Inspection report on compliance with HTA licensing standards
Inspection date: **19 and 20 September 2024**

Epsom and St Helier University Hospital NHS Trust

HTA licensing number 12345

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 Helier Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
A&E	-	*Carried out*	-
Satellite site **Epsom Hospital**	Not licensed	Licensed	Licensed
Mortuary (satellite site)	-	*Carried out*	*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 Epsom and St Helier University Hospital NHS Trust ('the establishment') had met the majority of the HTA's standards, 11 major and five 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
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity	Deviations from the viewing of deceased standard operating procedure (SOP) are not recorded or monitored by audit. *Refer to shortfall T1(c)*	**Major**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The scope of the audit schedule for licensed activities conducted under the licence is limited. The audit schedule does not include sufficient audits to check compliance with documented procedures, the completion of records or traceability of bodies.	**Major**

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	Although tissue audits are undertaken, the number of cases audited is not proportionate to evaluate if the storage of tissue is accurate. During the traceability audit of post mortem (PM) tissue two discrepancies were found with cases dating back to 2022. The number of wet tissue blocks recorded on the histology form sent to the laboratory did not match the number of blocks recorded as received on the laboratory information management system (LIMS) or in storage. The laboratory do not record if more than one piece of wet tissue is blocked together. There is a risk of loss of tissue.	**Major**
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	Not all procedures relating to licensed activities have been risk assessed. These include but are not limited to: • major equipment failure; • disposal or retention of organs or tissue against the wishes of the family; • removal of tissue without the appropriate authorisation or consent; and • incidents leading to unplanned closure of mortuary/inability to deliver services. <u>St Helier Hospital</u> Contingency temporary storage requires staff to transfer the deceased along a busy road used by the public, Trust staff and contractors, and then through a working office. This process has not been risk assessed to ensure the dignity of the deceased is maintained.	**Major**
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	Staff conducting viewings do not always receive a minimum of three identifiers of the deceased provided by relatives on arrival at the establishment that can be checked against the identification wristband on the body. There is a risk of a viewing of a wrong body.	**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	Issues were identified with the maintenance of the establishment. <u>St Helier Hospital</u> • large areas of exposed plaster in the body store; • extensive pealing of paint on the ceiling above the freezer units; • body store door chipped and exposed wood; • post mortem room door heavily damaged which could affect the ventilation system; • door from corridor to viewing reception area does not close properly; • exposed brick work near ceiling from removal of former ventilation ducting; and • post mortem room drains are damaged. <u>Epsom Hospital</u> • large areas of exposed wood on body store door. Area at base of door missing which has lead to a loss of integrity as a fire door; • floor seals at base of fridge units are damaged; • former post mortem room ingress of water to wall has damaged the plaster and lead to rusting; • pealing paint on ceiling in former post mortem room; and • a number of areas of exposed plaster on walls. There is no post mortem suite at this site, however, there are no suitable facilities to allow staff to adequately clean deceased if required or for the removal of tissue.	**Major**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The inspectors noted that contractors had access to the mortuary from the area that is currently being redeveloped to increase the capacity of the mortuary. This door is secured by a key code only and contractors entered the mortuary at the time of the inspection without informing the mortuary staff. There is a risk that contractors may enter the mortuary when the body store doors are open and view mortuary activities; and may enter out of hours (OOH) without the knowledge of mortuary staff. Although security audits are performed, no swipe card access audit is performed to provide assurance that those who have access to the mortuary continue to be authorised to do so. *See advice item 7.*	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	<u>Epsom Hospital</u> The movement of bodies in and out of the funeral director's entrance is overlooked. The funeral director entrance opens directly to a porter yard and while on site the inspectors noted a number of Trust staff used the yard to cross into another part of the hospital. This area is also used to discard rubbish, broken equipment and infectious waste material. This limits the access of the funeral directors to fully reverse up to the entrance. This does not ensure the dignity of the deceased on release.	**Major**
d) Fridge and freezer units are in good working condition and well maintained	<u>Epsom Hospital</u> Seals on fridge doors are deteriorating and mould was also observed on the seals of fridge doors and the outside of the fridge units. This poses a risk of the fridge banks not running at optimal temperature or contamination of the fridge units which may result in deterioration of the condition of the bodies stored.	**Major**

