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

Hemel Hempstead General Hospital

HTA licensing number 12082

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 **Hemal Hempstead General Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Satellite site **Watford General Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Maternity ward	-	*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.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Background

Hemel Hempstead General Hospital has been licensed by the HTA since May 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in March 2023. Since the previous inspection, there has been a change to the Corporate Licence holder contact in July 2023, and ongoing refurbishment of mortuary facilities at both Hemel Hempstead and Watford Hospitals.

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

This inspection was a follow up visit to assess the current storage arrangements and corrective and preventative actions implemented since the last inspection. As such 10 out of the 72 standards were assessed during this visit. These are listed in appendix 3.

Review of governance documentation
The inspection included a review of the establishment's governance documentation relating to the storage of bodies at Watford Hospital. This included the paper register, electronic traceability systems, and condition checking documentation.

Visual inspection
The inspection included a visual assessment of all mortuary body storage areas at Watford hospital. No visual inspection took place at Hemel Hempstead Hospital because the inspection team were informed that no regulated activity is currently taking place due to refurbishment of the premises.

Audit of records – Watford Hospital
Audits were conducted for seven bodies from refrigerated storage and one from freezer storage. Identification details on bodies were crosschecked against the information recorded in the mortuary electronic register and associated paperwork. No discrepancies were identified.

Meetings with establishment staff
The inspection team met with the Designated Individual, Chief Nurse, Deputy Divisional Manager and Mortuary Manager whilst on site.

Feedback was provided on 26 November 2024 to the Chief Executive Officer (CLHc), Designated Individual, Chief Nurse, Deputy Divisional Manager, Mortuary Manager, divisional Manager, and Divisional Director.

Report sent to DI for factual accuracy: 10 December 2024

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 31 December 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.

Appendix 3: HTA post mortem standards assessed at this visit

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
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff
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
b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents
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

PFE2 There are appropriate facilities for the storage of bodies and human tissue.
a) Storage arrangements ensure the dignity of the deceased
b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity
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
f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept