Inspection report on compliance with HTA licensing standards
Inspection date: **07 December 2023**

Medico-Legal Centre
HTA licensing number 12218

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 **Medico-Legal Centre**	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 Medico-Legal Centre ("the establishment") had met the majority of the HTA's standards, six major and two minor shortfalls were found against standards for Governance and quality systems, Traceability 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

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	There is a documented schedule of audits, however security audits of CCTV do not take place. The inspection team were informed that the DI requires authorisation from the security manager who also has to be present as the licenced person to view CCTV footage. The DI has informed the inspection team that they have been in contact with the security company to arrange this, however this has not yet taken place.	**Major**

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	The establishment has risk assessments in place for some activities in the mortuary, however the DI was not able to provide documented risk assessments for all applicable HTARI categories. Furthermore, existing risk assessments do not include adequate detail of mitigation controls and actions. For example: • The risk assessment relating to identification and viewing of bodies does not specify how identification is checked with the family prior to a viewing taking place *See major shortfall against T1(c)* • The risk assessment for post-mortem examination does not contain detail of control measures in place to mitigate the risk of PM examination on the wrong body. Details of this process are included in the relevant SOP and staff discussed this process with the inspection team. *See advice, item 4*	**Major**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
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	Three identifiers are not checked against details of the deceased provided by family members when attending the mortuary for viewings. This process is not detailed in the current standard operating procedure. This poses the risk of an incident relating to the viewing of the wrong body. *See advice, item 1 and 5*	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs.	The establishment does not have sufficient freezer storage to meet needs. At the time of the inspection, all freezer spaces were fully occupied. Whilst the establishment has contingency plans in place to move bodies requiring frozen storage when all freezers are occupied, the establishment informed the inspection team that occasionally bodies have been held in refrigerated storage longer than the recommended 30 days. The DI informed the inspection team that the lack of freezer storage is currently on the risk register and actions are being identified to address this risk.	**Major**

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 inspection team reviewed records of tests for fridge alarms, but these tests rely on staff remembering to carry these out. There is no regular schedule in place for testing of fridge alarms. Additionally, a freezer used to store tissue for DNA analysis is not connected to the central monitoring system. Although staff monitor and record temperatures of the freezer in hours, these are not recorded out of hours. This poses the risk of loss or damage to tissue in storage. *See advice, item 8*	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
g) Bodies are shrouded or in body bags whilst in storage.	During the visual inspection of the mortuary, the inspection team observed that although bodies were wearing shrouds, they were not fully covered. Current shrouding practices do not preserve the dignity of the deceased.	**Major**

Minor Shortfalls

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.	Whilst formal competency assessments take place for recently hired staff, staff who have been in the role for a number of years have not received a documented competency assessment.	**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	There is damage to the plaster on the wall in the body reception and the whiteboards in the PM room. Although the whiteboards are no longer used, the establishment is unable to properly clean and disinfect this area.	**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 (a)	The DI is advised to review Standard Operating Procedures (SOPs) to ensure that they reflect current practice for the identification of bodies.
2.	GQ1 (a)	Multiple documents are completed when booking deceased into the mortuary. The establishment is advised to review this process with a view to reducing the number of documents that staff complete in order to mitigate the risk of transcription errors and save time.
3.	GQ1 (a)	The DI is advised to consider a formal agreement with pathologists that sets out responsibilities for return and management of tissue taken during PM examinations. In addition, the DI is advised to include in the relevant SOPs the procedure for following up the return of tissue slides to the mortuary.
4.	GQ6 (a)	The DI is advised to have an overarching risk assessment which covers the applicable HTARI categories.
5.	T1 (c)	The DI may wish to consider the introduction of a form to be completed by relatives when they attend for viewings. This form could include relevant identification information so that three identifiers can be checked by mortuary staff on the body before the viewing takes place.
6.	T1 (g)	The establishment may wish to review the options given regarding consent for retention and disposal of tissues taken from PM examination to ensure that informed consent is given. If the establishment is retaining tissue for research but not using it for this purpose, then the timeframe for disposal of the tissue should be stated on the consent forms.
7.	PFE1 (e)	The DI is advised to give consideration to the following to ensure a more robust monitoring system: • Installation of swipe card access to all areas of the mortuary.

		• Review of the timeframe in which CCTV is kept prior to deletion of footage in order to determine the appropriate length of time needed to review the footage for adequate coverage of audits and incidents.
8.	PFE2 (e)	The DI is advised to formalise the process for testing of fridge alarms and to review the fridge alarms to ensure the upper and lower trigger points are set to an appropriate range to mitigate the risk of accidental damage to bodies.

Background

Medico-Legal Centre has been licensed by the HTA since June 2007. This was the third inspection of the establishment; the most recent previous inspection took place in August 2021.

Since the previous inspection there was a change in the Corporate Licence Holder contact (CLHc) and three Persons Designated (PD) have been added on 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

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, PM room and viewing room.

Audit of records
Audits were conducted for two 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. No discrepancies were found.

Audits of tissue in storage were conducted for blocks and slides and processes for sending and returning tissue taken from PM examinations were also reviewed. No discrepancies were found.

Report sent to DI for factual accuracy: 04 February 2024

Report returned from DI: 22 February 2024

Final report issued: 26 February 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: 8 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.