SERVICE STANDARD 16 : BLOOD TRANSFUSION SERVICES

PREAMBLE

Blood Transfusion Services may be provided from within, or external to the Facility. This Standard is applicable to Facilities where blood transfusion services are provided to patients. These services may include blood donation, blood component preparation, screening and release of blood and blood components, blood inventory management and immuno-haematology services which cover pre-transfusion testing, antibody screening and identification, and investigation of transfusion reaction.

TOPIC TOPIC 16.1
ORGANISATION AND MANAGEMENT

STANDARD STANDARD 16.1.1

The Blood Transfusion Services shall be organised and administered to provide safe donation and transfusion of blood and blood components appropriate to the level of clinical services provided by the Facility. The Head of the Blood Transfusion Services shall be a medical practitioner with training and experience in blood transfusion services.

CRITERION NO.	CRITERIA FOR COMPLIANCE		SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
					AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
16.1.1.1	Vision, Mission and values statements of the Facility are accessible. Goals and objectives that suit the scope of the Blood Transfusion 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 Blood Transfusion 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				
16.1.1.2 CORE	There is an organisation chart which:		NA			NA	

<table>
<tr><td></td><td>a) provides a clear representation of the structure, functions and reporting relationships between the Person In Charge (PIC), Head and staff of the Blood Transfusion 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.

<table><tr><th colspan="3">EVIDENCE OF COMPLIANCE</th></tr><tr><td>1.</td><td>Clearly delineated current organisation chart with line of functions and reporting relationships between the Person In Charge (PIC), Head and staff of the Blood Transfusion Services.</td><td>NA</td></tr><tr><td>2.</td><td>Organisation chart of the service is endorsed, dated and accessible.</td><td>NA</td></tr><tr><td>3.</td><td>The organisation chart is revised when there is a major change in any of the items (d)(i) to (iv).</td><td>NA</td></tr></table></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>16.1.1.3</td><td>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 Blood Transfusion Services. Minutes are kept; decisions and resolutions made during meetings shall be accessible, communicated to all staff of the service and implemented.

<table><tr><th colspan="3">EVIDENCE OF COMPLIANCE</th></tr><tr><td>1.</td><td>Minutes are accessible, disseminated and acknowledged by the staff.</td><td>NA</td></tr><tr><td>2.</td><td>Attendance list of members with adequate representatives of the service.</td><td>NA</td></tr><tr><td>3.</td><td>Frequency of meetings as scheduled.</td><td>NA</td></tr><tr><td>4.</td><td>Discussion and resolutions are implemented (Problems not solved to be brought forward in the next meeting until resolved).</td><td>NA</td></tr></table></td><td>NA</td><td></td><td></td><td>NA</td><td></td></tr>
<tr><td>16.1.1.4</td><td>The Head of Blood Transfusion Services is involved in the planning, justification and management of the budget and resource utilisation of the services.</td><td>NA</td><td></td><td></td><td>NA</td><td></td></tr>
</table>

	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				
16.1.1.5	The Facility shall establish a Transfusion Committee to review practices and policies with regard to blood supply and usage. The Transfusion Committee: a) is chaired by the Person In Charge (PIC)/appointed senior clinician and members include representatives from Blood Transfusion Services and main clinical services with significant transfusion activities; b) has Terms of Reference of the Transfusion Committee that shall include to: i) define blood transfusion policies adapted to the local clinical activities; ii) conduct regular review of blood transfusion practices; iii) analyse any adverse events due to blood donation and transfusion; iv) take any preventive and corrective measures if necessary; v) ensure all staff involved in transfusion chain receive adequate training.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Letters of appointment/assignment	NA				
	2.	Terms of Reference of Transfusion Committee	NA				
	3.	Minutes of Transfusion Committee meeting	NA				
16.1.1.6	The Head of Blood Transfusion Services is involved in the appointment and/OR assignment of the 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				
16.1.1.7	Appropriate statistics and records shall be maintained for defined retention periods in relation to the provision of Blood Transfusion Services and used for managing the services and patient care purposes.		NA			NA	

