



**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
<b>Hub site</b> <b>Hemel Hempstead General Hospital</b>	Licensed	Licensed	Licensed
<b>Mortuary</b>	<i>Carried out</i>	<i>Carried out</i>	<i>Carried out</i>
<b>Pathology lab</b>	-	-	<i>Carried out</i>
<b>Satellite site</b> <b>Watford General Hospital</b>	Licensed	Licensed	Licensed
<b>Mortuary</b>	<i>Carried out</i>	<i>Carried out</i>	<i>Carried out</i>

<b>Maternity ward</b>	-	<i>Carried out</i>	-
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### Summary of inspection findings

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

Although the HTA found that Hemel Hempstead General Hospital ('the establishment') had met the majority of the HTA's standards one critical, 13 major and three minor shortfalls were found against standards for consent, 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

#### *Critical shortfalls*

<b>Standard</b>	<b>Inspection findings</b>	<b>Level of shortfall</b>
<b>PFE2 There are appropriate facilities for the storage of bodies and human tissue.</b>		
a) Storage arrangements ensure the dignity of the deceased	The inspection team identified bodies that had deteriorated due to lack of long-term storage. The establishment was advised to complete an internal investigation and report these incidents to the HTA in line with the HTA reportable incident requirements.	<b>Critical (Cumulative)</b>

<p>b) There is sufficient capacity for storage of bodies, organs, and tissue samples, which takes into account predicated peaks of activity</p>	<p>Both Hemel Hempstead and Watford General Hospital sites have insufficient internal capacity for storage of bodies. Each site has a temporary unit erected within the mortuary which is being used on a permanent basis. Both hospitals utilise the floor space of the fridges for the storage of bodies. At the time of the inspection all these floor spaces were in use at Watford hospital.</p> <p>In addition, Hemel Hempstead has one, and Watford three, semi-permanent surge units located externally to the mortuary, which are also in constant use. The inspection team were informed that the number of bodies had recently reached double that of the internal mortuary capacity.</p>	<p><b>Critical (Cumulative)</b></p>
<p>c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs</p>	<p>Storage for long term and bariatric bodies is insufficient to meet needs. There are currently no bariatric freezer spaces or formal contingency arrangements in place if a bariatric body requires transferring to the freezer.</p> <p>Freezer units at both sites are at full capacity, and the freezer floors are utilised as an additional space.</p>	<p><b>Critical (Cumulative)</b></p>

<p>d) Fridge and freezer units are in good working condition and well maintained</p>	<p>Whilst internal fridge and freezers appear clean, they are showing signs of age. A recent internal servicing report has highlighted that replacement parts for the units are now difficult to source.</p> <p>The freezer at Hemel Hempstead has perished door seals and a build up of ice, the inspection team were informed that the temperature settings have been adjusted as the defrost cycle triggers the alarm unnecessarily. This poses a risk of mechanical breakdown of the units.</p> <p>In addition, poor seals on the refrigerator doors result in one door opening when another is closed. This poses the risk of a door being left open unintentionally.</p> <p>Two surge units, and one temporary unit fail to maintain temperature in the warmer weather. The inspection team was informed of mechanical breakdowns during the summer months, and an inability to use several of the surge units in warm weather.</p> <p>The 25 space surge unit at Watford hospital is currently at minus temperatures, and therefore not suitable for the refrigeration of bodies. This has been reported internally by mortuary staff and has been deemed unrepairable by maintenance staff. The mortuary manager was advised to report this to the HTA in line with the HTA reportable incident requirements, and advised to turn it off and lock the doors to mitigate the risk of it being used in error.</p>	<p><b>Critical (Cumulative)</b></p>
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**Major shortfalls**

Standard	Inspection findings	Level of shortfall
<p><b>GQ1 All aspects of the establishment's work are governed by documented policies and procedures</b></p>		
<p>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.</p>	<p>Standard Operating Procedures (SOPs) do not always include sufficient detail of procedures or reflect current practice. These include but are not limited to:</p> <ul style="list-style-type: none"> <li>• Procedure for recording viewings;</li> <li>• Procedure for transferring bodies to the freezer and mitigations of risk if space is unavailable; and</li> <li>• Procedure for following up tissue requests with the coroner's office. <i>(See shortfall T2b)</i></li> <li>• Procedure for completing external examination of bodies, by trainee pathologists.</li> </ul> <p>To fully address this shortfall the establishment should review all SOPs to ensure they contain sufficient detail, are reflective of current practice, and cover all mortuary and laboratory procedures relevant to licensable activities.</p>	<p><b>Major</b></p>

