

St Thomas' Hospital  
 HTA licensing number 12243

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
<b>Hub site</b> <b>St Thomas' Hospital</b>	Licensed	Licensed	Licensed
<b>Mortuary</b>	<i>Carried out</i>	<i>Carried out</i>	<i>Carried out</i>
<b>Pathology lab</b>	-	-	<i>Carried out</i>
<b>Maternity</b>	-	-	<i>Carried out</i>
<b>A&amp;E</b>	-	<i>Carried out</i>	-
<b>Satellite site</b> <b>Guys Hospital</b>	Not licensed	Not licensed	Licensed
<b>Mortuary (satellite site)</b>	-	-	<i>Carried out</i>

## 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 St Thomas' Hospital ('the establishment') had met the majority of the HTA's standards, 5 major and 3 minor shortfalls were found against standards for, Governance and quality systems, Traceability 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
<b>GQ1 All aspects of the establishment's work are governed by documented policies and procedures</b>		
a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPATH.	SOPs do not detail the use of three identifiers prior to visitors entering the viewing room.	<b>Major</b>
<b>GQ5 There are systems to ensure that all untoward incidents are investigated promptly</b>		
e) The establishment adopts a policy of candour when dealing with serious incidents	Review of the incident log discovered that whilst staff know how to identify and report incidents, a serious incident of viewing of the wrong body, falling within the HTA reportable incident (HTARI) categories had not been reported to the HTA. The establishment have reported this incident to the HTA for review following the inspection.	<b>Major</b>

<b>PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.</b>		
a) The premises are clean and well maintained	The flooring to the body store at the satellite site is damaged around the edges exposing porous material. The ceiling to the corridor leading to the bariatric body store at the satellite site is leaking. The flooring to the body store known as the 'Pods' at St Thomas is constructed of porous absorbent wooden boarding. These rooms cannot be thoroughly cleaned. The ceiling to the pods is leaking. The ceiling of the PM room at St Thomas is damaged due to leaking water from above. At the time of inspection there was no hot water supply to the satellite site.	<b>Major</b>
<b>PFE2 There are appropriate facilities for the storage of bodies and human tissue.</b>		
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	There is limited freezer storage. The inspection team noted 10 bodies that had been stored in excess of 30 days. Whilst the bodies were suitably condition checked, the establishment lacked enough freezer storage to facilitate transfer into suitable long term storage.	<b>Major</b>
<b>PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored</b>		
a) Items of equipment in the mortuary are in good condition and appropriate for use	The floor drain covers and exposed metal work supporting a work bench at the satellite body store is corroded and cannot be cleaned. Some floor drain covers are raised causing a trip hazard.	<b>Major</b>
<b>Minor Shortfalls</b>		
<b>Standard</b>	<b>Inspection findings</b>	<b>Level of shortfall</b>

<b>GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored</b>		
a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis	The route used by porting staff to transfer bodies from the main hospital building at satellite site to the mortuary is via an external pavement and road area which is frequented by members of the public and hospital staff. This does not ensure the dignity of the deceased and there is an increased risk to accidental damage to the body due to uneven road surfacing. This is not addressed in existing risk assessments.	<b>Minor</b>
<b>T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail</b>		
b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records)	There is no system to document the movement of bodies for the purpose of viewings facilitated by Porters at the satellite site.	<b>Minor</b>
c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier	Three points of identification are sought at the time of arranging viewings. However, the procedure for viewing of the deceased does not include a final check using a minimum of three points of identification of the deceased from the family, prior to visitors entering the viewing room.	<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.	PFE2 e)	Whilst fridges in the maternity unit are alarmed. The DI is advised to link these units to an external system in order to alert staff.

## Background

St Thomas' Hospital has been licensed by the HTA since 13 July 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in October 2016

Since the previous inspection, there have been no significant changes to the licence arrangements.

### 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 team reviewed the establishments self-assessment document provided by the DI in advance of the inspection. Policies and procedural documents relating to licensed activities were reviewed. The team also undertook a review of records relating to equipment servicing, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units and mortuary, reported incidents, and staff training. Consent seeking procedures and information for relatives giving consent were also reviewed.

### *Visual inspection*

The inspection team undertook a visual inspection of the premises which included the mortuary body storage areas, PM room and viewing rooms as well as the area for storage of relevant material held within the mortuary.

### *Audit of records*

The inspection team undertook audits of traceability for six bodies in storage. Traceability details were crosschecked between the identification band on the body, information on the digital mortuary register and paperwork. No discrepancies were identified.

One discrepancy was identified relating to one body marked as male rather than female on the computerised system. This was corrected instantly.

Audits were conducted of tissue taken at PM examination for five cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, consent for PM examination forms (where relevant), the laboratory database, and tissue blocks and slides being stored. One discrepancy was identified relating to a form relating to another patient being uploaded to a record on the computerised system. This was corrected instantly.

### *Meetings with establishment staff*

The inspection team met with staff carrying out processes under the licence, including mortuary staff, staff involved in the consent seeking process, staff from the maternity department, hospital porters and the DI.

**Report sent to DI for factual accuracy: 8 April 2022**

**Report returned from DI: 11 April 2022**

**Final report issued: 12 April 2022**

### **Completion of corrective and preventative actions (CAPA) plan**

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

**Date: 2 May 2023**

## **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.