	If blood collection activities are carried out within the Facility, appropriate donor statistics and records shall be maintained as above. **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) donation records; NA e) transfusion records; NA f) staffing number and staff profile; NA g) staff training records; NA h) data on performance improvement activities, including performance indicators. NA					
16.1.1.8	Where any part of the services is provided in areas within the Facility other than in the Blood Transfusion Services, responsibility for the operations of those services is clearly defined. Staff are trained, given appropriate instructions and closely supervised to operate these services. The appropriate equipment is properly maintained and quality control is carried out and documented. Notes/Explanations These services include the following: i. Storage. ii. Transport. **EVIDENCE OF COMPLIANCE** 1. Records are available for the following: a) Training and competency records NA b) Equipment maintenance records NA c) Records on quality control measures NA	NA			NA	

STANDARD STANDARD 16.1.2

Facilities that do not provide a full range of Blood Transfusion Services shall arrange with an external source to provide the services needed.

CRITERION NO.	CRITERIA FOR COMPLIANCE			SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
						AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
16.1.2.1	The Blood Transfusion Services provided by an external source shall comply with all relevant MSQH Standards of Accreditation.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Certification of accreditation for the following:						
	a)	Department of Standards Malaysia (ISO MS 15189) and	NA					
	b)	MSQH Standards of accreditation	NA					
	c)	Compliance to current Good Manufacturing Practice (cGMP) standards	NA					
16.1.2.2 CORE	Where services are provided from an external source, there is a written agreement between the external service provider and the Facility stating the requirements for service delivery, including the following but not limited to: a) formal lines of communication, responsibilities and reporting between the external service provider and the Facility; b) staff providing the services are appropriately qualified; c) requirement for written requests; d) effective and safe handling and transport of specimens, blood and blood products; e) arrangements for after-hours and emergency services; f) the external service provider shall have a quality system in place.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	There is written agreement with the external service provider and the Facility specifying items (a) to (f).	NA					

TOPIC TOPIC 16.2
HUMAN RESOURCE DEVELOPMENT AND MANAGEMENT

STANDARD STANDARD 16.2.1
The Blood Transfusion Services shall be headed by a registered medical practitioner with training and experience in Transfusion Medicine/ Haematopathology/Haematology. The day-to-day operations of the service may be delegated to a suitably qualified and experienced officer, supported by appropriately qualified staff.

CRITERION NO.	CRITERIA FOR COMPLIANCE	SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
				AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
16.2.1.1 CORE	The direction and overall supervision of the Blood Transfusion Services shall be by a Head who is a registered medical practitioner with training and experience in Transfusion Medicine/ Haematopathology/Haematology. There is evidence that the medical practitioner is actively practicing as evidenced by: a) being responsible for 24 hours cover for the Blood Transfusion Services; b) ensuring and participating in continuing medical education programme. EVIDENCE OF COMPLIANCE 1. Appointment/assignment letter — NA 2. Job description — NA 3. Primary qualifications of the Head of Blood Transfusion Services. — NA 4. Valid professional Annual Practising Certificate (APC) — NA 5. Documentation of participation in continuing medical education and meeting — NA	NA			NA	
16.2.1.2	The authority, responsibilities and accountabilities of the Head of Blood Transfusion Services are clearly delineated and documented. EVIDENCE OF COMPLIANCE 1. Appointment/assignment letter for Head of Service. — NA 2. Description of duties and responsibilities — NA	NA			NA	
16.2.1.3	The staffing of the Blood Transfusion Services is provided by individuals qualified by education, training, and experience and certification to meet the demands of the various positions and to achieve the scope of the services.	NA			NA	

	EVIDENCE OF COMPLIANCE						
	1.	The medical/nursing staff in Blood Transfusion Services shall have a valid professional Annual Practising Certificate (APC).	NA				
	2.	Experience of the staff of Blood Transfusion Services shall meet the demand of their positions, the scope and complexity of the Blood Transfusion Services activities. Staff credentials and privileges.	NA				
	3.	Current assigned duty roster	NA				
16.2.1.4	Sufficient numbers of personnel and support staff with appropriate qualifications are employed to meet the need of the services. Notes/Explanations Staff are properly trained and qualified to perform the task that are required of them. The number of staff employed shall commensurate with the workload of the Blood Transfusion Services.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Number of staff and qualification commensurate with workload.	NA				
	2.	Staffing pattern	NA				
	3.	Duty roster	NA				
	4.	Census and statistics	NA				
16.2.1.5	There are written and dated specific job descriptions for all categories of staff that include: a) qualifications, training, experience and certification required for the position; b) lines of authority; c) accountability, functions and responsibilities, d) reviewed when required and when there is a major change in any one 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.		NA			NA	

