)	staffing number and staff profile;	NA					
	e)	staff training records;	NA					
	f)	data on performance improvement activities, including performance indicators.	NA					

## TOPIC TOPIC 11.2

## HUMAN RESOURCE DEVELOPMENT AND MANAGEMENT

## STANDARD STANDARD 11.2.1

The Operating Suite Services shall be directed by a qualified and competent medical practitioner, and staffed by suitably qualified and competent clinical staff to achieve the goals and objectives of the services. Staff of the services have access to appropriate education programmes to maintain and improve their knowledge and skills.

CRITERION NO.	CRITERIA FOR COMPLIANCE			SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
						AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
11.2.1.1	The Head and staff of the Operating Suite Services shall be individuals qualified by education, training, experience and certification to commensurate with the requirements of the various positions.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Records on credentials of Head of Service and staff required to fill up the posts within the service (to match the complexity of the Facility and services) and certification/registration.	NA					
	2.	Appointment/assignment letters	NA					
	3.	Training and competency records	NA					
11.2.1.2	The authority, responsibilities and accountabilities of the Head of Operating Suite Services are clearly delineated and documented.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Appointment/assignment letter for Head of Service.	NA					
	2.	Description of duties and responsibilities	NA					
11.2.1.3	The Operating Suite Services are managed by a perioperative trained registered nurse who is experienced in operating suite nursing and who has management skills.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Letter of appointment and credentials of Operating Suite Services Nurse Manager/Sister	NA					
11.2.1.4	Sufficient numbers of personnel and support staff with appropriate qualifications are employed to meet the need of the services.			NA			NA	

	<b>EVIDENCE OF COMPLIANCE</b>							
	1.	Number of staff and qualification should commensurate with workload.	NA					
	2.	Staffing pattern (60% of scrub nurses are perioperative trained or at least one perioperative trained nurse per operating room) and this will include dedicated anaesthetic assistants (with post basic training) at least one (1) per operating theatre and staffing in recovery rooms to be at least one (1) qualified nurse to three (3) patients.	NA					
	3.	Duty roster	NA					
	4.	Census and statistics	NA					
11.2.1.5	<p>There are written and dated specific job descriptions for all categories of staff that include:</p> <p>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.</p> <p>e) administrative and clinical functions.</p>			NA			NA	
	<b>EVIDENCE OF COMPLIANCE</b>							
	1.	Updated specific job description is available for each staff that includes but not limited to as listed in (a) to (e) for the proper functioning of the Operation Suite Services	NA					
	2.	Job description includes specialisation skills	NA					
	3.	Relevant privileges granted where applicable	NA					
	4.	The nature and scope of work of each staff is specified.	NA					
	5.	The job description is acknowledged by the staff and signed by the Head of Service and dated.	NA					

