

Inspection report on compliance with HTA licensing standards  
Inspection dates: **21-22 November and 01 December 2022**



**Hospital Innovations Ltd**  
HTA licensing number 22512

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

‘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 Hospital Innovations Ltd				E	E	E	E*

<b>Satellite Hospital Innovations Limited, Brentford</b>				E	E		
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### **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.

<b>Tissue Category; Tissue Type</b>	<b>Procurement</b>	<b>Processing</b>	<b>Testing</b>	<b>Storage</b>	<b>Distribution</b>	<b>Import</b>	<b>Export</b>
<b>Musculoskeletal, Bone; Acellular Bone</b>				Authorised	Authorised	Authorised	Authorised*
<b>Membrane Amniotic; Amniotic Membrane</b>				Authorised	Authorised	Authorised	Authorised*
<b>Membrane, Fascia Lata; Fascia Lata</b>				Authorised	Authorised	Authorised	Authorised*
<b>Musculoskeletal, Bone; Bone</b>				Authorised	Authorised	Authorised	Authorised*
<b>Musculoskeletal, Bone; Bone Struts</b>				Authorised	Authorised	Authorised	Authorised*

<b>Musculoskeletal, Cartilage; Cartilage</b>				Authorised	Authorised	Authorised	Authorised*
<b>Musculoskeletal, Bone; DBM</b>				Authorised	Authorised	Authorised	Authorised*
<b>Musculoskeletal, Bone; DBM putty</b>				Authorised	Authorised	Authorised	Authorised*
<b>Musculoskeletal, Bone; Other Skeletal Tissue</b>				Authorised	Authorised	Authorised	Authorised*
<b>Musculoskeletal, Bone; Cancellous Bone Particles</b>				Authorised	Authorised	Authorised	Authorised*
<b>Musculoskeletal, Tendon &amp; Ligament; Tendons</b>				Authorised	Authorised	Authorised	Authorised*
<b>Musculoskeletal, Tendon &amp; Ligament; Ligaments</b>				Authorised	Authorised	Authorised	Authorised*
<b>Skin; Skin</b>				Authorised	Authorised	Authorised	Authorised*
<b>Musculoskeletal, Tendon &amp;</b>				Authorised	Authorised	Authorised	Authorised*

<b>Ligament; Ribs</b>							
<b>Musculoskeletal, Tendon &amp; Ligament; Menisci</b>				Authorised	Authorised	Authorised	
<b>Umbilical Cord; Cord Tissue</b>				Authorised	Authorised	Authorised	
<b>Neuronal; Nerves</b>					Authorised*		Authorised*

#### **Licensed activities – Human Tissue Act 2004**

The establishment is licensed for the storage of relevant material which has come from a human body for use for a scheduled purpose.

#### **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 Hospital Innovations Ltd (the establishment) had met the majority of the HTA's standards that were assessed during the inspection, four 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
<b>GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.</b>		
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.	During a review of records at the establishment's satellite site, an example was identified where a tissue product that was present in the establishment's ambient stock was listed as having been recently distributed within the establishment traceability systems. This error had not been detected during the establishment's two-person distribution checks. The establishment was able to resolve the discrepancy before the distributed tissue was used in human application.	<b>Minor</b>
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.		

<b>PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.</b>		
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.	<p>At the establishment's last site inspection, it was determined that the establishment did not have a system in place to ensure continuous temperature monitoring of the ambient tissue storage area.</p> <p>The establishment installed a system to address this requirement. However, during a review of records, examples were identified where an issue within the monitoring system resulted in a concurrent loss of data from a number of monitoring locations in August 2022. In addition to this, examples were identified where the system briefly recorded readings ranging from 125°C to -200°C, indicating a temporary error within the system.</p> <p>The loss of data and incorrect readings were not identified by the establishment during routine system checks or documented within governance records. Furthermore, the establishment has not been able to provide calibration certificates for the probes used to monitor ambient storage areas.</p>	<b>Minor</b>
<b>PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.</b>		
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.	<p>During a review of calibration records for a probe used to monitor one of the establishment's tissue storage freezers, it was identified that the equipment used to undertake the calibration activity had not been recorded. As a result, evidence demonstrating that a suitable reference thermometer had been used could not be provided.</p>	<b>Minor</b>

## Human Tissue Act 2004 standards

Standard	Inspection findings	Level of shortfall
<b>GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process</b>		
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.	The establishment's documented procedure 'Use of Human Tissue and/or Cells for Educational Purposes' (C-005-SOP) states that tissue will not be stored on unlicensed premises for longer than 48 hours, which is not aligned with regulatory requirements under the Human Tissue Act, 2004. In addition to this, the procedure does not provide sufficient detail to enable staff to undertake each element in a step-wise fashion from beginning to end in a consistent manner.	<b>Minor</b>

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.	General	During the inspection, the establishment discussed plans to relocate their current satellite premises in Brentford, London, to a larger premises. The DI is advised to submit the establishment's application to add the new satellite site in good time, to allow time for any requested evidence to be reviewed and authorisation granted ahead of the planned relocation date.
2.	GQ3e	The DI is advised to review the establishment's training and competency records to ensure that the identification numbers and titles of any documented procedures referenced within these records are up-to-date. This will help to ensure that staff training against current procedures can be robustly demonstrated in all cases.
3.	PFE3c	The DI is advised to consider increasing the frequency at which primary temperature records demonstrating the suitability of the freezer storage environments are downloaded, to ensure records are frequently reviewed and securely backed-up.
4.	PFE4e, g	The establishment may distribute several packets of acellular allograft to an end-user so that the end-user can select the amount or size of allograft best meeting their requirements. The remaining allograft may be returned to the establishment and released for further distribution provided that receipt checks are acceptable. The DI is advised to seek advice from the establishment's third country suppliers to ensure that this practice is aligned with their guidance for maintaining the quality and safety of each of the tissue products they supply.



