Inspection report on compliance with HTA licensing standards
Inspection date: **12 and 13 June 2023**

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 critical, 15 major and two minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities and equipment.

Three of the shortfalls (one critical and two majors) relate to findings from the last inspection. The HTA is concerned that adequate steps were not taken to address these findings in the intervening period and to embed suitable practices at the establishment. A similar issue was identified in standards GQ1(b), GQ3(a)(d) and T1(c) regarding shortfalls from the inspection conducted in 2018.

Concerns were discussed with the establishment as part of this inspection. The current DI has provided assurance that key personnel have been appointed to manage the activities under the licence and that the establishment is committed to meeting the regulatory requirements. Based on this assurance, 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. However, in light of the establishment's lack of progress with addressing shortfalls from previous inspections, the HTA will consider the need for regulatory action if appropriate action is not taken to meet the regulatory requirements in accordance with the timeframes detailed in Appendix 2.

Compliance with HTA standards

Critical Shortfalls

Standard	Inspection findings	Level of shortfall
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	Whilst risks are assessed on a regular basis, not all potential HTA reportable incidents have been identified and risk assessed. This means there is insufficient mitigation in place to minimise the risk to bodies and tissue of a reportable incident.	**Critical (cumulative)**
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	Risk assessments do not identify who is responsible for actions needed to be taken to mitigate risk and the timeframe for actions to be implemented. This means identified risks may not be mitigated in a timely way.	
c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register	The inspection team were not assured significant risks on the corporate risk register were actioned in a timely way. There are insufficient numbers of staff available to manage the volume and complexity of mortuary activity. Whilst assurance was provided there are plans in place to recruit more staff, the mortuary has been operating on reduced staff numbers for the previous 12 months. This has led to reduced capacity to undertake administrative tasks including activity relating to the release of bodies into the care of funeral directors. This poses the risk of a serious incident and has been identified as an underlying theme in respect of other shortfalls identified as part of this inspection. (Refer to the GQ1 standards below)	
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail.		
b) There is a system to track each body from admission to the mortuary to release for burial or	Whilst there is a system in place to track the location of bodies in storage, changes in storage location are not always updated in the mortuary register when bodies are moved from refrigerated to long term storage.	**Critical (cumulative)**

cremation (for example mortuary register, patient file, transport records)	This poses the risk of the release of the wrong body.	
c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier	The Inspection team are not assured three identifiers are used to identify bodies. Not all ID bands had three identifiers in place, and although the establishment assigned a unique mortuary number to each body, this was not documented on the paperwork used for viewings, release or post mortem examinations. Whilst viewings were not commonly facilitated, the establishment requires relatives to provide only two identifiers for the deceased when they attend the mortuary for a viewing. This practice poses the risk of viewing of the wrong body. The inspection team observed the release of a body into the care of funeral directors. The funeral director had three identifiers on their paperwork. However, the identifiers provided by the funeral director were different to the identifiers recorded on ID bands of the deceased. This means bodies are released with only two matching identifiers. This poses the risk of release of the wrong body. There were only two identifiers checked against the authorisation paperwork sent by the Coroner for bodies requiring a PM examination. This poses the risk of a PM being carried out on the wrong body.	
h) There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary, (such as to the lab or another establishment), including record-keeping	Whilst there is a process in place for the transportation of tissue offsite. There is no written procedure in place for staff to refer to. (Refer to GQ1(a) below) This poses the risk of loss of tissue traceability.	

requirements		

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.	Not all mortuary procedures had a documented policy in place. There was no Standard Operating Procedure (SOP) in place for the following activity: • Procedures for staff to follow when lone working. • Procedures for staff to follow when checking body condition • Procedures for staff to follow when transferring the deceased to long term storage • Procedures for staff to follow when transferring tissue removed during PM offsite. Some SOPs lack detail and do not reflect staff practice. At the time of inspection, some procedures observed by the inspection team were not consistent with that of the SOPs. These include, but are not limited to, SOPs detailing the process for: • Viewings and formal ID's • Release/transfer SOP • PM Examinations	**Major**

