

Walthamstow Public Mortuary
HTA licensing number 12420

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
Walthamstow Public Mortuary	Licensed	Licensed	Licensed
Mortuary	<i>Carried out</i>	<i>Carried out</i>	<i>Carried out</i>

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 **Walthamstow Public Mortuary** ('the establishment') had met the majority of the HTA's standards, one major and one 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.

Major shortfalls

Standard	Inspection findings	Level of shortfall
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods	The mortuary is not connected to a back-up generator system. In the event of a power failure, there is a risk to the dignity of the deceased. Whilst there is the possibility of transferring bodies to another HTA licensed establishment, this arrangement is insufficient due to the extent of storage facilities that would be required.	Major

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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 unauthorised access and ensure oversight of visitors and contractors who have a legitimate right of access	Whilst cameras are in place throughout the building, entry points to the PM and CT rooms are not covered by CCTV. This system does not give effective oversight of persons entering the Mortuary.	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 (a)	SOPs relating to lone working outline the use of mobile phones to raise an alarm in event of an incident. The SOP does not specify who should be contacted in this event. The DI may wish to consider formalising an escalation process including a point of contact that is permanently available.
2.	PFE1 (b)	At the time of inspection building works are incomplete. Whilst these clean, dirty and transition areas are defined the DI is advised to install measures to demarcate these areas.
3.	PFE1 (e)	Viewing of bodies is undertaken by the use of a window into a dedicated area of the fridge room. A curtain is to be installed to prevent fridges from being visible during the viewing process. A CCTV camera is installed in the corner of the room and may be obscured by the placement of the curtain. The DI is advised to consider this fact before installation of the curtain. Furthermore the DI is advised to consider installation of additional panic devices in the viewing area.

Background

Walthamstow Public Mortuary has recently been rebuilt following a programme of redevelopment. The Mortuary offers facilities for post mortem examination, CT scanning and storage of bodies of the deceased and relevant material for use for scheduled purposes.

Walthamstow Public Mortuary has been licensed by the HTA since 26 June 2007. This was the first inspection of the establishment since its rebuild in 2024 but the fourth under this licence; the most recent previous inspection took place in April 2023 covering the

satellite site at Chingford Mount Cemetery.

Since the previous inspection, the licence for “Making of a post-mortem examination” and “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 arrangements or the activities carried out under the licence” has been suspended whilst redevelopment work is undertaken. The establishment have made an application to be relicensed for these activities in April 2024.

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

43, out of the total 72, were covered during the inspection (standards published 3 April 2017). The inspection was focused on standards GQ1, GQ2, GQ3, GQ4, T1, PFE1, and PFE2

Review of governance documentation

The inspection team reviewed the establishment’s self-assessment document provided by the DI ahead of inspection. Standard operating procedures, risk assessments and policies were reviewed. Audit schedules, cleaning record forms, meeting minutes and a ventilation report were inspected as part of the review process.

Visual inspection

The inspection of the facility included a visual assessment of the Mortuary, viewing facilities and post mortem room.

Audit of records

No audits were conducted during the inspection process. The facility was not operational at the time of the inspection and is due to open imminently.

Meetings with establishment staff

As the facility was not operational at the time of inspection only one interview with the Designated Individual was conducted.

Report sent to DI for factual accuracy: 9 April 2024

Report returned from DI: 30 April 2024 No factual accuracy or request for redaction comments were made by the DI

Final report issued: 30 April 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: 3 October 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.