

Inspection report on compliance with HTA licensing standards
Inspection date: **30 March 2023**



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	-	<i>Carried out</i>	<i>Carried out</i>
Maternity	-	<i>Carried out</i>	<i>Carried out</i>
A&E	-	<i>Carried out</i>	-

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, two major and one minor shortfall were found regarding consent training and fridge capacity.

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
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent.		

<p>b) Records demonstrate up-to-date staff training</p>	<p>The only individual trained to take adult post mortem consent is not a permanent member of staff, and the inspection team were not assured that they had received up to date staff training.</p> <p>This was identified as a shortfall at the previous inspection, and whilst addressed at the time, training records were again unavailable.</p>	<p>Major (Cumulative)</p>
<p>d) Competency is assessed and maintained</p>	<p>There is no process, or documented evidence, that competency for adult post mortem consent taking is assessed or maintained.</p>	<p>Major (Cumulative)</p>
<p>PFE2 There are appropriate facilities for the storage of bodies and human tissue.</p>		

b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity	<p>There is insufficient capacity for the storage of bodies. Two temporary units have been erected within the mortuary and are used on a permanent basis. In addition, at the time of the inspection, floor space of the fridges were utilised as contingency spaces as the main fridges were full.</p> <p>The establishment provided evidence to the inspection team that draft business plans are in place to increase capacity.</p>	Major
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Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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 staff competency is discussed at annual appraisals, there is no formal process of recording that staff are competent for the tasks they perform.	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.	PFE1c	The mortuary has a fully signed cleaning schedule. The DI and mortuary manager are advised to expand this to include all specific cleaning tasks, such as the internal fridge floors and racking.
2.	PFE1e	The DI is advised to review the mortuary lone working arrangements to ensure the current practices of carrying a mobile phone are suitable to mitigate risks to staff when in the department alone.
3.	PFE2c	The DI is advised to review the arrangements for bariatric fridges and freezers in the ongoing business plans for increasing capacity.

Background

Bradford Royal Infirmary has been licensed by the HTA since October 2007. This was the third inspection of the establishment; the most recent previous inspection took place in August 2017.

Since the previous inspection, there has been a change to both the designated individual and mortuary management staff. Additional persons designate have been added to the licence to cover all areas of the establishment where regulated activity takes place. In January 2023 the licensed activity of '*making of a post mortem examination*' was removed from the licence, at the request of the designated individual. Procedures were introduced to transfer deceased patients, requiring a post mortem, to alternative licensed establishments.

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 post mortem examination' is not a licensed activity on the licence, and post mortem 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, records of servicing of equipment, audits, risk assessments, meeting minutes, reported incidents and training records for staff.

Visual inspection

The inspection included a visual assessment of mortuary fridge rooms, the viewing facilities, and the maternity storage area. The inspection team observed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records

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

A tissue audit was not conducted, as all retained tissue is stored at the referral licensed establishment.

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI, mortuary manager, APT, mortuary porter, bereavement officer and bereavement midwife.

Report sent to DI for factual accuracy: 21 April 2023

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

Final report issued: 09 May 2023

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: 11 September 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.