Inspection report on compliance with HTA licensing standards
Inspection date: **13 February 2024**

Queen Elizabeth Hospital

HTA licensing number 12368

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 Elizabeth 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 Elizabeth Hospital ('the establishment') had met the majority of the HTA's standards four major and five 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

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.	Standard Operating Procedures (SOPs) require review to ensure they are accurate and reflect practice. Examples include but are not limited to: • CP-MOR-SOP-001.UN Receipt of bodies into the mortuary refers to 'points 1 to 6 above' in the out of hours section for hospital bodies but there is only five points and 'points 1 to 7 above' in the out of hours section for community bodies, but there is eight points. The steps for admission of hospital bodies does not include adding bodies to the daily body audit form. • CP-MOR-SOP-012.UN Rapid / direct release of bodies is not clear about what documentation is used to release a body directly from a ward. • CP-MOR-SOP-035.QE Transfer of babies/ foetal remains to RVI / CFL for PM / Cytogenetics states foetuses less than 24 weeks are transferred directly to the laboratory only but also refers to foetuses transferred directly to the mortuary, which is confusing. In addition, this SOP refers to out of date documents - the 'Safe Working and the Prevention of Infection in the Mortuary and Post Mortem Room' 2003 and 'A Handbook of Mortuary Practice and Safety for Anatomical Pathology Technicians' 1991. • CP-MOR-SOP-005.UN The viewing of deceased is not reflective of current practice. There is a final check of three identifiers on the body against the viewing log form immediately prior to relatives arriving. These identifiers are then checked with the relatives when they arrive. • CP-MOR-SOP-013.UN Taking of samples at PM refers to specimens being sent off site with a tissue tracking form but does not include how this is followed up should confirmation of receipt not be received. • CP-MOR-SOP-024.QE Discard and retention of PM tissue blocks and slides and CP-MOR-SOP-28.QE Registering mortuary information on Meditech appear to be draft documents.	**Major**

	Where SOPs refer to checking three points of identification at different stages in a procedure the SOP needs to include what the identifiers could be and what they are checked against.	
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	The risk assessment for violence, aggression, security and lone working is past it's review date. Although risk assessments have been reviewed prior to the inspection, they have not always been reviewed annually in-line with the establishment's own policy. There is no risk assessment in place relating to the security or use of the external body storage unit.	**Major (Cumulative)**
b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed	Where risk ratings for an activity have been calculated at a level requiring action or escalation this has not been done. The risk ratings calculated for activities do not necessarily reflect the controls measures already in place. The inspection team was informed that permanent storage capacity for bodies is on the Trust's risk register. Despite this, the external body storage unit used during peak times of activity is due to be removed in April 2024. There are inadequate controls in place to mitigate the risk of insufficient storage capacity.	
c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register	The establishment's PM ventilation system was was tested in January 2024. The report states the ventilation system is over 20 years old and due for replacement and should be risk assessed, which has not been done. Failure of the ventilation system means the establishment cannot facilitate PM examinations.	

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The current schedule of audits for 2024 does not include the monthly mortuary swipe card access audit undertaken by the mortuary manager (see shortfall PFE1(e)). In addition, the establishment has identified the annual audit schedule does not lend itself well to ensuring audits can be completed when scheduled as audits cannot always be completed during peak times. Although audits of key activities are included in the audit schedule, the number of cases included in audits do not reflect representative numbers to provide sufficient assurance of an actvity. For example, the annual audit 'journey of a body from receipt to release' only includes one body. Evidence was not submitted to demonstrate audits were completed in 2023.	**Major**
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 establishments audits of PM tissue are scheduled annually. However, audits of PM tissue for 2019, 2020 and 2021 did not take place until 2022. Annual tissue audits mean tissue for disposal may be retained after the coroner's authority has ended; the likelihood of this increased for the years 2019 to 2021 due to the delay in these audits. While the tissue audits demonstrate that appropriate actions have been taken where instructions for tissue have not been received (disposed of), other cases were retained, for example, due to ongoing coroner's inquests. It is not clear if these cases have been subsequently followed up and dealt with either before or during subsequent annual audits. The establishment is required to review PM tissue they are storing to be assured they have appropriate consent in place to do so.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
d) Competency is assessed and maintained	Staff trained in seeking consent for post mortem (PM) examination are not competency assessed in this task.	**Minor**
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	HTA governance meetings and mortuary staff meetings have not been carried out on a regular basis and only recently re-introduced.	**Minor**
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
a) Staff know how to identify and report incidents, including those that must be reported to the HTA	Although porters are trained in mortuary activities, they are not fully aware of HTA reportable incidents (HTARIs) relevant to the activities they undertake.	**Minor**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The current security audit does not include checking mortuary swipe card access against CCTV. However, the establishment are already in the process of implementing this.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		

