SERVICE STANDARD 19: CENTRAL STERILISING SUPPLY SERVICES (CSSS)

PREAMBLE

The Central Sterilising Supply Services (CSSS) provide sterilising services for all areas within the Facility. It shall comprise of all activities relating to disinfection and sterilisation processes in the Facility. The services shall be located to:

a) avoid contamination of clean and sterile supplies and equipment;
b) prevent heat and noise to patient care areas;
c) eliminate thoroughfare traffic;
d) facilitate delivery and return of supplies and equipment to and from other services and/or external facility.

The scope of services at the Central shall include:

a) To receive, decontaminate (disassembling, washing, cleaning, disinfection and dry), packaging (inspection, functionality check and packing) and sterilization of reusable medical devices to a level that provides an assurance of sterility.
b) Disinfection and sterilization for Robotic Instruments.
c) Disinfection and sterilization of Rigid Endoscopic instruments
d) Preparation and Sterilization of soft goods before distribution to healthcare facilities.
e) Preparation and sterilization of reusable surgical textiles (dressing towels, operation gown, draped)
f) Sterile storage and distribution

Facilities that do not have their own CSSS or cannot provide a full range of services, shall arrange with an external facility to provide the services needed. The services provided by the external facility shall comply with the relevant MSQH Standards of Accreditation.

TOPIC TOPIC 19.1
ORGANISATION AND MANAGEMENT

STANDARD STANDARD 19.1.1

The Central Sterilising Supply Services (CSSS) is organised and administered to provide optimum support and service to patient care providers according to the goals and objectives of the Facility. The Head of CSSS shall be a healthcare professional with relevant professional certification and experience in infection control and management of supply and processing of CSSS.

CRITERION NO.	CRITERIA FOR COMPLIANCE	SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
				AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
19.1.1.1	Vision, Mission and values statements of the Facility are accessible. Goals and objectives that suit the scope of the Central Sterilising Supply Services are clearly documented and measurable. 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 Central Sterilising Supply 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				
19.1.1.2 CORE	There is an organisation chart which: a) provides a clear representation of the structure, functions and reporting relationships between the Head and staff of Central Sterilising Supply Services; b) is accessible to all staff and clients; c) includes off-site services if applicable; d) 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 Head and staff of Central Sterilising Supply 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 (d)(i) to (iv)	NA				
19.1.1.3	Where sterilisation services are provided in areas other than the main CSSS, for example operating theatre (OT), Dental Services, responsibility for the operation of these services is the Head of the CSSS and is clearly defined.		NA			NA	

	Appropriate instructions and supervision of staff equipment maintenance and quality control are carried out and documented. EVIDENCE OF COMPLIANCE 1. Letter of authorisation from the Person In Charge (PIC) that all sterilisation activities within the Facility which includes Dental, Endoscopy, operating suite services, etc to be monitored by the Head of CSSS. — NA 2. Documentation on regular monitoring of the sterilisation services outside the CSSS within the Facility to ensure effectiveness of the disinfection and sterilising process including validation. — NA					
19.1.1.4	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 Central Sterilising Supply 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	
19.1.1.5	The Head of Central Sterilising Supply Services is involved in the planning, justification and management of the budget and resource utilisation of the services. EVIDENCE OF COMPLIANCE 1. Minutes of Facility-wide management meeting – indicates Head of CSSS is involved in the planning, management and justification of the budget and resource utilisation of CSSS facilities and services. — 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	NA			NA	

19.1.1.6	The Head of the CSSS is involved in the appointment and/OR assignment of the staff. **EVIDENCE OF COMPLIANCE** 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	NA			NA	
19.1.1.7	Appropriate statistics and records shall be maintained in relation to the provision of CSSS and used for managing the services and patient care purposes. **EVIDENCE OF COMPLIANCE** 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	NA			NA	

STANDARD STANDARD 19.1.2

Facilities that do not have their own CSSS or cannot provide a full range of services, shall arrange with an external facility to provide the services needed. The services provided by the external facility shall comply with the relevant MSQH Standards of Accreditation.