	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					
16.2.1.6	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. 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) incidents at work; — NA h) confidentiality agreement; — NA i) health screening status; — NA j) immunisation status. — NA	NA			NA	
16.2.1.7	There is a structured orientation programme and on-the-job training to introduce new staff to the Blood Transfusion Services, operational policies and relevant aspects of the Facility to prepare them for their roles and responsibilities. This include but not limited to: a) rules and regulations on Blood Transfusion Services;	NA			NA	

	b) policies and procedures on all aspects of Blood Transfusion Services; c) all relevant manuals on hazards and safety precautions including requirements for immunisation against certain infections. **EVIDENCE OF COMPLIANCE** 1. Policy requiring all new staff to attend a structured orientation programme. NA 2. There is Blood Transfusion Services orientation programme with relevant topics not limited to topics covered from (a) to (c). NA 3. Attendance list NA					
16.2.1.8	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. **EVIDENCE OF COMPLIANCE** 1. Training needs assessment is carried out and gaps identified. NA 2. A staff development plan based on training needs assessment is available. NA 3. Training schedule/calendar is in place. NA 4. Training module NA	NA			NA	
16.2.1.9	There are continuing education activities for staff including medical practitioners to pursue professional interests and to prepare for current and future changes in practice. **EVIDENCE OF COMPLIANCE** 1. Training calendar includes in-house/external courses/ workshop/conferences NA 2. Contents of training programme NA 3. Training records on continuing education activities are kept and maintained for each staff including training in life support. NA 4. Certificate of attendance/degree/post basic training NA	NA			NA	
16.2.1.10	Staff including medical practitioners shall 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 are completed upon probationary period and as an annual exercise.	NA				
16.2.1.11	The Blood Transfusion Services shall provide a continuing education programme for non-transfusion services health professional staff to keep them informed of updates and advances in blood transfusion and related fields.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Records on continuing education activities for non-transfusion services health professional staff.	NA				
	2.	Records on attendance	NA				
16.2.1.12	The functions of the Blood Transfusion Services include continuous professional development, where relevant, as well as research projects and special studies, as appropriate.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Records on training	NA				
	2.	Records on research projects and special studies if available.	NA				

TOPIC TOPIC 16.3
POLICIES AND PROCEDURES

STANDARD STANDARD 16.3.1
There are written and dated policies and procedures that reflect current knowledge and principles of blood transfusion practice. They are consistent with statutory requirements and the objectives of the Blood Transfusion Services. There are Standard Operating Procedures (SOPs), consistent with current policy and guidelines: National Policy for Blood Transfusion Services in Malaysia, Transfusion Practice Guidelines for Clinical and Laboratory Personnel and Guideline for the Rational Use of Blood and Blood Products by the Ministry of Health Malaysia, available for staff reference.

CRITERION NO.	CRITERIA FOR COMPLIANCE	SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
				AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
16.3.1.1 CORE	There are written policies and procedures for each area of the Blood Transfusion Services that reflect the roles of the Facility and guide the activities of Blood Transfusion Services. They are consistent with the overall policies of the Facility, regulatory requirements and current standard practices. The policies and procedures include but not limited to the following: a) the conduct of professional activities in accordance with the ethical standards of the professions involved and code of ethics in transfusion; b) provision of services on a 24-hour basis, where necessary; c) provision of quality care to blood donors and patients who receive transfusion; d) provision of consultative service for the medical profession and other relevant staff on the appropriate use of blood and blood products and in the selection of the laboratory investigations, their interpretation and repeat of tests if required; e) communication and collaboration with clinical and other relevant staff on matters related to the services provided. 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 include items (a) to (e). NA	NA			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				
	5.	Written ethical standards for professions and transfusion.	NA				
	6.	Donor acceptance and deferral criteria	NA				
	7.	Donor Registration Form	NA				
	8.	Standard operating procedures on donor management – predonation, donation and post donation	NA				
	9.	Records on blood request forms	NA				
	10.	Records on blood transfusion in patient medical records	NA				
	11.	Standard operating procedures on transfusion – blood sampling and labelling, blood administration, management of adverse transfusion reactions.	NA				
	12.	Training and competency records	NA				
16.3.1.2 CORE	There are policies and procedures for blood donation that include: a) donor declaration and consent for donation shall be obtained and maintained; b) blood donation shall be on a voluntary and non-remunerated basis and payment for blood donated shall not be allowed; c) directed blood donation by the family members is not recommended except in special circumstances; d) criteria for donor acceptance shall be in accordance to current guidelines; e) blood donation shall not be allowed from donors with high risk behaviours; f) all blood collected shall be clearly and uniquely identified and traceable to the donors.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Policies and procedures for blood donation include items (a) to (f).	NA				
	2.	Donation and donor database	NA				
	3.	Blood donation consents	NA				

