



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
Brent, Harrow and Barnet Public Mortuary	Licensed	Licensed	Licensed
Mortuary	<i>Carried out</i>	<i>Carried out</i>	<i>Carried out</i>

Summary of assessment 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, one major and three minor shortfalls were found against standards for Governance and quality systems, Traceability and Premises, facilities and equipment. These related to freezer storage, standard operating procedures (SOPs), staff training and the ventilation system.

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.

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.		
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	There are not enough freezer storage spaces to match current service expectations.	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	<p>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.</p> <p>Some SOPs do not reflect current practice as described by staff during the assessment, this includes but is not limited to:</p> <ul style="list-style-type: none"> • MOP 019 – Freezing of bodies. This SOP does not detail the daily condition checks of bodies that are undertaken. • MOP 025 – Identification and viewings. This SOP does not document the final identification check undertaken prior to visitors entering the viewing room. 	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 establishment does not have a formalised system in place for assessing staff as competent in the key tasks they perform.	Minor
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 ventilation system in the secondary post-mortem examination room maintains positive pressure. This may pose a health and safety risk to staff; however, this is currently being mitigated by staff using individual respirator systems.	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 practices:

Number	Standard	Advice
1.	GQ1(h)	Whilst matters relating to HTA are frequently discussed at mortuary meetings, the DI is advised to add this as a standing agenda item.
2.	GQ5(a)	The DI is advised to review the HTARI reporting SOP against the updated guidance published by the HTA in June 2020 to ensure the SOP accurately reflects the types of incidents that should be reported. A copy of this guidance will be sent to the DI.
3.	GQ6(b)	The DI is advised to review and update risk assessments once the formalised system to assess staff competency is in place. This is to ensure that the additional control measure is captured as a mitigation for any relevant risk/s.

Background

Brent, Harrow and Barnet Public Mortuary has been licensed by the HTA since April 2007. This was the fourth inspection of the establishment; the last inspection took place in November 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 assessment team covered the following areas during the inspection:

Standards assessed against during inspection

61 standards out of the total of 72 standards were covered during the VRA (standards published 3 April 2017). The standards in relation to consent procedures (C1 a-g) and standards relating to consent training (C2 a-d) were not applicable as the establishment does not seek consent for PM examination.

Review of governance documentation

The assessment team reviewed the establishment's self-assessment document provided by the DI in advance of the VRA. Policies and procedural documents relating to licensed activities for the mortuary and post-mortem room, ventilation reports, traceability audits, risk assessments, meeting minutes, incidents, and staff appraisal and training records were also reviewed.

Visual inspection

There was no site visit inspection as part of this assessment.

Meetings with establishment staff

The assessment team met with staff carrying out activities under the licence. This included staff working within the mortuary, a pathologist who conducts PM examinations and the DI.

Report sent to DI for factual accuracy: 14 July 2021

Report returned from DI: 26 July 2021

Final report issued: 13 August 2021

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 Virtual Regulatory Assessment Report.

Date: 4 July 2022

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.