Australian Commission on **Safety and Quality** in Health Care

NPAAC
National Pathology Accreditation Advisory Council

Requirements for Haemopoietic Cellular Therapy

seventh edition
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2026

safetyandquality.gov.au

Acknowledgement

The Australian Commission on Safety and Quality in Health Care pays respect to the Gadigal people as the Traditional Custodians of Country where the Commission's office is located. We extend that respect to all Aboriginal and Torres Strait Islander peoples, and their deep time connections to land, water and sky.

We recognise that knowledge about healthy Country, community and culture has been developed by Aboriginal and Torres Strait Islander peoples over tens of thousands of years and has been shared for generations. We are committed to partnering with and learning from Aboriginal and Torres Strait Islander peoples through the work that we do.

Disclaimer

The content of this document is published in good faith by the Commission for information purposes. The document is not intended to provide guidance on particular healthcare choices. You should contact your health care provider for information or advice on particular healthcare choices.

The Commission does not accept any legal liability for any injury, loss or damage incurred by the use of, or reliance on, this document.

Table 1 Change log

Requirement Edition	Year	Changes
first edition	1998	First published.
second edition	2004	Introduced ISO 15189 aligned requirements.
third edition	2009	Reprinted with revisions and name change from *Guidelines for Laboratory Procedures related to the Processing, Storage and Infusion of Cells for Transplantation or Cell Therapy.*
fourth edition	2013	Reprinted and reformatted to be read in conjunction with the *Requirements for Medical Pathology Services.*
fifth edition	2015	Reprinted with revisions.
sixth edition	2021	Revised scope (only) and reprinted.
seventh edition	2026	Name change from *Requirements for Procedures Related to the Collection, Processing, Storage and Issue of Human Haemopoietic Progenitor Cells* to *Requirements for Haemopoietic Cellular Therapy.* Introduction of immune effector cells. Updates to the new Commission template with removal of references to the *Requirements for Medical Pathology Services.* Addition of: • Clinical Governance standard • Safety and Quality systems • Processing Facility Medical Director Replacement of: • Laboratory Director with Processing Facility Director

Contents

Background **5**

Scope **7**

Introduction **8**

1. Clinical Governance **11**

2. Safety and Quality Systems **14**

3. Donor evaluation, selection and collection **18**

4. Cellular therapy product processing and testing **22**

5. Labelling **25**

6. Cellular therapy product storage and transport **28**

7. Cellular therapy product issue, distribution and disposal **34**

Glossary **38**

Appendix 1 **45**
Clinical transplantation facility (Informative) 45

Appendix 2 **52**
Good Documentation Practices (Informative) 52

Background

The Australian Commission on Safety and Quality in Health Care leads and coordinates national improvements in health care safety and quality.

About the Australian Commission on Safety and Quality in Health Care

The Australian Commission on Safety and Quality in Health Care (the Commission) partners with the Australian Government, state and territory governments and the private sector to achieve a safe, high-quality, sustainable health system. It also works closely with patients, carers, clinicians, medical scientists, managers, healthcare organisations and policymakers.

Key functions of the Commission include:

- developing national safety and quality standards
- developing clinical care standards to improve the implementation of evidence-based health care
- coordinating work in specific areas to improve outcomes for patients
- providing information, publications and resources about safety and quality.

The Commission works in four priority areas:

- **High-quality care in an evolving environment** – so that high-quality health care is delivered consistently, reliably and equitably for all Australians.
- **Strong outcome focused clinical governance** – so that clinical governance, integrated standards and accreditation drive better patient outcomes.
- **Empowered patients, families, carers and communities** – so that health care is designed and delivered with patients and communities.
- **An improvement-driven workforce culture** – because better health care is everyone's responsibility, every day.

About the National Pathology Accreditation Scheme

The National Pathology Accreditation Scheme (NPAS) requires pathology practices to meet relevant standards for their pathology services to be eligible for Medicare benefits. The Health Insurance (Accredited Pathology Laboratory-Approval) Principles 2017 (the Approval Principles) underpin NPAS. The Approval Principles set the categories of accredited pathology laboratories, specify the standards to be met and the kind of pathology services provided.

The Approval Principles ensure that pathology practices providing Medicare eligible pathology services meet and maintain compliance with the standards. The Approval Principles objectives include:

- supporting the diagnosis and treatment of illness by linking Medicare benefits to pathology services that provide reliable results
- reducing the risk of misdiagnosis from pathology services that provide unreliable results
- maintaining public confidence in pathology services.

The Commission administers the NPAS on behalf of the Australian Government Department of Health, Disability and Ageing (the Department). The Department manages the policy and regulatory framework for pathology practice accreditation that are approved to provide Medicare eligible pathology services.

About the National Pathology Accreditation Advisory Council

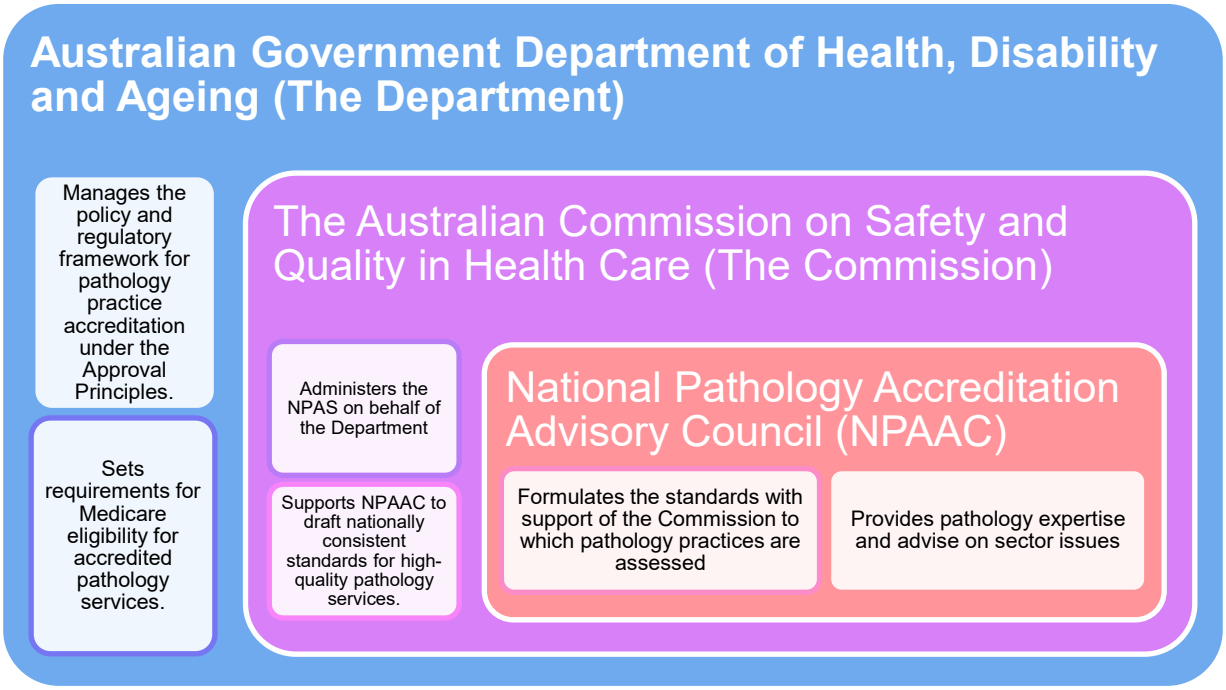
The National Pathology Accreditation Advisory Council (NPAAC) was established in 1979 to consider and make recommendations to the Australian, state and territory governments on:

- matters related to the accreditation of pathology practices
- the introduction and maintenance of uniform standards of practice in pathology practices throughout Australia.

The Commission supports NPAAC to formulate standards to which pathology practices are assessed.

The Approval Principles give effect to NPAAC endorsed standards by listing the standards and accreditation materials pathology practices seeking approval to provide Medicare eligible pathology services must meet. The pathology practice's conformity with the standards is assessed by the accrediting agencies defined in the Approved Principles.

Roles and responsibilities – National Pathology Accreditation Scheme



Scope

The *Requirements for Haemopoietic Cellular Therapy* (seventh edition, 2026) is a Tier 4 NPAAC document that must be used alongside the Tier 2 NPAAC document, which set overarching standards for high quality medical pathology practice focused on patient safety.

These standards apply to laboratories and facilities involved in donor selection, collection, processing, storage, issue, and disposal of the following directed products:

1. **Haematopoietic Progenitor Cells (HPCs)**

- Autologous or allogeneic-related
- Used for haemopoietic reconstitution
- Minimally manipulated

2. **Donor Mononuclear Cell**

- Used directly for therapy
- Used for modulating or effecting and immune response
- Collected for third-party manufacture of more-than-minimally manipulated cellular therapy products, for example, Therapeutic Goods Administration (TGA)-approved products, Special Access Scheme products, or clinical trials)
- Includes handling of these manufactured products when received, stored, or issued as part of treatment

Exclusions

The document does NOT apply to other cellular therapies such as banked HPC, from cord blood, that does not have a designated recipient, or HPC sourced from overseas donor registries.

Requirements for other clinical activities of transplantation facilities are outside the parameters of this document; however, guidelines for structure and operation of the clinical transplantation facility (including medical and allied staff, training, therapy administration and related policy and procedures), and good documentation practices are included in Appendices 1 and 2.

