Inspection report on compliance with HTA licensing standards
Inspection date: **05 June 2025**

St Peter's Hospital
HTA licensing number 12542

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 Peters Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Maternity	-	-	*Carried out*
A&E	-	*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 Peter's Hospital ('the establishment') had met the majority of the HTA's standards, three major and one minor shortfall were found against standards for 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.

Major shortfalls

Standard	Inspection findings	Level of shortfall
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
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	Viewings are facilitated by bereavement officers. The inspection team were not assured information provided by families is checked against the ID bands on the body, immediately before being shown into the viewing room.	**Major**
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	There is a procedure in place to provide confirmation of receipt of whole organs and tissue samples sent off site for analysis. However, the standard operating procedure (SOP) lacks detail for the escalation process for following up on forms not received from the contracted establishment. The inspection team found that the establishment had a case where confirmation of receipt of an organ had not been received.	**Major**
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 the premises are secure and there is use of CCTV to monitor access. It is unclear how external access doors are monitored out of hours and the alerting system in place in the event of unauthorised access.	**Major (cumulative)**
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 on a regular basis, however there is no audit of the centrally held swipe card signing in/out log held by porters against CCTV and access logs in the mortuary. Furthermore, the inspection team were not assured that security audits contained a sufficient sample size for the establishment to assure themselves that any access for an unauthorised purpose would be identified and follow up action taken in a timely manner.	

Minor Shortfalls

Standard	**Inspection findings**	**Level of shortfall**
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	Whilst there is regular alarm testing of the upper set range there is no testing of the lower set range. Furthermore, whilst fridge alarms were regularly tested, systems in place for contacting staff out of hours are not challenged.	**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(d)	The Standard Operating Procedures (SOPs) are currently being reviewed and updated. The DI is advised to ensure the person authorising the updated documents is different to the author.
2.	GQ4(a)	The DI is advised to review the electronic mortuary register to ensure dates are recorded in the standardised way for the United Kingdom.
3.	GQ6(b)	The Risk Assessments are currently being reviewed and updated. The DI is advised to add the regular condition checking of bodies undertaken by staff as a mitigating factor in the risk assessment of accidental damage to a body.
4.	T1(d)	There is a system in place to flag bodies with same and similar names, the DI is advised to review the current process and simplify it to prevent the risk of a transcription error, or a deviation from the SOP due to information being highlighted in similar ways in several different places.
5.	PFE3(a)	The DI is advised to monitor the minimal rusting to the electric saw in the post mortem suite, to ensure it does not deteriorate further and impede operational function.
6.	PFE3(d)	The DI is advised to ensure there is a system in place to highlight when staff are required to undertake a face fit test for the FFP3 masks used during Post Mortem Examinations.

Background

St Peter's Hospital has been licensed by the HTA since April 2009. This was the seventh inspection of the establishment; the most recent previous inspection took place in June 2024.

Since the previous inspection, there have been no significant changes to the licensed activity within the establishment. However, there has been a change to the licensed personnel with a change to the DI in January 2025 and Corporate Licence Holder contact (CLHc) in December 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

Sixteen out of the HTA's 72 standards were covered during the announced targeted inspection. Standards covered during this inspection are listed in Appendix 3. The inspection was triggered by several thematic incidents and was focused on mortuary security, tissue traceability and training of staff working outside the mortuary. The remaining 56 standards will be assessed during the next routine inspection.

Review of governance documentation

The inspection included a review of some of the establishment's governance documentation relating to licensed activities. This included risk assessments and Standard Operating Procedures (SOP's) relating to the oversight of contractors and authorised visitors to the mortuary tasked to carry out remedial work within the mortuary.

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Visual inspection

The inspection included a visual assessment of the establishment including the body storage area, viewing suite, and the Post Mortem (PM) suite.

Audit of records

Audits were conducted onsite of one body in frozen storage and three bodies from refrigerated storage, Identification details on bodies were crosschecked against the information recorded in the register and associated paperwork, in addition to information held on the mortuary white boards and in the electronic patient record system. A minor spelling error was identified in the mortuary register for one body; this was rectified by mortuary staff.

Audits of traceability were conducted for tissue removed at PM. These were limited to audits of the documentation relating to transfer of tissue offsite for analysis and confirmation of receipt from the receiving establishment. The inspection team identified one case with outstanding tissue receipt confirmation (see shortfall against T1(g) for further detail).

Meetings with establishment staff

The inspection team met with staff carrying out processes under the licence, this included the Corporate Licence Holder contact (CLHc), the DI, the Mortuary Manager, Quality Lead, the General Manager of Cellular Pathology and the network Mortuary Operations Manager.

Report sent to DI for factual accuracy: 24 June 2025

Report returned from DI: 30 June 2025

Final report issued: 30 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.

Appendix 3: Standards Assessed

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.
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these.
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.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks

a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised.
c) Staff are assessed as competent for the tasks they perform.
d) Staff have annual appraisals and personal development plans.
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.
b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.
c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register.
Traceability
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail
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.
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings). The traceability system ensures that the following details are recorded: i. material sent for analysis on or off-site, including confirmation of arrival ii. receipt upon return to the laboratory or mortuary iii. the number of blocks and slides made iv. repatriation with the body v. return for burial or cremation vi. disposal or retention for future use.
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.

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.

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored

a) Items of equipment in the mortuary are in a good condition and appropriate for use:
i. fridges / freezers
ii. hydraulic trolleys
iii. post mortem tables
iv. hoists
v. saws (manual and/or oscillating)