Inspection report on compliance with HTA licensing standards
Inspection dates: **25 and 26 August 2026**

St George's Hospital

HTA licensing number 12462

Licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)

Licensable activities carried out by the establishment

'E' = Establishment is licensed to carry out this activity and is currently carrying it out.
'SLA' = Service level agreement; the establishment is licensed for this activity but another HTA-licensed establishment carries out the activity on their behalf.

Site	Procurement	Processing	Testing	Storage	Distribution	Import	Export
St George's Hospital	E		E/SLA	E/SLA			

Tissue types authorised for licensed activities

Authorised = Establishment is authorised to carry out this activity and is currently carrying it out.

Authorised* = Establishment is authorised to carry out this activity but is not currently carrying it out.

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Mature Cell, MNC; PBMC	Authorised		Authorised				
Mature Cell, MNC; DLI	Authorised		Authorised				
Musculoskeletal, Bone; Bone				Authorised			
Musculoskeletal, Tendon & Ligament; Tendons				Authorised			
Progenitor Cell, Hematopoietic, Bone Marrow; Bone Marrow	Authorised*		Authorised*				
Progenitor Cell, Hematopoietic, PBSC; PBSC	Authorised		Authorised				
Skin; Skin	Authorised*		Authorised*	Authorised*			

PBMC – Peripheral blood mononuclear cells
PBSC – Peripheral blood stem cells
DLI – Donor lymphocyte infusion

Summary of inspection findings

The HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Although the HTA found that St George's Hospital (the establishment) had met the majority of the HTA standards assessed during the inspection, 1 major shortfall and 3 minor shortfalls were found against Governance and Quality, and Premises, Facilities and Equipment standards.

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Compliance with HTA standards

Major shortfalls

Standard	Inspection findings	Level of shortfall
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.		
a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 001/2021.	The establishment's donor selection questionnaire does not include all donor exclusion criteria required by Directions 001/2021. Specifically, the risk of transmission of diseases caused by prions and the ingestion of, or exposure to, a substance that may be transmitted to recipients in a dose that could endanger their health are not sufficiently described. Whilst the establishment confirmed malignant diseases are covered, the outcome of this assessment is not included in the harvest donor selection questionnaire. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.		
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.	Staff in the Haematology team and testing laboratory do not have documented training covering the relevant cell products, licensable activities and applicable regulatory framework.	**Minor**
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.		
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.		

b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 001/2021.	HTLV-I testing was not carried out on donor blood samples collected at the time of donation for several Advanced Therapy Medicinal Product (ATMP) starting material collections. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.		
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.	Temperature probes used to monitor tissue freezer temperatures are not subject to calibration in accordance with the manufacturer's instructions.	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

Advice

The HTA advises the DI to consider the following to further improve practice:

Number	Standard	Advice
1.	GQ1c	Governance meetings for theatre staff were found to have agendas and minutes in place; however, it was identified that HTA related topics were not always discussed and the meeting minutes did not contain enough detail to capture discussions. The establishment is advised to raise this as an internal incident and implement appropriate CAPA to address the issue.

2.	GQ1g	The DI is advised to contact current suppliers to obtain documentation confirming that products in storage are acellular. A process should also be established to ensure that a product's acellular status is confirmed and documented before procuring any new tissue type. Where products are identified as cellular, a storage licence will be required and the HTA should be contacted to arrange a variation to the existing licence.
3.	GQ1k	Using information provided by the supplier, the DI is strongly advised to review the tissue returns procedure to ensure that the quality and safety of products are maintained and that appropriate controls are in place throughout the returns process.
4.	GQ3e	The DI is advised to ensure apheresis training records document the training and supervised practice completed before operators are signed off as competent. The establishment should also consider documenting requalification or refresher competency assessment for less frequently undertaken activities.
5.	GQ3j	The DI is advised to review and update the Quality Manual to ensure it accurately reflects the full scope of HTA-licensed activities and the regulatory framework under which they are carried out. The review should include clear references to the Human Tissue Act 2004 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended). In addition, the key quality governance arrangements, including those relating to serious adverse events and reactions (SAEARs), record management, traceability and data retention should be incorporated. Any wording suggesting processes are "validated by the HTA" should be amended to clarify that validation is undertaken by the establishment, with the HTA assessing compliance through inspection and regulatory oversight.
6.	GQ4b GQ4c	The DI is advised to remind establishment staff to ensure records are completed in full, or marked N/A where appropriate, and that corrections are made by striking through the original entry, then

