Inspection report on compliance with HTA licensing standards
Inspection date: **06 August 2025**

Royal Oldham Hospital
HTA licensing number 12342

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

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 the Royal Oldham Hospital ('the establishment') had met the majority of the HTA's standards, nineteen major and ten minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities and equipment.

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

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	Whilst The Royal Oldham Hospital no longer facilitates adult hospital consented post-mortems, they do continue to offer perinatal post-mortems, which are transferred and carried out at a receiving hospital. At the time of the inspection, the establishment had not submitted a consent policy or standard operating procedure (SOP) that reflects the requirements of the Human Tissue Act and the HTA's Codes of Practice in relation to post-mortem examinations. As a result, the HTA was unable to assess relevant documents against consent standards C1(a), and C1(b). The Designated Individual (DI) advised that, as perinatal post-mortems are transferred and subsequently conducted at a receiving hospital, they understood responsibility for meeting HTA consent standards for these post mortem rested with that site. However, as consent is sought under The Royal Oldham's licence, the establishment retains responsibility for ensuring that consent is obtained in accordance with all relevant HTA standards prior to transfer. At the time of the inspection, there was limited oversight of this process.	**Major cumulative**
b) There is a documented standard operating procedure (SOP) detailing the consent process		

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	• The inspection team noted concerns with the written structure of option A on the coroner's consent form. This option combines multiple scheduled purposes, such as retention for review, audit, teaching, research, genetic counselling, and clinical testing, into a single consent choice. As a result, families wishing to consent to only one of these specific uses are unable to do so without also consenting to all other listed purposes. Due to this, families' ability to make a fully informed and specific decision regarding the retention and use of tissue may be limited. • During the inspection, it was identified that some options, such as research, are not now routinely undertaken at the establishment, despite still being offered on the coroner's consent form. *See advice item 1*	**Major**
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	Although the HTA's consent requirements were verbally acknowledged during an interview with the bereavement midwife, perinatal post-mortem consent documentation was not made available to the inspection team for review. As a result, the HTA was unable to fully assess relevant documents against consent standards C1(e), C1(f), and C1(g).	**Major** **Cumulative**
f) The deceased's family are given an opportunity to change their minds and it is made clear who should be contacted in this event and the timeframe in which they are able to change their minds		

g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided		

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	Although the HTA's C2 consent standards were verbally acknowledged during an interview with the bereavement midwife, training and competency records relating to perinatal post-mortem consent were not made available to the inspection team. As a result, the HTA was unable to fully assess relevant documents against consent standards C2(a), C2(b), C2(c), and C2(d).	**Major** **Cumulative**
b) Records demonstrate up-to-date staff training		
c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual		
d) Competency is assessed and maintained		

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 relating to mortuary activities are not reflective of current practice or do not contain sufficient details of procedures. These include but are not limited to: • The SOPs for assisting with post-mortems and forensic post-mortems do not specify the requirement to check a minimum of three identifiers, define which identifiers are acceptable, outline measures to prevent mix-ups of organs or tissue, or state what PPE must be worn during the postmortem. • The SOP for monitoring fridge temperatures does not include the requirement to test and record the lower temperature limit (see also standard PFE2(e)). • The SOP for HTA Reportable Incidents (HTARIs) does not reference near-miss incidents or the requirement to report them to the HTA. • The mortuary department's security SOP lacks sufficient written guidance on how to carry out the monthly security audit, as well as the end-of-day mortuary closing procedure, including separate steps relating to the contingency storage area if in use (see also standard PFE1(e)). • The SOP for Organ/Tissue Disposal states under options B and C (repatriation and disposal) that it is the responsibility of the Pathologist or coroner to manage these options. This wording is unclear and potentially misleading. Once the coroner's inquest has concluded and this has been confirmed, responsibility for the tissue, including fulfilling the family's wishes, falls under the responsibility of the establishment (see also standard T2(b)). • The SOP for decontamination of the body store lacks detail on the required frequency for cleaning fridges and freezers, and does not reference the cleaning of fridge and freezer seals.	**Major**