11.2.1.6	<p>Personnel records on training, staff development, leave and others are maintained for every staff.</p> <p><b>Note:</b> Staff personal record may be kept in Human Resource Department as per Facility policy.</p> <table><tr><th colspan="3">EVIDENCE OF COMPLIANCE</th></tr><tr><td>1.</td><td colspan="2">Staff personal records include:</td></tr><tr><td>a)</td><td>staff biodata;</td><td>NA</td></tr><tr><td>b)</td><td>qualification and experience;</td><td>NA</td></tr><tr><td>c)</td><td>evidence of current registration;</td><td>NA</td></tr><tr><td>d)</td><td>training record;</td><td>NA</td></tr><tr><td>e)</td><td>competency record and privileging;</td><td>NA</td></tr><tr><td>f)</td><td>leave record;</td><td>NA</td></tr><tr><td>g)</td><td>confidentiality agreement.</td><td>NA</td></tr></table>	EVIDENCE OF COMPLIANCE			1.	Staff personal records include:		a)	staff biodata;	NA	b)	qualification and experience;	NA	c)	evidence of current registration;	NA	d)	training record;	NA	e)	competency record and privileging;	NA	f)	leave record;	NA	g)	confidentiality agreement.	NA	NA			NA	
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e)	competency record and privileging;	NA																															
f)	leave record;	NA																															
g)	confidentiality agreement.	NA																															
11.2.1.7	<p>There is a structured orientation programme for all newly appointed staff to the Operating Suite Services including medical practitioners and for those new to specific areas that include the following:</p> <p>a) explanation of the goals, objectives, policies and procedures of the Facility and those of the Operating Suite 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; 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 Operating Suite Services; k) education on Patient and Family Rights; l) education on MSQH Standards requirements.</p> <table><tr><th colspan="3">EVIDENCE OF COMPLIANCE</th></tr><tr><td>1.</td><td>Policy requiring all new staff to attend a structured orientation programme.</td><td>NA</td></tr></table>	EVIDENCE OF COMPLIANCE			1.	Policy requiring all new staff to attend a structured orientation programme.	NA	NA			NA																						
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	2.	There is Operating Suite Services orientation programme with relevant topics not limited to topics covered from (a) to (l).	NA					
	3.	Attendance list	NA					
11.2.1.8	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.			NA			NA	
	<b>EVIDENCE OF COMPLIANCE</b>							
	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					
11.2.1.9	There are continuing education activities for staff including medical practitioners to pursue professional interests and to prepare for current and future changes in practice. Such programmes shall include but not limited to the following:  a) new surgical, anaesthetic, and operating suite procedures; b) regular fire and evacuation drills; c) resuscitation techniques; d) the use of new equipment in surgical operations and its maintenance and calibration; e) prevention and control of infection.			NA			NA	
	<b>EVIDENCE OF COMPLIANCE</b>							
	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					
11.2.1.10	Professional staff are actively assisted to attend relevant programmes conducted by their professional groups, other related associations, and educational institutions. Where the Facility cannot provide the necessary programme, cooperation is sought from external sources.			NA			NA	

	EVIDENCE OF COMPLIANCE							
	1.	Records on continuing professional education activities for staff.	NA					
	2.	Training records for degree or post-graduate training programmes	NA					
	3.	Certificate of attendance or CPD points at conferences	NA					
11.2.1.11	Staff including medical practitioners receive evaluation of their performance at the completion of the probationary period and annually thereafter, or as defined by the Facility.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Performance appraisal for staff including medical practitioners is completed upon probationary period and as an annual exercise.	NA					
11.2.1.12	In a teaching facility, the Operating Suite Services shall provide educational needs and teaching for undergraduates and postgraduates without compromising patient safety and comfort.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Memorandum of Understanding (MOU)	NA					
	2.	Compliance with the Terms of MOU	NA					
	3.	Ratio of supervisor to students	NA					
	4.	Log books	NA					
	5.	Assessment reports	NA					
	6.	Training timetable, continuing medical education and attendances list.	NA					
11.2.1.13	Where Facility has responsibilities in teaching and research, the staff cooperate and participate in these programmes as required.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Attendance list at teaching workshops	NA					
	2.	List of research papers	NA					

TOPIC TOPIC 11.3  
POLICIES AND PROCEDURES

STANDARD STANDARD 11.3.1

There are written and dated policies and procedures for all the activities of the Operating Suite Services. These policies and procedures reflect the current standards of operating suite practice, relevant regulations, statutory requirements, and the objectives of the services.

CRITERION NO.	CRITERIA FOR COMPLIANCE	SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS				
				AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK		
11.3.1.1 CORE	There are written policies and procedures for the Operating Suite 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 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
11.3.1.2	Policies and procedures are developed by a committee in collaboration with staff, medical practitioners, Management and where required with other external service providers and with reference to relevant sources involved. These policies and procedures are consistent with current international standards for perioperative care  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

	4.	Evidence that policies and procedures are consistent with current international standards of perioperative care.	NA					
11.3.1.3	Current policies and procedures are communicated to all staff.			NA			NA	
	<b>EVIDENCE OF COMPLIANCE</b>							
	1.	Training and briefing on the current policies and procedures/Minutes of meetings	NA					
	2.	Circulation list and acknowledgement	NA					
11.3.1.4 CORE	There is evidence of compliance with policies and procedures.			NA			NA	
	<b>EVIDENCE OF COMPLIANCE</b>							
	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 i.e. Safe Surgery Saves Lives (SSSL) initiatives;	NA					
	d)	practices not in line with established policies and procedures noted from incident reports.	NA					
11.3.1.5	Copies of policies and procedures, protocols, guidelines, relevant Acts, Regulations, By-Laws and statutory requirements are accessible to staff.			NA			NA	
	<b>EVIDENCE OF COMPLIANCE</b>							
	1.	Copies of policies and procedures, protocols, guidelines, relevant Acts, Regulations, By-Laws and statutory requirements are accessible on-site for staff reference.	NA					
11.3.1.6 CORE	Written policies and procedures include the following: a) booking system for all cases; b) development of guidelines to ensure patient and staff safety which include: i) patient transport; ii) patient positioning; iii) drug administration and errors; iv) handling and disposal of sharps; v) prevention of electrical hazards; vi) prevention of fire and explosion; vii) prevention of anaesthetic equipment hazards;			NA			NA	

