Inspection report on compliance with HTA licensing standards
Inspection date: **14 March 2024**

Liverpool City Mortuary

HTA licensing number 12033

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
Liverpool City 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 Liverpool City Mortuary (‘the establishment’) had met the majority of the HTA’s standards, two major and three minor shortfalls were found against standards for incident & document management, security arrangements 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
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents	The mortuary department does not have an agreed incident reporting system. The inspection team was told of a previous incident regarding the mortuary floor. Whilst investigated at the time, details of the incident and follow up actions were not recorded.	**Major (Cumulative)**
c) The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed		
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)	The mortuary doors are secured using manual key locks. Mortuary keys and their use are not fully traceable or tracked. Whilst a set number of keys were issued, the DI does not have assurance of the exact number of keys in existence. This poses a risk of unauthorised access.	**Major (Cumulative)**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	CCTV audits are not completed at randomly selected times. The inspection team noted that footage was only reviewed at times of known, granted access. This further poses a risk to the lack of access oversight.	

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use	The mortuary does not have a robust document management system. Documents are version controlled, but previous revision details are unavailable. The inspection team noted SOPs available to staff were not the latest versions, posing a risk of out of date procedures being followed. Furthermore, some documents (such as risk assessments) are unavailable to staff if undergoing review.	**Minor**
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	Establishment staff confirmed that licenced activities are risk assessed, however, at the time of the inspection these were unavailable to mortuary staff and not submitted to the inspection team for review.	**Minor**
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	The door seal on the mortuary freezer is perished. This poses a risk to the inefficient running of the freezer and ineffective decontamination.	**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(c)	The DI is advised to review and audit the condition checking procedure and scoring system to ensure that all checks, including those with no change to condition, are recorded.

2.	PFE1(a)	The DI is advised to remove all porous packaging from the floor within the fridge room, and review storage arrangements to ensure infection control risks are fully mitigated.
3.	PFE1(a)	During the inspection the mortuary courtyard was littered with rubbish. The DI is advised to add this area to a cleaning schedule to ensure it is kept clear and tidy.
4.	PFE2(e)	The DI is advised to ensure that formalin is decanted in the designated ventilation areas of the post mortem room.
5.	PFE2(i)	The mortuary has an external refrigeration unit that is no longer in use. The DI and CLHc are advised that if a decision is made to reinstate its use, a full risk assessment and audit against the HTA post mortem standards is required. Some areas that would require improvements include the wooden floor and the padlock.

Background

Liverpool City Mortuary has been licensed by the HTA since July 2007. This was the fifth inspection of the establishment; the most recent previous inspection, was a focused assessment which took place in June 2023.

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

56 of the total 72 HTA standards were covered during this inspection (standards published 3 April 2017). Standards regarding consent, tissue storage and disposal were not applicable.

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, cleaning records for the mortuary, records of servicing of equipment, audits, meeting minutes, and training records for staff.

Visual inspection
The inspection included a visual assessment of the mortuary fridge room, post mortem room and viewing facilities. The inspection team observed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records
Audits were conducted for three bodies from refrigerated storage and one from freezer storage. Identification details on bodies were crosschecked against the information recorded in the mortuary register and associated paperwork. No discrepancies were identified.
A tissue audit was not conducted, as any retained tissue is stored at the referral licensed establishment.

Meetings with establishment staff
Staff carrying out processes under the licence were interviewed including the Services Manager (Corporate Licence Holder contact), the Mortuary Manager (Designated Individual), an APT and a Pathologist.

Report sent to DI for factual accuracy: 05 April 2024

Report returned from DI: 17 April 2024

Final report issued: 18 April 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: 28 August 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.