	This is not an exhaustive list of the amendments required to all the SOPs and, to fully address this shortfall, the establishment should review all SOPs relating to all mortuary activities to ensure that they are accurate, reflect current practice and contain sufficient detail of procedures.	
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework	The inspection team was not assured that the DI has effective oversight of consent-seeking practices carried out by bereavement midwives, as there is currently no Person Designated (PD) in the maternity department. This impacts the DI's ability to maintain oversight and assurance in line with HTA standards (see also shortfalls C1 and C2).	**Major**

GQ2 There is a documented system of audit		
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	Although a tissue audit is undertaken annually, it focuses solely on recent cases and does not include a sample of historical cases dating back to the implementation of the Human Tissue Act. This limits the overall effectiveness of the audit and reduces assurance regarding long-term tissue retention. Furthermore, the number of slides retained is not documented.	**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	Although porters receive training, the porter training manual does not include the requirement to ensure that the rear mortuary gate, which leads directly onto a public footpath and road, is closed during admissions. This was further evidenced during an interview with a porter, who confirmed that the rear mortuary gate is routinely left unsecured during admissions.	**Major** **Cumulative**
c) Staff are assessed as competent for the tasks they perform	• The porter training manual states that competency will be assessed bi-annually. Records provided to the HTA confirm that the most recent assessment took place in June 2024. • While the porter competency documentation refers to incidents, it does not reference near-miss incidents, which limits awareness of the full scope of incident reporting requirements. • No documentation was provided to confirm that competency assessments for Anatomical Pathology Technologists (APTs) include an evaluation of the standard of reconstruction work.	

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 two accidental damage to a body incidents that met the threshold for reporting to the HTA but had not been reported.	**Major**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail

a) Bodies are tagged/labelled upon arrival at the mortuary	Whilst bodies are tagged upon arrival at the mortuary, the inspection team was not assured that identification bands are being consistently checked by staff in accordance with established procedures. During the inspection, discrepancies were identified on the identification bands of three of the four bodies audited. These included: • Two instances where the date of birth on the wristband did not match the information recorded in the mortuary register. • One instance where there was a minor spelling discrepancy in the surname between the wristband and the mortuary register. These discrepancies carry a serious risk, including the possibility of the wrong body being viewed or released. *See advice item 2*	**Major**
b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records)	The mortuary register was found to contain a significant number of incomplete entries, including missing records for several deceased patients. Key information, such as the release date and the name of the individual or organisation to whom the deceased was released, was not recorded. The lack of accurate and complete records poses a risk to the traceability of the deceased. *See advice item 2*	**Major**

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	• The establishment does not currently have a robust system in place to ensure full traceability of all tissue samples taken during post-mortem examinations. While tissue blocks are recorded and traceable, the number of slides created from these blocks is not routinely documented (see also shortfall GQ2(c)).
	
	• Although the establishment has recently transitioned to a new digital system, the current tissue management spreadsheet used in the mortuary remains limited and was found to contain several inaccuracies. During the inspection, several concerns were identified, including:
	
	  • A case marked *"do not dispose"* without any documented explanation or evidence of follow-up.
	
	  • Several historical cases highlighted in red, with staff at the time of the on-site inspection, unable to explain the meaning or rationale behind the notation.
	
	  • During the audit, a discrepancy was identified between mortuary and laboratory records in one case. The mortuary spreadsheet documented the tissue as returned to family, while the third-party storage provider recorded the tissue as being held in storage. Upon review by mortuary staff, it was determined that this was a recording error. A subsequent relatives' form requesting the retention of tissue had been received but was not reflected in the mortuary spreadsheet. This issue was identified during the audit and has since been amended.
	
	  • Traceability of historical tissue cases is limited, as existing oversight processes apply only from the point at which the current staff member was assigned responsibility for tissue traceability (see also shortfall GQ2(c)).
	
