Inspection report on compliance with HTA licensing standards
Inspection date: **05 February 2025**

Royal United Bath Hospital
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
Although the HTA found that United Hospitals Bath ('the establishment') had met the majority of the HTA's standards, two critical, twelve major and thirteen minor shortfalls were found against standards for Consent, Governance and quality systems, 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

Critical Shortfalls

Standard	Inspection findings	Level of shortfall
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access)	While a CCTV camera linked to security is present to monitor the funeral directors' access point, the lack of cameras at other access points does not provide effective oversight of individuals entering the mortuary. Furthermore, there is no assurance that security staff have been trained to distinguish between authorised and unauthorised activities. Coded locks on the changing room doors, which provide direct access to the post-mortem (PM) room, are not regularly changed. Additionally, the security shutter between the changing area and the PM room is not utilised to enhance security during out-of-hours periods. Access to the PM room is not adequately monitored. Although the main PM room door can be locked with a key, staff are unable to confirm the number of keys currently in circulation. A visitor log is maintained in the body store for funeral directors, hospital staff, and contractors. This log records the date, time, and purpose of entry; however, upon inspection, it was found to contain incomplete entries. Additionally, this log is not integrated into the access swipe audit system.	**Critical**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	Swipe access audits are conducted quarterly; however, these audits do not include reviews of CCTV footage or visitors' logs. The current quarterly review of swipe card access is insufficient to provide assurance that individuals accessing the mortuary are authorised and doing so for legitimate purposes. Maintenance staff and contractors attend the mortuary out of hours when required, there is currently no policy or procedure in place for the management or oversight of their activities. There is no audio-visual system on the main mortuary access door from the corridor. This door opens into the body store area, staff are unaware of who is present until they open the door risking oversight of mortuary activities. There are no measures in place to prevent access by staff or contractors during working hours when mortuary activities are taking place. During inspection, the site team observed a member of the estates department entering without restriction. There is no documented policy or procedure regarding mortuary security. A documented procedure should include details on who has legitimate access, how access is granted or revoked, and procedures for out-of-hours access, including for maintenance staff and contractors.	**Critical**

Major 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 Policy for the care of women with pregnancy loss after 24 weeks gestation (M97) does not stipulate that those obtaining consent must be trained and competency assessed or provide information on the training required.	**Cumulative Major**
c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice	Path-007 SOP for consenting to adult hospital post-mortem examinations requires that information for those giving consent be downloaded from the HTA website. This approach does not ensure that organisation-specific details regarding the post-mortem are included, nor does it provide relevant contacts and timescales for those who may wish to withdraw consent. The Designated Individual (DI) is required to ensure that information regarding the organisation's post-mortem process is provided to those giving consent. This information should include details of contacts and timescales for withdrawing consent.	

d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives	(See *Shortfall* against standard C1(c) above.)	
e) Where consent is sought for tissue to be retained for future use, information is provided about the potential uses to ensure that informed consent is obtained	Information is provided verbally during the adult consent process; however, this may not reflect information provided in the guidance document.	
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice	The establishment is unable to provide assurance that staff obtaining paediatric consent have undertaken relevant training or have been competency assessed to do so.	**Cumulative Major**
b) Records demonstrate up-to-date staff training	Records demonstrating training for clinical staff undertaking paediatric consent were not provided.	
c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual	Evidence was not provided to indicate that untrained staff are accompanied by a trained individual.	

d) Competency is assessed and maintained	Competency assessment for staff undertaking perinatal /paediatric consent is not undertaken.	
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.	The majority of SOPs lack detail regarding individual tasks required as part of the procedure these include but are not limited to: • QMS/SOPMO/8.8 Removal of an implantable Cardioverter defibrillator. • QMS/SOP/MO/48/2 Out of hours fridge alarm procedure detail • SOP/MO/8 Notification of risk to funeral directors. Lack of detail in this document has the potential to lead to a breach of patient confidentiality. • QMS/SOP/MO/42/6 Taking transplant material in the Mortuary. • QMS/SOP/MO/13/9 Standard autopsy procedure. The lack of details within standard operating procedures poses a risk of deviation from the required standards. Procedures discussed with staff during the site visit and during subsequent interviews were not consistent with that of some SOPs. These include, but are not limited to: • QMS/SOP/55/1 Mortuary fridge alarms • QMS/SOP/11/6 Procedure for visitors to the mortuary • SOP/MO/37 Out of hours procedure for undertakers delivering deceased to the mortuary. • QMS/SOP/MO/14/12 Storage and dispatch of bodies	**Major**

	• QMS/SOP/MO21/6 Procedures for dealing with high-risk autopsy cases. • SOP/MO/50 viewing arrangements out of hours. • QMS/SOP/MO/09/8 Death notification and procedures prior to postmortem examination. In addition, relevant HSE guidance, "Managing infection risks when handling the deceased" (HSE 283), is not referenced, nor are recommended practices included within departmental SOPs, such as the requirement for face fit testing for masks. (See *advice* item 2)	
e) There is a system for recording that staff have read and understood the latest versions of these documents	A system for reading and acknowledging documents is available for mortuary and pathology staff, however evidence to ensure site team, porters and funeral directors have read and understood SOPs related to the mortuary activities they undertake was not provided.	**Major**

