

Inspection report on compliance with HTA licensing standards
Inspection date: **07 June 2023**



Torbay Hospital
HTA licensing number 11088

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

Licensable activities carried out by the establishment

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

Site	Procurement	Processing	Testing	Storage	Distribution	Import	Export
Torbay Hospital				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
Musculoskeletal, Bone; Bone				Authorised			
Musculoskeletal, Tendon and Ligament; Tendons				Authorised			

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 Torbay Hospital (the establishment) had met many of the HTA's standards that were assessed during the inspection, two major and three 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

Major shortfalls

Standard	Inspection findings	Level of shortfall
<p>GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.</p>	<p>Governance arrangements under the licence require review and improvement in order to meet regulatory requirements. For example:</p> <ul style="list-style-type: none"> the establishment's quality manual and procedures have not been subject to review in the last two years and require comprehensive updating to reflect current arrangements under the licence; the establishment does not currently have a system or documented procedure covering expectations for the preparation, authorisation, version control, review and updating of governance documents such as procedures and risk assessments; and, primarily as a result of staff changes for key roles under the licence, preventative actions taken to address a major finding from the establishment's last site visit inspection in 2018 have not been embedded. As a result, a similar non-compliance was identified during the current inspection, as detailed below. 	<p>Major (cumulative)</p>
<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>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.</p>		
<p>GQ2 There is a documented system of quality management and audit.</p>		

a) There is a quality management system which ensures continuous and systematic improvement.		
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GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	At the establishment's last site visit inspection it was identified that the temperature at which frozen tissue was stored (between -30 and -40°C) was not in accordance with the product labelling, and the impact of this on the expiry date of the tissue had not been assessed.	Major
g) There are procedures to ensure that an authorised person verifies that tissues and / or cells received by the establishment meet required specifications.	Although the establishment took corrective actions to address this finding, during the current inspection it was determined that tissue supplied to the establishment had been issued by the supplier with expiry dates of either five years (applicable to tissue stored below -40°C) or six months (applicable to tissue stored between -20 and -40°C). This variation in expiry dates had not been identified by current staff working under the licence. It is noted that establishment records indicated that the supplier was routinely informed that the establishment's storage temperature was warmer than -40°C at the time of order placement.	
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.	A review of traceability records identified an example where tissue had been used in human application beyond the six month expiry date. This	

<p>d) There is a documented, specified maximum storage period for tissues and / or cells.</p>	<p>case has been reported to the HTA using the serious adverse event and reaction (SAEAR) reporting channel.</p> <p>A review of current stock determined that one of the two femoral heads in storage had exceeded the six month expiry date that should have been applicable based on the storage temperature of the freezer. The establishment disposed of this tissue at the time of the inspection.</p>	
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Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of quality management and audit.		
<p>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.</p>	<p>There has not been an independent audit of activities under the licence since the last HTA inspection.</p>	Minor

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.

<p>e) Personnel are trained in all tasks relevant to their work and their competence is recorded.</p>	<p>The establishment's previous system for undertaking and recording staff refresher training and the reading of documented procedures has not been maintained.</p>	<p>Minor</p>	
<p>GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.</p>		<p>Minor</p>	
<p>a) There are documented risk assessments for all practices and processes.</p>	<p>The establishment was unable to produce copies of risk assessments relating to activities under the licence, though it is noted that these were available for review at previous inspections.</p>		
<p>c) Staff can access risk assessments and are made aware of local hazards at training.</p>			
<p>PFE1 The premises are fit for purpose.</p>			
<p>a) A risk assessment has been carried out of the premises to ensure that they are fit for purpose.</p>			

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.	GQ1p	The establishment's end user agreement with one of its suppliers of tissue products has expired. The DI is advised to contact the supplier to request an updated version. The DI is further advised to review current agreements and any other instructions provided with purchased tissue, to ensure that internal procedures are aligned with current supplier instructions.
2.	GQ4b	Although the establishment has systems in place for the regular review of records, a small number of data entry errors were identified during the inspection. As part of corrective and preventative actions undertaken to address the findings of this inspection, the DI is advised to consider updating the traceability ledgers to provide a clearer indication of the information that should be recorded in each section, retrain staff accordingly and utilise the internal audit process to monitor the effectiveness of any changes.
3.	PFE5c,i	The DI is advised to ensure Blood Bank procedures are updated to reflect the process described during the inspection through which staff working under the licence would be made aware of any adverse events or incidents relating to the freezer in which tissue products are stored. This may help to assure

		the DI that any such incidents will be reported to staff working under the licence in a timely manner, so that they can be documented, assessed, and any corrective and preventative actions taken.
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Background

The establishment receives and stores bone (femoral heads) and, less frequently, tendons, from HTA-licensed suppliers. The establishment also purchases and stores a range of acellular tissue products such as bone struts and bone graft material, which are stored at room temperature.

