SERVICE STANDARD 18: PHARMACY SERVICES

PREAMBLE
The Pharmacy Services shall provide safe and efficient delivery of the following activities:

a) evaluation, appraisal and recommendation for selection of pharmaceutical products;
b) procurement, storage, distribution and delivery of pharmaceutical products;
c) manufacturing and reprocessing of pharmaceutical products;
d) drug information, dissemination and patient counseling;
e) poison information and advisory services;
f) clinical pharmacy services;
g) harm reduction therapy services, e.g. Methadone dispensing, counseling on smoking cessation.

TOPIC TOPIC 18.1
ORGANISATION AND MANAGEMENT

STANDARD STANDARD 18.1.1
The Pharmacy Services shall be organised and administered to provide efficient pharmaceutical care services including the purchase, distribution, and control of pharmaceutical products; and to disseminate appropriate drug information to the healthcare team and patients of the Facility in accordance with prevailing standards of pharmacy practice.

CRITERION NO.	CRITERIA FOR COMPLIANCE	SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
				AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
18.1.1.1	Vision, Mission and values statements of the Facility are accessible. Goals and objectives that suit the scope of the Pharmacy 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 Pharmacy 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				
18.1.1.2 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 and the staff of Pharmacy Services; b) is accessible to all staff and clients; c) includes off-site services and satellite pharmacies (where 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. All off-site and satellite pharmacies under the purview of Pharmacy Services shall be included in the main organisation chart.		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 and staff of Pharmacy 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				
18.1.1.3	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 Pharmacy Services. Minutes are kept; decisions and resolutions made during meetings shall be accessible, communicated to all staff of the service and implemented.		NA			NA	
		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				
18.1.1.4	The Head of Pharmacy Services is involved in the planning, justification and management of the budget and resource utilisation of the services.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Minutes of Facility-wide 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				
18.1.1.5	The Head of Pharmacy Services is involved in the appointment and/OR assignment of staff.			NA			NA	
	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				
18.1.1.6	The Head of the Pharmacy Services is responsible in the formulation of all administrative decisions relating to the provision of Pharmacy Services and the use of medicines.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Job description of Head of Pharmacy Services	NA				
	2.	Minutes of meeting	NA				
18.1.1.7	The Pharmacy Services provides services that include the procurement, distribution, provision of information, and the practice of safety and performance improvement activities of all pharmaceutical products in the Facility.			NA			NA	

	EVIDENCE OF COMPLIANCE						
	1.	Procurement record	NA				
	2.	Inventory control record	NA				
	3.	Audit report	NA				
	4.	Drug information record	NA				
	5.	Safety and performance improvement activities	NA				
18.1.1.8	Specific services provided by the Pharmacy Services shall include, as appropriate, the following: a) dispensing of medicines according to Good Dispensing Practices; b) clinical pharmacy services include: • i) quality use of medicines (dosage, indication for use, efficacy, adverse reactions, drug interaction and food interactions, patient consent for animal origin related medicines that affect their religious beliefs and in terms of legal requirements), where appropriate; • ii) total parenteral nutrition; • iii) clinical pharmacokinetics services; • iv) reconstitution of cytotoxic drugs; c) nuclear medicine services; d) educational services: • i) medicines usage and counselling for patients; • ii) drugs and drug therapy for medical, nursing, and other staff; • iii) poison information and advisory services; • iv) continuing education for pharmacy staff. e) manufacturing of pharmaceutical products shall be in accordance with Good Manufacturing Practice (GMP) or Good Preparation Practice (GPP) and guidelines for the following services: • i) reconstitution of cytotoxic drugs;	NA			NA	