	<p>viii) maintenance of scavenging equipment for removal of various vapours and anaesthetic gases;</p> <p>ix) notification of biohazards;</p> <p>x) prevention of radiation hazards;</p> <p>c) compliance to World Health Organization (WHO) Patient Safety, 'Safe Surgery Saves Lives', safety checklist - "Time out".</p> <p>d) patient identification, with the nature and site of the operation marked and verified by the surgeon and the consent documents checked.;</p> <p>e) infection control procedures, including aseptic technique, routine and terminal cleaning, and procedures for infectious patients;</p> <p>f) counting procedures for accountable items including the procedures to be adopted in the event of incorrect counts;</p> <p>g) patient management during recovery from anaesthesia and surgery;</p> <p>h) the role of the Operating Suite Services in the fire and disaster plans of the Facility;</p> <p>i) priorities in the use of operating suite time and space;</p> <p>j) "Group Cross Match" and "Screen and hold" policy for blood transfusion practices for patients undergoing surgery;</p> <p>k) clear communication lines for obtaining emergency blood and blood products for cases of unexpected haemorrhage.</p> <p>l) Clear written policies and procedure for the involvement of vendor in providing specialized equipment/consumables for patient care in the operation theater where applicable</p>				
EVIDENCE OF COMPLIANCE					
1.	Policies and procedures include all but not limited to the elements listed in (a) to (k).	NA			
2.	Documentation that Safe Surgery Saves Lives activities have been carried out and shortfalls discussed with actions taken.	NA			
3.	Policy on when to open a second emergency operating theatre, i.e. prioritisation for emergency surgery.	NA			

**TOPIC TOPIC 11.4**  
**FACILITIES AND EQUIPMENT**

**STANDARD STANDARD 11.4.1**

*There are adequate physical facilities and equipment for the safe and efficient functioning of the Operating Suite Services.*

CRITERION NO.	CRITERIA FOR COMPLIANCE			SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS											
						AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK									
11.4.1.1	<p>The design of the Operating Suite Services provides adequate space for the reception, anaesthesia induction, surgery, post-surgical recovery and observation of patients. This shall include:</p> <p>a) suitable areas for reception and for patients awaiting surgery; b) operating theatres; c) recovery area; d) adequate storage space for equipment, surgical supplies, linen, housekeeping equipment, and pharmaceutical supplies, including dangerous and psychotropic drugs; e) areas for administrative office, and where required, teaching facilities; f) areas for the collection and disposal of used equipment and waste; g) male and female staff change rooms; h) staff facilities like tea room, locker area, on-call room; i) there is plan for providing improved staff facilities when the Facility undergoes refurbishment or redevelopment if any of the above are deemed inadequate.</p> <table><tr><th colspan="3">EVIDENCE OF COMPLIANCE</th></tr><tr><td>1.</td><td>The design and layout of the Operating Suite Services provide adequate space and includes features as listed in (a) to (i).</td><td>NA</td></tr><tr><td>2.</td><td>Where the Post-Anaesthesia Care Unit (PACU) is located for patients requiring ventilation and critical care, there is a policy for staffing, ventilation and monitoring of the patient.</td><td>NA</td></tr></table>			EVIDENCE OF COMPLIANCE			1.	The design and layout of the Operating Suite Services provide adequate space and includes features as listed in (a) to (i).	NA	2.	Where the Post-Anaesthesia Care Unit (PACU) is located for patients requiring ventilation and critical care, there is a policy for staffing, ventilation and monitoring of the patient.	NA	NA			NA	
EVIDENCE OF COMPLIANCE																	
1.	The design and layout of the Operating Suite Services provide adequate space and includes features as listed in (a) to (i).	NA															
2.	Where the Post-Anaesthesia Care Unit (PACU) is located for patients requiring ventilation and critical care, there is a policy for staffing, ventilation and monitoring of the patient.	NA															
11.4.1.2	<p>The design of the Operating Suite Services supports efficient systems for the management of perioperative services which include:</p> <p>a) operating rooms are treated as "clean" rooms with yearly performance test undertaken to ensure "clean" room status is maintained;</p>			NA			NA										

