Site visit inspection report on compliance with HTA licensing standards
Inspection date: **21 January 2020**

Hackney Public Mortuary

HTA licensing number 12045

Licensed under the Human Tissue Act 2004

Licensed activities

The table below denotes whether the site is licensed to carry out an activity and whether or not the activity is currently carried out.

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
Hackney 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 Hackney Public Mortuary (the establishment) had met the majority of the HTA's standards, six major and three 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
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) do not include sufficient details of procedures. • The SOPs for receiving and releasing bodies from the mortuary, conducting a routine post-mortem (PM) examination and viewings of bodies do not include sufficient details of what identifiers could be used to identify the deceased and how identification checks should be performed. • The SOPs for sending toxicology and histopathology samples off-site do not contain sufficient detail of the procedure to store the material prior to collection and confirm receipt from the receiving establishments. • The establishment's HTA reportable incident (HTARI) SOP does not include the requirement to report near miss HTARIs to the HTA. In addition, the HTARI classifications detailed in the SOP are not up to date.	**Major**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	There is a limited audit schedule for licensed activities. Regular horizontal and vertical audits have not been undertaken of compliance with mortuary procedures, traceability of bodies and mortuary records.	**Major**

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	Procedures for identification of bodies do not always use a minimum of three identifiers of the deceased. • Identification of bodies for release from the mortuary to funeral directors may be performed using only two identifiers of the deceased provided by the funeral directors. • Identification of bodies for PM examination may be performed using only two identifiers. • Identification of bodies for viewings may be based on only two identifiers of the deceased (full name and address) provided by the family at the time of arranging a viewing and upon arrival at the mortuary.	**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	The floor of the PM room is showing signs of wear. • There are cracks in the tiles of the floor. • Areas of the floor at the base of the sinks are corroded. This means that the floor surface is difficult to clean and disinfect adequately.	**Major**
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 temperature monitoring or alarm system for the specimen fridge. The permanent fridge and freezer units for body storage are not connected to a remote alarm system. The department is not staffed at all times and this means that the local alarm may not be heard and responded to. Although the temperature alarm system is manually challenged to ensure that it will trigger as expected, these tests are not recorded.	**Major**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	The establishment cannot provide evidence that the PM room ventilation system has been serviced regularly. The last available report was from 2017 and did not provide evidence of the air changes within the PM room.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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	Funeral directors are trained by the mortuary staff to admit bodies into the mortuary out of hours. These funeral directors have not acknowledged that they have read and understood the establishment's SOPs for this activity.	**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 procedures for traceability of PM samples do not provide a full audit trail of transfer of the samples off-site. • The establishment does not receive confirmation that PM specimens are received at the histopathology or toxicology laboratories. • The inspection team's audit of tissue traceability found that for one case, PM tissue and toxicology specimens transported to the laboratories had not been signed for by couriers collecting the specimens.	**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	There are large areas of rust on the trolleys in the post mortem room and body store. There are areas of rust on the feet and legs of the post mortem tables This means that these items of equipment cannot be cleaned and disinfected adequately.	**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.	GQ2(c)	The DI is advised to document any verbal clarification of the consent wishes of the family relating to the fate of organs.
2.	GQ5(b)	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.	PFE1(a)	The DI is advised to review the condition of the viewing suite and waiting rooms. These rooms are showing signs of wear. There is some water damage to the ceiling and some areas of damage to the walls.
4.	PFE1(e)	The DI may wish to consider holding a list of the names of the funeral directors who have access to the establishment out of hours.

Background
Hackney Pubic Mortuary 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.

Hackney Public Mortuary has been licensed by the HTA since August 2011. This was the third site visit inspection of the establishment; the most recent previous inspection took place in October 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 under C1 and C2 were not assessed as they are not applicable to the activities undertaken. The remaining 57 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, cleaning records for the mortuary and PM room, contracts for servicing of equipment and records of servicing, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training records.

Visual inspection

The inspection included a visual inspection of the mortuary body store, PM room and viewing room.

Audit of records

Audits were conducted for three bodies in refrigerated storage. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and relevant documentation.

Audits of traceability were conducted for tissue samples taken from four PM cases, including audits of consent documentation for the retention of tissues. Information was crosschecked against paper records. Discrepancies were found for two cases. For one case the date and time of collection of the toxicology and histopathology samples was not recorded. For second case, whilst there was information about consent wishes for the whole organ retained at PM examination, the form did not distinguish between tissue blocks and organs for the fate of the tissue (*see Advice, item one*).

Meetings with establishment staff

The inspection team interviewed staff carrying out processes under the licence, including a consultant pathologist and the DI.

Report sent to DI for factual accuracy: 12 February 2020

Report returned from DI: 25 February 2020

Final report issued: 30 March 2020

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 site visit 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 site visit.

   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 site visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine site visit inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.