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Accredited Organisation 2022-2026

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PUBLIC NOTICE FOR COMMENTS ON DRAFT 1st EDITION QAI ACCREDITATION STANDARDS FOR HEMATOPOIETIC CELL TRANSPLANTATION AND CELLULAR THERAPY (PRODUCT COLLECTION, PROCESSING, AND ADMINISTRATION)

QAI CAHSC 's Technical Committee has drafted the accreditation standards for **Hematopoietic Cell Transplantation and Cellular Therapy (Product Collection, Processing, and Administration)**. These standards were developed based on standards development principles of RUMBA (Relevant, Understandable, Measurable, Beneficial and Achievable).

The 1st edition draft Standards are now being subjected to a wide consultation process of all our stakeholders, including experts and client organisations by hosting on our website www.qai.org.in and disseminating through emails and social media. You all are also requested to widely disseminate this information amongst your peers and groups.

We kindly request you to please provide your valuable comments to us on these standards in the following format:

Sl. No.	Page No.	Standard/ Criterion Number	Comments

Please send your feedback to shruti@qai.org.in latest by 26 February 2025.

On behalf of the Board of QAI's Centre for Accreditation of Health & Social Care (CAHSC), I would like to thank you all in advance for your valuable feedback.

With regards,

(Dr. B.K. Rana)
CEO

Quality & Accreditation Institute

Centre for Accreditation of Health & Social Care

Accreditation Standards for Hematopoietic Cell Transplantation and Cellular Therapy

Product Collection, Processing, and Administration

Final Draft for Stakeholder Consultation

1st Edition, February 2025

I Introduction

1. These accreditation standards are meant for the accreditation of the facilities involved in Collection, Processing and Administration of hematopoietic cell transplant and cellular therapy products. It may please be noted that a facility may involve in all or any of the following activities:

   A. Collection, processing, storage, distribution, administration
   B. Collection, processing, storage, administration
   C. Collection, processing, administration
   D. Collection, storage, administration
   E. Collection, administration
   F. Processing, storage, distribution
   G. Collection and distribution (for administration or to processing facility)
   H. Administration
   I. Manufacturing, storage, distribution
   J. Collection, processing, manufacturing, storage, distribution, administration

2. Collection facility may include bone marrow and/or apheresis collection. It may include collection of cellular products from donor (patient or another person).

3. Processing facility may be involved in processing, storage and distribution. Such facility may be a standalone facility.

4. Scope of the QAI Accreditation Standards includes:
   A. Hematopoietic progenitor cells (HPCs
   B. Nucleated cells or mononuclear cells from any hematopoietic tissue source
   C. Immune effector cells (IECs)
   D. Genetically modified cells

   CAR T Cell will be added subsequently as the things progresses.

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Chapter 1
Governance and Leadership (GAL)

Introduction

Each facility requires a governance structure that is ultimately responsible for the quality and safety of services provided. This responsibility is derived from its legal identity and operational authority for all activities undertaken by the facility within the ambit of applicable laws and regulations. Each facility, regardless of its complexity, also has a formal structure. Leaders ensure that a system exists that promotes safety and quality, provision of services that meet the needs of patient, availability of adequate resources e.g., human, financial & physical and, monitoring and evaluation of improvement activities.

STANDARDS AND CRITERIA		
Standard	**GAL.1:**	**The management of the facility is committed and accountable for the quality and safety of care delivered.**
Criterion	**a.**	The management of the facility demonstrates a culture of quality and safety through implementing these accreditation standards.
	b.	The management ensures the availability of necessary resources such as human, infrastructure including equipment and finance to support the smooth operation of the facility.
	c.	The management has oversight over defined quality & safety plan and the same is implemented by designated staff.
Standard	**GAL.2:**	**Accountability and responsibility of key leadership functions are assigned.**
Criterion	**a.**	There is a documented and updated organogram of the facility.
	b.	The management is aware of the applicable laws and regulations, and complies with the same at all time.
	c.	The management implements actions necessary to achieve planned results and effective implementation of the quality management system.
	d.	The management conducts reviews to determine achievement towards defined goals, objectives, and outcomes.
	e.	The facility reports its outcomes to an existing HCT registry such as ISBMT / EBMT/ APBMT/ CIBMTR.
Standard	**GAL.3:**	**The facility plans services to meet the needs of the patient population it serves and makes decisions in accordance with its values and ethical principles.**

Criterion	**a.**	The facility provides services that are in alignment with its objectives and the needs of its patients.
	b.	The facility coordinates the functioning with different departments and external agencies, and monitors the progress in achieving the defined goals and objectives.
	c.	The facility develops an annual operating budget to run its services and include a budget for quality & safety activities.
	d.	The management defines ethical framework which includes processes for managing issues with ethical implications, dilemmas, and concerns.
	e.	The facility discloses its ownership and transparently portrays its affiliations and accreditations.
Standard	**GAL.4:**	**The leadership ensures that clinical responsibilities of staff are defined and supervised by qualified and experienced personnel.**
Criterion	**a.**	The facility defines clinical responsibilities of staff in consonance with the prevalent laws and regulations.
	b.	The facility ensures supervision of clinical staff by qualified and experienced personnel.

Chapter 2
Human Resources Management (HRM)

Introduction

Human Resources include all the people that work in, for or with the facility and they are integral part for ensuring the delivery of high quality, patient-centred and safe care. The facility must be able to assure the public and/ or patients that it can meet their needs and deliver high quality and safe care through a team of dedicated and qualified staff. The support includes the management team providing a safe physical environment for staff to work in, which is free from harassment or accidents.

STANDARDS AND CRITERA		
Standard	**HRM.1:**	**The facility has a documented process for human resource planning with adequate professional and technical staff.**
Criterion	**a.**	The planning ensures that the facility has suitably qualified and trained adequate manpower to provide the defined scope of services.
	b.	The facility shall have adequate clinical, nursing, paramedical and other staff in accordance with the need and applicable regulatory requirements.
	c.	The facility shall have a coordinator, data manager, medical social worker, dietician, physical therapist, and psychologist, and access to psychiatrist and other clinical specialists as required.
	d.	The facility shall have adequate support staff to support clinical and non-clinical functions.
	e.	The facility shall have a defined recruitment process for all types of staff.
Standard	**HRM.2:**	**The facility has a documented performance evaluation process.**
Criterion	**a.**	The facility has a standardised documented process for evaluating the performance of its staff.
	b.	Performance evaluation is done based on the pre-determined criteria including necessary competence and periodicity.
Standard	**HRM.3:**	**The facility has a continuous training and professional development programme for its staff including outsourced staff.**
Criterion	**a.**	Staff are trained and updated regularly and when job responsibilities change/ new equipment or activity introduced.
	b.	Staff are trained on organisation safety programme, safety related to occupation, organization disaster management plan, fire and non-fire emergencies, surrounding environment and quality management programmes.

