Inspection report on compliance with HTA licensing standards
Inspection date: **15 and 17 December 2025**

ST MARYS HOSPITAL
HTA licensing number 12553

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
Hub site **St Marys Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Satellite site **Hammersmith Hospital**	Not licensed	Not licensed	Licensed

Mortuary (satellite site)	-	-	*Carried out*
Satellite site **Charing Cross Hospital**	Not licensed	Not licensed	Licensed
Mortuary (satellite site)	-	-	*Carried out*
Pathology lab	-	-	*Carried out*

Summary of inspection findings

The HTA found the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation. The Designated Individual (DI) is responsible for oversight of three licensed sites. Whilst the DI is considered capable to fulfil the DI role, she requires further authority across the organisation and protected time in her role to be able to effect change as DI, particularly in the context of a complex multi-site license. The suitability of the DI will remain under review.

Although the HTA found that St Marys Hospital ('the establishment') had met the majority of the HTA's standards, 16 major and two minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities, and equipment.

Two of the shortfalls (two major) relate to findings from the last inspection. A similar issue was identified in standards T1(c) and PFE3(a) at the previous inspection carried out in May 2023. This was acknowledged by the establishment and progress will be monitored through an agreed corrective action plan.

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
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
b) There is a documented standard operating procedure (SOP) detailing the consent process	The SOP currently in use for the adult or perinatal post mortem consent process is significantly out of date and does not reflect organisational change or current practice.	**Major**
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	Staff seeking consent for adult post mortems do not receive refresher training.	**Cumulative Major**
d) Competency is assessed and maintained	Competency for seeking Adult consent is not assessed or maintained for seeking consent. Competency for seeking consent in Maternity is initially assessed however this is not maintained.	

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	Regular audits of tissue are undertaken; however, these audits are limited in scope to the most recent years and so are not comprehensive in covering all holdings.	**Major**
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	Whilst the establishment has a system for undertaking competence assessments these have not been updated regularly. Some key tasks undertaken by staff have not been competence assessed, for example admission and release of bodies.	**Major**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register	The establishment has employed additional staff following the previous inspection and removed low staffing levels from the Trust's risk register. The risks arising from increasing activity, including the pressures of administrative duties on the DI, are not currently recorded on the organisational risk register.	**Major**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
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	Errors in written documents had been amended in a manner which obscures entries. This impedes the ability to audit records accurately. This is not in accordance with the SOP. This shortfall was identified at the previous inspection. (See *advice* item 6)	**Major**
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	The written registers at all three of the establishment sites are used to record admission and release of bodies. The registers only utilise two points of identification and do not include a unique identifier. Whilst these registers are not used as the primary record to track bodies, the lack of a third identifier presents a risk of loss of traceability. The maternity transfer viewing form does not contain three forms of identification; this presents a risk of viewing of the wrong body. Three identifiers are not routinely used by staff conducting out of hours viewing or release.	**Major**
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	Tissue taken at post mortem is not fully traceable. There is no system to record the location of tissue within the laboratory or what tissue has been transferred from the laboratory to the mortuary.	**Major**

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	Tissue removed during post mortems at the establishment is disposed of in line with consent documents. The laboratory receives tissue from other establishments with is stored in mortuary archives. However, the Mortuary does not receive information regarding the ongoing retention or disposal of this tissue.	**Cumulative Major**
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary	The establishment does not have effective systems to communicate with Coroners that refer tissue for examination which is subsequently stored at the Charing Cross site.	
c) Disposal is in line with the wishes of the deceased's family	The inspection team were not assured that tissue retained at the establishment but originating elsewhere has been disposed of in line with the wishes of the deceased's family.	

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
a) The premises are clean and well maintained	St Marys The wooden door used by funeral directors to enter the Mortuary has significant damage which is compromising the integrity of the locking mechanism. The flooring in the body store is tiled. Some damage is present with a tile missing. The temporary canopy used to cover the loading bay area shows significant signs of deterioration and is damaged in multiple areas. (see *Shortfall* against standard PFE2(a)) The fridge units are not routinely cleaned. Charing Cross The loading area used by funeral directors is cluttered. The fridge units are not routinely cleaned. Hammersmith Floor skirting in the body store has become detached and requires refixing. Door protection panels have become damaged and require readjustment. The door frame of the body store is damaged and requires repair.	**Major**

