Inspection report on compliance with HTA licensing standards Inspection date: **28 August 2025** 



# **Tameside General Hospital**

HTA licensing number 12067

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	I Waking of a post-	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	neceased person or rejevant
Hub site	Licensed	Licensed	Licensed
Mortuary	Carried out	Carried out	Carried out

# **Summary of inspection findings**

Although the HTA found that Tameside General Hospital ('the establishment') had met the majority of the HTA's standards, one critical, 16 major and 4 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**

## **Critical Shortfalls**

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment	's work are governed by documented policies and procedures	
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	During the inspection, the team identified five bodies that required frozen storage. These bodies were found to be in varying stages of deterioration, ranging from mould growth to advanced decomposition.	Critical
	Storage arrangements at the time of the inspection did not maintain the condition or the dignity of the deceased and increased the risk of accidental damage through decomposition.	
	Condition checks had not been documented as per procedure, and follow- ups were not being made to manage the movement of bodies through the mortuary.	
	The establishment submitted evidence to address this shortfall before the report was finalised.	

# Major shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment	's work are governed by documented policies and procedures	

f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity	Deviations from documented procedures are commonplace and are not escalated internally or documented. For example, staff have released deceased to Funeral Directors without the required paperwork, and have carried out viewings with families without carrying out the documented identity checks.	Major
GQ2 There is a documented system of	of audit	
a) There is a documented schedule of audits	There are a number of audits that have not been completed in line with the schedule. Overdue audits include those relating to consent (due May 2025), traceability (due May 2025), mortuary processes (due June 2025) and security (monthly audit not completed since May 2025).	Major
GQ3 Staff are appropriately qualified tasks	and trained in techniques relevant to their work and demonstrate compe	etence in key
a) All staff who are involved in mortuary duties are appropriately	Some members of pathology assist in mortuary duties; however, they are not formally trained in procedures.	Major
trained/qualified or supervised	Porters get automatic access to the mortuary at the start of their employment, which poses the risk of untrained staff carrying out mortuary duties. Furthermore, not all Porters have been formally trained, and refresher training for some Porters is overdue.	
b) There are clear reporting lines and accountability	The Designated Individual (DI) named on the licence is on long-term absence and no replacement has been put in place. As well as the oversight of the licenced activities, many tasks designated to the Mortuary Manager relating to HTA standards are not being carried out.	Major
	The establishment submitted evidence to address this shortfall before the report was finalised.	

c) Staff are assessed as competent for the tasks they perform	Some competencies for mortuary staff are not completed, signed or indate.	Major
	The Porters competency assessments are not fit for purpose. There is a self-assessment element which is not followed up should a Porter identify training needs. Furthermore, as with the mortuary staff competencies, many records are incomplete.	
GQ5 There are systems to ensure tha	t all untoward incidents are investigated promptly	
a) Staff know how to identify and report incidents, including those that must be reported to the HTA	Although an SOP is in place, the inspection team identified two incidents which met the threshold for reporting to the HTA which had not been reported.	Major
	This shortfall was identified at the last HTA inspection.	
c) The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed	Incidents are not managed effectively. Some incidents have not had a thorough investigation carried out to reduce the risk of repeat errors.	Major
GQ6 Risk assessments of the establis	shment's practices and processes are completed regularly, recorded a	nd monitore
a) All procedures related to the	Risk assessments are overdue for review.	Major
licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis	This shortfall was identified at the last HTA inspection. The DI provided evidence and assurance to the HTA this shortfall had been addressed following the last inspection.	
c) Significant risks, for example to the establishment's ability to deliver post-	The inspection team are not assured that the following risks are incorporated into the organisational risk register:	Major
mortem services, are incorporated into the Trust's organisational risk register	<ul> <li>Lack of long-term freezer storage</li> <li>Risk to delivery of service due to low staffing levels</li> </ul>	

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	The inspection team observed a viewing taking place and due to limited information for the deceased, only two identifiers were checked.  This increases the risk of viewing of the wrong body.	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	There were significant areas on the post mortem room wall where the paint was peeling exposing the plaster underneath.  Some of the trolleys have significant areas of rusting.	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)	The CCTV does not cover all the refrigerator units of the outdoor facility.  Although there is the potential to have controlled access throughout the facility, the internal doors from the offices and viewing suite to the body store are unlocked in working hours.	Major
PFE2 There are appropriate facilities	for the storage of bodies and human tissue.	