	• ii) preparation of radiopharmaceuticals used in nuclear medicine; • iii) preparation of extemporaneous preparations (non-sterile pharmaceutical products that are not stored but issued for immediate use). f) participate in research in pharmacy services to improve medicine related therapy and utilisation; where applicable; g) storage and dispensing of psychotropic substances shall be in accordance with the provisions of Poisons (Psychotropic Substances) Regulations (1989) as in the Third Schedule of the Poisons Act 1952; h) storage and dispensing of dangerous drugs shall be in accordance with the provisions of Dangerous Drugs Act and Regulations (1952). **EVIDENCE OF COMPLIANCE** 1. Specific services provided by the Pharmacy Services shall include items (a) to (h). — NA 2. Availability of standard operating procedures for various specific services provided, which include nuclear medicine and the disposal of radiopharmaceutical substances where applicable. — NA 3. List of medicines with animal origin — NA 4. Patient consent on animal origin related medicines — NA 5. Record of patient counselling — NA 6. Record of in-house training conducted by Pharmacy Services. — NA 7. Availability of pamplets/newsletter/bulletin for staff and patient education. — NA 8. List of research and publications made available. — NA					
18.1.1.9	Where there are decentralised sections of the Pharmacy Services, specific objectives are documented. **EVIDENCE OF COMPLIANCE** 1. Objectives for decentralised sections of the Pharmacy Services are specified and documented. — NA	NA			NA	

18.1.1.10	Appropriate statistics and records shall be maintained in relation to the provision of Pharmacy Services 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 for inpatients and outpatients; 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	
18.1.1.11	There shall be a Pharmacy and Therapeutic Committee and the Pharmacy Services shall be represented on multidisciplinary committees where pharmacy matters are discussed. The Terms of Reference of the Pharmacy and Therapeutic Committee shall include to: a) recommend and advise on matters pertaining to the choice of drugs; b) develop and review periodically a formulary or drug list for use in the hospital; c) recommend to the Ethics Committee regarding the standards on the use and control of investigational drugs and research; d) evaluate clinical data concerning new drugs or preparations requested for use in the Facility; e) make recommendations concerning drugs to be stocked on the nursing unit floors and by other services; f) make recommendations concerning drugs for which written orders to continue are necessary; g) make recommendations regarding policies and procedures on the administration of drugs. **EVIDENCE OF COMPLIANCE**	NA			NA	

	1.	Letters of appointment of members to the Pharmacy and Therapeutic Committee	NA				
	2.	Terms of reference include items (a) to (g).	NA				
	3.	Regular scheduled meeting	NA				
	4.	Call letter with agenda	NA				
	5.	Minutes of meeting acknowledged by the Chairperson of the committee.	NA				
	6.	Minutes of meetings circulated to all members – circulation list	NA				
	7.	Evidence that relevant outcomes of the meetings are disseminated to relevant staff	NA				
	8.	Drug Formulary being established.	NA				
18.1.1.12	Pharmacy Services maintain good communication with Governing Body, medical professionals and nursing staff through relevant committees and continuing education programmes.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Minutes of Facility-wide meetings/interdepartmental meetings / committee meetings.	NA				
	2.	Interdepartmental policies and procedures	NA				
	3.	Continuing medical education programme	NA				

TOPIC TOPIC 18.2
HUMAN RESOURCE DEVELOPMENT AND MANAGEMENT

STANDARD Standard 18.2.1
The Pharmacy Services shall be managed by a suitably qualified, experienced and registered pharmacist; and supported by other registered pharmacists, pharmacy assistants and other supporting staff to achieve the objectives of the services.

CRITERION NO.	CRITERIA FOR COMPLIANCE		SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
					AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
18.2.1.1 CORE	The Pharmacy Services is directed by the Head who is a registered pharmacist currently registered with the Pharmacy Board of Malaysia and possess a valid licence.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	The Head of Pharmacy Services has a valid professional Annual Practising Certificate (APC) and registered with Pharmacy Board of Malaysia.	NA				
	2.	The Head of Pharmacy Services possess a valid licence for manufacturing process (if applicable).	NA				
	3.	Appointment/assignment letter	NA				
	4.	Job description	NA				
18.2.1.2	The staffing of the Pharmacy Services is provided by 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 letter	NA				
	3.	Training and competency records	NA				
18.2.1.3	The authority, responsibilities and accountabilities of the Head of Pharmacy Services are clearly delineated and documented.		NA			NA	