Introduction

The document defines the minimum requirements for quality and competence to be met by facilities involved in the collection (including apheresis procedures), processing, testing, storage, and issue of cellular therapy products. It also applies to individuals responsible for preparing cellular therapy products for infusion, with the aim of ensuring the safety and quality of these products.

The *Requirements for Haemopoietic Cellular Therapy* (HCT Requirements) may be used by accreditation bodies to evaluate the competence of facilities undertaking haemopoietic cellular therapy product activities, including transplantation, collection, processing, storage, and issue.

It is intended that any cellular therapy product within the scope of these Requirements is collected, processed, tested, stored, and issued by a facility that is either accredited to these Requirements or has undergone a satisfactory accreditation advisory visit and is actively seeking accreditation. Notwithstanding this, the manufacture and clinical use of cellular therapy products may also be subject to regulatory oversight by the Therapeutic Goods Administration (TGA). Where clinical trials are undertaken, approval must be obtained from the relevant Human Research Ethics Committee (HREC), in addition to a Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) from the TGA, as applicable.

These Requirements are expressed as **high-level principles and are not intended to prescribe all procedures and practices** to be implemented by facilities or individuals. Each facility and individual is expected to assess their specific practices and procedures and determine whether additional standards or controls are required to ensure safety and quality.

Figure 1 Standards in this document

Regulatory Alignment

These Requirements have been developed with reference to current and emerging Australian regulatory frameworks and are aligned, where appropriate, with relevant international standards, including:

- AS ISO 15189 Medical laboratories – Requirements for quality and competence
- FACT-JACIE HCT Standards (9th ed.) [1]

Related Documents and Compliance

These Requirements should be read in conjunction with the National Pathology Accreditation Advisory Council (NPAAC) framework, including the current versions of:

- Tier 2 and Tier 3 NPAAC documents, and
- any other relevant Tier 4 NPAAC documents.

Pathology services must also comply with all applicable state and territory legislation, including mandatory reporting obligations. Services that operate under hospital governance also operate under the National Safety and Quality Health Service Standards.

Document Structure

Each section of this document identifies key requirements for practice as either **Standards (S)** or **Commentaries (C)**:

Standards (S):

These define the minimum requirements for procedures, methods, staffing and facilities that must be met for accreditation. Standards are presented in bold type and are prefixed with “S” (for example, **S 2.2**). The use of the word *must,* indicates a mandatory requirement.

Commentaries (C):

Commentaries provide clarification, guidance, and examples to support the Standards. They are prefixed with “C” (for example, **C 1.2**).

Any appendices attached to this document are **informative** and should be considered to be an integral part of this document.

[1] Foundation for the Accreditation of Cellular Therapy (FACT); Joint Accreditation Committee ISCT-Europe & EBMT (JACIE). *FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration*. 9th ed., version 9.1. Omaha (NE): FACT; 2025. Available from: https://www.ebmt.org/sites/default/files/2025-12/FACT-JACIE%20HCT%20Standards%209th%20Ed_V9-1.pdf

From 1 July 2021, the Commission took over responsibility for administering the NPAS and supporting NPAAC and its subcommittees in their work to develop and maintain the pathology standards.

NPAAC documents can be accessed on the Commission's website.

Comments from users are appreciated and can be directed to:

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Website Pathology Standards | Australian Commission on Safety and Quality in Health Care

1. Clinical Governance

Clinical governance establishes the conditions for high-quality pathology. It is the combination of culture, systems and structures that enables the pathology workforce to deliver pathology services that are consistently high quality and improving.

The requirements for clinical governance including for overall organisational leadership, culture, supervision, risk management and information governance, applicable to all laboratories, is described in the tier 2 NPAAC document. This document is not intended to duplicate these requirements and instead focuses on the aspects of clinical governance most applicable to the HCT program context.

Clinical Governance

The system by which boards, executives, clinical leaders and the workforce are accountable to patients and the community for providing high-quality services.

No.	Standard and commentary
S 1.1 Clinical governance framework	The governing body must endorse a clinical governance framework that is relevant and appropriate for cellular therapy programs and: a. aligns with the requirements for clinical governance outlined in the Tier 2 NPAAC document b. includes the systems and processes necessary to support: i. clear accountability for clinical and operational decision making ii. safe and effective workforce practice, scope of practice, supervision and training iii. risk management, including identification, monitoring and mitigation of patient safety risks iv. reliable information management, including accurate reporting and secure handling of patient data v. consumer partnership, ensuring services are person-centred, culturally safe and responsive to diverse needs vi. continuous quality improvement, supported by data, incident management, audit, review and feedback cycles

No.	Standard and commentary
S 1.2 Program governance structure	The governing body must ensure that the cellular therapy program: a. is under the direction and control of a Clinical Program Director[2] who has the delegated authority and responsibility for establishment, maintenance and oversight of the quality management system (QMS) b. appoints a Program Quality Manager[3] who is responsible for the implementation and operation of the QMS including establishment and maintenance of policies and standard operating procedures that support compliance and high-quality services across collection and processing facilities c. appoints a Collection Facility Medical Director[4] who has the delegated responsibility for: i. donor medical evaluation oversight ii. donor management during collection procedures d. appoints a collection Facility Director[5] with the delegated responsibility for: i. standard operating and technical procedures ii. collection procedure performance iii. workforce supervision iv. QMS oversight e. employs a Processing Facility Medical Director[6] with the delegated responsibility for the medical aspects of the processing facility f. employs a Processing Facility Director[7] with the delegated responsibility for: i. standard operating and technical procedures ii. processing procedure performance iii. workforce supervision iv. administrative operators v. QMS oversight

[2] Clinical Program Director is a medical practioner with specialist qualifications and experience in haematology, transplantation, cellular therapy, or a related field who has overall responsibility for the Clinical Program.
[3] The Program Quality Manager is an individual appointed by the organisation with responsibility for coordinating and overseeing the quality management system across the Clinical Program, Collection Facility, and Processing Facility, as applicable.
[4] The Collection Facility Medical Director is a registered medical practitioner with qualifications and experience relevant to donor assessment, apheresis, transplantation, transfusion medicine, haematology, or cellular therapy who is responsible for the medical oversight of the Collection Facility.
[5] Collection Facility Director is the individual with overall operational responsibility for the Collection Facility.
[6] Processing Facility Medical Director is a registered medical practitioner with expertise in haematology, transplantation, transfusion medicine, cellular therapy, or a related discipline who is responsible for medical oversight of the Processing Facility.
[7] Processing Facility Director is a Clinical Scientist or other suitably qualified professional with overall responsibility for the scientific, technical, and operational management of the Processing Facility.

No.	Standard and commentary	
	C 1.2 a	If responsibilities are assigned to another person within the organisation, the responsibilities **must** be documented
	C1.2 b	In the absence of a clinical scientist as the processing facility director, the Processing Facility Medical Director must delegate specific tasks to a suitably qualified and competent scientist

2. Safety and Quality Systems

This standard describes the requirements for safety and quality systems applicable to collection and processing facilities for cellular therapy products.

Requirements for safety and quality systems that apply to all accredited laboratories are contained in the Tier 2 NPAAC document. This standard describes the specific requirements of safety and quality systems relevant to HCT programs.

Risk Management

A strategic approach to risk management guides the monitoring, planning and allocation of resources across all parts of the organisation. Implementing a structured risk management framework demonstrates a deliberate and proportionate effort by governing bodies, the designated person who, in the context of HCT programs, is the Clinical Program Director, and the workforce to foster a culture and organisational structure that supports high-quality pathology services.

Effective management of a haemopoietic cellular therapy service requires the systematic identification, assessment, and management of risks. The risk management system should be:

- regularly reviewed to assess its effectiveness, with outcomes used to inform continuous improvement
- continuously monitored to ensure that material breaches, non-compliance, or operational failures are promptly identified and addressed.

The risk management system must document:

- patient safety risks
- the assessed level of each risk
- strategies implemented to mitigate identified risks
- the implementation status and progress of each mitigation strategy.

Quality management

Quality management systems (QMS) are an essential component of managing risk. They support high-quality pathology HCT services, patient care and continuous quality improvement. The Clinical Program Director oversees the quality management system's performance.

A HCT program's quality management systems include processes to mitigate and manage risks, including those related to workforce, patients, communication, equipment, specimen collection and testing.

