Inspection report on compliance with HTA licensing standards
Inspection date: **2 and 3 May 2024**

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	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 **Tameside General Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	-
Maternity	-	-	-
A&E	-	-	-

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.

The targeted unannounced site visit of Tameside General Hospital ('the establishment') found three major and three minor shortfalls against standards for Governance and quality systems, Traceability and Premises, facilities and equipment. These related to Standard Operating Procedures (SOPs), risk assessments, incident reporting, traceability processes and equipment used during the transfer of bodies for post mortem (PM)CT scanning.

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.	The SOPs relating to the transfer and post mortem (PM) scanning of bodies do not reflect practice or contain sufficient detail. For example, the SOPs do not include: • checking a minimum of three identifiers of the body immediately before transfer; • checking a minimum of three identifiers of the body with the radiology staff prior to scanning; • radiology staff are provided with patient details and information prior to the transfer for scanning; • the process for moving bodies within the scanning unit; • the return process for bodies when scanning is completed; • what vehicle is used, or how use of the vehicle is organised; • the number of mortuary staff required for the process. In addition, the SOP states: • three identifiers of the deceased are written on the outside of the body bag ready for transfer for scanning. The identifiers are checked against the coroner's paperwork when external examinations are completed. In practice, only two identifiers are written on the body bag • more than one body is transferred for scanning at a time. In practice, only one body can be transferred at a time. The emergency storage unit SOP refers to checking three identifers on bodies when they are transferred to a different storage location but not what these are checked against. In addition, the SOP does not include each contingency body storage option available at the establishment. *The establishment submitted evidence to partially address this shortfall before the report was finalised.*	**Major**
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	Hard copy risk assessments provided on site did not state the risk ratings for the activities being assessed. Completed risk assessments were provided to the inspection team following the site visit. All risk assessments are out of date, except the 'HTA Incident Reporting' risk assessment which was reviewed in May 2024. The out of date risk assessments have not been reviewed in-line with the timescales detailed in each risk assessment, for example, quarterly or annually. The following incomplete risk assessments were seen on-site but completed versions were not sent for review: - Accidental damage during PM by insufficiently competent staff. - Viewing of a wrong body. - Access to the mortuary due to doors being left open. - Family members accessing the body store. - Unauthorised access by contractors and maintenance staff In addition, post mortem related risk assessments have not been submitted for review, for example, 'post-mortem examination conducted was not in line with the consent given or the PM examination proceeded with inadequate consent'. The process for transferring bodies for PMCT scanning has not been risk assessed. The HTARI category 'PM cross-sectional imaging of the body of a deceased person included an invasive procedure for which consent had not been given' has not been risk assessed. *The establishment submitted evidence to partially address this shortfall before the report was finalised.*	**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	The small metal frame trolley used to place bodies on after scanning and before transfer back to the mortuary is not appropriate for use. Bodies are not secured onto this trolley and there is a risk of accidental damage to the body or injury to staff. The process to transfer bodies for scanning witnessed by the inspection team at the establishment is time consuming.The establishment routinely scan four and often more bodies in a scanning session. The vehicle used to transfer bodies for scanning can only accommodate transfer of one body at a time. The inspection team are not assured the vehicle or equipment is appropriate for the number of bodies requiring transfer for PMCT scanning.	**Major**

Minor Shortfalls

Standard	**Inspection findings**	**Level of shortfall**
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
a) Staff know how to identify and report incidents, including those that must be reported to the HTA	The inspection team identified two incidents that should have been reported to the HTA, although one incident report stated the HTA had been informed. Both incidents had been reported internally.	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
e) Identity checks take place each time a body is moved whether inside the mortuary or from the mortuary to other premises	Only the name of the deceased is confirmed with radiology staff on arrival at the CT scanning unit. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised*	**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	The door to the scanning unit was not consistently closed when transferring bodies into and out of the scanning room. There is a risk of oversight of this activity compromising the dignity of the deceased.	**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

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: • combine the transfer for scanning and PMCT scanning SOPs to ensure the details of the process is clear and in one document. • include the process for admitting and managing bodies with unknown identities in body receipt SOPs.
2.	GQ6(a)	The DI is advised to: • ensure all mortuary activities relevant to the establishment are included in risk assessments. Reviewing HTARI categories will assist with this. • risk assess using a nutwell unit for contingency body storage in an operational PM room. The use of the unit should not compromise PM room activities or cleaning and disinfection of the PM room. • ensure hard copy risk assessments are fully completed and available for staff to review in the risk assessment folder.

3.	PFE1(e)	The DI is advised to ensure the viewing forms completed by visitors are updated with the time they leave the mortuary.
4.	PFE2(a)	Although at the time of the inspection no bodies were being stored in the external body storage unit, this area is being used to store equipment and parking for cars. The DI is advised to keep this area clear should these units need to be used and maintain the dignity of the deceased.
5.	PFE3(a)	The DI is advised to explore options for equipment that will make the transfer of bodies for PMCT scanning more efficient and mitigate the risk of accidental damage to bodies and injury to staff.

Background

Tameside General Hospital has been licensed by the HTA since May 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in December 2022.

Since the previous inspection, there have been no significant changes to the licence arrangements. PMCT scanning for the coroner has commenced since the last inspection.

A decision to undertake an unannounced visit was made by the HTA's Director of Regulation at a Regulatory Decision-Making meeting on 8 March 2024. This followed concerns relating to mortuary traceability procedures, the transfer of bodies to and from CT scanning facilities on the hospital site and their subsequent storage and condition in the external body storage unit. Accordingly, this inspection focused on the following standards: GQ1(a), GQ1(c), GQ3(a), GQ3(c), GQ5(a)-(c), GQ6(a), GQ6(b), T1(c), T1(e), PFE1(e), PFE2(a) and PFE3(a).

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:

Review of governance documentation
A review of SOPs and risk assessments relevant to the activities being assessed and staff training records and competency assessments provided by the DI was undertaken. A full review of the remaining governance documentation, including staff training records not reviewed, will be undertaken at the next routine inspection to be scheduled.

Visual inspection
The inspection team observed the process for the transfer of bodies from the mortuary body store to the CT scanner and their subsequent return. All bodies were returned to the main mortuary body store.

Audit of records
The inspection team reviewed the number of PMCT cases undertaken every week in the last six months.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence. This included the Mortuary Manager (who is also the Designated Individual), their line manager and Anatomical Pathology Technologists. Feedback was discussed with the DI and their line manager.

Report sent to DI for factual accuracy: 20 May 2024

Report returned from DI: 19 June 2024

Final report issued: 21 June 2024

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: 15 January 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.