

Inspection report on compliance with HTA licensing standards  
Inspection date: **04 June 2025**



**East Surrey Hospital**  
HTA licensing number 12117

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 East Surrey Hospital	Licensed	Licensed	Licensed
Mortuary	<i>Carried out</i>	<i>Carried out</i>	<i>Carried out</i>
A&E	-	<i>Carried out</i>	-

**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 East Surrey Hospital ('the establishment') had met the majority of the HTA's standards, seven major and five minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities and equipment.

Five of the identified shortfalls (GQ3c, GQ5a, PFE1e, PFE2e and T1c) pertain to findings from the previous inspection conducted in October 2022. During the inspection feedback meeting, the HTA raised concerns that sufficient action had not been taken to adequately address this finding and that effective, fully embedded procedures, had not been implemented during the intervening period. This was acknowledged by the establishment and progress will be monitored through an agreed corrective action plan.

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***

<b>Standard</b>	<b>Inspection findings</b>	<b>Level of shortfall</b>
<b>C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent</b>		
b) Records demonstrate up-to-date staff training	Records provided by the establishment do not demonstrate up-to-date consent training for all designated consent seekers. Although refresher training dates have been documented in the consent tracker, staff do not appear to have completed the training or provided evidence of attendance.	<b>Major cumulative</b>

d) Competency is assessed and maintained	<ul style="list-style-type: none"> <li>• The establishment does not currently assess the competency of individuals seeking consent for adult post-mortem examinations.</li> <li>• Competency does not currently appear to be assessed and maintained for all bereavement midwife consent seekers.</li> </ul>	
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#### **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.	<ul style="list-style-type: none"> <li>• The inspection team was not assured there was written guidance in place for all mortuary and laboratory procedures undertaken. There were no documents available for review pertaining to the disposal of tissue removed during a post-mortem examination once it was no longer required.</li> <li>• The mortuary department's security Standard Operating Procedure (SOP) lacks sufficient detail and does not accurately reflect current staff practices. The SOP lacks clear, written guidance on how to carry out the monthly security audit, as well as the end-of-day mortuary closing procedure, including separate steps relating to the contingency storage area.</li> </ul>	<b>Major</b>
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#### **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	<p>The inspection team was not assured that all porters carrying out licensed activity had been assessed as competent.</p> <p>This shortfall was previously identified during the last HTA inspection in 2022.</p>	<b>Major</b>
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<b>GQ5 There are systems to ensure that all untoward incidents are investigated promptly</b>		
a) Staff know how to identify and report incidents, including those that must be reported to the HTA	<p>Whilst staff know how to identify and report incidents, the inspection team identified several incidents that led to the temporary, unplanned closure of the mortuary, resulting in an inability to deliver services. These incidents met the threshold for reporting to the HTA but had not been reported.</p> <p>This shortfall was previously identified during the last HTA inspection in 2022.</p>	<b>Major</b>
<b>T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail</b>		
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	<p>A minimum of three identifiers of the deceased on the body are not routinely checked against details of the deceased provided by family members when they attend the mortuary for viewings. This poses the risk of viewing the wrong body.</p> <p>This shortfall was previously identified during the last HTA inspection in 2022.</p>	<b>Major</b>
<b>PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.</b>		

<p>e) Security arrangements protect against unauthorised access and ensure oversight of visitors and contractors who have a legitimate right of access</p>	<ul style="list-style-type: none"> <li>• At the time of the inspection, security audits had not been undertaken since November 2024, resulting in a gap of seven months. As a result, the establishment cannot be assured that individuals accessing the mortuary, or the contingency storage area, are doing so for a legitimate purpose. The failure to undertake regular security audits means the establishment is unable to scrutinise the purpose, frequency, and duration of access, or maintain oversight of unusual patterns, times of entry, or other unexplained or potentially suspicious activity that would require immediate investigation.</li> </ul> <p><i>The establishment undertook immediate action to reinstate monthly security audits following the inspection.</i></p> <ul style="list-style-type: none"> <li>• Swipe card access lists have not been reviewed or updated since November 2024.</li> <li>• The inspection team was not assured security audits contain a sufficient sample size for the activity undertaken at the establishment.</li> <li>• Security arrangements do not adequately prevent unauthorised access during viewings to restricted areas of the mortuary. The doors situated between the viewing room waiting area and the viewing suite are not locked while viewings are in progress. If opened, these doors provide access to the body store, which presents a significant security risk.</li> <li>• The contingency storage area, currently in use at East Surrey, is located in a separate adjacent building that is also accessed by the estates department for their own operational purposes. At the time of the inspection, the establishment had no internal security measures</li> </ul>	<p><b>Cumulative Major</b></p>
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	<p>in place to segregate or secure both the temporary and permanent storage units in order to prevent access by non-mortuary staff entering the building for their own purposes. While there are plans to redevelop this area, the inspection team was not assured that the current arrangements sufficiently safeguard the dignity and security of the deceased. Under the existing set-up, there remains a risk that the area may be accessed inappropriately and without the knowledge or control of the DI.</p> <p>This shortfall was previously identified during the last HTA inspection in 2022.</p> <p><i>See advice item 1.</i></p>	
<b>GQ2 There is a documented system of audit</b>		
a) There is a documented schedule of audits	Monthly security audits are not included in the establishment's documented mortuary audit schedule.	
<b>PFE2 There are appropriate facilities for the storage of bodies and human tissue.</b>		
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	<p>Whilst fridge and freezer alarms are tested, the frequency of these tests is not clearly documented. In addition, current tests do not include the lower set point range. Alarm tests also do not incorporate or recorded the call-out procedure to confirm that the full alarm response process is functioning as intended.</p> <p>This shortfall was previously identified during the last HTA inspection in 2022.</p>	<b>Major</b>