No.	Standard and commentary
S 2.1 Environment	Facilities must have processes to ensure the environment is safe and fit for purpose aligned with the relevant regulatory requirements including to ensure: a. there is a designated area for: i. collection of cellular therapy products ii. processing iii. storage b. segregation of equipment used for processing cellular therapy from equipment used for microbial cultures or non-patient related work c. oxygen in liquid nitrogen storage areas is monitored and appropriately alarmed d. completion of documented risk assessments of critical facility parameters[8] e. critical facility parameters are monitored, controlled and recorded f. the environment is safe and appropriate for the patient g. policies and procedures align with *Guidelines for the Prevention and Control of Infection in Health Care*[i] and state or territory requirements
S 2.2 Incident Management	Facilities must have an incident management system to: a. ensure escalation of critical incidents[9] to the Medical Director and/or Clinical Program Director
S 2.3 Open Disclosure	Facilities must: a. use an open disclosure process consistent with the Australian Open Disclosure Framework[10] b. monitor and act to improve the use and effectiveness of the open disclosure process

[8] Guidance on what this is – link to glossary and add definition
[9] Guidance critical incidents
[10] Australian Commission on Safety and Quality in Health Care. *Australian Open Disclosure Framework*. Sydney: ACSQHC; 2026. Available from: Open disclosure | Australian Commission on Safety and Quality in Health Care

No.	Standard and commentary
S 2.4 QMS	Facilities must have a QMS that includes documented processes: a. for the management of critical supplies, reagents and equipment b. to collect and interpret safety and quality data
	C 2.4 To ensure the quality, safety, and integrity of cellular therapy products, procedures, and facilities the QMS processes include processes for: a. storage of supplies and reagents including the appropriate environmental conditions b. the quality and suitability of supplies to ensure that critical supplies and reagents that come into contact with cellular therapy products during collection, processing, storage and administration are sterile, where applicable, and of appropriate quality and grade for their intended use c. validation and verification of critical supplies and reagents that are not of an appropriate or designated grade to demonstrate their suitability for intended use prior to use d. expiry of critical supplies and reagents to ensure that expired items are identified, segregated as applicable, and not used e. use of equipment, supplies, and reagents to ensure mix-ups, contamination, and cross-contamination are prevented and that cellular therapy product function and integrity are not compromised f. documentation of the identity, status and availability of critical supplies and reagents to ensure sufficient stock is available when needed g. traceability of critical supplies and reagents used for each cellular therapy product, including traceability to the products for which each supply or reagent was used h. inspection of critical supplies and reagents prior to use to confirm acceptability, including integrity, labelling and expiry status i. storage of cellular therapy products and procedures for disposal
S 2.5 Information management	Facilities must have an information management system that includes processes for documentation and storage of information related to: a. cellular therapy product record creation, assembly, review, storage, archive and retrieval b. tracking and traceability of cellular therapy products lifecycle, including tracing of facility conditions that may affect cellular therapy product viability, integrity, contamination and cross-contamination c. maintaining chain of custody and chain of identity

No.	Standard and commentary
	d. roles and responsibilities for external parties performing manufacturing and testing e. non-conforming product authorisation f. the details of collection procedures that are documented concurrently with collection g. the details of processing procedures that are documented concurrently with processing h. the identity of the individual responsible for each significant step of collection or processing is recorded
S 2.6 Release specification	The QMS must include processes for the control and monitoring of the collection and manufacture of cellular therapy products to ensure that such products meet predetermined release specifications.

3. Donor evaluation, selection and collection

This standard applies to all aspects of donor selection, safety and treatment for both allogeneic and autologous donors in clinical transplant or collection facilities where individuals donate haematopoietic progenitor cells (HPCs) or mononuclear cells, either for themselves or for a designated recipient.

For the purposes of this document, syngeneic donors are included within the requirements applicable to allogeneic donors.

No.	Standard and commentary
S 3.1 Donor eligibility	Facilities must have processes to ensure allogeneic donor eligibility is: a. documented in the recipient's medical record b. documented and communicated to the collection and cell processing facilities prior to initiation of: i. donor mobilisation regimen ii. preparative regimen of the recipient
S 3.2 Donor suitability	Facilities must have processes for testing, screening and determining donor suitability. Donor suitability must be confirmed and documented prior to the initiation of donor mobilisation or preparative regimen of the recipient.
S 3.3 Informed Consent	Facilities must have processes to: a. ensure informed consent is obtained and documented by the transplant medical practitioner or other health care provider familiar with the collection procedure, prior to the collection procedure b. ensure informed consent processes comply with legislation and NPAAC tier 2 documents c. enable donors to consent to collection and where required, for specimen testing d. ensure allogeneic donors give their informed consent to a health care professional who is not the primary healthcare professional for the recipient e. ensure informed consent is sought for the release of relevant allogeneic donor health information to the transplant physician and the recipient

No.	Standard and commentary
	f. ensure informed consent is sought for release of deidentified clinical information to clinical registries
S 3.4 Selection approval	Facilities must have processes to ensure donor selection approval has been obtained by the relevant Director or delegate prior to implementing donor selection procedures and that the approval is documented
S 3.5 Selection and evaluation	Facilities must have documented processes for donor selection and evaluation that ensure the ongoing safety of the donor and the recipient, including: a. criteria for donor selection, evaluation and management, which must include CAR-T manufacturer's criteria where applicable b. criteria for paediatric or geriatric allogeneic donors c. for testing, screening, determining donor eligibility and suitability d. for ensuring compliance with any additional national or jurisdictional requirements e. for non-conforming donors, collection facilities must document: f. an identified demonstrable medical need g. a rationale for the selection, consideration of alternative options and risks to donor and recipient by the transplant medical practitioner h. informed consent from recipient and donor where applicable
S 3.6 Donor infectious disease testing	Facilities must have processes to ensure donors are tested for evidence of clinically relevant infection by any of the following communicable disease agents within 30 days before collection: a. human immunodeficiency virus, type 1 b. human immunodeficiency virus, type 2 c. hepatitis B virus d. hepatitis C virus e. human T lymphotropic virus I/II f. Treponema pallidum (syphilis) g. cytomegalovirus (CMV) antibodies (not mandatory for autologous) h. NAT and serological testing must be performed for (a), (b), (c) and (d) and: i. if indicated, tests should also be done for other infective agents including (but not limited to) Epstein–Barr virus, hepatitis A virus, varicella zoster virus, herpes simplex virus, toxoplasmosis ii. additional tests should be carried out for donors of paediatric recipients where clinically relevant, including tests for measles, tetanus and diphtheria.
S 3.7 Donor testing	Facilities must have processes to ensure all donor testing occurs in an accredited or licenced laboratory and that the necessary donor tests are completed in an appropriate time frame, including to ensure:

No.	Standard and commentary
	a. that donors are tested for ABO group and Rh (D) type before or on the day of the first collection with two independently collected samples[11] b. that ABO group and Rh(D) type result discrepancies are resolved and recorded before issue of the cellular therapy product c. that enumeration of HPC or target cell numbers occurs during the 24 hours prior to collection d. that testing HCG levels of female donors of childbearing potential within 7 days prior to initiation of a recipient's conditioning regimen or commencement of mobilisation therapy
S 3.8 Additional requirements allogeneic donors	Facilities must have processes to ensure allogeneic donors are: a. assessed for infectious disease risk using a current blood donation statement or similar b. tested for human leukocyte antigen (HLA)-A, -B and -DR type c. assessed for donor eligibility and suitability by a health care professional who is not the primary transplant medical practitioner
S 3.9 Collection request requirements	The recipients transplant physician must submit a request or prescription to the collection facility and a duplicate to the processing facility that includes: a. approved identifiers[12] for recipient and donor b. details of the requested procedure c. target cell number d. expected date and time of collection e. expected date of infusion (if applicable) f. information to accompany the medical practitioner's record including a statement of donor eligibility and suitability and, for non-conforming donors, a statement to show the reason for the use of that donor, records of demonstrable medical need, and donor, recipient and medical practitioner consent for use
S 3.10 Container requirements	Facilities must ensure cellular therapy products are packaged in containers approved for haemopoietic cellular therapy products

[11] confirmation of donor ABO group and Rh (D) typing requires that results from the two independently collected samples must match

[12] As defined in the facilities' SOPs. It is generally expected that at least two independent identifiers are used and that they match the identifiers used on laboratory, collection, processing, storage and issue records.

No.	Standard and commentary
S 3.11 Collection procedure validation	Collection procedures must be validated to ensure acceptable cell recovery and viability

4. Cellular therapy product processing and testing

This standard describes the systems and processes necessary to safely process and test cellular therapy products.

No.	Standard and commentary
S 4.1 Processing facility	Facilities must have processes to ensure all cellular therapy products[13] are collected in: a. an accredited collection centre b. a TGA licensed apheresis unit c. a collection centre that, if new, has undergone a satisfactory accreditation advisory visit and achieve accreditation within 18 months of the advisory visit
S 4.2 Emergency management	Facilities must have documented policies for emergency management of disasters and other events that pose high-risk of harm to products for transplant and the workforce including but not limited to exposure to: a. liquid nitrogen b. communicable diseases c. chemical and biological hazards
S 4.3 Efficacy of cellular therapy products	Facilities must have processes for documenting, reviewing and communicating the efficacy of cellular therapy following administration including the following metrics: a. For haematopoietic progenitor cell (HPC) products: i. time to neutrophil engraftment ii. time to platelet engraftment iii. correlation of infused viable cell dose or nucleated cell count with transplant outcomes

[13] HPCs sourced from overseas registries or cellular therapy products under clinical trial notification or clinical trials are exempt from S4.1