CRITERION NO.	CRITERIA FOR COMPLIANCE	SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
				AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
19.1.2.1	The services are approved by the Person In Charge (PIC) of the Facility. EVIDENCE OF COMPLIANCE 1. Evident of a valid agreement between external service provider and the Facility describing the Terms of Agreement including adequate number of appropriately qualified personnel on-site as approved by PIC of the Facility. — NA	NA			NA	
19.1.2.2	The external providers of the CSSS shall comply with all relevant MSQH Standards of Accreditation. EVIDENCE OF COMPLIANCE 1. External providers of CSSS comply with the requirements of MSQH Standards for the service. — NA	NA			NA	
19.1.2.3 CORE	Where CSSS are provided by an external source, there is a written agreement between the external service provider and the Facility stating the requirements for the services that include the following: a) formal lines of communication and responsibilities between the external service provider and the Facility; b) provision of adequate numbers of appropriately qualified personnel to perform their duties; c) participation, as appropriate, of the external service provider in committees of the Facility; d) arrangement for adequate pickup and delivery; e) arrangements for after-hours and emergency services; f) mechanisms for dealing with problems in service delivery;	NA			NA	

g) adequate facilities and equipment for providing the services at the Facility and at the site of the external services for decontamination, sterilisation, packaging, storage and issuance of supplies;

h) involvement of the external service provider in safety and performance improvement activities of the Facility, as appropriate;

i) comply with the appropriate MSQH Standards of Accreditation for CSSS which functions within the Facility.

EVIDENCE OF COMPLIANCE		
1.	Agreement between external service provider and the Facility address the requirements for the service but not limited to items (a) to (i).	NA
2.	Reports on verification (visits) on the provision of CSSS services provided by the external source based on:	
a)	established policies and procedures;	NA
b)	records and analysis report related to safety and performance improvement activities	NA
c)	regular audits of the site to verify the services involving decontamination, sterilisation, packaging, storage and issuance of supplies;	NA
d)	evidence of related audit reports;	NA
e)	evidence of valid autoclave licence by the Department of Occupational Safety and Health and operated by trained autoclave operator(s).	NA

TOPIC TOPIC 19.2
HUMAN RESOURCE DEVELOPMENT AND MANAGEMENT

STANDARD STANDARD 19.2.1
The CSSS is managed by a healthcare professional with the relevant professional certification and experience in infection control and in the management of supply and processing of CSSS and is adequately staffed to achieve the goals and objectives of the CSSS.

CRITERION NO.	CRITERIA FOR COMPLIANCE		SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
					AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
19.2.1.1 CORE	The Head of CSSS shall be a healthcare professional with training and experience and shall be responsible to coordinate all (on-site or off-site) disinfection and sterilisation processes in the Facility.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Duties and responsibilities for disinfection and sterilisation processes are:					
	a)	prescribed in the job description of Head of CSSS;	NA				
	b)	described in the services' policy	NA				
19.2.1.2	The Head and staff of the CSSS 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 registration.	NA				
	2.	Minimum post basic trained in perioperative care with CSSS module for Head of Service	NA				
	3.	Appointment letters	NA				
	4.	Certification where required, i.e. autoclave operator	NA				
	5.	Training and competency records including training in infection control and privileging for specific job scope.	NA				
19.2.1.3	The authority, responsibilities and accountabilities of the Head of CSSS are clearly delineated and documented.		NA			NA	
	EVIDENCE OF COMPLIANCE						

	1.	Appointment letter for Head of Service	NA				
	2.	Description of duties and responsibilities.	NA				
19.2.1.4	Sufficient numbers of personnel and support staff with appropriate qualifications are employed to meet the need of the services. EVIDENCE OF COMPLIANCE			NA			NA	
	1.	Number of staff and qualification should commensurate with workload.	NA				
	2.	Staffing pattern	NA				
	3.	Duty roster	NA				
	4.	Workload census and statistics	NA				
19.2.1.5	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) accountabilities, 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. EVIDENCE OF COMPLIANCE			NA			NA	
	1.	Updated specific job description is available for each staff that includes but not limited to as listed in (a) to (d).	NA				
	2.	Job description includes specialisation skills	NA				

