Inspection report on compliance with HTA licensing standards
Inspection date: **16 February 2022**

Bradford Public Mortuary and Forensic Science Centre
HTA licensing number 12046

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
Bradford Public Mortuary and Forensic Science Centre	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 Bradford Public Mortuary and Forensic Science Centre ('the establishment') had met the majority of the HTA's standards, one major and seven minor shortfalls were found against standards for, Governance and quality systems, Traceability and Premises, facilities and equipment. These related to temperature monitoring and alarm testing of fridges and freezers, Standard Operating Procedures (SOPs), staff appraisals and training opportunities, management of errors in written records, recording of tissue disposal methods and maintenance of premises 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**
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 fridge and freezer units are alarmed but are not subject to regular alarm testing to ensure alarms will trigger as expected.	**Major (cumulative)**
f) Temperatures of fridges and freezers are monitored on a regular basis	At the time of the inspection, two standalone units, one fridge and one freezer were being used for the storage of tissue samples. The units are not subject to temperature monitoring or alarmed. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised*.	

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.	SOPs do not include sufficient detail of the identifiers of the deceased used when procedures are undertaken relating to traceability of bodies and tissue. These include but are not limited to: • BPM-SOP-005: Routine Post Mortem (PM) Examination. Whilst this SOP states that three identifiers of the deceased are crosschecked between information on the body and the Coroner's authorisation form prior to a PM being undertaken, it does not detail the types of identifiers that are used for this check. • BPM-SOP-006: Removal, Storage, Release and Transport of Human Tissue. Whilst this SOP details the identifiers of the deceased used on the tissue traceability tracking forms, there is no detail of what identifiers of the deceased are used on the tissue sample containers to maintain traceability. To fully address this shortfall the establishment should review all SOPs relating to traceability of bodies, tissues, and organs to ensure they contain sufficient detail of identifiers of the deceased used in procedures.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
d) Staff have annual appraisals and personal development plans	Whilst staff working in the establishment are appropriately qualified and trained, annual appraisals have not been conducted for a number of years.	**Minor**

e) Staff are given opportunities to attend training courses, either internally or externally	Due to the lapse in the conducting of annual appraisals, staff have not been able to identify and request opportunities to attend training courses.	**Minor**
g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures	Whilst the establishment provide verbal training and induction to visiting pathologists, this does not include written evidence of sign off against the establishment's policies and procedures	**Minor**
GQ4 There is a systematic and planned approach to the management of records		
b) There are documented SOPs for record management which include how errors in written records should be corrected	The inspection team identified errors in mortuary written records which were illegible because of either being overwritten or correction fluid had been used. This means that some records are not fully auditable. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**
T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		
d) The method and date of disposal are recorded	Whilst the establishment routinely record the date of disposal of tissue, the method of disposal is not recorded in all cases. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**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	The establishment are currently undertaking planned refurbishment and maintenance. The inspection team identified the following areas which could be improved as part of the planned refurbishment and maintenance if not already considered: • Door frames in the body storage areas are made from wood and show signs of damage. One door frame is not effectively sealed to the adjoining wall. • There is damage to some walls which has left areas of porous plaster exposed. • There is minor rusting to the base of the PM tables where the tables meet the floor seal. Also, some body trollies have very minor rust spots. This means that effective decontamination of these areas would be difficult. Whilst the premises were clean at the time of the inspection, some drainage gullies contained small amounts of debris. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**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(h)	The DI is advised to ensure the meetings introduced to discuss HTA matters are held on a regular basis and the meeting minutes are sent to all relevant staff working at the facility.
2.	GQ3(c)	When undertaking competency assessments, the DI is advised to record the evidence of how staff have achieved competency in procedures.
3.	GQ5(c)	Whilst the error log in use demonstrates that follow up actions have been identified and are carried out, the DI is advised to record the dates actions have been taken for completeness.
4.	GQ6(b)	The DI is advised to include administrative control measures in place to mitigate identified risks in risk assessments where required.
5.	T1(c)	Whilst all bodies audited at the time of the inspection were labelled with three points of identification, the DI is advised to review the identification procedure for unidentified bodies to ensure the types of identifiers used are consistent.
6.	T2(a)	The establishment are storing tissue for use for scheduled purposes including research. The establishment do not undertake research as they are a standalone public mortuary. The DI is advised to review all tissue stored in the department for scheduled purposes to determine whether its continued storage is appropriate.
7.	PFE1(d)	Whilst the premises are secure, the DI is advised to consider additional steps to minimise the possible risk of oversight of activities to the funeral director and radiology entrances. The DI is also advised to consider the addition of swipe card access to the radiology entrance to prevent risk of unauthorised access should manual locks not be deployed. Furthermore, the DI is advised to review the panic alarm arrangements for staff working in the visitor area.

8.	PFE2(f)	The DI is advised to review the temperature monitoring system to identify trends. This may mitigate the risk of possible failures with body storage units.
9.	PFE2(g)	Whilst all bodies in storage were shrouded at the time of the inspection, the DI is advised to review the procedure for the shrouding of bodies to ensure full shrouding is applied consistently.

Background

Bradford Public Mortuary and Forensic Science Centre has been licensed by the HTA since May 2009. This was the fifth inspection of the establishment; the most recent previous full HTA inspection took place in January 2016 whilst a targeted unannounced site visit inspection took place in May 2021.

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

60 out of the total 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017). Consent standards C1 and C2 (11 in total) are not applicable as consent for post mortem examination is not sought by this establishment. Furthermore, the standard PFE2(h) is also not applicable as the establishment do not receive or store perinatal or paediatric bodies.

Review of governance documentation

The inspection team reviewed the establishment's self-assessment document provided by the DI in advance of the inspection. Policies and procedural documents relating to licensed activities were reviewed. This included cleaning records for the mortuary

and post-mortem room, records of servicing, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training and competency records

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 storage arrangements for relevant material held within the facility.

Audit of records

The inspection team undertook audits of traceability for four bodies in storage. This included bodies with same / similar name and a body in long term storage. Traceability details were crosschecked between the identification band on the body, information on the door of the storage unit, the electronic mortuary database and paperwork. One very minor discrepancy was identified and corrected at the time of the inspection.

The inspection team also witnessed a release of a body from the mortuary. Records produced and used to identify the body prior to the activity being undertaken were reviewed. The activity was conducted using three-points of identification of the deceased crosschecked between paperwork produced and the identification bands on the body. No discrepancies were identified.

Audits were conducted of 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 blocks, and slides being stored. One case reviewed demonstrated disposal of tissue had been completed in line with the wishes of the family. One case demonstrated disposal had occurred as it was not to be used for a scheduled purpose. Full traceability of tissues was demonstrated for all four cases.

Meetings with establishment staff

The assessment team met with staff carrying out processes under the licence, including mortuary staff, a pathologist who conducts PM examinations, and the DI.

Report sent to DI for factual accuracy: 16 March 2022

Report returned from DI: 29 March 2022

Final report issued: 14 April 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: 5 July 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.