Site visit inspection report on compliance with HTA minimum standards

St George's Hospital

HTA licensing number 12462

Licensed for the

- **procurement, testing, storage and distribution of human tissues and cells for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)**
- **storage of relevant material which has come from a human body for use for a scheduled purpose**

8 – 9 July 2019

Summary of inspection findings

The HTA found the Designated Individual and the Licence Holder 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, six minor shortfalls were found in relation to the consent, governance and quality systems and the premises, facilities and equipment standards. The shortfalls related to the lack of documented consent training, the scope of the independent audit, the donor exclusion criteria, labelling procedures not meeting the requirements of the Single European Code (SEC), the timing of blood sampling for donors of certain cell types and the lack of a documented, maximum storage period for cells.

Particular examples of good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

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

The statutory duties of the Designated Individual 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.

Licensable activities carried out by the establishment

'E' = Establishment is licensed to carry out this activity.

'E*' = Establishment is licensed to carry out this activity but is not currently carrying it out.

'SLA' = Service level agreement; another licensed establishment carries out the activity on behalf of the establishment.

Tissue category; Tissue type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Progenitor Cell, Hematopoietic, Bone Marrow; Bone Marrow	**E***		**E***	**E***	**E***		
Mature Cell, T Cell (DLI); DLI	**E**	**SLA**	**E**	**SLA**	**SLA**		
Progenitor Cell, Hematopoietic, PBSC; PBSC	**E**	**SLA**	**E**	**SLA**	**SLA**		
Musculoskeletal, Tendon & Ligament; Tendons & Ligaments				**E**			
Skin; Skin	**E***		**E***	**E***			
Cardiovascular, Vessels; Vessels (including Illiac)	**E***		**E***	**E***			

Background to the establishment and description of inspection activities undertaken

The establishment is licensed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) for the procurement, testing, storage and distribution of peripheral blood stem cells (PBSCs) and cells for donor lymphocyte infusions (DLIs). The establishment is also licensed to work with bone marrow, although there has been no procurement of bone marrow in the last three years. The establishment purchases frozen femoral heads and tendons from another HTA-licensed establishment and stores them for use in orthopaedic surgery. The establishment is also licensed for the procurement, testing and storage of skin and vessels, although these activities are not currently being undertaken. The organisation was accredited by the Joint Accreditation Committee - European Society for Blood and Marrow Transplantation (EBMT) and the International Society for Cellular Therapy (ISCT) (JACIE) in 2016. The establishment is also licensed for the storage of relevant material for use for a scheduled purpose under the Human Tissue (HT) Act 2004. Although licensed for this activity, the establishment does not currently store relevant material for use for a scheduled purpose. The establishment has been licensed by the HTA since 2007 and this was the seventh routine inspection to assess compliance with the HTA standards.

Peripheral Blood Stem Cells (PBSCs) and cells for Donor Lymphocyte Infusion (DLI)

Donors are provided with information booklets and seen in clinic to ensure they are fully informed regarding the procedure and the requirements for serology testing. Consultants undertake donor assessment and seek consent for procurement of PBSCs from autologous or allogeneic donors. Blood samples for the mandatory serology testing are taken no earlier than 30 days before procurement of stem cells. Blood samples from DLI donors are also taken no earlier than 30 days before procurement. Mandatory donor testing takes place at the onsite laboratory.

Procurement of PBSCs takes place in a dedicated room within the adult ward. On the day of procurement, autologous donors are monitored to ensure that the target CD34 counts are reached. For allogeneic donors, white blood cell counts are confirmed. Blood test results are checked to ensure there are no outstanding tests required and consent for the procedure to be undertaken is confirmed before apheresis commences. There are five apheresis machines maintained under a service contract and staff clean them after each apheresis session and once a month on a rota. The apheresis machines are rotated within the ward and the results from each machine are audited annually. Acid-Citrate-Dextrose Formula A (ACD-A) and apheresis kits are stored in separate rooms. The room in which ACD-A is stored is temperature-monitored and checked daily, including weekends. The room in which apheresis kits are stored is temperature-monitored, but in accordance with Pharmacy policy, the temperature is only checked periodically.