	3.	Relevant privileges granted where applicable/authorisation to operate specialised equipment , e.g. autoclave	NA				
	4.	The job description is acknowledged by the staff and signed by the Head of Service/Unit and dated.	NA				
19.2.1.6	Personnel records on training, staff development, leave and others are maintained for every staff. Note: Staff personal record may be kept in Human Resource Department as per Facility policy		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Staff personal records include:					
	a)	staff biodata;	NA				
	b)	qualification and experience;	NA				
	c)	training record;	NA				
	d)	competency record and privileging/authorisation to operate specialised equipment, e.g. autoclave;	NA				
	e)	leave record;	NA				
	f)	confidentiality agreement.	NA				
	g)	immnunisation records	NA				
19.2.1.7 CORE	Provision of vaccination programmes for all staff exposed to sharps injury and biological hazards.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Vaccination programme	NA				
	2.	Vaccination records	NA				
19.2.1.8	There is a structured orientation programme where new staff are briefed on their services, operational policies and relevant aspects of the Facility to prepare them for their roles and responsibilities.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Policy requiring all new staff to attend a structured orientation programme.	NA				

	2.	Records on structured orientation programme	NA				
	3.	Orientation Brief	NA				
	4.	List of attendance	NA				
19.2.1.9	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	
	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				
19.2.1.10	There are continuing education activities for staff to pursue professional interests and to prepare for current and future changes in practice.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Continuing education activities and schedule	NA				
	2.	Contents of training programme	NA				
	3.	Training records on continuing education activities are kept and maintained for each staff.	NA				
	4.	Certificate of attendance/degree/post basic training.	NA				
19.2.1.11	Staff 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 is completed upon probationary period and as an annual exercise.	NA				

TOPIC TOPIC 19.3
POLICIES AND PROCEDURES

STANDARD STANDARD 19.3.1
There are documented policies and procedures that reflect current principles of disinfection and sterilising practices and processes of CSSS. These policies and procedures shall be consistent with relevant regulations, statutory requirements and goals and objectives of the CSSS.

CRITERION NO.	CRITERIA FOR COMPLIANCE	SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
				AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
19.3.1.1 CORE	There are written policies and procedures for the CSSS 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. **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	NA			NA	
19.3.1.2	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. Cross departmental collaboration is practised in developing relevant policies and procedures where applicable, e.g. infection control in Central Sterilising Supply Services. **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	NA			NA	

19.3.1.3	Current policies and procedures are communicated to all staff. EVIDENCE OF COMPLIANCE 1. Training and briefing on the current policies and procedures/Minutes of meetings — NA 2. Circulation list and acknowledgement — NA	NA			NA	
19.3.1.4 CORE	There is evidence of compliance with policies and procedures. 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	NA			NA	
19.3.1.5 CORE	Policies and procedures of the CSSS shall include the following: a) receiving and decontamination processes (disassembling, washing, cleaning and disinfection); b) packaging process (inspection, functionality check and packing); c) sterilisation process; d) validation processes; e) sterile storage and distribution; f) traceability and product recall; g) services provided to other healthcare facilities; h) environmental control (storage condition, effective maintenance of sterility); i) Management of sterile items (event related or shelf life) j) safety practices in CSSS; k) utilisation of "flash" autoclave	NA			NA	

	l) Management of Loaner Instrumentation (refer to Guideline On Loaner Instrumentation book MSSA, ANSI/AAMI ST79:2017 Page 30 5.2.3 Loaned or borrowed instrumentation.) m) Management of Robotic Instrumentation n) Management implantable items (MSSA : Malaysian Standard Of Sterilization Process Book 3rd Edition 2018 Page 121) cross reference with infection control standard **EVIDENCE OF COMPLIANCE** 1. Policies and procedures that address CSSS processes but not limited to items (a) to (k) are available. — NA					
19.3.1.6	Disinfection and sterilising processes in other services, e.g. Dental Services, Theatre Sterile Supply Unit (TSSU), Endoscopy, Cardiovascular Invasive Laboratory, Fertility Centre etc should be consistent with the requirements of policies and procedures of the CSSS. **EVIDENCE OF COMPLIANCE** 1. Specific policies and procedures and/or practice guidelines which address disinfection and sterilising processes that meet the requirements of CSSS are available in other services, i.e. Dental Services, TSSU, Endoscopy, Cardiovascular Invasive Laboratory, Fertility Centre etc — NA	NA			NA	
19.3.1.7	Copies of policies and procedures, protocols, guidelines, relevant Acts, Regulations, ByLaws and statutory requirements are accessible to staff. **EVIDENCE OF COMPLIANCE** 1. Copies of policies and procedures, protocols, guidelines, relevant Acts, Regulations, By-Laws and statutory requirements are accessible on-site for staff reference: a) Equipment operating manuals — NA b) Factory and Machinery Act — NA c) Medical device operating manuals — NA d) Occupational Safety and Health Act — NA e) Infection Control Manual — NA	NA			NA	