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)	St Marys The gates into the loading bay area are only lockable from the outside. Gates cannot be secured whilst transfers are being undertaken which presents a risk to the security of the department. Charing Cross The door between the viewing room and transfer lift is not fitted with a locking mechanism. This presents a risk of access to clinical areas of the Mortuary. Hammersmith A key operated lift is used within the mortuary to transfer bodies from the Mortuary to funeral vehicles on the ground floor. The key mechanism is sited in the Mortuary whilst the ground floor utilises a call button to summon the lift. The doors to the lift are located in a busy service area adjacent to an insecure set of doors leading to a public corridor. The security of the department relies on staff manually locking the lift mechanism when not in use. The inspection team were made aware of an incident that occurred out of hours when this mechanism was not engaged. This system is not robust and presents a risk to Mortuary security.	**Major**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	Security audits are undertaken regularly however, swipe access is not crosschecked against CCTV footage, rather image stills are provided by the security department. This arrangement prevents effective oversight of access and activities of visitors to the Mortuary out of hours. Furthermore, written guidance for security audits do not include sample size for each site.	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	The temporary canopy present at St Marys has gaps in its construction which allows the oversight of licensable activity. (see *Shortfall* against standard PFE1(a)).	**Major**
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	There is insufficient long term storage for the activity across the establishment. At the time of inspection existing storage was at capacity impeding transfer of those requiring to be moved into long term storage.	**Major**
d) Fridge and freezer units are in good working condition and well maintained	The fridge units at St Marys have damage which requires attention. The hinge on fridge unit one to five requires repair. The integrity of the door opening on fridge unit 21 – 25 is compromised and requires repair and decontamination.	**Major**
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	St Marys Linen skips in the post mortem room are heavily corroded, and the structure is compromised. A small set of steps used in the post mortem room are corroded which prevents effective decontamination. This was identified at then previous inspection. Hammersmith Linen skips in the body store are corroded which prevents effective decontamination	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	There is no written guidance for the frequency of condition check or actions to be taken in event of deterioration.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range	The lower threshold for the fridge alarms is not tested regularly.	**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.	C1(a)	The DI is advised to review the *Adult Post Mortem Examination Consent* and *Retention of Tissues and Organs Policy* and include key duties of the Designated Individual. The DI may also wish to include details relating to the retention period of tissue.
2.	C2(a)	The DI advised to undertake an externally sourced consent training course.
3.	GQ1(g)	The DI is advised to increase the numbers of Persons Designate (PD) in the Laboratory and Maternity. The DI may also wish to consider additional PDs in other key areas of the establishment.
4.	GQ3(g)	A general induction package is available for visiting staff however the DI is advised to enhance this with greater detail of specific functions within the Mortuary.
5.	GQ4(a)	The DI is advised to continue with the review of operational documents and transfer to the recently installed records management system.
6.	GQ4(b)	The DI is advised to review the documentation process for Porters admitting bodies to the Mortuary. Changing the existing process will reduce the number of written errors in documents used for traceability.
7.	T1(c)	The DI is advised to review all SOPs associated with transfer and viewing of bodies and specify which points of identification should be used to establish identity.
8.	PFE1(a)	The DI is advised to continue with the plans to redevelop the viewing facilities at St Marys Hospital. The DI is also advised to declutter and remove items no longer in use at all sites.
9.	PFE1(c)	The DI may wish to enhance the existing cleaning records to include specific tasks. This will ensure that scheduled cleaning duties are undertaken within the specified frequencies.

Background
St Marys Hospital is licensed for the making of a PM examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes.

St Marys Hospital has been licensed by the HTA since February 2010. This was the fifth inspection of the establishment; the most recent previous inspection took place in May 2023.

Since the previous inspection, there has been a change of corporate licence holder contact.

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 documentation on site and submitted after the inspection. Standard operating procedures, risk assessments, and policies were reviewed. Audit schedules, competency records, cleaning record forms, and meeting minutes were inspected as part of the review process.

Visual inspection
The inspection team undertook a visual inspection of the hub and satellite premises which included the mortuary body storage areas, viewing facilities, the PM suite at St Mary's as well as the storage arrangements for relevant material held at Charring Cross Hospital.

Audit of records
The inspection team undertook audits of traceability for 12 bodies in storage, this comprised of hospital cases including cases with same and similar names.
Traceability details were crosschecked between the identification band on the body and information in the mortuary register and

electronic records. One minor discrepancy was noted which was immediately rectified.

Audits were conducted of stored tissue taken at PM examination for four cases. Information was crosschecked between the mortuary documentation, consent paperwork, family wishes forms, the mortuary electronic database, and tissue being stored. No discrepancies were identified.

Meetings with establishment staff
The inspection team conducted interviews with staff carrying out processes under the licence. This included the Designated Individual, Pathologist, Mortuary Manager, Bereavement Officer, Bereavement Midwife and Porter.

Report sent to DI for factual accuracy: 6 January 2026

Report returned from DI: 20 January 2026

Final report issued: 27 January 2026

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.