Inspection report on compliance with HTA licensing standards
Inspection date: **27 June 2023**

Royal Bolton Hospital

HTA licensing number 12035

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
Royal Bolton Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	-	-
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 Royal Bolton Hospital ('the establishment') had met the majority of the HTA's standards, one major and five minor shortfalls were found against standards for Governance and quality systems, 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
PFE2 There are appropriate facilities for the storage of bodies and human tissue		
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	There is insufficient freezer storage capacity to meet needs. There are five freezer spaces for the long-term storage of bodies. During the site visit the inspection team identified a body that had been in refrigerated storage for 84 days. The body was in a poor condition and required freezing however the freezer spaces were all in use. *Whilst this shortfall was identified at the time of the inspection, it is noted that the establishment is currently going through a refurbishment of the mortuary and freezer capacity is being addressed.*	**Major**

Minor 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 'Informed consent of PM' policy has not been reviewed since 2018. Furthermore the policy references the 'next of kin' throughout. *The HTA did not find evidence that the establishment had removed or used relevant material without the consent of the appropriate person under the Human Tissue Act 2004 (HT Act), namely the person highest in the hierarchy of qualifying relationships, as set out in the legislation. However, if "next of kin" is used instead of the statutory hierarchy of relationships, it could result in a breach of the HT Act.*	**Minor**
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework	The Corporate Licence Holder contact (CLHc) and Persons Designated (PDs) that are listed on the licence are no longer at the establishment, and have not been for a number of years. *Prior to the final report being published the DI submitted evidence of the actions taken in relation to this shortfall. The HTA has assessed this evidence as satisfactory and considers this standard to be now met.*	**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 porters have training provided by the portering supervisors, the mortuary team has not facilitated any training with the portering team for a number of years. This lack of oversight increases the risk of mortuary tasks not being carried out as the mortuary expects.	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		

a) Bodies are tagged/labelled upon arrival at the mortuary	Although wristbands are primarily used to identify bodies within the mortuary, for those in the mortuary for extended periods or those that may be decomposed, identification from the wristband is copied onto the outside of the body bags. In some cases it is this information which is used to facilitate the traceability of the body. Bodies should be identified using information that is attached to the body at all times to minimise the risk of misidentification.	**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	Some of the fridges within the main body store are not connected to the remote alarm systems. *Whilst this shortfall was identified at the time of the inspection, it is noted that the establishment is currently going through a refurbishment of the mortuary and temperature monitoring of storage areas is being addressed.*	**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 practices:

Number	Standard	Advice
1.	C1(e)	The establishment gives the option to families for retention of PM material for future use including education, training, and research. The establishment does not carry these out and has not done for many years. The DI is advised to consider providing this information to families to set expectations and to ensure that any consent given by families for tissue to be retained is suitably informed.
2.	C2(a)	There is a restricted number of staff trained in the process of seeking of consent for perinatal PMs. The DI is advised to have more staff trained in the procedure so that they can provide a seven day service.

3.	GQ1(a)	There is some duplication of processes in the establishment's SOPs and Risk Assessments relating to licensable activity. The DI may wish to review these and amalgamate those which overlap. This will help to streamline documentation and also reduce the time taken for staff to review the documents.
4.	GQ6(a)	The establishment's risk assessment HY-SOP-H&S-0092 relating to 'Failure of Fridge units', is not up to date in relation to the fridge alarm systems that are in place for the different storage areas. For example, the external units are not connected to the Tutela system, however the risk assessment does not reflect this. The DI is advised to review all the risk assessments following completion of the mortuary refurbishment to ensure that they are relevant, current and that all risks have been assessed appropriately.
5.	PFE2(e)	There is an external body store unit that is only for use in an emergency situation. The unit is not connected to the remote temperature monitoring and alarm system. Although not currently in use, the DI is advised to have a remote temperature monitoring system prepared should the unit be needed for storage.
6.	PFE3(f)	The ventilation system within the PM room is subject to regular testing and servicing however records are not kept within the mortuary and 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 the Mortuary Manager for review and monitoring purposes.

Background

Royal Bolton Hospital has been licensed by the HTA since May 2007. This was the fourth inspection of the establishment; the most recent inspection took place in June 2018.

Since the previous inspection, there have been significant changes to the licence arrangements including a change of CLHc in June 2023. The establishment are also currently undergoing a refurbishment of the body store areas.

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 team reviewed the establishment's self-assessment document provided by the DI and Laboratory Medicine Quality Manager. Policies and procedural documents relating to licensed activities were reviewed. This included standard operating procedures, risk assessments, audits, incidents, ventilation, and equipment servicing reports, and training and competency assessment documents. Consent seeking procedures and information for relatives giving consent for adult and perinatal PMs was also reviewed.

Visual inspection

The inspection team undertook a site visit inspection of the premises which included the mortuary body storage areas, the PM suite and the storage arrangements for relevant material held within the histology facility.

Audit of records

The inspection team undertook audits of traceability for three bodies in storage. This included community and hospital cases in the fridge as well as one long stay body. Traceability details were crosschecked between the identification band on the body and information in the mortuary register and electronic records. Although no traceability discrepancies were identified, one body had been stored in the fridge for 84 days as there was no freezer space available. See shortfall for PFE2(c).

Audits were conducted of stored tissue taken at PM examination. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, the mortuary electronic database, and tissue being stored. No discrepancies were identified.

Meetings with establishment staff

The assessment team met with staff carrying out activities under the licence, including the Mortuary Manager, an Anatomical Pathology Technologist (APT), a porter, the portering assistant manager, the Histology Service Manager, staff involved in the consent seeking processes, the Bereavement Midwife, and a pathologist who holds the position of DI.

Report sent to DI for factual accuracy: 17 July 2023

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

Final report issued: 17 August 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 December 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.