Inspection report on compliance with HTA licensing standards
Inspection date: **03 July 2024**

**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 |
|---|---|---|---|
| **Hub site 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, three major and three minor shortfalls were found against standards for Governance and Quality systems, Traceability and Premises, and 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 |
|---|---|---|
| **GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored** | | |
| 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 | Some risk assessments lack detail with not all risks to the dignity and safety of bodies identified. Furthermore, not all mitigating controls used by staff are reflected in the risk assessments.<br>These include but are not limited to:<br>• Admission of deceased patients<br>• Patient release, transfer of care<br>• Storage and long term storage of the deceased.<br>This is not an exhaustive list of the risk assessments requiring review. To fully address this shortfall, the establishment should review all risk assessments relating to mortuary activities to ensure that they are accurate and contain sufficient detail to reflect current practice.<br>*See Advice item 1* | **Major** |
| **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 | Whilst three forms of identification on the body are checked against the information provided by the family, staff do not consistently re-check this information immediately before a viewing is carried out.<br>This practice is not in line with the SOP and poses the risk of viewing the wrong body.<br>*The establishment submitted sufficient evidence to address this shortfall before the report was finalised.* | **Major** |
| **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 | There is damage to the floor seal of one of the post mortem (PM) tables, this poses the risk of ineffective cleaning and decontamination. Whilst the inspection team were shown evidence of a request for the repair being raised, there was no proposed start date for the work.<br>Furthermore, whilst the PM suite had been recently cleaned there was some minor residual debris on the PM tables and in the drainage holes. | **Major** |

***Minor Shortfalls***

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| **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 | There is a system in place for following up with the Coroner to establish and act on family wishes with regards to the disposal or retention of tissue. However, there are a small number of cases from which blocks and slides are held in storage and the family wishes are either not known or have not yet been actioned.<br>This poses the risk of retention of tissue against the express wishes of the family.<br>*See Advice item 3*<br>*The establishment submitted sufficient evidence to address this shortfall before the report was finalised.* | **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 | Whilst the fridge and freezer units are subject to regular maintenance checks, several of the fridge doors have sustained minor damage which has led to a loss of paint, exposing the metal below. Furthermore, some of the fridge door seals were in poor condition and contained debris.<br><br>*The establishment submitted sufficient evidence to address this shortfall before the report was finalised.* | **Minor** |
| **PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored** | | |
| d) Staff have access to necessary PPE | Whilst face masks are available for staff to use in the PM suite, there is no record to demonstrate that staff have received face fit testing for use of this personal protective equipment. | **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. | GQ6(a) | The DI is advised to separate risk assessments so that risks to staff undertaking licensed activities are separate to the HTARI categories. This will help to mitigate risks to the deceased and stored tissue. |
| 2. | T1(g) | Viscera bowls are colour coded with PM tables using adhesive tape. The DI is advised to obtain some coloured bowls as this will mitigate the risk of contamination if the tape becomes damaged. |
| 3. | T2(a) | There is a system in place for the oversight of tissue blocks and slides and their disposal, this is the responsibility of one member of staff. The DI should consider training an additional member of staff to oversee the traceability of tissue taken during post mortem examination to ensure there is service resilience.<br>Furthermore, consideration should be given to the allocation of protected time for the management of tissue. |
| 4. | PFE3(f) | The systems and equipment within the mortuary are subject to regular testing and servicing however records are not kept within the mortuary and are only available upon request. The DI is advised to request copies of all maintenance, servicing and repair reports so that they are easily accessible to mortuary staff for review and monitoring purposes. |

**Background**
Bradford Public Mortuary and Forensic Science Centre has been licensed by the HTA since 2009. This was the sixth inspection of the establishment; the most recent previous inspection took place in February 2022.
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 of the 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017), Consent standards are not applicable (C1(a-g), C2(a-d)) as the establishment does not obtain consent. Standard PFE2(h) does not apply as the care of paediatric or perinatal deceased is not undertaken.

*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 for the mortuary, records of servicing of equipment, audits, risk assessments, meeting minutes, reported incidents and training records for mortuary staff and the deceased person removal operatives

*Visual inspection*

The inspection included a visual assessment of the establishment including body and tissue storage areas, the PM suite and viewing rooms. The inspection team observed the processes for admission and release within the mortuary.

*Audit of records*

Audits were conducted onsite of one body from frozen storage and three bodies from refrigerated storage. Additionally, the release of one body into the care of funeral directors and one body admitted by the establishment employed deceased person removal operatives was audited. Identification details on bodies were crosschecked against the information recorded in the electronic database and associated paperwork in addition to fridge door plates. No discrepancies were identified.

Audits of traceability were conducted for tissue blocks and slides for three cases. These included audits of the consent documentation for the retention of these tissues. No discrepancies were identified.

*Meetings with establishment staff*

Staff carrying out processes under the license were interviewed including the DI, Deputy Mortuary Manager, APT, Tissue lead and Pathologist.

**Report sent to DI for factual accuracy: 22 July 2024**

**Report returned from DI: 05 August 2024**

**Final report issued: 05 August 2024**

## 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: 1 October 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.