16.3.1.3 CORE	There are policies and procedures for screening of blood for Transfusion Transmissible Infections (TTIs): a) mandatory screening for HIV, Hepatitis B, Hepatitis C and Syphilis shall be performed on all donated blood; b) technology and methodology of the tests to be followed shall be based on current guideline; c) only blood screened negative for TTIs shall be released for use; d) unscreened blood shall not be used for transfusion. **EVIDENCE OF COMPLIANCE** 1. Policies and procedures for screening of blood for Transfusion Transmissible Infections (TTIs) include items (a) to (d). — NA 2. Enzyme Immune Assay (EIA) is performed for HIV, Hepatitis B, Hepatitis C screening. — NA 3. Records on screening results — NA 4. Blood release records — NA	NA			NA	
16.3.1.4 CORE	There are policies and procedures for blood component preparation as follows: a) donated blood shall be processed into suitable blood components for use; b) blood component preparation shall be in accordance with national standards and current Good Manufacturing Practice (cGMP); c) proper equipment, validated and maintained shall be used to process components; d) regular quality control shall be carried out to ensure quality of components. **EVIDENCE OF COMPLIANCE** 1. Standard operating procedures for blood component preparation. — NA 2. Records on types of components prepared — NA 3. Records on quality control (QC) of components prepared. — NA 4. Records on equipment maintenance — NA	NA			NA	

16.3.1.5 CORE	There are policies and procedures for blood inventory management as follows: a) proper storage and transport of blood and blood products shall follow current Good Manufacturing Practice (cGMP) and Good Distribution Practice (GDP) to ensure blood cold chain is maintained at all times; b) a minimum quantity of blood and blood components appropriate to the level and type of services offered by the Facility shall be maintained at all times; c) an inventory management system shall be established and should include contingency plans during shortages; d) expired and unsuitable blood and blood components shall be appropriately disposed of. EVIDENCE OF COMPLIANCE 1. Policies and procedures for blood inventory management include items (a) to (d). — NA 2. Records on temperature monitoring during storage and transport — NA 3. Records on discarded blood and blood components. — NA	NA			NA	
16.3.1.6 CORE	There are policies and procedures for immunohaematology as follows: a) processes and procedures shall be put in place to ensure only safe and compatible blood and blood components are issued to all patients; b) ABO and Rh typing shall be carried out and documented for all donated blood in accordance to national guideline; c) antibody screening shall be performed on patients and documented; d) patient's ABO and Rh typing shall be determined, and screening for red cell antibodies shall be performed. Compatibility testing shall be performed prior to transfusion and documented; e) all near misses, incorrect blood component transfused (IBCT) and ABO discrepancies shall be investigated and documented. EVIDENCE OF COMPLIANCE	NA			NA	