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	Testing of the fridge and freezer temperature alarms is conducted in hours at both sites however; the lower temperature alarm is not challenged. Manual alarm testing of the fridge and freezer units OOH are not undertaken at both sites to ensure that alarms trigger and that the call-out procedures are effective.	**Major**
i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods	Epsom Hospital At the time of the inspection the permanent freezer unit had been inoperative since the beginning of August 2024. A freestanding permanent fridge unit temperature was lowered to -5^{o}C to allow the transfer of deceased stored in the broken freezer unit. The establishment was made aware that this fridge unit was not designed to maintain this lowered temperature for an extended period of time and there was a risk that the unit would fail leading to a lack of freezer capacity. There had been no follow up of the repair of the freezer unit at the time of the inspection. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Major**

Minor Shortfalls

Standard	**Inspection findings**	**Level of shortfall**
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	Although clinical site managers have been initially competency assessed, competency reassessments are not up to date for conducting OOH viewings.	**Minor**
GQ4 There is a systematic and planned approach to the management of records		
b) There are documented SOPs for record management which include how errors in written records should be corrected	A number of corrections made in the mortuary register at both the hub and satellite site are illegible. This does not allow for full auditability of any changes to a record.	**Minor**

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
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	Not all mitigating controls that are in place have been recorded on risk assessments for example; staff training, competency assessments and SOPs.	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The establishment does not receive confirmation that toxicology samples sent off site for analysis are received at the receiving establishment.	**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	The trolley hoists are suffering from signs of wear and tear; large areas of rust were seen making them difficult to clean and decontaminate sufficiently.	**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(g)	The DI is advised to update the link to the Human Tissue Authority (HTA) website in the adult consent form.

2.	GQ1(a)	The DI is advised on the next review of the standard operating procedures (SOPs) to ensure that the same/similar name procedure reflects the current practice and what identifiers are checked are specified in the documents.
3.	GQ1(d)	The DI is advised to ensure that the title page of SOPs accurately reflect who has authored and authorised the documents.
4.	GQ5(a)	The DI is advised to place an aide memoire in the mortuary to raise awareness amongst porters working there of the importance of reporting any incidents, including a list of all the appropriate HTA Reportable Incident (HTARI) categories.
5.	T1(b)	The DI is advised to look at aligning the electronic register systems across both sites to help with traceability of the deceased.
6.	PFE1(b)	The DI is advised to place signage in the changing rooms to determine clean areas from dirty areas in the mortuary.
7.	PFE1(e)	The DI is advised to include in the current security audits that a check of the over-ride key held with security at Epsom Hospital is conducted.

Background

St Helier Hospital (hub) 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. Epsom Hospital (satellite site) is licensed for removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes.

Epsom and St Helier University Hospitals NHS Trust has been licensed by the HTA since 2008. This was the fifth inspection of the establishment; the most recent previous inspection took place in March 2022.

Since the previous inspection works to increase the number of fridge and freezer units at St Helier Hospital is currently being undertaken.

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, records servicing of equipment, ventilation reports, audits, risk assessments, meeting minutes, reported incidents and staff training records.

Visual inspection

The inspection included a visual inspection of the mortuary body store, temporary store room, PM room and viewing room at St Helier Hospital and mortuary body store and viewing room at Epsom Hospital.

Audit of records

Audits were conducted for seven bodies in refrigerated storage. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and electronic system. Whilst one minor discrepancy was found this was corrected at the time of the inspection.

Audits of traceability were conducted for tissue blocks and slides from three PM cases, including audits of the consent documentation for the retention of these tissues. Two discrepancies found (see shortfall against GQ2(c)).

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI, Anatomical Pathology Technologists (APT), portering staff, pathologist, consent seeker for perinatal PM examination and mortuary manager.

Report sent to DI for factual accuracy: 23 October 2024

Report returned from DI: 13 November 2024

Final report issued: 9 December 2024

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.