

**Holy 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.

<b>Area</b>	<b>Making of a post-mortem examination</b>	<b>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</b>	<b>Storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose</b>
<b>Holly Tree Lodge</b>	Licensed	Licensed	Licensed
<b>Mortuary</b>	<i>Carried out</i>	<i>Carried out</i>	<i>Carried out</i>

**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 Holy Tree Lodge ('the establishment') had met the majority of the HTA's standards, one minor shortfall was found against standards for 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

### Minor Shortfall

Standard	Inspection findings	Level of shortfall
<b>PFE3</b> Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually.	The establishment could not provide documented evidence that the ventilation system meets the required air changes per hour.	<b>Minor</b>

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.

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

Number	Standard	Advice
1.	GQ1(a)	The DI is advised to formalise an agreement with pathologists regarding their responsibilities for the return and management of histology slides.

2.	GQ2(a)	The establishment is advised to complete regular security audits of access to the mortuary. The audit should include a cross check of legitimate rights of access against frequency, duration and patterns of attendance to ensure access is in line with the purpose for which it was granted.
3.	T1(b)	The DI is advised to consider the use of a single database to record all traceability information relating to the deceased. This will help reduce the risk of transcription errors and improve time management.
4.	PFE2(e)	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.
5.	PFE2 (e)	Prior to the pandemic the establishment regularly tested the alarms for the fridges and freezers, however, recently this process is not carried out. The DI is advised to reinstate the testing of alarms to ensure the call out processes are working.

## Background

The establishment has been licensed by the HTA since February 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in July 2017.

Since the previous inspection no significant changes have been made.

## 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*

61 out of 72 licensing standards were covered during the inspection (standards published 3 April 2017). Standards relating to consent procedures (C1a-g) and consent training (C2a-d) were not assessed as they are not applicable as staff at the establishment do not seek consent for PM examinations.

#### *Review of governance documentation*

The inspection team reviewed the establishment's self-assessment document provided by the DI in advance of the inspection. Policies and procedural documents relating to licensed activities for the mortuary were reviewed. Traceability audits, risk assessments, meeting minutes and incidents were reviewed.

#### *Visual inspection*

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

#### *Audit of records*

Audits were conducted for two bodies in refrigerated storage and two bodies in freezer storage. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and relevant documentation. Audits were also conducted on tissue taken from PM examination and cross checked against records of receipt. No discrepancies were found.

#### *Materials held for the police*

Under section 39 of the HT Act, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. Any information provided by the establishment in relation to police holdings have been shared with the Home Office, but do not appear in the report as they are outside the scope of the HT Act.

#### *Meetings with establishment staff*

Staff carrying out processes under the licence were interviewed including the DI, Anatomical Pathology Technologist, and a Pathologist.

**Report sent to DI for factual accuracy: 09 January 2023**

**Report returned from DI: 24 January 2023**

**Final report issued: 25 January 2023**

## **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.