



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	<i>Carried out</i>	<i>Carried out</i>	<i>Carried out</i>

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, five majors and two minor shortfalls were found against standards for Governance and Quality 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

GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
<p>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.</p>	<p>Some SOPs lack sufficient detail of processes carried out by staff. For example:</p> <ul style="list-style-type: none"> • The SOP for the PM procedure does not specify how the identity of the deceased is checked prior to PM examination (e.g. identification on body cross referenced against paperwork) • The SOP for lone working does not reflect mitigations stated within the lone working risk assessment (e.g. use of personal alarms) <p><i>The establishment addressed this shortfall prior to the publication of the final report.</i></p>	<p>Major</p>

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	There is no formalised process for competency assessment for existing staff or locum staff.	Major
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PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.

a) The premises are clean and well maintained	<p>The establishment has recently designated two separate buildings for contingency storage, known to staff as ‘the extra-mural chapel areas’ and ‘the crypt’.</p> <p>Whilst these do have refrigerator units and racking, they do not meet HTA standards for their safe and dignified use. Examples include:</p> <ul style="list-style-type: none"> • Uneven and porous flooring and surroundings • Exposed and crumbling brickwork • Leaking roof and signs of dampness • No risk assessments or cleaning rotas <p><i>The DI was advised that these required a full audit of HTA standards and should not be used until reassessed. The DI confirmed to the inspection team that these areas had never been used for storage.</i></p>	Major
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PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
<p>c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs</p>	<p>At the time of the inspection, the freezer spaces were at capacity and the DI informed the inspection team that contingency for long term storage includes the rotation of bodies between fridge and freezer spaces.</p> <p>Whilst this is rarely required, this procedure poses an increased risk to both the deterioration and dignity of the deceased.</p> <p><i>See advice, item 4</i></p>	<p>Major</p>
PFE2 There are appropriate facilities for the storage of bodies and human tissue		
<p>i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods.</p>	<p>The establishment does not have access to a back up generator should there be a power failure in the mortuary. In addition, some contingency plans are not suitable as the potential designated storage areas relating to the crypt and extra-mural chapel areas do not meet HTA standards.</p> <p><i>See shortfall PFE1(a).</i></p>	<p>Major</p>

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	Many of the risk assessments submitted by the establishment were dated in 2018, however the documents state that they are reviewed annually. <i>The establishment addressed this shortfall prior to the publication of the final report.</i>	Minor

Minor shortfalls

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
a) The premises are clean and well maintained	Whilst the premises were clean at the time of the inspection, some areas of the mortuary was showing signs of minor wear and tear. Examples include: <ul style="list-style-type: none"> • Paint peeling on the fans and areas of rust on the rollers inside the fridges and near the bottom of the fridges • Some exposed plaster on the walls inside the mortuary • Small areas of cracking on the floor in the PM room and body store 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.	GQ2 (b)	The DI is advised to include a section in the audits of CCTV for follow up actions and timeframes for completing actions in case of any discrepancies.
2.	GQ6 (c)	Recruitment for a vacancy in the mortuary was put on hold for a number of years due to staff restructuring. The establishment is advised to continue with their plans to recruit more staff to help alleviate some of the pressures of lone working.
3.	PFE1 (e)	The DI is advised to risk assess the blind spots within the mortuary and give consideration to additional CCTV.
4.	PFE2 (c)	The DI may wish to review the body storage area within the mortuary to consider if additional freezer spaces can be accommodated.

Background

The establishment has been licensed by the HTA since February 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in March 2022.

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 storage areas.

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. Processes for sending tissue taken from PM examination to other licensed establishments were also reviewed. 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: 16 September 2024

Report returned from DI: 16 September 2024

Final report issued: 25 September 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.