	This includes upholding the laws regulating the practice of pharmacy and the control and distribution of pharmaceuticals products. The Head is also responsible for appropriate liaison with the authorities administering these laws. EVIDENCE OF COMPLIANCE 1. Appointment/assignment letter for Head of Service. NA 2. Description of duties and responsibilities. NA					
18.2.1.4	Sufficient numbers of personnel and support staff with appropriate qualifications are employed to meet the need of the services. EVIDENCE OF COMPLIANCE 1. Number of staff and qualification should commensurate with workload. NA 2. Staffing pattern NA 3. Duty roster NA 4. Census and statistics NA	NA			NA	
18.2.1.5	There is a registered pharmacist on duty or on call at all times. EVIDENCE OF COMPLIANCE 1. Availability of duty roster of pharmacy staff. NA	NA			NA	
18.2.1.6	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;	NA			NA	

	• 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 4. The job description is acknowledged by the staff and signed by the Head of Service and dated. — NA					
18.2.1.7	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. **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	
18.2.1.8	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. **EVIDENCE OF COMPLIANCE**	NA			NA	

	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				
18.2.1.9	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				
18.2.1.10	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				
18.2.1.11	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.	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				

TOPIC TOPIC 18.3
POLICIES AND PROCEDURES

STANDARD STANDARD 18.3.1
There are documented policies and procedures for the core business of the Pharmacy Services to achieve its goals and objectives. Policies and procedures shall be consistent with the relevant regulations and legal requirements of relevant government agencies.

CRITERION NO.	CRITERIA FOR COMPLIANCE	SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
				AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
18.3.1.1 CORE	There are written policies and procedures for the Pharmacy 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. **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 such as Private Healthcare Facilities and Services Act (PHFSA) (1998) and its Regulations (2006), Poison Act 1952 and it Regulations, Dangerous Drug Act 1952 and other relevant guidelines. — NA 3. Evidence of periodic review of policies and procedures. — NA 4. The policies and procedures are endorsed and dated. — NA	NA			NA	
18.3.1.2	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 practiced in developing relevant policies and procedures where applicable. **EVIDENCE OF COMPLIANCE** 1. Minutes of committee meetings on development and revision on policies and procedures. — NA	NA			NA	

	2.	Minutes of meeting with evidence of cross reference with other departments	NA				
	3.	Documented cross departmental policies	NA				
18.3.1.3	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					
18.3.1.4 CORE	There is evidence of compliance with policies and procedures.			NA			NA	
	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					
18.3.1.5 CORE	There are policies and procedures on ordering and administering of medicines which include: a) incorporation of inpatient and outpatient medication orders into the patient's medical record; b) recording in the patient's medical record for every dose of medicine administered; c) keeping accurate and accessible records on medicines supplied and administered to inpatients and outpatients; d) administering of medicines brought into the Facility by patients; e) administering of medicines by patients, where appropriate; f) access to patients' medical records, where appropriate;			NA			NA	

	g) abbreviations where used are in accordance with an approved list by Pharmacy and Therapeutic Committee and endorsed by the Person In Charge (PIC); h) reconstitution, storage, transportation and administration of cytotoxic drugs; i) storage, preparation and transportation of radiopharmaceutical. **EVIDENCE OF COMPLIANCE** 1. Policies and procedures on ordering and administering of medicines include (a) to (i). — NA 2. Prescription patterns — NA 3. Medication administration — NA 4. Patient medication record — NA 5. Records on order, worksheet, preparation, supply and transportation of radiopharmaceuticals. — NA 6. Records on order, worksheet, preparation, supply and transportation of cytotoxic drug. — NA 7. Drug reconciliation policy — NA					
18.3.1.6	There are policies and procedures on patient education and counselling which include: a) explanation and instructions by a pharmacist on the use and storage of medications; b) provision of education and counselling as appropriate to patients and their families relating to medicines prescribed. **EVIDENCE OF COMPLIANCE** 1. Policies and procedures on patient education and counselling include (a) and (b). — NA 2. Record of counselling — NA 3. Evidence of counselling materials (e.g. inhaler placebo, insulin pen, pamphlet, flipchart) — NA	NA			NA	
18.3.1.7	There are policies and procedures on manufacturing, reprocessing and storage of medicines which include:	NA			NA	

a) preparation of parenteral nutrition and labelling shall only be done by trained staff;

b) intravenous admixtures, reconstitution and preparation of intravenous and other sterile preparations;

c) reconstitution, handling and disposal of cytotoxic drugs;

d) preparation, handling, quality control and disposal of radiopharmaceuticals;

e) repackaging and pre-packaging medicines;

f) labelling of medicines;

g) storage of all medicines within the Facility with respect to statutory regulations and any other requirements;

h) inventory control systems;

i) provision of emergency services outside normal pharmacy hours;

j) disposal of discontinued, outdated, or unwanted or unused portions of medicines;

k) guidelines on spillage and decontamination;

l) quality control procedures to be carried out on products prepared in the Pharmacy Services.

