Inspection report on compliance with HTA licensing standards
Inspection date: **09 April 2025**

Royal Blackburn Hospital
HTA licensing number 12309

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 Blackburn Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	-
Maternity	-	-	-
A&E	-	-	-

Summary of inspection findings

Although the HTA found that Royal Blackburn Hospital had met some of the HTA's standards, two critical, 19 major and 11 minor shortfalls were found against standards these relate to Governance and Quality Systems, Premises, facilities and equipment, traceability and dignity.

Five of the shortfalls relate to findings from the last inspection. A similar issue was identified in two of the Critical shortfalls GQ1(c), PFE 1(e) that were found in the previous inspection carried out in September 2022. This was acknowledged by the establishment and progress will be monitored through an agreed corrective action plan.

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
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	During the inspection, the team identified five bodies, three hospital patients and two coronial cases that required frozen storage. These bodies were found to be in varying stages of deterioration, ranging from mould growth to advanced decomposition. Of the five bodies examined, three were wrapped in heavily soiled sheeting and not placed in body bags. Additionally, a body from the freezer was examined and found in a body bag wrapped in soiled sheets and laid on soiled cut clothing with a shroud laid over the anterior surface. Storage arrangements at the time of the inspection did not maintain the condition or the dignity of the deceased and increased the risk of accidental damage through decomposition. This has subsequently been reported as a HTARI *This shortfall was identified at the previous inspection in 2022*	**Critical**

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 inspection team was not assured that adequate audits of swipe access and CCTV were undertaken, nor that the use of a visitor log had been implemented. *This was a shortfall in previous inspections 2022* Concerns were also raised regarding the lack of CCTV covering mortuary access points and the method employed for out-of-hours access.	**Critical**

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.	There is a lack of Standard Operating Procedures (SOPs) relating to licensed activities undertaken within the mortuary. These include, but are not limited to: • Lone working procedures, including out-of-hours • Security SOP, including the supervision of visitors and contractors • Record keeping • Access to the mortuary by non-mortuary staff, contractors, and visitors • Receipt and release of bodies, reflecting out-of-hours procedures • Contingency arrangements While SOPs stipulate who can undertake the documented activity, they do not reflect the current staffing structure. Additionally, some SOPs did not reflect practices described by staff during interviews, including CP/M9 Viewing and Identification of Deceased. Furthermore, there is no evidence of SOPs being reviewed and updated, with many referencing outdated guidance documentation such as HSE Managing Infection within the Mortuary, which was replaced in 2018. To fully address this shortfall, the Designated Individual (DI) is required to: • Review all relevant activities undertaken within the mortuary and ensure they are covered by a documented procedure. • Ensure all new and current SOPs contain sufficient detail and are fully reflective of current practice. See advice and guidance item 2.	**Major**

c) Procedures on body storage prevent practices that disregard the dignity of the deceased	Items of personal property were observed on the trays with the deceased including a lady's handbag and contents. Not all property was placed in bags or labelled and therefore risks contamination or loss. *This shortfall was identified at the previous inspection in 2022* Discarded used sheets and gloves were present on the floor along with a quantity of plastic tie wraps in the external storge unit.	**Major**
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	Although SOPs are managed by an electronic system some SOPs do not appear to have been reviewed since 2019 and reference outdated guidance. Some SOPs are authored and authorised by the same person. This includes but is not restricted to, CP/M2 Identification of Bodies for Postmortem *This shortfall was identified at the previous inspection in 2022*	**Major**
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework	Although the mortuary sits within the Pathology directorate, they are not included within any governance framework.	**Major**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	There are no documented mortuary staff meetings or governance meetings with staff involved in HTA-licensed activities.	**Major**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Although there is a document schedule of audits this does not include sufficient vertical and horizontal audits relating to mortuary procedures. Furthermore, scheduled audits relating to HTA compliance had not been completed. Failure to audit processes risks unidentified deviations from the required standards.	**Cumulative Major**
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	Audit findings do not document who is responsible for follow-up actions and the timeframe for completing these.	
c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention	The evidence submitted does not provide assurance that regular audits are carried out of tissue being stored, staff awareness of what is held and why. or include relevant supporting information.	**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	Training records for mortuary staff were not submitted. Portering supervisors provide training for portering staff, however portering supervisors to are not provided with refresher training or competency assessed. There is no documented training in mortuary procedures for housekeeping staff who undertake cleaning within the body store and postmortem rooms. There are no documented training or competency assessments for funeral directors undertaking out-of-hours admissions.	**Cumulative Major**
c) Staff are assessed as competent for the tasks they perform	See GQ3(a) above.	
g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures	See GQ3(a) above.	

