Inspection report on compliance with HTA licensing standards
Inspection date: **19 September 2024**

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
Basildon University Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Maternity	-	*Carried out*	-
Accident and emergency	-	*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, one major and two minor 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.	Some SOPs have not been updated to reflect current practices, for example; ○ The ‘Removal of Deceased from Mortuary’ SOP (MORT-BAS-PR-16) makes reference to the release on the ‘Green form’ which has been changed to a ‘Transfer of Care’ form. ○ The ‘Transfer of Deceased for Viewing’ SOP (MORT-BAS-PR-19) does not detail the final identification check that takes place after the family has arrived to visit the deceased. ○ The ‘Mortuary Security’ SOP (MORT-BAS-PR-29) does not incorporate all security arrangements that are in place within the mortuary. ○ The ‘Deceased in Cold Storage’ SOP does not reference the condition checking that takes place (MORT-BAS-PR-27). ○ The ‘Mortuary Winter Capacity and Escalation’ policy refers to the use of Nutwell units which is a contingency option that is no longer used. There are a number of SOPs that reference the ‘Next of Kin’ which is incorrect and should reference the appropriate person in relation to the hierarchy of qualifying relationships. SOPs that need to be revised include; ○ The ‘Carrying out Autopsies’ SOP (MORT-BAS-PR-9). ○ The ‘Tracking Tissue at PM’ SOP (MORT-BAS-PR-25). To fully address this shortfall the establishment should review all documents to ensure that they are reflective of current practice at each of the sites they cover.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
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)	There is one door to the mortuary that is rarely used which has a key lock. Although the key to the door is restricted and covered by CCTV, the door access is not controlled in line with all other entrances and exits and is potentially an area of weakness in the overall security arrangements.	**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 is a metal chemical store cabinet within the PM room that has an extensive area of rust. This is a porous material that is difficult to fully clean and decontaminate.	**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.	C2(b)	Consent seekers involved in perinatal consent taking have up-to-date training records however the refresher training is not on a formalised schedule. The DI is advised to formalise the training plan to ensure that it is carried out in line with expectations.
2.	GQ1(h)	Mortuary incidents are discussed in the 'AOB' part of governance meetings. The DI is advised to add this as a standalone agenda item to ensure that they are routinely discussed.
3.	GQ3(a)	Porters were fully trained in mortuary procedures and the schedule of refresher training was up to date. As they do not carry out routine portering duties, the portering manager had not undertaken any refresher training for a significant period of time. It is recommended that the portering manager is also fully trained in procedures to enable them to have up to date knowledge of practices, and be able to advise their team accordingly.
4.	GQ6(b)	The risk assessment for PM examination and evisceration refers to the next of kin which is incorrect and should reference the appropriate person in relation to hierarchy of qualifying relationships.
5.	PFE1(c)	On the day of the inspection, the facility was very clean however the PM room cleaning checklist was not completed after the session as per the 'Cleaning and Decontamination' SOP (MORT-BAS-PR-2). The DI is advised to check that records are completed as expected.
6.	PFE1(d)	After a security review the establishment are awaiting some improvements including an intruder alarm and door ajar alarms. The DI is advised to monitor this acquisition process to ensure that the improvements are made as per action plan.
7.	PFE2(c)	One of the establishments freezer banks is currently not working halving the overall freezer capacity. The DI is advised to monitor the work to ensure that it is completed as soon as possible.

Background

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

Since the previous inspection, there has been a change of Corporate Licence Holder contact (CLHc) in July 2024.

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 policies and procedural documents relating to licensed activities. This included standard operating procedures, risk assessments, audits, incidents, meeting minutes, equipment servicing reports, and training and competency assessment documents. Consent seeking procedures and information for families giving consent for adult and perinatal PM's were also reviewed.

Visual inspection

The inspection team undertook an unannounced site visit inspection which included the mortuary body storage areas, PM room and histopathology store.

Audit of records

The inspection team undertook traceability audits for four bodies in storage including one perinatal case. Traceability details were crosschecked between the identification bands on the body and information on the electronic register. No discrepancies were identified.

Audits were conducted of stored tissue taken at PM examination for four 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 inspection team met with staff carrying out activities under the licence, including the Mortuary Manager, Deputy Mortuary Manager, Lead Nurse for Professions and Pathology, a Bereavement Midwife, a Porter, and a Consultant Histopathologist who is the establishment's DI.

Report sent to DI for factual accuracy: 22 October 2024

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 1 November 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.