Inspection report on compliance with HTA licensing standards
Inspection date: **08 July 2025**

Bradford Royal Infirmary
HTA licensing number 12244

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 Bradford Royal Infirmary	Not licensed	Licensed	Licensed
Mortuary	-	*Carried out*	*Carried out*
Maternity	-	*Carried out*	*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 Bradford Royal Infirmary ('the establishment') had met the majority of the HTA's standards, seven major and six minor shortfalls were found against standards for Consent, Governance and Quality, Traceability 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
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	The bereavement policy includes a section on adult post-mortem consent and links to relevant forms. However, it lacks sufficient detail and does not reflect the requirements of the HT Act and the HTA's codes of practice. For example, the information does not state who is responsible for obtaining consent or the requirement for them to be trained and assessed as competent to do so. Additionally, the flow chart for the adult hospital post mortem process indicates that consent is obtained from the next of kin - rather than the person ranked highest in the hierarchy of qualifying relationships.	**Major** **(Cumulative)**
b) There is a documented standard operating procedure (SOP) detailing the consent process	The document submitted entitled "*standard operating procedure for requesting a hospital consultant post mortem (HCPM) examination and gaining informed consent"* does not appear to be a formalised document, additionally it lacks detail and does not reflect current practice.	

c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice	Information provided does not reflect the requirements of the HT Act or the HTA's codes of practice. For example, information relating to who can give consent for the removal and retention of tissue from the deceased is not included.	
d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives	Options for how tissue may be handled after post mortem are not included within the written information provided.	

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 been merged to cover a number of mortuary activities. For example, M/2025:15 *Mortuary security including lone working, COSHH, cleaning and swipe access audit.* The combining of activities has led to a lack of detail relating to individual processes. The lack of details within standard operating procedures poses a risk of deviation from the required standards. Other SOPs lacking detail include but are not limited to: • Procedures for cleaning is included within M.2025:15, however this does not include the equipment required to clean or solution to be used or procedures for managing body fluids or spillages. In addition, relevant HSE guidance, "Managing infection risks when handling the deceased" (HSE 283), is not referenced within any SOPs. • SOPs refer to the use of personal protective equipment (PPE). However, do not detail the minimum PPE required for the activity undertaken. • M/2025:01 *Reporting of adverse events* does not fully reflect the current guidance on HTA reportable incidents. • Reference to condition checking of the deceased is present in a number of SOPs, however they do not outline how and who is responsible for completing them. To fully address this shortfall the Designated Individual is required to review all relevant activities undertaken within the mortuary and ensure they are covered by a documented procedure.	**Major**

e) There is a system for recording that staff have read and understood the latest versions of these documents	There is a system for recording that staff have read and understood mortuary documentation, however this is used for mortuary staff only, and does not extend to external staff such as porters, funeral directors or command centre staff. This poses a risk that staff are not following the latest versions of documents relevant to the activities they perform.	**Major**

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	Records were not available to review to demonstrate that mortuary staff have received role specific training. Additionally, there is no documented training for funeral directors undertaking out-of-hours admissions or command Centre staff undertaking out-of-hours viewings and releases. The inspection team are therefore not assured that all staff who undertake activities within the mortuary are appropriately trained to do so. Evidence of porter training was provided, however this indicated some had not received refresher training since 2021.	**Major (cumulative)**
c) Staff are assessed as competent for the tasks they perform	No records were available for review relating to the competency assessment of mortuary staff, command centre staff, porters and contracted funeral directors for the mortuary activities they undertake. The inspection team were therefore not assured that all staff who carry out licensed activities have been assessed as competent to do so.	

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	Three identifiers obtained from family members prior to viewing are not always recorded on the viewing forms. At the time of inspection fifteen forms were audited and eleven were found to be incomplete. The inspection team are not assured that this information was checked against the wrist band prior to the family being shown into the viewing room. This poses the risk of viewing of the wrong body.	**Major**

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)	Upon arrival the inspection team found the funeral director entrance to be insecure providing direct access to the body store. As this door is in a public area of the hospital, it poses a risk of unauthorised access to the restricted areas of the mortuary. *Staff took immediate action to address this shortfall before the inspection team left the site.*	**Major**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	• Visitors and non-mortuary staff are not required to sign in and out of the mortuary. Therefore, there is no system for recording who has been in the mortuary, the duration of their stay, or the reason for entry. • Swipe access audits are conducted biannually; however, these audits do not include reviews of CCTV footage. The current review of swipe card access is insufficient to provide assurance that individuals accessing the mortuary are authorised and doing so for legitimate purposes. Furthermore, the inspection team are not assured that security audits contain a sufficient sample size for the activity undertaken to assure themselves that any access for an unauthorised purpose would be identified. • A security alarm was installed within the mortuary following a security review; however, this is not used. • Keys and swipe cards required to access the mortuary out of hours are located at A & E, maternity and the main reception. Staff are required to sign the key in and out at the main reception, however this practice is not mirrored within the maternity or A & E departments. Furthermore, the key and swipe card in the maternity department is located on a notice board in a staff rest room. • The inspection team identified a period where the key and swipe card held at the main reception had not been signed back in for a period of 20 hours. This loss of traceability had not been followed up. • The fridge on the maternity ward is not secured and although there is swipe access to the room where the fridge is located, access is not restricted to essential staff only.	**Major**

	• The current practice of use of a mobile phone does not mitigate risks for staff who undertake lone working, and a review of this procedure is required.	

