Inspection report on compliance with HTA licensing standards
Inspection date: **19 October 2023**

**Broomfield Hospital**
HTA licensing number 12441

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**<br>**Broomfield Hospital** | Licensed | Licensed | Licensed |
| **Mortuary** | *Carried out* | *Carried out* | *Carried out* |
| **Pathology lab** | - | - | *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 Broomfield Hospital 'the establishment' had met the majority of the HTA's standards, seven major shortfalls were found against standards for Governance and quality systems 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***

| 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. | Current SOPs are not up to date, do not cover all procedures taking place and do not reflect current practice. For example, the transfer of bodies to contingency storage and the receipt and release of bodies.<br><br>At the time of the inspection this was already subject to an action plan being overseen by the designated individual. | **Major** |
| **GQ2 There is a documented system of audit** | | |
| a) There is a documented schedule of audits | The audit schedule is not up to date. For example, security audits are taking place but do not form part of the formal audit schedule.<br>At the time of the inspection this was already subject to an action plan being overseen by the designated individual. | **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 | Risk assessments are not up to date and do not cover all activities. For example, the transfer of bodies from the mortuary to the on-site additional storage facility and the use of the lower level of storage in the additional storage facility.<br><br>At the time of the inspection this was already subject to an action plan being overseen by the designated individual. | **Major** |
| **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 | The viewing room has water damage to some walls with peeling paintwork following a leak to the roof. This presents a risk to effective decontamination. | **Major** |
| d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access) | The additional body storage unit power supply control units to external condenser units are not secure. Whilst some of these condenser units are within a fenced gated area the gate does not currently lock. This presents a risk of unauthorised access and tampering. | **Major** |
| e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access | Cleaning staff have access to the mortuary including the body store out of hours. This access is not supervised or audited. | **Major** |
| **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 | Additional storage unit consists of large hard sided fridge units with internal racking containing plastic trays for bodies. The racking is not secured. Trolleys in use in this area do not reach the bottom level of these units. Staff therefore manually handle bodies which increases the risk of accidental damage to bodies and injury to staff. | **Major** |

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. | PFE1d | The DI is advised to progress works to install swipe card access to the additional body store unit. This would provide additional oversight, and allow access to the unit to be audited along with security audits for the main mortuary. |
| 2. | PFE1e | The viewing room waiting area is secure with lockable doors preventing access to the staff office and other areas of the mortuary. The DI is advised to consider the addition of CCTV to this area to allow staff oversight from the office when entering and leaving. |

**Background**

Broomfield Hospital has been licensed by the HTA since 23 March 2007. This was the fourth inspection of the establishment; the most recent inspection took place in January 2020.

Since the previous inspection, there have been a number of changes to staff working at the establishment.

**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 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

*Review of governance documentation*

The inspection 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 were reviewed. This included standard operating procedures, risk assessments, audits, incidents, equipment servicing reports, and training and competency assessment documents. Consent seeking procedures and information for relatives giving consent for adult and perinatal PMs were also reviewed.

*Visual inspection*

The inspection team undertook a visual inspection of the premises which included the mortuary and additional body storage area, viewing facilities, the PM suite and the storage arrangements for relevant material held.

*Audit of records*

The inspection team undertook audits of traceability for six bodies in storage. This included community and hospital cases. Traceability details were crosschecked between the identification band on the body and information in the mortuary register and electronic records. No discrepancies were identified.

Audits were conducted of stored tissue taken at PM examination for five cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, the mortuary electronic database, and tissue being stored. No discrepancies were identified.

*Meetings with establishment staff*

The assessment team met with staff carrying out activities under the licence, including the DI, the Mortuary Manager, an Anatomical Pathology Technologist (APT), bereavement midwives, porters and staff involved in the consent seeking processes.

**Report sent to DI for factual accuracy: 30 October 2023**

**Report returned from DI: 7 November 2023**

**Final report issued: 10 November 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.