Inspection report on compliance with HTA licensing standards
Inspection date: **02 May 2025**

Queen Alexandra Hospital
HTA licensing number 12237

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 Queen Alexandra Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Maternity	-	-	*Carried out*
A&E	-	*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 Queen Alexandra Hospital ('the establishment') had met the majority of the HTA's standards, three major and one minor shortfall 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.

Major shortfalls

Standard	Inspection findings	Level of shortfall
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
b) Records demonstrate up-to-date staff training	Records do not demonstrate up to date training in HTA requirements when seeking consent. Documents reviewed indicated not all staff seeking consent for perinatal Post Mortem Examinations (PMs) had received regular refresher training.	**Major (cumulative)**
d) Competency is assessed and maintained	Whilst staff are assessed as competent after receiving initial consent training, there were no documents available to review indicating those seeking consent for perinatal PMs had received regular competency assessments.	
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		

a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised	Whilst there are plans in place for the training of contracted Funeral Directors who undertake activity under the licence this has not yet been implemented.	**Major (cumulative)**
c) Staff are assessed as competent for the tasks they perform	Whilst there are plans in place for assessing the competency of contracted Funeral Directors who undertake activity under the licence this has not yet been implemented.	
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	During the body audit one case reviewed had only two identifiers on the ID band. The mortuary team had identified this prior to the arrival of the inspection team and a request had been sent to the relevant staff to rectify. Furthermore, whilst family members provide three identifiers when attending the mortuary for a viewing. These do not correspond with information held on the ID bands. This poses the risk of a viewing of the wrong body.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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 there is regular alarm testing of the upper set range there is no testing of the lower set range and no Out of Hours (OOH) testing is carried out.	**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 PM consent policy is currently being reviewed, as part of this review the DI is advised to consider detailing the frequency of staff refresher training and the associated competency assessment.
2.	GQ3(a)(c)	The DI is advised to expedite existing plans in place to deliver training and assess the competency of Funeral Directors who undertake activity under the licence.
3.	GQ6(b)	The DI is advised to risk assess the windows between the funeral director entrance and the mortuary to ensure the window film in place is sufficient to prevent the oversight of activity being undertaken within the mortuary. Additionally, the screening of the outside storage area should be risk assessed to ensure it effectively prevents the oversight of mortuary activity.
4.	PFE2(e)	The DI is advised to expedite existing plans to upgrade the control panel for the fridge and freezer units in the mortuary. Furthermore, the DI is advised to review the trigger points for fridge and freezer

		temperatures to ensure there is no risk of bodies being stored at suboptimal temperatures for a prolonged time.
5.	PFE3(f)	The systems and equipment within the mortuary are subject to regular testing and servicing however records are not kept within the mortuary and are only available upon request. The DI is advised to request copies of all maintenance, servicing and repair reports so that they are easily accessible to mortuary staff for review and monitoring purposes.

Background

Queen Alexandra Hospital has been licensed by the HTA since 2007. This was the fifth inspection of the establishment and the first inspection using the unannounced methodology. 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, ventilation reports, audits, risk assessments, meeting minutes, reported incidents and training records for both the mortuary staff, maternity staff and porters.

Visual inspection
The inspection included a visual assessment of the establishment including, body storage areas in the mortuary and in the maternity department, PM room, viewing room and tissue storage area. The inspection teams observed the processes for the release of bodies within the mortuary.

Audit of records
Audits were conducted onsite of three bodies from refrigerated storage, and one body stored in long term frozen storage. The release of two bodies into the care of funeral directors was witnessed.
Identification details on bodies were crosschecked against the information recorded in the register, electronic records and associated paperwork. A discrepancy was identified for one case. Refer to shortfall T1(c) above.
Audits of traceability were conducted for tissue blocks and slides from four cases, these included audits of the consent documentation for the retention of these tissues. No discrepancies were identified.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence, including the DI, Pathology Manager, Mortuary Manager, Pathologist, Bereavement Midwife, Trainee APT's and a Porter.

Report sent to DI for factual accuracy: 20 May 2025

Report returned from DI: 10 June 2025

Final report issued: 11 June 2025

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 21 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.