

Inspection report on compliance with HTA licensing standards  
Inspection date: 19 March 2024



**Broomfield Hospital**  
HTA licensing number 12404

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**

'E' = Establishment is licensed to carry out this activity and is currently carrying it out.

Site	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Broomfield Hospital				E		E	

**Tissue types authorised for licensed activities**

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

Tissue Category; Tissue Type	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Skin; Skin				Authorised		Authorised	
Ocular, Cornea; Cornea				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 but is not carrying out this activity.

#### 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 Broomfield Hospital (the establishment) had met the majority of the HTA's standards that were assessed during the inspection, one major and 11 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**

***Major shortfalls***

<b>Standard</b>	<b>Inspection findings</b>	<b>Level of shortfall</b>
<b>GQ2 There is a documented system of quality management and audit.</b>		
a) There is a quality management system which ensures continuous and systematic improvement.	<p>The establishment was authorised to import and store cornea tissue in September 2021 on the basis that it would implement corrective and preventative actions (CAPA) to address minor shortfalls against certain licensing standards in relation to the proposed activity.</p> <p>However, the processes underpinning the licensable activity of the import and storage of corneas have not been suitably integrated into the establishment's quality management system in the intervening period, as reflected in the findings below relating to standards GQ1b, GQ1d, GQ2b, GQ2c, GQ3e and PFE5b.</p>	<b>Major</b>

Standard	Inspection findings	Level of shortfall
<b>GQ1 All aspects of the establishment’s work are supported by ratified documented policies and procedures as part of the overall governance process.</b>		
<p>b) There are procedures for all licensable activities that ensure integrity of tissue and / or cells and minimise the risk of contamination.</p>	<p>Some practices that were reviewed and/or discussed did not reflect the establishment’s documented procedures for storing and handling skin allografts.</p> <p>Examples of discrepancies identified within standard operating procedures (SOPs) for skin allografts include:</p> <ul style="list-style-type: none"> <li>• procedures for when tissue products are removed from the freezer and are subsequently not used;</li> <li>• procedures for registering tissue products into the tissue register log book, including recording the temperature of the freezer upon receipt and release; and</li> <li>• the correct location of the polystyrene boxes to be used to transfer tissue products in the event of a freezer failure.</li> </ul> <p>Furthermore, the procedure for unpacking tissue products does not set out the process to be followed when receipting samples from a particular supplier.</p>	<p><b>Minor</b></p>

	<p>Examples of omissions in SOPs for handling cornea allografts included:</p> <ul style="list-style-type: none"> <li>• procedures for recording temperatures of the packaged corneas before distribution to, and upon receipt at, another hospital site within the Trust; and</li> <li>• procedures for monitoring the temperature of stored corneas.</li> </ul> <p>In addition, the current SOPs for cornea allografts do not clearly describe procedural steps to be taken to ensure uniformity and consistency when staff carry out required tasks.</p>	
c) There are regular governance meetings, for example health and safety, risk management and clinical governance committees, which are recorded by agendas and minutes.	The establishment does not hold governance meetings which are recorded by agendas and minutes.	<b>Minor</b>
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.	The SOPs for the activities involving cornea allografts are still in draft and are currently stored on a shared drive with no controlled editing permissions. There is no document control system in place to ensure changes are dated and reviewed by authorised persons, and no procedures to archive older versions of documents.	<b>Minor</b>

<b>GQ2 There is a documented system of quality management and audit.</b>		
b) There is an internal audit system for all licensable activities.	The establishment has not carried out audits for activities involving corneal allografts.	<b>Minor</b>
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.		

<b>GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.</b>		
e) Personnel are trained in all tasks relevant to their work and their competence is recorded.	There is no documented training programme for staff working with cornea tissue products.	<b>Minor</b>

**GQ4 There is a systematic and planned approach to the management of records.**

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.

The establishment was not able to demonstrated that raw data is retained for 10 years after use, expiry or disposal of the tissue products.

**Minor**

**GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.**

c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.

The documented procedure for managing adverse events does not set out who is responsible for investigating incidents and ensuring corrective actions are sufficient and effective.

**Minor**

**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.

There is no risk assessment in place for the transport of corneal allografts between hospital sites within the Trust.

**Minor**

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.	Risk assessments are not reviewed annually.	<b>Minor</b>
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<b>PFE1 The premises are fit for purpose.</b>		
a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.	A premises risk assessment has not been carried out to assess the suitability and security of storage facilities, temperature monitoring equipment for stored corneal allografts, the skin allograft back-up freezer and the storage of data.	<b>Minor</b>

<b>PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.</b>		
b) Critical equipment is maintained and serviced in accordance with the manufacturer's instructions.	The establishment was not able to demonstrate that the thermometer used for recording the storage temperature of cornea products has been maintained and calibrated.	<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.	GQ1b	The establishment has work instructions laid out in Theatres to guide staff working with skin allografts. The DI should consider displaying the work instructions in the -80°C freezer room and should ensure steps within the work instructions are aligned with the SOP. The DI should also ensure the work instructions are document controlled.
2.	GQ1c	The HTA-licensable activities are undertaken at the Ophthalmology department and the Burns Unit. The DI is advised to hold regular meetings with both teams to share practices and unify the quality and governance processes for both tissue types.
3.	GQ1p	The DI is advised to review agreements with HTA-licensed suppliers to ensure they are still within date.
4.	GQ2b/c	The establishment's governance team performs audits for the skin allograft activities. During the inspection, the establishment was only able to produce a summary of results from traceability audits

