Inspection report on compliance with HTA licensing standards
Inspection date: **1 to 3 February 2022**

Basildon University Hospital
HTA licensing number 12051

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 **Basildon University Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Maternity	-	*Carried out*	-
A&E	-	*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 Basildon University Hospital ('the establishment') had met the majority of the HTA's standards, two major and five minor shortfalls were found against standards for Governance and quality systems, Traceability, and Premises, facilities and equipment. These related to standard operating procedures, risk assessments and audits, security arrangements in the mortuary, storage arrangements and mortuary maintenance.

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**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	The inspection team identified the following issues: • There is a door to the body store that was missing, awaiting replacement. This meant the body store could be seen when the secure exterior access door was open. • The air conditioning system in the body store does not regulate room temperature effectively. This affects the efficiency of the fridge units and risks accelerated deterioration of bodies in storage.	**Major**

e) Fridge and freezer units are alarmed and alarms tested regularly to ensure that they trigger when temperatures go out of upper and lower set range	Although serviced and calibrated annually, there is no formal testing of the fridge and freezer temperature alarms to ensure call-out procedures work and are followed.	**Major**

Minor Shortfalls

Standard	**Inspection findings**	**Level of shortfall**
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity	There is no formal procedure for documenting deviations from SOPs.	**Minor**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Audits are not being carried out in line with the establishments audit schedule.	**Minor**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The establishment does not have a system in place to formally review records of swipe card access to the mortuary to ensure that it is limited to those with legitimate right of access.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
g) Bodies are shrouded or in body bags whilst in storage	The establishment's procedures for the shrouding of bodies are ineffective leading to the partial exposure of the deceased.	**Minor**
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	Whilst three points of identification are sought at the time of arranging 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 prior to visitors entering the viewing room.	**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.	C2(a)	The DI is advised to instigate training of additional staff members in consent taking.
2.	GQ1(a)	During movement of body procedures three points of identification on the deceased are checked with paperwork prior to commencement. The DI is advised to detail what specific points of ID are checked within the SOPs for clarity and consistency.
3.	GQ2(a)	The DI is advised to include audits of bodies in storage in the audit schedule to ensure that any discrepancies which arise within internal paperwork (such as transcription or administrative errors) are identified and managed appropriately. Whilst the audit conducted on traceability of bodies in the body store demonstrated full traceability, the inspection team identified a minor error on the mortuary register for one body.
4.	T1(d)	The DI is advised to adopt the practice of using coloured wrist bands and fridge magnets to further highlight patients with same or similar names.
5.	PFE1(a)	The fridges are clean however the DI is advised to formalise the cleaning schedule and record when each fridge unit is cleaned.
6.	PFE2(a)	The DI is advised to record the condition checks of bodies. This should include the date of the check, the condition of the body and include sufficient detail of actions taken in relation to expediting release from the mortuary and/or actions taken to prevent deterioration to the body. The DI may wish to review the Guidance on body storage recently published by the HTA.

Background

Basildon University Hospital has been licensed by the HTA since March 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in November 2017.

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

Review of governance documentation

The inspection team reviewed the establishments self-assessment document provided by the DI in advance of the inspection. Policies and procedural documents relating to licensed activities were reviewed. The team also undertook a review of records relating to equipment servicing, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units and mortuary, reported incidents, and staff training. Consent seeking procedures and information for relatives giving consent were also reviewed.

Visual inspection

The inspection team undertook a visual inspection of the premises which included the mortuary body storage area, PM room and viewing room as well as the area for storage of relevant material held within the mortuary.

Audit of records

The inspection team undertook audits of traceability for five bodies in storage. Traceability details were crosschecked between the identification band on the body, information on the digital mortuary register and paperwork. One discrepancy was identified relating to one body marked as male rather than female on the computerised system. This was corrected instantly.

Audits were conducted of tissue taken at PM examination for two cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, consent for PM examination forms (where relevant), the laboratory database, and tissue blocks and slides being stored. No discrepancies were identified.

Meetings with establishment staff

The inspection team met with staff carrying out processes under the licence, including mortuary staff, staff involved in the consent seeking process, staff from the bereavement team, staff from the maternity department, hospital porters and the DI.

Report sent to DI for factual accuracy: 18 February 2022

Report returned from DI: 04 March 2022

Final report issued: 07 March 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: 15 June 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 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.