### Minor Shortfalls

Standard	Inspection findings	Level of shortfall
<b>GQ1 All aspects of the establishment's work are governed by documented policies and procedures</b>		
d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use	<p>Whilst most SOPs have been reviewed, some SOPs have not been reviewed in line with the documented review date.</p> <p>This includes SOPs for:</p> <ul style="list-style-type: none"> <li>- Cleaning and disinfecting mortuary equipment and accommodation</li> <li>- High-risk PM work</li> <li>- Lone working</li> </ul> <p>This poses the risk of staff following processes which are no longer in place.</p>	<b>Minor</b>
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	<p>While scheduled governance meetings relating to HTA licensed activities are held, there is no representation from staff outside the mortuary who are involved in activities under the licence. Persons Designated, Emergency Department staff, and Porters are not invited to attend HTA meetings, or receive minutes or updates on discussions concerning HTA related matters.</p> <p><i>See advice item 2</i></p>	<b>Minor</b>

**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	<p>Whilst all procedures relating to licensed activities have been risk assessed, not all risks have been reviewed in line with the establishment governance framework.</p> <p>These include but are not limited to:</p> <ul style="list-style-type: none"> <li>- Release of incorrect deceased to undertaker</li> </ul> <p>To fully address this shortfall, the establishment should review all risk assessments relating to mortuary activities to ensure that they are accurate and contain sufficient detail to reflect current practice.</p>	<b>Minor</b>
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**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	<p>Wooden door wedges are in use at East Surrey mortuary. Due to their porous construction, they present a risk of ineffective cleaning and decontamination.</p> <p><i>The establishment submitted sufficient evidence to address this shortfall before the report was finalised.</i></p>	<b>Minor</b>
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**PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored**

f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept	Maintenance checks of the autopsy saws at East Surrey mortuary were last carried out in 2022.	<b>Minor</b>
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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.	PFE1 e	<p>The DI is advised to implement the following interim measures while awaiting the planned redevelopment work of the contingency storage area:</p> <ul style="list-style-type: none"> <li>• Remove the Nutwell unit currently not in use, located at the front of the contingency storage area, or relocate it to the rear of the building, behind the set of double doors, where the permanent fridge units are situated. The current position of this unit is not secure and therefore unsuitable for use.</li> <li>• Install a key or swipe access lock on the set of double doors located within the contingency storage area. This measure is necessary to ensure that both temporary and permanent storage units are properly segregated and secured, preventing unauthorised access by estates staff entering the building for their own purposes.</li> </ul>

2.	GQ1 h	The DI is advised to schedule meetings to which all Persons Designated and staff working under the licence are invited, including those outside of the mortuary. This will support the DI in maintaining full oversight, including oversight of staff training, competency and potential HTA reportable incidents.
3.	PFE3 c	The ventilation system report undertaken on the 9 <sup>th</sup> June 2025, indicates the currently ventilation system is not meeting the minimum recommended air supply rate of ten air changes an hour, or the recommended extract rate of twelve air changes an hour to the post mortem room. The DI is advised to continue with current plans to ensure the ventilation system achieves the expected air supply and extraction rates.
4.	GQ6 c	<p>Whilst assurance was provided by the DI that there are plans in place to recruit additional staff, and that staff currently on long-term sick leave are expected to return imminently, the mortuary has been operating with reduced staffing levels for several months. This has resulted in staff regularly working alone. The DI is advised to escalate staffing concerns to the corporate risk register if recruitment is delayed or the expected return of staff does not occur as planned. Prolonged reduced staffing levels pose a risk to both staff wellbeing and the safe delivery of the service.</p> <p>In addition, the DI is advised to introduce regular testing of the lone working alarms used by staff when lone working. This will help ensure that the system is operating as intended and that the process in place is effective.</p>
5.	T1 h	Although off-site tissue analysis has recently transitioned to the use of digital imaging, the DI is advised that if physical slide removal is required in the future, the process is fully traceable. This includes having robust record-keeping procedures, which were not in place previously.
6.	PFE3 d	Following a meeting with a pathologist at East Surrey, it was highlighted that the gloves provided by the establishment for post-mortem work frequently split during use. The DI is advised to review both the suitability of the gloves provided for pathologists and the conditions in which they are stored, to ensure they are appropriate for their intended purpose.

## **Background**

East Surrey 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 October 2022. Since the previous inspection, there has been a change to the Designated Individual in March 2023.

### **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:

#### **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, ventilation reports, audits, risk assessments, meeting minutes, reported incidents and training records for staff.

#### **Visual inspection**

The inspection team undertook an unannounced visual inspection of the mortuary body storage areas, the post mortem room and the viewing suite at East Surrey Hospital. The inspection team also observed the process for release within the mortuary.

#### **Audit of records**

Audits were conducted for five bodies from refrigerated storage. Identification details on bodies were crosschecked against the information recorded in the mortuary electronic register and associated paperwork. The inspection team identified no discrepancies. Audits of tissue traceability were also undertaken for three histology cases; the inspection team identified no discrepancies.

#### **Meetings with establishment staff**

The inspection team met with staff carrying out activities under the licence, including an APT, a Porter, a Pathologist, an adult consent seeker, a bereavement midwife and the Designated Individual.

**Report sent to DI for factual accuracy: 15<sup>th</sup> July 2025**

**Report returned from DI: 25<sup>th</sup> July 2025**

**Final report issued: 28<sup>th</sup> July 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.