Inspection report on compliance with HTA licensing standards
Inspection date: **22 January 2025**

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, thirteen major and twelve minor shortfalls were found against standards for Consent Governance and quality systems, traceability and Premises,

facilities and equipment. These related to staff training and competencies, Standard Operating Procedures, traceability, audits and security arrangements.

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
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice	Whilst there is a departmental SOP (MABSOP C1 26) detailing consent for post-mortem examination and the retention of tissue, and which reflects the requirements of the HT Act and the HTA's Codes of Practice, this is a draft unpublished document.	**Cumulative Major**
b) There is a documented standard operating procedure (SOP) detailing the consent process	Whilst there is documented SOP (MABSOP C1 26, Paediatric Hospital Postmortem Consent) detailing the consent process, this is currently in draft it is unclear as to how and who this is distributed to. Lack of formalised consent documentation poses the risk of staff not following procedure.	
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.	All SOPS are currently being reviewed and updated to reflect current practice across site. There are no published versions available. This poses a risk of inconsistent outcomes and deviations from the required procedures.	**Major**
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	All Standard Operating Procedures (SOPs) are currently being reviewed and updated to reflect current practices across the site. At present, there are no published versions available. There is a quality system in place to manage documents, but currently this is not used within the Mortuary. Staff undertaking regulated activities do not have access to up-to-date versions. Printed copies of documents are not available within the department and therefore not accessible to porters or site staff undertaking licensable activities should they wish to check compliance with any procedure.	**Major**
e) There is a system for recording that staff have read and understood the latest versions of these documents	Whilst there is system in place to ensure staff have read and understood the latest versions of documents this is not currently being used. The inspection team are therefore not assured that staff have read, acknowledged and understood mortuary documented procedures.	**Major**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Although an audit schedule is documented, only audits in relation to security and tissue traceability have been undertaken. The audit schedule does not include a range of vertical and horizontal audits, to ensure compliance with documented procedures or licensable activities.	**Major**

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	The inspection team are not assured that all staff who carry out licensed activity receive regular competency assessment. Whilst some evidence was provided, following the on-site inspection, demonstrating competency assessment of newer staff, competency assessment for qualified and locum staff are not undertaken. Mortuary Contingency SOP MOWI 0602.2 issued 31/10/2024 requires release of deceased to be undertaken by site and portering team. records relating to training and competency of staff required to undertake this task were not available. This poses the risk of release of the wrong body and untrained staff undertaking licensable activities.	**Major**

GQ4 There is a systematic and planned approach to the management of records		
a) There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record	Whilst there is a system available, it is not utilised by the mortuary.	**Cumulative Major**
b) There are documented SOPs for record management which include how errors in written records should be corrected	Document GQPL 0003.6 - Control and management of documents and records was provided; however, this does not reflect current practice within the Mortuary.	

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 postmortem number, name, date of birth/death), including at least one unique identifier	Whilst 3 identifiers are used to identify bodies and tissues. The inspection team identified two discrepancies during the body audit. • The name of one body was spelt differently between mortuary electronic record and the identification bands. This had not been identified during postmortem, transfer, or condition checking. The wrist bands did not contain the relevant unique identifier allocated on admission for this mortuary as required in SOP MASOP GQ13 Procedure for admission of deceased adults to Bedfordshire hospital. • The electronic mortuary register number, for a second case, did not match the identification recorded on the door or the identification band. This error had not been identified during condition checks. • The establishment transfer bodies between sites and to other licensed establishments for long-term storage and PM examination. The inspection team are not assured that appropriate identity checks are carried out at the point of transfer.	**Major**

T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		
a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete	The establishment is in the process of auditing all tissue blocks and slides, this has yet to be completed. The DI is currently unable to provide assurance of what tissue is held and if this is in line with relatives wishes.	**Cumulative Major**
c) Disposal is in line with the wishes of the deceased's family	The DI could not provide assurance that disposal is in line with the wishes of the deceased family. See T2 (a)	

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)	The inspection team identified 3 areas that posed a potential risk to premises security • Access to the changing rooms, PM room, office area and PM observation area is not secured during working hours, and although the access to the main corridor is only accessible by portering and microbiology staff, this provides the opportunity for unauthorised staff to access this area and observe PM room activities. • During the external inspection of the premises, the inspection team found that the external condenser units, which control the internal refrigeration units are easily accessible from the adjacent footpath accessed by staff and public. This provides opportunity for units to be switched off leading to fridge failure. • The doors between the PM Suite and body store cannot be secured due to damage. This poses the risk of unauthorised access to the PM suite via the body store.	**Major**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	Staff access pathology stores via a locked gate in the rear of the mortuary. Previously this has been left open allowing contractors to enter the delivery/ external storage area without authorisation. This poses the risk of unauthorised access and oversight of regulated activities.	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.

a) Storage arrangements ensure the dignity of the deceased	The condensate from the evaporator units in the external freezers collects in the storage trays beneath causing a build-up of ice around the deceased. This poses a risk of accidental damage when moving the deceased. Blocks and slides are currently stored in the PM observation area and are accessible to users of that area.	**Major**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	Testing carried out 28/05/24 does not demonstrate the air changes per hour within the PM suite. The establishment has no assurance that the ventilation system is working to the required standard.	**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	Evidence was not provided to demonstrate deviations from documented SOPs are recorded or monitored as part of the audit schedule.	**Minor**

