Inspection report on compliance with HTA licensing standards
Inspection date: **15 November 2023**

City of Westminster Public Mortuary

HTA licensing number 12188

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 **Westminster 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 City of Westminster Public Mortuary ('the establishment') had met the majority of the HTA's standards, four major and six 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

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Although the establishment has undertaken audits, the audit schedule does not include all licensable activities for example, security and viewing forms. Regular vertical audits have not been undertaken of compliance with mortuary procedures, traceability of bodies and mortuary records.	**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	Not all procedures relating to licensed activities have been risk assessed. These include but are not limited to: • accidental damage to a body. • security. • viewing of the wrong body. This is not an exhaustive list of the risks not assessed and, to fully address this shortfall, the establishment should review all risk assessments relating to all licensed activities to ensure that all risks have been identified.	**Major**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		

d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access)	Although the establishment has had swipe card access installed this is currently not active and does not extend to the external access doors. Access to the mortuary by the external doors is currently by key only. Access to the site is by an electronic access controlled gate however, at the time of the inspection the electronic controlled access was broken and the gate was secured by a padlock only. There is a risk that a security breach could occur with the limited secure access in place out of hours. The establishment has no CCTV coverage in the body store areas. *See advice item 4.*	**Major**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	Although swipe card access has been installed this has not been activated and there are no CCTV cameras in place, so the establishment cannot assure themselves oversight of persons who have legitimate access out of hours.	**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	Although standard operating procedures (SOPs) are reviewed by someone other than the author there is no version control on the documents. This poses a risk that staff may follow a previous version of the procedure.	**Minor**
GQ2 There is a documented system of audit		

b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	The audit template does not include a timeframe for completion of the audit finding.	**Minor**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
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	The establishment's risk assessments do not include all mitigating actions to reduce the risk score.	**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	Three identifiers are not recorded on the viewing from those wishing to view the deceased. This poses a risk of viewing the wrong body.	**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	There is no lower alarm trigger point for the fridge units to mitigate the risk of unintentionally freezing bodies. Although not currently in use the temporary unit is not alarmed meaning staff will not be alerted if temperatures deviate from the expected range out of hours.	**Minor**
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	The trolleys have multiple areas of rust. This means it is difficult for staff to adequately clean and disinfect this equipment.	**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 look at how updated versions of SOPs are disseminated to all staff working under the licence and that there is a record staff have signed that they have read and understood the updated versions.
2.	GQ3(h)	The DI is advised to minute the mortuary meetings and that the minutes are available for the visiting pathologists to read to ensure that any changes or lessons learnt are disseminated to all staff involved in mortuary activities.
3.	GQ5(a)	The DI is advised to create and display an aide memoire of HTARI categories and process of notifying on-call staff in the body store area for reference for staff admitting deceased out of hours.
4.	PFE1(d)	The DI is advised to look at installing motion activated CCTV cameras in the body store areas to ensure that activities in these areas have the appropriate oversight.
5.	PFE3(c)	The DI is advised to move forward in actioning the high and medium recommendations highlighted in the latest ventilation report.

Background

City of Westminster Public Mortuary (WPM) is licensed for the making of a PM examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes.

WPM has been licensed by the HTA since June 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in August 2021.

Since the previous inspection, there have been no significant changes to the licence arrangements, or the activities carried out under the

licence. However, the establishment is due to undergo major building work in 2024 to provide additional capacity, including long term and bariatric storage.

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

56 of the 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017), standards C1(a-g), C2 (a-d) are not applicable as the establishment does not seek consent for post mortem examinations. Standards GQ2(c) and T2 (a-d) were not assessed as the establishment does not store or dispose of tissue taken during post mortem examinations.

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 relating to licensed activities, cleaning records for the mortuary, records of servicing of equipment, audits, risk assessments, meeting minutes, reported incidents and training records for mortuary staff.

Visual inspection

The inspection included a visual assessment of the establishment including body storage areas and viewing rooms.

Audit of records

Audits were conducted onsite of bodies from four bodies in refrigerated storage and one body in long term frozen storage. Identification details on bodies were crosschecked against the information recorded in the register and associated paperwork in addition to information held electronically. No discrepancies were identified.

Audits of traceability were conducted for tissue removed at PM. These were limited to audits of the documentation relating to transfer of tissue offsite for analysis and confirmation of receipt from the receiving establishment. No discrepancies were identified.

Meetings with establishment staff

Staff carrying out processes under the license were interviewed including the DI, senior anatomical pathology technologist (APT) and trainee APT.

Report sent to DI for factual accuracy: 21 December 2023

Report returned from DI: No Response From Establishment

Final report issued: 18 January 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.