		initial and date the amendment.
7.	GQ4e	During a review of the Freezer A tissue log in theatres, a transcription error was identified whereby a product was recorded as both "used in patient" and "returned to company". The establishment was able to demonstrate full traceability of the product during the inspection. However, the DI is advised to raise this incident internally for investigation and to consider reviewing procedures relating to freezer defrosting, as well as the processes used to record product movements.
8.	GQ5a	When undertaking a risk-based assessment of donor travel, establishment staff follow the relevant JPAC guidelines. The DI is advised to document that this review has been completed as part of the donor assessment process, including the decision taken.
9.	GQ5b	The DI is advised to formally risk assess the establishment's current approach to the testing of autologous PBSC donors, taking into account the current requirement under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) that blood samples must be obtained at the time of donation or, if not possible, within seven days post donation for all living donors except allogeneic bone marrow stem-cell and peripheral blood stem-cell donors. The DI is also advised to implement a standardised blood test request panel to ensure all necessary investigations are carried out in accordance with the requirements of Directions 001/2021.
10.	PFE1a	The DI is advised to maintain close oversight of the temperature of the rooms used for apheresis and the storage related to consumables and equipment, especially during periods of high external temperatures. The use of interim control measures such as portable air conditioning units should be clearly documented within the establishment's premises risk assessment and related SOPs and temperature deviations/near misses should be recorded in relevant incident and risk registers to highlight and inform the need for a more sustainable, long-term solution to the issues faced over recent months.

11.	PFE4h	The DI is advised to review transport box validation to consider real-world temperature and viability data.

Background

The establishment undertakes the procurement and testing of PBSC and peripheral blood lymphocytes for DLI. Collections are from adult donors for autologous transplants or from directed, related adult donors for allogeneic transplants at the establishment. Transportation, processing and storage are carried out by a separate HTA-licensed establishment under the terms of an SLA. The establishment also undertakes procurement of PBMCs as an ATMP starting material. After procurement, PBMCs are exported by the manufacturer to a manufacturing facility in a third country.

The establishment is licensed for the procurement and testing of bone marrow for autologous and allogeneic transplantation but has not undertaken this activity in several years.

The establishment undertakes the storage of cryopreserved bone and tendons for surgical use. The tissue is purchased from HTA-licensed suppliers. Although the establishment is licensed for the procurement, testing and storage of skin for autologous use in plastic surgery, there has been no related procurement, testing or storage under the licence for several years.

The establishment has been licensed by the HTA since July 2007. This was the establishment's tenth inspection. The last inspection took place in August 2024. CAPAs implemented to address the findings from the previous inspection were reviewed during the site visit.

Since the last inspection, the establishment has removed storage of relevant material from a human body for use for a scheduled purpose from its licence.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The following areas were covered during the inspection:

Review of governance documentation
The inspection included a review of procedural documents relating to licensed activities, records of servicing, cleaning records, audits, risk assessments, reported incidents, meeting minutes, temperature monitoring records and staff training records. In addition, 4 incidents were discussed during the inspection.

Visual inspection
The inspection team undertook a visual inspection of areas where licensable activity is undertaken. This included the apheresis suite where PBSC and PBMCs are collected, the testing laboratory on site and the areas where tissues, consumables and reagents are stored.

Audit of records
Records for the following tissues and cells were reviewed:

- 1 autologous PBSC procurement;
- 2 allogeneic PBSC procurements, 1 of which was from a donor registry;
- 1 PBMC procurement as ATMP starting material;
- 1 bone that had been implanted; and
- 4 tendons, 2 that were still in storage and 2 that had been implanted.

Where relevant, the records audited included product receipt and shipping records, procurement and testing records, evidence of donor consent, and storage and release documentation. Where samples were present at the establishment, a traceability audit from the physical storage location to records, and vice versa, was carried out.

Meetings with establishment staff
The inspection included discussions with the DI (The Head of Nursing for Theatres), the Haematology Programme Directors and members of the clinical team, the Matron for Theatres, the Quality Manager and the Head of Nursing for Haematology. Discussions also included staff working under the licence in the Theatres, and staff working with stem cells and involved in ATMP starting material

procurement. Staff were involved in the receipt and management of material, donor assessment and seeking consent, apheresis, operational management, and in quality management.

Report sent to DI for factual accuracy: 23 September 2026

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 16 October 2026

Appendix 1: The HTA's regulatory requirements

The HTA must assure itself that the DI, Licence Holder, premises and practices are suitable.

