Inspection report on compliance with HTA licensing standards
Inspection date: **16 and 23 February 2023**

Gloucester Royal Hospital
HTA licensing number 30008

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 Gloucester Hospital**	Not licensed	Licensed	Licensed
Mortuary	-	*Carried out*	*Carried out*
Maternity	-	*Carried out*	-
A&E	-	*Carried out*	-
Satellite site	Not licensed	Licensed	Licensed

Cheltenham General Hospital			
Mortuary	-	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
A&E	-	*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. In the current establishment governance structure, the Corporate Licence Holder Contact (CLHc) reports to the DI, this arrangement has been in place since 2007.

Although the HTA found that Gloucester Royal Hospital ('the establishment') had met the majority of the HTA's standards, one critical, five major and 10 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.

Compliance with HTA standards

Critical 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.		

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	CCTV is in operation, however, not all mortuary access points are covered. Whilst swipe card access lists are reviewed and updated, mortuary staff do not have access to CCTV recordings. There was no evidence available for review that swipe access is cross checked against CCTV footage to ensure security arrangements protect against unauthorised access and ensure oversight of visitors and contractors who have a legitimate right of access. This means mortuary staff do not have oversight and are not able to effectively audit all individuals accessing the mortuary or their time of entry and exit to the restricted areas. Access to the body store out of hours is with a key which is located in the porters lodge. However, there is no system in place for the key to be signed in and out and there were no records available to review indicating that the use of the key was audited against requests for the transfer of bodies to the mortuary and swipe card access. Following the site visit, the establishment submitted a HTA reportable incident under the category of serious security breach. The initial investigation report from the establishment has identified the body store is not routinely locked out of hours by porters on completion of their mortuary duties. This is not reflective of the SOP in place.	**Critical**

Major shortfalls

Standard	**Inspection findings**	**Level of shortfall**
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		

b) Records demonstrate up-to-date staff training	Records do not demonstrate up to date training in HTA requirements when seeking consent. There are no records available to review indicating which staff have received training in obtaining consent for adult and perinatal PMs. However, the establishment has not received a request for an adult hospital consented PM for at least five years.	**Major (cumulative)**
d) Competency is assessed and maintained	The establishment does not have a system in place for assessing staff as competent with the HTA requirements when seeking consent for PMs. This includes those who have received consent training.	
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath.	SOPs describing the procedures for identification of the deceased do not always make it clear that a minimum of three identifiers should be checked, what the identifiers could be and what they should be checked against. This includes the SOPs for: • Receipt of bodies into the mortuaries • Release of bodies • Viewings of bodies. This is not an exhaustive list of the SOPs requiring amendment. To fully address this shortfall, the establishment should review all SOPs relating to mortuary activities where there is a requirement for checking the identity of bodies to ensure they are accurate and contain sufficient detail to reflect current practice.	**Major**
GQ2 There is a documented system of audit		

a) There is a documented schedule of audits	Whilst there is a schedule of audits checking compliance with documented procedures, there is no documented schedule of audits to check CCTV against records of mortuary access. This means the establishment cannot be assured that all mortuary access is taking place for a legitimate purpose (see shortfall against PFE1(e)).	**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	The establishment only require relatives to provide two identifiers when booking a viewing and one identifier for the deceased when they attend the mortuary for a viewing. Whilst three identifiers are checked against paperwork provided by funeral directors for the release of bodies into their care with the mortuary register, the funeral director information is then not used to check the identifiers against identification information on the body. This means release can occur with less than three agreed identifiers being checked. This practice poses a risk of viewing or release of 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.		
a) The premises are clean and well maintained	Across both sites there are significant areas of exposed wood, and damage to the fabric of the building leaving areas of exposed plaster. Where there has been leakage from condenser units used for temporary storage, there are areas of superficial water damage to the floor. This poses the risk of ineffective cleaning and decontamination.	**Major**

Minor 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 there is a documented consent policy in place, it does not outline consent for post-mortem (PM) examination, the retention of tissue or the requirements of the HT Act and HTA's code of practice.	**Minor**
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 on body storage prevent practices that disregard the dignity of the deceased, condition checks undertaken on admission are only documented if there are any changes. Condition checks carried out on a weekly basis and on release are not documented. This means there is no written record of condition checks should there be a query from family members or funeral directors.	**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 Designate for every area that carries out HTA licensed activity. The inspection team were therefore not assured that the DI has oversight of regulated activities on the maternity ward and emergency department.	**Minor**