<p>c) Procedures on body storage prevent practices that disregard the dignity of the deceased</p>	<p>The condition of bodies is checked on admission and when approaching 30 days. However, additional condition checks occur in an ad hoc manner and there is no formal documented procedure to ensure these checks take place.</p> <p>Due to staffing and capacity limitations procedures to mitigate deterioration of bodies are reactive rather than preventative.</p> <p><i>See shortfall PFE2b</i></p>	<p><b>Major</b></p>
<p>g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework</p>	<p>There are no persons designate (PD) for the maternity wards. This poses a risk to the DI not having sufficient oversight of regulated activities in these areas.</p> <p>In addition, the corporate licence holder contact (CLHc) currently named on the licence has left the establishment and no new CLHc has been appointed. As a result, the areas where activities are carried out under the HTA licence are not incorporated within the establishment's governance framework, and the DI has no support available to escalate issues to the executive level.</p>	<p><b>Major</b></p>
<p>h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff</p>	<p>Matters relating to HTA-licensed activities are not discussed at regular governance meetings involving the Designated Individual (DI) and establishment staff.</p>	<p><b>Major</b></p>
<p><b>GQ5 There are systems to ensure that all untoward incidents are investigated promptly</b></p>		

<p>a) Staff know how to identify and report incidents, including those that must be reported to the HTA</p>	<p>Reporting of incidents, including those reportable to the HTA, forms part of the mortuary training schedule. However, the inspection team identified two recent reportable incidents that were not reported. These incidents related to the HTA reportable categories of accidental damage to a body and major equipment failure.</p> <p>In addition, porter staff were unable to identify examples of incidents reportable to the HTA.</p>	<p><b>Major (Cumulative)</b></p>
<p>b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents</p>	<p>The DI and mortuary manager do not have access to completed reports on the incident reporting system. The inspection team did not receive a requested list of mortuary related incidents and are therefore not assured that this standard is met.</p>	<p><b>Major (Cumulative)</b></p>
<p><b>GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored</b></p>		
<p>a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis</p>	<p>The transfer of bodies to external surge units has not been fully risk assessed. This process includes the transfer of bodies through carpeted areas of the hospital, past wards and main reception, through car park traffic, over kerbstones, and broken pavements.</p> <p>This poses a risk to infection control, dignity of the deceased due to oversight of body transfers, and accidental damage to bodies.</p>	<p><b>Major</b></p>
<p>c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register</p>	<p>Significant risks to the mortuary service, such as lack of capacity, shortage of staff, and failing refrigeration equipment, have not been incorporated into the Trust's organisational risk register.</p> <p>The inspection team identified that these risks had been raised internally by the DI and mortuary manager but had not been escalated further as there was no formal route of escalation.</p>	<p><b>Major</b></p>

<b>T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail</b>		
<p>g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).</p>	<p>Tissue taken at post mortem examination is not fully traceable.</p> <p>A recent audit completed by the establishment identified 19 coronial cases where glass slides containing post mortem tissue were missing.</p> <p>In addition, a second audit completed by the inspection team identified a further case where post mortem tissue was missing, and two cases where the disposal information was incomplete.</p> <p>The inspection team advised that an internal investigation takes place and that this incident is reported, in line with the HTA reportable incident requirements.</p>	<p><b>Major</b></p>
<b>T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.</b>		
<p>a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete</p>	<p>In line with documented procedures, tissue is disposed of 12 months following the post mortem examination, rather than when the coroner's authority has ended.</p> <p>This poses a risk that tissue is being disposed of before the coroner's investigation has finished or is being retained longer than required.</p> <p><i>See shortfall T2b</i></p>	<p><b>Major</b></p>



<p>b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary</p>	<p>Family wishes for retained tissue is not routinely received from the coroner's office, and there is no formal procedure in place to follow these up.</p> <p>A recent audit identified that families' wishes were not received for 25 out of 29 cases selected from 2021, and the establishment defaulted to disposing of the tissue. In addition, blocks and slides from two of ten cases reviewed at this inspection had been disposed of without receiving confirmation of the families' wishes.</p> <p>This poses a risk that families' wishes, such as for it to be reunited with the body or stored for research are not being adhered to prior to the funeral.</p>	<p><b>Major</b></p>
<p><b>PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.</b></p>		

<p>a) The premises are clean and well maintained</p>	<p>Although the mortuary premises are subject to regular cleaning, the age and subsequent deterioration of some areas means there is a risk that they cannot be maintained, cleaned, and decontaminated effectively. Examples include:</p> <p><b>Hemel Hempstead &amp; Watford General Hospital fridge rooms</b></p> <ul style="list-style-type: none"> <li>• Significant damage to walls with exposed plaster;</li> <li>• Significant damage to ceiling tiles;</li> <li>• The use of porous wooden storage equipment and splintered wooden door frames;</li> <li>• Chips and cracking to floors with exposed porous concrete; and</li> <li>• Damaged floor edges in transition areas.</li> </ul> <p><b>Hemel Hempstead General Hospital post mortem Room</b></p> <ul style="list-style-type: none"> <li>• The post mortem room floor has perished floor seals and water is trapped underneath the flooring. This was identified as a shortfall at the last inspection, and whilst addressed at the time, this has since deteriorated;</li> <li>• Damaged drain covers have been removed, leaving exposed drains. This poses a risk of trip hazards to staff and accidental damage to the deceased when the trolley is in use; and</li> <li>• There are broken taps on post mortem tables with poor drainage.</li> </ul>	<p><b>Major</b></p>
<p><b>PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored</b></p>		

