

## **Stoke-on-Trent City Council Public Mortuary**

HTA licensing number 12057

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<br>Stoke-on-Trent City Council Public Mortuary | Licensed                            | Licensed   | Licensed   |
| Mortuary   | <i>Carried out</i>                  | <i>Carried out</i>   | <i>Carried out</i>   |

### Summary of inspection findings

This was an announced targeted site visit to inspect the progress of the corrective and preventative actions taken by the establishment in response to the shortfalls identified during the last previous targeted inspection carried out 16 July 2024, the most recent previous inspection of all 72 Post Mortem (PM) standards was carried out in October 2023.

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

Stoke-on-Trent City Council Public Mortuary ('the establishment') was found to have met all HTA standards assessed. The HTA has assessed the establishment as suitable to be licensed for the activities specified.

### Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

### Advice

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

| Number | Standard   | Advice   |
|--------|------------|--|
| 1.     | PFE1(a)    | The DI is advised to consider long term solutions to mitigate the risk of a build up of scale to stainless steel equipment, including sinks in the PM suite. Additionally, the DI is advised to consider techniques for cleaning the floors in the PM suite and body store to mitigate the risk of a build-up of scale which could detrimentally impact effective decontamination. |
| 2.     | PFE1(d)(e) | The DI is advised to continue with existing plans in place for the installation of additional security measures including CCTV cameras. Furthermore, the DI should consider the frequency of the deactivation code change for the newly installed intruder alarm.  |
| 3.     | PFE2(b)(c) | The DI is advised to continue with existing plans in place for the refurbishment of the mortuary to provide additional capacity. The recommendations in the following document should be considered in   |

|  |  |  |
|--|--|--|
|  |  | the design for the refurbishment <a href="#">NHS England » Health Building Note 16-01: Facilities for mortuaries, including body stores and post-mortem services</a> |
|--|--|--|

## Background

Stoke on Trent City Council Public Mortuary has been licensed by the HTA since June 2007. This was the seventh inspection of the establishment; the most recent previous inspection took place in July 2024. During this targeted follow up inspection, we identified the shortfalls previously identified had been fully met.

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under the licence. However, early discussions have taken place for an extensive refurbishment of the mortuary facilities to provide additional capacity.

## 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*

Six out of the HTA's 72 standards were covered during the announced targeted inspection. The inspection focussed on areas of concern, five of which were identified during the most recent previous inspection; the remaining standards will be assessed during the next routine inspection.

Standards covered at this inspection are listed in Appendix 3.

### *Review of governance documentation*

The inspection included a review of some of the establishment's governance documentation relating to licensed activities. This included risk assessments and Standard Operating Procedures (SOP's) relating to the oversight of contractors and authorised visitors to the mortuary tasked to carry out remedial work within the mortuary.

### *Visual inspection*

The inspection included a visual assessment of the establishment including the body storage area, loading bay and the Post Mortem (PM) suite.

#### *Audit of records*

Audits were conducted onsite of one body in frozen storage and two bodies from refrigerated storage. Identification details on bodies were crosschecked against the information recorded in the register and associated paperwork, in addition to information held on the fridge plaques and in the electronic patient record system. No discrepancies were identified.

#### *Meetings with establishment staff*

The inspection team met with staff carrying out processes under the licence, this included the Corporate Licence Holder contact (CLHc), the DI, the Coroners Service Manager, APT, and Estates Manager.

**Report sent to DI for factual accuracy: 16/05/2025**

**Report returned from DI: 23/05/2025**

**Final report issued: 23/05/2025**

## **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.



### Appendix 3: Standards Assessed

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|---|
| <b>Traceability</b>   |
| <b>T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail</b>  |
| 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. |
| <b>Premises, facilities and equipment</b>   |
| <b>PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue</b>                                 |
| a) The premises are clean and well maintained.  |
| d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access).                  |
| e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access.                |

**PFE2 There are appropriate facilities for the storage of bodies and human tissue**

c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs.

d) Fridge and freezer units are in good working condition and well maintained.