Inspection report on compliance with HTA licensing standards
Inspection date: **02 June 2023**

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
Hub site **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.

The targeted unannounced site visit of Liverpool City Mortuary (‘the establishment’) found two minor shortfalls against standards for Governance and quality systems and Premises, facilities and equipment. These related to condition monitoring and recording of information on condition of bodies in storage and fridge and freezer alarm testing.

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

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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	At the time of the inspection, the establishment had recently implemented a procedure to record the condition of bodies upon arrival and at the point of release. However, the procedure is limited and does not include monitoring and recording of the condition of bodies at regular intervals whilst in storage, or details of actions to be taken to prevent deterioration. (*see advice item 1)*	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
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 external fridge and freezer alarms have not been tested for approximately two months due to the alarm panel in the mortuary requiring replacement. (*see advice item 7)*	**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 inform and record discussions with relevant parties, such as the Coroner's office or family nominated funeral directors as to the condition of bodies starting to show signs of deterioration. This may assist with expediting services outside of the control of the mortuary, especially if relevant parties are aware that a delay to their services could potentially impact the dignity of the deceased by leading to more advanced deterioration in the condition of the body. The DI is also advised to discuss and agree the condition of the body with funeral directors upon release from the mortuary.
2.	GQ6(a)	Whilst the inspection did not focus on this standard, the inspection team identified that the establishment are using body scoops on the base of the fridges to increase storage capacity. The DI is advised to complete a full risk assessment of this practice and implement actions to mitigate any risks to the deceased or to staff as the body trolley does not lower sufficiently to this level. This will be identified as a shortfall at the next routine inspection if not addressed.
3.	T1(a)	The inspection team identified one case where the identification tag on the body had started to become illegible due to the use of non-waterproof ink. The DI is advised to ensure tags are still legible following PM examination or are replaced if water exposure affects legibility.
4.	PFE1(a)	Whilst the inspection did not focus on this standard, the DI is advised to address the maintenance requirements of the premises, in particular the body store and funeral director entrance. There are several areas where the walls and ceilings are damaged exposing porous plaster. Wooden door frames and fittings are also showing signs of damage. These areas would be difficult to clean and decontaminate. This will be identified as a shortfall at the next routine inspection if not addressed.
5.	PFE1(c)	Whilst the inspection did not focus on this standard and the establishment routinely clean and decontaminate the fridges and freezers, the DI is advised to record the dates of the regular 'fogging' undertaken which aids to prevent mould contamination in the units.

6.	PFE1(e)	Whilst the mortuary was secure at the time of the inspection, the DI is advised to ensure the roller shutter door to the mortuary yard area is routinely kept closed. The DI is also advised to expedite the plans to add a canopy to this area to prevent oversight of activity from the surrounding buildings and to move the current CCTV location, so it covers the doors to the temporary body storage unit.
7.	PFE2(e)	Due to the alarm panel requiring replacement in the mortuary, there was doubt that the external alarm would trigger out-of-hours, however, the DI provided assurance within days following the inspection that the external alarms do trigger, and out-of-hours procedures work as expected. The DI is advised to ensure alarm testing recommences once the panel is replaced. The DI is further advised to lower the upper alarm trigger point which is currently set at 10 degrees Celsius as bodies may be stored in suboptimal temperatures for a prolonged period prior to the alarm sounding.
8.	PFE3(a)	Whilst the inspection did not focus on this standard, the DI is advised to also address the maintenance requirements of the fridges. Some fridge seals are damaged and in need of repair or replacement. This will be identified as a shortfall at the next routine inspection if not addressed.
9.	N/A	The DI is advised to ensure the plans to install deodorisers into the entrance and viewing room areas of the mortuary are expedited. This will greatly assist with odour control in these areas.

Background

Liverpool City Mortuary has been licensed by the HTA since July 2007. The most recent previous inspection took place in February 2020. Since the previous inspection, an extension to the premises took place in February 2023 to increase fridge capacity by a further 32 spaces with the use of temporary fridge storage units. One unit is still located within the yard to the rear of the mortuary (not in use), with a further unit placed at Allerton Cemetery as an unlicensed body store facility. This unit has now been removed as it was no longer required. In February 2020 there was a change of Person Designated and a change to the Corporate Licence Holder contact. A change to the role of DI took place in June 2020.

A decision to undertake an unannounced visit was made by the HTA's Director of Regulation at a Regulatory Decision-Making meeting on 10 May 2023. This followed concerns relating to body storage and conditions that may impact dignity of the deceased. Accordingly, this inspection focused on the following standards: GQ1(c), T1(a), T1(b), T1(c), T1(d), T1(f), PFE2(a), PFE2(b), PFE2(c), PFE2(d), PFE2(e), PFE2(f), PFE2(g), and PFE2(h).

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:

Review of governance documentation

A review of governance documents was not undertaken as part of this inspection. A full review of governance documentation will be undertaken at the next routine inspection to be scheduled.

Visual inspection

The inspection team undertook a visual inspection of the premises which included the body storage area, the viewing room, and the temporary body storage unit to the rear of the premises.

Audit of records

The inspection team undertook audits of traceability for six bodies in storage. This included two bodies still in refrigerated storage over 30 days and two bodies with a same or similar name. Traceability details were crosschecked between the identification band on the body, information on the door of the storage unit, the mortuary register and associated paperwork. Whilst all bodes were traceable with the use of three identifiers, some minor discrepancies were identified with the establishment procedures. The same or similar name procedure for one body had not been fully completed. Whilst there was a same / similar name tag attached to the tray of the body, a magnet highlighting a same or similar name had not been placed on the fridge door. The establishments procedure is to write the unique mortuary identification number on the exterior of body bags, however in two cases, these numbers were not present. The DI rectified these identified discrepancies at the time of the inspection. One body had an identification tag that was not fully legible (*see advice item 3*).

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence. This included the mortuary manager who is also the DI, mortuary staff and pathologists undertaking PM examination activity.

Report sent to DI for factual accuracy: 20 June 2023

Report returned from DI: 03 July 2023

Final report issued: 05 July 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: 13 October 2023

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.