a) Storage arrangements ensure the dignity of the deceased	If deceased are stored within the external fridges, establishment staff confirmed that the external examinations prior to PMCT take place outside the unit which is exposed. The SOP details that this should take place within the main mortuary or the scanning unit. This procedure risks compromising the dignity of the deceased.	Major
	The process to transfer bodies to the scanning facility is poor. The establishment rely on funeral directors collecting bodies for funerals or bringing bodies to the mortuary for PM examination to transfer them to the scanning unit. The hospital vehicle that can be used for transfers is not always available. Occasionally, transfer of bodies occurs on foot to the facility. This has previously resulted in complaints from members of staff witnessing the transfer and members of the public.	
	The processes and practices for the transfer of bodies to and from the scanning unit were reviewed during the last HTA inspection. The DI provided evidence and assurance to the HTA that shortfalls relating to this activity had been addressed following the last inspection.	
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	There is insufficient freezer storage capacity to meet needs.  During the site visit the inspection team identified five bodies that had been in refrigerated storage for over 30 days. The bodies were in a poor condition and required freezing however the freezer spaces were all in use.	Major
PFE3 Equipment is appropriate for us	se, maintained, validated and where appropriate monitored	
a) Items of equipment in the mortuary are in good condition and appropriate for use	The trolley used to transfer the deceased into and out of the outside fridge units is not fit for purpose. Staff were required to stand on the side of the unit to be able to reach the top tray.	Major
	Previously this has resulted in an incident however has not been addressed.	

ne ar	The ventilation system provides the ecessary ten air changes per hour nd is checked and maintained at ast annually	The establishment could not provide an up-to-date report confirming that the air handling system meets the necessary standard.	Major	
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# Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishmen	t's work are governed by documented policies and procedures	
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Mortuary staff do not have regular formal documented meetings, meaning there is a risk of staff not being aware of important information relating to licensed activities at the establishment.	Minor
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
d) Staff have annual appraisals and personal development plans	The annual appraisals for mortuary staff are overdue.	Minor
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  PFE3 Equipment is appropriate for	Although there is a mortuary visitors log, records were incomplete. At the time of the visit, maintenance was being carried out however the maintenance staff did not sign in. Some visitors were signed in, but were not signed out, and the purpose of the visit was not filled in.  This was identified as an area on which advice and guidance was given at the previous HTA inspection.  use, maintained, validated and where appropriate monitored	Minor
f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept	No evidence of the servicing of PM tables and equipment was provided.	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.

#### DI and CLH/LH suitability

Since the inspection the DI has been replaced.

## **Advice**

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

Number	Standard	Advice
1.	T1(g)	There is a whiteboard in the PM preparation room which details organs taken at Post-Mortem examination. The whiteboard is used by some staff but not all and the information is also detailed

	elsewhere. The whiteboard was not up-to-date at the time of inspection, however records were. To avoid any confusion the DI is advised to either consistently use the whiteboard, or cease to use it.
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## **Background**

Tameside General Hospital is licensed for the making of a PM examination, removal of relevant material from the deceased, and storage of bodies of the deceased and relevant material for use for scheduled purposes.

Tameside General Hospital has been licensed by the HTA since May 2007. This was the sixth inspection of the establishment; the most recent inspection was an unannounced focussed inspection covering standards- GQ1(a), GQ2(a), GQ6(a), GQ6(c), PFE1(d) and PFE1(e), and took place in May 2024.

Since the previous inspection, there has been a significant change to license including the change of DI in September 2025.

## 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

All 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

#### Review of governance documentation

The inspection included a review of the establishment's governance documentation relating to licensed activities. This included policies and procedural documents relating to licensed activities, maintenance and records of servicing of some equipment, incident logs, some audits, risk assessments, and some mortuary staff competencies. Training records and meeting minutes were not provided.

## Visual inspection

The inspection of the facility included a visual assessment of the Mortuary, Post Mortem room, viewing facilities and external body store.

#### Audit of records

The inspection team undertook audits of traceability of five bodies in storage. This included hospital and community cases including one in long term storage. Traceability details were crosschecked between the identification bands on the body, and the Mortuary register. Whilst one minor discrepancy was found, this was not sufficient to amount to a shortfall, but oral advice was given to the establishment at the time of the inspection.

The mortuary register was audited to identify bodies that should be stored in long term storage. The team identified five bodies that required frozen storage. These bodies were found to be in varying stages of deterioration, ranging from mould growth to advanced decomposition.

The inspection team undertook audits of three cases where material had been taken at post-mortem. Traceability details were crosschecked between records and transfer documentation. No discrepancies were identified.

## Meetings with establishment staff

The establishment was understaffed at the time of the inspection and the DI was on long term absence.

The inspection team conducted interviews with staff carrying out processes under the license. This included Anatomical Pathology Technologists, the Pathology Quality Manager, Porters, the Bereavement Midwife and the Corporate License Holder contact.

Report sent to DI for factual accuracy: 31 October 2025

Report returned from DI: 17 November 2025

Final report issued: 4 December 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 o	f the follow-up approach the HTA will take.