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 were no documents to review to indicate deviations from documented SOPs are recorded and monitored via scheduled audit activity.	**Minor**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Although the DI has contact with persons designate and establishment staff, the human tissue management group meetings have not taken place since April 2024.	**Minor**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
f) There is a documented induction and training programme for new mortuary staff	Although staff undertake a formal trust induction there is no formalised induction and training programme for new staff within the mortuary.	**Minor**

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	The SOP M/2025:11 *Local Records Management* relates to physical records and does not include electronic records held within the mortuary. It does not provide relevant details relating to the location of records and who has access to each type of record. Additionally, mortuary documentation was found to be stored in an unlocked cupboard in the public viewing area. This poses a risk of breach of patient confidentiality.	**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	Not all potential HTA reportable incidents have been included within the mortuary risk assessments For example, risk assessment *Admission of deceased* relates to injuries sustained by staff and visitors, rather than risks to the deceased. A review of all risk assessments should be undertaken to ensure that risks related to the deceased are included.	**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	Risk assessments do not include all mitigations, such as documented procedures training and competency assessment of staff undertaking procedures.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
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 lower trigger point for the fridge alarms is not tested. This lack of testing means there is no assurance that alarms will activate should temperatures fall below acceptable levels, posing a risk of accidental damage to bodies in storage. Additionally, there is no documented procedure for the testing of the alarms, frequency of testing or information regarding alarm parameters. *(See Advice item 9)* Whilst there is an external alarm monitoring system for the fridge in maternity that links to estates there is no audible alarm on the fridge.	**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.	GQ1a	The DI and Mortuary Manager are advised to review the storage of anatomical and theatre waste within the mortuary and if continued, SOP M/2025 should be updated to remove all references to HTA standards.

2.	GQ1c	The Mortuary Manager is advised to consider the amendment of the release form to add a section for Funeral Directors to confirm a condition check has been undertaken immediately before release into their care.
3.	GQ2a	The Mortuary Manager is advised to consider increasing the number of audits undertaken to ensure compliance with current practice and procedures and the frequency of which these are undertaken.
4.	GQ4a	The DI and Mortuary Manager should review the procedure for disposal of records relating to condition checks as this is currently undertaken 3 weeks following release. Enquiries following this date, would not have the traceability to evidence condition checks, and required actions, had taken place.
5.	GQ5a	Th DI is advised to include awareness of the types of HTA incident that are to be reported to the HTA for porters, command centre staff and funeral directors undertaking out of hours transfers and admissions.
6.	PFE2a	The DI is advised to consider if the continued storage of non-post mortem forensic specimens is considered suitable practice within the mortuary environment.
7.	PFE2a	The Mortuary Manager is advised to ensure the alarm parameters on the refrigeration units are adequate to prevent accidental damage to bodies should there be a failure.
8.	PFE2a	The Mortuary Manager is advised to ensure the security gate to the newly installed condenser units is locked to prevent unauthorised access.
9.	PFE2e	The fridge on the maternity unit is monitored by estates, however the lack of audible alarm could lead to delays in identification of a fridge failure.

Background

Bradford Royal Infirmary has been licensed by the HTA since October 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in March 2023.

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

65 out of the 72 licensing standards were covered during the inspection (standards published 22 September 2022). The remaining standards of T1(g), T2(a),(b),(c),(d), PFE(c) & (e) were not applicable as '*making of a postmortem* examination' is not a licensed activity on the licence, and postmortem tissue is not stored on site.

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, cleaning records for the mortuary, contracts for servicing of equipment and records of servicing, audits, risk assessments, meeting minutes, temperature monitoring for the storage units and reported incidents. Staff training and competency assessments related to mortuary activities were not provided. This review also included all relevant documentation relating to licenced activities undertaken in the maternity unit.

Visual inspection

The inspection team undertook a visual inspection of the premises which included the mortuary body store areas and viewing facility. The inspection team observed the process for admission and release of bodies within the mortuary.
The inspection team also undertook a visual inspection of storage facilities on the Maternity unit.

Audit of records
The inspection team undertook audits of traceability of four bodies in storage. Traceability details were crosschecked between the identification bands on the body, information on the body store door, and the mortuary register. No discrepancies were identified. An audit of viewing forms was undertaken whilst on site which identified incomplete forms and a failure to record identifiers provided by relatives at the time of viewing.

Meetings with establishment staff
The inspection team conducted interviews with the Designated Individual and staff carrying out processes under the license. This included the Mortuary Manager, Mortuary Assistant, Bereavement Midwife, Bereavement Officer, and staff obtaining consent for perinatal, paediatric and adult hospital consented postmortem examinations.

Report sent to DI for factual accuracy: 5 August 2025

Report returned from DI: 15 August 2025

Final report issued: 20 August 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.