Inspection report on compliance with HTA licensing standards
Inspection date: **19 September 2024**

Medway Maritime Hospital
HTA licensing number 12090

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
Medway Maritime Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Maternity	-	*Carried out*	-
A&E	-	*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 Medway Maritime Hospital ('the establishment') had met the majority of the HTA's standards, one cumulative major, one major and four 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
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	Some small areas of the body store walls are damaged exposing porous plaster. This poses a risk that it cannot be cleaned or decontaminated effectively. In the post mortem (PM) room the inspection team identified areas that had not been cleaned appropriately: • Dark fluid stains were seen on the walls, whiteboards and door handle; and • hair was identified in the rollers of one PM table. There is a build-up of limescale on the PM room floor affecting the staff's ability to adequately clean and disinfect it. *See advice item 8.*	**Cumulative 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 servicing records for the PM tables from 2023 indicated the tables were ‘end of life’ and are showing age-related wear. There is also a significant build-up of limescale on the PM tables affecting the staff’s ability to adequately clean and disinfect them. The surfaces of the whiteboards in the PM room used to record details for each PM case are damaged and cannot be adequately wiped off after each case. *See advice item 8*	
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	At the time of the inspection a bank of freezers had failed and was awaiting repair. Repairs had been delayed due to sourcing parts for the older equipment. The failure of this bank impacted the establishment’s ability to freeze bodies after 30 days in refrigerated storage on site and arrangements to transfer bodies to the external contingency company had not been made.	**Major**

Minor 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.	Whilst Standard Operating Procedures (SOPs) refer to checking identification at relevant stages of a procedure, they do not consistently state a minimum of three points of identification should be checked, what these could be and what they are checked against. Examples include but not limited to: • SOP-MMH-MOR-005 Reception of deceased into the mortuary (in relation to hospital bodies). • SOP-MMH-MOR-012 The post mortem examination (in relation to community body identifiers, p4 and identification checks by pathologists).	**Minor**

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 a near-miss HTARI that was not reported to the HTA. However, this was reported internally within the Trust.	**Minor**
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	Although there is a robust process for booking and preparing bodies for viewing, the mortuary staff do not always undertake a final identification check of community deceased prior to viewing, using identification details provided by the relatives when they attend.	**Minor**
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The mortuary does not always receive confirmation that PM tissue has been received at a referring laboratory. *See advice item 5*	**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.	GQ2(a)	The mortuary manager is advised to include more horizontal audits of mortuary activities within the audit schedule and ensure audits include representative numbers to provide assurance of an activity.
2.	GQ6(a)	The DI is advised to: • include staff training and competency as a control measure in relevant risk assessments; • reassess the risk rating for out of hours release of bodies as this does not seem to reflect the control measures in place; and • ensure that misidentification of bodies is detailed as a risk in relevant risk assessments.
3.	GQ6(c)	The DI is advised to keep the risks relating to the mortuary already on the Trust register until they are resolved and consider adding the risks relating to the mortuary premises, facilities and equipment outlined in this report.
4.	T1(b)	The mortuary manager is advised to include paediatric/perinatal cases on the mortuary electronic database.
5.	T1(g)	To help address the shortfall, the DI is advised to formally contact the DI and/or other senior managers at the establishment that does not provide confirmation they have received PM tissue for analysis.
6.	T2(b)	The DI is advised to liaise with the coroner's office to amend their tissue form to offer the options for use of tissue separately, when the coroner's authority has ended.

		In addition, the DI is advised to contact the coroner regarding the few older cases for which instructions for tissue have not been received and the coroner's authority has ended. A timeframe of disposal may be given as there is no consent in place to retain the tissue. Please refer to Code of Practice B (Annex B) for further information.
7.	PFE1(c)	The mortuary manager is advised to consider using appropriate cleaning agents to help address the limescale issues and alternative disinfectants to assist with maintaining the condition of the equipment.
8.	PFE1(a) PFE3(a)	Due to the age of the mortuary premises, facilities and equipment and the risks already identified on the Trust's risk register, the DI is advised to consider and plan for investment to help ensure the mortuary remains fit for purpose and can continue to provide an effective mortuary service.

Background

Medway Maritime Hospital has been licensed by the HTA since July 2008. This was the seventh 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 or the activities carried out under the licence.

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 team reviewed policies and procedural documents relating to licensed activities for the mortuary. This included SOPs, risk assessments, audits, incidents, meeting minutes, training records and competency assessment documents. Consent

seeking procedures and information for families giving consent for perinatal PM examinations and servicing and maintenance records for mortuary equipment were also reviewed.

Visual inspection
The inspection team undertook a visual inspection of the premises which included the mortuary body storage areas (including the permanent on-site body store and the location of where a temporary external body store would be located), viewing room and PM room.

Audit of records
The inspection team undertook audits of traceability for five bodies in storage. This included a body in long term storage and one perinatal case. Traceability details were crosschecked between the identification bands on the bodies, information in the mortuary electronic record and mortuary register. No discrepancies were identified.

A review of the establishments tissue database was carried out and audits of three cases conducted. Information was crosschecked between the database, mortuary documentation, Coroner's paperwork and family wishes forms. No discrepancies were identified. The establishment do not have a histopathology laboratory onsite.

Meetings with establishment staff
The assessment team met with staff carrying out processes under the licence, including mortuary and bereavement staff, portering staff, a pathologist, staff involved in the consent seeking process for perinatal PM examination, staff responsible for the removal of relevant material in the Emergency Department and the DI.

Report sent to DI for factual accuracy: 08 November 2024

Report returned from DI: 22 November 2024

Final report issued: 29 November 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.