EVIDENCE OF COMPLIANCE		
1.	Policies and procedures on manufacturing, reprocessing and storage of medicines to include items (a) to (l).	NA
2.	Records on implementation process of (a) to (l)	NA
3.	Drug labels contain name and strength of medication, expiry date, batch number and name of manufacturer.	NA
4.	List of items/drugs that require refrigeration and temperature monitoring	NA
5.	Records on medicine movement, regular stock inspection schedule, monitory of expiry date, delivery order, issue notes, first expired first out system of drug stocking, minimum and maximum stock level.	NA

	6.	24 hours on-call duty schedule	NA				
	7.	Disposal records	NA				
	8.	Spillage kit and reporting of incident/spillage	NA				
18.3.1.8	There are policies and procedures on drug and poison information and advisory services. Active dissemination and provision of drug information shall be provided to healthcare professionals. EVIDENCE OF COMPLIANCE			NA			NA	
	1.	Policies and procedures on drug and poison information and advisory services.	NA				
	2.	Dissemination of information on drugs and poison (e.g. pamphlet, newsletter, bulletin, circular, continuing medical education)	NA				
18.3.1.9	There is participation by the pharmacist in the adverse drug reaction reporting system of the Facility. Policies and procedures for Adverse Drug Reaction (ADR) Reporting shall include the method of detection, a mechanism for reporting to the medical practitioner, the pharmacist, the Adverse Drug Reaction Advisory Committee/appropriate internal committee. EVIDENCE OF COMPLIANCE			NA			NA	
	1.	Appropriate committee to discuss the ADR incidents	NA				
	2.	Policies and procedures are in place for ADR reporting	NA				
	3.	Sample of ADR reports and dissemination of findings	NA				
18.3.1.10	There are policies and procedures on monitoring and controlling of sample medicines brought into the Facility. EVIDENCE OF COMPLIANCE			NA			NA	
	1.	Policies and procedures on monitoring and controlling of sample medicines brought into the Facility.	NA				
	2.	Records on monitoring and control of sample medicines by Pharmacy Services.	NA				
18.3.1.11	There are policies and procedures of the Pharmacy Services that address the following: a) dispensing, storage and handling of psychotropic drugs;			NA			NA	

	b) a drug recall procedure; c) security of the Pharmacy Services and storage areas at all times; d) complaints procedure. **EVIDENCE OF COMPLIANCE** 1. Policies and procedures of the Pharmacy Services that include items (a) to (d). — NA					
18.3.1.12 CORE	There are documented policies and procedures on prescribing medication that state: a) medicines can only be dispensed by qualified pharmacy personnel based on written order from the medical practitioner; b) electronic prescribing, using an open or closed network if practiced, conform to established conventions with regards to the identity of the prescriber and patient; c) drugs dispensed and administered are based on the original of the medical practitioner's order. Drug orders are not transcribed. **EVIDENCE OF COMPLIANCE** 1. Policies and procedures include (a) to (c) are available. — NA 2. Security access is established for electronic prescribing. — NA 3. Records on original prescription — NA 4. Updated sample of doctors' signature for manual prescribing. — NA	NA			NA	
18.3.1.13	Telephone ordering of medicines is limited to exceptional circumstances as defined by regulations and policy of the Facility. If such ordering is accepted, written confirmation by the prescribing medical practitioner shall be obtained within 24 hours. No verbal order for cytotoxic/radiopharmaceutical drugs. **EVIDENCE OF COMPLIANCE** 1. Policy is in place for telephone ordering. — NA 2. Written confirmation by the prescribing medical practitioner is obtained within 24 hours. — NA	NA			NA	

