Inspection report on compliance with HTA licensing standards
Inspection date: **06 November 2024**

Queen Elizabeth Hospital
HTA licensing number 12298

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
Queen Elizabeth Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Maternity	-	*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 Queen Elizabeth Hospital ('the establishment') had met the majority of the HTA's standards, two major and four minor shortfalls were found against standards regarding consent training, storage arrangements, access audits, reportable incidents and tissue traceability.

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
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
b) Records demonstrate up-to-date staff training	There are no records to demonstrate up to date training for staff taking perinatal or paediatric post mortem consent. The inspection team were informed that training had taken place, but names and dates were not recorded.	**Major (Cumulative)**
d) Competency is assessed and maintained	There is no process in place for assessing competency of staff trained to take adult, paediatric or perinatal post mortem consent. This combined with the lack of documented training increases the risk of unsuitable individuals taking consent and deeming it invalid.	
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		

a) Storage arrangements ensure the dignity of the deceased	The external mortuary vicinity and funeral service collection point is currently accessible from the main hospital building. At the time of the inspection, some windows to the body store were open. Whilst screening is in place, this does not obscure oversight from hospital staff who have access to the area outside. This increases the likelihood of oversight of regulated activity and poses a risk to both security and dignity of the deceased. *The establishment took immediate action to rectify this shortfall before the inspection team left the site.*	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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	There are no training records to demonstrate that mortuary staff have been assessed as competent for the activities they perform. The inspection team was informed that peer review competency assessments took place on an *ad hoc* basis but were not documented.	**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	Whilst incidents are reported to the designated individual as required, non-mortuary staff working under the licence were unaware of the requirements to report incidents to the HTA.	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The mortuary has recently received historical post mortem tissue for storage, following histology services moving off site. Whilst this tissue was originally stored with consent, the mortuary staff do not have access to these records and traceability has therefore been lost. *Establishment staff were in the process of auditing all retained tissue and taking appropriate actions at the time of the inspection. See advice item 4.*	**Minor**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access)	Whilst CCTV is used to monitor access to the mortuary, it is only reviewed if there are any discrepancies in the access audit, or to investigate incidents. CCTV review should form part of the audit schedule, both to routinely monitor visitors, and to mitigate against unauthorised access.	**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.	GQ1(c)	The mortuary manager is advised to further strengthen the body condition checking process by documenting the condition of the deceased when transferring to the funeral service.
2.	GQ1(h)	Departmental meetings include discussions of the HTA and regulated activities, this however does not always include the designated individual. The designated individual is advised to continue plans to reinstate HTA specific governance meetings.
3.	T1(b)	Whilst the establishment has full traceability of bodies, the current system involves multiple paper processes. The DI is advised to explore electronic systems to improve efficiency and further mitigate against the risk of loss of traceability.
4.	T1(g)	The designated individual is advised to continue the audit of all retained tissue within the mortuary. Any tissue that no longer has documented consent should be sensitively disposed of in line with the HTA's *Code B Post Mortem Examination Code of Practice and Standards.*
5.	PFE1(e)	The mortuary is secured by swipe access, and as a secondary mitigation by key. The designated individual and mortuary manager are advised to implement a process of signing the porter's key in and out of their office. This will strengthen traceability and access audits.
6.	PFE3(c)	The ventilation within the post mortem room is sufficient to be compliant with the HTA standards. However, the 2024 ventilation report highlighted improvements regarding the ventilation system and downdraft post mortem tables. The designated individual is advised to continue with plans to address these recommendations.
7.	PFE3(a)	Mortuary trolleys are showing slight signs of rust. The designated individual and mortuary manager are advised to monitor the condition of the trolleys, as any further deterioration may result in a shortfall to standard PFE3(a).

Background

Queen Elizabeth Hospital has been licensed by the HTA since 30 August 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in June 2022.

Since the previous inspection, there has been a change to the corporate licence holder contact in August 2023, and the designated individual in February 2024.

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 of equipment, audits, risk assessments, meeting minutes, reported incidents, and training records for staff.

Visual inspection

The inspection included an unannounced visual assessment of the mortuary access points, mortuary fridge room, post mortem room, tissue storage areas, and the viewing facilities. 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 crosschecked 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 four coronial cases. These included audits of the consent documentation for the retention of these tissues. Whilst there were no discrepancies for these cases, the audit highlighted historical tissue that had lost traceability. *See shortfall T1(g).*

Meetings with establishment staff
Staff conducting processes under the licence were interviewed including the Designated Individual, Mortuary lead, Senior APT, Mortuary Porter, and Bereavement Midwife.

Feedback was provided on 27 November 2024 to the Designated Individual, Mortuary Lead, Senior APT, Divisional Services Manager, and Operations Manager.

Report sent to DI for factual accuracy: 09 December 2024

Report returned from DI: 18 December 2024

Final report issued: 31 December 2024

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.