Inspection report on compliance with HTA licensing standards
Inspection date: **19 & 27 April 2023**

Poplar Public Mortuary
HTA licensing number 12087

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 **Poplar Public Mortuary**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*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 Poplar Public Mortuary ('the establishment') had met the majority of the HTA's standards, nine major and four minor shortfalls were found against standards for Governance and quality systems, Traceability and Premises, facilities and equipment. These related to consent competency assessment, SOPs, audit schedule, record security, cleaning and maintenance and the identification of bodies.

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		
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	The current SOP relating to release refers to the storage of bodies in the post mortem room after being removed from frozen storage to allow them to defrost prior to post-mortem examination. Whilst staff indicated that this does not in practice take place, it is included in the SOP. This practice presents a risk to the dignity and security of the deceased. The inspection team noted two bodies in storage for over thirty days which had not been transferred to frozen storage. One body showed signs of early decomposition. This presents a risk to the dignity of the deceased by accidental damage.	**Major**
GQ4 There is a systematic and planned approach to the management of records		

a) There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record	Some mortuary records were stored in unlocked cabinets in the funeral director entrance. Whilst contracted funeral directors have restricted access to the rest of the mortuary, they have access to this area unsupervised out-of-hours.	**Major**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
a) The premises are clean and well maintained	The post-mortem (PM) room tables are showing signs of wear and there are areas of rusting and damage in the sinks. Repairs completed are not optimal and risk not being able to fully decontaminate. Furthermore, the PM room floor had a large area of pooled water which indicated a leak from one of the PM tables. The interior of the fridges require decontaminating. The bases of the fridge units require cleaning. The blinds to the viewing room window were broken and had not yet been replaced, meaning families are providing identification outside the building in a courtyard.	**Major**
c) There are documented cleaning and decontamination procedures and a schedule of cleaning	There is no cleaning record for the body store.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Whilst some audits are taking place, there is no documented audit schedule in place.	**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	The DI disclosed an incident relating to a fire door to the PM room being left open. Whilst there was no adverse outcome this incident had not been reported to HTA as a near-miss incident.	**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	The fridge and freezer alarms are not routinely subject to testing, although a test had been completed on the day of the inspection.	**Minor**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		

f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept	Fridges and freezers are not subject to regular servicing.	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier	The date of birth is not routinely recorded on mortuary systems and is occasionally substituted by age which is not a robust identifier – although all deceased audited were traceable with the date of death. The date of movement of bodies to freezer storage is not routinely recorded.	**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.	PFE2(c)	The DI is advised to review the procedure for contingency transfer off site, where capacity for frozen storage is reached and communication with the Coroner permitting freezing of bodies that have been cleared for Coroner purposes.
2.	PFE3(d)	Whilst staff have access to necessary PPE, some staff were observed wearing regular clothing whilst working. The DI is advised to ensure that all staff utilise PPE whilst working in the body store.

3.	GQ3(a)	Whilst all staff have regular 1-1s and competency checks performed, the DI is advised to consider implementing an overarching record of all staff training and competency assessment. This would allow the DI to see at a glance which staff have been trained and assessed as competent in relevant mortuary key tasks.

Background

Poplar Public Mortuary has been licensed by the HTA since 5 June 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in November 2019.

Since the previous inspection, there has been a change to the Designated Individual (DI). The current DI has been authorised since January 2023. Whilst the establishment is managed by the London Borough of Tower Hamlets, the mortuary is currently staffed by a team from the London Borough of Waltham Forest, this includes the Designated Individual. This is documented in a service level agreement and is likely to be reviewed later this year.

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 establishments self-assessment document provided by the DI in advance of the inspection. Policies and procedural documents relating to licensed activities were reviewed. The team also undertook a review of records relating to equipment servicing, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the

storage units and mortuary, reported incidents, and staff training. Consent seeking procedures and information for relatives giving consent were also reviewed.

Visual inspection
The inspection team undertook a visual inspection of the premises which included the mortuary and body storage areas.

Audit of records
The inspection team undertook audits of traceability for five bodies in storage. Traceability details were crosschecked between the identification band on the body, information on the digital system and paper mortuary register. One minor discrepancy was noted which was immediately corrected by staff. It was noted that the date of birth is not routinely recorded on mortuary systems and is occasionally substituted by age which is not a robust identifier.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence, including mortuary staff, staff involved in the consent seeking process who is also the DI.

Report sent to DI for factual accuracy: 24 May 2023

Report returned from DI: 2 June 2023

Final report issued: 5 June 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: 8 September 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.