	<p>b) fire detection, alarm, and suppression systems; firefighting equipment and appropriate sign posting;</p> <p>c) ventilation system should provide positive pressure from the cleanest areas to less clean area;</p> <p>d) definitive traffic flow patterns and demarcation of sterile and non-sterile zones which enable enforcement of sterility discipline;</p> <p>e) ready access for routing emergency patients;</p> <p>f) adequate means of egress from the operating suite in the event of fire;</p> <p>g) free movement of patient trolleys throughout the suite with a minimum of cross traffic;</p> <p>h) reception of the patient in close proximity to the junction of sterile and non-sterile zones (air-lock zone);</p> <p>i) uninterrupted power supply (UPS) system in operating theatres shall be provided with an alarm system at the reception counter which will be triggered when the system is not charged;</p> <p>j) the medical gas system in the operating theatres shall be monitored to ensure that it is functioning;</p> <p>k) the quantity of medical gas terminal units be sufficient as required under national and international standards;</p> <p>l) colour coding for electrical outlets shall be according to international standards.</p>				
<b>EVIDENCE OF COMPLIANCE</b>					
1.	The design and layout of the Operating Suite Services provide adequate space and includes features as listed in (a) to (l)	NA			
2.	Internal air quality report (IAQ) report, i.e. temperature and humidity confirms to relevant standards.	NA			
3.	Fire escape plan clearly posted.	NA			
4.	Verification of the appropriateness of the design of the operating suite by onsite inspection.	NA			

	5.	Log book on medical gas monitoring	NA														
11.4.1.3	The requirements for other systems to support perioperative services include:  a) adequate numbers of general power outlets distributed according to needs of each area;  b) adequate provision for emergency power outlets for lighting and suction of an appropriate nature complying with current Malaysian Standards;  c) suitable lighting;  d) adequate medical gas and suction supplies complying with current Malaysian Standards;  e) a means of environmental control of temperature and humidity within safe limits for anaesthetised patients undergoing surgery/procedures.  <b>Note:</b> Environmental control shall ensure that air quality complies with relevant standards for various treatment or functional areas in respect of temperature, relative humidity and particle count.  <b>EVIDENCE OF COMPLIANCE</b> <table><tr><td>1.</td><td>Verification of other support systems in the operating suite includes items listed (a) to (e).</td><td>NA</td></tr><tr><td>2.</td><td>Evidence of minimum of two suction ports (one for anaesthesia and one for surgeon) per operating room. (If inadequate, then there must be portable suction devices for operating theatre needs)</td><td>NA</td></tr><tr><td>3.</td><td>Temperature maintained at 18°C - 22°C and relative humidity 50% - 60%.</td><td>NA</td></tr></table>			1.	Verification of other support systems in the operating suite includes items listed (a) to (e).	NA	2.	Evidence of minimum of two suction ports (one for anaesthesia and one for surgeon) per operating room. (If inadequate, then there must be portable suction devices for operating theatre needs)	NA	3.	Temperature maintained at 18°C - 22°C and relative humidity 50% - 60%.	NA	NA			NA	
1.	Verification of other support systems in the operating suite includes items listed (a) to (e).	NA															
2.	Evidence of minimum of two suction ports (one for anaesthesia and one for surgeon) per operating room. (If inadequate, then there must be portable suction devices for operating theatre needs)	NA															
3.	Temperature maintained at 18°C - 22°C and relative humidity 50% - 60%.	NA															
11.4.1.4	The Operating Suite Services shall comply with all safety features in accordance with regulatory requirements which include:  a) compliance with electrical standards for cardiac-protected or body-protected electrical areas, where required. In critical life support applications where loss of power supply cannot be tolerated, special power outlets powered by isolation transformers Line Isolation and Overload Monitor (LIOM) are installed;  b) scavenging of anesthetic gases and vapors;			NA			NA										