	f)	Malaysian Standard of Sterilization Process (MSSA document)	NA				
19.3.1.8	There shall be no reprocessing of any single-use medical-surgical instruments, equipment or supplies. EVIDENCE OF COMPLIANCE			NA			NA	
	1.	Policy on 'No reprocessing' of any single-use medical-surgical instruments, equipment or supplies.	NA				
	2.	Compliance with 'No reprocessing' policy.	NA				
19.3.1.9	Records for all activities in the processing of sterile items shall be maintained for a period of time as defined by respective regulatory authorities or in their absence as per policy of the healthcare facility. EVIDENCE OF COMPLIANCE			NA			NA	
	1.	Daily production statistics to assess stock (e.g. medical-surgical instruments, equipment or supplies) levels for safe, continuous service, efficient stock and cost control.	NA				
	2.	All tests performed on equipment and results.	NA				
	3.	Steriliser records, e.g. number of cycles	NA				

TOPIC TOPIC19.4
FACILITIES AND EQUIPMENT

STANDARD STANDARD 19.4.1
There are adequate facilities and equipment to enable the CSSS to meet its goals and objectives in accordance with regulatory requirements.

CRITERION NO.	CRITERIA FOR COMPLIANCE	SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
				AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
19.4.1.1 CORE	The design and set up of the Central Sterilising Supply Services allows for: a) The CSSS to be equipped and arranged to provide proper separation of clean and dirty routes and processes with clear demarcation of the different zones. The airflow is from clean to soiled areas. b) Areas within CSSS shall be adequate to provide for: i) Receiving of unsterile supplies ●Handling of supplies and equipment in accordance with planned stores and supply system and parking of carts. ●Facilities for receiving, disassembling and cleaning of supplies and equipment shall be appropriately located avoiding non-sterile items passing through sterile areas of the CSSS. ii) Assembling and Packaging ●Facilities for assembling, packaging supplies and equipment shall have hand hygiene facilities, work counter (a non-porous material work benches) or its equivalent as required by types and volume of items. iii) Sterilising ● Facilities for sterilising shall be located between packaging area and sterile storage area. ● An exhaust is installed over the back room of sterilisers to prevent condensation and heat building up. ● A designated cooling area with good ventilation to allow cooling of sterilised items. v) Storage Facilities ● Dedicated store for storage and issue of sterile instruments and supplies ● Facilities for storage and issues of unsterilised linen for sterilization. ● Facilities for storage and issue of unsterile instruments, ● Facilities for storage and issue of chemical detergents and disinfectants	NA			NA	

	● Facilities for storage of soft goods ● Facilities for storage (sterilization wrapping paper, autoclave tape etc) c) Hand washing facilities d) Staff changing room are readily available. e) Suitably planned layout of work benches and equipment.					
	EVIDENCE OF COMPLIANCE					
	1.	The design and set up of the CSSS address all items (a) to (e) as per relevant regulations and as evidenced by:				
	a)	demarcation with physical structure where control of airflow is from positive to negative pressure;	NA			
	b)	facilities for reception process; there should be no crises crossing of non-sterile and sterile items;	NA			
	c)	appropriate areas/zones that facilitates the activities of CSSS;	NA			
	d)	compliance with Infection Control Policies;	NA			
	e)	absence of porous work benches at assembling and packaging area.	NA			
19.4.1.2	There are adequate and appropriate facilities and equipment with proper utilisation of space to enable staff to carry out their professional and administrative functions.			NA		NA	
	EVIDENCE OF COMPLIANCE					
	1.	Adequate and proper utilisation of space.	NA			
	2.	Appropriate equipment to match the complexity of services.	NA			
	3.	Easy access and clear exit routes	NA			
19.4.1.3	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. Department of Occupational Safety and Health (DOSH), Standards and Industrial Research Institute of Malaysia (SIRIM), etc as evidence of compliance to the relevant standards and Acts.	NA			

