Inspection report on compliance with HTA licensing standards
Inspection date: **08 January 2025**

Holly Tree Lodge

HTA licensing number 12405

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
Holly Tree Lodge	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 Holly Tree Lodge ('the establishment') had met the majority of the HTA's standards, one major and five minor shortfalls were found against standards for consent, documentation governance, viewing facilities, and freezer temperatures.

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
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		
b) There is a documented standard operating procedure (SOP) detailing the consent process	The SOP for consent incorrectly states that consent must be obtained from the deceased's next of kin, rather than the person in the highest qualifying relationship.	**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	Review of recently completed post mortem consent forms identified an occasion where a post mortem was performed without the family being informed of a timeframe to change their mind.	
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	Bodies are transferred to the establishment, with completed consent forms from the referring hospitals. However, staff do not have records to confirm that the documented consent takers are trained individuals. Further, staff conducting the post mortems have not received consent training, this combined with inaccurate SOPs and incomplete consent forms poses a risk that a post mortem may be completed with invalid consent. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	

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	Bodies have regular condition checks; however, these are not routinely documented. Those checks that were documented were not dated and therefore did not evidence that they were completed at regular intervals.	**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	Whilst reviewed on regular basis, policies and SOPs are not reviewed by someone other than the author.	**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	The establishment are currently using an external refrigerated unit. This process has not been risk assessed. This assessment should include: • Transfer of deceased between the mortuary and the unit. • Effectiveness of infection control procedures when using a corrugated floor and coated wooden shelves. • Lateral transfer of the deceased within the unit. • Security arrangements.	**Minor**
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	Viewings of the deceased takes place in a secure area which protects against unauthorised access to the restricted areas. However the seal on the door has recently perished, and the inspection team noted that regulated activities could be observed through the gaps in the doors.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
f) Temperatures of fridges and freezers are monitored on a regular basis	The mortuary currently has units that can alternate between refrigerators and freezers. When in use as a freezer, the temperature does not go down to the recommended temperatures for the storage of bodies.	**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.	GQ1e	Staff acknowledge SOPs by signing and dating the document. The DI is advised to extend this process to include visiting pathologists for the SOPs relevant to their role.
2.	GQ6b	Whilst staff have access to lone worker alarms, the DI is advised to monitor their use and consider further mitigations of risk, such as installed panic alarms.
3.	T1a	The DI is advised to remove patient identifiers from outer body bags of the deceased. This will further mitigate against traceability errors.
4.	T1b	The DI is advised to consider the use of an electronic database to record all traceability information relating to the deceased. This will help reduce the risk of transcription errors and improve efficiency.
5.	PFE1d	The DI is advised to regularly monitor the locations of the external CCTV to ensure they are not obstructed by the nearby shrubbery.
6.	PFE2e	The lower trigger point for the alarm for the fridges is set at 0 degrees. The DI is advised to adjust the temperature within an acceptable range to avoid the risk of bodies freezing should the temperatures deviate and the systems for call out fail to contact staff.
7.	PFE3(f)	The DI is advised to remove condemned equipment from the premises, to mitigate against the risk of it being used in error.
8.	N/A	The DI is advised to assess staffing levels to ensure they are proportionate to the current workload.

Background

Holly Tree Lodge has been licensed by the HTA since 21 February 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in December 2022.

Since the previous inspection there has been a change of the corporate licence holder contact in May 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.

62 out of 72 licensing standards were covered during the inspection (standards published 3 April 2017). Standards relating to taking consent and tissue storage were not applicable as staff at the establishment are not involved in the consent taking or retention of tissue processes.

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, cleaning records for the mortuary, records of servicing of equipment, audits, risk assessments, meeting minutes, reported incidents, and training records for staff.

Visual inspection

The inspection included an unannounced visual assessment of the mortuary access points, mortuary fridge room, post mortem room, contingency storage areas, and the viewing facilities. The inspection team observed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records
Audits were conducted for four bodies from refrigerated storage and one from frozen storage. Identification details on bodies were crosschecked against the information recorded in the mortuary register and associated paperwork. No discrepancies were identified.

Meetings with establishment staff
Staff conducting processes under the licence were interviewed including the Designated Individual, Senior APT, Trainee APT and pathologist.

Feedback was provided on 24 January 2025 to the Corporate Licence Holder, Senior APT, and Trainee APT.

Report sent to DI for factual accuracy: 03 February 2025

Report returned from DI: 05 February 2025

Final report issued: 14 February 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.