	c.	The facility shall implement the documented process of initial orientation and ongoing training for the staff involved in the care of patient.
	d.	Staff are provided continuing education or other equivalent educational activity at least annually.
	e.	The facility shall maintain records of education, training, skills and experience.
Standard	**HRM.4:**	**A documented disciplinary and grievance handling system exists in the facility.**
Criterion	**a.**	Disciplinary and grievance handling policies and procedures including those for violence and harassment are documented.
	b.	These policies and procedures also address requirements of applicable laws.
	c.	Staff are made aware about such policies and procedures.
	d.	Actions are taken to address the grievances and complaints and same is documented.
Standard	**HRM.5:**	**A documented policy exists to address health and safety needs of staff.**
Criterion	**a.**	Staff is subjected to an appropriate pre-employment and annual medical examination.
	b.	Health issues including occupational health hazards of staff are addressed as per documented policy.
	c.	Staff is vaccinated as per the policy of the facility however at a minimum prescribed by the government/ regulator.
	d.	The facility has measures in place for prevention and handling of workplace violence's.
Standard	**HRM.6:**	**The facility has a documented system of competence, credentialing and privileging of medical, nursing and paramedical staff.**
Criterion	**a.**	The facility verifies credentials of medical, nursing and paramedical staff.
	b.	Medical, nursing and paramedical staff are privileged to provide required care as per their credentials based on education, training, competence, experience, and regulatory requirements.
	c.	Medical, nursing and paramedical staff privileges are periodically reviewed.
Standard	**HRM.7:**	**The facility has a documented system of maintaining personnel files for all staff members.**
Criterion	**a.**	Personnel file is a document that contains at least the personal information, qualifications; credential and privileges; results of evaluation and appraisals, employment history, trainings attended, job description and disciplinary actions.
	b.	A personnel file is updated as necessary for each staff member and their confidentiality is ensured.

Standard	**HRM.8:**	**The facility has a Lead/ Director of Hematopoietic Cell Transplantation & Cellular Therapy (or designate/s).**
Criterion	**a.**	The Lead/ Director (or designate) for the facility must have significant amount of training and expertise/knowledge required for activities related to cellular therapy. The Lead/ Director must be licensed to practice medicine, and have the requisite training and experience in Clinical Haematology/ Medical Oncology/ Immunology/ and/or Paediatric Haematology/ Oncology with 10 or more years of experience including exp in HCT.
	b.	The Lead/ Director (or designate) shall participate in a minimum of ten (10) hours of educational activities related to cellular therapy annually.
	c.	The Lead/ Director (or designate) shall have clearly defined authority and responsibilities to provide leadership and manage medical and administrative issues.
	d.	The Lead/ Director (or designate) shall be available to provide leadership and manage medical and administrative issues.
	e.	The Lead/ Director (or designate) shall be involved in the care of patients and provide consultative advice to other treating physicians.
Standard	**HRM.9:**	**The facility has qualified and competent Cellular Therapy Physician(s).**
Criterion	**a.**	Physician(s) performing peripheral blood, cord blood, and bone marrow transplantations must be licensed to practice medicine. He should be certified and have the requisite training and experience in Haematology, Medical Oncology, Immunology, and/or Paediatric Haematology/ Oncology.
	b.	Physician must hold any one of the following qualifications: • DM/DrNB Clinical Haematology with training in HCT • DM/DrNB Medical Oncology with training in HCT • DM/FNB Paediatric Haematology / Oncology with training in HCT • Candidates with MD/DNB (Internal Medicine/ Paediatrics/ Pathology) should undergo at least 2 years of training in a recognised department of Haematology/ Medical Oncology with at least one year of training in HCT. • Equivalent recognised qualifications from other countries with at least one year of training in HCT.

Chapter 3
Facility and Risk Management (FRM)

Introduction

The facility will prevent people from receiving unsafe care and treatment and prevent avoidable harm or risk of harm. Safe, high-quality care and support is intrinsically linked to how resources are used including how they are planned, managed and delivered. Facility must assess the risks to people's health and safety during any care or treatment and make sure staff have the skills, experience and competence to keep patients safe. Premises and equipment must be safe and available in sufficient quantities. Good clinical practices are followed in all its operations. Facility must prevent the spread of infection.

STANDARDS AND CRITERIA		
Standard	**FRM.1:**	**Facility is appropriate to scope of services and is managed in accordance with applicable laws and regulations.**
	a.	There is a process for planning, designing, development and maintenance of the infrastructure to ensure optimum quality and safety outcomes and compliance with all applicable laws and regulations.
	b.	The updated drawings are available which deal with site-layout, floor plans, fire including emergency escape routes, electrical, plumbing, HVAC and piped medical gas drawings.
	c.	The management ensures the availability of adequate infrastructure (building, space, equipment, manpower and supplies) to provide the defined scope of services.
Standard	**FRM.2:**	**There is a documented risk management plan focusing on safety and security.**
Criterion	**a.**	The facility has a risk management plan to address identified safety and security threats.
	b.	The plan provides and maintains safe and secure environment for patients, staff and visitors.
	c.	Patient-safety devices & required infrastructure are installed across the facility and inspected at regular intervals.
	d.	The organization has facilities for the differently-abled population.
	e.	There are signage available both internally and externally in the facility in a language understood by patient, family and community.
	f.	The facility conducts facility inspection at least once every quarter of the year to identify security and safety threats and findings from inspection

		are acted upon, and records are maintained.
Standard	**FRM.3:**	**The facility has round the clock provision of potable water and electricity.**
Criterion	**a.**	The facility ensures round the clock availability of potable water and electricity.
	b.	Inspection, maintenance and testing of the systems including alternative sources to be ensured on regular basis.
Standard	**FRM.4:**	**There is a documented emergency response plan.**
Criterion	**a.**	The facility has plans and earmarked resources to manage fire and non-fire emergencies.
	b.	There is a maintenance plan for fire related equipment and support infrastructure.
	c.	Staff are educated on the fire safety plan and non-fire safety plan on a periodic basis.
Standard	**FRM.5:**	**There is a documented programme for the facility, engineering support services, utility system and biomedical equipment management.**
Criterion	**a.**	The facility maintained a list of all biomedical and engineering equipment and utility system required and usage logs are maintained.
	b.	There is a documented operational and maintenance (preventive/ breakdown) plan for all equipment.
	c.	Equipment are periodically inspected and calibrated as applicable to ensure proper functioning.
Standard	**FRM.6:**	**There is a documented plan and system for management of hazardous materials.**
Criterion	**a.**	Documented plan includes those hazardous materials are identified, labeled, handled, stored, transported, disposed and used safely within the facility.
	b.	Staff is trained on the proper use of protective equipment and procedures during use, storing, handling, transportation, disposal, spill or exposure to hazardous materials.
Standard	**FRM.7:**	**The hospital has a programme for medical gases, vacuum and compressed air.**
Criterion	**a.**	Documented procedures govern procurement, handling, storage, distribution, usage and replenishment of medical gases.
	b.	Medical gases are handled, stored, distributed and used in a safe manner.
	c.	Alternate sources for medical gases, vacuum and compressed air are provided in case of failure.
	d.	There is a documented operational, inspection, testing and maintenance plan for piped medical gas, compressed air and vacuum installation.

