Inspection report on compliance with HTA licensing standards
Inspection date: **28 October 2025**

Wednesfield Public Mortuary
HTA licensing number 12285

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 Wednesfield 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 Wednesfield Public Mortuary ('the establishment') had met the majority of the HTA's standards, four major and six 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
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).	Whilst the establishment has a system to track specimens taken during post mortem examinations, it lacks sufficient detail for full traceability. The number and types of tissues taken during post mortem examination is not recorded prior to dispatch to the laboratory. Furthermore, the establishment does not routinely confirm receipt of the tissue at the laboratory.	**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	A transparent door panel leading to the PM room is missing. This affects the ability of the air handling unit to deliver necessary air changes. Furthermore, the missing panel prevents contamination being restricted to the post mortem room. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.* A small amount of contamination was noted on the dissection bench in the post mortem room. (See *shortfall* against standard PFE3(c).	**Major**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	Cleaning staff have access to the Mortuary and undertake lone working regularly. This arrangement does not ensure sufficient oversight of staff with a legitimate right of access.	**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	Whilst the ventilation has been regularly serviced the air flow has not been tested since 2023.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	There are no regular meetings with establishment staff and the DI to discuss HTA related matters.	**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	Errors in written documents had been amended using correction fluid. This impedes the ability to audit errors accurately.	**Minor**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register	Various risks associated with service delivery are on the organisation's risk register however staffing levels are not included.	**Minor**

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access)	Whilst the building has an alarm system it is not tested, and staff were unsure of the response in event of activation. Internal doors are not secured outside of working hours; this presents an increased risk of entry to clinical areas in event of a break in.	**Minor**
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.	**Minor**
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 lower threshold for the fridge alarms is not tested regularly.	**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(d)	SOPs and Policies are compiled by groups of staff rather than named individuals. The DI should review this arrangement and ensure that individuals are named on documents.
2.	GQ6(b)	Risk ratings are based on risks before mitigations have been implemented. The DI is advised to review the risk ratings to reflect the level of risk following mitigations being actioned. Furthermore, mitigations that have been introduced should be listed as control measures rather than actions required. Mitigations such as staff training and competency should be included as control measures. The addition of break-in should be added to the listed hazards relevant risk assessments.
3.	T1(b)	The DI may wish to replace the whiteboards used on fridge doors as the lines used to separate information for each fridge space are partially erased.
4.	PFE1(e)	The DI may wish to routinely use an independent member of non Mortuary staff to assist with the security audits.
5.	PFE2(d)	The DI may wish to introduce a contract for regular maintenance of fridge and freezer units.
6.	PFE3(a)	The DI is advised to monitor the condition of the bone saw which is showing early signs of deterioration.
7.	General	The DI is advised to review the list of Persons Designate on the licence and remove any who are no longer connected with the establishment.

Background

Wednesfield 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.

Wednesfield Public Mortuary has been licensed by the HTA since 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in November 2023

Since the previous inspection, there has been a change of DI.

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 standards were assessed (standards published 3 April 2017). Standards relating to consent procedures (C1a-g) and consent training (C2a-d) were not assessed. They are not applicable as staff at the establishment do not seek consent for PM examinations.

Review of governance documentation

The inspection team reviewed documentation on site and submitted after the inspection. Standard operating procedures, risk assessments, and policies were reviewed. Audit schedules, competency records, cleaning record forms, and meeting minutes were inspected as part of the review process.

Visual inspection

The inspection included a visual assessment of the body storage areas in the mortuary, PM room and viewing room. The inspection team observed the processes for release of bodies within the mortuary.

Audit of records
A traceability audit of four bodies in storage was undertaken. This included bodies from both the community with one in long term storage. Details were cross checked against identity bands, mortuary register and an electronic database. One minor discrepancy was found and immediately corrected.

Audits were conducted of tissue taken at PM examination for five cases. Information was cross-checked between the mortuary documentation, Coroner's paperwork, and the mortuary database. 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 APT.

Report sent to DI for factual accuracy: 24 November 2025

Report returned from DI: 26 November 2025

Final report issued: 27 November 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.