	The lack of comprehensive and accurate record-keeping poses a risk to the effective traceability of retained tissue.
		Major

T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary	• During the tissue audit, one historical case was marked as *"Keep"*, with no explanation provided for the instruction. The staff member currently managing tissue had no knowledge of this case and confirmed they do not audit or oversee cases prior to assuming their current responsibilities (see also shortfall T1(g)). Following further investigation, after the HTA had completed their on-site inspection, the DI confirmed that a coroner's request from April 2018 instructed that specific tissue must be retained pending an investigation. However, there is no evidence that any follow-up communication has been sought in the intervening five years to confirm whether the investigation has concluded, or whether the families' wishes regarding the relevant tissue can now be fulfilled. • There is no routine process in place for reviewing or following up on tissue and organs where the family has indicated a wish for repatriation. Staff confirmed that they routinely wait for the family to make contact following the conclusion of the coroner's inquest. This approach places the responsibility on the family. The establishments organ and tissue disposal SOP, along with staff interviews, confirmed that for options B and C, return to family and disposal, it is the responsibility of the Pathologist or Coroner to deal with these options. This wording is unclear and potentially misleading. Once the Coroner's inquest has concluded and this has been confirmed, responsibility for the tissue, including fulfilling the family's wishes, falls under the responsibility of the establishment (see also standard GQ1(a)).	**Major**

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 following areas within the mortuary were identified as requiring maintenance during the on-site inspection: • Visible water was present beneath the vinyl flooring in the post-mortem room, causing widespread lifting. This poses a significant infection control, hygiene, and health and safety risk. Although quotes have been obtained for replacement prior to the HTA inspection the work has not yet been completed • The inspection team observed water pooling in the post-mortem room, including in the doorway leading to a storeroom. This water could have been removed using appropriate equipment, such as a mop or squeegee, but had been left standing. As a result, the flooring has become heavily stained. • The door and surrounding frame of the forensic post-mortem room, as well as the door frame between the body store and viewing room, were found to be damaged. This damage has exposed porous surfaces, which impedes effective cleaning and decontamination. • Several fridge doors were found to be significantly damaged, with visible impact marks (see also shortfall PFE2(d)). • Evidence of mould and fungal growth inside fridges and on racking, along with visible debris on lower surfaces, indicating the need for a comprehensive deep clean. • Two electrical sockets in the body store had damaged lid-catch covers. • Rust and debris were present in the drains within the post-mortem room and body store, indicating inadequate cleaning and maintenance.	**Major**

c) There are documented cleaning and decontamination procedures and a schedule of cleaning	No cleaning records were available for review during the on-site inspection. Additionally, the post-mortem room appeared to have been ineffectively cleaned following a post-mortem conducted earlier that day. Visible biological residue was observed in three areas of the room, raising concerns about infection control and adherence to appropriate cleaning protocols.	**Major**
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)	Although self-identified prior to the inspection, the electric gate at the rear of the mortuary, opening directly onto a public footpath and road, was not operational at the time of inspection and has been awaiting repair for a significant period. During the inspection, the inspection team observed that the interim control measure of manually closing the gate was not being carried out. This was further confirmed during a meeting with a porter, who confirmed that due to practical difficulties, the gate is frequently left open during admissions, including out-of-hours. This poses serval risks, including a risk to the dignity of the deceased during transfers, compromises the security of the mortuary if left insecure, and introduces a significant occupational health and safety concern due to the manual handling of the heavy gate by staff (see also shortfallGQ3(a)).	**Major**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	• Although a security audit is in place, the inspection team found that they are not being conducted effectively. The establishment currently reviews only the list of individuals granted swipe access and does not audit access logs to review who has entered the mortuary, despite this being identified as a control measure in the establishment's own Security Risk Assessment. Additionally, the audit is limited to a narrow, pre-selected timeframe, rather than sampling access events across the month, reducing its ability to identify unauthorised or inappropriate access. As a result, the establishment is unable to adequately scrutinise the purpose, frequency, and duration of access, or maintain oversight of unusual patterns, times of entry, or other unexplained or potentially suspicious activity that would require immediate investigation. Furthermore, the security audit process is not well defined and lacks written guidance (see also shortfall GQ1(a)). In its current format, security audits are deemed limited in their effectiveness for reviewing and managing access to the mortuary. *See advice item 3* • Although the mortuary is secured via proximity access card, mortuary and portering staff indicated that porters are automatically granted access when they start employment at the Trust, prior to receiving appropriate mortuary training. While a process is in place to ensure mortuary duties are only assigned to porters after receiving training, this process is not clearly defined or fully understood by all relevant staff. This lack of clarity and oversight presents a risk of untrained staff gaining access to the mortuary.	**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	Whilst fridge and freezer alarms are tested, the frequency of these tests is not clearly documented. In addition, current tests do not include the lower set point range. Alarm tests also do not incorporate or record the call-out procedure to confirm that the full alarm response process is functioning as intended (see also shortfall GQ1(a)).	**Major** **Cumulative**
f) Temperatures of fridges and freezers are monitored on a regular basis	Temperature trend analysis is not currently being undertaken on fridges and freezers.	

