

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	<i>Carried out</i>	<i>Carried out</i>	<i>Carried out</i>

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, two major and four 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

GQ1 All aspects of the establishment’s work are governed by documented policies and procedures		
b) Procedures on evisceration ensure that this is not undertaken by an APT unless the body has first been examined by the pathologist who has instructed the APT to proceed.	At the request of the pathologist, Anatomical Pathology Technologists (APTs) undertake evisceration before external examination of the body. The SOP for PM examination does not describe when evisceration takes place.	Major
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).	There is key access to the mortuary and CCTV is in operation at the entrance and exit points, however there has not been a change of locks for many years. The establishment could not provide assurance that the only keys in operation were those currently held by staff. This poses a risk of unauthorised access to the mortuary.	Cumulative Major

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access.	<p>The establishment have informed the inspection team that they only review CCTV in the event of an identified incident and do not audit CCTV to ensure those accessing the mortuary have a legitimate right to do so.</p> <p>See advice, item 6</p>	
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Minor shortfalls

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.	<p>The condition of the deceased is recorded on arrival to the mortuary. The establishment have informed the HTA that regular condition checks of the deceased are undertaken as described in the SOP to ensure there is no onset of deterioration, however these additional checks are not recorded.</p>	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	<p>There is no formalised or recorded process for competency assessments.</p> <p>See advice, item 2</p>	Minor

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
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.	<p>Whilst the establishment had control measures in place to mitigate risk, which were discussed with the inspection team, risk assessments lacked the detail that staff were verbally able to provide during the discussions.</p> <p>For example, whilst the establishment informed the inspection team that bodies are only released following a cross check of three points of ID against information brought by the funeral director, the risk assessment does not adequately detail this as a control measure.</p> <p><i>See advice, item 3</i></p>	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 floor in the fridge room has some cracks which makes it difficult to adequately disinfect and clean.	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.

The HTA advises the DI to consider the following to further improve practice:

Number	Standard	Advice
1.	GQ1 (a)	The establishment are advised to review all Standard Operating Procedures (SOPs) to ensure they contain sufficient detail of procedures which reflect current practice for identification of bodies.
2.	GQ3 (c)	In relation to the shortfall, staff may wish to assess competency by observing each other carrying out mortuary procedures in line with SOPs and recording that this has been conducted.
3.	GQ6 (b)	The DI is advised to consider formal staff training in conducting risk assessments. The DI is further advised to fully review all risk assessments to ensure there is adequate detail of control measures in place to mitigate identified risks.
4.	T1 (c)	Staff are advised to record the date of birth for bodies in the mortuary on all of the relevant paper documentation.
5.	T1 (g)	To strengthen procedures, staff are advised to: <ul style="list-style-type: none"> • Review the receipt forms from the referring histology establishment to see that they are fully completed. • Record the type of tissue taken for histology in addition to the number of tissue samples which is already recorded
6.	PFE1 (e)	In relation to the shortfall, the DI is advised to give consideration to the installation of additional CCTV inside the mortuary and swipe card access to ensure a more robust monitoring system.
7.	PPE3 (a)	The DI is advised to monitor the condition of the floor in the PM room for signs of further deterioration.
8.	PFE2 (i)	The DI is advised to review the contingency plans in place for a power failure to determine if access to a back up generator is needed.

Background

Wednesfield Public Mortuary has been licensed by the HTA since 2007. This was the third inspection of the establishment; the most recent previous inspection took place in February 2019.

Since the previous inspection there has been a change of Corporate Licence Holder contact (CLHc) and 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 September 2022). 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 assessment 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 for the mortuary were reviewed. Traceability audits, risk assessments and incidents were also reviewed.

Visual inspection

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

Audit of records

Audits were conducted for three bodies in refrigerated storage and one body in freezer storage. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and relevant documentation. Processes for sending tissue taken from PM examinations were also reviewed. No discrepancies were found.

Meetings with establishment staff

The inspection team met with staff carrying out processes under the licence, including the DI, Pathologist, Senior Anatomical Pathology Technologist, Mortuary Technician, Health and Safety Advisor and a Bereavement Service Manager.

Report sent to DI for factual accuracy: 15 January 2024

Report returned from DI: 29 January 2024

Final report issued: 31 January 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: 13 December 2024

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.