No.	Standard and commentary
	iv. graft failure and graft durability outcomes, where relevant b. for immune effector cell (IEC) products, the endpoint of clinical function i. assessment of intended clinical function and therapeutic response against defined treatment endpoints ii. monitoring of persistence, expansion or detectability of administered immune effector cells, where applicable iii. assessment of product durability and sustained clinical response, where relevant c. for CAR-T cell products: i. monitoring and documentation of circulating viable CAR-T cells, or other validated measures of CAR-T cell persistence and expansion, where clinically indicated ii. correlation of CAR-T cell persistence with treatment response, relapse, or loss of efficacy, where data are available
S 4.4 Processing request documentation	Facilities must receive a written and signed request from the recipient's transplant medical practitioner before the collection, that specifies: a. the product type b. the recipient and donor identifier c. the type of processing that is to be performed d. the anticipated date of processing
S 4.5 Standard operating procedures	Facilities must have documented standard operating procedures that include: a. cryopreservation procedures that define: i. proper name of the cellular therapy product ii. cryoprotectant solution and its final concentration iii. maximum cell concentration that can be frozen iv. cooling rate(s) v. endpoint temperature of cooling vi. storage temperature vii. alternative validated procedure in case of equipment failure during the freezing process b. defined critical control points for associated assays performed on each cellular therapy product c. the objectives and acceptable endpoints for each procedure
S 4.6 Validation	Facilities must have documented validation of processing procedures, that demonstrates acceptable target cell viability and recovery

No.	Standard and commentary
S 4.7 Product Testing	Facilities must have processes to: a. monitor and record microbial cultures of the final cellular therapy product b. ensure the Processing Facility Laboratory Director (or delegate) reviews the results of microbial cultures before issue c. notify the recipient's medical practitioner and the donor's medical practitioner of any positive microbial cultures d. require exceptional release of cellular therapy product with positive microbial culture e. perform a root cause analysis for cellular therapy products with positive microbial cultures
S 4.8 Test samples prior to cryopreservation	Facilities must have processes to ensure cellular therapy products undergoing cryopreservation, have: a. at least two test samples of the cellular therapy product (cryopreserved and stored under conditions that ensure a valid representation of the clinical cellular therapy product) that must be available for testing, as and when required b. procedures in place for the identification and handling of test samples to ensure that they accurately relate to the cellular therapy product, the donor and the recipient, where applicable c. a sample of the cellular therapy product tested for microbial growth, immediately prior to cryopreservation
	C 4.8 a Before the issue of a cryopreserved cellular therapy product or initiation of conditioning therapy, the viability and enumeration of a relevant target cell population must be evaluated from a cryopreserved sample of the cellular therapy product using a relevant and validated test
S 4.9 Processing records	The Processing Facility Director (or delegate) must review the processing record for each cellular therapy product before issue, and: a. when clinically relevant processing endpoints are not met, the Processing Facility Medical Director and the recipient's medical practitioner must be notified in a timely manner b. record notifications and appropriate corrective actions, where applicable

5. Labelling

This Standard describes the requirements for labelling of products to ensure global consistency, traceability, and patient safety across collection, processing and clinical use.

The ISBT 128 labelling system is an internationally standardised framework for the identification, coding, and labelling of medical products of human origin (MPHO), including blood, haematopoietic progenitor cells (HPCs), tissues and organs.

No.	Standard and commentary
S 5.1 Labelling standards	Cellular therapy collections and products must be identified, coded, and labelled in accordance with the ISBT 128 international standard[14]
S 5.2 Labelling system requirements	The labelling system must support use of: a. standard terminology b. defined data structures c. internationally consistent product descriptions d. where possible, machine-readable barcoding C 5.2 An ISBT 128-compliant label includes both human-readable text and machine-readable barcodes, containing information such as: i. Donation Identification Number (DIN) ii. product code (product description) iii. blood group (ABO/RhD) where relevant iv. expiry date and time v. special processing or testing information

[14] ICCBBA Home - ICCBBA International Council for Commonality in Blood Banking Automation (ICCBBA). *ISBT 128 Standard Technical Specification*. San Bernardino (CA): ICCBBA; [cited 2026 Jun 22]. Available from: https://iccbba.org/technical_library/

No.	Standard and commentary
S 5.3 Labelling system validation	Facilities must ensure that ISBT 128 coding and labelling systems are: a. validated b. controlled c. applied consistently
S 5.4 Labelling and traceability	Facilities must have processes to ensure primary containers, secondary containers, product samples, and associated documentation clearly state identifiers that enable unambiguous linkage to the donor, the recipient, and relevant records
S 5.5 Mislabelling risk mitigation	Facilities must have processes that mitigate the risk of mislabelling or misidentification, including: a. verification steps b. label version control c. reconciliation of labels d. segregation or removal of obsolete or unused labels
S 5.6 Labelling requirements	Facilities must ensure that cellular therapy products have labels that are: a. accurate b. complete c. legible d. indelible e. remain affixed f. compliant with applicable regulatory and legal requirements
S 5.7 Labelling for collection	Facilities must ensure, prior to commencement of collection, the cellular therapy product container is labelled with a proper name of the product and the unique numeric or alphanumeric identifier
S 5.8 Labelling at completion of collection	Facilities must have processes to ensure that, prior to disconnection, the primary container is labelled with information in accordance with S 5.2
S 5.9 Partial labelling	Facilities must have processes to ensure partial labelling is used only when the container size or collection limits the use of a full label and that partial labels include: a. the unique cellular therapy product identifier b. the proper name of the cellular therapy product c. the intended recipient name or identifier, if known C 5.9 The processing facility has processes that ensure cellular therapy products bearing a partial label are not transferred, issued, or

No.	Standard and commentary
	administered unless accompanied by documentation or an attached tag containing the full labelling information required for issue
S 5.10 Distribution or issue label requirements	At the time of distribution or issue, the cellular therapy product must be labelled, or accompanied by documentation, that includes complete and accurate information on the product, donor, recipient, handling, storage, and safety requirements, to ensure safe transport and administration
S 5.11 Outer container label	Facilities must ensure that, at distribution, the outer transport container is labelled to ensure correct handling, maintenance of storage conditions, traceability between sending and receiving facilities, and inclusion of required cautionary statements
S 5.12 Biohazard label	Facilities must ensure that a biohazard label is affixed to the cellular therapy product where the results of mandatory testing indicate a risk of communicable disease transmission, with the exception of cytomegalovirus (CMV)

6. Cellular therapy product storage and transport

This standard sets out the requirements for the storage, monitoring, quarantine, inventory management, and transport of cellular therapy products to maintain product integrity, patient safety and traceability.

No.	Standard and commentary
S 6.1 Storage environment	Facilities must have processes to ensure cellular therapy products are contained in a controlled environment and stored under appropriate conditions
S 6.2 Storage duration	Facilities must have documented processes that outline the following requirements for storing cellular therapy products: a. duration b. conditions of storage c. testing requirements before issue d. indications for disposal C 6.3 Patients, donors and associated facilities should be informed about these policies before cellular therapy product collection
S 6.3 Storage with materials	Facilities must have processes to ensure materials that may adversely affect cellular therapy products are not stored in the same refrigerators or freezers as the cellular therapy products
S 6.3 Thawed products	Facilities must have processes to ensure both fresh cellular therapy products and cellular therapy products thawed after cryopreservation are assigned an expiry date and time
S 6.4 Liquid state	Processing facilities must have processes to ensure cellular therapy products stored in a liquid state are maintained in conditions that: a. preserve viability and function b. inhibit infectious agents c. do not exceed the time period specified in the standard operating procedures

No.	Standard and commentary
S 6.6 Temperature	Processing facilities must have processes to ensure cryopreserved cellular therapy products are validated and stored within a temperature range: a. appropriate for the cellular therapy products b. appropriate for the cryoprotectant solution used c. defined in the standard operating procedures
S 6.5 Stability program	Processing facilities must have a documented process for a stability program that periodically evaluates the viability and potency of cryopreserved cellular therapy products. Samples should be representative of all processing methods and of maximum storage duration
S 6.7 Container integrity	Facilities must have processes to manage the loss of integrity of a cellular therapy product container
S 6.8 Storage requirements	Facilities must have processes to ensure materials that may adversely affect cellular therapy products are not stored in the same refrigerators or freezers as the cellular therapy products
S 6.9 Liquid nitrogen cross contamination	Facilities must have processes that reduce the risk of cross contamination for cellular therapy products immersed in liquid nitrogen
S 6.10 Quarantine requirements	Facilities must quarantine the cellular therapy product as defined by government regulations until completion of the donor eligibility determination
S 6.11 Positive infectious disease	Facilities must have processes to ensure cellular therapy products with positive infectious disease test results for relevant communicable disease agents and/or microbial cultures are quarantined
S 6.12 Non-conforming and quarantined products	Facilities must have processes to ensure non-conforming and quarantined cellular therapy products are: a. easily and reliably identifiable b. stored in a manner that reduces the risk of: i. cross-contamination ii. inappropriate issue
S 6.13 Temperature monitoring	Refrigerators and freezers for cellular therapy product storage must have a system to monitor the temperature continuously and record the temperature at least every four hours

