Inspection report on compliance with HTA licensing standards
Inspection date: **24 October 2024**

Royal Berkshire Hospital
HTA licensing number 12232

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 Royal Berkshire Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Maternity	-	-	*Carried out*
Satellite site Harborne House	Not licensed	Not licensed	Licensed
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 Berkshire Hospital NHS Foundation Trust ('the establishment') had met the majority of the HTA's standards, five major and five 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

Major 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.	SOPs describing the procedures for identification do not always make it clear that a minimum of three identifiers should be checked, what the identifiers could be and what they should be checked against. *(See advice item 1)*	**Major**

c) Procedures on body storage prevent practices that disregard the dignity of the deceased	Whilst condition checks are carried out on admission and release, documented condition checks of the deceased are not routinely undertaken during the patients stay. This means there is no written record of condition checks should there be a query from family members or funeral directors.	**Major**
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	The Inspection team are not assured staff carrying out viewings and releases in maternity are competency assessed.	**Major**
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 a number of incidents which met the threshold for reporting to the HTA which had not been reported.	**Major**
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	During the inspection, one body at Royal Berkshire Hospital had started to show signs of deterioration. Although the deceased had not reached 30 days in refrigerated storage, due to their condition, mortuary staff should have transferred the deceased into frozen storage. In addition to their condition, there was also no indication they were soon to be released, or further examined. *(See advice item 2)*	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
d) Competency is assessed and maintained	The establishment could not provide assurance that competency assessments are in place for those seeking consent for adult post mortem examinations.	**Minor**
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use	SOPs are currently out of the documented review timeframes. *(see advice item 3)*	**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	The Inspection team were not assured procedures related to the licensed activities are risk assessed on a regular basis. • Risk Assessments are currently out of the documented review timeframes. *(see advice item 3)* • Although there are procedures in place, the inspection team were not provided with evidence that the transfer of the deceased via the internal main corridor is risk assessed. This means there is insufficient documented mitigations in place to minimise the risk to the dignity of the deceased.	**Minor**

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	The mitigating controls used by staff are not always reflected in risk assessments. • Staff training and competency assessments are not listed as existing controls in relevant risk assessments. • The viewing risk assessment lacks sufficient detail on the existing controls in the viewing process. • The unexpected deterioration of a deceased in long term storage risk assessment lacks sufficient detail on the existing controls of transferring the deceased to frozen storage.	**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	Whilst fridges and freezers have audible alarms and there is a monitoring system in place: • The specimen fridge in the post mortem room is not tested to ensure that the alarm triggers when temperatures go out of the upper or lower set range and that the call out procedure works. • Temperature trend analysis is not routinely undertaken to identify trends and the extent of any variations in storage temperatures. *(see advice item 7)*	**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)	To fully address this shortfall, the establishment should review all SOPs relating to mortuary activities where there is a requirement for checking the identity of bodies to ensure they are accurate and contain sufficient detail to reflect current practice.
2.	PFE2(c)	The DI is advised to review and formalise the long stay list currently used by mortuary staff.
3.	GQ1(d) and GQ6(a)	SOPs and risk assessments are currently out of the review timeframe. Although a full review of documentation is planned to take place following the establishments rebuild, expected to finish early 2025, all SOPs or risk assessments that are not relevant to the rebuild should be reviewed at the earliest opportunity. The DI is advised to remove references to ‘next of kin’ when documents are next reviewed.
4.	GQ3(a)	The DI is advised to review the robustness of the process which ensures new porters are fully trained before carrying out mortuary activities.
5.	GQ1(a)	The DI is advised to incorporate the opening and closing down process of the mortuary into the security SOP. This will ensure there is sufficient written guidance for staff.
6.	PFE1(e)	The DI is advised to change the codes to the mortuary keypad locks on a frequent basis. Written guidance on the trigger points for code changes should also be included in the security SOP.
7.	PFE2(e)	Although out of hours temperature failing tests are carried out by staff, the DI is advised to carry out a full and complete test to ensure processes are followed should on call staff not respond. This will ensure the call out procedure is tested in its entirety.

Background
Royal Berkshire Hospital NHS Foundation Trust has been licensed by the HTA since 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in May 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 the mortuary and post-mortem room, records of servicing of equipment, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents and staff training records.

Visual inspection
The inspection included a visual inspection of the mortuary body store, PM room, viewing room and maternity fridge.

Audit of records
Audits were conducted for four bodies in refrigerated storage. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and electronic database. No discrepancies were found.

Audits of traceability were conducted for tissue blocks and slides from three Post mortem cases, including audits of the consent documentation for the retention of these tissues. No discrepancies were found.

Meetings with establishment staff
Staff carrying out processes under the licence were interviewed including the DI, mortuary manager, histology staff, portering staff and maternity staff.

Materials held for the police
Under section 39 of the HT Act, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. Any information provided by the establishment in relation to police holdings has been shared with the Home Office, but these do not appear in the report as they are outside the scope of the HT Act.

Report sent to DI for factual accuracy: 21 November 2024

Report returned from DI: 09 December 2024

Final report issued: 12 December 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: 09 June 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.