Chapter 4
Information Management System (IMS)

Introduction

An effective information management system is based on the information needs of the facility. The system should be able to capture, transmit, store, analyse, utilise and retrieve information as and when required for improving clinical outcomes as well as individual and overall performance of the facility. Information can be in any form- paper, electronic, or a mix of both.

STANDARDS AND CRITERIA		
Standard	**IMS.1:**	**Documented policy and procedure exist to meet the information needs of the facility.**
Criterion	**a.**	Documented policies and procedures to meet the information needs, exist.
	b.	Information technology and management, including telemedicine or EMR are in accordance with the laws and documented policies & procedures.
	c.	The information needs of the facility are identified and are appropriate to the scope of services being provided by the facility.
Standard	**IMS.2:**	**The facility defines what constitutes a medical record and maintains a complete & accurate record for every patient.**
Criterion	**a.**	Every medical record has a unique identifier.
	b.	Entry in the medical record must have time, date, name and signature.
	c.	The medical record provides a complete, up-to-date and chronological account of patient care.
	d.	The medical record contains information regarding reasons for admission/ observation, assessment and re-assessment, diagnosis, investigation/ tests carried out, procedure(s) performed, monitoring and the care provided.
	e.	When patient is transferred to another facility/hospital, the medical record contains the details of the transfer.
	f.	The medical record contains a copy of the treatment note/ summary, duly signed by appropriate and qualified personnel.
Standard	**IMS.3:**	**There is a documented policy and procedure regarding retention time of records, data and information.**
Criterion	**a.**	Documented policy and procedure are in place on retaining the patient's

		clinical records, data and information in accordance with best practices, local or national laws and regulations.
	b.	The destruction of medical records, data and information is in accordance with the laid-down policy.
Standard	**IMS.4:**	**The facility has documented policy and procedure in place for maintaining confidentiality, integrity and security of records, data and information.**
Criterion	**a.**	Documented policy and procedure exist for maintaining confidentiality, integrity and security of records, data and information. are in accordance with the applicable laws.
	b.	The policy is in accordance with the applicable laws.
Standard	**IMS.5:**	**The facility conducts medical record audit.**
Criterion	**a.**	The medical record audit is periodically conducted.
	b.	The audit is conducted by trained individual.
	c.	The audit covers timeliness, legibility and completeness of the medical records.
	d.	The audit includes records of both active and discharged patients.
	e.	Appropriate corrective and preventive measures, against any deficiency observed, are undertaken within a defined period of time and are documented.

Chapter 5
Continual Quality Improvement (CQI)

Introduction

Quality management system (QMS) is defined and includes quality improvement processes. Performance indicators and benchmarks are identified for both positive outcomes and areas for improvement. Any necessary actions to improve the quality and safety of the services are implemented and learning is disseminated both internally and externally.

STANDARDS AND CRITERIA		
Standard	**CQI.1:**	**The management documents and implements a structured quality management system and safety programme in the facility.**
Criterion	**a.**	The leaders of the facility are accountable for service performance.
	b.	The leaders and management are involved in QMS and allocate resources for implementing the same.
	c.	The QMS includes a comprehensive quality improvement and patient safety programme which is developed, documented, implemented, maintained and reviewed by a multidisciplinary quality management & safety committee.
	d.	There is a transplant committee that shall include the Lead/ Director (or designate), the nurse coordinator, a quality representative and/or any other discipline representatives at the discretion of the facility leadership.
	e.	This transplant committee shall conduct quality and clinical reviews periodically.
	f.	Appropriate corrective and preventive actions are implemented and documented based on the identified gaps.
	g.	There is a designated individual (s) for coordinating the quality management and safety programme.
	h.	The quality and safety programme is communicated and coordinated amongst all the staff of the facility through appropriate training mechanism periodically.
	i.	The facility periodically (minimum annually) updates and controls all documented plans, policies and procedures.
	j.	Regular audits are conducted to ensure continuous compliance to the quality and safety programme.
Standard	**CQI.2:**	**The facility measures clinical and managerial structures, processes and outcomes to promote quality improvement.**

Criterion	**a.**	Data collection requirements, including verification for measurements of clinical and managerial structures, processes and outcomes are defined.
	b.	Measurements are used to determine areas for improvement and results are communicated to all concerned.
	c.	The facility defines and measures at a minimum, the following key clinical indicators. I. Length of stay in hospital II. Donor screening and testing III. Frequency of ICU transfers IV. Number of patients who enter the program that are not transplanted V. Complications During Apheresis in donor/ patient VI. Complications During Bone Marrow harvest in donor/ patient
	d.	The facility defines and measures at a minimum, the following key managerial indicators. I. Monitoring of the assigned nurse/patient ratio II. Nurse retention/turnover ratio III. Frequency of nurse training session IV. Patient satisfaction at discharge and at transitions V. Readmission rates within 30 days of discharge VI. Waiting time for admission and discharge of the patient
	e.	The facility also monitors the following: I. Consent taking II. Use of a checklist before starting the hematopoietic cell transplant as per institution policy III. Use of SOP for cross checking of the appropriateness of conditioning chemotherapy before the infusion into patient. IV. Use of SOP for appropriate checking of cross matching of blood products at bed side V. All cellular (except stem cell product) blood products are irradiated appropriately VI. Use of SOP for cross checking appropriateness of stem cell graft which should not be irradiated. VII. SOP for blood product reactions VIII. Recording of all medicines to which the patient/ donor is allergic IX. Recording of all known allergies in patient/ donor X. Checklist for discharge XI. SOP for shifting of patient to non-HEPA filtered area for diagnostic evaluations (Risk Benefit analysis based on severity of immune compromised status and necessity of diagnostic procedure, wearing of proper PPE for transportation, hand hygiene, minimise

		waiting time by good coordination, to avoid exposure to crowded pathways inside the hospital, dedicated corridor, elevator, disinfect equipment and environment before and after use and documentation of the same)
	f.	The facility shall define and measures the following key indicators for infection control. I. Hand hygiene (direct observation, CCTVs monitor, product consumption, use of fluorescent light lamp, monthly audit, comparison with other departments, hand swab) II. Catheter Associated Urinary Tract Infection (CAUTI) (calculate CAUTI rate, catheter check list, daily catheter necessity review, review of CAUTI cases and root cause analysis) III. Central Line Associated Blood Steam Infection (CLABSI) (CLABSI incidence tracking, central line insertion bundle and maintenance bundle, daily review, root cause analysis) IV. Ventilator Associated Pneumonia (VAP) (VAP incidence tracking, VAP prevention bundle, Roo cause analysis, oral care, antibiotic stewardship, ventilator circuit monitoring and maintenance) V. Surgical Site Infection (SSI) (SSI incidence tracking, compliance with surgical bundle, antibiotic stewardship, operating room environment, wound care protocol, hand hygiene protocol, root cause analysis of SSI) VI. Surface and air cultures (surface cultures of high-touch areas, regular air sampling, pre and post cleaning audit, microbiological identification and monitoring, isolate Clostridium difficile infection, HEPA filter monitoring, regular environment rounds by infection control team, protocol for outbreak of infections, documentation, staff training
Standard	**CQI.3:**	**The facility has implemented robust incident reporting and monitoring mechanisms.**
	a.	Type of reportable incidents and its management is defined and implemented.
	b.	Sentinel events are identified, reported, analysed and corrective action is taken.
	c.	Various stakeholders are informed of the detailed incidents and corrective actions taken.
	d.	Incident reports from the following areas needs to be documented: • laboratories, • wards,

		• pharmacy, • apheresis unit, • outpatient and • daycare.

