Inspection report on compliance with HTA licensing standards
Inspection date: **14 October and 16 November 2022**

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*
Accident and emergency department	-	*Carried out*	-
Maternity department	-	*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 minor shortfall was found against the standard for Premises, facilities and equipment. This related to the shrouding of bodies.

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 shortfall identified during the inspection.

Compliance with HTA standards

Minor shortfalls

Standard	**Inspection findings**	**Level of shortfall**
PFE2 There are appropriate facilities for the storage of bodies and human tissue		
g) Bodies are shrouded or in body bags whilst in storage.	During the visual inspection some bodies were not fully shrouded. The sheets loosely covered the bodies and, in some cases areas of the deceased were exposed. This poses a risk to 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 shortfall 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.	C1(c)	The establishment do not carry out perinatal or pediatric PMs, however they do take consent on behalf of the establishment conducting the PM using the '*Post Mortem Examination Consent Form (baby/child) (version 2.1)'.* The consent form was due for review in February 2021. The DI is advised to flag this to relevant teams in order to obtain an in-date version.
2.	GQ6(a)	The establishment has a comprehensive suite of risk assessments however the DI is advised to review the risk assessments to ensure that all risks relating to the procedures have been covered including HTA reportable incident categories. The risk assessment ("RA") for carrying out PMs does not include accidental damage to a body at PM, and the security breach RA does not include breaches by someone with legitimate a right of access. Although these risks have not been documented the establishment do have mitigations in place to reduce the risk.
3.	T1(b)	Whiteboards are in use within the establishment's body store however there are ink smears making the writing unclear. The DI is advised to renew the boards or use a more effective cleaning procedure.
4.	PFE1(d)	The establishment has had some issues restricting access to the mortuary which has now been rectified. In order to ensure that the access control mechanisms now in place are fully embedded and adhere to HTA standards, the DI is advised to increase security audits and swipe card access reviews.
5.	PFE3(c)	The annual validation of the PM room ventilation system has been delayed due to a maintenance repair. The DI is advised to follow-up the rescheduling to ensure that it takes place as soon as possible.

Background

Medway Maritime Hospital has been licensed by the HTA since July 2008. This was the fourth inspection of the establishment; the most recent inspection took place in October 2017.

Since the previous inspection, there have been some significant changes to the licence arrangements including the change of Designated Individual (DI) in June 2022 and a change in Corporate Licence Holder contact in October 2022.

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 the establishment's self-assessment document provided by the DI. Policies and procedural documents relating to licensed activities were reviewed. This included standard operating procedures, risk assessments, audits, incidents, meeting minutes, equipment servicing reports, and training and competency assessment documents. Consent seeking procedures and information for families giving consent for perinatal PMs was also reviewed.

The establishment does not conduct hospital PMs.

Visual inspection

The inspection team undertook an unannounced site visit inspection of the premises including the mortuary body storage area, the PM suite, and the contingency storage facility.

Audit of records

The inspection team undertook audits of traceability for four bodies in storage this included community and hospital cases in the fridge. Traceability details were crosschecked between the identification band on the body and information on the electronic records. No discrepancies were identified.

There is no PM tissue stored on site.

Meetings with establishment staff

The assessment team met with staff carrying out activities under the licence, including an Anatomical Pathology Technologist (APT), Mortuary Manager, a Porter, a Bereavement Midwife involved in the perinatal PM consent seeking process and the Chief Medical Officer who is the DI.

Report sent to DI for factual accuracy: 14 December 2022

Report returned from DI: 21 December 2022

Final report issued: 22 December 2022

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.