Site visit inspection report on compliance with HTA licensing standards
Inspection date: **28-30 January 2025**

Royal Victoria Infirmary
HTA licensing number 11122

Licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)
and
Licensed under the Human Tissue Act 2004

Licensable activities carried out by the establishment
Licensed activities
'E' = Establishment is licensed to carry out this activity and is currently carrying it out.
'E*' = Establishment is licensed to carry out this activity but is not currently carrying it out.

Site	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Hub **Royal Victoria Infirmary**	E	E	E	E	E		E
Satellite **Newcastle Bio-Manufacturing Facility**		E		E*	E		

Satellite **Freeman Hospital**	E		E	E	E		

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
Musculoskeletal, Bone; Bone				Authorised	Authorised		
Musculosketal, Bone; Bone Struts				Authorised	Authorised		
Musculoskeletal, Tendon & Ligament; Tendon				Authorised	Authorised		
Progenitor Cell, Hematopoietic, PBSC; PBSC	Authorised	Authorised	Authorised	Authorised	Authorised		
Progenitor Cell, Hematopoietic, Bone Marrow; Bone Marrow	Authorised	Authorised	Authorised	Authorised	Authorised		
Mature Cell, T Cell	Authorised	Authorised	Authorised	Authorised	Authorised		

(DLI); DLI**							
Progenitor Cell, Hematopoietic, Cord Blood; Cord Blood	Authorised*	Authorised*	Authorised*	Authorised	Authorised*		
Progenitor Cell, Hematopoietic, Unspecified; Peripheral Blood Mononuclear Cells (PBMC)	Authorised	Authorised	Authorised	Authorised	Authorised		Authorised
Cardiovascular, vessels; Others			Authorised	Authorised	Authorised		
Other; Limbal Stem Cells (ATMP)***	Authorised		Authorised				Authorised
Membrane, Amniotic: Amniotic Membrane				Authorised			
Mature Cell, Pancreatic Islets; Pancreatic Islets	Authorised	Authorised	Authorised				
Other; Tumour	Authorised		Authorised				Authorised

(ATMP)* **							
Cardiovascular, Valves; Heart Valves				Authorised	Authorised		
Cardiovascular, Valves; Pulmonary Patches				Authorised	Authorised		
Cardiovascular, Vessels; Conduits				Authorised	Authorised		
Other; hESCs** **				Authorised			

**DLI - donor lymphocytes for infusion

***ATMP - advanced therapy medicinal product

****hESCs- human embryonic stem cells

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 Royal Victoria Infirmary (the establishment) had met the majority of the HTA's standards that were assessed during the inspection, ten minor shortfalls were found against standards for Governance and Quality, and Premises, Facilities and Equipment.

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

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

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.		
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.	At the time of the inspection, and for a couple of months prior to the inspection, the establishment's testing laboratory was unable to carry out in-house HBsAg testing. Testing of this marker was outsourced to an external testing laboratory. There is no agreement with the external laboratory for the testing of HBsAg that sets out: • the reporting requirements for serious adverse events and reactions (SAEARs) within 24 hours of discovery; or • the requirement to retain raw data for 10 years after use, disposal and expiry of the tissues and cells.	**Minor**
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.		

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.		
k) The establishment is sufficiently staffed to carry out its activities.	The establishment previously had five members of staff that were able to undertake paediatric apheresis procedures. Two trained staff members are required to be present for all paediatric apheresis procedures. At the time of the inspection, the department only had one part-time staff member who is fully signed-off to undertake all apheresis procedures. A second staff member is able to undertake some, but not all procedures. Two new staff members are not yet trained to undertake any apheresis procedures. Furthermore, the adult apheresis team cannot offer any assistance to the service because they are not trained on low body-weight patients. At the time of the inspection there was no staff contingency for unplanned procedures and prolonged staff sickness. The inspection team was told that the number of fully trained staff who are able to undertake apheresis was recently raised to the senior management team and there are plans to include it on the establishment's risk register. However, no action had been taken at the time of the inspection in this regard, despite the fact that the establishment acts as a contingency centre for other paediatric centres in the UK, which is likely to increase the number of paediatric patients, and that it is currently expanding the cellular therapies service to include haemoglobinopathies.	**Minor**