Chapter 6
Patient Assessment and Care (PAC)

Introduction

Patients are made aware of the services being offered through different modes. Processes are defined for various activities including registration, admission, referral and discharge. Patients once taken into the facility either as an out-patient or as in-patient are assessed and re-assessed as per policy for their clinical needs and treatment.

STANDARDS AND CRITERIA		
Standard	**PAC.1:**	**The facility defines and displays its services.**
Criterion	**a.**	The facility plans its services as per needs of the community and clearly defines those being provided.
	b.	Services being provided are displayed prominently for easy access of the user.
Standard	**PAC.2:**	**The facility has a documented registration and admission process.**
Criterion	**a.**	The facility has documented policy and procedure for registration of all patients.
	b.	A unique number is generated for each patient upon registration.
	c.	The facility has documented policy and procedure for admission of patients.
Standard	**PAC.3:**	**Patients in the facility are appropriately assessed and care is provided.**
	a.	Patients are appropriately assessed, monitored and documented.
	b.	Assessments include initial assessment and regular re-assessment as applicable and appropriate for each patient.
	c.	All patients (out-patient, day-care, emergency and in-patients) undergo an assessment based on their clinical needs.
	d.	All assessments are documented and signed/ authenticated appropriately by staff.
	e.	Assessment results in formulation of appropriate care plan and the same is documented.
	f.	Re-assessments resulting in modification of appropriate care/ monitoring plan is documented.
	g.	There are documented guidelines/ pathways to identify, evaluate and treat patients as per the evaluation.
	h.	There are documented guidelines for communication and prompt identification for transfer to an intensive care unit or emergency department

		when required.
	i.	Staff in the transplant team shall demonstrate knowledge in the delivery of treatment related to patient's outcome.
	j.	Medical Board/ Multidisciplinary committee/ Speciality committee as appropriate is constituted as and when uncommon/rare/severe complications are encountered during HCT/cellular therapy.
Standard	**PAC.4:**	**The facility shall have a documented criteria for donor selection, evaluation, and management.**
Criterion	**a.**	There shall be a documented criteria for the allogenic and autologous donor selection, evaluation and management.
	b.	Criteria shall include requirements for age specific donors (minors and older age group).
	c.	Criteria shall also include selection of allogenic donors when more than one eligible donor is available.
	d.	Donors should undergo health check for determining the suitability.
Standard	**PAC.5:**	**The facility shall have a designated transplant team with trained personnel.**
Criterion	**a.**	All members of the transplant team should have current job description available that contains the experience, educational and physical requirements, and performance expectations for their role in the team.
	b.	Annual performance evaluations shall include performance of transplant related duties and activities for fulfilment of transplant requirements.
	c.	The facility shall define the criteria, qualifications, roles and responsibilities (through plan, policy or procedure) required for designation of qualified professionals and other personnel as assigned to the transplant team.
	d.	Members of the transplant team will receive initial orientation and ongoing training.
Standard	**PAC.6:**	**The facility provides appropriate and adequate laboratory & imaging services.**
Criterion	**a.**	Laboratory & imaging services are as per the scope of services of the facility.
	b.	Laboratory & imaging services are planned in accordance with laws, regulations and applicable national/ international guidelines.
	c.	Laboratory & imaging services not available are outsourced to an accredited laboratory/ facility which is able to demonstrate its competence to conduct such tests/ procedures.
	d.	There is a system of laboratory & imaging equipment maintenance and calibration.
Standard	**PAC.7:**	**The facility ensures uniform care and continuity of patient care.**
Criterion	**a.**	Documented procedure guides uniform care to patients and care is provided according to the best practices and appropriate laws & regulations.

	b.	The care plan for every patient is individualised and is dependent on their needs at assessment and reassessment.
	c.	The organisation adapts evidence-based clinical practice guidelines and/or clinical protocols to guide uniform patient care.
	d.	Clinical care pathways are developed, consistently followed across all settings of care, and reviewed periodically.
Standard	**PAC.8**:	**Resuscitation services are available throughout the facility.**
Criterion	**a.**	Appropriate medical equipment, medications and trained staff provide resuscitation services.
	b.	Events and treatment provided during resuscitation events are recorded and resultant data is analysed by multidisciplinary committee to identify opportunities for improvements.
	c.	Identified improvements are implemented and monitored.
Standard	**PAC.9:**	**The facility provides nursing care in accordance with standard protocols, practices, and current evidences.**
Criterion	**a.**	The facility provides appropriate equipment and staff for providing nursing care.
	b.	Patient care assignment and nursing staffing is as per current practice guidelines.
	c.	Nurses are empowered to make decision for patient care as per their scope.
	d.	Nursing care is aligned and integrated with overall patient care.
	e.	The organisation implements acuity-based staffing to improve patient outcomes.
Standard	**PAC.10:**	**Intensive care services are provided in an appropriate manner.**
Criteria	**a.**	Intensive and high dependency units have adequate and appropriate equipment and trained staff.
	b.	Infection control processes are implemented in accordance with current practice and evidence.
Standard	**PAC.11:**	**Nutritional requirements are assessed and addressed appropriately.**
Criteria	**a.**	Documented procedures define implementation of nutritional needs of all patients.
	b.	Procedures for provision of patient diet including therapeutic diet are implemented in a collaborative manner.
Standard	**PAC.12:**	**Rehabilitation services are consistent and appropriate to the scope of facility.**
Criteria	**a.**	Rehabilitation services are aligned with the scope of services of the facility.
	b.	Services are provided in a safe, consistent and collaborative manner.
	c.	Care is guided by functional assessment and periodic reassessments which are

		documented.
Standard	**PAC.13:**	**End of life and palliative care are provided appropriately.**
Criteria	**a.**	Documented procedures guide end of life and palliative care.
	b.	End of life and palliative care is consistent with laws, regulations and best practices.
Standard	**PAC 14:**	**A documented discharge process exists and a discharge/ treatment summary is provided to all patients.**
Criteria	**a.**	The facility plans the discharge process in consultation with the patient and/or family.
	b.	Documented policy and procedure exist for patients leaving against medical advice.
	c.	Discharge/ treatment summary contains the patient's name, unique identification number, treating physician name, qualification and registration number, date of admission and date of discharge duly signed by the appropriate qualified medical professional.
	d.	Discharge/ treatment summary contains the reasons for admission, significant findings and diagnosis and the patient's condition at the time of discharge.
	e.	Discharge/ treatment summary contains information regarding investigation results, any procedure performed, medication administered and other treatment given.
	f.	Discharge/ treatment summary contains follow-up advice, medication and other instructions in a manner understood by patient/ family.
	g.	Discharge/ treatment summary incorporates instructions about when and how to obtain urgent care.
	h.	In case of death, patient records include death summary.

