Inspection report on compliance with HTA licensing standards
Inspection date: **17 September 2025 (Unannounced)**

Royal Preston Hospital

HTA licensing number 12037

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
Royal Preston Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*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 Royal Preston Hospital ('the establishment') had met the majority of the HTA's standards, six major and one minor shortfall was 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
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	Audits of blocks and slides stored in histology are carried out regularly and follow up actions are undertaken. However, the process is not formalised. *This shortfall was addressed prior to the publication of the final report.*	**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).	Whilst there is a system in place to track each body, this is only recorded within a range of fridge bays and does not specify the actual fridge space. There were also some inconsistencies in recording information in mortuary registers such as: • Staff not signing paperwork for release of bodies • Practices for recording information relating to paediatric cases is duplicated which could lead to confusion of information during release	**Major (cumulative)**

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 identifiers are not directly cross-referenced with information on identification bands of deceased for release of bodies for hospital cases to funeral directors or with families prior to a viewing. *This shortfall was addressed prior to the publication of the final report.*	
e) Identity checks take place each time a body is moved whether inside the mortuary or from the mortuary to other premises.	The inspection team observed a release of a body in a body bag where mortuary staff did not check the identification of the deceased, on the wrist band, with the funeral director during the release procedure. Staff checked the identification of the deceased after a request by the inspection team prior to the completion of the release.	
T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		
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 a formalised process for communicating with the Coroner's office to ensure tissue is not kept longer than necessary. *This shortfall was addressed prior to the publication of the final report.*	**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	There are some areas of damage to the structure of the building and equipment including the following: • One of the PM tables does not have a brake and the table can move when this is leaned upon, therefore increasing the risk of damage to a deceased or injury to staff during a PM examination • Seals at the base of the PM table and rear of dissection bench are coming apart • There is a broken electrical socket in the body store • One of the decommissioned hoists which is currently in the high-risk PM room has not been disposed of and there is a cloth chair in this room • The Computed Tomography (CT) fridge had a water leak that has caused the subframe of the fridge unit to bow which has caused the floor to lift • Damage to the doors and frames connecting the body store to the isolation PM room exposing porous wooden surfaces. Porous surfaces cannot be effectively decontaminated.	**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)	Keys for the external fridges were seen hanging on hooks on the office wall and body store door frames. This poses a risk to security of the body store.	**Major**
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.	All mortuary staff are sent an email to their personal email address to notify them of fridge alarm triggers out of hours as the email is not limited to on-call staff only. There is a risk that an email notification may not be seen by staff to act within an appropriate time frame.	**Major**

Minor shortfalls

Standard	Inspection findings	Level of shortfall
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
f) Key items of equipment, including fridges/freezers, trolleys and postmortem tables (if downdraught) are subject to regular maintenance and records are kept	The PM tables are not subject to a regular maintenance servicing contract.	**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 establishment is advised to remove references to Next of Kin in documents that detail who can give consent for PM examination and removal and retention of relevant tissue. Examples include the following documents: • SOP-TP-203 Tissue Donation Policy • Information leaflets for families for post-mortem examination The HTA's Codes of Practice provide information on the consent requirements of the Human Tissue Act 2004.
2.	GQ1 (a)	The DI is advised to review the relevant SOPs to ensure the most recent Health and Safety Executive (HSE) information is referenced.
3.	GQ3 (a)	Mortuary staff are advised to confirm that porters have completed the mortuary specific training prior to authorising access to the mortuary.
4.	T2 (b)	The Coroner's tissue retention form groups scheduled purposes together and does not list them individually. The establishment is advised to discuss amending the form with the Coroner so that informed consent can be given.
5.	PFE2 (e)	The mortuary may wish to have a dedicated phone for on-call staff to use and be contacted in case of an emergency.

Background

Royal Preston Hospital has been licensed by the HTA since 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in March 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, records of servicing of equipment, audits, risk assessments, meeting minutes, reported incidents and training records for mortuary staff, porters and consent seekers.

Visual inspection
The inspection included a visual assessment of the establishment including the PM room, body storage areas, CT scanning area and viewing room. The inspection team observed the processes for admission and release and of bodies within the mortuary.

Audit of records
Audits were conducted onsite of five bodies from refrigerated storage, and one body in long term storage. Identification details on bodies were crosschecked against the information recorded in the register, associated paperwork and electronic records. (See shortfall against T1 (b) and (c)).

Audits of traceability were conducted for tissue blocks and slides from six PM cases, including audits of the consent documentation for the retention of these tissues. There was a discrepancy in one case where a block was not in storage that was recorded on paperwork and the electronic system.

Meetings with establishment staff

Discussions with staff including the DI, Senior Anatomical Pathology Technologist (APT), APT, Pathologist, porters, staff in the histology department and consent seekers for PM examinations.

Report sent to DI for factual accuracy: 28 October 2025

Report returned from DI: 11 November 2025

Final report issued: 12 November 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.