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	Mortuary staff undergo training in procedures; however, this training is not documented. There are no records to demonstrate that other staff and service users undertaking licensable activities, both during and outside of regular hours, are provided with formal ongoing and refresher training or competency assessments. These activities include: • Porters (this was identified in the previous HTA inspection) • Site team/nurses • Chaplaincy • Bereavement officers • Funeral directors	**Cumulative Major**
c) Staff are assessed as competent for the tasks they perform	There was no evidence of competency assessments in place for Porters, site team, bereavement staff or funeral directors.	
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
a) Staff know how to identify and report incidents, including those that must be reported to the HTA	Whilst staff know how to identify and report incidents, the inspection team identified four incidents which met the threshold for reporting to the HTA which had not been reported. These include serious security breach, equipment failure and accidental damage to a body. Furthermore, Portering staff were unaware of what incidents constituted a HTARI or that they should be reported. (See *advice* item 4)	**Major**
d) Information about incidents is shared with all staff to avoid repeat errors	Evidence submitted demonstrates significant numbers of recurring incidents/errors relating to mortuary related practices within the organisation. The inspection team were not assured adequate process are in place to prevent repeated errors and demonstrate learning.	**Major**

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	Some risk assessments lack detail of existing controls and do not reflect practice for example: • RA/MO/33 does not include assessment for out of hours viewing procedures including cases where babies and infants are removed from the mortuary. • RA/GEN/21 Lone worker assessment is a pathology generic assessment does not reflect the procedures within the mortuary. Actions to mitigate risk include notifying friends and family and providing them with security contact number should they have concerns, however this is not reflected in the SOP. • RA/MO/30 Postmortem examination refers to PPE being used for infective cases this includes respirators. Respirators are not provided for staff and therefore should not be included as existing control measures. • RA/MO/31 Registration and Storage of the deceased. Documents training in place for APTs and Porters, however there are no documented training records or competency assessment for porters. Admissions are undertaken Out of Hours by Funeral directors; this process is not included. Risk assessment for the use of the maxi store has not been undertaken *This was a finding in the previous HTA inspection.* This is not an exhaustive list, and the DI is required to undertake a review of all risk assessment to ensure all risks related to mortuary activities are appropriately assessed.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		

a) Storage arrangements ensure the dignity of the deceased	There is no oversight of activity undertaken within the mortuary out of hours this includes admissions, release, viewings and attendance by maintenance staff and funeral directors. Arrangements for contingency storage with another establishment is included within the pathology wide business continuity policy but are not formalised nor is there a documented procedure relating to this process. (See *advice* item 5)	**Major**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
b) Equipment is appropriate for the management of bariatric bodies	The current facility for storage of larger bariatric patients is within the post mortem room. Access to this area is not restricted or monitored.	**Major**
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	Ventilation tests carried out in January 2025 demonstrates nine air changes per hour. This does not meet the standard 10 air changes per hour required. *This was identified as a shortfall in previous inspections*	**Major**
d) Staff have access to necessary PPE	Staff are not provided with respirators / air hoods and are not face fit tested for any masks used. This poses a risk to staff undertaking high risk post mortems involving airborne pathogens.	**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		
g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided	PATH-007 SOP- Consenting for adult hospital postmortem examinations states the consent form is to be downloaded from the HTA website. The DI is required to ensure that a ratified Trust version of the documentation, which does not contain HTA branding, is used and stored to prevent access by those who are not trained to undertake consent.	**Minor**

GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	There are no documented processes in place for condition checking of bodies, including those in long-term storage. (See *advice* item 3)	**Minor**
f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity	Audits related to deviations from SOP's were not included in the audit schedule.	**Minor**
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework	There is no Person Designate (PD) within the Mortuary or Maternity unit. This poses a risk of lack of oversight and failure to ensure incidents are reported.	**Minor**
GQ2 There is a documented system of audit		

a) There is a documented schedule of audits	There is a schedule of audits, however, these primarily relate to security and traceability. Audit schedules should include a range of vertical and horizontal audits checking compliance with documented procedures. Failure to audit processes risks unidentified deviations from the required standard.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures	The establishment employs a member of bank staff, however, there were no documents available to review to demonstrate training and competency assessments have been completed.	**Minor**

Commented [MG1]: Was there evidence of induction?