The establishment has SLAs with two other HTA-licensed establishments, one for the processing, storage and transport of cells and one for storage only of cells. Each collection is assigned a unique code, which ensures traceability from procurement through to processing, storage, distribution and end-use or disposal. The labels with the unique code are provided by the other licensed establishment. The stem cell collection is placed in an insulated transport box along with four pre-chilled ice packs, together with relevant documentation. The temperature is monitored with a temperature strip. The courier picking up the stem cell collection signs the driver record logbook. Following this, the stem cell collection is delivered by the courier to the other licensed establishment for processing and storage.

Patient records were reviewed for cells collected by apheresis (one autologous and two matched related donor/recipient records). The audit covered the donor consent, the ‘Adult Patient Consent to Apheresis Procedure’ form, the cell collection records, the consumables used, the record of transfer of product for processing and storage, seal tag numbers, timing of

sample collection for mandatory serology testing, and the testing results. The Single European Code Donation Identification (SEC-DI) sequence was not applied for any of the products reviewed, and for one of the matched, related donor products details of the apheresis machine used had not been recorded on the associated worksheet. No other discrepancies were found although advice has been given with respect to the apheresis consent form (see advice item 4).

Bone and tendon allografts

Allograft material is ordered by the Theatre team leader and the order details are recorded in the 'PCT Loan Book'. Allograft is delivered directly to the establishment's theatres where a trained member of staff checks the integrity of the outer packaging. The accompanying paperwork is used to verify that the shipment details match the order and the details recorded within the 'PCT Loan Book'. Once it has been confirmed that the correct order has been received and there is no damage, staff accept the allograft into the theatre inventory. The unique tissue identifiers on the container are verified against the paperwork to check that they match. Following verification against the paperwork, tissue identifiers, tissue type, expiry date and date of receipt are recorded on an 'Allograft Traceability Record' form and in the 'Allograft Freezer Inventory Record'.

Audits of traceability for allografts included four femoral heads and one tendon cross-checked against the 'Allograft Traceability Record' and 'Allograft Freezer Inventory Record'; there were no discrepancies noted.

Autologous skin and vessels

In the past, the establishment procured and stored skin and vessel samples for longer than 48 hours, in a refrigerator, for potential use in surgery. Since the last inspection, the establishment has taken the decision to store skin for no longer than 24 hours. A review of the skin storage records confirmed this. No skin samples were being stored on site at the time of the inspection which was also reflected in the skin storage records. The establishment has taken the decision to no longer store vessel samples.

A visual inspection was undertaken of the apheresis unit, the allograft and skin storage area within Theatres and the testing laboratory, including the laboratory undertaking the pre-apheresis CD34 count. A review of the establishment's documentation was conducted and round table discussions were held with key members of staff including the Designated Individual (DI), the quality manager for the stem cell transplant programme, the transplant coordinator and the Theatre team leaders for Plastic Surgery and Trauma and Orthopaedics.

Inspection findings

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

Compliance with HTA standards

Consent

Standard	Inspection findings	Level of shortfall
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 and Code of Practice on Consent.	While staff do undertake GCP training, no evidence was provided that staff receive training on how to take informed consent in accordance with the requirements of the HT Act and Code of Practice on Consent. *See advice item 5*	**Minor**

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of quality management and audit.		
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.	An independent audit has been completed for the activities carried out under the establishment's licence. However, the scope of the audit did not include all the applicable HTA standards.	**Minor**
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 002/2018.	The establishment's donor selection procedure does not include all of the donor exclusion criteria as set out in Annex A of the Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment. For example, the donors are not asked about ingestion of, or exposure to, a substance (such as cyanide, lead, mercury, gold) that may be transmitted to recipients in a dose that could endanger their health or transplantation with xenografts.	**Minor**
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 002/2018.	The establishment's testing procedures for donors of cells for DLI, collected independently of PBSCs, are not in line with Directions 002/2018 which stipulate that blood samples must be obtained on the day of collection, or if not possible within seven days post donation.	**Minor**

