Inspection report on compliance with HTA licensing standards
Inspection date: **18 October 2022**

Cumberland Infirmary

HTA licensing number 12091

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
Cumberland Infirmary	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Accident and emergency department	-	*Carried out*	-
Maternity	-	*Carried out*	*Carried out*
West Cumberland Hospital	Not licenced	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 Cumberland Infirmary ('the establishment') had met the majority of the HTA's standards, six major and six minor shortfalls were found against standards for Governance and quality systems, Traceability and Premises, facilities and equipment. These related to audits, incidents, security arrangements, SOPs, temperature monitoring, disposal of PM tissue, governance across sites, staff training and competencies, maintenance of the facility at Cumberland Infirmary and capacity at Cumberland infirmary.

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
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	The establishment store extensive amounts of PM tissue for future use including education, training, and research. There are multiple storage areas for blocks and slides including within the laboratory, archive storage room and an off-site storage facility. This stored material is not audited.	**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.	There is no refresher training for portering staff carrying out licensable activities at the satellite site after their initial training and sign off.	**Major (cumulative)**

c) Staff are assessed as competent for the tasks they perform	There are no competency assessments for portering staff carrying out licensable activities at the satellite site after their initial training and sign off.	
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.	The SOP for the reporting of incidents (including those that must be reported to the HTA) has not been distributed to mortuary staff at the satellite site. During interviews with staff there was a clear unawareness of HTA reportable incidents (HTARIs) and some incidents that have been reported internally have not been reported to the HTA despite them falling into one of the HTARI categories.	**Major**
T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		
c) Disposal is in line with the wishes of the deceased's family	During the site visit, the inspection team carried out an audit of tissue taken during PM. One of the cases selected for review had been stored since 2020 despite the family having requested for the tissue to be disposed of once the coroner's process had ended.	**Major**
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	There is a door alongside the Funeral Directors entrance which leads into a body storage area. The door is secured by a key; however, the DI was not aware of who has the keys to this door. The establishment does not have a system in place to formally review records of swipe card access to the mortuary to ensure that it is limited to those with legitimate right of access. There is an internal door between the viewing room and mortuary corridor that cannot be effectively secured during viewings which poses a risk of unauthorized access.	**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.	The temporary storage fridges (that are in continual use) and the fridge within the maternity department do not have remote monitoring and alarm systems. This is not sufficient to alert staff in the event that the storage temperature deviates from an acceptable range.	**Major**

Minor 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 the guidance from the RCPath.	Standard Operating Procedures (SOPs) relating to mortuary activities lack sufficient detail and/or are not reflective of current practice. These include, but are not limited to, SOPs detailing the process for: • Security procedures • Release of the deceased from the maternity department. • Identification checking at post-mortem. • Identification checking at release. • Long stay procedure. This is not an exhaustive list of the SOPs that need to be amended. To fully address this shortfall the establishment should review all SOPs relating to mortuary activities to ensure that they reflect current practice.	**Minor**
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework	There is no Persons Designated (PDs) nominated for the mortuary at the satellite premises.	**Minor**

