Inspection report on compliance with HTA licensing standards
Inspection date: **28 September 2023**

East Ham Public Mortuary

HTA licensing number 12032

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 **East Ham Public Mortuary**	Licensed	Not licensed	Licensed
Mortuary	*Carried out*	-	*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 East Ham Public Mortuary (‘the establishment’) had met the majority of the HTA’s standards, three major and six minor shortfalls were found against standards for governance, quality systems, mortuary security, and fridge alarm arrangements.

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) lack sufficient detail. Key steps are included but these do not specify the individual actions that need to be undertaken to accomplish each step. These include, but are not limited to, SOPs detailing the process for: • Checking of three unique identifiers each time a body is admitted, transferred to a new location, or released to a funeral service; • Checking and recording condition of bodies at regular intervals; • The documented procedure of booking, preparing the body and meeting families for viewings and police identifications; • Contingency plans and temperature monitoring of fridges and freezers; • The requirement to report near miss incidents. 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. *The inspection team gained assurance that whilst not documented the above procedures were embedded into mortuary practices.*	**Major**
GQ2 There is a documented system of audit		

a) There is a documented schedule of audits	There is no documented audit schedule for regulated activities within the mortuary. *This was identified as a shortfall at the last inspection. Whilst addressed at the time the documented audit schedule was not embedded into mortuary routine or practice.*	**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	Key procedures relating to licensed activities are not included on the mortuary risk assessment schedule. These include: • Risk of removal of tissue without consent; • Risk of loss of tissue or organs; • Risk to delivery of service; • Risk to mortuary security and unauthorised access. Furthermore, existing risk assessments do not include adequate detail in mitigation controls and actions.	**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	Documents are reviewed on a regular basis by someone other than the author, however they are not version controlled and staff could not evidence original authors, or previous review details.	**Minor**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Whilst HTA-licensed activities are discussed, these are not at formal documented meetings which include all mortuary staff.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
c) Staff are assessed as competent for the tasks they perform	There is no formal, documented procedure to assess mortuary staff as competent for the tasks they perform.	**Minor**
f) There is a documented induction and training programme for new mortuary staff	Whilst new mortuary staff have an induction to the organisation, this does not include mortuary specific areas or regulated activities.	**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	Key fobs are shared between contracted funeral staff. This combined with the lack of access audits and internal CCTV poses a risk that establishment staff cannot monitor who has entered the mortuary out of hours. *See shortfall GQ6(a)*	**Minor**
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	Trigger points for fridge alarms are currently too low. Whilst temperatures are regularly monitored, this poses a risk of accidental freezing of a body without mortuary staff being aware out of working hours.	**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.	GQ1(d)	The DI is advised to review the method of recording the author, authoriser of reviewer of mortuary documentation, as the current method of recording this on the document header includes discrepancies.
2.	GQ5(a)	The DI and mortuary manager are advised to further staff's understanding of the HTARI classifications and reporting procedure by displaying this information in working areas, available to visiting funeral and mortuary staff.
3.	PFE1(d)	The DI and mortuary manager are advised to monitor small areas of splinted wood on door panels, within the fridge room to ensure they do not deteriorate further as this could result in a shortfall of HTA standard PFE1(d).
4.	PFE3(a)	The DI and mortuary manager are advised to monitor minor rust to the mortuary trolleys and tables to ensure they do not deteriorate further as this could result in a shortfall of HTA standard PFE3(a).

5.	PFE3(e)	Whilst suitable mitigations are in place, the DI is advised to review the servicing of the fume cupboard within the post mortem room. This will further mitigate the risk to staff when decanting formalin.

Background

East Ham Public Mortuary has been licensed by the HTA since 26 July 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in April 2019.

Since the previous inspection, there has been a change to the mortuary staffing structure, and a new Corporate Licence Holder contact, in January 2020. The mortuary has had upgrades to facilities, refrigeration, ventilation, and security systems.

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

57 out of the 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017). 11 standards regarding consent and four standards regarding retained tissue were not applicable to the regulated activities carried out by the establishment.

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, cleaning records for the mortuary, records of servicing of equipment, risk assessments, meeting minutes, reported incidents and training records for staff.

Visual inspection

The inspection included a visual assessment of the mortuary fridge room, post mortem room and viewing facilities. The inspection team observed the processes for admission, release and viewing of bodies within the mortuary.

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

Audits of traceability were conducted for tissue blocks and slides from three coronial consented cases. These included audits of the consent documentation for the transfer of the tissue on and off site. No discrepancies were identified.

Meetings with establishment staff
Staff carrying out processes under the licence were interviewed including the DI, APT, pathologist and CLH contact.

Report sent to DI for factual accuracy: 16 October 2023

Report returned from DI: 23 October 2023

Final report issued: 24 October 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: 17 April 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.