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.		
d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018.	The establishment does not currently have procedures in place to ensure that the SEC-DI is applied after procurement as set out in Directions 002/2018. *See advice item 2*	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.		
d) There is a documented, specified maximum storage period for tissues and / or cells.	Although the establishment has documented the minimum storage time for stem cells, there is no documented, specified maximum storage period.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1d	The DI is advised to refer to the most current epidemiological guidance to determine risks of infectious diseases based on travel history and country of origin.
2.	GQ1r	The establishment has SLAs with other HTA-licensed establishments for the processing and/or storage of cells. The DI is advised to amend these agreements to include details of the responsibilities for the assignment, use, and recording of the Single European Code.
3.	GQ1s	The DI is advised to update the agreement with the establishment undertaking storage of cells collected historically, to include the time period in which incidents must be reported to the establishment.
4.	GQ2a	Knowledge, consent and storage audits are undertaken in Theatres in relation to allograft products. The DI is advised to consider including process audits within the audit schedule to further support compliance with the procedures.
5.	GQ3f	The DI is advised to give consideration to updating the 'Donor Assessment' PowerPoint presentation (dated: 4/12/2015) to include

		information relating to the requirements of the HT Act and Code of Practice on Consent and the selection criteria for donors.
6.	GQ4f	The current apheresis consent form is a triple page carbon copy form and includes the instructions to retain one copy within the patient record and distribute the remaining two copies to the quality manager and patient. During discussions with establishment staff, it was confirmed that this practice does not take place. The DI is advised to update the procedure 'General Policies 03' in which the retention and distribution of the consent form is described, to reflect current practices.
7.	PFE3a	Apheresis kits (temperature range 0-35°C) are stored in an ambient store room overseen by the pharmacy department. Following the pharmacy department policy, when ambient temperature begins to increase (i.e. in summer) the temperature is manually recorded daily. The DI is advised to institute a process to record the minimum and maximum temperature range to provide an assurance that the 35°C maximum storage threshold has not been exceeded.
8.	PFE3b	The Plastic Surgery and Trauma and Orthopaedics unit have well documented processes to follow should there be a failure of their fridge or freezer units. These processes detail different responses dependent on whether the unit has failed for more, or less, than two hours. The DI may wish to consider the process in relation to the temperature that the storage unit has reached, as this parameter may affect the quality and safety of the stored tissue.
9.	PFE4h	The DI is advised to give consideration to periodically checking that containers used for transportation of cells maintain the critical transport conditions, as specified by the validation.

Concluding comments

Good practice was also observed during the inspection. The documents used within Theatres, for example the 'Allograft Traceability Record' form and the poster for guidance on freezer malfunction, displayed next to the allograft freezers, provide an effective prompt / reference when tasks are undertaken. In addition, 'Allograft Traceability Records' were bound by year and indexed according to whether the allograft was implanted or disposed and enabled efficient retrieval and review of traceability records.

There are a number of areas of practice that require improvement, resulting in six minor shortfalls. The HTA has given advice to the Designated Individual with respect to Consent processes, Governance and Quality Systems and Premises, Facilities and Equipment with a view to helping the establishment further develop its working practices.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan 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.
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.

Report sent to DI for factual accuracy: 29 July 2019

Report returned from DI: 23 August 2019

Final report issued: 27 August 2019

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 17 February 2020

Appendix 1: 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

Consent

Standard
C1 Consent is obtained in accordance with the requirements of the HT Act 2004, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 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 (Q&S Regulations) 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 002/2018 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 European directives on medical devices and in vitro diagnostic medical devices.
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 002/2018.
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 002/2018, is collected and maintained.
g) There is a system to ensure records are secure and that donor confidentiality is maintained in accordance with Directions 002/2018.
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 002/2018 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 002/2018.
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 to ensure records of traceability are maintained for 10 or 30 years 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 002/2018.
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 002/2018.
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 CE marked diagnostic tests.
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.
d) The requirements of the Single European Code are adhered to as set out in Directions 002/2018.
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.
d) Where appropriate, there are procedures to ensure that the premises are of a standard that ensures the dignity of deceased persons.
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 002/2018.
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 002/2018.
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.
j) Shipping packaging containing tissues and / or cells is labelled with the information required by Directions.
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 standards
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) Consent forms are available to those using or releasing relevant material for a scheduled purpose.

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 system standards

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 standards
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 standards
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.

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 HT Act 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:

   (1) A notice of proposal being issued to revoke the licence

(2) 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.

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

(5) 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 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 both

the draft and final inspection report. You 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 desk-based or site-visit inspection.

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