GQ4 There is a systematic and planned approach to the management 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. j) Records are kept of products and material coming into contact with the tissues and / or cells.	Examples were seen at the adult apheresis department where forms were not fully completed and key information was not consistently recorded, such as: • the Lot number of cannula used for apheresis procedures; • the CD34 measurement and volume processed; and • the apheresis machine used. Establishment staff did not regularly review the records to identify and resolve any discrepancies.	**Minor**
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.	Between 18 March and 16 May 2024, the transmitter for the temperature monitoring system in the paediatric apheresis department was offline and a deviation was not raised. The temperature monitoring data for the apheresis ward and store cupboard have been lost and cannot be recovered. Following the inspection, the establishment was able to obtain some of the ambient temperature monitoring data for some, but not for all, of the areas within the ward. The ambient temperature monitoring data from the cupboard where reagents are stored, and the data from the harvest of Peripheral Blood Stem Cells (PBSCs) on 23 April 2024, have been lost.	**Minor**

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.	During the inspection, two examples were seen where mandatory serology testing was not carried out on blood samples collected on the day of donation or within seven days post donation for tumour tissue procured as ATMP starting material. This had not been identified by the establishment and dealt with appropriately.	**Minor**
GQ7 There are systems to ensure that all adverse events 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.	Although examples were seen where serious incidents related to procurement, testing and processing were logged and investigated internally, these were not reported to the HTA as SAEARs, as required. Furthermore, there is no SAEARs reporting SOP within the testing laboratory that requires staff to report incidents to the DI within 24 hours of discovery.	**Minor**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.		
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.	The requirement is for risk assessments to be reviewed as a minimum annually or when any changes are made. However, the establishment's policy requires risk assessments to be reviewed every two years on a risk basis.	**Minor**
PFE2 Environmental controls are in place to avoid potential contamination.		

b) Where processing of tissues and / or cells involves exposure to the environment, it occurs in an appropriate, monitored environment as required by Directions 001/2021.	At the previous inspection, it was observed that the sampling head of the non-viable particle monitor (NVPM) was positioned in the direction of the cells being processed rather than in the direction of the filtered airflow. This did not provide a representative analysis of the airflow in the Grade A environment. During this inspection, it was observed that the NVPM was again positioned in the direction of the cells being processed rather than in the direction of the filtered airflow. Soon after the inspection, the establishment confirmed that they have displayed a laminated picture of the cabinet set-up, which is placed at the front of the processing cabinets as a visual aid to set up. It is understood that the incorrect positioning of the NVPM was an isolated incident. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, 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.	The apheresis reagents and consumables are required to be stored under temperature monitored conditions and within a temperature range of 15-25°C. The cupboard in the adult apheresis department where apheresis reagents are stored is not temperature monitored.	**Minor**

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.		
f) Cleaning, disinfection and sanitation of critical equipment is performed regularly and this is recorded.	The establishment's procedure for cleaning of the apheresis machines sets out that they will be routinely cleaned following apheresis, as well as weekly and monthly. A review of the cleaning records indicated a few occasions where the weekly cleaning of the apheresis machines was not carried out.	**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.	C1a	The establishment's PBSC Collection patient and donor information leaflet for adults and children does not include that testing for HTLV-I antibody will be performed. The DI is advised to review patient-facing documentation and consent forms to ensure that the range of infectious disease marker tests that will be performed is clearly set out.
2.	GQ1c/ GQ7a	The DI is advised to nominate a Person Designated (PD) for the testing laboratory to act as a point of contact for this activity.

3.	GQ4b/ GQ5d	During the review of records from vessel donors, a couple of examples were observed where additional tests, such as HHV8, were noted as being undertaken, but the results had not been recorded. The DI is advised to review the establishment's approach to the audit of records to provide an assurance that they are sufficiently robust, able to identify any issues with completion of records and ensure appropriate remedial actions are taken, when required.
4.	GQ5a	During the review of donor records and of the "Haematopoietic Stem Cell Related Donor Medical Assessment Form", an example was seen where there was ambiguity about what questions had been asked of the donor as part of their medical assessment for donating DLI. Furthermore, there is insufficient space on this form for the person undertaking the medical assessment to record the donor's answers within the sections "Systems Review" and the "Past Medical History". The DI is strongly advised to review the Medical Assessment form to ensure there is sufficient space under each of the questions to record relevant information and to consider whether the form can be amended to make it easier to evidence that individual risks have been considered. The DI is also strongly advised, as part of the donor assessment process, to include more specific, follow up questions within the Medical Assessment form, in accordance with Annex A of the HTA Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment, including: • whether the donor has systemic infection; and • whether the donor is taking immunosuppressive medication and/ or pre- and post- exposure prophylaxis medication for people at risk of HIV. The DI is also advised to include examples of heavy metals and toxic substances as per the wording of Annex A.
5.	GQ7a	A few examples were noted where incidents that should have been reported as SAEARs were categorised as "Minor" and as such were not required to be reported to the HTA. The DI is advised to