	1.	Policies and procedures for immunohaematology include items (a) to (e).	NA				
	2.	Records on ABO and Rh grouping for donated blood	NA				
	3.	Records on pre-transfusion testing for patient	NA				
16.3.1.7	There are policies and procedures for Clinical Transfusion Practice as follows: a) Informed consent for transfusion shall be obtained by registered medical practitioner and maintained. b) There are policies and procedures relating to requests for blood transfusion including: i) only registered medical practitioners are authorised to prescribe and request for blood transfusion; ii) identification of the patient by identity card (IC) number/passport number, full name, medical record number iii) signature and name of the requesting medical practitioner; iv) blood components and blood products requested; v) relevant medical history of patient and the indication for transfusion; vi) signature and name of the staff who performed the blood sampling and labelling; vii) the specimen shall be clearly and correctly labeled. c) There are policies and procedures relating to the administration of blood and blood components including: i) prior to administration of blood and blood components, all information identifying the blood for the intended recipient shall be verified according to the checklist as stipulated in the national guideline; ii) transfusion therapy is under the overall responsibility of a registered medical practitioner; iii) signature and name of the staff who performed the administration of blood and/or components; iv) all patients receiving transfusion of blood or blood components shall be monitored during and after the transfusion process; v) all near misses shall be managed appropriately, documented and reported; vi) all adverse events shall be managed appropriately, documented and reported to the Transfusion Committee and National Haemovigilance Coordinating Centre (NHCCC). d) All transfusion records shall be included in the patient's medical record in accordance to defined retention periods.		NA			NA	

	EVIDENCE OF COMPLIANCE						
	1.	Documentation of informed consent in patient's medical record.	NA				
	2.	Record of blood transfusion request	NA				
	3.	Record of blood transfusion checklist	NA				
	4.	Record of adverse events and near misses in relation to blood transfusion	NA				
16.3.1.8	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.		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				
16.3.1.9	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				
16.3.1.10	Copies of policies and procedures including Standard Operating Procedure Manual, protocols, guidelines, relevant Acts, Regulations, By-Laws and statutory requirements are accessible for staff reference.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Copies of policies and procedures including Standard Operating Procedure Manual, protocols, guidelines, relevant Acts, Regulations, By-Laws and statutory requirements are accessible on-site for staff reference.	NA				

16.3.1.11	The following records shall be kept in accordance to defined retention periods to ensure traceability and accountability: a) blood specimens received from other facilities; b) blood issued to patients for transfusion; c) blood received from other facilities; d) blood issued to other facilities.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Records on the following are available and maintained in according to retention periods.					
	a)	blood specimens received;	NA				
	b)	blood issued to patients for transfusion;	NA				
	c)	blood received from other facilities;	NA				
	d)	blood issued to other facilities.	NA				
16.3.1.12	There are policies and procedures on Haemovigilance as follows: a) adverse events relating to blood donation and transfusion; b) lookback and recall for seroconvert donor/recipient. All adverse events and seroconvert cases shall be investigated, documented and reported; c) reports shall be reviewed periodically by the Facility Transfusion Committee for preventive and corrective action and reported to National Haemovigilance Coordinating Centre (NHCCC), National Blood Centre, Ministry of Health.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	Standard operating procedures on management of reporting of adverse events	NA				
	2.	Standard operating procedures on look back and recall with management of these cases.	NA				
	3.	Minutes Facility Transfusion Committee on Haemovigilance.	NA				

16.3.1.13	There are written standard precautions and safety guidelines for Blood Transfusion Services. All blood transfusion staff shall adhere to these standard precautions and safety guidelines. EVIDENCE OF COMPLIANCE 1. Standard Precautions and Safety Guidelines — NA 2. Training records on standard precautions and safety guidelines. — NA	NA			NA	

TOPIC TOPIC 16.4
FACILITIES AND EQUIPMENT

STANDARD STANDARD 16.4.1
There are adequate facilities and equipment for the safe and efficient provision of Blood Transfusion Services.

CRITERION NO.	CRITERIA FOR COMPLIANCE		SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
					AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
16.4.1.1	The administrative, blood donation, blood component, blood procurement, processing, screening, testing, storage and technical laboratory areas are separate.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	There are designated areas for:					
	a)	administrative functions;	NA				
	b)	blood donation;	NA				
	c)	blood component;	NA				
	d)	blood procurement;	NA				
	e)	processing;	NA				
	f)	screening;	NA				
	g)	testing;	NA				
	h)	storage;	NA				
	i)	technical laboratory areas.	NA				
16.4.1.2	Technical work areas shall be adequately spaced out and arranged in such a way to facilitate workflow to ensure safety and efficiency.		NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	On-site observation to verify layout of facility complies with safety requirements	NA				
	2.	Unidirectional flow of blood donors, blood samples and blood components.	NA				
16.4.1.3	There are adequate storage facilities and equipment which comply with current regulations and guidelines. The storage facilities include:		NA			NA	