## **Background**

The establishment imports a wide range of human-derived tissue products for distribution within the United Kingdom (UK) for clinical application under the terms of suitable agreements with its four third-country suppliers. Under these agreements, the establishment takes responsibility for ensuring imported tissues meet standards of quality and safety that are equivalent to those in the UK, as stipulated in the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended). The establishment is also licensed for the storage of relevant material under the Human Tissue Act, 2004, and was undertaking this activity at the time of the inspection.

The establishment has been licensed by the HTA since March 2008. This was the establishment's seventh inspection; the last inspection took place in June 2019. Since the last inspection, the establishment has opened a new satellite site in Brentford, London, which is supplied with tissue products from the hub premises for distribution to end users in London and surrounding areas.

The establishment has also added a new third country supplier and expanded the range of tissue products imported for human application. The majority of imported tissues are terminally sterilised, whilst some are aseptically processed. Finally, the establishment's DI and CLHc have exchanged roles to better align their respective responsibilities under the licence with their day-to-day responsibilities within the organisation.

## **Description of inspection activities undertaken**

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

### *Review of governance documentation*

The inspection included a review of policies and procedural documents relating to licensed activities, contracts for servicing of equipment, records of servicing, risk assessments, reported incidents, temperature monitoring records for storage areas at the hub and satellite site, and staff training records.

### *Visual inspection*

The inspection included a review of the premises at the establishment's hub and satellite site. Areas where ambient and frozen products are received and distributed, stored and, when necessary, placed in quarantine, were reviewed. This included a review of the single freezer storage location at the satellite and three freezers at the hub, one of which was also used for the storage of relevant material under the Human Tissue Act, 2004. The establishment also shared floor plans for a proposed new satellite site in Brentford, London.

### *Audit of records*

The inspection included a review of records associated with consent, donor selection, processing, import, storage, release to the satellite site and distribution of selected examples of tissue supplied by each of the establishment's third country suppliers, including:

- a terminally sterilised cancellous bone product;
- a terminally sterilised human dermis product;
- an amniotic cord tissue product;
- an aseptically processed DBM putty product; and,
- a terminally sterilised costal cartilage product.

### *Meetings with establishment staff*

The inspection team met with the DI, who is the establishment's Managing Director, the CLHc, who is the company Chairman, and staff working under the licence at both the hub and satellite sites.

### *Storage of relevant material under the Human Tissue Act, 2004.*

The establishment is also licensed for the storage of relevant material for use in a Scheduled Purpose. This activity was reviewed at a high level as part of this inspection, as many storage and governance arrangements are the same as those used for tissue intended for human application. The establishment's arrangements regarding the tissue used in a recent educational event were discussed and the documented procedure relating to this activity was reviewed.

**Report sent to DI for factual accuracy: 20 December 2022**

**Report returned from DI: 12 January 2023**

**Final report issued: 16 January 2023**

**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: 6 October 2024**

## **Appendix 1: The HTA's regulatory requirements**

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

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

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

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

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

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

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

## **Appendix 2: Classification of the level of shortfall**

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

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

### **1. Critical shortfall:**

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

*or*

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

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

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

## **2. Major shortfall:**

A non-critical shortfall.

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

*or*

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

*or*

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

*or*

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

*or*

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

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

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

### Appendix 3: HTA standards

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

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

##### 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.
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.
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.
n) The establishment ensures imports from third countries meet the standards of quality and safety set out in Directions 001/2021.
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.
<b>GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.</b>
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.
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 to ensure records of traceability are maintained for 10 or 30 years as required.
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

<b>Standard</b>
PFE1 The premises are fit for purpose.
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.
b) There are procedures to review and maintain the safety of staff, visitors and patients.
c) The premises have sufficient space for procedures to be carried out safely and efficiently.
e) There are procedures to ensure that the premises are secure, and confidentiality is maintained.

f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.
PFE2 Environmental controls are in place to avoid potential contamination.
a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.
c) There are procedures for cleaning and decontamination.
d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.
PFE3 There are appropriate facilities for the storage of tissues and / or cells, consumables and records.
a) Tissues, cells, consumables and records are stored in secure environments and precautions are taken to minimise risk of damage, theft or contamination.
b) There are systems to deal with emergencies on a 24-hour basis.
c) Tissues and / or cells are stored in controlled, monitored and recorded conditions that maintain tissue and / or cell integrity.
d) There is a documented, specified maximum storage period for tissues and / or cells.
PFE4 Systems are in place to protect the quality and integrity of tissues and / or cells during transport and delivery to its destination.
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.
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

<b>Standard</b>
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

<b>Standard</b>
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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.

## Governance and Quality

<b>Standard</b>
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.
<b>GQ2 There is a documented system of audit</b>
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.
<b>GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills</b>
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.
<b>GQ4 There is a systematic and planned approach to the management of records</b>
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).
<b>GQ5 There are systems to ensure that all adverse events are investigated promptly</b>

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.
<b>GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored</b>
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

<b>Standard</b>
<b>T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail</b>
a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it.
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.
<b>T2 Bodies and human tissue are disposed of in an appropriate manner</b>
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

<b>Standard</b>
<b>PFE1 The premises are secure and fit for purpose</b>
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.
<b>PFE2 There are appropriate facilities for the storage of bodies and human tissue</b>
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.
<b>PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored</b>
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.