Inspection report on compliance with HTA licensing standards
Inspection date: **21 and 23 March 2022**

Gloucestershire Coroner's Court

HTA licensing number 12595

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 **Gloucestershire Coroner's Court**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*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 Gloucestershire Coroner's Court ('the establishment') had met the majority of the HTA's standards,

three major and three minor shortfalls were found against standards for Governance and quality systems, Traceability and Premises, facilities and equipment. These related to standard operating procedures, meetings to discuss HTA activities, the use of three identifiers of the deceased for some procedures and staff competency assessments.

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
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
e) There is a system for recording that staff have read and understood the latest versions of these documents	The establishment does not have a system in place to record that staff have read and understood documented policies and procedures for the mortuary activities they are undertaking.	**Major**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	There are no scheduled governance or departmental meetings to discuss HTA activities which involve establishment staff.	**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	Three identifiers of the deceased are not routinely used to identify bodies and tissue for the following procedures: • Preparing a body for a viewing • A second check for viewings with identifiers being provided by the family prior to entry to the viewing room, to minimise the risk of the wrong family being in attendance; and • Labelling of toxicology samples.	**Major**

Minor Shortfalls

Standard	**Inspection findings**	**Level of shortfall**
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	Whilst competency is regularly discussed and observed, the establishment does not have a formalised system in place for assessing staff as competent in specific key tasks.	**Minor**
g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures	Whilst the establishment provide a verbal housekeeping induction to visiting pathologists and funeral director staff, this does not include written evidence of sign off against the establishment's documented policies and procedures.	**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	The inspection team found the premises to be clean with documented cleaning schedules in place, however records relating to the cleaning schedule were not completed.	**Minor**

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

DI and CLH/LH suitability

The HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

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

Number	Standard	Advice
1.	GQ1(d)	The DI is advised to ensure the document review process is consistent and that the authoriser does not form part of the review process.
2.	GQ4(b)	The inspection team found very occasional use of white stickers to redact information in the mortuary registers. The DI is advised to ensure the correction of errors is consistent to ensure mortuary records are fully auditable.
3.	T1(g)	The DI is advised to ensure that receipt for arrival of relevant material sent of site, is recorded in all cases.
4.	T2	The DI is advised to liaise with the Coroner to include three points of identification on the tissue retention forms. This will further mitigate the risk of organs returning to the wrong body.

5.	PFE1(d)	Whilst the premises are secure, the DI is advised to consider additional steps to minimise the possible risk of oversight of activities at the funeral director's entrance and unauthorized access to chiller control panels.
6.	PFE1(e)	The DI is advised to consider removing the family side facing latch in the viewing room and ensuring this door is always locked during a viewing.
7.	PFE2(e)	The DI is advised to review the fridge alarm trigger points. Currently the alarm trigger points are set at points which may not ensure bodies in storage continue to be stored at an optimal temperature should there be a temperature deviation prior to the activation of the alarm.
8.	PFE2(f)	The DI is advised to introduce a formal system to review and record trends in storage temperatures of the fridges within the body store.

Background

Gloucestershire Coroner's Court is licensed for the making of a PM examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes.

Gloucestershire Coroner's Court has been licensed by the HTA since 13 February 2012. This was the third inspection of the establishment; the most recent previous inspection took place in September 2016.

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
60 of the 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017). The remaining 12 standards, C1, C2 and PFE2(h) are not applicable to this establishment as they relate to consent seeking standards and storage of bodies of babies and infants.

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, records of servicing of equipment, ventilation reports, audits, risk assessments, staff appraisal minutes, temperature monitoring for the storage units, reported incidents and training records for mortuary staff.

Visual inspection
The inspection included a visual inspection of the mortuary body store, PM room, viewing room and tissue storage areas.

Audit of records
Audits were conducted for four bodies in refrigerated and frozen storage. Identification details on bodies were crosschecked against the information recorded in the mortuary register, the electronic mortuary data base and associated paperwork. No discrepancies were found.

Audits of traceability were conducted for tissue blocks and slides for two PM cases, including audits of the consent documentation for the retention of these tissues. These were the only tissue blocks and slides stored in the mortuary and no discrepancies were found.

Meetings with establishment staff
Staff carrying out processes under the licence were interviewed including the DI and Anatomical Pathology Technologist.

Report sent to DI for factual accuracy: 10 May 2022

Report returned from DI: 25 May 2022

Final report issued: 30 May 2022

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: 16 August 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.