19.4.1.4	Where specialised equipment is used, there is evidence that only staff who are trained and authorised by the Facility operate such equipment, e.g. autoclave. 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	
19.4.1.5 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. EVIDENCE OF COMPLIANCE 1. Planned Preventive Maintenance records such as schedule, stickers, etc — NA 2. Planned Replacement Programme where applicable — NA 3. Certificate of Fitness of Autoclave/pressure vessels from Department of Occupational Safety and Health (DOSH) — NA 4. Complaint records — NA 5. Asset inventory — NA	NA			NA	

TOPIC TOPIC 19.5
SAFETY AND PERFORMANCE IMPROVEMENT ACTIVITIES

STANDARD STANDARD 19.5.1
The Head of CSSS shall ensure the provision of quality performance with staff involvement in the continuous safety and performance improvement activities of CSSS in risk mitigation.

CRITERION NO.	CRITERIA FOR COMPLIANCE	SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
				AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
19.5.1.1	There are planned and systematic safety and performance improvement activities to monitor and evaluate the performance of the CSSS. The process includes: a) Planned activities i.e. risk identification using the risk rating matric and develop risk register b) Data collection and verification 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. / studies — NA					
	3. Minutes of performance improvement meetings — NA					
	4. CSSS risk register — NA					
	5. Evidence of risk register being reviewed — NA					
	6. Records on innovation if available — NA					
19.5.1.2	The Head of CSSS 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.	Collection, tabulation and verification of data	NA				
	2.	Discussed with relevant department	NA				
	3.	Identify areas for improvement	NA				
	4.	Endorcement of outcome to Head of Nursing and PIC	NA				
19.5.1.3	The Head of the CSSS shall ensure that the staff are trained in incident reporting. Incident reports are reported timely, investigated, discussed by the staff with learning objectives and forwarded to the Person In Charge (PIC) of the Facility. Incidents reported have 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.	Timely complete incident reports	NA				
	3.	Root Cause Analysis	NA				
	4.	Corrective and preventive action plans	NA				
	5.	Remedial measures implemented and monitored	NA				
	6.	Minutes of meetings	NA				
	7.	Acknowledgment by Head of Service and PIC/Hospital Director	NA				
	8.	Outcome of lesson learnt from the incident shared with other Feedback given to staff regarding incident reporting.	NA				
19.5.1.4 CORE	There is evidence of tracking and trending of specific performance indicators for improvement of the services /patient care such as : a) percentage of sterile instrument sets rejected (Target: Not more than 5%) b) percentage of incidents reported monthly that have had Root Cause Analysis (RCA) done and action taken to prevent recurrence			NA			NA	

	c) Internal Customer feed back d) Leak testing for rigid container system to ensure sterility **EVIDENCE OF COMPLIANCE** 1. Specific performance indicators monitored. NA 2. Records on tracking and trending analysis. NA 3. Remedial measures taken where appropriate NA 4. Review performance indicators if trending shows consistent achievement over 1 year. Identify new performance indicators NA					
19.5.1.5	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 education activities/meetings. NA 3. Minutes of service/unit meetings NA	NA			NA	
19.5.1.6	Appropriate documentation of safety and performance improvement activities are 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 19.6
SPECIAL REQUIREMENTS

STANDARD STANDARD 19.6.1
The CSSS shall be responsible to provide centralised sterilising services and sterile supplies for all areas within the Facility that use sterile instruments, dressings, linen and other items.

CRITERION NO.	CRITERIA FOR COMPLIANCE	SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
				AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
19.6.1.1 CORE	There is a properly set up centralised sterile supply system designed to reduce the risk of infection to both patients and staff. This system shall be an integral part of the Facility's infection control programme that address: a) structural layout of CSSS with clear delineation between sterile and non-sterile areas to prevent cross contamination; b) building finishes; c) mechanical and electrical installation including fire safety system; d) appropriate equipment and fixtures; e) environmental control; f) staff traffic flow.	NA			NA	

