Inspection report on compliance with HTA licensing standards
Inspection date: **11 December 2024**

Calderdale Royal Hospital
HTA licensing number 12108

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 **Calderdale Royal Hospital**	Not licensed	Licensed	Licensed
Mortuary	-	*Carried out*	*Carried out*
Accident & Emergency Department	-	*Carried out*	-
Paediatric wards	-	*Carried out*	-
Satellite **Huddersfield Royal Infirmary**	Not licensed	Licensed	Licensed
Mortuary	-	*Carried out*	*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 Calderdale Royal Hospital ('the establishment') had met the majority of the HTA's standards, three major and one minor shortfall were found against the standards for 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 shortfall identified during the inspection.

Compliance with HTA standards

Major 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)	There is inadequate CCTV coverage to monitor all access points, both during and outside of operating hours at Calderdale Royal Hospital and Huddersfield Royal Infirmary. <u>Calderdale Royal Hospital</u> • There is no CCTV in place to monitor access at the internal post mortem room door or the family viewing entrance door. • There is no CCTV in place to monitor access out of hours at the main internal mortuary entrance door, the internal post mortem room door or the family viewing entrance door. <u>Huddersfield Royal Infirmary</u> • There is no CCTV in place to monitor out of hours access at the main internal mortuary entrance door or the family viewing entrance door.	**Major**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The establishment have a number of security arrangements in place to protect against unauthorised access, however, the inspection team found the following: • Although staff are in the process of introducing a new security audit at Calderdale Royal Hospital and Huddersfield Royal Infirmary, the inspection team were not provided with evidence that security audits are currently being carried out routinely at the time of the site visit. (see advice item 1) • During the inspection mortuary staff confirmed the family viewing door at Calderdale Royal Hospital is routinely left unlocked while staff collect the family from reception. As such, during this part of the viewing process security arrangements do not protect against unauthorised access. This poses the risk of a serious security breach. (see advice item 2) • While there is a system for recording when porters enter the mortuary, non-mortuary staff, such as cleaners or maintenance workers, are currently not required to complete any documentation when entering the mortuary. As a result, there is no system that comprehensively records who enters the mortuary, the purpose of their visit, or their arrival and departure times. (see advice item 3)	**Major**
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		

a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath.	Standard operating procedures for the viewing process and security audit process are not fully reflective of current practice and lack sufficient written detail. (see advice item 7)	**Major**

Minor Shortfalls

Standard	**Inspection findings**	**Level of shortfall**
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	Although outside of the subset of standards assessed during this focused inspection, the inspection team noted a number of items of equipment in the mortuary which are in an inadequate condition: • A number of mortuary doors across both sites were damaged. This damage has resulted in multiple areas of exposed wood, posing the risk of ineffective cleaning and decontamination. • Wooden door wedges are in use across both sites. This poses the risk of ineffective cleaning and decontamination. • The bier trolleys used at both sites show significant signs of rust. This poses the risk of ineffective cleaning and decontamination.	**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.	PFE1 (e)	The DI is advised to adjust the monthly security audit sample size to ensure it includes activity across the full audited month, opposed to focusing on only a set number of selected days. In addition to covering in hours activity the security audit should also include out-of-hours activity, instances involving non-mortuary staff accessing the mortuary and any unusual events.
2.	PFE1 (e)	The DI is advised to introduce proximity access readers to the mortuary viewing room entrance points at both Calderdale Royal Hospital and Huddersfield Royal Infirmary to help mitigate the risk of unauthorised access.
3.	PFE1 (e)	The DI is advised to extend the use of the porter signing in sheets currently being used in both mortuaries to include all visitors and contractors.
4.	PFE1 (e)	The DI is advised to review and update access rights following recent changes to how non-mortuary staff access both mortuaries. The list of persons with authorised access to the mortuaries should be kept under regular review.
5.	PFE1 (e)	The DI is advised to explore options to maintain the dignity of the deceased when mortuary activities are carried out in the post mortem room at Calderdale Royal Hospital as this area is fully covered by CCTV.
6.	PFE1 (e)	The DI is advised to introduce the use of lone worker alarms as part of the lone working procedure.
7.	GQ1 (a)	The DI is advised to incorporate the process for activating the CCTV cameras in the viewing room when a viewing is being undertaken in all relevant SOPs. This will help ensure there is sufficient written instruction for staff involved in the viewing process and oversight of the activity.

