Inspection report on compliance with HTA licensing standards
Inspection date: **7th and 9th of March 2022**

Brighton and Hove City Mortuary
HTA licensing number 12007

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
Brighton and Hove 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 Brighton and Hove City Mortuary ('the establishment') had met the majority of the HTA's standards, four minor shortfalls were found against standards for 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

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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	Although three identifiers are checked on the deceased when preparing a body for viewing, the procedure for viewing of the deceased does not include a final check using a minimum of three points of identification of the deceased provided by the visitors prior to them entering the viewing room.	**Minor**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
d) Fridge and freezer units are in good working condition and well maintained	There are some areas of rust on the fridges as follows: - the door surrounds on the admissions fridges; and - some of the tray rollers in the main fridge banks and freezers. The areas of rust make it difficult to disinfect and clean the fridges and freezers properly.	**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 are areas of rust on the hydraulic trolleys making them difficult to clean and disinfect.	**Minor**
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	Although the ventilation system is serviced on an annual basis, the establishment could not provide evidence that the system provides the necessary 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 practice:

Number	Standard	Advice
1.	GQ6(b)	The establishment has a comprehensive suite of risk assessments. However, the DI is advised to record the review date to ensure there is a record that all assessments are reviewed regularly.
2.	GQ2(a)	Although there is a documented schedule of audits, the DI is advised to include further description of what each audit involves.
3.	GQ3(c)	All staff have been assessed as competent for the tasks they perform. However, the DI is advised to revisit the competency assessment framework currently in place to standardise the process and documentation.

Background

The establishment has been licensed by the HTA since February 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in December 2015.

The establishment is licensed for the making of a PM examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes.
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
All HTA licensing standards under the overarching standards for Traceability, Governance and Quality Systems and Premises, Facilities and Equipment were covered during the inspection (standards published 3 April 2017). The HTA standards relating to Consent were not applicable, as the establishment is not involved in consent seeking.

Review of governance documentation
The assessment team reviewed the establishment's self-assessment document provided by the DI in advance of the inspection. A review was also carried out on: the policies and procedural documents relating to licensed activities for the mortuary; audits; risk assessments; meeting minutes and HTA reportable incidents.

Visual inspection
The inspection included a visual inspection of the mortuary body store, PM room and viewing room as well as the contingency storage area.

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.

Meetings with establishment staff
Staff carrying out processes under the licence were interviewed including the DI (an Anatomical Pathology Technologist) and a Pathologist.

Report sent to DI for factual accuracy: 04/04/2022

Report returned from DI: [date]

Final report issued: 17 May 2022

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 February 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.