Chapter 7
Patient Rights and Education (PRE)

Introduction

Patients under care of the facility are provided with all necessary services. It is therefore important that patients' rights are documented and known to patients. It is also important to provide education to patients related to their care. Better patient satisfaction or outcome is achieved when patients are adequately informed about their care, their rights are respected and they are involved in the decision-making process.

STANDARDS AND CRITERIA		
Standard	**PRE.1:**	**The facility protects rights of patients/donors and informs patients/donors about their responsibilities while receiving care.**
Criterion	**a.**	Patient/ donor rights and responsibilities are documented and displayed bilingually.
	b.	Violation of rights is reported, and action taken is documented.
Standard	**PRE.2:**	**The facility identifies and documents the rights of patient/ donor supporting individual beliefs and values.**
Criterion	**a.**	Patient/ donor rights include privacy while receiving care.
	b.	Patient/ donor rights include dignity and respect while receiving care.
	c.	Patient/ donor rights include confidentiality of information.
	d.	Patient/ donor rights include personal safety and security.
	e.	Patient/ donor rights include informed consent.
	f.	Patient/ donor rights include refusal of treatment.
	g.	Patient/ donor rights include information on the expected cost of treatment.
	h.	Patient/ donor rights include access to his/her medical records.
	i.	Patient/ donor rights include right to complain and how to voice a complaint.
	j.	Patient/ donor rights include information on his/her treatment and healthcare needs.
	k.	Patient/ donor rights include respecting any special preferences, spiritual and cultural needs.

	l.	Patient/ donor rights include to seek an additional opinion regarding clinical care.
Standard	**PRE.3:**	**The facility educates the patient/ donor and family to make informed decisions and their involvement in planning their care.**
Criterion	**a.**	Patients/ donors and/or family are informed and explained about the planned care and treatment.
	b.	Patients/ donors and/or family are explained about their medicines, diagnostic and therapeutic procedures, nutrition, and use of medical equipment.
	c.	Patients/ donors and/or family members are explained about the possible complications.
	d.	Patients/ donors and/or family members are informed about the results of diagnostic tests and the diagnosis.
Standard	**PRE.4:**	**The facility documents a procedure to obtain informed consent.**
Criterion	**a.**	Documented procedure incorporates the list of situations where informed consent is required and adheres to applicable statutory norms.
	b.	Informed consent includes information regarding the procedure, its risks, benefits, possible complication, alternatives and as to who will perform the procedure in a language that they can understand.
	c.	The procedure describes who can give consent when patient is incapable of independent decision making.
	d.	Informed consent from the patient/ Next of Kin/family is taken by the person performing the procedure with signature, date and time.
	e.	Informed consent is dated with time and particulars of the authorised medical personnel with their signatures on each page of the consent form.
	f.	Informed consent is to be signed by an independent witness with name, contact details, date and time.
Standard	**PRE.5:**	**The facility has a documented feedback (compliment and complaint) system.**
Criterion	**a.**	A documented feedback (compliment and complaint) procedure exists.
	b.	The procedure includes how to receive, investigate and resolve complaints in a timely manner.
	c.	Patient and/or family is made aware of such procedure for giving feedback (compliment and complaint) and the procedure is publically available.
	d.	The facility uses the results of such investigations, if any to make improvements/modifications.

Chapter 8
Medication Management and Safety (MMS)

Introduction

The purpose of medication management is to provide a frame work for safe and effective medication management system. Safe and effective medication management includes the processes for procurement, storage, prescribing, transcribing, preparing, dispensing and administration. All processes of medication management of the facility comply with rules and regulations of the law of the land.

STANDARDS AND CRITERIA		
Standard	**MMS.1:**	**Documented policy and procedure exist for the management of medication.**
Criterion	**a.**	There is a documented policy and procedure on medication management which is implemented.
	b.	A qualified individual (s) has oversight function of medication management in the facility.
	c.	The medication management complies with the applicable laws and regulations.
Standard	**MMS.2:**	**The facility develops a drug formulary based on the needs.**
Criterion	**a.**	Drug formulary based on the need as per the scope of its services is developed by collaborative process by a multidisciplinary committee.
	b.	Drug formulary is reviewed and updated annually.
	c.	The facility defines process for procurement of medications and supplies.
Standard	**MMS.3:**	**There is a documented policy and procedure for storage of medication.**
	a.	The facility ensures that medicines are stored according to manufacturer's recommendation.
	b.	Look-Alike and Sound-Alike medications are identified and stored physically apart from each other with sign posting.
	c.	Emergency medications are identified and readily available for use in patient care areas.
	d.	All expired or contaminated medicines are stored separately according to a documented policy in consonance with regulatory requirements to prevent inadvertent dispensing in the pharmacy and ward.
Standard	**MMS.4:**	**There is a documented policy and procedure for prescription of**

		medication.
Criterion	**a.**	Medication prescription is in consonance with the law, good practices and guidelines for the rational prescription of medications.
	b.	Only qualified healthcare providers according to licensure, training or certification can prescribe.
	c.	The facility defines and implements minimum requirements of medication prescription as per law.
	d.	Medication orders are clear, legible (written in capital letters or typed), dated, timed, named and signed.
	e.	Drug allergies and previous adverse drug reactions are ascertained before prescribing.
	f.	The facility determines and implements policy and procedure for verbal order.
	g.	A prescription audit is conducted periodically to ensure implementation of prescription policy.
Standard	**MMS.5:**	**A documented policy and procedure exist for safe dispensing of medications.**
Criterion	**a.**	Documented policy and procedure are implemented for dispensing of medications and return of medication to the pharmacy is included.
	b.	Medication preparation prior to dispensing is done safely and high-risk medications are verified before dispensing.
Standard	**MMS.6:**	**A documented policy and procedure exist for safe administration of medications.**
Criterion	**a.**	Documented policy and procedure exist for medication administration.
	b.	Medication administration is done only by a qualified person permitted by law.
	c.	Medication is verified from the order, physically inspected prior to administration and recorded in the patient records
	d.	Patients are monitored after medication administration.
Standard	**MMS.7:**	**There is a documented policy and procedure for the use of narcotic drugs, chemotherapeutic agents, radioactive agents and psychotropic substances.**
Criterion	**a.**	There is a documented policy for use of such medications in consonance with applicable regulations and best practices.
	b.	A documented procedure is implemented.
	c.	Narcotic drugs, chemotherapeutic agents, radioactive agents, & psychotropic substances are prepared properly and safely and administered by qualified personnel.

	d.	The administration of narcotic drugs, chemotherapeutic agents, radioactive agents and psychotropic substances is documented.
Standard	**MMS.8:**	**The facility has a system of reporting and analysing near misses, medication errors and adverse drug events.**
Criterion	**a.**	Near miss, no harm, adverse event and sentinel event relating to drugs are defined.
	b.	Documented procedure exists to capture and report near miss, no harm, adverse drug event and sentinel event relating to drugs.
	c.	Data is collected and analysed for such incidents to make improvement.

