Inspection report on compliance with HTA licensing standards
Inspection date: **25-26 October 2023**

Queen's Medical Centre
HTA licensing number 12258

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 Medical Centre**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology laboratory	-	-	*Carried out*
Labour Ward		*Carried out*	*Carried out*
Accident and Emergency (A&E) department	-	*Carried out*	-

Museum	-	-	*Carried out*
Satellite site City Hospital	Licensed	Licensed	Licensed
Mortuary	-	-	*Carried out*
Labour Ward			*Carried out*
National Repository Centre	-	-	*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 Medical Centre ("the establishment") had met the majority of the HTA's standards, two major and three 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

GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
c) Procedures on body storage prevent practices that disregard the dignity of the deceased.	During the traceability audit of deceased in the mortuary, the inspection team observed inconsistencies in staff following the procedure for: • Recording of condition checks for bodies • Moving bodies into long term frozen storage when required and recording of communication about their continued storage and reason	**Major**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) Items of equipment in the mortuary are in good condition and appropriate for use	Although the premises were clean, there were several areas which required maintenance work: • Rust at the base of racking systems within the fridges, the protective metal seal coming away from the wall, and damaged doors in the body storage area • The floor between the body storage areas has several pot holes which increases the risk of accidental damage to bodies being transferred between body stores • The community body store shows signs of wear and tear with the floor coming away from the drain edges • Some of the mortuary trolleys have minor areas of rust which may make them difficult to properly disinfect	**Major**

Minor shortfalls

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits.	The documented audit schedule does not include the following: • Lone working process for viewings to ensure staff are following documented procedures • Audits of consent documentation for specimens in Neuropathology to ensure consent was taken in accordance with the requirements of the Human Tissue Act 2004	**Minor**

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.	The ventilation system in the post mortem (PM) examination room where staff undertake high risk PM examinations maintains positive pressure. This may pose a health and safety risk to staff. *(See advice, item 10)*	**Minor**

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 accepts referrals from other hospitals for paediatric pathology cases. When samples are returned to the referring establishment they do not receive confirmation of receipt of these samples.	**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.

The HTA advises the DI to consider the following to further improve practice:

Number	Standard	Advice
1.	C1 (d)	The DI is advised to include disposal of tissue samples taken from PM examination for paediatric cases as an option on the relevant consent form.
2.	C2 (b) & (d)	The DI is advised to formalise the sign off procedure for paediatric consultants to confirm they have read and understood the requirements of consent in line with the Human Tissue Act and Codes of Practice. The process for competency checks should also be recorded.
3.	GQ2 (c)	For perinatal consented PM examinations, a set number of cassettes are created and recorded on the tissue form. If not all cassettes are used, staff are advised to note the unused number of tissue cassettes on the lab system.
4.	GQ3 (a)	The DI is advised to formalise the process for recording that porters have read and understood training and include understanding of incidents that need to be externally reported in the training and include this in their competency assessments.
5.	GQ4 (a)	Staff at the National Repository Centre are advised to consider digitising the consent paper documents (e.g. scanning) and risk assess the current storage area of these paper documents.
6.	GQ5 (a)	The DI is advised to put an aide memoire in the mortuary for porters for awareness of incidents that need to be reported to the HTA.
7.	PPE1 (d)	The establishment may wish to consider extending the CCTV coverage to the area at the clinical skills suite that currently lacks coverage.
8.	PPE1 (d)	Key codes are used by staff to access the mortuary if the swipe card access points fail. The DI is advised to consider implementing a regular change of the key codes to further mitigate the risk of a security breach.

9.	PPE3 (a)	The establishment is advised to continue with their plans to: • Refurbish the clinical skills room • Replace the lift that is used by porters and mortuary staff to transfer bodies
10.	PFE3 (c)	In relation to the minor shortfall, staff are advised to use individual respirator systems to reduce the risk to the health and safety to staff.
11.	General	Staff are advised to review the labelling system for the museum specimens as part of their planned audit.

Background

Queen's Medical Centre has been licensed by the HTA since August 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in September 2019.

Mortuary

There are two mortuaries under the licence at Queen's Medical Centre and City Hospital. Mortuary processes have been aligned between the sites. PM examinations are conducted at the Queen's Medical Centre mortuary.

National Repository Centre

The National Repository Centre at City Hospital has a clinical skills suite which is located at the satellite site at City Hospital. Fresh frozen bodies and body parts are stored here for use in surgical skills training. Specimens may be transported to other establishments.

Museum

The establishment holds a large number of potted specimens that pre-date the Human Tissue Act 2004. The specimens are occasionally used for teaching pathology to medical students.

Since the previous inspection there has been a change of Corporate Licence Holder contact (CLHc) contact, change of DI and nine

Persons Designated added on 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 assessment team reviewed the establishment's self-assessment document provided by the DI in advance of the inspection. Policies and procedural documents relating to licensed activities for the mortuary, museum and national repository were reviewed. Traceability audits, risk assessments, meeting minutes, incidents, consent seeking procedures and information for relatives giving consent were also reviewed.

Visual inspection

The inspection included a visual inspection of the mortuary body stores, location of the museum specimens, contingency storage, viewing rooms, PM room and the clinical skills suite at the National Repository Centre.

Audit of records

Audits were conducted for five bodies in refrigerated storage and one body in freezer storage at the hub site and two bodies in refrigerated storage and one body in freezer storage at the satellite site. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and relevant documentation.

Audits were also conducted of museum specimens at the hub site and for bodies and specimens used for training and education at the National Repository Centre. Identification details were checked on the bodies and specimens and crosschecked against information on relevant documentation. No discrepancies were found.

Audits of traceability were conducted for tissue blocks and slides from two coronial cases and one hospital consented PM case, including audits of the consent documentation for the retention and disposal of these tissues. No discrepancies were found.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the license, including the DI, Anatomical Pathology Technologists, Porters, a Pathologist, staff at the National Repository Centre, and consent seekers for PM examinations.

Materials held for the police
Under section 39 of the HT Act, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' audit of tissue held under police authority, that police exhibits held on HTA licensed premises should be included within the regular HTA inspection process, police holdings stored in a designated area in the PM suite were reviewed by the HTA during the inspection. Any findings in relation to police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the HT Act.

Report sent to DI for factual accuracy: 22 November 2023

Report returned from DI: 6 December 2023

Final report issued: 11 December 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: 3 May 2024

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.