a) Storage arrangements ensure the dignity of the deceased	The temporary external body storage chiller unit power switch is not secured to prevent power to the unit being turned off, potentially compromising the condition of any bodies being stored in there. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised*	**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)	Although SOPs and policies relating to seeking consent refer to the hierarchy of qualifying relationships, the DI is advised to remove reference to 'next of kin' to help ensure consent is sought in line with the HT Act 2004.
2.	C2(b)	The DI is advised to ensure PM consent training is completed annually in line the hospital PM consent policy.
3.	GQ1(a)	The DI is advised to consider revising the wording 'indefinite storage' of tissue in SOPs and policies when consent is in place for retention. In reality, tissue retained as part of the medical record is usually stored for 30 years. Where SOPs are cross referenced in other SOPs and policies, the mortuary manager is advised to check these references to make sure they are correct.
4.	GQ1(a) GQ6(a)	The external body storage unit was not in use at the time of the site visit. The DI is advised to ensure that SOPs and risk assessments are in place for the operation and use of the unit if/when it is required for use again.
5.	GQ1(e)	The mortuary manager is advised to ensure that all bank APT staff are included in the Q-Pulse distribution lists for SOPs and risk assessments relevant to their work.

6.	GQ1(c)	Mortuary staff conduct daily condition checks of bodies. The DI is advised to implement a more detailed condition check at regular intervals. For example, at 14 and 21 days to help identify those bodies that may need transferring in to long-term storage.
7.	GQ6(a)	The DI is advised to seek training for staff to correctly and competently carry our risk assessments to help ensure appropriate levels of risk are identified, recorded and escalated when required.
8.	T2(a)	The DI is advised to continue with the plan to move to quarterly audits of PM tissue. This will help ensure relatives instructions for tissue are carried out in a timely manner and cases requiring continued retention, for example, inquest cases are regularly followed up and dealt with in accordance with the relatives wishes. In addition, regular audits of PM tissue blocks and slides in archive should also take place.

Background

Queen Elizabeth Hospital has been licensed by the HTA since May 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in November 2018.

Since the previous inspection, the list of Persons Designated under the licence has been updated to reflect changes in staff working 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 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 were reviewed. This included standard operating procedures, risk assessments, audits, incidents, meeting minutes, equipment servicing reports, and training and competency assessment documents. Consent seeking procedures and information for families giving consent for adult and perinatal PM examinations were also reviewed.

Visual inspection

Audit of records

The inspection team undertook audits of traceability for five bodies in storage. This included bodies with same/similar names and a body in long term storage. Traceability details were crosschecked between the identification bands on the bodies, information on the door of the body store, the mortuary register, paperwork and mortuary electronic system. Two discrepancies were identified. A body with a same/similar name did not have a same/similar name sticker on their shroud, as per the SOP and the surname of one body was incorrectly recorded on the fridge door.

Audits were conducted of stored tissue taken at PM examination for five cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms and tissue being stored. Two minor discrepnacies were identified. The spelling of two names in the mortuary specimen log book differed to other documentation and electronic records.

Meetings with establishment staff

The assessment team met with staff carrying out processes under the licence, including cellular pathology and mortuary staff, quality manager, a portering staff member, pathologist staff involved in the consent seeking process for adult and perinatal PM examination, staff responsible for the removal of relevant material in the Emergency Department and the DI.

Report sent to DI for factual accuracy: 18 March 2024

Report returned from DI: 1 April 2024

Final report issued: 8 April 2024

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 December 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.