<p>a) Items of equipment in the mortuary are in good condition and appropriate for use</p>	<p>The establishment is currently using four semi-permanent surge fridge units externally to the main mortuaries. The inspection team noted that whilst cleaning schedules were signed, these areas contained buildup of outside debris, with stained flooring and equipment.</p> <p>Concerns were raised to the inspection team that the racking structure and embossed metal flooring made these areas difficult to clean.</p> <p>The area also included porous materials and areas of deterioration, which means there is a further risk that the areas cannot be maintained, cleaned, and decontaminated effectively. Examples include:</p> <p><b>Hemel Hempstead General Hospital</b></p> <ul style="list-style-type: none"> <li>• Buildup of condensation and black mold.</li> </ul> <p><b>Watford General Hospital</b></p> <ul style="list-style-type: none"> <li>• Nine trays are made of wood with porous areas and mold;</li> <li>• Extensive rusting and exposed metal on trolleys.</li> </ul>	<p><b>Major</b></p>
<p>f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept</p>	<p>The DI and mortuary manager do not have oversight of the maintenance records for the four external fridge units.</p> <p>At the time of the inspection maintenance records were unavailable, the inspection team are therefore not assured that regular maintenance records are kept.</p>	<p><b>Major</b></p>

### Minor Shortfalls

Standard	Inspection findings	Level of shortfall
<b>C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice</b>		
f) The deceased's family are given an opportunity to change their minds and it is made clear who should be contacted in this event and the timeframe in which they are able to change their minds	Whilst families are given time to change their minds, this varies across documentation. Some consent guidelines state 24 hours whilst others state 48. This poses a risk to a post mortem being completed before the cooling off period is over.	<b>Minor</b>
<b>GQ1 All aspects of the establishment's work are governed by documented policies and procedures</b>		
d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use	The mortuary manager writes, reviews, and authorises the mortuary policies and procedural documents.	<b>Minor</b>
<b>T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail</b>		
b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records)	The establishment are currently using six additional storage units, in addition to the main mortuary fridges. Whilst each body is assigned a fridge number on admission, there is no formal procedure to record when a body is moved between fridges and / or freezers.  This poses a risk to the loss of traceability of body storage location.	<b>Minor</b>

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.	PFE1d	The DI is advised to review the CCTV coverage to ensure it covers the fire escape at the Hemel Hempstead funeral entrance.
2.	PFE1d	The DI is advised to review the arrangements for retaining CCTV data to provide an assurance it is retained for a suitable period of time and backed-up appropriately.
3.	PFE2f	The mortuary manager is advised to document the routine temperature trend analysis of the fridge temperatures, in order to have documented evidence of fridge efficiency.
4.	PFE3c	The DI is advised to review the ventilation in the Hemel Hempstead post mortem room, to ensure it is still compliant to ten air changes per hour, following recent modifications to the ceiling cavity.
5.	PFE3d	The DI is advised to review the PPE available and infection control policy as staff are currently performing regulated activities, such as transfer of bodies, in casual clothing.
6.	PFE3e	The mortuary manager is advised to amend documented procedures to reflect the current requirement, described during the inspection, that formalin must always be decanted on the ventilated bench.

### Background

Hemel Hempstead 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 November 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 22 September 2022)

#### *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, cleaning records for the mortuary, records of servicing of equipment, ventilation reports, audits, risk assessments, meeting minutes, reported incidents and training records for staff.

#### *Visual inspection*

The inspection included a visual assessment of all mortuary body and tissue storage areas, the post mortem rooms and viewing facilities at both Hemel Hempstead and Watford General Hospital sites. The inspection team observed the processes for admission, release and viewing of bodies within the mortuaries.

#### *Audit of records – Hemel Hempstead General Hospital*

Audits were conducted for four 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.

Audits of traceability were conducted for tissue blocks and slides from ten coroners consented cases. These included audits of the consent documentation for the retention of these tissues. Two discrepancies were identified, both had wishes to retain the tissue, however the tissue could not be found in the histology store. In addition, two further cases had their tissue disposed of without confirmation of the families' wishes having been received from the coroner's office. *See shortfalls T1g and T2b.*

*Audit of records – Watford General Hospital*

Audits were conducted for four 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. However, one body was in a state of deterioration. *See shortfall PFE2a.*

*Meetings with establishment staff*

Staff carrying out processes under the licence were interviewed including the DI, mortuary manager, APTs, pathologist, mortuary porters, bereavement officer and bereavement midwife. Feedback was provided to staff involved in the inspection and the Trust Chief Executive Officer, Pathology Services Manager, Chief Pharmacist and Clinical Services Manager, Cellular Pathology Manager, and the Divisional Manager for Clinical Support Services.

**Report sent to DI for factual accuracy: 20 April 2023**

**Report returned from DI: 04 May 2023**

**Final report issued: 25 May 2023**

**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: 6 November 2023**

## **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.