

**Uxbridge Mortuary**  
HTA licensing number 12435

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
<b>Uxbridge Mortuary</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 Uxbridge Mortuary ('the establishment') had met the majority of the HTA's standards, one minor shortfall was found against the standard 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

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	<p>During the inspection there were several temporary power outages. Although the establishment has raised this with the council, and electricians have attended the site, the cause has not been identified.</p> <p>Although the outage affects non-essential services, this could happen during a viewing. When the outage occurs, the locks on the door disable and any member of the public attending a viewing could gain access to other areas of the mortuary. In addition, staff are unable to complete essential documents on the computer when there is an outage.</p>	<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.

### Advice

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

Number	Standard	Advice
1.	GQ1 (a)	The DI is advised to explore whether protected time for staff, away from the day to day activities of the mortuary, could be considered to allow them time to carry out work related to governance activities.

2.	GQ2 (a)	The establishment is advised to continue with plans to undertake audits of swipe card access to the mortuary.
3.	PFE2 (a)	The establishment is advised to continue to take appropriate measures to mitigate the risk of the external fridge plant equipment being switched off.
4.	PFE1 (e)	The establishment may wish to consider installing a panic alarm in the viewing room to further support lone working.

## Background

Uxbridge Mortuary has been licensed by the HTA since March 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in March 2019.

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*

61 out of the total 72 standards were assessed (standards published September 2022). Standards relating to consent procedures (C1a-g) and consent training (C2a-d) were not assessed. They are not applicable as staff at the establishment do not seek consent for PM examinations.

### *Review of governance documentation*

The assessment 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 also reviewed.

#### *Visual inspection*

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

#### *Audit of records*

Audits were conducted for three bodies in refrigerated storage and one body in freezer storage. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary and computer records. Audits were also conducted on tissue taken at 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 has 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, Trainee Anatomical Pathology Technologist, Senior Anatomical Technologist and a Pathologist.

**Report sent to DI for factual accuracy: 18 August 2023**

**Report returned from DI: 22 August 2023**

**Final report issued: 24 August 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: 7 March 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.