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



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
Hub site Walthamstow Public Mortuary	Not licensed	Not licensed	Licensed
Mortuary	-	-	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.

Walthamstow Public Mortuary ('the establishment') was found to have met all HTA standards assessed during this inspection.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Compliance with HTA standards

All applicable HTA standards assessed have been assessed as fully met.

Advice

The HTA advises the DI to consider the following to further improve practice:

Number	Standard	Advice
1.	PFE1 d)	The premises are secure, within a locked compound with high fencing. The DI is advised to secure the access to the fridge and freezer controls within the compound. This would prevent tampering should exterior security be breached.

Background

Walthamstow Public Mortuary has been licensed by the HTA since 26 June 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in November 2018.

Since the previous inspection, there have been significant changes to the licence arrangements and activities carried out under the licence.

The mortuary site at Queens Road, Walthamstow, E17 is closed and is currently subject to a full rebuild. This is scheduled to be completed in the later part of 2023. Mortuary services are reduced to body storage which is taking place at a purpose built facility at Chingford Mount Cemetery, E4. This facility consists of an office and refrigerated containers for the storage of bodies. The facility is gated and surrounded by 12 foot fencing on all sides. Licensed activities relating to post mortem was ceased in August 2022 and removal of relevant material ceased in October 2022. Staff working under this licence are also deployed to work at the Poplar Public Mortuary site under licence 12087. The Designated Individual for Walthamstow is also currently the DI for Poplar. This arrangement is managed by formal agreement between the London Borough of Waltham Forest and the London Borough of Tower Hamlets. Post mortem services take place by arrangement with other HTA licensed premises when required.

This arrangement is likely to be reviewed in late 2023 when building work is completed at Walthamstow.

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

A total of 25 of the 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017). The inspection was focused on traceability and premises facilities and equipment. Standards covered - T1 a, b, c, d, e, f and h. PFE1 a, b, c, d, e, f, g, i. PFE 3 a, b, d, e, f. Standards relating to consent and governance and quality were not assessed during this inspection.

Visual inspection

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

Audit of records

The inspection team undertook audits of traceability for four bodies in storage. Traceability details were crosschecked between the identification band on the body, information on the digital system and paper mortuary records. No discrepancies were noted.

Meetings with establishment staff

The inspection team met with staff carrying out processes under the licence, including mortuary staff and the DI.

Report sent to DI for factual accuracy: 22 May 2023

Report returned from DI: 23 May 2023

Final report issued: 23 May 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.	