Inspection report on compliance with HTA licensing standards
Inspection date: **21 May 2025**

St Mary's Hospital
HTA licensing number 12357

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 Mary's Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	-	-

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 Marys Hospital ('the establishment') had met the majority of the HTA's standards four major and four 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
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 current lack of freezer capacity presents a risk that bodies may not be transferred to long-term storage after 30 days, potentially leading to deterioration and compromising preservation standards. Although this has been identified as a risk, it is not currently recorded on the establishment's risk register. *The establishment submitted evidence to address this shortfall before the report was finalised.*	**Major**

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	The inspection team observed two areas where body fluids were present and had not been effectively cleaned in the PM room. Additionally, debris was observed around the edge and underside of the drain cover in the PM room. Areas of the mortuary premises are showing signs of wear and require maintenance to ensure decontamination procedures are effective. These include but are not limited to: • The cover on a mounted light fitting in the high-risk area was partially detached, posing a potential injury risk to staff if it were to fall. • Rusting was noted on the radiator pipes in the PM room. • Staining was observed in the body store and specimen area of the PM room, where leaks were present. It was unclear whether these leaks are still active. • A wooden plank was screwed to the floor in the specimen/sluice area. Its purpose was unclear. • The doors leading into the body store and between the PM room and body store are made of wood. Significant damage was observed, exposing irregular and porous surfaces. • Mould was present on three ceiling tiles in the main body store, due to previous leaks. • The wooden hatch door between the specimen store and PM room was damaged, exposing a porous and irregular surface. • A small section of flooring and upstand was missing in the body store, exposing the underlying surface. • A number of areas within the body store had damaged or detached flooring upstands. • In the PM room, some floor seams require replacement, and upstands have separated from the wall. • Gaps were noted in the flooring around the frame of the high-risk roller door, exposing the underlying surface.	**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)	There is currently no CCTV coverage of the mortuary entrance or the door to the porter access area from the main hospital corridor. In addition, the one-way viewing panel on the mortuary door has been obscured by additional screening, preventing staff from being able to visually verify individuals prior to opening it. Furthermore, the temporary storage unit located within the main body store is not covered by the CCTV in this area. This prevents effective oversight of the unit when in use.	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	The inspection team was informed that the establishment currently lacks sufficient freezer storage capacity for long-term body storage during periods of peak activity. Although a business case has been completed to address this issue by increasing freezer capacity, it has not yet progressed within the organisation.	**Major**

Minor Shortfalls

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	On-call staff are sent an email to notify them of fridge alarm triggers out of hours. There is a risk that an email notification may not be seen or heard by staff to act within an appropriate time frame.	**Minor**
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 establishment does not routinely test the lower alarm trigger points of the body store fridges. This lack of testing means there is no assurance that alarms will activate should temperatures fall below acceptable levels, posing a risk of accidental damage to bodies in storage.	**Minor**
g) Bodies are shrouded or in body bags whilst in storage	During the inspection, two bodies were observed in storage with insufficient shrouding, leaving them partially uncovered. Furthermore, a body in freezer storage was not within a body bag. This is not in-line with the establishment's Standard Operating Procedure for the long-term storage of bodies. *The establishment took immediate corrective action during the inspection to address this shortfall.*	**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	• Areas of rusting were identified on the wheels and base of the saw unit, the high-risk dissection bench, and the trolley located in the high-risk area. • Some tools were found in the PM room which are not fit for purpose. For example, a wooden mallet which has porous surfaces. • The hoist in the main body store was observed to have areas of flaking paint. These issues present a risk of ineffective cleaning and decontamination.	**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.	GQ2(a) & PFE1(e)	The DI is advised to include the visitors log in the security audits currently undertaken.
2.	PFE2 (b)	The Mortuary Manager is advised to use space within the permanent body storage units before using the contingency temporary unit as routine body storage.
3.	T1a (c)	Some documents reference multiple identifiers for establishing an individual's identity, including age. However, age is not considered a robust or reliable identifier. The Mortuary Manager is advised to remove age as an optional identifier from relevant documentation.
4.	PFE2(a)	A donated human skeleton previously used for medical training is stored within the post-mortem room. The inspection team was informed that the skeleton is not currently used for teaching, training, or educational purposes. The DI should review the necessity of retaining the skeleton. If it is deemed no longer required, appropriate arrangements for its respectful and compliant disposal should be made.
5.	PFE3 (a)	The high-risk partition roller door was observed to descend at a rapid rate, which may pose a potential risk of injury to staff. The Mortuary Manager should review the operation of the roller door and consider implementing measures to reduce the rate of descent. Adjustments or modifications should be made to ensure the door operates in a controlled and safe manner.

Background

St Mary’s 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 Mary’s Hospital has been licensed by the HTA since 21 November 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in February 2023.

Since the previous inspection, there have been no significant changes to the licence arrangements, or the activities carried out under the licence.

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 relating to licensed activities, cleaning records for the mortuary, post-mortem room and body stores, contracts for servicing of equipment and records of servicing, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training and competency records.

Visual inspection
The inspection team undertook a visual inspection of the premises which included the Mortuary body store areas, Pm suite and viewing facility. The inspection team observed the process for admission and release of bodies within the mortuary.

Audit of records
The inspection team undertook audits of traceability for five bodies in storage. Traceability details were crosschecked between the identification band on the body, information in the electronic mortuary register and associated patient tracking documentation. Whilst one minor discrepancy was identified, this was not sufficient to amount to a shortfall, but oral advice was given to the establishment at the time of the inspection.

Audits were conducted of tissue taken at PM examination for five cases including one hospital consented postmortem. Information was cross-checked between the mortuary documentation, family wishes forms, and tissue blocks and slides being stored. No discrepancies were noted.

Meetings with establishment staff
The inspection team conducted interviews with staff carrying out processes under the license. This included the Designated Individual, Mortuary Manager, Anatomical Pathology Technologist, Consultant Histopathologist, a Porter, Quality Manager, Bereavement Midwife and Pathology Service Manager. The inspection team also met with a Trainee Anatomical Pathology Technologist and Security Manager whilst on Site.

Report sent to DI for factual accuracy: 13 June 2025

Report returned from DI: 20 June 2025

Final report issued: 24 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.