		review the establishment's incident scoring matrix, used to classify incidents, and ensure it is aligned with the HTA's requirement for reporting SAEARs.
6.	GQ7a	During the review of incident records, it was noted that they did not always document patient outcomes. The DI is advised to ensure that future incident records include this information consistently.
7.	GQ8a	The DI is advised to expand the scope of the risk assessment covering apheresis machine failure to include the transportation of the apheresis machines between the adult and paediatric departments as part of the contingency arrangements.
8.	GQ8a	The DI is advised to include as part of the Anticoagulant Citrate Dextrose Solution (ACD-A) storage requirements risk assessment, the manufacturer's recommendations for the use of this reagent, where ambient temperature exceeds 25°C.
9.	PFE1a	The door of the store-room within the paediatric ward, where apheresis reagents are kept, does not have a hinge and cannot close automatically. This may result in temperature deviations. Establishment staff have raised the matter with estates, but no action has been taken for approximately nine months. In the meantime, staff have implemented control measures to ensure the temperature of the store-room is maintained within set limits. The DI is advised to expand the premises risk assessment to include all the mitigating actions taken to prevent temperature deviations for apheresis reagents. The DI is also advised to raise this incident on the internal incident reporting system.
10.	PFE2b	For sterility testing during processing of pancreatic islets, the establishment uses culture bottles that are able to detect both aerobic and anaerobic microorganisms. However, during processing of bone marrow, PBMCs, PBSCs and DLI, the establishment uses culture media for the recovery of aerobic and facultative anaerobic microorganisms. The DI is advised to seek an expert opinion, if they haven't done so already, and document the rationale for this decision.

11.	PFE3a	The perfusion fluid used by the establishment is required to be stored under temperature monitored conditions, and within a range of 2-25°C. However, the temperature monitoring system is set to alarm at a minimum temperature of 1°C. The DI is advised to ensure the reagent is stored within the required temperature parameters and adjust the minimum temperature above 2°C to allow staff to respond to any temperature excursions.
12.	PFE5a	The DI is advised to label the apheresis machines used within the paediatric apheresis department to ensure there is an audit trail of the equipment used for the harvest of haematopoietic stem cells.
13.	PFE5k	During the inspection, establishment staff described the contingencies in place for critical equipment, such as the apheresis machines for paediatric patients and the islet centrifuge. The DI is advised to document the contingencies to ensure all members of staff understand the process.

Background

Royal Victoria Infirmary has been licensed by the HTA since April 2008. This was the ninth site visit inspection of the establishment; the most recent previous inspection took place in November 2022. Royal Victoria Infirmary (the hub) has two satellites, the Freeman hospital and the Newcastle Bio-Manufacturing Facility, where licensable activities also take place. The testing laboratory is located at the Freeman Hospital and the cleanrooms where processing of tissues and cells takes place are located at the hub and Newcastle Bio-Manufacturing Facility.

Since the previous inspection, the establishment has added export of tumour tissue for ATMP manufacture and added new persons designated under the licence. There have been no other significant changes to the licence arrangements or the activities carried out under the 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
A review of selected documentation relevant to the establishment's licensable activities and quality management system was undertaken, including a review of policies and procedural documents, donor selection, consent, medical history questionnaires, processing records including environmental monitoring and cryopreservation records, temperature monitoring records, equipment maintenance records, risk assessments, agreements, staff training records and reported incidents.

Visual inspection
A review of the establishment's facilities was conducted, including areas where procurement, processing and storage of tissue products and consumables takes place. The inspection team also visited the Newcastle Bio-Manufacturing Facility where receipt, processing, storage of tissues products and reagents, and distribution takes place. The Freeman satellite was also visited as part of this inspection, including the areas where procurement and storage of reagents and iliac vessels take place. The testing laboratory at the Freeman satellite was also visited. A visual inspection of the storage areas for femoral heads, struts and tendons was not undertaken as part of this inspection.

Audit of records
Representative records relating to two autologous adult PBSCs, two paediatric PBSCs, one autologous and one allogeneic donation, one allogeneic PBMC CD45 depletion, one paediatric bone marrow donation, two vessels, two autologous limbal stem cells, two tumour tissue ATMP samples, one DLI from a sibling donor and one islet donation were reviewed. The records reviewed included, where applicable: records related to procurement dates and times, consent, testing for the mandatory serology markers, microbiology sterility testing results, processing, storage, distribution, export and disposal. Some discrepancies were identified which did not amount to shortfalls (see Advice items 1, 3 and 4). The liver vessel tissue register was cross-checked against storage of a couple of vessels.