	<p>c) regular maintenance and monitoring of facilities and equipment, and a system to respond immediately to breakdown, repair, and replacement;</p> <p>d) electrical equipment which comply with Malaysian Standards;</p> <p>e) appropriate shielding and protective clothing are provided in the presence of biohazards or radiographic equipment.</p> <p><b>Note:</b> Body Protection means basically that every power point needs to be protected by 10milli amp R.C.D.'s or a safety switch which is the same as in most houses but more sensitive to earth leakage currents. This includes dental chairs and X-ray machines</p> <table><tr><th colspan="3">EVIDENCE OF COMPLIANCE</th></tr><tr><td>1.</td><td>The operating theatre complies with all safety features in accordance to regulatory requirements as addressed in (a) to (e).</td><td>NA</td></tr><tr><td>2.</td><td>Verification of the above through on-site inspection.</td><td>NA</td></tr><tr><td>3.</td><td>Warning signs if radiology equipment is in use</td><td>NA</td></tr><tr><td>4.</td><td>If operating theatre is not lead-lined, there must be adequate protective shields available.</td><td>NA</td></tr></table>	EVIDENCE OF COMPLIANCE			1.	The operating theatre complies with all safety features in accordance to regulatory requirements as addressed in (a) to (e).	NA	2.	Verification of the above through on-site inspection.	NA	3.	Warning signs if radiology equipment is in use	NA	4.	If operating theatre is not lead-lined, there must be adequate protective shields available.	NA				
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11.4.1.5 CORE	<p>The requirements for equipment used in the Operating Suite Services shall include the following:</p> <p>a) a range of basic and general surgical equipment in quantities sufficient to support the surgical programme;</p> <p>b) where specialised equipment appropriate to the surgical procedure is provided by the surgeon, such equipment shall have prior approval by the Person In Charge (PIC) of the Facility and shall be checked to comply with the relevant safety requirements and be appropriately sterilised before use;</p> <p>c) minimum standards for monitoring in anaesthesia as defined by the Malaysian Society of Anesthesiologists or the College of Anaesthesiologists of the Academy of Medicine of Malaysia (current edition);</p> <p>d) emergency and resuscitation equipment and supplies; with clearly defined instructions on how to operate the equipment and there is evidence that staff are trained to use the equipment;</p> <p>e) availability of point of care testing equipment for urgent laboratory tests (e.g. Arterial Blood Gas investigation) OR process to ensure that results of such tests sent to the laboratory can be reported immediately;</p>	NA			NA															

	<p>f) there shall be a blood refrigerator or alternative storage facilities for group and cross matched blood in the operating room.</p> <table><tr><td colspan="3">EVIDENCE OF COMPLIANCE</td></tr><tr><td>1.</td><td>The requirements for equipment used in the Operating Suite Services shall include items (a) to (f).</td><td>NA</td></tr><tr><td>2.</td><td>Verification of above through on-site inspection</td><td>NA</td></tr><tr><td>3.</td><td>Policy on handling and maintenance of borrowed equipment</td><td>NA</td></tr><tr><td>4.</td><td>. Resuscitation drugs and equipment are in accordance to "Recommendations for Patient Safety and Minimal Monitoring Standards during Anaesthesia and Recovery" (Current Edition).</td><td>NA</td></tr></table>	EVIDENCE OF COMPLIANCE			1.	The requirements for equipment used in the Operating Suite Services shall include items (a) to (f).	NA	2.	Verification of above through on-site inspection	NA	3.	Policy on handling and maintenance of borrowed equipment	NA	4.	. Resuscitation drugs and equipment are in accordance to "Recommendations for Patient Safety and Minimal Monitoring Standards during Anaesthesia and Recovery" (Current Edition).	NA					
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11.4.1.6	<p>There is documented evidence that equipment complies with relevant national/international standards and current statutory requirements.</p> <table><tr><td colspan="3">EVIDENCE OF COMPLIANCE</td></tr><tr><td>1.</td><td>Testing, commissioning and calibration records (certificates or stickers)</td><td>NA</td></tr><tr><td>2.</td><td>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.</td><td>NA</td></tr></table>	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							
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11.4.1.7	<p>Emergency biomedical equipment is thoroughly tested as a routine, e.g. defibrillators are discharged and output checked every day or after each use, and the results recorded.</p> <table><tr><td colspan="3">EVIDENCE OF COMPLIANCE</td></tr><tr><td>1.</td><td>Records on regular inspection and checking biomedical equipment (electrocardiogram strips for defibrillator)</td><td>NA</td></tr><tr><td>2.</td><td>Policy and schedule on checking biomedical equipment</td><td>NA</td></tr></table>	EVIDENCE OF COMPLIANCE			1.	Records on regular inspection and checking biomedical equipment (electrocardiogram strips for defibrillator)	NA	2.	Policy and schedule on checking biomedical equipment	NA	NA			NA							
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11.4.1.8 CORE	<p>There is evidence that the facility has a comprehensive maintenance programmed such as predictive maintenance, planned preventive maintenance and calibration activities, to ensure the facilities and equipment are in good working order.</p> <table><tr><td colspan="3">EVIDENCE OF COMPLIANCE</td></tr><tr><td>1.</td><td>Planned Preventive Maintenance records such as schedule, stickers, etc.</td><td>NA</td></tr></table>	EVIDENCE OF COMPLIANCE			1.	Planned Preventive Maintenance records such as schedule, stickers, etc.	NA	NA			NA										
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	2.	Planned Replacement Programme where applicable	NA					
	3.	Complaint records	NA					
	4.	Asset inventory	NA					
11.4.1.9	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						

