Inspection report on compliance with HTA licensing standards
Inspection date: **17 October 2023**

# 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 Site**<br>**Stoke-on Trent City Council Public Mortuary** | 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 Stoke-on-Trent City Council Public Mortuary ('the establishment') had met the majority of the HTA's standards, eight major and five minor shortfalls were found against standards for Governance and quality systems, Traceability and 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 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** | | |

| | | |
|---|---|---|
| a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath. | SOPs lack sufficient detail for procedures undertaken in the Mortuary.<br><br>For example, SOP1 states that a name and address should be present on an identification band but a third form of identification is not mentioned.<br><br>SOP11 states that a "Mortuary Release form" is issued by the Coroner however it does not state that a physical copy must be brought by Funeral Directors for release. Whilst this is a practice that the establishment staff require for release of a body, the SOP does not reflect this.<br><br>Whilst bodies are checked and their condition is recorded upon arrival, and it was evident that staff are monitoring condition, there is no documented procedure in place for this process. | **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 | Bodies admitted by ambulance do not have identification bands attached, rather labels are attached to body bags. During the body audit, the HTA found a body with only two identifiers.<br><br>Furthermore, unidentified bodies do not have unique identifiers on admission. Whilst the establishment add further means of identification during the booking in process there is a risk of misidentification. | **Major** |
| **PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.** | | |

| | | |
|---|---|---|
| a) The premises are clean and well maintained | Multiple areas within the Mortuary and post mortem room require maintenance as porous surfaces are exposed which may prevent effective cleaning and decontamination. The following areas were noted:<br>• The flooring, skirting boards and walls of the post mortem room have not been maintained. This was identified as a shortfall in the previous inspection and was corrected, however they have deteriorated again.<br>• There are heavy deposits of limescale around dissection stands and post mortem tables in the post mortem room.<br>• External doors and frames leading to the fridge room show signs of damage exposing wood. | **Major** |
| 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) | An external contingency store is located within the establishment's courtyard area. This area is accessed by passing through roller shutters which remain open during working hours.<br>Whilst the courtyard is partially covered by CCTV, this does not extend to the locked external contingency store nor to a roof access ladder which is also located within the area.<br>Access to the external contingency store is gained via a second set of roller shutter doors. Both this roller shutter and the external contingency store are accessed manually by key lock mechanisms which are not audited.<br>These arrangements pose a security risk to the establishment.<br>(See *Advice and Guidance* item 3). | **Major** |
| **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 | The Mortuary lacks refrigerated storage for bariatric bodies. | **Major** |
| d) Fridge and freezer units are in good working condition and well maintained | The door on the refrigeration unit was so damaged that it prevented the door from closing. Furthermore, the door's construction was compromised leaving the internal wood substructure exposed. | **Major** |
| **PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored** | | |
| a) Items of equipment in the mortuary are in good condition and appropriate for use | Mortuary trolleys are in a state of disrepair. The inspection team noted damage to hydraulic systems and rollers on separate trolleys. These faults increase the risk of mechanical failure and misloading of fridge trays. Furthermore, trolleys do not reach all fridge spaces therefore reducing operational capacity.<br>Dissection boards in the post mortem room are heavily worn and the surfaces damaged. This presents a risk of ineffective decontamination. | **Major** |
| c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually | The air handling unit was last serviced in 2019 and therefore the inspection team cannot be assured that this standard has been met. | **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 | Members of mortuary staff are not competency assessed after their initial sign off. | **Minor** |
| f) There is a documented induction and training programme for new mortuary staff | The establishment has a generic induction package however it does not contain a training programme relevant to Mortuary specific tasks. | **Minor** |
| g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures | The establishment's generic induction does not include review of policies and procedures.<br>(See *Shortfall* against standard GQ3 (f)). | **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 has a suite of risk assessments however some specific activities have not been assessed. These activities include;<br>• withdrawing bodies from high fridge spaces.<br>• external contractors moving bodies through the Mortuary to access the Digital Autopsy service. | **Minor** |
| **T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail** | | |
| g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings). | Whilst the establishment have a system to track specimens taken during post mortem examinations it lacks sufficient detail for full traceability. | **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. | T1(b) | The DI should review mortuary body traceability systems and consider condensing the number of paper records to reduce the risk of errors. Furthermore, the DI may wish to consider the use of an electronic system for traceability.<br>The mortuary register is completed with the location the of body upon admission. This not updated when bodies are moved to other storage locations within the Mortuary. The DI is advised to update records to ensure a robust audit trail. |
| 2. | PFE1(a) | The DI is advised to consider the purchase of a motorised floor cleaner to use on body store floor areas. |
| 3. | PFE1(d) | The DI is advised to review the level of security associated with the main mortuary entrance and upgrade the existing measures.<br>The DI is advised to enhance security measures including additional CCTV coverage in the courtyard area. Furthermore, the DI should consider closing roller shutters in this area throughout the working day to strengthen existing security measures. |
| 4. | PFE2(g) | The Mortuary uses plastic modesty sheets and body bags. The DI is advised to review the practice of shrouding bodies in storage and the use of full shrouds should be considered. |

## Background

Stoke-on-Trent City Council Public Mortuary has been licensed by the HTA since 7 June 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in January 2019.

Since the previous inspection, there has been a change of Corporate Licence Holder contact and an extension to the existing premises.

## 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 HTA licensing standards, were covered during the inspection (standards published 3 April 2017). Consent standards C1 and C2 (11 in total) are not applicable as consent for post mortem is not sought by the establishment.

*Review of governance documentation*

The inspection team reviewed the establishment's self-assessment document provided by the DI ahead of inspection. Standard operating procedures and policies were reviewed. Risk assessments, audits, cleaning records, meeting minutes and a ventilation report were inspected as part of the review process.

*Visual inspection*

The inspection included a visual assessment of the body storage areas in the Mortuary, post mortem room and external contingency storage areas. External areas encompassed in the mortuary perimeter were assessed.

*Audit of records*

A traceability audit of four bodies in storage was undertaken. This included bodies from the community and one body in long term storage. Details were cross checked against identity bands, multiple mortuary registers and an electronic database. Although there was full traceability one discrepancy that had been previously identified had not been corrected by establishment staff.

*Meetings with establishment staff*
The inspection team conducted interviews with staff carrying out processes under the licence. This included the Designated Individual, Pathologist and Trainee APT.

**Report sent to DI for factual accuracy: 25 October 2023**

**Report returned from DI: 9 November 2023**

**Final report issued: 20 November 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.