Inspection report on compliance with HTA licensing standards
Inspection date: **25 April 2024**

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
Poplar Public Mortuary	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*

Summary of inspection findings

The HTA found the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation. The Designated Individual (DI) is responsible for oversight of two licensed establishments. Concern has been raised over the ability of the DI to commit the necessary time to fulfil duties required by the role at both establishments. The suitability of the DI will remain under review.

Although the HTA found that Poplar Public Mortuary ('the establishment') had met the majority of the HTA's standards, two critical and three major 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

Critical Shortfalls

Standard	Inspection findings	Level of shortfall
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	Bodies that are admitted with unknown identity only have two forms of identification present recorded on documentation despite three or more forms of identification being present on ID bands. Furthermore, on occasion trained volunteers release bodies without direct supervision. (*See advice item 1*)	**Critical**
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 premises were not effectively decontaminated when inspected. Areas including the Post Mortem room, fridge room and fridge floors displayed evidence of debris and body fluids that had not been cleaned. Some items of equipment were also contaminated with body fluids.	**Critical**

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.	SOPs reviewed were not in line with practices being undertaken at the establishment. For example SOPs state that alert bands should be attached to bodies carrying high risk pathogens however these bands were not in use at the time of the inspection. Information pertaining to the safe handling of inanimate loads stated in SOPs were different from notices in the Mortuary.	**Major**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised	At the time of the inspection, staff were not appropriately supervised. A Trainee APT is permanently based in Poplar Mortuary with qualified staff working at the establishment on a rotational basis. At the time of the inspection qualified staff were not present to supervise the Trainee. Poplar Mortuary also utilises a volunteer who was supervised by the Trainee APT. Furthermore, the duties of the volunteer include the release of bodies which is undertaken without direct supervision of permanent staff.	**Major**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records)	Whilst there is a system in place to track each body, fridge location numbers are not updated on paper documentation to reflect movement of the deceased. This presents a risk of releasing the wrong body.	**Major**

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.	T1c	The DI is advised to use Police log numbers as a third unique identifier when unidentified bodies are admitted to the Mortuary.

Background

Poplar Public Mortuary has been licensed by the HTA since June 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in April 2023

Since the previous inspection, the Corporate Licence Holder contact has changed.

The inspection team undertook an unannounced site visit inspection following concerns relating to traceability that may impact dignity of the deceased. Accordingly, this inspection focused on the following standards: GQ1(a), GQ1(c), GQ1(e), GQ3(a), GQ3(c), GQ3(f), GQ3(g), T1(a), T1(b), T1(c), T1(f), PFE1(a), PFE1(b), PFE1(c), PFE2(a), PFE2(g) and PFE3 (d).

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:

Review of governance documentation
A review of staff training and competency assessments was undertaken. A full review of the remaining governance documentation will be undertaken at the next routine inspection to be scheduled.

Visual inspection
The inspection included an on-site visual assessment of the security arrangements, body storage areas in the mortuary, PM room and tissue storage areas.

Audit of records
A traceability audit of five bodies in storage was undertaken. This included bodies from the community including those with same and similar names and one in long term storage. Details were cross checked against identity bands and the mortuaries' electronic database. Three discrepancies were found.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the license. This included the Corporate License Holder contact, Designated Individual, Trainee Anatomical Pathology Technologist and Mortuary volunteer.

Report sent to DI for factual accuracy: 2 May 2024

Report returned from DI: 16 May 2024

Final report issued: 17 May 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: 23 September 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.