Inspection report on compliance with HTA licensing standards
Inspection date: **22 June 2022**

Royal United Hospital Bath

HTA licensing number 12250

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 United Hospital Bath	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*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 United Hospital Bath ('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, facilities and equipment.

Two of the shortfalls (two majors) relate to findings from the last inspection. The HTA is concerned that adequate steps were not taken to address these findings in the intervening period and to embed suitable practices at the establishment.

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. However, in light of the establishment's lack of progress with addressing shortfalls from previous inspections, the HTA will consider the need for regulatory action if appropriate action is not taken to meet the regulatory requirements in accordance with the timeframes detailed in Appendix 2.

Compliance with HTA standards

Major shortfalls

Standard	Inspection findings	Level of shortfall
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.	The procedure for conducting viewings does not include steps to check a minimum of three identifiers of the deceased, provided by relatives, against the identification on the body before a viewing takes place.	**Major**
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.	Although serviced and calibrated annually, there is no formal testing of the fridge and freezer temperature alarms to ensure call-out procedures work and are followed. This was identified as a shortfall on the previous HTA inspection. Furthermore, although not currently in use, the contingency storage fridges and freezers do not have remote monitoring and alarm systems. This is not sufficient to alert staff in the event that the storage temperature deviates from an acceptable range out of hours.	**Major**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
(c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually.	The ventilation system within the post mortem (PM) room does not provide the necessary ten air changes per hour. This was identified as a shortfall on the previous HTA inspection.	**Major**

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.	Standard Operating Procedures (SOPs) relating to mortuary activities do not contain sufficient detail to reflect current practice. Examples include- • The SOP for carrying out a PM does not detail specifically what identification procedures take place. • The SOP for cleaning and decontamination does not detail the cleaning of floors, drains and fridges. • The SOP for carrying out a PM does not detail by whom and when the external examination is carried out. • There is a generic SOP for incidents which does not include enough detail in relation to HTA reportable incidents (HTARIs). • The SOP for out of hours viewing does not detail identification checks.	**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 licensable activities are covered in the establishments risk assessments. Examples include- • There is no risk assessment covering accidental damage to bodies. • There is no risk assessment for the use of the PM suite to store the Maxistore bariatric storage unit.	**Minor**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		

(e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The establishment does not have a system in place to formally review records of swipe card access to the mortuary to ensure that it is limited to those with legitimate right of access.	**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(a)	There are some duplications of SOPs relating to licensable activity. For example, there is an SOP entitled '*Procedures Prior to Undertaking Autopsies'* and another entitled *'Death notification and procedures prior to post mortem examination'.* Both contain similar procedures however differ in levels of detail. For clarity, the DI is advised to review these and amalgamate SOPs which overlap.
2.	GQ1(a)	The *'Death notification and procedures prior to post mortem examination'* document references the Human Tissue Act 2006. The DI is advised to update this reference to the correct year of 2004.
3.	GQ1(e)	The establishment only redistribute SOPs after changes have been made. The DI is advised to redistribute SOPs after review even when there are no changes made as part of refresher training.
4.	GQ1(h)	Due to the COVID pandemic the HTA governance meeting schedule has been disrupted. The DI is advised to reinstate the regular meetings.

5.	GQ3(a)	Porters are trained in the mortuary tasks they undertake however they do not have formalised refresher training in place. The DI is advised to include routine refresher training for porters into the training schedule.
6.	GQ6(b)	The establishment has a suite of risk assessments however the DI is advised to review the mitigating factors to ensure that all are detailed against the relevant risk.
7.	PFE2(a)	Although condition checks are carried out routinely for all bodies, the DI is advised to formalise the checks and document the findings.
8.	PFE2(i)	There is a separate bank of fridges used for contingency purposes which is switched off when not in use. The establishment is advised to lock and label the fridges to avoid staff using them inadvertently.
9.	PFE3(a)	The dissection board within the PM room is starting to show signs of wear and the DI is advised to replace it.

Background

Royal United Hospital Bath has been licensed by the HTA since August 2007. This was the fourth inspection of the establishment; the most recent inspection took place in May 2018. Since the previous inspection, there has been no significant changes to the licence arrangements.

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 Cellular Pathology and

Pathology Services Manager in advance of the inspection. Policies and procedural documents relating to licensed activities were reviewed. This included standard operating procedures, risk assessments, audits, incidents, ventilation reports, 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 visual inspection of the premises which included the mortuary body storage areas, the PM suite 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 community and hospital cases, adults and a perinatal case. Traceability details were crosschecked between the identification band on the body and information on the mortuaries electronic database. No discrepancies were identified.

Audits were conducted of stored tissue taken at PM examination for 3 cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, the mortuary electronic spreadsheet and the tissue being stored. No discrepancies were identified.

Meetings with establishment staff
The assessment team met with staff carrying out activities under the licence, including mortuary staff, the Cellular Pathology and Pathology Services Manager, a portering staff member, staff involved in consent seeking processes and the DI.

Report sent to DI for factual accuracy: 15 July 2022

Report returned from DI: 20 July 2022

Final report issued: 21 July 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: 28 November 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.