h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff.	There are no meetings to discuss HTA-licensed activities which include mortuary staff from the satellite premises.	**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.	Not all procedures relating to licenced activity are risk assessed and many of the establishment's risk assessments do not identify risks to the deceased.	**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	In general, the mortuary was clean and well maintained. Some areas for improvement include: • Damage to the floor of the post-mortem suite exposing concrete. • Damage and wear to the sealant around the post-mortem tables. • Human debris was identified in the drains in the post mortem suite. • There is a pipe leading from an external refrigeration unit to the temporary body storage tent. The point at which the pipe is attached has been damaged/ worn such that tape is needed to secure it in place. The tape is coming away and it is not sealed securely. This may affect efficiency of the refrigeration.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue		
b) There is sufficient capacity for storage of bodies, organs and tissue samples, which take into account predicted peaks of activity	There are insufficient refrigerated storage facilities. Contingency storage arrangements and temporary body storage facilities are being used by the establishment continually.	**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(c)	Although consent is always taken from the appropriate persons in the hierarchy of qualifying relationships, the 'Consent for post-mortem and the removal of tissue document' (CS-MOR-SOP-36) references the Next of Kin. The DI is advised to update this reference.
2.	C1(c)	The establishment do not carry out perinatal or paediatric PMs, however they take consent using the referring hospital's consent documentation. The consent form was due for review in February 2022. The DI is advised to flag this to the partnering Trust in order to obtain an in-date version.
3.	C1(e)	The establishment gives the option to families for retention of PM material for future use including education, training, and research. The establishment does not carry these out and has not done for many years. The DI is advised to consider providing this information to families to set expectations and to ensure that any consent given by families for tissue to be retained is suitably informed.
4.	C1(f)	Families are given up to 12 hours to withdraw consent for a hospital post-mortem. The HTA recommends giving up to 24 hours. The DI is advised to consider extending the time at the next policy and procedural review.
5.	GQ1(a)	The Trust is currently reviewing the Lone Working Policy and is implementing the use of personal alarms to provide additional protection for staff. Although lone working in the mortuary is very rare, the DI is advised to implement the use of this device to strengthen procedures and safe-guard staff.
6.	GQ3(e)	The staff working in the mortuary at the satellite site are relatively new in the roles and have not visited the hub site or observed a post-mortem examination. To facilitate shared learning, build relationships and to give staff further experiences relevant to their work the DI is advised consider combining training/ development across both sites.

7.	GQ4(b)	During the body audit at Cumberland Hospital the inspection team found that errors in the mortuary register had been corrected using correction fluid. This does not allow for full auditability of any changes to a record and the DI is advised to change this practice.
8.	PFE1(d)	The satellite site is currently seeking CCTV to monitor access and activity within the mortuary. The DI is advised to actively monitor the progress of these plans as the use of CCTV will significantly strengthen security arrangements.
9.	PFE2(a)	The Funeral Directors entrance at Cumberland Infirmary is overlooked by hospital wards. The DI may wish to consider a canopy over the entrance to maintain dignity of the deceased during admission and release.
10.	PFE2(i)	There is a freezer bank at West Cumberland Hospital which is identified on the whiteboard however unlabeled. The establishment is advised to label the freezer door to avoid mortuary staff and porters using it inadvertently.

Background

Cumberland Infirmary has been licensed by the HTA since April 2007. This was the fourth inspection of the establishment; the most recent inspection took place in November 2017.

Since the previous inspection, there has been some significant changes to the licence arrangements including the change of Designated Individual (DI) in April 2019 and after the inspection in October 2022, and a change in Corporate Licence Holder contact in August 2022.

During the site visit inspection of Cumberland Infirmary, it was identified that PM material was being stored for a scheduled purpose at an unlicensed storage facility adjacent to the hospital site. This finding is being addressed as part of a HTA investigation and subsequent licence application assessment.

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 team reviewed the establishment's self-assessment document provided by the DI. Policies and procedural documents relating to licensed activities were reviewed. This included standard operating procedures, risk assessments, audits, incidents, ventilation, and equipment servicing reports, and training and competency assessment documents. Consent seeking procedures and information for relatives giving consent for adult and perinatal PMs was also reviewed.

Visual inspection
The inspection team undertook a site visit inspection of the premises. At the hub site, Cumberland Infirmary, this included the mortuary body storage areas, the PM suite and the storage arrangements for post-mortem material held within the facility. At the satellite site, West Cumberland Hospital, this included the mortuary body storage area and the preparation room where removal from the deceased takes place.

Audit of records
The inspection team undertook audits of traceability for four bodies in storage at the hub site and two bodies in storage at the satellite site. This included community and hospital cases in the fridge. Traceability details were crosschecked between the identification band on the body and information in the mortuary register and electronic records. No discrepancies were identified.

Audits were conducted for nine cases of stored post-mortem tissue taken at the hub site. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, the mortuary electronic database, and tissue being stored. One case in storage was audited and the family had requested disposal. The blocks and slides had been stored for over two years after the request. See shortfall for T2(c).

Meetings with establishment staff
The assessment team met with staff carrying out activities under the licence, including an Anatomical Pathology Technologist (APT), mortuary assistant, a porter, staff involved in the consent seeking processes, the Bereavement Midwife, the laboratory manager, and the DI.

Report sent to DI for factual accuracy: 11 November 2022

Report returned from DI: 22 November 2022

Final report issued: 28 November 2022

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.