	3.	Documentation of the verbal order by the receiving Medical Officer / Nurse in the patient record/ nursing note.	NA				
18.3.1.14	There is a system for reporting of medication errors, identifying the root cause and corrective action taken to prevent similar errors.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Standard operating procedures for reporting of medication error	NA				
	2.	Sample of medication error report	NA				
	3.	Evidence of corrective action taken and dissemination of findings.	NA				
18.3.1.15	Copies of policies and procedures, protocols, guidelines, relevant Acts, Regulations, ByLaws and statutory requirements are accessible to staff.		NA			NA	
	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.	NA				

TOPIC TOPIC 18.4
FACILITIES AND EQUIPMENT

STANDARD STANDARD 18.4.1
Adequate and appropriate space, equipment and supplies shall be provided for the Pharmacy Services to fulfil its administrative, professional and technical functions according to standards set by the relevant authorities and regulatory requirements. Segregated areas are required for services related to oncology and nuclear medicine.

CRITERION NO.	CRITERIA FOR COMPLIANCE	SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
				AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
18.4.1.1 CORE	Adequate and safe storage facilities are provided in the Pharmacy Services to ensure that all pharmaceuticals and related substances are kept according to Good Storage Practice guidelines that include: a) protection of the stored materials from all potentially harmful influences, such as undue variations of temperature and humidity, dust and odour, entry of animals, vermin and insects; b) areas shall be sufficiently large, and if necessary, shall have physically separated zones for orderly segregated storage; c) special precautions for the storage of hazardous, sensitive, or dangerous materials such as combustible liquids and solids, pressurised gases or liquids, dangerous and psychotropic drugs and other potent habit-forming substances, highly toxic substances, radiopharmaceutical materials, herbal drugs and remedies; d) special facilities shall be constructed and equipped for materials requiring specific storage conditions relating to temperature, humidity and other physical conditions.	NA			NA	

EVIDENCE OF COMPLIANCE		
1.	Adequate and safe storage facilities are available and proper utilisation of space	NA
2.	Easy access and clear exit routes	NA
3.	Absence of overcrowding	NA
4.	Physical inspection on asset to treat and prevent from harmful influences where appropriate, such as air conditioning system, humidifier, vacuum cleaner, air freshener, etc.	NA

	5.	Scheduled pesticides control programme	NA				
	6.	Floor plan/Physical layout inspection of storage conditions	NA				
	7.	Special precautions for the storage of hazardous, sensitive, or dangerous materials.	NA				
	8.	Special facilities for materials requiring specific storage conditions relating to temperature, humidity and other physical conditions.	NA				
18.4.1.2	Where controlled environmental storage conditions are required, these conditions shall be continually monitored and appropriate corrective action shall be taken where necessary. The desired conditions shall include: a) Temperature Control: The following parameters are complied: • i) room temperature, temperature below 30°C; • ii) refrigerator, temperature between 2 - 8ºC; • iii) freezer, temperature not higher than 0°C; • iv) ultra low, temperature between -65°C to -95°C. b) Humidity not more than 80%; materials requiring dry or humidity control storage shall be stored in areas where the relative humidity and temperature is maintained within prescribed limits. c) Containment • i) Inflammable or corrosive material requires effective ventilation and precautions to handle spillage. • ii) Radioactive material requires containment measures like differential pressures.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Temperature monitoring records	NA				
	2.	Humidity monitoring records where necessary	NA				
	3.	Floor plan and proper signage for containment facilities	NA				
	4.	Physical layout inspection to verify storage conditions	NA				

	5.	Separate stores and evidence of effective ventilation for inflammable, corrosive and radioactive materials (where necessary).	NA				
18.4.1.3	Facilities for storing any psychotropic substances shall be locked and unlocked by the person authorised to handle such substances and the keys to such facilities shall be kept by him/her only in accordance with the Poisons (Psychotropic Substances) Regulations (1989). EVIDENCE OF COMPLIANCE 1. List of authorised personnel handling facilities for storing any psychotropic substances — NA 2. Records on handing/taking over keys — NA 3. On-site inspection on facilities for storing of psychotropic substances — NA		NA			NA	
18.4.1.4	There are adequate space, facilities, and equipment in the Pharmacy Services for compounding, repackaging, or reprocessing and dispensing of drug products including parenteral, intravenous admixtures, eye-drops, cytotoxic drugs, and radiopharmaceutical preparation where appropriate and with private area for patient counseling session. Designated and properly equipped areas are provided for the following: a) preparation of cytotoxic drugs in accordance with the statutory requirements. The Pharmacy Services shall ensure that cytotoxic waste materials are contained and disposed of in a safe and approved manner; b) preparation for extemporaneous c) manufacturing of bulk non-sterile products in accordance with statutory regulations and Good Manufacturing Practice (GMP) or Good Preparation Practice (GPP) guidelines if only processing is done; d) preparation of sterile products and intravenous additives in accordance with statutory regulations and Good Manufacturing Practice (GMP) or Good Preparation Practice (GPP) guidelines depending on the services provided; e) preparation of radiopharmaceuticals in accordance with statutory regulations and Good Preparation Practice (GPP) guidelines; f) dispensing counter g) counseling area/room		NA			NA	