	This is not an exhaustive list of the SOPs requiring amendment. To fully address this shortfall, the establishment should review all SOPs relating to mortuary activities to ensure that they are accurate and contain sufficient detail to reflect current practice.	
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	The inspection team were not assured procedures on evisceration ensure this is not undertaken by an APT unless the body has first been examined by the pathologist who is undertaking the PM examination. On occasion bodies are held in unrefrigerated conditions overnight prior to the pathologist undertaking the external examination. This poses a risk to the dignity of the deceased.	**Major**
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	The establishment does not undertake documented condition checks of the deceased upon arrival to the mortuary. Whilst twice weekly body condition checks are undertaken on bodies in refrigerated storage these are not documented. During our inspection two bodies in refrigerated storage had started to show signs of deterioration. There are no procedures in place for staff to follow when shrouding the deceased. This poses the risk of accidental damage to a body and risks to the dignity of the deceased.	**Major**
e) There is a system for recording that staff have read and understood the latest versions of these documents	There were no records available to review indicating staff had read and understood the latest versions of SOPs.	**Major**

f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity	There were no documents to review to indicate deviations from documented SOPs are recorded and monitored via scheduled audit activity.	**Major**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	There were no records available to review to review to indicate regular governance meetings were undertaken to discuss matters relating to HTA business.	**Major**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	There were no records available to review indicating there is a schedule of audits. Staff do not undertake regular documented audits of the traceability of bodies and CCTV feed against mortuary access via key fob. (Refer to shortfall PFE1(e) below)	**Major**
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	There were no documented audits available for review indicating any actions taken in response to identified non-conformances, timeframes for completing these and the staff completing the action.	**Major**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised	The Inspection team are not assured all staff who carry out licensed activities are appropriately trained. Contracted Funeral Directors who undertake licensed activities out of hours have not received training from the mortuary team.	**Major (cumulative)**

	This poses the risk of a serious incident.	
c) Staff are assessed as competent for the tasks they perform	The inspection team are not assured all staff who undertake mortuary duties receive regular competency assessments. There were no documents available to review relating to mortuary staff and funeral directors being assessed as competent for tasks undertaken under the licence.	
d) Staff have annual appraisals and personal development plans	There were no documents available to review indicating staff receive annual appraisals and personal development plans.	
f) There is a documented induction and training programme for new mortuary staff	Whilst new members of staff do receive a formal corporate induction, the local mortuary induction is not documented.	
g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures	Whilst the establishment does not employ locum mortuary staff. The inspection team were not assured that visiting/external staff receive an induction which includes the establishment's policies and procedures. There were no documents available to review in support of an induction and competency check for external visiting staff.	
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	There are significant areas of damage to the structure of the building and equipment in use: • The entrance to the mortuary is overgrown and cluttered with stored equipment, litter and rubbish.	**Major**

