Inspection report on compliance with HTA licensing standards
Inspection date: **14 November 2023**

Fulham Public Mortuary
HTA licensing number 12489

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
Fulham 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 Fulham Public Mortuary ('the establishment') had met the majority of the HTA's standards, five major and three minor shortfalls were found against standards for Consent, 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
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The establishment has started to undertake audits; however, an audit schedule is not yet in place. Whilst CCTV and partial swipe access is present in the facility there are no audits of the access to visitors' areas. This is due to the lack of swipe access in this area. A visitor log book records entry and exit to the facility however this does not record access to the internal areas.	**Major**
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	Issues were identified with the maintenance of the establishment, making it difficult to adequately clean or decontaminate the body store areas, posing a potential health and safety risk to mortuary staff and visitors. Issues include but are not limited to: • Within the body store, areas of damage to ceilings had not been repaired following maintenance. • Areas of damage were present on the walls of the body store. • Within the post mortem (PM) room the floor is worn leaving areas of porous surface exposed. There are cracks present in the surface of the floor. The floor is uneven with limited drainage causing water to pool. • There are small areas of exposed plaster in the PM room walls and an area of water damage on the wall. These areas are permeable and could prevent effective decontamination.	**Major**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	Swipe card access is installed in parts of the building and some entrances. The absence of swipe access on the public access door and internal visitors' areas within the building prevents effective oversight of visitors to the facility.	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	There is a partially glazed clear glass door between the body store and the PM room. There is a risk of unintentional oversight of PM room activities by Funeral Directors visiting the mortuary. The lower alarm trigger points for the fridges in the body store are set at 0^{o}C. This will not ensure the alarms are triggered at appropriate temperatures to optimally maintain bodies stored.	**Major**
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	The fridge unit for storage of specimens pending collection is not connected to the remote alarm system and is in an area where the local alarm would not be heard out-of-hours. This poses a risk of the deterioration of samples should there be an equipment failure. The lower temperature range of body store fridges is not routinely tested. This does not provide assurance that the alarms will trigger when temperatures deviate from the expected range.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	Whilst bodies are checked and their condition is recorded upon arrival, and it was evident that staff are monitoring condition, there is no documented procedure in place for this process.	**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	Whilst equipment is serviced the following items require attention: • The fridge used to store specimens in the PM room has areas of rust present. • Some evisceration docking stations have areas of rust forming at their base. • Dissection board stands have areas of rust present. • Trollies do not reach all levels of the freezer which reduces operational capacity. • The racking inside the contingency store unit is not secure and presents a risk of risk of accidental damage to bodies. (See *Advice* item 5)	**Minor**
f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept	The inspection team noted that hydraulic trolleys have not been serviced recently. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**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(b)	The DI is advised to review SOPs and ensure that number indexing is correct.
2.	T1(b)	The DI should review mortuary body traceability systems and consider condensing the number of paper and electronic records to reduce the risk of errors. Furthermore, the DI may wish to consider the use of a single unique reference number added at admission instead of two reference numbers, which is the current practice. The contingency storage unit does not have any location identification numbering. The DI is advised to number the doors and body trays to assist with traceability.
3.	PFE1(c)	Records of cleaning for various areas of the Mortuary are completed. The DI is advised to review the format of these records to reflect what specific tasks are undertaken as part of the cleaning process.
4.	PFE2(f)	The DI is advised to review trends in storage temperatures. This may help to identify trends and the extent of any variations in storage temperatures.
5.	PFE3(a)	There is a single saw unit in the Mortuary. The DI is advised to consider procuring a second unit for contingency purposes.
6.	PFE3(c)	The DI is advised to consider running the ventilation permanently to assist with humidity within the PM room. Humidity could pose a health and safety risk to staff when working for extended periods of time in the PM room.

Background

Fulham Public Mortuary has been licensed by the HTA since May 2008. This was the fourth inspection of the establishment; the most recent previous inspection took place in June 2019.

Since the previous inspection, there have been changes to the Corporate Licence Holder contact, Designated individual and Persons Designate.

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

39 out of the total 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017). The inspection focused on standards GQ1, GQ2, T1, PFE1, PFE2 and PFE3.

Review of governance documentation

The inspection team reviewed the establishment's self-assessment document provided by the DI ahead of inspection. Standard operating procedures and policies were reviewed. Audits, cleaning records, meeting minutes and a ventilation report were inspected as part of the review process.

Visual inspection

The inspection included a visual assessment of the mortuary viewing facilities, body storage areas and post mortem room.

Audit of records

A traceability audit of three bodies in storage was undertaken. This included bodies from the community. Details were cross checked against identity bands; mortuary register and an electronic database. No discrepancies were found.

Audits were conducted of tissue taken at post mortem (PM) examination for three cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, consent for PM examination forms and electronic records. No discrepancies were found.

Meetings with establishment staff
The inspection team conducted interviews with staff carrying out processes under the licence. This included the Designated Individual, Pathologist and Trainee APT.

Report sent to DI for factual accuracy: 4 December 2023

Report returned from DI: 5 December 2023

Final report issued: 8 December 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.