No.	Standard and commentary
	C 6.13 If cellular therapy products are always fully immersed in liquid nitrogen, continuous temperature monitoring is not required
S 6.14 Liquid nitrogen levels in freezers	Facilities must have processes in place to ensure that liquid nitrogen levels in liquid nitrogen freezers are consistently maintained to keep cellular therapy products within the specified temperature range C 6.14 Automatic fill mechanisms are recommended
S 6.15 Alarm system requirements	Facilities must have processes to ensure an alarm system for storage devices for cellular therapy products or reagents for cellular therapy product processing is: a. continuously active b. has dedicated responsible personnel 24 hours a day c. is activated at a temperature or level of liquid nitrogen that allows time to salvage cellular therapy products
S 6.16 Device failure instructions	Facilities must have documented instructions in the event of storage device failure, displayed in the immediate area containing the storage device and at each remote alarm location that includes: a. a procedure for notifying processing personnel b. procedures to ensure that cellular therapy products are maintained at safe temperatures and the process for documentation of any corrective actions in order to maintain integrity of the cellular therapy products C 6.16 Additional storage devices of appropriate temperature must be available for cellular therapy product storage if the primary storage device fails. Off-site storage devices must conform to these requirements
S 6.17 Inventory control system	Facilities must have an inventory control system in use to identify the location of each cellular therapy product and associated sample aliquots that includes: a. recipient name or unique identifier b. cellular therapy product name or specimen type c. date of collection d. storage device identifier e. location within the storage device of cellular therapy product and associated sample aliquots

No.	Standard and commentary
Transport Transport of cellular therapy products must be planned, managed and undertaken using documented procedures to ensure product integrity, patient safety, and the health and safety of the workforce.[15]	
S 6.18 Transportation, shipping and receipt	Facilities must establish, maintain and document procedures for transportation, shipping and receipt of cellular therapy products
S 6.19 Non-frozen and/or cryopreserved products	Facilities must have processes that protect the integrity and safety of the cellular therapy products during the transportation of non-frozen and/or cryopreserved cellular therapy products
S 6.20 Accompanying records during transport	Facilities must have processes that ensure cellular therapy products are transported with requisite accompanying records, including determination of allogeneic donor suitability and eligibility
S 6.21 Primary and secondary container	Facilities must ensure the primary cellular therapy product container for non-frozen cellular therapy products is placed in a sealed secondary container
S 6.22 Outer container requirements	Facilities must ensure cellular therapy products transported internally within a facility are packaged in a closed and rigid outer container
S 6.23 Internal transport	Facilities must have documented processes for internal transport which include the requirements for: a. product identification (including chain of identity) b. product integrity c. product quality d. product safety e. product traceability (including chain of custody) f. temperature control g. biosafety

[15] Further information on the transport and courier requirements of cellular therapy products can be found in the STEMAU Guidelines[3] and NPAAC's Requirements for the Packaging and Transport of Pathology Specimens and Associated Material.

No.	Standard and commentary
S 6.24 Transport between facilities	Facilities must have processes to ensure that cellular therapy products that are shipped to another facility are: a. packaged in a rigid outer container that i. conforms to the applicable regulations regarding the mode of transport ii. is made of material adequate to withstand leakage of contents, shocks, pressure changes and other conditions or incidents as a result of ordinary handling in transportation iii. prevents unauthorised access b. maintained at the storage temperature specified by the receiving facility c. labelled as outlined in S 5 and in accordance with applicable regulations regarding the cryogenic material used and the transportation of biological materials d. transported by a qualified courier if intended recipient has received high dose myeloablative therapy C 6.24a Cellular therapy products that require a temperature-controlled environment and that are transported or shipped over an extended period of time must be transported in a container validated to maintain the appropriate temperature range for the anticipated transport time C 6.24b Processes are in place to ensure a risk assessment to evaluate the need for continuous temperature monitoring during transport occur
S 6.25 Transport arrangements	Facilities must have processes to ensure appropriate transport arrangements are made and communicated between sending and receiving facilities
S 6.26 Contingency transport plan	Facilities must have a documented contingency transport plan in case of a delay
S 6.27 Acceptance, rejection and quarantine	Facilities must have documented processes for acceptance, rejection and quarantine of cellular therapy products
S 6.28 Receiving facility receipt	Facilities must ensure receipt of each cellular therapy product includes: a. inspection to verify product container integrity b. inspection of cellular therapy product c. confirmation of correct labelling d. risk evaluation of microbial contamination

No.	Standard and commentary
S 6.29 Verification of transport method	Facilities must have processes to verify the cellular therapy product, when shipped between facilities, was appropriately transported or shipped, including the documentation of temperature at the time of arrival
S 6.30 Quarantine prior to release	Facilities must have processes that ensure cellular therapy products remain in quarantine until they have been determined to meet criteria for release
S 6.31 Transport container for cryogenic material	Facilities must ensure the transport container is of appropriate design and construction for transportation of the cryogenic material used
S 6.32 Liquid nitrogen levels for shipping	Facilities must ensure cryopreserved cellular therapy products with an indicated storage temperature below –80ºC are shipped in a liquid nitrogen 'dry shipper' that contains adequate absorbed liquid nitrogen to maintain temperature for at least 48 hours beyond the expected time of arrival at the receiving facility
S 6.33 Transit temperature evidence	Facilities must ensure provision of evidence to the receiving facility of transit temperature range for cryopreserved cellular therapy products
S 6.34 Transport record establishment and maintenance	Facilities must have processes to ensure the transport records are established and maintained, and include the following: a. name of sending facility b. name of receiving facility c. responsible personnel for sending and receiving d. identity of the courier e. details of any delays or transport problems f. product tracing between facilities g. date and time cellular therapy products were shipped

7. Cellular therapy product issue, distribution and disposal

This standard describes the systems and processes necessary to ensure the safe issue, distribution, return, recall, and disposal of cellular therapy products while maintaining product quality, traceability, regulatory compliance, and patient safety. It establishes requirements for product release, exceptional release of non-conforming products, documentation, chain of custody and authorised disposal practices throughout the cellular therapy product lifecycle

No.	Standard and commentary
S 7.1 Request prior to conditioning	Facilities must have processes to ensure a signed request for the HPC cellular therapy product from the treating medical practitioner is received prior to initiation of conditioning regimen, and is retained in the patients' health care record
S 7.2 Cryopreserved cellular therapy products	Facilities must have processes to ensure that prior to commencement of conditioning, and again before issue, each cryopreserved product is visually inspected to confirm appropriate labelling and integrity of the product container
S 7.3 Time between issue and infusion	Facilities must have processes to minimise the period of time between the issue and infusion of the cellular therapy products
S 7.4 Processing and tracking records	Facilities must have processes to ensure the processing and tracking records for each cellular therapy product are reviewed for compliance of these requirements by the Processing Facility Director, prior to cellular therapy product issue
S 7.5 Issue of non-conforming cellular therapy products	If cellular therapy products are issued before completion of the donor eligibility determination or upon exceptional release, additional documentation (which must be provided at or immediately after issue) must include: a. a list of any screening or testing that has not been completed b. written notification and approval from the Clinical Program Director and the recipient's medical practitioner of the incomplete screening or testing

No.	Standard and commentary
	c. records that donor eligibility determination was completed during or after the use of the cellular therapy product d. authorisation for cellular therapy product release by the Clinical Program Director or designee
S 7.6 Exceptional release of non-conforming products	Issuing facilities must have processes for the exceptional release of non-conforming cellular therapy products which ensure: a. issue will only occur when the product does not meet established technical or clinically relevant release criteria and release is justified under defined exceptional circumstances b. the Processing Facility Director or a formally designated delegate shall authorise release of products that do not meet technical release criteria and documented authorisation is recorded in the patients' health care record c. the Processing Facility Medical Director authorises the release of cellular therapy products that do not meet clinically relevant criteria and documents agreement between the Processing Facility Medical Director, Clinical Program Director and recipient's physician to use any non-conforming product d. documented informed consent is received and retained from the recipient for the use of clinically relevant non-conforming products
Distribution Distribution of cellular therapy products must be planned and coordinated to maintain product integrity, safety, quality and traceability between issuing and receiving parties.	
S 7.7 Processing records	Facilities must have processes to ensure the cellular therapy product processing records contain documented evidence of: a. distribution date b. name and unique identifier of the intended recipient c. cellular therapy product name and identifier d. donor eligibility determination e. identification of the collection facility f. chain of custody
S 7.8 Cellular therapy infusion form at issue	Facilities must ensure cellular therapy products are issued with a cellular therapy infusion form which includes all the information required on the final cellular therapy product issue label
S 7.9 Return of released products	Cellular therapy products accepted for return must meet the following conditions: a. The integrity of the primary container must not have been compromised subsequent to issue by the processing facility

No.	Standard and commentary
	b. Evidence must be provided that the cellular therapy product has been maintained at all times within the specified temperature range
	C 7.9 If the conditions have not been met, the Processing Facility Director or designee must give specific authorisation to accept such cellular therapy products for return to inventory
S 7.10 Reissue or disposal	Facilities must have processes to ensure the processing facility director consults with the recipient's medical practitioner regarding reissue or disposal of the returned cellular therapy product, and that this is recorded in the patient's health care record
S 7.11 Cellular therapy product recall	Facilities must have processes to ensure the cellular therapy product recall, including actions to be taken and notification of appropriate regulatory agencies
Disposal Disposal of cellular therapy products must be undertaken in accordance with documented procedures and regulatory requirements to minimise risk to patients, the workforce and the environment.	
S 7.12 Disposal compliance	Facilities must have processes for disposal of cellular therapy products that comply with relevant legislation including any applicable Human Tissue Act or Regulations
	C 7.12 If there is no pre-existing recorded agreement describing conditions for cellular therapy product storage and/or discard, the storage facility should communicate with the designated recipient's medical practitioner about the continuing need for storage of the cellular therapy products and document efforts to notify the donor or designated recipient about cellular therapy product transfer or disposal
S 7.13 Records for discarding	Facilities must retain documents of discarded cellular therapy products that indicate the cellular therapy product discarded, date of discard and method of disposal. Retention of such records must comply with the requirements for medical record retention of the relevant jurisdiction or legislation
S 7.14 Disposal	The Processing Facility Medical Director, in consultation with recipient's medical practitioner, must give written approval of cellular therapy product discard and method of disposal
S 7.15 Research samples	Where surplus unused samples are used for research, this must be in accordance with the National Health and Medical Research Council