Chapter 9
Surgical Care and Safety (SCS)

Introduction

It is important that the facility has adequate space and competent personnel to carry out various procedures. Policies and procedures are in place to ensure intended outcomes with safety of all patients. Surgical procedures adhere to best practices for use of anaesthesia, use of blood and blood components.

STANDARDS AND CRITERIA		
Standard	**SCS.1:**	**Documented procedure exists for the performance of various surgical procedures.**
Criterion	**a.**	The facility defines and documents processes for various surgical procedures.
	b.	Only qualified individuals assess the patients, determine the need for surgery and perform the surgical procedure.
	c.	All phases of surgical care of the patient, including pre, intra and post operative are appropriately and adequately planned, monitored and documented.
	d.	The facility adheres to defined consent procedures and statutory norms.
Standard	**SCS.2:**	**The facility follows a documented procedure for surgical care and has a surgical-safety programme.**
Criterion	**a.**	Documented policy and procedure guide surgical care and a documented patient-safety programme is implemented.
	b.	Surgical or invasive procedure site is marked before procedure by the person performing the procedure.
	c.	The facility uses a validated surgical safety checklist (e.g., WHO surgical safety checklist) to document the process.
	d.	The patient-safety programme is comprehensive and covers all the major elements related to patient safety as per the national/ international patient safety guidelines such as WHO guidelines.
Standard	**SCS.3:**	**Documented policy and procedure are used for administration of anaesthesia & sedation.**
Criterion	**a.**	Only qualified individuals conduct pre anaesthesia and pre induction assessments to administer anaesthesia/sedation for patients requiring anaesthesia.
	b.	The anaesthesia/sedation care of each patient is adequately planned and

		informed consent is obtained by anaesthetist & documented.
	c.	Patients/family are educated and counselled about the procedure of anaesthesia/sedation which includes the risks, benefits and alternatives and all these are documented in the patient records.
	d.	Patient condition and vitals are monitored pre, intra and post-op during anaesthesia/sedation as per hospital policy.
	e.	Documented criteria are used for transfer out of patients from recovery area to ICU/HDU/ward.
Standard	**SCS.4:**	**Documented policy and procedure exist for any research activity.**
Criterion	**a.**	Documented policy and procedure address any research activity carried out in the facility which is in compliance with applicable regulatory, national and international guidelines.
	b.	Appropriate Ethics Committee oversees all research activity.
	c.	Patient's informed consent is taken before enrolling into research/ clinical trial.
	d.	Patients are informed on expected benefits, potential discomforts & risks, their right to withdraw from research at any stage.
	e.	As appropriate, patients and families are identified and informed about how to gain access to clinical research, clinical investigations, or clinical trials relevant to their treatment needs.

Chapter 10
Hygiene and Infection Control (HIC)

Introduction

Changing technology and disease profile continue to present new challenges for infection prevention and control within the facility. Patients are at risk of developing healthcare associated infections because of decreased immunity, immune-suppressive drugs and invasive medical procedures. Healthcare associated infections are among the most common complications affecting patients.

STANDARDS AND CRITERIA		
Standard	**HIC.1:**	**The facility has a documented infection prevention and control policy.**
Criterion	**a.**	The facility has an infection prevention and control policy based on current evidence and best practices.
	b.	Management provides supervision and adequate resources.
	c.	Infection prevention and control is implemented in accordance with statutory requirements.
Standard	**HIC.2:**	**The facility has a comprehensive infection prevention and control programme.**
Criterion	**a.**	There is a documented infection prevention & control programme that covers clinical & non-clinical areas which is managed by appropriately trained personnel (s).
	b.	The facility has a multidisciplinary infection control committee.
	c.	The facility has infection control team consisting of infection control officer and infection control nurse (s) for coordination of infection control activities.
	d.	The programme includes hand hygiene practices.
	e.	The programme includes infection prevention and control training for appropriate categories of staff.
Standard	**HIC.3:**	**Infection prevention and control programme includes clinical services.**
Criterion	**a.**	The programme covers critical care areas.
	b.	The programme covers surgical services.
	c.	The programme covers safe infusion and injection practices.
	d.	The programme covers diagnostic services and blood bank.
Standard	**HIC.4:**	**Infection prevention and control programme includes ancillary services.**
Criterion	**a.**	The facility has policies and protocols for safe handling for used, soiled and clean linen.
	b.	The facility adheres to kitchen sanitation measures to reduce the risk of infection.

	c.	The facility adheres to housekeeping practices consistent with infection prevention and control.
	d.	The airflow, ventilation, temperature and humidity control should be maintained as per guidelines to minimize and to prevent the risk of infection in the facility.
	e.	The facility monitors air handling units (AHUs), particle count, number of air changes, positive air pressure, etc in the transplant unit.
Standard	**HIC.5:**	**There is a documented process to ensure cleaning, disinfection and sterilization practices across the facility.**
Criterion	**a.**	Cleaning, disinfection and sterilization are defined and implemented across the various units.
	b.	The facility has identified area with adequate space for sterilization activities with proper zoning to avoid cross-contamination.
	c.	The process of disinfection & sterilization is performed in accordance with the current good practice guidelines and as per manufacture recommendation (wherever applicable).
	d.	Disinfected and sterilized instruments are stored in designated areas.
	e.	Appropriate validation tests are carried out at regular intervals for sterilisation activities in CSSD/sterilisation unit which is documented.
	f.	Recall procedure is in place in case of breakdown in sterilisation.
Standard	**HIC.6:**	**The facility has a documented policy on biomedical waste segregation and disposal in accordance with statutory regulations.**
Criterion	**a.**	A documented policy on handling biomedical waste exists and complies with statutory requirements.
	b.	Waste segregation is performed at the site of generation.
	c.	Appropriate personal protective equipment is available and used while handling the waste.
	d.	The facility identifies a centralised area for collection and storage of medical and non- medical wastes in accordance with statutory regulations.
	e.	The centralised area for waste collection is secured and free from pests and vermin.
	f.	There is a process of safe transportation of waste within the facility.
	g.	Staff is appropriately trained to handle biomedical waste.
	h.	Biomedical waste is disposed appropriately as per the regulatory requirements.
Standard	**HIC.7:**	**The facility addresses occupational health requirements relating to infection control for staff.**
Criterion	**a.**	The facility has system for appropriate use and disposal of Personal Protective Equipment (PPEs).

	b.	Staff is appropriately vaccinated as per national/ international guidelines and the same is documented.
	c.	Appropriate post exposure prophylaxis protocols exist and are expeditiously implemented as and when indicated.
	d.	Adequate hand washing facilities with liquid soap/disinfectants and hand drying facilities should be available in all patient care areas.
Standard	**HIC.8:**	**The facility implements monitoring and surveillance for infection prevention and control.**
Criterion	**a.**	Mechanism of prevention and control of healthcare associated infection are implemented and monitored.
	b.	Regular audits are conducted for infection prevention and control activities.
	c.	Appropriate corrective and preventive actions are implemented and documented based on the identified gaps.