		<p>that were performed. The DI should ensure the final report is received and reviewed to ensure all relevant HTA standards are covered during the audit.</p> <p>The DI should also consider devising an audit template encompassing the relevant HTA standards that can be used to audit both the skin and ocular tissue activities.</p>
5.	GQ6b	<p>During the inspection, it was noted in the corneal allograft tissue register log book that the initials of a staff member receiving one allograft was not recorded. The DI is advised to expand the scope of audits to include a review of the register log book to help prevent transcriptional errors..</p>
6.	PFE5b	<p>The -80°C freezer is new and currently under warranty. The freezer's first maintenance was due in January 2024 but this did not take place. Although maintenance of the freezer has since been organised following the inspection, the DI is advised to ensure that there is a schedule in place for when the annual maintenance of the -80°C freezer is due, to enable follow-up with the maintenance company if delayed. The DI is also advised to ensure that the servicing provided includes calibration of temperature probes.</p>

## Background

The establishment stores skin tissue for the treatment of burns cases and imports and stores ocular tissue for use in eye surgery.

The establishment has been licensed by the HTA since February 2007. This was the establishment's eighth routine inspection; the last inspection took place in January 2022.

Since the last inspection, the establishment has ceased the licensable activity of Procurement.

## 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 selected documents and records relating to licensable activities. These included procedures for the receipt, storage and release of allografts, monitoring temperatures of storage units, reporting incidents, risk assessments and agreements with suppliers.

### *Visual inspection*

The inspection team visited the storage facilities for both the skin and corneal allografts. Quarantine storage arrangements were also reviewed for the skin allografts.

### *Audit of records*

A review of clinical records for recipients of both skin and ocular tissues was undertaken. Three records relating to skin recipients were reviewed. Records of tissue receipt, receipt checks, end use of tissue and tissue identifiers both in the tissue register and recipient's clinical notes were reviewed. A record of tissue receipt and receipt checks of an allograft stored in the freezer was also assessed. No anomalies were identified.

Three sets of records relating to recipients of ocular tissue were also reviewed. Records relating to receipt and use in the tissue tracking folder and records of tissue use and tissue identifiers in the recipient's clinical notes were reviewed. One transcription error in a set of recipient clinical notes was identified. The error did not result in a loss of tissue traceability (see advice and guidance number 5).

### *Meetings with establishment staff*

The inspection included meetings involving key staff working under the licence from both the Burns Unit and the Ophthalmology Department. The DI was present throughout the inspection.

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: 18 April 2024**

**Report returned from DI: 8 May 2024**

**Final report issued: 8 May 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.
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.
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.
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.
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.
GQ6 A coding and records system facilitates traceability of tissues and / or cells, ensuring a robust audit trail.
a) There is a donor identification system which assigns a unique code to each donation and to each of the products associated with it.

b) An audit trail is maintained, which includes details of when the tissues and / or cells were acquired and from where, the uses to which the tissues and / or cells were put, when the tissues and / or cells were transferred elsewhere and to whom.

c) The establishment has procedures to ensure that tissues and / or cells imported, procured, processed, stored, distributed and exported are traceable from donor to recipient and vice versa.

GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.

a) There are procedures for the identification, reporting, investigation and recording of adverse events and reactions, including documentation of any corrective or preventative actions.

b) There is a system to receive and distribute national and local information (e.g. HTA regulatory alerts) and notify the HTA and other establishments as necessary of serious adverse events or reactions.

c) The responsibilities of personnel investigating adverse events and reactions are clearly defined.

d) There are procedures to identify and decide the fate of tissues and / or cells affected by an adverse event, reaction or deviation from the required quality and safety standards.

e) In the event of a recall, there are personnel authorised within the establishment to assess the need for a recall and if appropriate initiate and coordinate a recall.

f) There is an effective, documented recall procedure which includes a description of responsibilities and actions to be taken in the event of a recall including notification of the HTA and pre-defined times in which actions must be taken.

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.

a) There are documented risk assessments for all practices and processes.

b) Risk assessments are reviewed regularly, as a minimum annually or when any changes are made that may affect the quality and safety of tissues and cells.

c) Staff can access risk assessments and are made aware of local hazards at training.

d) A documented risk assessment is carried out to decide the fate of any tissue and / or cells stored prior to the introduction of a new donor selection criteria or a new processing step, which enhances the quality and safety of tissue and / or cells.

## Premises, Facilities and Equipment

### Standard

PFE1 The premises are fit for purpose.

a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.

b) There are procedures to review and maintain the safety of staff, visitors and patients.

c) The premises have sufficient space for procedures to be carried out safely and efficiently.

e) There are procedures to ensure that the premises are secure, and confidentiality is maintained.

f) There is access to a nominated, registered medical practitioner and / or a scientific advisor to provide advice and oversee the establishment's medical and scientific activities.

PFE2 Environmental controls are in place to avoid potential contamination.

a) Tissues and / or cells stored in quarantine are stored separately from tissue and / or cells that have been released from quarantine.

c) There are procedures for cleaning and decontamination.

d) Staff are provided with appropriate protective clothing and equipment that minimise the risk of contamination of tissue and / or cells and the risk of infection to themselves.

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

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

## Disposal

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

## Human Tissue Act 2004 standards

### Consent

<b>Standard</b>
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

<b>Standard</b>
<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.
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.

**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

<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.
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.
<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.