No.	Standard and commentary
	(NHMRC) National Statement on Ethical Conduct in Human Research[16] unless this is in contravention of specific legislation, including the applicable Human Tissue Act, which would then apply
S 7.16 Waste management policy	Facilities must have a waste management policy that: a. comply with jurisdictional regulations relating to the disposal of biological material from pathology testing b. ensure that clinical programs involving genetically modified cellular therapy products comply with, or reference, applicable institutional and regulatory biosafety requirements, including requirements for handling and disposal

[16] National Health and Medical Research Council; Australian Research Council; Universities Australia. *National Statement on Ethical Conduct in Human Research*. Canberra: National Health and Medical Research Council; 2025. Available from: https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2025

Glossary

Term	Definition
Adverse event	Means any unintended and unfavourable sign, symptom, abnormality or condition associated temporally with an intervention which may or may not have a causal relationship with that intervention.
Adverse reaction	Means an unfavourable and unintended response to the collection or infusion of any cellular therapy product for which there is a reasonable possibility that the cellular therapy product caused the response. Any adverse reaction is an adverse event.
Allogeneic	Means cells obtained from a human donor who is genetically different from the intended human recipient.
Audit	Means a documented, independent inspection and review of one or more activities of a facility.
Autologous	Means cells obtained from a donor who is also the intended recipient.
Cellular therapy product	Means, for the purposes of these Requirements: haemopoietic progenitor cells, apheresis (HPC(A)); haemopoietic progenitor cells, marrow (HPC(M)); haemopoietic progenitor cells, cord blood (HPC(CB)); T cells collected by apheresis, mononuclear cells collected by apheresis (MNC(A)), or whole blood.
Chain of custody	Means the documented and traceable process that records the handling, storage, transfer, and location of a cellular therapy product from collection through processing, transport, and final disposition, ensuring the integrity and security of the product at all times.
Chain of identity	Means the documented system that ensures the correct association between the donor, the cellular therapy product, and the intended recipient throughout all stages of collection, processing, storage, and administration.

Term	Definition
Clinical governance	An integrated component of corporate governance that ensures the pathology workforce understands their roles and accountability for delivering high-quality services. It combines organisational culture, systems, and structures to achieve consistently high-quality, patient-focused care.
Clinical Program Director	The physician with overall responsibility and authority for the Clinical Program. The Clinical Program Director is accountable for the clinical care delivered by the program, compliance with applicable standards, oversight of transplant and cellular therapy activities, and ensuring appropriate staffing, resources, training, and quality management systems are in place[17].
Clinical Scientist	For haemopoietic cellular therapy processing facilities a clinical scientist: a. has a higher degree (PhD, Fellowship or Masters) in a subject relevant to cellular therapy or a minimum of 5 years full-time experience in a haemopoietic cellular therapy Processing Facility Director's role; and b. demonstrated broad based scientific knowledge of cell biology, with expertise and/or specialised training in haemopoietic progenitor cell transplant, cellular therapy, immunology, haematology and/or cryobiology; and c. experience in the application of standards for cellular therapy product manufacture, storage and issue; and d. experience in experimental design and problem solving; and e. experience in the management of a clinical laboratory as appropriate to the services provided with demonstrable continuing education in all relevant laboratory aspects.
Clinical transplantation facility	Means an integrated health care team housed in a dedicated and adequate space with a Director, common staff training programs, protocols and quality assessment systems.
Collection	Means any procedure for harvesting cellular therapy product regardless of technique or source.
Collection facility	Means a facility that collects HPCs and/or lymphocytes as defined under ‘cellular therapy product’.
Collection facility Director	The individual with overall operational responsibility for the Collection Facility. The Collection Facility Director is responsible for ensuring collection activities are conducted in accordance with approved policies and procedures, that personnel are trained and assessed as competent, and that equipment, facilities, and quality systems support safe and effective collection of cellular therapy products. The Collection Facility Director must possess qualifications, training, and experience appropriate to the complexity of the collection services provided.
Collection facility Medical Director	A registered medical practitioner with qualifications and experience relevant to donor assessment, apheresis, transplantation, transfusion medicine, haematology, or cellular therapy who is responsible for the medical oversight of the Collection Facility. The Collection Facility Medical Director is responsible for donor suitability assessment, donor safety, collection procedures, adverse event

Term	Definition
	management, clinical governance, and compliance with applicable regulatory and accreditation requirements. The Medical Director must maintain continuing professional development relevant to the scope of collection activities performed by the facility.
Competency	Means the ability to perform a specific task satisfactorily in conformance with the requirements of the quality system and according to direction.
Consumer	The term 'consumer' refers to a person who has had or may have a pathology service, a representative of the person or an advocate.
Contamination	Means the presence or introduction of microbial agents to cellular therapy products.
Critical	Any element used in cellular therapy product manufacturing that could affect the product's identity, purity, potency, or safety if altered or omitted. 'Element' includes, but is not limited to, materials, equipment, personnel, documents, and facilities.
Critical facility parameter	Means any environmental condition that can affect product integrity or test results and therefore must be monitored, controlled and recorded.
Critical control points	Means those points in the manufacture of HPCs to which controls or assessment are applied to assure continuing consistency of cellular therapy production to meet final cellular therapy product specifications.
Cross-contamination	Means the contamination of one cellular therapy product with another cellular therapy product.
Demonstrable medical need	Means a situation in which a comparable cellular therapy product is not available, and the recipient is likely to die or suffer serious morbidity without the cellular therapy product.
Designee	Means a person delegated by the relevant Director to perform one or more duties or tasks.
Deviation	Means the action of departing from an established course or accepted standard.
Directed	Means collected by a medical practitioner, registered under a law of a State or Territory or a person supervised by such a practitioner, for a designated recipient with a pre-existing condition.
Director	Means the responsible person(s) including Collection Facility Director, Program Director, Collection Facility Medical Director, Processing Facility Director, and Processing Facility Medical Director as defined in the Requirements.
Distribution	Any transportation or shipment of a cellular therapy product that has been determined to meet release criteria or urgent medical requirements.
Donor	Means a person who provides the source cells for a cellular therapy product.

Term	Definition
Donor eligibility	Means the process of determination that a donor is suitable following screening, history assessment and testing.
Donor suitability	Means the process of determining that a donor is medically and physically appropriate for collection.
Engraftment	Means the process by which infused haemopoietic cells grow, reproduce and ultimately form the mature elements of the recipient's haemopoietic system.
Examination	Set of operations having the objective of determining the numerical value, text value or characteristics of a property. This definition must also be taken to include all aspects of cellular therapy product collection, processing and issue.
Exceptional release	Removal of a product that fails to meet specified criteria from quarantine or in-process status for distribution through a defined approval process.
Facility	Means any premises where some or all activities covered by these requirements are performed.
Governing body	A board, chief executive officer, organisation owner, partnership or other highest level of governance (individual or group of individuals) that has ultimate responsibility for the strategic and operational decisions of cellular therapy collection and processing facilities. An approved pathology authority (APA) is an example of a governing body.
Haemopoietic progenitor cell therapy	Means administration of haemopoietic therapy products for treatment or support requiring haematopoietic reconstitution.
Haemopoietic progenitor cells	Means haemopoietic cells capable of bone marrow reconstitution.
Immune effector cell (IEC)	Is a cell that has differentiated or been manufactured into a form capable of modulating or effecting a specific immune response.
Internal transport	Refers to the planned and controlled movement of cellular therapy products within a facility or organisation.
Issue	Means removal of the cellular therapy product from quarantine or in-process status for distribution or destruction.
Labelling	Means identification ensuring traceability of a cellular therapy product throughout its lifecycle.
Lymphocytes	Means a white blood cell of the immune system, including B cells, T cells, and natural killer (NK) cells, that plays a central role in immune function and may be used in cellular therapy products.
Manufacture	Means any steps including recovery, processing, packaging, labelling, storage or distribution of a cellular therapy product.