The establishment has been licensed by the HTA since January 2007. This was the establishment's eighth inspection; the last inspection took place in July 2021 and was a virtual regulatory assessment (VRA). The last site visit inspection took place in August 2018.

The traceability of purchased tissue from receipt to end use is maintained using hand-written ledgers. Following advice at the establishment's last inspection in 2021, staff have implemented electronic traceability records, updated regularly from the ledgers, as a contingency should hand written ledgers be misplaced or damaged.

Shortly prior to the establishment's 2018 inspection, the role of DI was transferred to a new post holder. There was a further DI change in 2020 before the current DI took up the role in 2022. Since the last inspection in 2021 there has also been a change of Corporate Licence Holder contact (CLHc).

The storage location for frozen tissue has been permanently relocated to the hospital's Blood Bank, which has suitable temperature monitoring systems in place and, at the time of the inspection, was set to run at approximately -33°C.

Description of inspection activities undertaken

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

Review of governance documentation

The inspection included a review of procedural documents relating to licensed activities, records for servicing of equipment, audits, incident records, temperature monitoring for the storage freezer, and staff training records.

Visual inspection

The inspection included a visit to the hospital Blood Bank, where the freezer used to store frozen tissue products is located, and areas where tissue held at room temperature is securely stored.

Audit of records

During the inspection traceability records associated with two femoral heads stored in the freezer at the time of the inspection and three femoral heads used in patient treatment were reviewed. Information captured in the establishment's traceability ledgers, traceability spreadsheets and in patient notes was compared. Advice has been provided to help ensure traceability records are completed accurately and completely. This is captured against standard GQ4b in the advice and guidance section above.

Meetings with establishment staff

The inspection included round table discussions with the DI and staff working under the licence.

Report sent to DI for factual accuracy: 03 July 2023

Report returned from DI: 13 July 2023

Final report issued: 17 July 2023

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.
o) There is a complaints system in place.
p) There are written agreements with third parties whenever an activity takes place that has the potential to influence the quality and safety of human tissues and / or cells.
q) There is a record of agreements established with third parties.
r) Third party agreements specify the responsibilities of the third party and meet the requirements set out in Directions 001/2021.
s) Third party agreements specify that the third party will inform the establishment in the event of a serious adverse reaction or event.
t) There are procedures for the re-provision of service in an emergency.
GQ2 There is a documented system of quality management and audit.
a) There is a quality management system which ensures continuous and systematic improvement.
b) There is an internal audit system for all licensable activities.

c) An audit is conducted in an independent manner at least every two years to verify compliance with protocols and HTA standards, and any findings and corrective actions are documented.

d) Processes affecting the quality and safety of tissues and / or cells are validated and undergo regular evaluation to ensure they continue to achieve the intended results.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.

a) There are clearly documented job descriptions for all staff.

b) There are orientation and induction programmes for new staff.

c) There are continuous professional development (CPD) plans for staff and attendance at training is recorded.

d) There is annual documented mandatory training (e.g. health and safety and fire).

e) Personnel are trained in all tasks relevant to their work and their competence is recorded.

f) There is a documented training programme that ensures that staff have adequate knowledge of the scientific and ethical principles relevant to their work, and the regulatory context.

g) There is a documented training programme that ensures that staff understand the organisational structure and the quality systems used within the establishment.

h) There is a system of staff appraisal.

i) Where appropriate, staff are registered with a professional or statutory body.

j) There are training and reference manuals available.

k) The establishment is sufficiently staffed to carry out its activities.

GQ4 There is a systematic and planned approach to the management of records.
a) There are procedures for the creation, identification, maintenance, access, amendment, retention and destruction of records.
b) There is a system for the regular audit of records and their content to check for completeness, legibility and accuracy and to resolve any discrepancies found.
c) Written records are legible and indelible. Records kept in other formats such as computerised records are stored on a validated system.
d) There is a system for back-up / recovery in the event of loss of computerised records.
e) The establishment keeps a register of the types and quantities of tissues and / or cells that are procured, tested, preserved, processed, stored and distributed or otherwise disposed of, and on the origin and destination of tissues and cells intended for human application.
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.
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.
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.

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.
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.