EVIDENCE OF COMPLIANCE		
1.	Structural layout	
a)	Physically demarcated zones for decontamination, packaging, sterilising, sterile store and distribution counter	NA
b)	Good ventilation system with temperature and humidity control as per standard requirements.	NA
c)	Infection control aspects – appropriate personal protective equipment, staff changing room and hand washing facilities.	NA
d)	Workplace safety – staff safety, noise control, waste management.	NA
e)	Fire safety fixtures, e.g. fire suppression system.	NA
2.	Building finishes cross references with standard 3 (Transfer to engineering)	

	a)	Floors and walls should be constructed of materials that will withstand periodic wet vacuuming or washing. These materials should not be of a particulate- or fibre-shedding composition.	NA					
	b)	The finish, the screed and sub-floor must be suitable for heavy trolley traffic. The flooring should be turned up at wall in an integral cover skirting which should be continuous with floor and be finished flush with the wall. The finish must be hardwearing and easy to clean.	NA					
	c)	Work areas ceilings should be constructed to create a flush surface with recessed, enclosed fixtures.	NA					
	d)	For new CSSS facilities, the pipes and sewerage line should be routed away from the structure design of ceilings, walls and floors of the operation areas of the facilities.	NA					
	e)	For the existing CSSS facilities, the pipes and sewerage line running above the ceiling, walls and floors, periodic risk assessment and control measures to be instituted and documented.	NA					
	f)	Artificial lighting – Good artificial lighting is required, supplementing natural light when appropriate. Switching should permit control in different work areas of large rooms. The lighting is required where instruments and other items are inspected and should preferable be adjustable to suit the operative and the task being undertaken.	NA					
	g)	The ventilation system should be designed so that air flows into relatively soiled areas from clean adjoining spaces (via negative pressure), and is exhausted to the outside or to a filtered partial recirculation system. The air circulation should be of a down draft-type. Fans should not be permitted in any area of central service.	NA					
	h)	Washer disinfectors and steriliser emit considerable heat and humidity. Electronic controls essential for the correct operating of equipment can be affected. Working condition can become intolerable unless fully insulated machine are selected, all pipe work is insulated and extract ventilation is provided specific to these machines.	NA					
	3.	Mechanical and electrical installation:						
	a)	Certificates from relevant authorities i.e. Department of Occupational Safety and Health (DOSH) for autoclaves	NA					
	b)	Planned Preventive Maintenance (PPM) and repair records	NA					
	c)	Competent staff for mechanical and electrical installation as per regulatory requirements.	NA					

	d)	Validation of installations (e.g. Testing and Commissioning records).	NA				
	4.	Appropriate equipment and fixtures:					
	a)	automated equipment and fixtures as per 19.6.1.6;	NA				
	b)	Non automated equipment and fixtures:					
	i)	manual cleaning – appropriate cleaning tools, three - compartments sinks	NA				
	ii)	spray gun;	NA				
	iii)	dryer;	NA				
	iv)	magnify glass	NA				
	c)	transportation trolley;	NA				
	d)	Sterilizer	NA				
	5.	Environmental control					
	a)	All work areas shall maintain temperature between 20°C ±2 - 24°C	NA				
	b)	Temperature for sterile storage as per criterion 19.6.1.5 and humidity 50% -60%.	NA				
	6.	Fire safety system:					
	a)	Fire safety system shall meet fire authority's requirements.	NA				
	b)	Appropriate fire suppression system according with the natural of fire agents.	NA				
	c)	Fire evacuation plan is easily visible at the respective zones.	NA				
	d)	Fire safety requirements:					
	i)	fire safety training and records;	NA				
	ii)	appropriate firefighting systems are available;	NA				
	iii)	fire safety audit;	NA				
	iv)	evacuation plan;	NA				
	v)	evacuation route;	NA				
	vi)	fire drill and report.	NA				
	7.	Staff traffic flow					
	a)	For internal staff, there is designated route with sign posting between the demarcated zones.	NA				
	b)	For external client, entrance and exit to the CSSS facility is restricted and compliance with dress code.	NA				