8.	GQ6 (b)	The DI is advised to continue with the current plan to review all risk assessments to ensure they provide sufficient detail and include all mitigating controls.
9.	PFE2 (b)	At the time of the inspection a temporary refrigeration unit was erected in the main viewing room at Huddersfield Royal Infirmary. As such, the family viewing waiting area was being used as the primary room to facilitate viewings. Due to the size, location and suitability of this room the DI is advised to reassess current arrangements.
10.	GQ3 (c)	The DI is advised to ensure site commanders, whose responsibilities include carrying out mortuary releases, have regular up to date training and competency assessments for the tasks they perform within the mortuary.
11.	PFE3 (a)	The DI is advised to explore alternative arrangements in the event of an external lift breakdown at Huddersfield Royal Infirmary. While the establishment currently has an external ramp as a contingency for admission and release of bodies, the ramp appears unsuitable for the purpose of transferring the deceased due to its steep gradient. Using the ramp poses a risk of accidental damage to a body or musculoskeletal injury to staff.

Background

Calderdale Royal Hospital has been licensed by the HTA since June 2007. This was the fifth inspection of the establishment; the most recent inspection took place in June 2023. Since the previous inspection, there has been a change of Designated Individual (DI) in November 2024.

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

The Inspection focused on areas of concern identified following an Evidential Compliance Assessment (ECA) submitted by the establishment at the HTA's request against a subset of standards relevant to security. 6 out of the HTA's 72 standards were covered during the focused inspection (standards published 3 April 2017). Standards covered at this inspection are listed in Appendix 3. The remaining 52 standards will be assessed during the next routine inspection of the establishment.

Review of governance documentation

The inspection team reviewed policies and procedural documents relating to licensed activities. This included standard operating procedures, risk assessments and audits.

Visual inspection

The inspection team undertook a site visit inspection which included reviewing security systems in place in the mortuary body storage areas, the viewing rooms and the post mortem suites at both the hub and satellite site.

Meetings with establishment staff

The assessment team met with staff carrying out activities under the licence, including the establishment's DI, the Cellular Pathology Manager and mortuary staff.

Report sent to DI for factual accuracy: 2nd January 2025

Report returned from DI: 2nd January 2025

Final report issued: 3rd January 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.

Appendix 3: Standards Assessed during onsite Inspection

Governance and quality systems
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. These include: i. post-mortem examination, including the responsibilities of Anatomical Pathology Technologists (APTs) and Pathologists and the management of cases where there is increased risk; ii. practices relating to the storage of bodies, including long term storage and when bodies should be moved into frozen storage; iii. practices relating to evisceration and reconstruction of bodies; iv. systems of traceability of bodies and tissue samples; v. record keeping; vi. receipt and release of bodies, which reflect out of hours arrangements; vii. lone working in the mortuary; viii. viewing of bodies, including those in long-term storage, by family members and others such as the police; ix. transfer of bodies internally, for example, for MRI scanning; x. transfer of bodies and tissue (including blocks and slides) off site or to other establishments; xi. movement of multiple bodies from the mortuary to other premises, for example, in the event that capacity is reached; xii. disposal of tissue (including blocks and slides), which ensures disposal in line with the wishes of the deceased person's family; xiii. access to the mortuary by non-mortuary staff, contractors and visitors; xiv. contingency storage arrangements.
GQ2 There is a documented system of audit
a. There is a documented schedule of audits.

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.
c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register.

Premises, facilities and equipment
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).
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access.