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

Haringey Public Mortuary
HTA licensing number 12263

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 **Haringey Public Mortuary**	Licensed	Not licensed	Licensed
Mortuary	*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 Haringey Public Mortuary ('the establishment') had met the majority of the HTA's standards, two major and eight minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises,

facilities and equipment. These related to monitoring and alarm procedures for a refrigerated unit in use, standard operating procedures (SOPs), security and traceability audits, mortuary staff induction and competency assessment, risk assessments and maintenance of the mortuary.

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	The establishment have a fridge in use for the storage of samples taken at PM examination awaiting transfer for specialist analysis. This unit 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.	**Major (cumulative)**
f) Temperatures of fridges and freezers are monitored on a regular basis	The fridge for the storage of samples is not temperature monitored on a regular basis.	
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Whilst the premises are secure and there are systems in place to prevent unauthorised access, security audits of access and review of CCTV are not currently undertaken. *(see Advice item, 8)*	**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.	Some SOPs do not always include sufficient detail of procedures or fully reflect current practice. These include but are not limited to: • The long-term storage SOP does not include detail of the identification check performed prior to movement of bodies into long term storage. • The mortuary viewings SOP does not contain sufficient detail of the check performed in practice to ensure the correct visitors have arrived to view the correct body. To fully address this shortfall the establishment should review all SOPs to ensure they contain sufficient detail and are fully reflective of current practice.	**Minor**
GQ2 There is a documented system of audit		
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	The body traceability audit does not include an area on the audit form to capture who is responsible for completion of actions or the timeframe for completion.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
c) Staff are assessed as competent for the tasks they perform	The DI holds regular one-to-one meetings with mortuary staff as part of the appraisal process. This process covers general competence in mortuary practice and sets objectives for individuals where required, however, there is no framework to assess whether staff are competent in specific key tasks they perform.	**Minor**

f) There is a documented induction and training programme for new mortuary staff	All new mortuary staff undergo a corporate induction, however, at the time of the inspection, a local mortuary induction and training programme was not provided to the inspection team for review.	**Minor**
GQ4 There is a systematic and planned approach to the management of records		
b) There are documented SOPs for record management which include how errors in written records should be corrected	The SOP for record retention does not include how long records should be retained. Furthermore, the inspection team identified that some mortuary records were amended with the use of correction fluid.	**Minor**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis	Whilst not in use at the time of the inspection, the temporary storage unit located in the PM room had not been risk assessed to ensure the location of this unit does not pose any risk of contamination to bodies that may be stored there.	**Minor**
b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed	Whilst there are risk assessments in place that cover licensable activity, they do not always contain sufficient detail on control measures in place to mitigate identified risks. For example: • Viewing of the wrong body does not include the use of the viewing form in operation or detail that staff should be trained and assessed as competent in the procedure. • The risk assessment of the contingency storage units only considers risks to staff using the units, it does not cover risks to the deceased or risks relating to security of the units. *(see Advice item, 3)*	**Minor**
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	Whilst the premises were clean at the time of inspection and appeared well maintained overall, some areas are showing signs of wear which require maintenance: • One side of the wall between the PM room dissection benching and the PM room viewing gallery is cracked exposing porous plaster. • One of the body storage areas had minor damage to the walls and ceiling. This poses a risk to the effective cleaning and decontamination of these areas	**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(h)	Whilst the staff and DI meet regularly as part of a small team, the DI is advised to ensure that the quarterly governance meetings are routinely recorded and shared with staff as the last documented meeting appeared to have been held in June 2022.
2.	GQ5(a)	Whilst there is a system to report and manage incidents, the DI is advised to consider the introduction of an error log to capture any minor errors that may occur within the establishment. This may assist in identifying and correcting any consistent errors that may lead to an incident.
3.	GQ6(b)	The DI is advised to review all risk assessments related to licensable activity to ensure control measures to mitigate risks are fully captured and include risks relating to the deceased where relevant.

		Should any additional actions be identified to lower risks further during this review, the DI is advised to ensure these actions are captured within the risk assessment and include detail of who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.
4.	T1(d)	Whilst there is a procedure in place to identify bodies with a same or similar name, the DI is advised to consider additional methods to strengthen this procedure, such attaching a visual indicator directly to the body, due to the number of body storage locations in operation.
5.	T1(g)	Whilst organs and tissue taken during forensic PM examination are collected by police officers and follow a police ‘chain of custody’ to the referral establishment, the DI is advised to also get confirmation of receipt of arrival in these cases.
6.	T2(b)	The DI is advised to liaise with the Coroner regarding the family wishes form that is currently in use. The form refers to consent being obtained from the ‘Next of Kin’ (NOK). The NOK may not be the most appropriate person to give consent under the HT Act 2004. Furthermore, the form does not provide clear information on all options available for how tissue may be handled following PM examination. The form only gives the option of consenting to ‘research and other scheduled purposes under the HT Act’.
7.	PFE1(d)	At the time of the inspection, the DI provided assurance that the external components of the contingency units were secure and that systems were in place to prevent tampering, however, the DI is advised to review these arrangements as some of the electrical components appeared accessible. The DI may wish to consider caging all external components for full assurance tampering is prevented.
8.	PFE1(e)	Whilst access to the mortuary is restricted out-of-hours to a single body store and rest room facility for contracted funeral service staff, the DI is advised to consider the use of CCTV in the body storage area for review should any incidents occur whilst mortuary staff are not on site. Whilst all visitors are accompanied by mortuary staff, the DI is further advised to reintroduce the use of the in-hours visitor log so this can be reviewed as part of the security audit process.
9.	PFE3(e)	The DI is advised to monitor and implement preventative maintenance actions for the hydraulic body trolleys in operation as some are showing areas of minor rusting.

Background

Haringey Public Mortuary has been licensed by the HTA since February 2009. This was the fifth inspection of the establishment; the most recent previous inspection took place November 2019. 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

61 out of the total 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017). Consent standards C1 and C2 (11 in total) are not applicable as consent for post mortem examination or removal of relevant material from the deceased is not sought by this establishment.

Review of governance documentation

The inspection team reviewed the establishment's self-assessment document provided by the DI in advance of the inspection. Policies and procedural documents relating to licensed activities were reviewed. This included cleaning records for the mortuary and post-mortem room, records of servicing of equipment, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring records for the storage units, the incident reporting system, and staff training records.

Visual inspection

The inspection team undertook a visual inspection of the premises which included, mortuary security arrangements, body storage areas including the contingency storage units, the PM room and viewing room as well as the storage arrangements for relevant material held within the facility.

Audit of records
The inspection team undertook audits of traceability for five bodies in storage. This included bodies with the same / similar name, a body in long term storage and a perinatal body. Traceability details were crosschecked between the identification bands on the body, information on the door of the storage unit, mortuary whiteboards and the mortuary register. No discrepancies were identified.

The inspection team witnessed a release of a body from the mortuary. Records produced and used to identify the body prior to the activity being undertaken were reviewed. The activity was conducted using three-points of identification of the deceased crosschecked between paperwork produced by funeral directors and the identification bands on the body. No discrepancies were identified.

Audits were conducted of tissue taken at PM examination for three cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms and receipt documentation from referral centres. No discrepancies were identified. All cases were fully documented and recorded as received by the referral centres to process the tissue for analysis.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence, including mortuary staff, a pathologist who conducts PM examinations, and the DI.

Report sent to DI for factual accuracy: 12 July 2023

Report returned from DI: 18 July 2023

Final report issued: 18 July 2023

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: 20 October 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.