Inspection report on compliance with HTA licensing standards
Inspection date: **30 July 2025**

Miller House Mortuary
HTA licensing number 12125

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 Miller House 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 Miller House Mortuary ('the establishment') had met the majority of the HTA's standards, two major and one minor shortfall 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.	The SOPs detailing the Release of a body and body condition checks lack detail and are not reflective of staff practice. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
d) Fridge and freezer units are in good working condition and well maintained	Whilst there is a maintenance schedule in place, there is a build-up of ice in the external freezer unit which is impacting on the correct operation of the door.	**Major (cumulative)**

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	Whilst fridge and freezer alarms are regularly tested, a test of the lower set range is not undertaken.	

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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	Whilst staff know how to identify and report incidents, the inspection team identified one incident which met the threshold for reporting to the HTA which had not been reported. *See advice item five.* *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**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.	GQ3(c)(d)	Whilst staff undertaking activity under the licence have received training and been assessed as competent, the DI is advised to introduce a formalised system for staff refresher training, the reassessment of competency and performance reviews.
2.	GQ4(a)	The DI is advised to continue with the existing plans in place to review the implementation of an electronic mortuary database. This will enable mortuary records relating to the care of the deceased to be held in one place.
3.	GQ6(a)(c)	The DI is advised to separate risk assessments so that risks to staff undertaking activity under the licence are separate to the risks to the deceased. Additionally, the DI is advised to monitor the temperature of the post mortem suite and if necessary implement suitable mitigations to reduce the temperature of the room to ensure any risk of accelerated deterioration to the condition of bodies is minimised. Furthermore, the DI is advised to continue with existing plans to recruit more staff in response to the recent benchmarking exercise.

4.	T2(c)	The DI is advised to continue with existing plans to work with HM Coroner to agree a procedure to follow to ensure tissue blocks and slides are not retained for longer than necessary when the wishes of the family regarding storage and use are not known.
5.	N/A	The DI is advised to review the number of personnel named on the licence as Persons Designate to ensure HTA incident reporting requirements can be met in their absence.

Background

Miller House Mortuary has been licensed by the HTA since 2007. This was the sixth inspection of the establishment; in April 2024 a targeted follow up inspection was undertaken in response to shortfalls identified during the routine inspection carried out in June 2023.

Since the previous inspection, the mortuary has received a major refurbishment with an upgrade of the body store and post mortem suite. There have been no significant changes to the activities carried out under the licence. However, there has been a change to key personnel with a change to the DI in March 2024 and the Corporate Licence Holder Contact (CLHc) in June 2025.

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

57 of the 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017), standards C1, C2, GQ2(c), T2 (b)(d) and PFE2(h) are not applicable as the establishment does not undertake consented PM examinations, undertake the care of peadiatric or perinatal deceased or store and dispose of tissue taken during coronial PM 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.

Visual inspection

The inspection included a visual assessment of the establishment including body storage areas and viewing rooms. The inspection team observed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records

Audits were conducted onsite of three bodies from refrigerated storage and three bodies in long term frozen storage. Identification details on bodies were crosschecked against the information recorded in the register and associated paperwork in addition to information held on the mortuary whiteboard. Additionally, the release of three bodies into the care of Funeral Director was observed. Identification details on the body were crosschecked against the information recorded in the register and associated paperwork brought by the Funeral Director. No discrepancies were identified.

Audits of traceability were conducted for tissue removed at PM. These were limited to audits of the documentation relating to transfer of tissue offsite and confirmation of receipt from the receiving establishment. No discrepancies were identified.

Meetings with establishment staff

Staff carrying out processes under the license were interviewed including the DI, Mortuary Manager and Pathologist.

Report sent to DI for factual accuracy: 04 August 2025

Report returned from DI: 19 August 2025

Final report issued: 20 August 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.