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	The following items were found to be in an unsuitable condition and require maintenance or replacement: • A metal tray of autopsy instruments in active use was found containing wet, visibly rusted instruments with significant residue at the bottom. This raised serious concerns regarding hygiene, infection control, and instrument suitability. Following identification by the inspection team, the establishment made the decision to dispose of the instruments. • Areas of rust were observed on several items, including a stainless steel cabinet in the post-mortem room, a mop bucket, a set of steps, a measuring stick in the body store, and on transfer trolleys. • The autopsy saw was found to have areas of rust and was missing its blade extraction hood cover, compromising both hygiene and operator safety.	**Major**

Minor 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	Whilst procedures for body storage are in place to safeguard the dignity of the deceased, condition checks were found to be inconsistently documented. As a result, written records may not always be available in the event of queries from family members or funeral directors.	**Minor**
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	The establishment uses a quality management software to manage its documents; however, during the site visit, it was identified that some SOPs had not been reviewed in accordance with their scheduled review dates. This presents a risk that staff may follow outdated procedures that are no longer in effect.	**Minor**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Whilst scheduled governance meetings do take place, there is no attendance by staff from areas outside the mortuary. For example, bereavement midwives and porter managers or supervisors do not attend these meetings, nor do they receive the minutes when matters related to HTA activity are discussed.	**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	Whilst all procedures relating to licensed activities have been risk assessed, not all risks have been reviewed in line with the establishment governance framework. These include but are not limited to: • Lone Working in the Mortuary • Risk of Misidentification During Post-Mortem, Visits, Release, and Same/Similar Names • Movement of Deceased Patients in the Mortuary This is not an exhaustive list of the risk assessments requiring review. To fully address this shortfall, the establishment should undertake a comprehensive review of all risk assessments related to mortuary activities.	**Minor**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
d) There is system for flagging up same or similar names of the deceased	Whilst there is a process in place to flag cases involving deceased individuals with the same or similar names, the procedure outlined in the SOP *Receipt of Deceased Patient into the Mortuary at ROH* was found not to be fully followed during the body audit. The SOP states that an orange same/similar name wristband should be placed on the wrist of each individual. However, during the inspection, it was observed that wristbands were being placed loosely on the trays rather than secured to the wrist, as detailed in the SOP. *See advice item 2*	**Minor**

T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.

d) The method and date of disposal are recorded	Records do not specify the method used for tissue disposal.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	Although mortuary staff informed the inspection team that funeral director vehicles are required to be positioned to shield the mortuary doors during admissions and releases, this was not observed in practice during the inspection. During one release, a funeral director's van was not fully aligned with the doors, leaving the body store exposed. As a result of this procedure not being fully implemented, the adjacent building, overlooking the yard from across the road, had a direct line of sight into the body store. This poses a risk to the dignity of the deceased during transfer.	**Minor**
d) Fridge and freezer units are in good working condition and well maintained	• Whilst fridge and freezer units are subject to regular maintenance, several fridge doors were found to be significantly damaged, with visible impact marks. This damage may compromise the integrity of the door seals and affect the overall functionality and efficiency of the units (see also shortfall PFE1(a). • During the inspection, refrigerated units 96–107, located in the body store, were found to be non-operational. Staff advised that these units have been out of service for an extended period and are currently awaiting repair. However, no signage was in place to indicate that the units were not in use, meaning porters may inadvertently attempt to use them during out-of-hours admissions.	**Minor**