h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Regular meetings to discuss HTA business have recently restarted after the pandemic. However, there is no attendance by establishment staff from areas outside the mortuary and governance teams. Maternity staff and porters do not attend or receive the minutes of governance meetings discussing matters relating to HTA activity.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
c) Staff are assessed as competent for the tasks they perform	The Inspection team are not assured all staff who carry out licensed activity receive regular competency assessments. No records were available for review relating to site managers being assessed as competent to undertake out of hours release of the deceased. This poses a risk of release of the wrong body. Although porters receive competency assessments as part of their induction, reassessments take place on an ad hoc basis in response to incidents. Whilst the inspection team were assured through interviews that competency assessments are undertaken, not all mortuary staff competency records were available for review.	**Minor**
d) Staff have annual appraisals and personal development plans	Whilst the inspection team were assured through interviews that regular staff appraisals are undertaken, not all staff appraisal records were available for review.	**Minor**
e) Staff are given opportunities to attend training courses, either internally or externally	Whilst staff attend mandatory training provided by the establishment, there are limited opportunities for mortuary staff to attend external training courses to support personal development and update practice.	**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 risks are assessed on a regular basis, not all potential HTA reportable incidents have been identified and risk assessed. This means there is insufficient mitigation in place to minimise the risk to bodies and tissue of a reportable incident.	**Minor**
b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed	Some risk assessments lack detail of actions put in place to mitigate risks and when these have been completed. This means identified risks may not be mitigated in a timely way.	**Minor**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
c) There are documented cleaning and decontamination procedures and a schedule of cleaning	Whilst there are documented cleaning and decontamination procedures and a schedule of cleaning in place, records of cleaning carried out are incomplete. Domestic staff tasked with cleaning the mortuary are not always available, this means the establishment has limited oversight of when cleaning and decontamination of areas within the mortuary have been carried out.	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

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

Number	Standard	Advice
1.	GQ1(c)	The DI is advised to add a section in the care of the deceased paperwork for funeral directors to sign to confirm the condition of the body being released into their care.
2.	GQ3(c)	The DI is advised to ensure staff have received a competency assessment from an independent person prior to completing competency assessments on their colleagues.
3.	GQ3(d)	The DI is advised to obtain a visitors book for the hub and satellite sites to enable oversight of when visitors and authorised staff enter and leave the mortuary.
4.	GQ3(e)	The DI is advised to ensure all mortuary staff have access to the HTA website and have read the standards and guidelines outlined in Code B – Post Mortem Examination. Standards and guidance. Microsoft Word - Post-mortem examination licensing standards and guidance version 3 (hta.gov.uk)
5.	GQ4(a)	The DI is advised to ensure relevant personnel have access to mortuary staff training and development records including annual appraisals and competency assessments. Existing plans to implement an electronic record system in the mortuary should continue to be progressed.
6.	T1(a)	The DI is advised to consider the use of an alternative form of identification on the deceased to that of paper labels currently in use as there is a risk of paper labels becoming illegible or damaged
7.	PFE2(c)	The DI is advised to continue to progress existing plans for the refurbishment of the mortuaries to provide additional capacity and long-term storage.
8.	PFE2(e)	The DI is advised to add alarm testing of fridges out of hours to the existing fridge temperature testing schedule to ensure the system works as expected during times when the mortuary is closed.

9.	PFE3(a)	The DI is advised to remove all equipment no longer in use from the mortuaries and declutter storage areas.
10.	N/A	The establishment is advised to consider the governance structure pertaining to the DI and CLCh roles both in terms of everyday oversight of mortuary activity and the availably of effective escalation routes.

Background

Gloucester Royal Hospital has been licensed by the HTA since 2007. This was the third inspection of the establishment; the most recent previous inspection took place in September 2017.

Since the previous inspection, there have been no significant changes to the licence arrangements, or the activities carried out under the licence. However, there has been a change to the named personnel on the licence with a change of DI in June 2019.

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

69 of the 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017), standards GQ1(b), PFE1(b), PFE3(c) are not applicable as the establishment does not undertake PM examinations.

Review of governance documentation

The inspection included a review of the establishment's governance documentation relating to licensed activities. This included policies and procedural documents relating to licensed activities, cleaning records for the mortuary, records of servicing of equipment, audits, risk assessments, meeting minutes, reported incidents and training records for mortuary staff, porters and consent seekers.

Visual inspection

The inspection included a visual assessment of the establishment including, body storage areas and viewing rooms The inspection team observed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records

Hub Site

Audits were conducted onsite of five bodies from refrigerated storage. Identification details on bodies were crosschecked against the information recorded in the register and associated paperwork in addition to fridge door plates No discrepancies were identified.

Satellite Site

Audits were conducted onsite of three bodies from refrigerated storage. Identification details on bodies were crosschecked against the information recorded in the register and associated paperwork in addition to fridge door plates. No discrepancies were identified.

Audits of traceability were conducted for tissue blocks and slides for five cases. These included audits of the consent documentation for the retention of these tissues. No discrepancies were identified.

Meetings with establishment staff

Staff carrying out processes under the license were interviewed including the DI, mortuary manager, mortuary assistant, porter supervisor, bereavement midwife and consent seekers.

Report sent to DI for factual accuracy: 27 March 2023

Report returned from DI: 6 April 2023

Final report issued: 17 April 2023

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 8 May 2024

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.