Inspection report on compliance with HTA licensing standards
Inspection date: **12-14 April 2022**

Bedford Hospital

HTA licensing number 12324

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
Bedford Hospital	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 Bedford Hospital ('the establishment') had met the majority of the HTA's standards, four minor shortfalls were found against standards for governance and quality systems. These were regarding mortuary standard operating procedures, governance meetings and staff competency assessments.

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
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.	There is lack of consistency in the level of detail in Standard Operating Procedures (SOPs). Key steps are included but these do not specify the individual actions that need to be undertaken to accomplish each step. These include, but are not limited to, SOPs detailing the process for: • Completion of the computer software and condition checks; • Confirming three points of identification when transferring tissue or the deceased within the mortuary; and • Contingency planning. This is not an exhaustive list of the SOPs requiring amendment. To fully address this shortfall the establishment should review all SOPs relating to mortuary activities to ensure that they are accurate and contain sufficient detail to reflect current practice.	**Minor**
d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use	The Mortuary Manager writes, reviews, and authorises the mortuaries policies and procedural documents.	**Minor**

h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Matters relating to HTA-licensed activities are not discussed at regular, formalised governance meetings involving the Designated Individual (DI) and establishment staff.	**Minor**
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	Whilst all mortuary staff receive competency assessment as part of their induction process, only porters receive refresher training and competency reassessment.	**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.

DI and CLH/LH suitability

The HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Advice
The HTA advises the DI to consider the following to further improve practices:

Number	Standard	Advice
1.	GQ1(a)	The establishment have recently merged with another trust and are currently in the process of upgrading the quality management software system. The DI is advised to continue to roll-out this system in order to strengthen record management.
2.	PFE1(e)	The establishment routinely review mortuary access arrangements. The DI is advised to formalise this process and include a cross check of legitimate rights of access to the mortuary against frequency, duration, and patterns of attendance to ensure access is in line with the purpose for which it was granted.
3.	PFE2(e)	Whilst fridge alarm tests are undertaken as part of an internal monitoring system, the DI is advised to implement regular unannounced fridge alarm tests from within the mortuary. This will provide robust challenge procedure to

		ensure the call out procedures work as expected in the event of a unit failure
4.	PFE3(c)	Although the ventilation system within the PM room provides the necessary air changes per hour, they are dropping below what the system is set at and the DI is advised to consider whether the system needs further maintenance or replacing in the short to medium term.

Background

Bedford Hospital has been licensed by the HTA since March 2010. This was the fourth inspection of the establishment; the most recent previous inspection took place in May 2017.

Since the previous inspection, there has been two changes of the Designated Individual (DI), one in December 2021 due to the merger of NHS Trusts, and the second in April 2022 due to retirement.

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 included a review of the establishment's governance documentation relating to licensed activities. This included policies and procedural documents relating to licensed activities, cleaning records, records of servicing of equipment, ventilation reports, audits, risk assessments, meeting minutes, reported incidents and training records for both the mortuary staff and porters.

Visual inspection

The inspection included a visual inspection of the mortuary body store, PM room, viewing room and tissue storage area.

Audit of records

Audits were conducted for four bodies in refrigerated and frozen storage. Identification details on bodies were crosschecked against the information recorded on the mortuary electronic register. No discrepancies were identified.

Audits of traceability were conducted for tissue blocks and slides from three PM cases, including the consent documentation for the retention of these tissues, electronic and paper records. No discrepancies were identified.

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI, Anatomical Pathology Technologist, Pathologist, Portering Supervisor, maternity staff, and an adult consent seeker.

Report sent to DI for factual accuracy: 04 May 2022

Report returned from DI: 06 May 2022

Final report issued: 10 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: 14 March 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.