

Inspection report on compliance with HTA licensing standards
Inspection date: **16 July 2024**



**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 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 inspection carried out 17 October 2023. The HTA found the Licence Holder (LH) and Designated Individual (DI) to be suitable in accordance with the requirements of the legislation. However, the DI is responsible for the day to day running of the establishment and actively participates in mortuary activity including Post Mortem examinations, admissions and releases. Concern has been raised over the ability of the DI to commit the necessary time to affect the change needed to maintain compliance with HTA standards. The suitability of the DI will remain under review.

The targeted announced site visit of Stoke-on-Trent City Council Public Mortuary ('the establishment') found three critical, three major and one minor shortfall against standards for Governance and quality systems, Traceability and Premises, facilities and equipment.

Six of the shortfalls relate to findings from the last inspection. The HTA is concerned that adequate steps were not taken to address these findings in the intervening period and to embed suitable practices at the establishment. A similar issue was identified in standards GQ3(g), T1(g), PFE1(a)(d) and PFE2(c)(d) during the last previous inspection carried out 17 October 2023.

Concerns were discussed with the establishment as part of this inspection. The current DI has provided assurance that the establishment is committed to meeting the regulatory requirements. Based on this assurance, 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. However, in light of the establishment's lack of progress with addressing shortfalls from previous inspections, the HTA has issued regulatory directions and will consider the need for further regulatory action if appropriate action is not taken to meet the regulatory requirements in accordance with the timeframes detailed in Appendix 2.

Compliance with HTA standards

Critical Shortfalls

Standard	Inspection findings	Level of shortfall
<p>PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.</p>		
<p>a) The premises are clean and well maintained</p>	<p>There are significant areas of damage to the structure of the building and equipment in use. These include but are not limited to:</p> <ul style="list-style-type: none"> • There is significant damage to the external fire exit doors, and interior door frames leading to storage rooms in the body store. This has led to large areas of exposed wood which poses the risk of ineffective cleaning and decontamination. • The flooring in the Post Mortem (PM) room is reaching the end of its natural life. There is significant wear which has led to the exposure of the concrete subfloor. This increases the risk of porosity which may prevent effective decontamination. • The sink used to clean equipment in the PM room has significant amounts of scale which may prevent effective cleaning and decontamination. • One of the floor drains in the PM room had significant amounts of debris in the drainage trap. 	<p>Critical</p>

<p>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)</p>	<p>Whilst there are roller shutters to provide security at the entrance used by funeral directors these are not routinely deployed during working hours. The shutters open onto roads accessed by the public and are overlooked by a carpark posing the risk of oversight of the activity being undertaken. Furthermore, [redacted].</p>	<p>Critical (cumulative)</p>
<p>e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access</p>	<p>The inspection team are not assured security arrangements protect against unauthorised access and ensure oversight of visitors and contractors who have a legitimate right of access. Audits of keys used to secure the temporary external unit, CCTV and swipe card access logs are not routinely carried out. Furthermore, visitors and non-mortuary staff undertaking mortuary duties are not required to sign in and out of the mortuary.</p>	
<p>PFE2 There are appropriate facilities for the storage of bodies and human tissue.</p>		
<p>c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs</p>	<p>The mortuary lacks refrigerated space for the storage of bariatric bodies. Whilst there are contingency plans in place for the transfer of bariatric bodies to a third party establishment, the short term interim storage arrangements do not protect the dignity and safety of the deceased.</p>	<p>Critical (cumulative)</p>
<p>d) Fridge and freezer units are in good working condition and well maintained</p>	<p>The Inspection team are not assured fridge and freezer units are in good working condition and well maintained. One of the fridge doors in the PM room has sustained significant damage, which has led to it buckling preventing it from closing correctly. This poses the risk of an incident relating to the dignity and safety of the deceased in addition to the risk of accidental damage.</p> <p>Furthermore, the damage has led to the exposure of the wooden substructure which poses the risk of ineffective cleaning and decontamination.</p>	