	a) adequate and proper storage space for reagents, consumables, and other materials; b) sufficient space and refrigeration for storage of blood and blood components with proper records; c) screened and unscreened blood and blood components shall be kept in separate refrigerators and freezers respectively; d) temperature control of all blood refrigerators, freezers and platelet agitators shall be monitored and documented. **EVIDENCE OF COMPLIANCE** 1. Adequate facilities and proper utilisation of space within the Facility. a) Clear exit route — NA b) No over crowding — NA 2. Adequate storage space — NA 3. Record of temperature monitoring — NA 4. Dedicated refrigerators and freezers for screened and unscreened blood and blood components. — NA 5. Records of alarm checks carried out for blood refrigerators, freezers and platelet agitators. — NA					
16.4.1.4	All blood that has been screened and found reactive shall be removed from the stock. All tainted blood bags shall be autoclaved and subsequently incinerated. **EVIDENCE OF COMPLIANCE** 1. Standard operating procedures for disposal of reactive donations — NA 2. Records on disposal due to reactive donations — NA	NA			NA	
16.4.1.5	There are suitably located staff facilities with locker facilities and staff are provided with appropriate personal protective clothing. **EVIDENCE OF COMPLIANCE** 1. Appropriate Personal Protective Equipment (PPE) available. — NA 2. Staff facilities, i.e. lockers. — NA	NA			NA	

16.4.1.6	There is suitable, adequate and safe provision for air conditioning, ventilation, lighting, power, gases, water and drainage, which include the following: a) air conditioning shall be efficient to maintain low humidity, constant and comfortable room temperature; b) power supply shall be adequate with sufficient suitably located power outlets; c) adequate and appropriate lighting; d) alarm and emergency power supply for critical equipment including but not limited to refrigerators for blood and blood products, freezers platelet agitators and apheresis machines. EVIDENCE OF COMPLIANCE 1. Provisions for items (a) to (d) are available on-site. NA 2. Record of ambient temperature monitoring in appropriate locations such as component processing area, etc. NA	NA			NA	
16.4.1.7	Equipment are appropriate and adequate to meet the scope of the services. EVIDENCE OF COMPLIANCE 1. Adequate equipment NA 2. Appropriate equipment commensurate with the scope of services provided NA	NA			NA	
16.4.1.8	The Blood Transfusion Services shall have adequate and appropriate information management system and communication facilities. EVIDENCE OF COMPLIANCE 1. Bidirectional traceability and audit trail is available. NA	NA			NA	
16.4.1.9	Where specialised equipment is used, there is evidence that only staff who are trained and authorised by the Facility operate such equipment. EVIDENCE OF COMPLIANCE 1. User training records NA 2. Competency assessment record NA 3. Letter of authorisation NA	NA			NA	

	4.	List of staff trained and authorised to operate specialised equipment	NA				
16.4.1.10	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, e.g. Medical Device Authority certification.	NA				
16.4.1.11	Each equipment shall have a logbook and maintenance record.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Equipment log book	NA				
	2.	Equipment maintenance record	NA				
16.4.1.12 CORE	There is evidence that the Facility has a comprehensive maintenance programme such as predictive maintenance, planned preventive maintenance and calibration activities, to ensure the facilities and equipment are in good working order.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Planned Preventive Maintenance records such as schedule, stickers, etc.	NA				
	2.	Planned Replacement Programme where applicable	NA				
	3.	Complaint records	NA				
	4.	Asset inventory	NA				
16.4.1.13	Cleanliness in the Blood Transfusion Services shall be maintained at all times.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Good housekeeping is evidenced.	NA				
	2.	Cleaning records	NA				
16.4.1.14	There are proper facilities for the disposal of biohazard wastes.			NA			NA	
	EVIDENCE OF COMPLIANCE							

	1.	Proper facilities for disposal of biohazard wastes.	NA					

TOPIC TOPIC 16.5
SAFETY AND PERFORMANCE IMPROVEMENT ACTIVITIES

STANDARD STANDARD 16.5.1
The Head of Blood Transfusion Services shall ensure the provision of safe and adequate blood and components with staff involvement in the continuous safety and performance improvement activities of the Blood Transfusion Services.