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	Three identifiers are used for identification: name, date of birth, and address or hospital number if the death occurred in a hospital. During the inspection, the team was advised that the mortuary number is also used as an additional unique identifier. However, this number is only recorded on paperwork and not on the patient's identity band. This prevents the unique identifier from being used to support identification, which is particularly useful when dealing with unidentified patients or those with the same or similar names.	**Minor**

e) Identity checks take place each time a body is moved whether inside the mortuary or from the mortuary to other premises	The requirement to undertake identity checks each time a body is moved was not evident in some procedures. SOP/MO/48 Mortuary Fridge Alarms requires bodies to be relocated in the event of a fridge failure by non-mortuary staff. However, the procedure does not specify how this relocation should be conducted or include any checks to be undertaken during this process.	**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	Although the premises appeared to be clean at the time of inspection there were a number of areas that required some maintenance: • Limescale is present at the base of the tables. • Areas of rust are present on dissection unit doors in the postmortem room. • A number of cracks were noted in the body store and postmortem room flooring, one of which created an opening in the surface. Areas with damage or inadequate sealing cannot be adequately cleaned and disinfected. • The presence of a slope in the postmortem room prevents the use of some storage due to the instability of the hoist when accessing some of the body store. • A temporary bariatric tent is available for large bariatric patients who cannot be accommodated within the standard bariatric unit. However, this has become a permanent structure within the PM room despite not being in use which prevents effective cleaning and decontamination of the PM room.	**Minor**

c) There are documented cleaning and decontamination procedures and a schedule of cleaning	Whilst the SOPs provided document cleaning, this lacks detail. Cleaning procedures in the pm room do not include walls or fridge doors. Cleaning records for January were provided for the post-mortem room, saw, and fridges however records relating to the cleaning of the body store area were not provided.	**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	Lower limits are not tested. This creates a risk of bodies being inadvertently frozen if lower alarm triggers fail. Staff are unaware of the alarm trigger points or alarm activation timescales.	**Minor**
f) Temperatures of fridges and freezers are monitored on a regular basis	Mortuary fridge alarm testing SOP/MO/55 details the requirement to monitor fridge and freezer temperatures however documented evidence to support this process was not submitted.	**Minor**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored

a) Items of equipment in the mortuary are in good condition and appropriate for use	Areas of the mortuary premises are showing signs of wear and require maintenance to ensure decontamination procedures are effective. These include but are not limited to: • The electronic fly killer in the body store is damaged and held together with tape. • The body measure was broken and held together with tape. • The dissection board is heavily stained and in need of replacement. • The autoclave instrument tray was heavily rusted. • The electrical plug socket in the PM at low level is damaged.	**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.

DI and CLH/LH suitability
At the time of inspection, the establishment did not have a Corporate License holder Contact CLhC in post and have agreed to appoint to the role as a matter of urgency. The establishment is advised to consider the governance structure pertaining to the DI and CLhC roles both in terms of everyday oversight of mortuary activity and the availably of effective escalation routes.

The suitability of the DI is to be reviewed.

Advice

The HTA advises the DI to consider the following to further improve practice:

Number	Standard	Advice
1.	C1(b)	The DI is advised to ensure the Path-007 SOP Consenting for adult postmortems section 4.3 clearly states who is able to seek consent ensuring the establishments requirements are clear and prevent any ambiguity.
2.	GQ1(a)	The DI is advised to ensure those working within the mortuary or responsible for the development of mortuary SOP's are familiar with, the guidance issued by the Health and Safety Executives "Managing infection risks when handling the deceased" (HSG 283) and that documented procedures reflect the guidance provided.
3.	GQ1(c)	The DI is advised to consider the amendment of the release form to add a section for Funeral Directors to confirm a condition check has been undertaken immediately before release into their care.
4.	GQ5(a)	The DI is advised to display a list of HTA reportable incidents to all areas of the establishment undertaking licensed activity.
5.	PFE2(a)	The current Pathology business continuity plan is a generic policy and does not contain adequate detail relating to mortuary specific procedures. The DI is advised to consider a separate Business continuity plan that is mortuary specific.

Background

Royal United Hospitals Bath is licensed for the making of a PM examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes.

Royal United Hospital Bath has been licensed by the HTA since 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in June 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
All 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

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 post-mortem room, maintenance and records of servicing of equipment, and records of servicing, a recent ventilation report, audits, risk assessments, meeting minutes, reported incidents, and mortuary staff competencies. Competency assessment and training records for two Consultant Histopathologists who undertake adult consent process were also reviewed.

Visual inspection
The inspection team undertook a visual inspection of the premises which included the Mortuary body store areas, Pm suite and viewing facility. The inspection team observed the process for admission and release of bodies within the mortuary.

Audit of records
The inspection team undertook audits of traceability of four bodies in storage. This included two hospital and two community cases. Traceability details were crosschecked between the identification bands on the body, information on the body store door, and the electronic patient record. No discrepancies were identified.
Audits were conducted of tissue taken at PM examination on three cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, HTA retention spread sheet, tissue blocks and slides being stored and disposal records and receipts. Retention and disposal of tissue had been completed in line with the wishes of the family and compliant with HTA requirements. Full traceability of tissues was demonstrated for all three cases.

Meetings with establishment staff

The inspection team conducted interviews with staff carrying out processes under the license. This included the Designated Individual, Mortuary Manager, Anatomical Pathology Technologist, Trainee Anatomical Pathology Technologist, Consultant Histopathologist, Porter, Quality Manager and Bereavement Midwife.

Report sent to DI for factual accuracy: 17 March 2025

Report returned from DI: 19 March 2025

Final report issued: 3 April 2025

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.