Term	Definition
Minimal manipulation	Means processing that does not alter the biological characteristics of cells relevant to their clinical utility.
Mobilisation	Means administration of drugs or growth factors to increase circulating HPCs.
Mononuclear cells	Mononuclear cells are immune white blood cells comprising mainly lymphocytes and monocytes that are collected for therapeutic infusion
Outcome analysis	Means process by which the result of a procedure is formally assessed.
Partial label	Means minimum essential elements on product containers.
Pathology laboratory	Premises used for the examination of biological samples for the purpose of providing information for the diagnosis, monitoring, management, prevention and treatment of disease, or assessment of health. This definition must also be taken to include cellular therapy product collection and processing facilities.
Patient	Patient refers to a person receiving pathology services. The term ‘patient’ encompasses all other relevant terms the pathology sector may use, including ‘client’, ‘person’, and ‘people’.
Policies	Means documented principles and actions guiding organisational goals and decision-making.
Potency	Means the therapeutic activity of a cellular therapy product.
Procedure	Means a detailed description of steps required to perform a task.
Procedures manual	Means a compilation of detailed written instructions for procedures.
Processing	Means handling, labelling, cryopreservation, storage, and issue of cellular therapy products.
Processing facility	Means premises where cellular therapy product processing is performed.
Processing facility director	A Clinical Scientist or other suitably qualified professional with overall responsibility for the scientific, technical, and operational management of the Processing Facility. The Processing Facility Director is responsible for processing, testing, cryopreservation, storage, issue, validation, equipment management, personnel competency, quality systems, and regulatory compliance. The Processing Facility Director must possess: • an appropriate tertiary qualification in science, medical science, laboratory medicine, or a related discipline. • advanced knowledge and experience in cellular therapy processing and laboratory quality management. • demonstrated experience in management of a cellular therapy, transplantation, blood cell processing, or equivalent laboratory service. • ongoing participation in continuing professional development and relevant educational activities.

Term	Definition
	For the purposes of these standards, a Processing Facility Director should be eligible for professional membership or fellowship of a recognised scientific professional body, such as the Australian Institute of Medical and Clinical Scientists (AIMS), the Bone Marrow Transplant Scientists Association of Australasia (BMTSAA), the Royal College of Pathologists of Australasia (RCPA), or an equivalent organisation, commensurate with the scope of services provided by the facility.
Processing facility Medical Director	A registered medical practitioner with expertise in haematology, transplantation, transfusion medicine, cellular therapy, or a related discipline who is responsible for medical oversight of the Processing Facility. The Processing Facility Medical Director provides medical oversight of processing activities, product suitability and release decisions where applicable, clinical consultation, and governance of cellular therapy products processed within the facility. The Processing Facility Medical Director shall: • maintain current knowledge of cellular therapy and processing practices. • participate in continuing professional development and educational activities relevant to cellular therapy. • review emerging scientific, clinical, regulatory, and safety developments relevant to the facility's scope of practice. • ensure that processing activities are consistent with current professional standards and regulatory requirements.
Proficiency testing (External Quality Assessment)	Means a program comparing laboratory results with peers or assigned values.
Program Quality Manager	An individual appointed by the organisation with responsibility for coordinating and overseeing the quality management system across the Clinical Program, Collection Facility, and Processing Facility, as applicable. The Program Quality Manager is responsible for document control, audits, occurrence management, corrective and preventive actions, risk management, quality indicators, outcome monitoring, and continuous quality improvement activities. The Quality Manager must be appropriately qualified and experienced in quality management principles and have sufficient authority to implement and maintain the quality management system.
Quality	Means conformance with pre-established specifications or standards.
Quality assurance	Means activities providing confidence that quality requirements will be fulfilled.
Quality control	Means operational techniques used to meet quality requirements.
Quality improvement	Means actions taken to improve quality.
Quality manager	Means a designated individual responsible for quality systems oversight.
Quality system	Means management activities for directing and controlling quality.

Term	Definition
Quality system assessment	Means evaluation of systems affecting product quality.
Quarantine	Means storage in a separate area to prevent improper use or contamination.
Recipient	Means the intended patient to receive the cellular therapy product.
Release	Removal of a product from quarantine when criteria are met.
Release criteria	Requirements that must be met prior to release.
Requirements for Medical Pathology Services (RMPS)	Means the overarching NPAAC document outlining standards for good pathology practice.
Safety	Means relative freedom from harmful effects to persons.
Scope of practice	The range of professional activities that a workforce member is educated, trained and competent to perform, consistent with their qualifications, knowledge, experience and skills, and within the defined roles, responsibilities and accountabilities of their position in the cellular therapy product collection and processing facility.
Shipping	The transfer of a cellular therapy product between facilities where it leaves direct control.
Storage facility	Means accommodation of cellular therapy products prior to processing or distribution.
Systems	This Standard relies on collection and processing facilities to establish safety and quality systems. A system includes resources, policies, processes, and procedures that are organised, integrated, regulated, and delivered to accomplish a stated goal. Safety and quality systems will vary depending on the size of the pathology practice and the associated service risks.
Time of collection	Means the local time at the end of the collection procedure.
Tracking	Means following the history of a product or process.
Transport	Transfer of a product within or between facilities under staff control.
Validation	Means confirmation through evidence that requirements are met.
Viability	Means living cells as measured by validated techniques.
Written	Means documentation in human-readable form.

Appendix 1

Clinical transplantation facility (Informative)

No.	Requirement area	Description
1	**General**	
1.1	Integrated Clinical Transplantation Facility	The clinical transplantation facility should consist of an integrated medical team housed in a geographically contiguous or proximate space, with a single Program Director and common staff training procedures and quality management systems. Clinical transplantation facilities that include non-contiguous institutions in the same metropolitan area should demonstrate common protocols, staff training procedures, quality management systems, review of clinical results and evidence of regular interaction.
1.2	Delegated Responsibilities	Persons delegated by the Program Director and who have responsibility for procedures, administrative procedures, performing tests and reporting of results, should be listed for the purpose of limiting access to patient information.
1.3	Multi-site Facilities	The clinical transplantation facility may have more than one clinical site in different hospitals if the other criteria in 1.1 are met. 1.3.1 A general guide for units undertaking centres undertaking allogeneic transplantation is that a minimum of 10 new allogeneic patients should be transplanted per year. Centres undertaking allogeneic transplantation will usually perform autologous transplantation as well while centres may perform autologous transplantation only and those should undertake a minimum of five transplants per year. Syngeneic transplants should only be undertaken by centres performing allogeneic transplants. 1.3.2 For a combined clinical transplantation facility caring for paediatric and adult patients on the same site, facilities should perform a minimum of five transplants for each patient population.
2	**Clinical Transplantation Facility**	
2.1	Inpatient Unit	There should be a designated inpatient unit that minimises airborne microbial contamination.
2.2	Donor Assessment Facilities	There should be suitable and confidential space for donor examination and evaluation.
2.3	Outpatient Care Area	There should be a designated area for out-patient care that reasonably protects the patient from transmission of infectious agents and can provide, as necessary, appropriate patient isolation, administration of intravenous fluids, medications and/or cellular therapy products.

No.	Requirement area	Description
2.4	Medical Availability	There should be provisions for prompt evaluation and treatment by a transplant medical practitioner available each day on a 24-hour basis.
2.5	Donor Follow-up	All donors should have a post-collection procedure medical assessment.
2.6	Nursing Workforce	There should be an adequate number of nurses experienced in the care of transplant patients.
2.7	Pharmacy Services	There should be a pharmacy providing 24-hour availability of medications needed for the care of transplant patients.
2.8	Renal Support Services	There should be ready access to renal replacement therapy.
2.9	Anaesthetic Support	An appropriately qualified anaesthetist should be available for procedures associated with cell collection that requires general or regional anaesthesia should be performed by an appropriately qualified anaesthetist.
2.10	Central Venous Catheter Placement	Central venous catheters, where applicable, should be placed by a medical practitioner qualified to perform the procedure. 2.10.1 Adequacy of line placement should be verified by a radiologist or medical practitioner qualified to perform the procedure.
2.11	Mobilisation Agents	Administration of mobilisation agents should be under the supervision of a medical practitioner experienced in the administration and management of complications in people receiving these agents.
2.12	Transfusion Services	There should be a transfusion service providing 24-hour availability of CMV-appropriate and irradiated blood product therapy products needed for the care of transplant patients.
2.13	Intensive Care Access	There should be immediate access to on-site intensive care facilities or equivalent coverage for critically ill patients.
2.14	Collection and Processing Facility	There should be a collection and processing facility that meets these requirements with respect to their interaction with the clinical transplantation facility.
2.15	HLA Testing Laboratory	Clinical transplantation facilities performing allogeneic haemopoietic cell transplants should also use HLA-testing Laboratories accredited by ASEATTA or ASHI, or an equivalent Laboratory, and have the capability of carrying out high-resolution HLA-typing.

No.	Requirement area	Description
	Database Reporting	Cell Therapy Programs shall submit required data for allogeneic and autologous transplants to a national or international database.
3	**Staff and training**	
3.1	**Facility Director**	
3.1.1	Dedicated Transplant Team	A dedicated transplant team, including a Program Director and at least one other medical practitioner trained and/or experienced in HPC therapy is essential.
3.1.2	Paediatric Transplant Team	Transplantation facilities performing paediatric transplants should have a transplant team trained in the management of paediatric patients.
3.1.3	Paediatric Haematology/Oncology Expertise	For transplantation facilities performing paediatric transplantation, there should be at least one medical practitioner who is qualified in paediatric haematology/oncology.
3.1.4	Qualified Collection Practitioners	The clinical transplantation facility should have access to appropriately qualified haematology and/or medical oncology medical practitioners who are trained and competent in bone marrow harvesting and cellular therapy product collection by apheresis in facilities that meet NPAAC requirements.
3.1.5	Program Director Qualifications	The Facility Director should have at least one year of specific clinical training in HPC transplantation as defined in 3.3, or two years' experience as a medical practitioner responsible for the clinical management of HPC transplant patients in in-patient and out-patient settings. The Program Director should have written confirmation of his/her training or experience from the Director of the facility or institution in which that training or experience was obtained.
3.1.6	Continuing Education	The Program Director should participate regularly in educational activities related to the field of HPC transplantation.
3.1.7	Program Oversight Responsibilities	The Program Director is responsible for administrative and clinical procedures, including compliance with these standards. The Program Director should have oversight of all elements of the design of the clinical transplantation facility, including quality management, the selection and care of patients and donors, cell collection and processing.
3.1.8	Medical Care Oversight	The Program Director should have oversight of the medical care provided by the clinical transplantation facility, including medical care provided by the medical practitioners on the transplant team. The Program Director is responsible for verifying the knowledge and skills of the medical practitioners of the transplant team. Management of the clinical transplantation facility may be delegated to a Medical Director who fulfils the requirements.