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	Staff involved in licensed activities, including staff working outside of the mortuary and porting staff, are not aware of the HTARI reporting requirements. The inspection team identified three incidents which met the threshold for reporting to the HTA which had not been reported. Furthermore, there are no documented procedures relating to HTARI categories or reporting requirements within the department. Incident logs for the last 12 months were requested but not submitted for review. (as a result, standards GQ5(b), (c), (d) and (e) could not be assessed)	**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	Whilst there are risk assessments in place these are incorporated into the SOPs, they do not contain sufficient detail of control measures in place. Some risk assessments do not appear to have been reviewed since 2019. The inspection team were therefore not assured that risks are assessed on a regular basis.	**Major cumulative**

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	Limited details of how to mitigate identified risks are documented, however mitigation such as training and competency assessment of staff or those working under the licence are not included. Risk assessments do not include responsible people, time frames, or further actions to be taken to mitigate risk.	
c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register	The inspection team are not assured that the following risks are incorporated into the organisational risk register. • Lack of long-term freezer storage • Risk to delivery of service due to low staffing levels	**Major**

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	SOP CP/M5 does not document the requirement of three identifiers to be used when labelling toxicology or histology specimens. The current procedure for viewing does not include a physical check of a minimum of three identifiers of the deceased before viewing by relatives.	**Major**
d) There is system for flagging up same or similar names of the deceased	Although there is a procedure in place for same or similar names this is not documented, the inspection team were not satisfied that this system was robust enough to ensure identification of patients with same and similar names and reduce the risk of releasing the wrong body.	**Major**

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)	The contingency body storage unit is located on a pavement frequently used by hospital staff and visitors, adjacent to a car park. The refrigeration plant equipment for the unit is located in an insecure outside area. Power switches for the plant equipment are not fitted with tamperproof mechanisms. CCTV coverage of this unit is monitored by the Trust Security and is therefore not included within the mortuary access audits.	**Major**
e) Security arrangements protect against unauthorised access and ensure oversight of visitors and contractors who have a legitimate right of access	There is no documented policy or procedure regarding mortuary security. A documented procedure should include details of who has legitimate access, how access is granted or revoked, and procedures for out-of-hours access, including for maintenance staff and contractors. Although audits of those with swipe access is undertaken annually. This does not provide assurance that access is limited to those with legitimate purpose for entry.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	The external body store is situated on a pavement adjacent to a road and car park. Funeral directors collect the deceased directly from the external body store. Access to the unit can be directly overseen by laboratory staff during the transfer or release of bodies.	**Major**
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	The inspection team were advised that the establishment does not have sufficient freezer storage for long-term bodies. Bodies are not routinely transferred to freezer storage after 30 days in refrigerated storage.	**Major**

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	Fridge and freezer alarms are tested annually. The frequency of testing does not give assurance that units are functioning correctly or that the escalation process in the event of an alarm event is effective. The lower fridge alarm temperature is set at -5 and does not meet the required standard. This creates a risk of bodies being inadvertently frozen. This could lead to accidental freezing of a damage to the deceased. Testing of the external storage unit is not undertaken.	**Cumulative Major**
f) Temperatures of fridges and freezers are monitored on a regular basis	Evidence of regular monitoring of internal or external storage units was not provided.	
i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods	The establishment does not have a documented contingency plan in place should there be a power failure or insufficient number of refrigerated storages during peak periods.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
e) There is a system for recording that staff have read and understood the latest versions of these documents	Evidence to demonstrate documents have been read and understood by staff was not provided.	**Minor**

f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity	Deviations from documented SOPs are not documented or monitored via scheduled audit activity.	**Minor**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
e) Staff are given opportunities to attend training courses, either internally or externally	Due to workload pressures and staff shortages the staff have not been able to attend any development opportunities or training courses	**Minor**
f) There is a documented induction and training programme for new mortuary staff	New mortuary staff attend a corporate induction, and the inspection team were advised that a departmental induction and training program is provided for new mortuary staff; however, this is not documented.	**Minor**