	• The visitors entrance is not accessible and has an inadequate paving substrate. • There is significant damage to the fabric of the building within the funeral directors entrance, with areas of exposed plaster, peeling paint and cracking in the brickwork. The area is used as a storage area for excess stores leaving the area cluttered posing the risk of manual handling incidents. • The viewing suite is used as a storage area for excess equipment, which staff move to another area of the mortuary before a viewing can be facilitated. • The viewing room floor has superficial damage in the finish which could prevent effective cleaning and decontamination. • The flooring in the PM room is cracked and there are areas of exposed wood and damage to wooden fire doors, posing the risk of ineffective cleaning and decontamination. • There are areas of exposed wood in the body store with damage to the wooden shelf housing the mortuary register. This poses the risk of ineffective cleaning and decontamination.	
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 there is CCTV in place and there is controlled access to body store areas, the inspection team were not assured the premises were secure. During the inspection an unrestricted window was identified. The window opened onto the street from an intermittently occupied office. There was an unlocked key box located in an unlocked cupboard just outside this office- staff were unable to identify the locks the keys were used for. This poses a risk of unauthorised access to restricted areas of the mortuary.	**Major**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	Access to the mortuary is gained via an electronic fob and use of a key, there is restricted access to the PM room, viewing suite and offices out of hours. However, electronic access records are not reviewed against CCTV footage. (Refer to GQ2(a) above) Trees are overgrown posing the risk of causing blind spots in the security cameras. The intercom system at the funeral directors entrance to the mortuary is broken meaning staff cannot assure themselves of the identity of the visitor before raising the roller shutter door. There is no visitors book in place for the use of contractors, and other visitors attending the mortuary for an authorised purpose. This means mortuary staff do not have oversight and are not able to effectively audit all individuals accessing the mortuary or their time of entry and exit to the restricted areas. *Assurance was provided by the DI before the publication of the inspection report that the overgrown trees have been coppiced and do not pose the risk of occluding CCTV cameras.*	**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 temporary freezer and one of the freezer banks in the body store.	**Major (cumulative)**
e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures	Whilst most of the fridges are monitored centrally and there is an alerting system in place, two of the temporary storage units are not attached to the monitoring system. However, there is an audible alarm which would alert staff in the event of a temperature excursion.	

go out of upper or lower set range	Additionally, the fridge used for the storage of toxicology samples does not have an audible alarm or inbuilt thermometer.	
f) Temperatures of fridges and freezers are monitored on a regular basis	The fridge used for the storage of toxicology samples awaiting transfer offsite for testing is not monitored on a regular basis.	
g) Bodies are shrouded or in body bags whilst in storage	The inspection team identified some occasions where bodies were not shrouded whilst in storage. Whilst there is a requirement for the mortuary to remove clothing / shrouding for bodies undergoing post mortem examination, some bodies had not been re-shrouded inside the body bags following the procedure being undertaken. This compromises the dignity of the deceased. (Refer to shortfall GQ1(c) above)	**Major**
i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods	There were no documents available for review relating to contingency planning in the event of a power failure or insufficient numbers of refrigerated storage.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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	Whilst there is signage within the mortuary instructing staff how to correct errors in written records. There is no documented SOP for record management which includes how errors in written records should be corrected.	**Minor**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
c) There are documented cleaning and decontamination procedures and a schedule of cleaning	Whilst the establishment was clean and odour free. There were no documents available to review relating to cleaning and decontamination procedures, there is no cleaning schedule in place, and there are no records of when cleaning and decontamination tasks have been completed by staff.	**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.	GQ5(a)	The DI is advised to display a list of HTA reportable incidents to all areas of the establishment undertaking licensed activity.
2.	T1(c)	The DI should consider expanding the use of the individual mortuary numbers given to each body to be used as an additional identifier.
2.	T1(d)	The DI is advised to review and strengthen the process relating to same or similar names. Consideration should be given to the use of fridge magnets, or additional ID bands on the body.
3.	T1(g)	The DI is advised to consider the addition of a column in the specimen record book to indicate the date of receipt by the third party establishment who analyse and store tissue. This will provide a quick overview in addition to the email confirmation.
4.	PFE3(a)	The DI is advised to monitor the minimal rusting to the hydraulic trolleys within the body store, to ensure it does not deteriorate further and impede the usual operational function.

Background
Miller House Mortuary has been licensed since 2007. This was the fourth Inspection of the establishment; the most recent previous inspection was carried out in August 2018.

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 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 two 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. Id bands for one body did not have three points of Identification and there was a discrepancy in the name of one body between the ID band and the mortuary whiteboard (refer to the shortfall identified in standard T1(c) above).

The release of one body into the care of a 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. The identifiers provided by the funeral director were different to those on the body of the deceased. (refer to the shortfall identified in standard T1(c) above)

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, APT and Pathologist.

Report sent to DI for factual accuracy: 04/07/2023

Report returned from DI: 17/07/2023

Final report issued: 17/07/2023

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: 30 April 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.