No.	Requirement area	Description
3.2	**Other Medical Staff and Nurse Practitioners**	
3.2.1	Qualification	Other medical practitioners working in the clinical transplantation facility should be appropriately qualified to practise medicine in the jurisdiction of the clinical facility.
3.2.2	HPC Training	Other medical practitioners working in the clinical transplantation facility should have specific clinical training in HPC transplant medicine as defined in 3.3, and should participate regularly in educational activities related to the field of HPC transplantation.
3.2.3	Nurse Practitioner Scope of Practice	Appropriately credentialed nurse practitioners may perform the roles of medical practitioners within their approved scope of practice.
3.3	**Training for medical and nurse practitioner staff**	
3.3.1	Clinical Skills	3.3.1.1 Adequate specific clinical training in HPC transplant medicine should be defined as a minimum of one year's experience in the management of transplant patients in both the in-patient and out-patient settings. 3.3.1.2. Clinical transplantation facilities transplanting paediatric patients should have medical practitioners experienced in treating paediatric patients, as defined in 3.1.3.
3.3.2	Cognitive skills	3.3.2.1. Specific training and competency in each of the following areas is required for medical practitioners in HPC transplantation facilities: (a) indications for haemopoietic progenitor cell transplantation (b) selection of appropriate patients and preparative high-dose therapy regimens (c) pre-transplant patient evaluation, including assessment of appropriate patient eligibility and haemopoietic progenitor cell adequacy with respect to collection (d) administration of high-dose therapy (e) administration of growth factors for HPC mobilisation and for post-transplant haemopoietic cell reconstitution (f) management of neutropenic fever (g) diagnosis and management of infectious and non-infectious pulmonary complications of transplantation (h) diagnosis and management of fungal disease (i) diagnosis and management of veno-occlusive disease (sinusoidal obstructive syndrome) of the liver (j) management of thrombocytopenia and bleeding (k) management of haemorrhagic cystitis (l) management of nausea and vomiting

No.	Requirement area	Description
		(m) management of pain (n) management of terminal care patients (o) documentation and reporting for patients on investigational protocols (p) diagnosis and management of HPC graft failure (q) management of CAR-T cell therapy toxicities, assessment, grading, monitoring, differential diagnosis and appropriate escalation. 3.3.2.2. Specific clinical training and competency in each of the following additional areas is required for medical practitioners in clinical transplantation facilities for allogeneic HPC transplantation: (a) identification and selection of HPC source, including use of donor registries (b) methodology and implications of HLA typing (c) management of patients receiving ABO-incompatible cellular therapy product (d) diagnosis and management of CMV infection and disease (e) diagnosis and management of other viral infections in immunocompromised hosts (f) diagnosis and management of acute and chronic graft versus host disease (g) diagnosis and management of post-transplant immunodeficiency's (h) evaluation of Chimerism.
3.3.3	Procedural Skills	3.3.3.1. The HPC transplant medical practitioner should be proficient in cellular therapy product infusion procedures. 3.3.3.2. The HPC transplant medical practitioner should be knowledgeable in the following procedures: (a) HPC processing (b) HPC cryopreservation (c) bone marrow harvest procedures (d) apheresis procedures.
3.4	**Consulting medical staff**	
3.4.1	Specialist Support	The transplantation facility should have access to appropriately qualified consulting medical practitioners from key disciplines who are capable of assisting in the management of patients requiring medical care, including but not limited to surgery, pulmonary medicine, intensive care, gastroenterology, nephrology, infectious disease, cardiology, pathology, psychiatry and, if radiation therapy is administered, radiation oncology, with experience in large-field (e.g. total body or total lymphoid) irradiation treatment protocols.

No.	Requirement area	Description
3.4.2	Paediatric Consultants	Transplantation facilities treating paediatric patients should have consultants, as defined in 3.4.1, qualified to manage paediatric patients.
3.5	**Nursing staff**	
3.5.1	Training and Experience	Clinical transplantation facilities should have nurses and nurse supervisors formally trained and experienced in managing patients receiving haemopoietic progenitor cell transplants and cellular therapy recipients.
3.5.2	Paediatric Nursing Experience	Clinical transplantation facilities treating paediatric patients should have nurses formally trained and experienced in managing paediatric patients.
3.5.3	Core Training Requirements	Training should include haematology or oncology patient care; administration of high-dose chemotherapy and radiation therapy, growth factors and immunosuppressive medications; management of infectious complications associated with compromised host defence mechanisms; administration of blood product; and an appropriate degree of intensive medical or paediatric nursing care.
3.5.4	Written Policies and Procedures	There should be written policies for all relevant nursing procedures, including, but not limited to, infection prevention and control, administration of the preparative regimen, infusion of HPCs, use of immunosuppressive agents, growth factor administration, oral care, central venous catheter care, blood product infusion and transplant nurse competency evaluation processes.
3.6	**Allied staff**	
3.6.1	Pre and Post-transplant Support	The clinical transplantation facility should have one or more designated staff to assist in the provision of appropriate pre-transplant patient evaluation, treatment and post-transplant follow-up and care.
3.6.2	Pharmacy Staff Expertise	The clinical transplantation facility should have pharmacy staff knowledgeable in the use and monitoring of pharmaceuticals used by the clinical transplantation facility.
3.6.3	Dietetic Services	Dietetic staff should be capable of providing dietary consultation regarding the nutritional needs of the transplant recipient, including enteral and parenteral support, and appropriate dietary advice to avoid food-borne illness.
3.6.4	Social Services	Social services staff should be fully experienced and qualified in dealing with donors, recipients, and their relatives as well as related staff involved in the apheresis, processing and infusion processes.
3.6.5	Physical Therapy Services	Physical therapy staff should be adequately trained and experienced in dealing with both donors and recipients of cellular therapy products. They should also be cognisant of the full process involved in the collection and administration of cellular therapy products.

No.	Requirement area	Description
3.6.6	Data Management	Data management staff should be aware of the importance of confidentiality and attention to detail. Approved organisational client and cellular therapy product identification protocols are required to be followed at all times.
4.	**Therapy administration**	
4.1	Safe Administration Policy	There should be a written policy to ensure that the preparative therapy regimen is administered safely. 4.1.1 The treatment orders should include patient height and weight, specific dates, daily doses (if appropriate) and route of each agent. Pre-printed orders should be used for protocols and standardised regimens. 4.1.2 The pharmacist preparing the chemotherapy should confirm the doses against the protocol or standardised regimen listed on the orders. 4.1.3 Before administration of chemotherapy, two people qualified to administer chemotherapy should confirm the drug and dose against the orders and the protocol, and the identity of the patient to receive the chemotherapy. 4.1.4 There should be a written request for radiotherapy, including details of diagnosis, any prior radiotherapy that the patient has received, and any other factors that may increase the toxicity of radiotherapy. 4.1.5 There should be a written consultation from a radiation therapist before initiation of therapy. The consultation should include radiotherapy planning. 4.1.6 Before administration of each dose of radiotherapy treatment, the dose should be verified and recorded as per radiation therapy standards. 4.1.7 A final report of the radiotherapy details administered should be filed in the patient's records.

Appendix 2

Good Documentation Practices (Informative)

Good documentation practices support the safety, quality, traceability, and regulatory compliance of cellular therapy activities across the continuum of collection, processing, storage, distribution, issue, and disposal. Documentation provides evidence that procedures have been followed as intended and supports clinical governance, auditability, and continuous improvement.

Documentation should be legible, accurate, complete, and permanent, whether maintained in paper or electronic form.

Records are expected to be contemporaneous, meaning they are completed at the time the activity occurs or as soon as practicable afterward.

Documentation systems should support full traceability of cellular therapy products from donor to recipient and, where applicable, to final disposition.

Controlled documents (including policies, procedures, forms, and templates) should be approved, version-controlled, periodically reviewed, and accessible to relevant personnel.

Records must be maintained in a manner that protects confidentiality, data integrity, and security, in accordance with institutional and regulatory requirements.

Programs must implement health information systems that are interoperable and conformant with relevant national digital health information standards[17] and legislative requirements.

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[i] Australian Commission on Safety and Quality in Health Care. *Australian guidelines for the prevention and control of infection in healthcare*. Sydney: ACSQHC; 2019 [updated 2026 Apr 8; cited 2026 Jun 18]. Available from: https://www.safetyandquality.gov.au/resources/australian-guidelines-prevention-and-control-infection-healthcare

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[17] Australian Digital Health Agency | Standards search | Digital Health Implementer Hub