The statutory duties of the DI are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as ‘Critical’, ‘Major’ or ‘Minor’. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the Human Tissue Act 2004, Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended), or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant direct risk of causing harm to a recipient patient or to a living donor,

   or

   A number of ‘major’ shortfalls, none of which is critical on its own, but viewed cumulatively represent a systemic failure and therefore are considered ‘critical’.

   A critical shortfall may result in one or more of the following:

   - A notice of proposal being issued to revoke the licence
   - Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

A non-critical shortfall.

A shortfall in the carrying out of licensable activities which poses an indirect risk to the safety of a donor or a recipient

or

A shortfall in the establishment's quality and safety procedures which poses an indirect risk to the safety of a donor or a recipient;

or

A shortfall which indicates a major deviation from the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) or the HTA Directions;

or

A shortfall which indicates a failure to carry out satisfactory procedures for the release of tissues and cells or a failure on the part of the designated individual to fulfil his or her legal duties;

or

A combination of several 'minor' shortfalls, none of which is major on its own, but which, viewed cumulatively, could constitute a major shortfall by adversely affecting the quality and safety of the tissues and cells.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 12 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

A shortfall which cannot be classified as either critical or major and, which can be addressed by further development by the establishment.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by

the HTA either by desk-based review or at the time of the next on-site inspection.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 34 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with the final inspection report. Establishments must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of:

- a follow-up inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.

Appendix 3: HTA standards
The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Human Tissue (Quality and Safety for Human Application) Regulations 2007 Standards (as amended)

Consent

Standard
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act), the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) and as set out in the HTA's Codes of Practice.
a) If the establishment acts as a procurer of tissues and / or cells, there is an established process for acquiring donor consent which meets the requirements of the HT Act 2004 the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) and the HTA's Codes of Practice.
Q c) The establishment or the third party's procedure on obtaining donor consent includes how potential donors are identified and who is able to take consent.
d) Consent forms comply with the HTA Codes of Practice.
e) Completed consent forms are included in records and are made accessible to those using or releasing tissue and / or cells for a Scheduled Purpose.
C2 Information about the consent process is provided and in a variety of formats.
a) The procedure on obtaining consent details what information will be provided to donors. As a minimum, the information specified by Directions 001/2021 is included.
c) Information is available in suitable formats and there is access to independent interpreters when required.

d) There are procedures to ensure that information is provided to the donor or donor's family by trained personnel.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.
a) Staff involved in obtaining consent are provided with training on how to take informed consent in accordance with the requirements of the HT Act 2004 and Code of Practice on Consent.
b) Training records are kept demonstrating attendance at training on consent.

Governance and Quality

Standard
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.
a) There is an organisational chart clearly defining the lines of accountability and reporting relationships.
b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.
d) There is a document control system to ensure that changes to documents are reviewed, approved, dated and documented by an authorised person and only current documents are in use.
e) There are procedures for tissue and / or cell procurement, which ensure the safety of living donors.

g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.
h) There are procedures for the management and quarantine of non-conforming consignments or those with incomplete test results, to ensure no risk of cross contamination.
i) There are procedures to ensure tissues and / or cells are not released from quarantine until verification has been completed and recorded.
j) There are procedures detailing the critical materials and reagents used and where applicable, materials and reagents meet the standards laid down by the Medical Devices Regulation 2002 (SI 2002 618, as amended) (UK MDR 2002) and United Kingdom Conformity Assessed (UKCA).
k) There is a procedure for handling returned products.
l) There are procedures to ensure that in the event of termination of activities for whatever reason, stored tissues and / or cells are transferred to another licensed establishment or establishments.
o) There is a complaints system in place.
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
q) There is a record of agreements established with third parties.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 001/2021.
s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.
t) There are procedures for the re-provision of service in an emergency.

GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.
b) There is an internal audit system for all licensable activities.
c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.
d) Processes affecting the quality and safety of tissues and / or cells are validated and undergo regular evaluation to ensure they continue to achieve the intended results.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.
a) There are clearly documented job descriptions for all staff.
b) There are orientation and induction programmes for new staff.
c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.
d) There is annual documented mandatory training (e.g. health and safety and fire).
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.
f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.
g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.
h) There is a system of staff appraisal.

