Inspection report on compliance with HTA licensing standards
Inspection date: **28-30 June 2022**

Milton Keynes University Hospital

HTA licensing number 12201

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 **Milton Keynes University 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 Milton Keynes University Hospital ('the establishment') had met the majority of the HTA's standards, three minor shortfalls were found against standards for consent, governance and quality systems. These were regarding consent training, support staff competency assessments and condition checking of the deceased.

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

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual	While midwives undergo documented training in the HTA requirements for consent, pediatric post mortem consent is occasionally taken by consultants with no documented training in the HTA specific consent requirements.	**Minor**
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	The condition of bodies is checked on admission and after 30 days. However, condition checks between this time are ad hoc, and there is no formal documented procedure to ensure these additional checks take place.	**Minor**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
c) Staff are assessed as competent for the tasks they perform	Whilst mortuary porters are signed as competent upon induction to the role, the establishment could not provide evidence that these competencies are reassessed following this initial training.	**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

The HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Advice

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

Number	Standard	Advice
1.	T1(c)	The DI is advised to consider implementing a formal process for documenting the check of three points of ID of the deceased when visitors attend a viewing. This will further strengthen the traceability of identification checks during viewings.
2.	GQ1(A)	The DI is advised to review the mortuary SOPs to document contingency planning for bariatric spaces.
3.	GQ4(b)	Whilst not used for patient information, the DI is advised to remove the use of pencil and erasers from

		the mortuary register.
4.	PFE2(a)	The DI is advised to review the alarm set points and time delays for the refrigerated storage to provide an assurance that there is no risk of bodies beginning to freeze.
5.	PFE2(e)	The mortuary team are advised to record the occasions when they are called out of hours for fridge alarms as a documented assurance that the procedure works.
6.	PFE3(a)	The DI is advised to organise monitoring of very minor chips to the post mortem room floor and very minor pitted rust on one post mortem table, to prevent further deterioration.

Background

Milton Keynes University 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.

Milton Keynes University Hospital has been licensed by the HTA since 23 May 2007. This was the third inspection of the establishment; the most recent previous inspection took place in July 2017.

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 included a review of the establishment's governance documentation relating to licensed activities. This included policies and procedural documents relating to licensed activities, cleaning records for the mortuary, records of servicing of equipment, ventilation reports, audits, risk assessments, meeting minutes, reported incidents and training records for mortuary staff, maternity staff, consultant clinicians, pathologists and porters.

Visual inspection

The inspection included a visual assessment of the mortuary body store, PM room, viewing room, tissue storage areas and a maternity ward. The inspection team reviewed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records

Audits were conducted for three bodies in refrigerated storage and one body in frozen storage. Identification details on bodies were crosschecked against the information recorded in the mortuary register and associated paperwork. No discrepancies were identified.

Audits of traceability were conducted for tissue blocks and slides from two coroners and two hospital consented cases. These included audits of the consent documentation for the retention of these tissues. No discrepancies were identified.

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI, the mortuary manager, an Anatomical Pathology Technician, a pathologist, a mortuary porter, and a bereavement midwife.

Report sent to DI for factual accuracy: 15 July 2022

Report returned from DI: 28 July 2022

Final report issued: 01 August 2022

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: 11 November 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.