Section B
Processing Facility for Hematopoietic Cellular Therapy Products

Introduction

A processing facility may use cell-based products that may be minimally or more than minimally manipulated, including cellular immunotherapies, and other types of autologous and allogeneic tissues or cells. These products may be but not limited to:

- CD 34 cells (autologous and allogeneic)
- DLI
- CAR T Cells
- Virus specific CTLs
- Others if any

Chapter B-1
Human Resource Management (HRM)

Standard	**HRM.1.:**	**The processing facility has a Lead/ Director (or designate/s).**
Criterion	**a.**	The operation of facility should be conducted under the directions and supervision of a full-time Lead/ Director.
	b.	The Lead/ Director should hold a post graduate degree in medicine– MD/ DNB (Pathology/Transfusion Medicine/Microbiology) and has experience / training in the processing and cryogenic storage.
	c.	In cases when the Lead/ Director delegates his responsibilities to a designee, the Lead/ Director shall hold responsibility of the work.
Standard	**HRM.2.:**	**The processing facility has qualified and competent personnel.**
Criterion	**a.**	The processing laboratory in-charge should have a post graduate qualification in Biological/ Life Sciences with a minimum of five years experience in cell processing and storage.
	b.	The laboratory Technician should have post graduate degree in Biological/ Life Sciences/Medical Laboratory Technology with a minimum of one year experience in cell processing and storage.

Standard	**HRM.3:**	**A documented policy exists to address health and safety needs of staff.**
Criterion	**e.**	Staff is subjected to an appropriate pre-employment medical examination to ensure that they are free from infectious and contagious diseases, and subjected to annual medical examination.
	f.	Health issues including occupational health hazards, such as protection against virus and other microbial infections, of staff are addressed as per documented policy.

	g.	Staff is vaccinated as per the policy of the facility however at a minimum prescribed by the government/ regulator.
	h.	The facility has measures in place for prevention and handling of workplace violence's.

Standard	**HRM.4:**	**The processing facility has a continuous training and professional development programme for its staff including outsourced staff.**
Criterion	**f.**	Staff are trained and updated regularly in practices which ensure high level of personal hygiene.
	g.	There is a mandatory training & competency assessment for staff engaged in cell-based product processing, testing, storing & release.
	h.	Staff should wear clean body coverings appropriate for their duties prior to entering the processing area.
	i.	Smoking, eating and drinking is prohibited inside the Laboratory.

Chapter B-2
Facility and Risk Management (FRM)

STANDARDS AND CRITERIA		
Standard	**FRM.1:**	**The processing facility is appropriate to the scope of services and is managed in accordance with the applicable laws and regulations.**
Criterion	**a.**	The premises used for processing and storage are designed, constructed and maintained to ensure smooth functioning under hygienic conditions and in sterile areas wherever required.
	b.	The building(s) for storage of cell-based products is situated and have such measures as to avoid risk of contamination from external environment including open sewage, drain, public lavatory or any factory which produces disagreeable or obnoxious odour or fumes, excessive soot, smoke, chemical or biological emissions.
	c.	The Facility has adequate working space to allow orderly and logical placement of equipment, material and movement of personnel so as to maintain safe operations and prevent contamination.
	d.	The facility is designed and maintained to prevent entry of insects, pests, birds, vermins and rodents.
	e.	The facility flooring is unbroken and provided with a cove both at the junction between the wall and the floor as well as the wall and the ceiling.
	f.	The facility is provided with suitable fire safety measures.
	g.	The facility provides with the furniture in aseptic areas which is smooth, washable and made of stainless steel or any other appropriate non shedding material other than wood.
	h.	The facility has separate areas for processing and storage of products to prevent mix-ups, product contaminations and cross contamination.
	i.	The facility has defined and implemented environmental conditions for temperature, humidity, ventilation and air filtration as per ISO 14644, and records are maintained.
	j.	The facility has a documented policy on biomedical waste segregation and disposal in accordance with statutory regulations. (Please refer to HIC.6)
	k.	Appropriate facility is provided within the premises for proper washing and sterilisation.
	l.	The facility has a general storage area to store all non-medical items.
	m.	The facility has change rooms with adequate facilities.

Standard	FRM.2:	**The processing facility has appropriate reception area.**
Criterion	**g.**	Reception area with space for transient storage of units and physical examination shall have adequate facilities for registration, data entry and generation of bar-coded labels.
	h.	Air-conditioned area of at least 10.00 Sq. meters shall be provided.

Standard	FRM.3:	**The processing facility has appropriate Haematology and Serology laboratory.**
Criterion	**a.**	The facility is equipped for independent testing of cell-based products, ABO Grouping and Rh Typing of blood, Total Nucleated Cell Count, Progenitor Cell Count and Viability Test.
	b.	Air-conditioned area of at least 10.00 Sq. meters shall be provided.

Standard	FRM.4:	**The processing facility has appropriate sterility testing laboratory.**
Criterion	**a.**	The laboratory is equipped for performing sterility tests on cell-based products.
	b.	The room should be air-conditioned with adequate ancillary area for media preparation, sterilisation, incubation and decontamination.
	c.	Area of at least 10.00 sq. meters is provided.

Standard	FRM.5:	**The processing facility has appropriate area for processing.**
Criterion	**a.**	The facility has a clean room with a minimum of 10 sq. meters and equipped with an air handling system to provide a Class 10,000 environment. Air handling system for sterile area shall be different from those for other areas.
	b.	Entry to this area should be through an air lock.
	c.	The clean room has a Class 100 biological safety cabinet for processing.
	d.	The clean room shall be maintained at 20°C to 25°C and with a positive differential pressure of 10-15 pascals and relative humidity of 50-60%.

Standard	FRM.6:	**The processing facility has appropriate arrangements for cryogenic storage.**
Criterion	**a.**	The facility has an air-conditioned cryogenic storage space of minimum 20 sq. meters.
	b.	The cryogenic storage room has provision for monitoring of room temperature and oxygen level.
	c.	The cryogenic storage room has provision for monitoring of temperature of storage vessels.

	d.	The cryogenic storage room has provision for monitoring of liquid Nitrogen level of storage vessels.
	e.	The space between each liquid Nitrogen storage vessels, supply cylinders and connecting hose should be minimum one square meter.

