Inspection report on compliance with HTA licensing standards
Inspection date: **17 June 2025- Unannounced**

George Eliot Hospital
HTA licensing number 12171

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 **George Eliot Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*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 George Eliot Hospital ('the establishment') had met the majority of the HTA's standards, three major and three minor shortfalls 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.

Compliance with HTA standards

Major shortfalls

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).	Although secure with controlled access, the main mortuary entrance does not have a video-intercom or CCTV system to see who is attending the mortuary from outside. Therefore, staff cannot identify who is attending prior to opening the door. *The establishment submitted evidence to address this shortfall before the report was finalised.*	**Major**

PFE2 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue		
a) Storage arrangements ensure the dignity of the deceased	At the time of the inspection the Post-mortem (PM) room was 30 degrees Celsius. This poses a risk of accelerated deterioration of bodies. *The establishment submitted evidence to address this shortfall before the report was finalised.*	**Major**

PFE2 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of 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 all fridge and freezer units are temperature monitored and alarmed, the fridge alarm trigger points are set for high temperature alarm at +10°C. This poses a risk of bodies not being stored at an optimum temperature, which may cause deterioration. *The establishment submitted evidence to address this shortfall before the report was finalised.*	**Major**

Minor shortfalls

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 retain PM tissue long-term for use in a scheduled purpose, and therefore only tissue where the cases are still open or being stored for civil proceedings were audited. For one case however, additional slides had been cut, and these were not documented on the relevant paperwork. See advice, item 2. *The establishment submitted evidence to address this shortfall before the report was finalised.*	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue		
a) Storage arrangements ensure the dignity of the deceased.	During the inspection, there was a significant amount of ice build-up on the top tray of the freezer unit and as a result it cannot be used to store a body in that space.	**Minor**

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.	Although the upper temperature trigger point for the fridges is tested regularly to ensure call out procedures are working, tests do not include the lower temperature trigger point. *The establishment submitted evidence to address this shortfall before the report was finalised.*	**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.	C2 (b)	Although all adult consent seekers training was up to date at the time of the inspection, there is no documented timeframe to detail when refresher training is carried out. As the process is very rare, the establishment may wish to consider completing refresher training prior to seeking consent for a PM examination on a case-by-case basis.
2.	T1 (g)	The DI is advised to ensure mortuary records are completed in a timely manner when PM tissue slides are returned to the mortuary.
3.	PFE1 (e)	The establishment is advised to ensure that the escalation process in place is documented for security staff who conduct audits of the CCTV. The current procedure for escalating incidents states that the Chief Medical Officer will be informed but does not mention any escalation to the DI as per practice.
4.	PFE1 (d)	The establishment is advised to: • Consider installing an automatic shutter on the mortuary door to mitigate the risk of it not closing properly • Continue with plans to repair the PM tables in the PM room which makes a clunking sound when the height is adjusted • Consider removing the temporary storage unit which is located in the primary viewing suite Mortuary documentation states the unit will not be used and the DI also informed the inspection team that it would not be used as it is currently not fit for purpose.
5.	General	The establishment is advised to identify protected time for the DI to carry out governance duties.

6.	General	The establishment is advised to contact the HTA once the refurbishment is completed and additional capacity of the mortuary is operational. The HTA may wish to conduct a follow up site visit to review the arrangements.

Background

George Eliot Hospital has been licensed by the HTA since October 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in November 2022.

At the time of the inspection the mortuary was in the final stages of renovation which will significantly increase storage capacity (see, advice, item 6)

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

Policies and procedural documents relating to licensed activities were reviewed. This included cleaning records for the mortuary and PM room, records of servicing of equipment, fridge and freezer alarm testing records, ventilation reports, body and tissue traceability audits, security audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training and competency records. Consent seeking policies and procedures, information for relatives giving consent and current consent forms in use for both adult and perinatal PM examination were also reviewed.

Visual inspection
The inspection team undertook a visual inspection of the premises which included the mortuary body storage area, PM room and viewing room.

Audit of records
The inspection team undertook audits of traceability for two bodies in refrigerated storage and two bodies in long-term storage. This included same / similar name procedures. Traceability details were crosschecked between the identification band on the body, information on the door of the storage unit and the electronic mortuary database. No discrepancies were identified.

Audits were conducted of tissue taken at PM examination for the three cases. Information was crosschecked between the mortuary traceability documentation, Coroner's paperwork, family wishes forms, and the tissue blocks and slides being stored in the mortuary. One discrepancy was noted where the additional slides were not recorded in mortuary documentation (See minor shortfall against T1(g)).

Meetings with establishment staff

The inspection team met with staff carrying out processes under the licence, including mortuary staff during the onsite visual inspection, a porter, staff involved in the consent seeking process for both adult and perinatal PM examination, the DI and a Pathologist.

Report sent to DI for factual accuracy: 7 July 2025

Report returned from DI: 23 July 2025

Final report issued: 11 August 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.