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 report provided by the establishment does not confirm that the system meets the required minimum of ten air changes per hour. The current extract rate recorded for the Home Office post-mortem room is 8.19 air changes per hour, which falls below the recommended standard.	**Minor**
f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept	The inspection team were not provided with servicing records for the mortuary autopsy saws.	**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.	C1(d)	The DI is advised to work with the coroner to review and update the consent form. The current version includes activities that are no longer carried out, as well as combined consent options. These should be removed to prevent families from receiving inaccurate or conflicting information at the time of consent.
2.	T1(a) and T1(b)	The DI is advised to implement a mortuary register audit to support complete record management and ensure accuracy. In addition, the DI is advised to implement regular body audits to verify the accuracy

		of identification bands in order to fully address the types of discrepancies identified during the inspection.
3.	PFE1(d)	• As discussed during the HTA on-site inspection, the DI is advised to review information pertaining to CCTV in the *Health Building Note 16-01: Facilities for mortuaries, including body stores and post-mortem services*, and consider the installation of CCTV within the mortuary. CCTV would support comprehensive monitoring and oversight of access, help ensure procedures are correctly followed, and assist in the review of incidents where necessary. This measure would also address a gap in controls identified in the establishment's own Security Risk Assessment. • The DI is advised to investigate options for repairing and reinstating the use of the mortuary alarm system, which is currently not in operation due to repeated false alarms.
4.	PFE1(e)	The DI is advised to ensure that the lone working device in use is regularly tested and that results are documented. Additionally, the DI should consider introducing a second lone working device as a backup in case the primary device fails or cannot be accessed in an emergency.
5.	PFE2(d)	• While mortuary staff have access to the appropriate personal protective equipment (PPE), interviews confirmed that face masks are not always worn routinely during post mortems due to discomfort concerns. The DI is advised to review current PPE practices to ensure that risks are effectively managed and that staff compliance aligns with expected health and safety standards. Consideration should be given to addressing barriers to PPE use, such as comfort, through staff training or alternative PPE options where appropriate. • The inspection team observed partially wet gowns at the end of the dissection bench in the post-mortem room. The DI is advised to ensure compliance with *Health Technical Memorandum (HTM) 01-04: Decontamination of linen for health and social care*. This guidance should be followed to ensure the appropriate handling, processing, and decontamination of linen, in order to maintain hygiene standards.
6.	C1(a) and (b)	The DI confirmed that The Royal Oldham Hospital no longer facilitates adult hospital consented post-mortems. However, during the document review, the inspection team noted that the establishment had

		uploaded a SOP titled *Consent for Adult Post-Mortem*. The DI is advised to archive this document to avoid potential confusion.
7.	PFE3 (a)	The DI is advised to review the use of door wedges on fire doors, as observed during the inspection. The DI should ensure that all fire doors are used in accordance with fire safety guidance to maintain a safe environment for staff and visitors.

Background

The Royal Oldham Hospital has been licensed by the HTA since 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in November 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 governance documentation related to licensed activities, including policies and procedures, cleaning records, equipment servicing records, ventilation reports, audits, risk assessments, meeting minutes, incident reports, and staff training records.

Visual inspection

The inspection team conducted an unannounced visual inspection of the premises, including the mortuary, body storage areas, post-mortem room, and viewing suite. The team also observed the release process within the mortuary.

Audit of records

Audits were conducted for four bodies in refrigerated storage, with identification details cross-checked against the mortuary's electronic register and associated paperwork. Three discrepancies were identified, along with a significant number of incomplete entries found within the mortuary register. Tissue traceability audits were also carried out for six histology cases, with one recording error identified and subsequently corrected.

Meetings with establishment staff
The inspection team met with staff involved in licensed activities, including the Mortuary Manager, an APT, a Bereavement Midwife, a Porter, a Pathologist, and the DI.

Report sent to DI for factual accuracy: 23rd September 2025

Report returned from DI: 07th October 2025

Final report issued: 13th October 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.