i) Where appropriate, staff are registered with a professional or statutory body.
j) There are training and reference manuals available.
k) The establishment is sufficiently staffed to carry out its activities.
GQ4 There is a systematic and planned approach to the management of records.
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.
b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.
c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.
d) There is a system for back-up / recovery in the event of loss of computerised records.
e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application.
f) There are procedures to ensure that donor documentation, as specified by Directions 001/2021, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 001/2021.
h) Raw data which are critical to the safety and quality of tissues and cells are kept for 10 years after the use, expiry date or disposal of tissues and / or cells.
i) The minimum data to ensure traceability from donor to recipient as required by Directions 001/2021 are kept for 30 years after the use, expiry or disposal of tissues and / or cells.

j) Records are kept of products and material coming into contact with the tissues and / or cells.
l) The establishment records the acceptance or rejection of tissue and / or cells that it receives and in the case of rejection why this rejection occurred.
m) In the event of termination of activities of the establishment a contingency plan is in place to ensure raw data and records of traceability are maintained for 10 or 30 years respectively, as required.
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.
a) Donors are selected either by the establishment or the third party acting on its behalf in accordance with the criteria required by Directions 001/2021.
b) The testing of donors by the establishment or a third party on behalf of the establishment is carried out in accordance with the requirements of Directions 001/2021.
c) In cases other than autologous donors, donor selection is carried out by authorised personnel and signed and reviewed by a qualified health professional.
d) There is a system in place either at the establishment or at a third party acting on its behalf to record results of donor selection and associated tests.
e) Testing of donor samples is carried out using UKCA or CE marked diagnostic tests, in line with the requirements set out in Directions 001/2021.
f) Samples taken for donor testing are clearly labelled with the time and place the sample was taken and a unique donor identification code.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.

b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.
c) The establishment has procedures to ensure that tissues and / or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa.
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.
a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.
b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.
c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.
d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.
e) In the event of a recall, there are personnel authorised within the establishment to assess the need for a recall and if appropriate initiate and coordinate a recall.
f) There is an effective, documented recall procedure which includes a description of responsibilities and actions to be taken in the event of a recall including notification of the HTA and pre-defined times in which actions must be taken.
GQ8 Risk assessments of the establishment’s practices and processes are completed regularly and are recorded and monitored appropriately.
a) There are documented risk assessments for all practices and processes.
b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.

c) Staff can access risk assessments and are made aware of local hazards at training.
d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and / or cells.

Premises, Facilities and Equipment

Standard
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.
e) There are procedures to ensure that the premises are secure, and confidentiality is maintained.
f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.

PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24-hour basis.
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
d) There is a documented, specified maximum storage period for tissues and / or cells.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
b) There are procedures for the transport of tissues and / or cells which reflect identified risks associated with transport.
c) There is a system to ensure that traceability of tissues and / or cells is maintained during transport.
d) Records are kept of transportation and delivery.
e) Tissues and / or cells are packaged and transported in a manner and under conditions that minimise the risk of contamination and ensure their safety and quality.
f) There are third party agreements with courier or transport companies to ensure that any specific transport conditions required are maintained.
g) Critical transport conditions required to maintain the properties of tissue and / or cells are defined and documented.
h) Packaging and containers used for transportation are validated to ensure they are fit for purpose.
i) Primary packaging containing tissues and / or cells is labelled with the information required by Directions 001/2021.

j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions 001/2021.
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.
a) Critical equipment and technical devices are identified, validated, regularly inspected and records are maintained.
b) Critical equipment is maintained and serviced in accordance with the manufacturer’s instructions.
c) Equipment affecting critical processes and storage parameters is identified and monitored to detect malfunctions and defects and procedures are in place to take any corrective actions.
d) New and repaired equipment is validated before use and this is documented.
e) There are documented agreements with maintenance companies.
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly, and this is recorded.
g) Instruments and devices used for procurement are sterile, validated and regularly maintained.
h) Users have access to instructions for equipment and receive training in the use of equipment and maintenance where appropriate.
i) Staff are aware of how to report an equipment problem.
j) For each critical process, the materials, equipment and personnel are identified and documented.
k) There are contingency plans for equipment failure.

Disposal

Standard
D1 There is a clear and sensitive policy for disposing of tissues and / or cells.
a) The disposal policy complies with HTA's Codes of Practice.
b) The disposal procedure complies with Health and Safety recommendations.
c) There is a documented procedure on disposal which ensures that there is no cross contamination.
D2 The reasons for disposal and the methods used are carefully documented.
a) There is a procedure for tracking the disposal of tissue and / or cells that details the method and reason for disposal.
b) Disposal arrangements reflect (where applicable) the consent given for disposal.