Meetings with establishment staff
Discussions were held with the DI, the PDs and staff carrying out licensable activities at the hub, both satellites and the testing laboratory.

The establishment is also licensed for the storage of relevant material for use in a Scheduled Purpose. This activity was not reviewed as part of this inspection.

Report sent to DI for factual accuracy: 02 – April – 2025

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

Final report issued: 16 – May – 2025

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 (HA)

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 1-2 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 inspection.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 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 site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine site-visit inspection.

After an assessment of your proposed action plan you 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.
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.
m) The criteria for allocating tissues and / or cells to patients and health care institutions are documented and made available to these parties on request.
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.
k) There are documented agreements with end users to ensure they record and store the data required by Directions 001/2021.
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.
g) Establishments distributing tissue and / or cells provide information to end users on how to report a serious adverse event or reaction and have agreements with them specifying that they will report these events or reactions.

h) Establishments distributing tissues and / or cells have systems to receive notifications of serious adverse events and reactions from end users and notify the HTA.
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.
b) Where processing of tissues and / or cells involves exposure to the environment, it occurs in an appropriate, monitored environment as required by Directions 001/2021.
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.
a) There is a system to ensure tissue and / or cells are not distributed until they meet the standards laid down by Directions 001/2021.
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.

Human Tissue Act 2004 standards

Consent

Standard
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice.
b) Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice.
c) Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice.
d) Written information is provided to those from whom consent is sought, which reflects the requirements of the HT Act and the HTA's Codes of Practice.
e) Language translations are available when appropriate.
f) Information is available in formats appropriate to the situation.
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent
a) There is suitable training and support of staff involved in seeking consent, which addresses the requirements of the HT Act and the HTA's Codes of Practice.
b) Records demonstrate up-to-date staff training.
c) Competency is assessed and maintained.

Governance and Quality

Standard
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.
b) There is a document control system.
c) There are change control mechanisms for the implementation of new operational procedures.
d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff.
e) There is a system for managing complaints.
GQ2 There is a documented system of audit
a) There is a documented schedule of audits covering licensable activities.
b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills
a) Qualifications of staff and all training are recorded, records showing attendance at training.
b) There are documented induction training programmes for new staff.
c) Training provisions include those for visiting staff.

d) Staff have appraisals and personal development plans.
GQ4 There is a systematic and planned approach to the management of records
a) There are suitable systems for the creation, review, amendment, retention and destruction of records.
b) There are provisions for back-up / recovery in the event of loss of records.
c) Systems ensure data protection, confidentiality and public disclosure (whistleblowing).
GQ5 There are systems to ensure that all adverse events are investigated promptly
a) Staff are instructed in how to use incident reporting systems.
b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made.
GQ6 Risk assessments of the establishment’s practices and processes are completed regularly, recorded and monitored
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA’s Codes of Practice.
b) Risk assessments are reviewed regularly.
c) Staff can access risk assessments and are made aware of risks during training.

Traceability

Standard
T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail
a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it.
b) A register of donated material, and the associated products where relevant, is maintained.
c) An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom.
d) A system is in place to ensure that traceability of relevant material is maintained during transport.
e) Records of transportation and delivery are kept.
f) Records of any agreements with courier or transport companies are kept.
g) Records of any agreements with recipients of relevant material are kept.
T2 Bodies and human tissue are disposed of in an appropriate manner
a) Disposal is carried out in accordance with the HTA’s Codes of Practice.
b) The date, reason for disposal and the method used are documented.

Premises, facilities and equipment

Standard
PFE1 The premises are secure and fit for purpose
a) An assessment of the premises has been carried out to ensure that they are appropriate for the purpose.
b) Arrangements are in place to ensure that the premises are secure and confidentiality is maintained.
c) There are documented cleaning and decontamination procedures.
PFE2 There are appropriate facilities for the storage of bodies and human tissue
a) There is sufficient storage capacity.
b) Where relevant, storage arrangements ensure the dignity of the deceased.
c) Storage conditions are monitored, recorded and acted on when required.
d) There are documented contingency plans in place in case of failure in storage area.
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored
a) Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept.
b) Users have access to instructions for equipment and are aware of how to report an equipment problem.
c) Staff are provided with suitable personal protective equipment.