Major 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		
g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures	<p>The inspection team are not assured visiting staff who carry out activity under the licence receive an induction and training. No records were available for review relating to temporary support staff receiving a local induction, or the reading of policies and procedures relevant to their role.</p> <p><i>The establishment submitted sufficient evidence to address this shortfall before the report was finalised.</i></p>	Major
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed	<p>The Security Risk Assessment lacks detail regarding the actions in place to mitigate the risk of a serious security breach, who is responsible for each action and the completion date of identified actions.</p> <p><i>For further detail see shortfalls PFE1(d) and PFE1(e) above</i></p>	Major
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
d) Staff have access to necessary PPE	<p>Whilst face masks are available for staff to use in the PM suite. There is no record staff have received face fit testing since 2019 for use of this personal protective equipment.</p>	Major

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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).	<p>Whilst a significant amount of work has been carried out to improve systems and processes to ensure tissue transferred off site is fully traceable. The tissue traceability log only records two identifiers, this poses the risk of a loss of tissue traceability.</p> <p><i>The establishment submitted sufficient evidence to address this shortfall before the report was finalised.</i></p>	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 give consideration to the construction of the notebooks used by mortuary staff to record information relating to bodies in storage. Whilst there is a system in place for the governance and retention of these notebooks there is a risk of pages becoming detached from the main notebook and mislaid. Additionally, the DI should consider the use of an electronic records management system to document the care of the deceased.

2.	PFE1(d)	Whilst there is a CCTV camera in place in the body store. The DI should consider risk assessing the installation of an additional CCTV camera to oversee the fridge and freezer doors in the body store, to provide additional oversight and support the investigation of incidents.
3.	N/A	The DI should risk assess the current fire alerting systems within the establishment and implement suitable mitigations regarding the alerting of staff in the event of a fire out of hours.

Background

Stoke-on-Trent City Council Public Mortuary has been licensed by the HTA since June 2007. This was the sixth inspection of the establishment; the most recent previous inspection took place in October 2023. During this targeted follow up inspection, we identified seven shortfalls that have not been fully addressed in standards GQ3(g), T1(g), PFE1(a)(d), PFE2(c)(d) and PFE3(c), these were identified during the last previous inspection.

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 the potential relocation of the mortuary to a bigger site. The DI was not present onsite during the inspection, whilst high level feedback was given to the CLHc at the end of the inspection, a feedback meeting was held remotely with the DI and CLHc after the inspection team had left site.

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

11 out of the HTA's 72 standards were covered during the announced targeted inspection. Standards covered at this inspection are listed in Appendix 3. The inspection focussed on areas of concern, seven of which were identified during the most recent previous inspection; the remaining 62 standards will be assessed during the next routine inspection.

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 relating to licensed activities and cleaning records for the mortuary. The most recent ventilation reports and security audits were requested but were not made available for review.

Visual inspection

The inspection included a visual assessment of the establishment including internal and external body storage areas and the PM suite.

Audit of records

Audits were conducted onsite of three 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 mortuary whiteboard and in the electronic patient record system. No discrepancies were identified.

Audits of traceability were conducted for tissue removed at PM. These were limited to audits of the documentation relating to transfer of tissue offsite for analysis and confirmation of receipt from the receiving establishment.

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, APT, and member of staff providing mortuary cover.

Report sent to DI for factual accuracy: 30/07/2024

Report returned from DI: 09/08/2024

Final report issued: 13/08/2024

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.

Appendix 3: Standards Assessed

Governance and quality systems

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks

g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures.

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored

b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.

Traceability

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). The traceability system ensures that the following details are recorded:

- i. material sent for analysis on or off-site, including confirmation of arrival
- ii. receipt upon return to the laboratory or mortuary
- iii. the number of blocks and slides made
- iv. repatriation with the body
- v. return for burial or cremation
- vi. disposal or retention for future use.

Premises, facilities and equipment

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.

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.

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored

a) Items of equipment in the mortuary are in a good condition and appropriate for use:

i. fridges / freezers

ii. hydraulic trolleys

iii. post mortem tables

iv. hoists

v. saws (manual and/or oscillating)

Guidance

Equipment should be made of material that is easy to clean, impervious, non-rusting, non-decaying and non-staining.

c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually.

d) Staff have access to necessary PPE.