Inspection report on compliance with HTA licensing standards
Inspection date: **17-18 August 2021**

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 **City of 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, one major and five 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
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 alarm system for the toxicology fridge. The temperature alarm trigger points for the fridges and freezers are not set at appropriate temperatures to ensure that the alarms will trigger when storage temperatures deviate from acceptable ranges. Mortuary staff stated that Corporate Estates carry out testing of the fridge and freezer temperature alarms but could not provide evidence of assurance of this or that call-out procedures were tested and are followed.	**Major**

Minor 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) relating to mortuary activities lack sufficient detail to ensure to ensure they are accurate and reflect current practice.	**Minor**
c) Procedures on body storage prevent practices that disregard the dignity of the deceased.	The establishment do not document the condition of bodies at any point during the length of stay in the mortuary.	**Minor**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits.	Although the establishment has undertaken audits, regular vertical audits have not been undertaken of compliance with mortuary procedures, traceability of bodies and mortuary records.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		

g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures.	The establishment has no documentation for funeral directors to train or induct them on local mortuary procedures. The establishment verbally induct visiting trainee pathologists or external visitors, such as observers of post-mortem examinations, but do not document that the establishment's local policies and procedures have been read and understood.	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The establishment does not receive confirmation that PM specimens have been received at the toxicology laboratories. The procedures for traceability of PM samples do not provide a full audit trail of transfer of the samples off-site.	**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.	GQ1h	The DI is advised to ensure that all external staff involved in licensable activities are informed of matters relating to the establishment's HTA licence.
2.	GQ5b	The DI is advised to ensure that funeral directors working in the mortuary out of hours are aware of the HTARI reporting requirements and the procedure to follow in the event of an incident occurring out of hours.

3.	GQ5c	The DI is advised to ensure that the root cause investigation of incidents involving visiting personnel are followed up by the establishment once the staff member has returned to their permanent place of work.
4.	GQ5d	The DI is advised to ensure that information about incidents is shared with external staff involved in licensable activities.
5.	PFE2f	The frequency of the temperature monitoring may not enable the establishment to identify trends and the extent of any variations in storage temperatures.
6.	PFE2h	The DI is advised to ensure that on the rare occasion that bodies of babies and infants are stored at the establishment that the storage arrangements are included in the SOP.
7.	PFE3c	The DI is advised to ensure that the medium and high priority findings identified in the last ventilation servicing report have been resolved.

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 September 2015.

Since the previous inspection, there have been no significant changes to the licence arrangements, or the activities carried out 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
Standards C1a-g, C2a-d and T2a-d were not assessed as they are not applicable to the activities undertaken. Standards GQ3d, GQ4b, PFE1a, PFE1b and PFE2d are applicable but were not assessed as this was a virtual regulatory assessment.
The remaining 52 HTA licensing standards (standards published 3 April 2017) were assessed.

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, records of equipment servicing, audits, risk assessments, meeting minutes and reported incidents.

Visual inspection
No visual inspection was undertaken as part of this inspection.

Meetings with establishment staff
Staff carrying out processes under the licence were interviewed including the DI, senior Anatomical Pathology Technologist and a Pathologist.

Report sent to DI for factual accuracy: 2 September 2021

Report returned from DI: 28 September 2021

Final report issued: 22 November 2021

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 Virtual Regulatory Assessment Report.

Date: 27 April 2022

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.