	EVIDENCE OF COMPLIANCE					
	1.	Physical layout inspection to verify the following:				
	a)	Adequate space, facilities, and equipment for compounding, repackaging, or reprocessing and dispensing of drug products including parenteral, intravenous admixtures, eye-drops, cytotoxic drugs, and radiopharmaceutical preparation.	NA			
	b)	Designated and properly equipped areas for processes of (a) to (f).	NA			
	c)	Private area for patient counseling session	NA			
18.4.1.5	Security requirements for the Pharmacy Services shall address both facilities and staff protection including proper access controls and equipment. a) the design and operational policy shall facilitate controlled access and secure locking up of the facility to ensure the security of goods and staff at all times; b) the design and operation shall include equipment and features like duress alarms.		NA			NA	
	EVIDENCE OF COMPLIANCE					
	1.	Design and operational policy for controlled access and security of the pharmacy facilities.	NA			
	2.	Physical layout inspection of the pharmacy conforms to security and access control requirements.	NA			
18.4.1.6	The equipment used for measuring and monitoring shall be checked and calibrated at suitable predetermined intervals and the results of such checks shall be recorded and retained. i) measuring or monitoring equipment need to be calibrated; ii) alarms or alerts need to be remotely connected		NA			NA	
	EVIDENCE OF COMPLIANCE					
	1.	Records on planned preventive maintenance (PPM), corrective maintenance and calibration on equipment used for measuring and monitoring.	NA			
	2.	Alarm tests and records	NA			
18.4.1.7 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 and Predictive Maintenance records such as schedule, stickers, etc.	NA				
	2.	Planned Replacement Programme where applicable	NA				
	3.	Complaint records	NA				
	4.	Asset inventory	NA				
18.4.1.8	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				
18.4.1.9	Where specialised equipment is used, there is evidence that only staff who are trained and authorised by the Facility operate such equipment. Notes/Explanations Examples of specialised equipment are laminar flow cabinets, isolators, etc.			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 18.5
SAFETY AND PERFORMANCE IMPROVEMENT ACTIVITIES

STANDARD STANDARD 18.5.1
The Head of Pharmacy Services shall ensure the provision of quality performance and safety of patients with staff involvement in the continuous safety and performance improvement activities of the Pharmacy Services.

CRITERION NO.	CRITERIA FOR COMPLIANCE	SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
				AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
18.5.1.1	There are planned and systematic safety and performance improvement activities to monitor and evaluate the performance of the Pharmacy 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. Records on innovation if available — NA					
18.5.1.2	The Head of Pharmacy 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.	Terms of Reference/Job description	NA				
18.5.1.3	The Head of Pharmacy Services shall ensure that the staff are trained in risk management 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 measures	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				
18.5.1.4 CORE	There is tracking and trending of specific performance indicators not limited to but at least two (2) of the following: a) percentage of prescription error b) percentage of dispensing error c) average time for a prescription to be dispensed from time received at counter to time medication given to patient d) number and value of expired drugs at end of month over a specified period			NA			NA	

	EVIDENCE OF COMPLIANCE						
	1.	Specific performance indicators monitored.	NA				
	2.	Records on tracking and trending analysis	NA				
	3.	Remedial measures taken where appropriate	NA				
18.5.1.5	Feedback on results of safety and performance improvement activities are regularly communicated to the staff and relevant authority.			NA			NA	
	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/committee meetings	NA				
18.5.1.6	Appropriate documentation of safety and performance improvement activities is kept and confidentiality of medical practitioners, staff and patients is preserved.			NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Documentations 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 :	-