Inspection report on compliance with HTA licensing standards
Inspection date: **5 June 2024**

Brent Harrow and Barnet Public Mortuary

HTA licensing number 12017

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 **Brent Harrow and Barnet 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 Brent Harrow and Barnet Public Mortuary ('the establishment') had met the majority of the HTA's standards, six major and eight minor shortfalls were found against standards for Governance and quality systems 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) covering traceability of bodies, tissues and organs lack sufficient detail of the checks performed and the types of identifiers of the deceased used: • MOP 006 – bodies currently held in storage - does not detail what checks are made against the deceased from the list created at the end of the day. • MOP 022 – Histology - does not include that confirmation of receipt is received for tissue, organs and toxicology. The process for sending away tissue and organs does not include a confirmation of receipt form for the receiving establishment to complete. • MOP 031 - opening, preparing and closure of mortuary - does not include that tissue retrieval teams or maintenance staff should also sign the visitors log. The closure of mortuary process does not include the post mortem (PM) examination rooms. Some SOPs do not reflect current practice as described by staff during the inspection, this includes but is not limited to: • MOP 025 – Identification and viewings. This SOP details that two labels are printed when preparing the deceased for viewing. The current practice is to print one label which is used to check the identifiers on the body and with the family. • MOP 040 – receipt of deceased. This SOP details that an orange band is to be added to the tray alongside an orange magnet for same and similar names. To fully address this shortfall, the establishment should review all SOPs relating to mortuary activities to ensure that they are accurate. *See advice item 1*	**Major**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Although a schedule of audits is in place, the scope for licensed activities conducted under the licence is limited. The audit schedule does not include sufficient vertical or horizontal audits to check compliance with documented procedures, the completion of records and traceability of bodies or tissues. Although a security audit is undertaken the audit does not include checking of CCTV as well as records of mortuary access. *See advice item 3*	**Major**
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	Coroners contracted funeral directors involved in licensed activities have no competency assessments in place following initial training and sign-off. *See advice item 4*	**Major**
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	Some procedures relating to licensable activities have not been risk assessed, for example: • Major equipment failure; • Incident leading to the temporary unplanned closure of a mortuary; • Post mortem cross-sectional imaging; and • PM examination proceeded with inadequate consent. The area that the funeral directors park to admit and collect bodies is in an alcove adjoining a public car park and opposite a Trust staff bicycle store. The car park is in constant use and there is a risk that the public and Trust staff can oversee the transfer of the deceased. This activity has not been risk assessed and does not ensure the dignity of the deceased.	**Major**
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 unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	When funeral directors arrive at the mortuary, they use the audio/visual bell to alert mortuary staff. Once mortuary staff have verified who is requesting access, the external doors are released to allow entry along with a second set of doors to the shared NHS mortuary and public mortuary corridor. There is a risk that unauthorised persons could follow funeral directors through to the mortuary body store doors which are only secured by a key lock.	**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	Manual alarm testing of the fridge and freezer units are not undertaken regularly to ensure that alarms trigger and that the call-out procedures are effective. The temperature alarm trigger points for the fridges are not set at appropriate temperatures to ensure that there will be no accidental damage to the deceased.	**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	A procedure is in place to document the condition of the deceased on arrival and throughout the length of stay in the mortuary. The procedure does not include the recording of any actions undertaken before the deceased is released. *See advice item 2*	**Minor**
f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity	Deviations from documented SOPs are not recorded or monitored via audit activity.	**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	Audits do not document who is responsible for any follow-up actions and the timeframe for completing these.	**Minor**
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	Although visiting pathologists have an initial induction and training in the mortuaries policies and procedures, reviewed SOPs have not been signed as read and acknowledged.	**Minor**
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
a) Staff know how to identify and report incidents, including those that must be reported to the HTA	Visiting pathologists are not aware of HTA reportable incidents and how to identify them. *See advice item 5*	**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	Issues were identified with the maintenance of the establishment, making it difficult to adequately clean or decontaminate this area: • Rusted drain covers in the post-mortem room; • Small areas of rust on the fixed PM tables; • Small hole in wall; • Seal around the floor of the main post-mortem room has deteriorated; and • Paint has flaked away from the wall under the sinks.	**Minor**
b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors	There is no demarcation of the transition area between the body store room and the post-mortem rooms for transferring bodies.	**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	The trolley hoists are suffering from signs of wear and tear; areas of rust were seen making it difficult to clean and decontaminate sufficiently.	**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)	The DI is advised to introduce a viewing appointment form that can be completed with three unique identifiers when the viewing appointment is made with the family. This form can then be used to check the identifiers on the

		deceased and with the family and be attached to the electronic database.
2.	GQ1(c)	The DI is advised to consider the transfer of bodies showing signs of deterioration to long-term storage following discussions with the Coroner and family, where appropriate before 30 days of refrigerated storage if the condition of the body is deteriorating.
3.	GQ2(a)	The DI is advised to develop an audit schedule to include horizontal and vertical audits of all licensable activities for example, receipt of a body, release of a body, viewing of a body and relevant material going off site for analysis. The DI is advised to use these procedural audits as an opportunity to review SOPs to ensure practice reflects what is written in the SOP for each activity. Swipe card access lists should be reviewed and updated regularly. Records of access (both electronic and paper-based) and CCTV footage should be regularly audited to ensure adherence to relevant policies and procedures. Anyone entering the mortuary should have a legitimate right of access and audits should scrutinise the purpose, frequency and duration of access. Any unsuccessful attempts to access the mortuary should also be followed up.
4.	GQ3(a)	The DI is advised to ensure that they have a list of the coroners contracted funeral directors trained to undertake activities in the mortuary including the date trained.
5.	GQ5(a)	The DI is advised to place signage in the mortuary to raise awareness for coroners contracted funeral directors of the importance of reporting any incidents, including a list of all the appropriate HTA Reportable Incident (HTARI) categories.
6.	PFE2(f)	The DI is advised to record that the temperatures of the fridges and freezers have been monitored on the daily closure list. The DI is advised to undertake trend analysis of the temperatures to identify trends and the extent of any variations in storage temperatures.

Background

Brent, Harrow and Barnet Public 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.

Brent, Harrow and Barnet Public Mortuary has been licensed by the HTA since April 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in June 2021 which was a virtual regulatory assessment.

Since the previous inspection, there have been no significant changes to the licence arrangements, or the activities carried out under the licence. However, the establishment is in the process of finalizing budget approval to undergo major building work in 2025 to provide additional capacity, including long term and bariatric storage.

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

56 of the 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017); standards C1(a-g), C2 (a-d) are not applicable as the establishment does not seek consent for post mortem examinations. Standards GQ2(c) and T2 (a-d) were not assessed as the establishment does not store or dispose of tissue taken during post mortem examinations.

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, records of servicing of equipment, audits, risk assessments, meeting minutes, reported incidents and training records for mortuary staff and contracted funeral directors.

Visual inspection

The inspection included a visual assessment of the establishment including body storage areas, post mortem rooms and viewing room.

Audit of records

Audits were conducted onsite of four bodies in refrigerated storage and one body in long term frozen storage. Identification details on bodies were crosschecked against the information recorded in the electronic database. No discrepancies were identified.

Meetings with establishment staff

Staff carrying out processes under the license were interviewed including the DI, mortuary supervisor, anatomical pathology technologist (APT), trainee APT and pathologist.

Report sent to DI for factual accuracy: 26 June 2024

Report returned from DI: 9 July 2024

Final report issued: 7 August 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: 20 January 2025

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.