GQ4 There is a systematic and planned approach to the management of records		
a) There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record	An electronic system is in place for documentation. However, no evidence was provided to demonstrate how records are maintained, backed up, where records are kept, how long each type of record is retained and who has access to each type of record was not provided.	**Minor**
b) There are documented SOPs for record management which include how errors in written records should be corrected	SOPs for record management including how errors in written records should be corrected was not provided	**Minor**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
h) There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary, (such as to the lab or another establishment), including record-keeping requirements	Whilst a documented procedure was available for the transfer of specimens within histology and toxicology, information relating to transfer to alternate laboratories was not evidenced.	**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	The inspection team found the main body store, office, and visitor areas to be clean at the time of inspection. However, the following areas required attention: • **External Body Store**: The area was malodorous, with discarded used sheets and gloves present on the floor, along with a quantity of plastic tie wraps. • **Post Mortem Room Dissection Benches**: The benches were very cluttered, preventing adequate decontamination. The inspection team observed a discarded soiled towels and several stained absorbent sheets on the benches. • **Post Mortem Room Usage**: The room is currently being utilised for additional pathology cut-up workstations and specimen storage. The excessive number of specimens stored on the benches prevented the completion of LEV testing on one bench. • **Post Mortem Room Floor**: Leaf debris and mud were present on the floor. • **Flooring Condition**: There were significant areas in the post mortem room where the flooring had become extremely worn, exposing the underlying surface. • **Protective Barrier Damage**: Some areas of damage were noted to the protective barrier within the main body store.	**Minor**

c) There are documented cleaning and decontamination procedures and a schedule of cleaning	The SOP relating to cleaning and decontamination lacks details and does not include the following: • Cleaning of saw unit. • Cleaning of fridge doors and walls in the postmortem rooms and body store. • Cleaning of external body store. Additionally, the cleaning record submitted provides insufficient detail to demonstrate that adequate cleaning and decontamination of the facility have taken place or when they were performed.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
h) There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies	Foetal remains awaiting cremation were stored in containers on the floor of the body store. This poses a risk of contamination should there be leakage from a body above.	**Minor**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept	Servicing / maintenance records for the external refrigerated storage unit were not provided. Servicing and maintenance records for mortuary trolleys were not provided.	**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
Since the inspection the DI and CLHc have been replaced.

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

Number	Standard	Advice
1.	PFE2(f)	The DI is advised to review trends in storage temperatures. This may help to identify the extent of any variations in storage temperatures and emerging faults.
2.	GQ1(a)	Th DI is to consider use of a suitable SOP format to ensure SOPS are specific to mortuary activities simplified and easy to follow.
3.	PFE2(a)	The DI is to consider the relocation of the external storage unit to prevent oversight of licenced activity.

Background
Royal Blackburn Hospital 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 Blackburn Hospital has been licensed by the HTA since 2007. This routine unannounced inspection was the fifth inspection of the establishment; the most recent previous inspection took place in September 2022. Since the previous inspection, there have been no significant changes to the license arrangements, or the activities carried out under the license.

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

55 of 61 applicable standards were assessed. The inspection team felt it necessary to conclude the inspection following the identification of critical shortfalls to allow the establishment to take immediate corrective action. As a result, the following standards were not assessed T1 (g), (h) and T2. Standards C1 and C2 were not assessed as not applicable.

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, maintenance and records of servicing of some equipment, a recent ventilation report, audits, risk assessments, and mortuary staff competencies. Training records, meeting minutes, incident logs, and cleaning records for post-mortem room were not provided.

Visual inspection

The inspection team undertook a visual inspection of the premises which included the Mortuary body store and external contingency unit, Post mortem suite and viewing facility. The inspection team observed the process for release of bodies within the mortuary.

Audit of records

The inspection team undertook audits of traceability of five bodies in storage. This included two hospital and three community cases including one in long term storage. Traceability details were crosschecked between the identification bands on the body, and the Mortuary register. Whilst one minor discrepancy was found, this was not sufficient to amount to a shortfall, but oral advice was given to the establishment at the time of the inspection.

Meetings with establishment staff

The inspection team conducted interviews with staff carrying out processes under the license. This included the Designated Individual and Mortuary Manager, Anatomical Pathology Technologist, a Mortuary Assistant, Patient movement supervisors, Pathology Quality Manager and the Corporate License Holder contact.

Report sent to DI for factual accuracy: 2 June 2025

Report returned from DI: 11 June 2025

Final report issued: 30 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.