Inspection report on compliance with HTA licensing standards
Inspection date: **28-29 September 2022**

Queen's Hospital

HTA licensing number 12154

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's 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's Hospital ('the establishment') had met the majority of the HTA's standards, four major and seven minor shortfalls were found against standards for 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		

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.	At the time of inspection, procedures observed by the inspection team were not consistent with that of the Standard Operating Procedures (SOPs). These include: • condition checking of the deceased. • Identification checks during viewings and preparing the body. • release; and • retention and disposal of tissue samples processes. This is not an exhaustive list of the SOPs requiring amendment. To fully address this shortfall the establishment should review all SOPs relating to mortuary activities to ensure that they are accurate and contain sufficient detail to reflect current practice.	**Major**
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	The condition of bodies are not monitored following their initial check on admission. The inspection team identified bodies that had been in the fridge for over 30 days with no condition checks or updates to their records.	**Major**
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	Submitted risk assessments do not include all regulated activities. The following risks should also be assessed: • Viewing of a body • Loss of tissue or organs • Security breaches This is not an exhaustive list of the risk assessments required. To fully address this shortfall the establishment should review all licensed activities and associated reportable incidents. In addition to some activities not being risk assessed, others have not been updated since the last inspection.	**Major**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	Ventilation reports were unavailable. The inspection team were therefore not assured that the ventilation system provides the necessary ten air changes per hour.	**Major**

Minor Shortfalls

Standard	**Inspection findings**	**Level of shortfall**
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		

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	Mortuary SOPs are written, reviewed and authorised by the same member of staff.	**Minor**
e) There is a system for recording that staff have read and understood the latest versions of these documents	The establishment does not have a system in place to ensure doctors have read and understood documented policies and procedures relevant to the mortuary activities they undertake.	**Minor**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Whilst a schedule is in place, this does not contain an adequate sample of audits, and has not been completed since 2020.	**Minor**
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	Audits submitted do not document actions, responsible persons or timeframes of completion.	**Minor**
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 inspection team identified one set of slides that were being retained since 2019, contrary to the wishes of the family. The establishment took immediate actions to address this shortfall prior to the inspection team leaving the site.	**Minor**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		

c) There are documented cleaning and decontamination procedures and a schedule of cleaning	The inspection team found the premises to be clean with documented cleaning schedules in place, however records relating to the cleaning have not been completed since 2018.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	The inspection team identified three bodies that had been in the fridges for over 30 days. Whilst there was no sign of deterioration, updates or rationale for not transferring to the freezer were not documented.	**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 is advised to review ‘guidelines’ for paediatric and perinatal consent taking, to ensure they have the same document management as standard operating procedures.
2.	GQ1(h)	The DI is advised to establish a routine schedule of HTA governance meetings that include all relevant staff working under the licence, which has been disrupted due to the pandemic and staff changes.

3.	GQ5(a)	Whilst there is a robust procedure for reporting incidents, the DI is advised to include the HTA reportable incident classifications in the consent and porter training.
4.	PFE2(b)	The DI is advised to risk assess and monitor the use of temporary fridge units in the mortuary to ensure they are only used as contingency, as this could result in a shortfall of HTA standard PFE1(b).
5.	PFE2(e)	Mortuary staff are advised to document when they attend for out of hours fridge alarms. This can then be used as documented evidence that the procedure works.
6.	PFE3(e)	The DI is advised to remove stored items from in front of vents of the formalin preparation room, to ensure adequate ventilation.

Background

Queen's 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 January 2018.

Since the previous inspection, there has been a change to the corporate licence holder contact, designated individual and mortuary manager.

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

Visual inspection
The inspection included a visual assessment of the mortuary body storage areas, contingency storage areas, PM room, viewing room and tissue storage areas within the pathology department. The inspection teams observed the processes for admission, release and viewing of bodies within the mortuary.

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

Audits of traceability were conducted for tissue blocks and slides from four coroners consented cases. These included audits of the consent documentation for the retention of these tissues. One discrepancy was found, see shortfall T2(a)

Audits of condition checking was completed for four bodies in refrigerated storage. There were no documented condition checks, other than that from the initial admission. See shortfall GQ1(c)

Meetings with establishment staff
Staff carrying out processes under the licence were interviewed including the DI, acting mortuary manager, APT, pathologist, mortuary porter, and bereavement midwife.

Report sent to DI for factual accuracy: 04 November 2022

Report returned from DI: 12 November 2022

Final report issued: 17 November 2022

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: 19 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.