Standard	**FRM.7:**	**The processing facility has a documented programme for equipment management.**
	a.	The facility should establish and implement policies, processes, and procedures to identify, control, operate, maintain, and monitor critical equipment.
	b.	The facility defines equipment specifications before selection and purchase.
	c.	The facility has a process for scheduled monitoring, maintenance, repair, calibration and accuracy check of all critical equipment.
	d.	The facility should maintain records of all critical equipment used in testing, processing, storage and distribution of the cellular therapy product.

Standard	**FRM.8:**	**The processing facility has a documented programme for material management.**
	a.	The facility should define critical & non critical materials including supplies and reagents.
	b.	There is a documented procedure to select suppliers of critical materials based on defined criteria.
	c.	The facility should establish a programme of quality control to ensure proper performance of critical materials.
	d.	The facility has policy and procedures for the receipt, acceptance, handling, storage, and utilisation of all materials used in the testing, processing, and storage of cellular therapy products.
	e.	The facility should maintain records of all critical equipment used in testing, processing, storage and distribution of the cellular therapy product.
Standard	**FRM.9:**	**The processing facility has appropriate arrangements for record keeping.**
	f.	The facility has a designated record room of at least 10 sq. meters with access to authorised personnel only.
	g.	The room has adequate protective facilities to ensure that documents and records are safe and secure over a period of time as per the applicable guidelines/ regulations from time to time.

	h.	Recording of temperature and humidity of the storage room is to be done and records kept.
	i.	All records to be backed up digitally.

Standard	**FRM.10:**	**There is a documented risk management plan.**
Criterion	**a.**	The facility has a risk management plan to identify and evaluate the risks related with personnel, equipment, method, material, product and environment.
	b.	The plan includes mitigation and contingency procedure.
	c.	The facility conducts facility inspection at least once every year to identify security and safety threats and findings from inspection are acted upon, and records are maintained.

Chapter B-3
Continual Quality Improvement (CQI)

Standard	CQI.1:	**The management documents and implements a structured quality management system and safety programme in the processing facility.**
	k.	The Lead/ Director and senior staff are involved in QMS and allocate resources for implementing the same.
	l.	The QMS includes a comprehensive quality improvement and patient safety programme which is developed, documented, implemented, maintained and reviewed by a multidisciplinary quality management & safety committee.
	m.	This committee shall conduct quality and clinical reviews periodically.
	n.	Appropriate corrective and preventive actions are implemented and documented based on the identified gaps.
	o.	There is a designated individual(s) for coordinating the quality management and safety programme.
	p.	The quality and safety programme is communicated and coordinated amongst all the staff of the facility through appropriate training mechanism periodically.
	q.	The facility periodically (minimum annually) updates and controls all documented plans, policies and procedures.
	r.	Regular audits are conducted to ensure continuous compliance to the quality and safety programme.

Chapter B-4
Cellular Product Management (CPM)

Standard	**CPM.1:**	**The processing facility has a system for product management.**
Criterion	**a.**	The facility has necessary authorisation for receiving, testing, processing, storage & release of cellular therapy products as approved from time to time by the regulatory agency.
	b.	The facility has agreement in place with the concerned transplant/cellular therapy unit prior to responding to the requisition for various cellular products.
	c.	The agreement must highlight product specific purity, potency, identity & safety measures taken by cellular therapy facility.

Standard	**CPM.2:**	**The processing facility has a system for receipt of the cellular product.**
Criterion	**a.**	The facility has a procedure for visual inspection of incoming product.
	b.	The facility has defined acceptance & rejection criteria for the incoming product.
	c.	Cellular therapy products are labelled in conformance with the current versions of ISBT 128.
	d.	The facility verifies the labelling information for accuracy and completeness.
	e.	The facility uses a unique numeric or alphanumeric system for the identification of the product which enables to trace any cellular therapy product or sample from donor/source to recipient/final disposition and back to the donor/source.
	f.	This unique identifier shall not be obscured, altered, or removed.

Standard	**CPM.3:**	**The processing facility has a system for processing of the cellular therapy product.**
Criterion	**a.**	The facility has a validated procedure to make cell-based product for cellular therapy.
	b.	The facility has defined acceptance & rejection criteria for the processed cellular product to be used for cellular therapy.
	c.	Processed cellular therapy products are labelled in conformance with the current versions of ISBT 128.
	d.	The facility maintains processing records which at a minimum include information of staff used during processing & check, quality control records of environmental conditions, equipment and materials used during processing.
	e.	The facility maintains critical time and temperature records of processing.

Standard	**CPM.4:**	**The processing facility has a system for testing and reporting of the processed cellular therapy product.**
Criterion	**a.**	The facility has a validated procedure for testing purity, potency, identity & safety of the cellular product.
	b.	The facility has defined acceptance & rejection criteria for the processed cellular product to be used for cellular therapy.
	c.	The facility maintains testing records which at a minimum include information of staff used during testing & cross check, quality control records of environmental conditions, equipment and materials used during testing.
	d.	The facility maintains critical time and temperature records.
	e.	All test reports are verified by the Lead/ Director prior to release.
	f.	The facility has a procedure to identify any non-conformity in the test reports, and has a recall procedure for test reports & initiate necessary corrective actions.
	g.	The facility participates in the EQAS for all tests performed & reported by the facility. In case of non-availability of EQAS for any specific test, the facility can participate in inter-laboratory comparison.

Standard	**CPM.5:**	**The processing facility has a system of cryopreservation of the processed cellular therapy product.**
Criterion	**a.**	Cellular therapy products are cryopreserved using a controlled-rate freezing/dump freezing procedure to maintain viability.
	b.	The temperature of the product(s) and/or freezing process are monitored & recorded.
	c.	An aliquot of cryopreserved cellular therapy products is retained and stored under conditions equivalent to those of the cellular therapy product.
	d.	There is a procedure for the use and disposition of the aliquot.
	e.	The facility has an inventory control system to ensure that a cellular therapy product, aliquots, and reference samples can easily be identified and located while in storage.
	f.	Cryopreserved cellular products are stored at the defined temperatures in liquid or vapor phase of nitrogen.
	g.	Records of cryopreserved products are maintained.
	h.	The facility develops a stability programme to monitor all cryopreserved products. The stability program includes product container integrity, viable cell recovery, and an assessment of potency of the relevant cell population.

Standard	CPM.6:	**The processing facility has a system for release of the processed cellular therapy product.**
Criterion	**a.**	The facility defines requirements for inspections and test results necessary to make a product available for release.
	b.	The facility ensures that these defined requirements are met before release of the product.
	c.	The facility makes the product available for distribution or listed on a registry only after the approval of the Lead/ Director or designee.
	d.	The facility provides the product label and information sheet, certificate of analysis (result of post processing & post thaw), and adverse event monitoring form along with the product.

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