Inspection report on compliance with HTA licensing standards
Inspection date: **02 December 2024**

St George's Hospital
HTA licensing number 12387

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
St George's Hospital	**Licensed**	**Licensed**	**Licensed**
Mortuary	*Carried out*	*Carried out*	*Carried out*
Accident and emergency department	-	-	-
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 St George's Hospital ('the establishment') had met the majority of the HTA's standards, one minor shortfall was found against standards for Premises, facilities and equipment.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Compliance with HTA standards
All applicable HTA standards have been assessed as fully met.

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		

e) Security arrangements protect against unauthorised access and ensure oversight of visitors and contractors who have a legitimate right of access	Whilst security arrangements protect against unauthorised access to the mortuary, the inspection team found the following: • Corridors leading to the main internal mortuary doors are restricted to defined staffing groups. However, once inside these corridors, staff are able to see directly into the mortuary due to large clear glass panels on the main mortuary doors. As such, there is a risk that the transfer of the deceased inside the mortuary can be viewed by non-mortuary staff from these corridors. (*see advice item 1 and 2*) • Although the funeral directors entrance has appropriate security arrangements in place, funeral directors are unable to fully reverse inside the enclosed entrance bay due to a raised curb. Consequently, funeral directors are required to park adjacent to the cytology office windows. As a result, during admissions and releases, staff working in these offices are able to view regulated activity which poses a risk to the dignity of the deceased. (*see advice item 3)*	**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 practices:

Number	Standard	Advice
1.	PFE1 e)	The DI is advised to adopt similar privacy vision panels, currently being used on other doors within the mortuary, to all main internal entrance doors.
2.	PFE1 e)	While secure, the internal mortuary entrance door located on the cytology corridor appears to be approaching the stage where replacement will soon be necessary to ensure continued functionality. The DI is advised to consider replacement options similar to a recently upgraded internal entrance door which was demonstrated to have a greater level of robustness. The DI is also advised to carry out a risk assessment of this access point at the earliest opportunity.
3.	PFE1 e)	The DI is advised to consider either: • Introducing the use of a retractable privacy screen during admissions and releases. • Increase the visible light transmission rating on the preexisting window tint in the cytology offices. • Dropping the raised curb to enable funeral directors to fully reverse inside the enclosed entrance bay.
4.	PFE1 e)	Although refrigeration and ventilation plant equipment has been fitted with tamperproof mechanisms at the main power switches, the DI is advised to explore if the secondary switch, located on the side of the equipment, also requires the fitting of a similar tamperproof mechanism.
5.	GQ6 b)	The DI is advised to review the mortuary security risk assessment to ensure all mitigating controls used by staff are reflected in the risk assessment.

Background

St George's Hospital has been licensed by the HTA since February 2007. This was the seventh inspection of the establishment; the most recent inspection took place in April 2022.

Since the previous inspection, there has been a change of Designated Individual (DI) in February 2023.

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
The Inspection focused on areas of concern identified following an Evidential Compliance Assessment (ECA) submitted by the establishment at the HTA's request against a subset of standards relevant to security. 6 out of the HTA's 72 standards were covered during the focused inspection (standards published 3 April 2017). Standards covered at this inspection are listed in Appendix 3. The remaining 52 standards will be assessed during the next routine inspection of the establishment.

Review of governance documentation
The inspection team reviewed policies and procedural documents relating to licensed activities. This included standard operating procedures, risk assessments, audits and training assessment documents.

Visual inspection
The inspection team undertook a site visit inspection which included reviewing security systems in place in the mortuary body storage areas, the viewing room and the post mortem suite.

Meetings with establishment staff
The assessment team met with staff carrying out activities under the licence, including the establishment's DI and mortuary staff.

Report sent to DI for factual accuracy: 9th December 2024

Report returned from DI: 23rd December 2024

Final report issued: 6th January 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.

Appendix 3: Standards Assessed during onsite Inspection

Governance and quality systems
GQ1 All aspects of the establishment's work are governed by documented policies and procedures
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. These include: i. post-mortem examination, including the responsibilities of Anatomical Pathology Technologists (APTs) and Pathologists and the management of cases where there is increased risk; ii. practices relating to the storage of bodies, including long term storage and when bodies should be moved into frozen storage; iii. practices relating to evisceration and reconstruction of bodies; iv. systems of traceability of bodies and tissue samples; v. record keeping; vi. receipt and release of bodies, which reflect out of hours arrangements; vii. lone working in the mortuary; viii. viewing of bodies, including those in long-term storage, by family members and others such as the police; ix. transfer of bodies internally, for example, for MRI scanning; x. transfer of bodies and tissue (including blocks and slides) off site or to other establishments; xi. movement of multiple bodies from the mortuary to other premises, for example, in the event that capacity is reached; xii. disposal of tissue (including blocks and slides), which ensures disposal in line with the wishes of the deceased person's family; xiii. access to the mortuary by non-mortuary staff, contractors and visitors; xiv. contingency storage arrangements.
GQ2 There is a documented system of audit
a. There is a documented schedule of audits.
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored
a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis.

c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register.

Premises, facilities and equipment
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).
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access.