Inspection report on compliance with HTA licensing standards
Inspection date: **22 and 23 October 2024**

Tunbridge Wells Hospital at Pembury
HTA licensing number 12616

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 Tunbridge wells Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Maternity	-	*Carried out*	-
Pathology lab	-	-	*Carried out*
Satellite site Maidstone 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 Tunbridge Wells Hospital at Pembury ('the establishment') had met the majority of the HTA's standards, five major and two minor shortfalls were found against standards for Consent, 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		
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	Whilst the establishment have a documented procedure for checking the condition of bodies it is not consistently being undertaken.	**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	The mortuary has recently taken over the responsibility for auditing and disposal of tissue from the histology department. The inspection team found that tissue had not been disposed of as soon as was reasonably possible. *(See Advice item 4)*	**Major (cumulative)**
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary	The establishment has a system to ensure tissue is disposed of in line with family wishes. There has been a delay in disposal of tissue due to a delay in correspondence from the Coroner's office. This has resulted in tissue being held for extended periods after receiving notification that Coroner's authority has ended.	

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	Whilst the mortuaries at the hub and satellite site are clean the inspection team identified the following areas which require maintenance: • Corrosion on external skirting of fridges at the hub site. • A panel under fridge doors loose in the post mortem room. • Areas of exposed plaster are present in the post mortem room. • The floor of the post mortem room is worn exposing areas of porous surface beneath. • An access panel beneath a hand wash sink in the post mortem room requires re securing. • Corrosion is present on an access panel in the post mortem room. • The door frame to the post mortem room from the body store is damaged. • Multiple areas of damage to door frames are present leaving exposed wood at hub and satellite sites. • A repair to a door handle using untreated wood has been made at the satellite site. This surface is porous and cannot be effectively cleaned. • Areas of floor covering at the satellite site are damaged and have been covered with tape. This prevents effective decontamination.	**Major**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The mortuary entrance used by funeral directors at the satellite site is located in a busy courtyard. Whilst there is some privacy screening to the mortuary it is not fully enclosed. The courtyard is used by several departments in close proximity to the Mortuary entrance and receive multiple deliveries from couriers. The inspection team were told of potential for oversight of licensable activity. At the hub site a mobile office unit has been placed in the location used for siting the temporary body store. This prevents the body store from being positioned in an area which is not overlooked. The establishment does not have any alert devices in place for lone workers in the satellite site. This inhibits the ability of lone working staff to call for assistance.	**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	Whilst mortuary fridges are connected to an alarm system and checked when serviced the alarms are not tested regularly. The fridge in the maternity unit is not subject to regular alarm testing.	**Major (cumulative)**
f) Temperatures of fridges and freezers are monitored on a regular basis	Whilst there is a procedure in place for monitoring the temperature of the fridge in the maternity unit this has not been recorded since August 2024. This, with the lack of alarm testing, poses the risk of mechanical breakdowns not being identified. Monitoring of temperature trends at the satellite site is not undertaken.	

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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	Risk assessments do not give deadlines for actions to be implemented, name a responsible individual to complete an action and do not confirm actions have been completed. This presents a risk of mitigation actions not being completed.	**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 saw in the post mortem room is corroded which prevents effective 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.	C1(b)	The DI should consider adding the title of the printed information given to persons giving consent for perinatal Post Mortems in the relevant SOP.
2.	GQ4(a)	The DI is advised to finalise the implementation of an electronic mortuary register. This will reduce administrative burden and reduce the opportunity for errors.
3.	T1(c)	The DI is advised to continue training with the Coroner's contracted funeral staff to ensure consistent traceability standards are met.
4.	T2(a)	The DI is advised to undertake an audit of all retained tissue and develop a procedure to ensure timely disposal of tissue where family wishes are not known.
5.	PFE1(e)	The Porter's concealment trolley is stored within the mortuary at the satellite site. Porters access the department to collect the trolley before transferring a body to the mortuary and return it following use. The DI is advised to arrange removal of the trolley to another storage location to enhance security measures and reduce access to the mortuary. Porters attend the mortuary in pairs to undertake any tasks. Upon entry to the mortuary, one Porter uses their swipe card for entry and the other Porter will use their swipe card on exit. The DI is advised to consider altering the procedure so both Porters use cards on entry and exit to strengthen traceability of audits.
6.	PFE3(a)	The trolleys used for the temporary body store are showing early signs of corrosion. The DI is advised to monitor the condition of these trolleys.

Background
Tunbridge Wells Hospital at Pembury 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.

Tunbridge Wells Hospital at Pembury has been licensed by the HTA since March 2014. This was the fourth inspection of the establishment; the most recent previous inspection took place in June 2022.

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

Visual inspection

The inspection included a visual assessment of the body storage areas in the mortuary, PM room, viewing room, and tissue storage areas as well as the maternity unit at the hub site. The inspection team observed the processes for release of bodies within the mortuary. A visual assessment of the body storage areas in the mortuary and viewing room was made at the satellite site.

Audit of records

A traceability audit of four bodies in storage was undertaken at the hub site. This included bodies from both the community and hospital. Details were cross checked against identity bands and the mortuaries' electronic database. No discrepancies were found.

A traceability audit of three bodies in storage was undertaken at the satellite site. This included bodies from the hospital including those with same and similar names and one in long term storage. Details were cross checked against identity bands and the mortuaries' electronic database. No discrepancies were found.

Audits were conducted of tissue taken at post mortem examination for seven cases. Information was crosschecked between the mortuary electronic database, Coroner's paperwork, family wishes forms, the laboratory database, and tissue blocks and slides being stored. No discrepancies were found.

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, quality manager, Bereavement Midwife, Porter and Security Operational Manager.

Report sent to DI for factual accuracy: 11 November 2024

Report returned from DI: 25 November 2024

Final report issued: 2 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.