Virtual regulatory assessment (VRA) report on compliance with HTA licensing standards
Assessment date: **23-24 August 2021**

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
Medico-legal Centre	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*

Summary of assessment 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, five minor shortfalls were found against standards for Governance and quality systems and Premises, facilities and equipment. These related to standard operating procedures, document control, risk assessments, fridge and freezer alarms and ventilation records.

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.

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		
(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.	Standard Operating Procedures (SOPs) relating to mortuary activities do not contain sufficient detail to reflect current practice.	**Minor**
(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.	Many of the establishment's SOPs have the same author and authoriser.	**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.	Not all procedures relating to licensed activity are risk assessed.	**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.	Fridges and freezers do not have remote monitoring systems, they only have audible alarms. This is not sufficient to alert staff in the event that the storage temperature deviates from an acceptable range out of hours.	**Minor**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
(c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually.	Although service records were available, the establishment did not supply records to show that the ventilation system provides the necessary ten air changes per hour.	**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 practices:

Number	Standard	Advice
1.	GQ1(a)	The DI is advised to ensure that on the rare occasion that deceased children are stored at the

		establishment that the storage arrangements are included in relevant SOPs.
2.	GQ1(e)	Due to staff absence some of the revised SOPs have not been read and acknowledged by staff members. The DI is advised to ensure that staff read and acknowledge the latest versions of these documents as soon as they return to work.
3.	GQ1(h)	The DI is advised to have matters relating to licensable activity as a standard agenda item at relevant governance meetings. The DI is also advised to provide a template for minute taking at the governance meetings to formalise and standardise the process.
4.	GQ3(c)	Due to the COVID pandemic, the competency assessment training audits have been delayed. The DI is advised to complete the training as soon as possible, in line with the audit schedule.
5.	PFE2(i)	The establishment has sufficient capacity and internal contingency arrangements. However, the DI is advised to consider formalising external contingency storage plans should there be an insufficient number of temperature-controlled storage spaces on site.

Background

Medico-legal Centre has been licensed by the HTA since June 2007. This was the fourth inspection of the establishment; the last inspection took place in April 2016.

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 assessment team covered the following areas during the inspection:

Standards assessed against during inspection
61 of the 72 HTA standards were covered during the VRA (standards published 3 April 2017). As the establishment does not take consent for post-mortem examinations, standards C1 (a), (b), (c), (f), (g) and C2 (a), (b), (c) and (d) were not applicable.

Review of governance documentation
The assessment team reviewed the establishment's self-assessment document provided by the DI in advance of the VRA. Policies and procedural documents relating to licensed activities for the mortuary and post-mortem room, audits, meeting minutes and incidents were also reviewed.

Visual inspection
There was no site visit inspection as part of this assessment.

Meetings with establishment staff
The assessment team met with staff carrying out activities under the licence. This included the mortuary manager (and Designated Individual), service managers, health and safety officer, Coroner's officer and Police and Criminals Evidence (PACE) representative.

Report sent to DI for factual accuracy: 27 August 2021

Report returned from DI: 2 September 2021

Final report issued: 2 September 2021

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 Virtual Regulatory Assessment Report.

Date: 11 May 2022

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 site visit 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 site visit.

   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 site visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine site visit inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.