## TOPIC TOPIC 11.5

## SAFETY AND PERFORMANCE IMPROVEMENT ACTIVITIES

## STANDARD STANDARD 11.5.1

*The Head of the Operating Suite Services shall ensure the provision of quality performance with staff involvement in the continuous safety and performance improvement activities of the Operating Suite Services. The Head of Operating Suite 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
11.5.1.1	There are planned and systematic safety and performance improvement activities to monitor and evaluate the performance of the Operating Suite 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					
11.5.1.2	The Head of Operating Suite Services has assigned the responsibilities for planning, monitoring and managing safety and performance improvement 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					
11.5.1.3	The Head of the Operating Suite 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.  <div>EVIDENCE OF COMPLIANCE</div> <div>1. System for incident reporting is in place, which include:<div>a) Training of staffNA</div><div>b) Policy on incident reportingNA</div><div>c) Methodology of incident reportingNA</div><div>d) Register/records of incidentsNA</div>2. Completed incident reportsNA</div> <div>3. Root Cause AnalysisNA</div> <div>4. Corrective and preventive action plansNA</div> <div>5. Remedial measureNA</div> <div>6. Minutes of meetingsNA</div> <div>7. Acknowledgment by Head of Service and PIC/Hospital DirectorNA</div> <div>8. Feedback given to staff regarding incident reporting.NA</div>			NA			NA	
11.5.1.4 CORE	There is tracking and trending of specific performance indicators not limited to but at least of the following, a minimum of 5 indicators: <div>a) Mandatory indicator compliance to Safe Surgery Saves Lives (SSSL) practice</div> <div>b) elective operation cancellation rate (Target: &lt;10%)</div> <div>c) percentage of patients awaiting emergency surgery for more than 24 hours due to lack of theatre time (Target: &lt;1%);</div> <div>d) number of patients returning to surgery within 24 hours (sentinel event)</div> <div>e) time taken for lower segment caesarean section (LSCS) for fetal distress within 30 minutes of informing operating theatre (sentinel event)</div> <div>f) number of unnecessary delay in starting surgery after induction of anaesthesia due to lack of personnel or equipment (sentinel event)</div> <div>g) number of incidents reported in the operating room</div>			NA			NA	

	h) number of peri-operative mortality and morbidity review i) percentage of cases done as day care or day of surgery admission (DOSa) (30% of all surgeries) j) number of adverse events following positioning (sentinel event)					
	<b>EVIDENCE OF COMPLIANCE</b>					
	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				
11.5.1.5	Feedback on results of safety and performance improvement activities are regularly communicated to the staff.	NA			NA	
	<b>EVIDENCE OF COMPLIANCE</b>					
	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/committee meetings	NA				
11.5.1.6	Appropriate documentation of safety and performance improvement activities is kept and confidentiality of medical practitioners, staff and patients is preserved.	NA			NA	
	<b>EVIDENCE OF COMPLIANCE</b>					
	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				

SERVICE SUMMARY

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OVERALL RATING : NA

OVERALL RISK : -