Inspection report on compliance with HTA licensing standards
Inspection date: **8 and 10 March 2023**

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
Queen Alexandra Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*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 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

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Whilst regular meetings to discuss HTA business do take place there is no attendance by establishment staff from areas outside the mortuary and governance teams. Maternity staff, staff from the emergency department and porters do not attend or receive the minutes of governance meetings discussing matters relating to HTA activity.	**Minor**
GQ2 There is a documented system of audit		

a) There is a documented schedule of audits	Whilst there is a documented schedule of audits, this does not reflect the audit of CCTV feed against mortuary access records which is carried out monthly.	**Minor**
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	Whilst risks are assessed on a regular basis, not all potential HTA reportable incidents have been identified and risk assessed. This means there is insufficient written guidance for staff to minimise the risk to bodies and tissue of a reportable incident. See advice and guidance item three below.	**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)	Whilst there are written processes in place to support perinatal consent seeking, procedures are outlined across more than one document. The DI is advised to consolidate the information into a single perinatal consent seeking SOP.
2.	GQ3(a)	The DI is advised to add HTARI training to the paper copies of training sign sheets for porters.

3.	GQ6(a)	The DI is advised to separate risk assessments into risks to staff undertaking licensed activities and HTARI categories to mitigate risks to the deceased and stored tissue.
4.	PFE1(d)	The DI is advised to continue to progress existing plans to install CCTV to the temporary outside storage unit.
5.	PFE2(c)	The DI is advised to continue to progress existing plans to increase the capacity within the mortuary for the storage of bariatric bodies, and bodies requiring long-term storage.
6.	PFE2(e)	The DI is advised to install a system to alert staff of any temperature deviations in the temporary storage units prior to them being used.

Background

Queen Alexandra 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 August 2017.

There have been changes to the named personnel on the licence with a change of DI in April 2020 and Corporate Licence Holder Contact (CLHc) in July 2021.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The inspection included a visual assessment of both establishments including, body storage areas in the mortuaries and in the maternity department, PM room, viewing room and tissue storage areas. The inspection teams observed the processes for admission, release and viewing of bodies within the mortuary.

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, audits, risk assessments, meeting minutes, reported incidents and training records for mortuary staff, porters and consent seekers.

Visual inspection
The inspection included a visual assessment of the establishment including the PM room. body storage areas and viewing rooms The inspection team observed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records
Audits were conducted onsite of three bodies from refrigerated and one body from frozen storage. Identification details on bodies were crosschecked against the information recorded in the register, associated paperwork and electronic records. No discrepancies were identified.

Audits of traceability were conducted for tissue blocks and slides from five coronial consented cases. No discrepancies were identified.

Audits of traceability were conducted for whole organs from three coronial consented cases. These were limited to audits of the documentation relating to transfer of tissue offsite and consent documentation for the family wishes regarding the retention of tissue. No discrepancies were identified.

Meetings with establishment staff
Staff carrying out processes under the license were interviewed including the DI, mortuary manager, pathologist, SUDIC lead, APT, mortuary porter, bereavement midwife and consent seekers.

Report sent to DI for factual accuracy: 27 March 2023

Report returned from DI: 28 March 2023

Final report issued: 30 March 2023

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: 28 April 2023

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.