CRITERION NO.	CRITERIA FOR COMPLIANCE	SELF RATING	FACILITY COMMENTS	SURVEYOR FINDINGS		
				AREAS FOR IMPROVEMENT / RECOMMENDATIONS	SURVEYOR RATING	RISK
16.5.1.1	There are planned and systematic safety and performance improvement activities to monitor and evaluate the performance of the Blood Transfusion 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					
16.5.1.2	The Head of the Blood Transfusion Services has assigned responsibilities to appropriate individuals/team/committees for safety, quality assurance, performance improvement and risk management activities within the services.	NA			NA	

	EVIDENCE OF COMPLIANCE						
	1.	Assigned individual/committee for safety, risk management and quality assurance activities	NA				
	2.	Terms of Reference/Job description	NA				
	3.	Written document for safety and quality assurance activities, e.g. standard operating procedures, audit reports, proficiency testing. Quality control activities.	NA				
	4.	Minutes of meetings	NA				
16.5.1.3	The Head of the Blood Transfusion 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. The Head of Blood Transfusion Services leads the team in the investigation and reporting of transfusion transmitted diseases.			NA			NA	
	EVIDENCE OF COMPLIANCE						
	1.	System for incident reporting/adverse event reporting is in place, which include:					
	a)	Training of staff	NA				
	b)	Policy on incident/adverse event reporting	NA				
	c)	Methodology of incident//adverse event reporting	NA				
	d)	Register/records of incidents/adverse event	NA				
	2.	Completed incident/adverse event reports	NA				
	3.	Root Cause Analysis	NA				
	4.	Corrective and preventive action plans	NA				
	5.	Remedial measure	NA				
	6.	Minutes of meetings	NA				
	7.	Acknowledgment by Head of Service and PIC/Hospital Director	NA				
	8.	Feedback given to staff regarding incident reporting.	NA				

16.5.1.4 CORE	There is tracking and trending of specific performance indicators not limited to but at least two (2) of the following. a) crossmatch to transfusion ratio (C:T ratio) (Target: ≤ 2.0) b) expiry rates of different blood components (Target: red cell: ≤ 2.5% platelet concentrates: ≤ 15% apheresis (platelet or plasma): 0%) c) number of adverse events in donors (adverse donor reactions and seroconversion) d) number of adverse events in patients [near misses, transfusion errors (Incorrect blood component transfused), transfusion reactions, transfusion transmitted infections] Notes/Explanations These specific indicators to be monitored depending on the scope of the services. The reports on indicators are available and submitted to the national coordinating agency (National Blood Centre, Ministry of Health). EVIDENCE OF COMPLIANCE 1. Specific performance indicators monitored. NA 2. Records on tracking and trending analysis. NA 3. Remedial measures taken where appropriate NA	NA			NA	
16.5.1.5	The Blood Transfusion Services shall have relevant internal quality control programme and subscribe to approved external quality assessment. The results of the performance shall be communicated to the staff. EVIDENCE OF COMPLIANCE 1. Records on Internal Quality Control (QC) and External Quality Assurance performance. a) QC of tests performed NA b) Proficiency testing (External quality assurance program) NA	NA			NA	
16.5.1.6	The feedback on results of quality assurance activities are regularly communicated to the staff. EVIDENCE OF COMPLIANCE	NA			NA	

	1.	Minutes of meeting	NA				
	2.	Staff acknowledgement documented in communication book.	NA				
	3.	Circulation of analysis report.	NA				
16.5.1.7	Audit shall be carried out to cover processes and activities of the services.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Audit schedule.	NA				
	2.	Audit report.	NA				
16.5.1.8	A Blood Transfusion Services officer shall be appointed to monitor laboratory safety and observance of standard precautions and safety guidelines.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Letter of appointment	NA				
16.5.1.9	Appropriate documentation of safety and performance improvement activities is kept and confidentiality of medical practitioners, staff, donors and patients are preserved.			NA			NA	
	EVIDENCE OF COMPLIANCE							
	1.	Documentation on performance improvement activities and performance indicators.	NA				
	2.	Policy statement on anonymity on donors and patients involved in performance improvement activities.	NA				

SERVICE SUMMARY	
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OVERALL RATING :	NA
OVERALL RISK :	-