Inspection report on compliance with HTA licensing standards
Inspection date: **13 May 2025**

Torbay Hospital

HTA licensing number 12181

Licensed under the Human Tissue Act 2004

Licensed activities

The table below shows the activities this establishment is licensed for and the activities currently undertaken at the establishment.

Area	Making of a post-mortem examination	Removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation	Storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose
Torbay Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	-	*Carried out*
A&E	-	*Carried out*	-

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 the majority of the HTA's standards, one major and four minor shortfalls were found against standards for tissue traceability and governance, staff inductions, and refrigeration 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 Shortfall

Standard	**Inspection findings**	**Level of shortfall**
GQ2 There is a documented system of audit		
c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention	There are currently no designated staff to audit post mortem tissue to ensure it is being retained or disposed of in line with family wishes. Retained tissue has not been audited since 2022.	**Major (cumulative)**
T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		

a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete	The inspection team completed a post mortem tissue audit and identified that tissue was not being disposed of in a timely manner. One case identified tissue that was being stored, without consent, eight months following the authority of the coroner ending. *Staff took immediate actions to rectify this before the inspection team left the site.*	
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary	Communication with the coroner's office is inconsistent, and there is no one designated to follow up tissue retention consent, when it has not been received. This lack of oversight, audit and ineffective communication poses a risk that staff are not aware of what tissue is being stored and why.	

Minor Shortfalls

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
c) Staff are assessed as competent for the tasks they perform	Staff are assessed as competent as part of their training; however, this is not always recorded. Staff were unable to provide evidence that competency had been assessed for bereavement midwifes, or trainee mortuary staff. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**

f) There is a documented induction and training programme for new mortuary staff	Two trainee members of mortuary staff have been employed for six months but have yet to have a documented induction to the department. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
a) Staff know how to identify and report incidents, including those that must be reported to the HTA	The inspection team identified two recent near miss incidents that should have been reported to the HTA, in line with their licensing requirements, but were not. *The inspection team was provided with evidence that these incidents were fully investigated at the time and had no adverse outcomes.*	**Minor**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) Items of equipment in the mortuary are in good condition and appropriate for use	The inspection team noted that the external mortuary fridge condenser units had no mechanism to protect against unauthorised access to the on/off switches. As these are in a public area it increases the risk to the fridges being inadvertently turned off, without oversight of the mortuary staff.	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

Advice
The HTA advises the DI to consider the following to further improve practice:

Number	Standard	Advice
1.	C2 (d)	The DI is advised to progress with the recently implemented consent competency assessments, and ensure the process is reflected in documented standard operating procedures.
2.	T1 (d)	The mortuary manager is advised to ensure the same/similar name process outlined in standard operating procedures is always being completed during admission checks.
3.	T1 (h)	The DI and mortuary manager are advised to implement a process of signing histology samples out of the mortuary following a post mortem. This will further strengthen traceability of post mortem tissue.
4.	PFE2 (e)	The mortuary manager is advised to include testing the lower limits of the fridge temperatures as part of the routine testing schedule.
5.	PFE3 (a)	The DI and mortuary manager are advised to monitor minor rust to the trolleys used within the fridge room. Further deterioration may result in difficulty to decontaminate effectively, and result in a shortfall to standard PFE3 (a).
6.	PFE3 (c)	The DI and mortuary manager are advised to have oversight of the annual ventilation report. The general condition of the air handling unit in 2024 was deemed to be ‘poor’. This was not escalated to mortuary staff, and further deterioration to this unit could result in a shortfall to standard PFE3 (c).

Background

Torbay Hospital has been licensed by the HTA since June 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in November 2022.

Since the previous inspection, there has been a change to the mortuary department management structure, a new designated individual in December 2023, and new corporate licence holder contact in March 2025.

Description of inspection activities undertaken
The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

Standards assessed against during inspection
All 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

Review of governance documentation
The inspection included a review of the establishment's governance documentation relating to licensed activities. This included policies and procedural documents, cleaning records for the mortuary, records of servicing equipment, audits, risk assessments, meeting minutes, reported incidents, and training records for staff.

Visual inspection
The inspection included an unannounced visual assessment of the regulated areas of Torbay Hospital including the mortuary access points, mortuary fridge rooms, post mortem room, viewing facilities, maternity bereavement suite, and tissue storage areas. The inspection team observed the processes for admission, release, and viewing of bodies within the mortuary.

Audit of records
Audits were conducted for three bodies from refrigerated storage and one from frozen storage. Identification details on bodies were cross-checked against the information recorded in the mortuary register and associated paperwork. No discrepancies were identified.

Audits of traceability were conducted for tissue blocks and slides from five coronial cases. These included audits of the consent documentation for the retention of these tissues. One discrepancy was identified, see shortfall T2 (a).

Meetings with establishment staff
Staff conducting processes under the licence were interviewed including the DI, Mortuary Manager, Trainee Anatomical Pathology Technologist, Pathologist, Quality Lead, Mortuary Porter, and Bereavement Midwife.

Report sent to DI for factual accuracy: 05 June 2025

Report returned from DI: 18 June 2025

Final report issued: 26 June 2025

Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

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.

Its programme of inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

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. They are grouped under four headings:

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

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, 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 provided.

HTA inspection reports 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 (HT Act) or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the HT Act or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   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 that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or
   - indicates a breach of the relevant Codes of Practice, the HT Act and other relevant professional and statutory guidelines, or

- has the potential to become a critical shortfall unless addressed

or

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

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, but which indicates a departure from expected standards.

   This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next inspection.

   In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. 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.