GQ2 There is a documented system of audit		
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	Audits undertaken do not document who is responsible for follow-up actions and the time frame for completion.	**Minor**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised	Although Porter training and competency is undertaken, this does not include information relating to the HTA and reportable incidents. SOP (MOWI 0602 Mortuary Contingency Plan) documents site and portering team having responsibility for transfer and release of deceased out of hours. Evidence to demonstrate relevant training and competency assessments have been completed for these staff was not provided. Training records were not available for qualified and locum staff. Evidence was not available to demonstrate new mortuary staff received appropriate training of mortuary duties. Whilst training folders where available, minimal evidence was present. The Establishment took immediate action to ensure training and competency documentation for new Mortuary staff was completed prior to the report being issued.	**Minor**

GQ5 There are systems to ensure that all untoward incidents are investigated promptly

a) Staff know how to identify and report incidents, including those that must be reported to the HTA	Staff involved in licensed activities, including staff working outside of the mortuary and porting staff, are not aware of the HTARI reporting requirements and the procedure for reporting HTA reportable incidents.	**Minor**
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	Whilst evidence of risk assessments related to licenced activities was provided, these are currently unpublished and in draft format.	**Minor**
b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed	There are varying draft templates in use, some of which do not document deadlines for completing actions and confirmation that actions have been completed.	**Minor**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	Receipts are provided for toxicology samples by the laboratory, however there is no system in place or audit undertaken to identify cases when receipts are not received and how this is followed up.	**Minor**
h) There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary, (such as to the lab or another establishment), including record-keeping requirements	Pathologists occasionally take tissue slides home for reporting. No evidence of a documented procedure was provided to ensure traceability of tissues when this occurs. This process poses a risk of loss of traceability, loss of tissue and breach of patient confidentiality.	**Minor**

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	Areas of the mortuary premises are showing signs of wear and require maintenance to ensure decontamination procedures are effective. These include but are not limited to • The doors between the PM suite and body store are significantly damaged exposing porous wood. • There are several areas in the body store where plaster is exposed on walls due to damage • The doors between the body store and funeral director entrance are damaged exposing porous wood. • The seal on the freezer door needs replacing. This poses a risk of inadequate decontamination.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
d) Fridge and freezer units are in good working condition and well maintained	The inspection team observed a faulty evaporator unit, of external fridge units, which had been reported but not rectified.	**Minor**
e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range	The establishment does not currently test the lower alarm trigger points for the body store fridges to provide assurance they will trigger should temperatures drop too low.	**Minor**

i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods	There is an SOP/ Working instruction (MOWI 0602 Mortuary Contingency Plan) in draft format, however, this does not reflect the procedures discussed with the inspection team when on-site.	**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.	GQ1(a)	The proposed use of SOPS and working instructions creates significant duplication of process and increases the number of documents in use.The DI is advised to simplify current SOPs (in draft) and consider developing shorter procedure specific SOPs for staff to follow and reduce duplication across SOPs and Working instructions.
2.	GQ3(b)	The DI is advised to ensure that clear lines of accountability and organisational structure are implemented. Interviews with staff indicated there may be some uncertainty or lack of detail around formalised departmental structure.
3.	GQ5(a)	The organisation is advised to include reference to the Human Tissue Authority (HTA) and the requirement to report incidents within 5 working days in the Incident Response Policy QG2T
4.	GQ5(b)	The DI is advised to consider discussions with the risk team to ensure the InPhase reporting system meets the requirements of the reporting of mortuary incidents and HTARi's.

5.	GQ6(a)	The DI is advised to include staff training and competency as a control measure in relevant risk assessments.
6.	T1(h)	Options relating to digital scanning of slides should be considered to reduce risk of loss of tissue, improve traceability and prevent a breach of patient details.
7.	T2(a)	The DI is advised to arrange disposal of historic tissue (blocks and slides) if no longer required.
8.	PFE1(d)	The DI is advised to relocate the CCTV monitor to ensure staff have oversight of activity when in the office. This also prevents potential unauthorised observation of activities when staff are participating in virtual meetings where backdrops are not used.

Background

Bedford Hospital 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.

Bedford Hospital has been licensed by the HTA since 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in April 2022.
Since the previous inspection, there has been the addition of two licensed person designate in December 2022 and a change of Designated Individual in August 2024. There has been a cross-site merger with Luton and Dunstable Mortuary, however both sites still retain separate licenses.

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. Policies and procedural documents relating to licensed activities, cleaning records for the mortuary and post-mortem room, contracts for servicing of equipment and records of servicing, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training records including portering staff working under the licence.

Visual inspection

The inspection team undertook a visual inspection of the premises which included the Mortuary body store areas, Pm suite, viewing facility as well as storage arrangements for relevant material held within the facility. The inspection team observed the process for admission and release of bodies within the mortuary.

Audit of records

The inspection team undertook audits of traceability of four bodies in storage. This included two hospital and two community cases, one of which had been placed in long term storage. Traceability details were crosschecked between the identification bands on the body, information on the body store door, the body store whiteboard and the electronic patient record and mortuary documentation. Two discrepancies were identified. (See shortfall against standard T1(c).)

Audits were conducted of tissue taken at PM examination on four cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms and tissue blocks and slides being stored. Retention and disposal of tissue had been completed in line with the wishes of the family and compliant with HTA requirements. Full traceability of tissues was demonstrated for all four cases.

Meetings with establishment staff

The inspection team conducted interviews with staff carrying out processes under the licence. This included the Designated Individual, Mortuary Manager, Anatomical Pathology Technologist, Trainee Anatomical Pathology Technologist, Consultant Histopathologist, Porter, Quality Officer and Bereavement Midwife.

Report sent to DI for factual accuracy: 27 February 2025

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

Final report issued: 02 April 2025

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.