19.6.1.2	All sterilising systems (e.g. hot air, steam, gas) are maintained in accordance with statutory regulations. EVIDENCE OF COMPLIANCE 1. Valid licence for steam sterilisers and other type of sterilisers. NA 2. Log book of CSSS installation of vessels and chambers. NA	NA			NA	
19.6.1.3	Clean linen to be sterilised shall be inspected and folded in a room set aside for this purpose, which shall be separate from the main sterilising area. An exhaust system shall be installed to remove cotton fluff and ensure staff safety. EVIDENCE OF COMPLIANCE 1. Separate room for linen inspection and preparation NA 2. Illuminated linen inspection table NA 3. Exhaust system/Lint extractor NA	NA			NA	
19.6.1.4	Arrangements are made for supplies required after normal office hours. EVIDENCE OF COMPLIANCE 1. Policy on accessibility of Central Sterilising Supply Services for 24 hours. NA 2. On call roster of assigned staff to attend to CSSS NA 3. Mechanism to retrieve sterilised instruments from sources where not required. NA	NA			NA	
19.6.1.5 CORE	In the sterile store, there is environmental control on ventilation (100% fresh air intake with positive pressure), temperature (20ºC ± 2) and humidity (55% ± 5) and the system is regularly inspected and maintained. Air discharge exhaust shall be located to avoid cross circulation to air supply intakes. EVIDENCE OF COMPLIANCE 1. Appropriate temperature and humidity measurement devices NA 2. Record of humidity and temperature readings NA 3. Records on corrective actions where there are deviations to the readings above. NA	NA			NA	
19.6.1.6 CORE	There are special automated equipment appropriate to the CSSS for the cleaning, drying, and sterilisation of medical equipment and instruments, and they comply with acceptable standards.	NA			NA	

	EVIDENCE OF COMPLIANCE						
	1.	Appropriate equipment to match complexity of the facility's services such as:					
	a)	washer disinfector • Dosage of detergent • Dosage of lubricant (if available) • Quality of water • Carried out test of Instrument - any cleaning verification that is reliable method for evaluating the cleaning effectiveness of the automated instrument washer and registered with the Medical Device Authority (MDA)	NA				
	b)	Ultrasonic machine • To check efficacy of ultrasonic wave • Any test to check efficacy of ultrasonic wave - ultrasonic washer (dosimeter) test and registered with the Medical Device Authority (MDA)	NA				
	c)	Dryer • Temperature monitoring	NA				
	d)	Heat sealing machine • Seal check	NA				
	e)	Sterilizer • quality of water (the best water to use is distilled water or demineralized water or water prepared by process known as reverse osmosis). • quality of steam	NA				
	f)	rapid biological test incubator;	NA				
	g)	endoscope washer (cross reference to PCI and endoscopic standard)	NA				
	h)	Laparoscopic Insulation Tester.	NA				
19.6.1.7 CORE	Validation tests on sterilisation process using mechanical, chemical and biological tests are conducted and results monitored and recorded accordingly.			NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Performance of relevant tests and results:					
	a)	mechanical test results records;	NA				
	b)	chemical test result records;	NA				
	c)	biological test result records.	NA				
	2.	Records on deviations if any and corrective and preventive actions taken	NA				
	3.	Relevant efficacy test records considering mechanical aspects, chemical aspects, temperature and time.	NA				
19.6.1.8	The CSSS Unit shall make appropriate arrangement for the collection of dirty instruments and the distribution of sterilised surgical instruments/surgical supplies			NA			NA	

	from the CSSS Unit to the various services areas of the Facility which include but not limited to: a) policy on distribution of sterilised surgical instruments and supplies; b) planned schedule and timing; c) dedicated and cleaned vehicle for distribution; d) cleaned transport trolley EVIDENCE OF COMPLIANCE 1. On-site inspection on compliance with (a) to (d). NA					
19.6.1.9	Waste management a) Waste disposal shall be in accordance with national and local regulations. Waste generated by the sterilising processing unit shall be placed in appropriate containers/bags. b) All contaminated waste such as: • i) soiled surgical dressings , e.g. cottonwool, gloves, swabs; • ii) human biopsy materials, human tissue, blood, urine, stools. shall be discarded into appropriate containers and disposed in accordance with the Facility's policy. c) Used vials of biological indicators for monitoring of sterilisation shall be disposed in accordance with the Facility's policy. d) Sharp containers shall be provided for disposal of condemned needles, used single needles and syringes, blades and other sharp items inadvertently returned to the sterilising processing facility with reusable items. The collection container must be puncture resistant and leak tight. This category of waste has to be disposed/destroyed completely as to prevent potential risk of injury/infection. e) All waste should be removed from the sterilising processing facility via a designated disposal exit.	NA			NA	

	EVIDENCE OF COMPLIANCE						
	1.	Policy on segregation and collection of waste.	NA				
	2.	Planned schedule by facilities.	NA				
	3.	Dedicated route.	NA				
	4.	Record of waste collection.	NA				

SERVICE SUMMARY	
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OVERALL RATING :	NA
OVERALL RISK :	-