Inspection report on compliance with HTA licensing standards
Inspection date: **25 November 2025**

The Grange University Hospital
HTA licensing number 12036
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 The Grange University Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Satellite site Nevill Hall Hospital	Not licensed	Licensed	Licensed
Mortuary	-	*Carried out*	*Carried out*
Satellite site Royal Gwent Hospital	*Licensed*	*Licensed*	*Licensed*
Mortuary	-	*Carried out*	*Carried out*
Pathology	-	-	*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 targeted unannounced site visit of Grange University Hospital found five major and one minor shortfall out of the nine HTA postmortem standards assessed. These were identified in the standards relating to 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.

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	There are significant areas of damage to the structure of the building These include but are not limited to: • A wooden measuring stick was in use at Grange University Hospital • There is significant damage to internal doors which has resulted in areas of exposed wood at the satellite sites at Nevill Hall and Royal Gwent Hospitals, and wooden door stops are in use at Royal Gwent Hospital. • The floor drains in the one of the body stores at Royal Gwent Hospital had collected significant amounts of debris following building work. • The flooring in the body stores at Royal Gwent Hospital were uneven and there were areas of wear which has led to the exposure of the concrete subfloor. Additionally, the floor in the corridors leading to the body store and changing rooms at Nevill Hall Hospital had sustained damage exposing the concrete subfloor. This increases the risk of porosity which may prevent effective decontamination. • There was damage to the ceiling in the body store at Nevill Hall Hospital where there had been a water leak. • A radiator in the body store at Nevill Hall Hospital had areas of corrosion and had started to rust. *The establishment submitted sufficient evidence to partially address this shortfall before the report was finalised.*	**Major**

d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access)	Across all three sites, not all external entrance and egress points are monitored by CCTV. During the inspection it was confirmed two windows identified in a storage area at Nevill Hall Hospital had been permanently left open for some time. Due to their location, the windows would be difficult to use to gain access to the mortuary. However, they opened onto an outside space which was accessible by staff and members of the public. *The establishment submitted sufficient evidence to partially address this shortfall before the report was finalised.*	**Major**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The inspection team are not assured security arrangements at Royal Gwent Hospital protect against unauthorised access to the mortuary. During the inspection several doors were not sufficiently secured, meaning access to the body store could be gained by members of the public and unauthorised hospital staff. Additionally, the body store could be accessed by families attending a viewing as there was no ability to effectively secure the door from the body store. Furthermore, across the three sites, there is no external monitoring of the CCTV feed out of hours	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	Whilst regular body condition checks were carried out. The inspection team is not assured storage arrangements ensure the dignity of the deceased. There were no documents available to review for one body which had been in refrigerated storage for longer than the HTA's recommended 30 days indicating release into the care of Funeral Directors was imminent. This represents a deviation from the establishment's procedural document.	**Major**

d) Fridge and Freezer units are in good working condition and well maintained	The inspection team are not assured the fridge and freezer units are in good working condition, during the inspection of Nevill Hall hospital, one fridge bank could not be used as it was awaiting repair. Additionally, there were areas of corrosion at the base of some of the fridges and a compressor unit. Furthermore, a buffer strip was coming loose from its housing, potentially compromising the intended function. The sealant at the base of one of the fridge banks at Royal Gwent hospital had areas of damage, which could lead to a risk of water ingress during cleaning. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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	A trolley used in the body store at Royal Gwent Hospital had significant areas of corrosion around the housing for the casters. This poses the risk of ineffective cleaning and decontamination.	**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.	T1(b)	The DI is advised to continue with existing plans to install an electronic mortuary management system to mitigate the risk of a transcription error and provide oversight of traceability.
2.	PFE1(a)	The DI is advised to progress the plans in place for the refurbishment of the mortuary at Nevill Hall Hospital.
3.	PFE3(a)	The DI is advised to monitor the minimal rusting to the hydraulic trolleys within the body stores at all three sites to ensure it does not deteriorate further and impede the usual operational function
4.	N/A	The DI is advised to review and consider the revocation of the Licence for the making of a post mortem examination at Royal Gwent Hospital as there are no facilities available to undertake a post mortem examination.

Background
Grange University Hospital has been licensed by the HTA since October 2007. This was the sixth inspection of the establishment; the most recent previous inspection took place in November 2022

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under the licence. This was an unannounced targeted inspection relating to concerns received about cleanliness and suitability of premises

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
Nine out of the HTA's 72 standards were covered. Standards covered at this inspection are listed in Appendix 3. The inspection focussed on areas of concern; the remaining 63 standards will be assessed during the next routine inspection.

Review of governance documentation
The review of documents was limited to those relating to cleaning and decontamination procedures, and body condition checks. A full review of governance documents will be undertaken at the next routine inspection.

Visual inspection
The inspection included a visual assessment of the establishment including body storage areas and viewing rooms. The post mortem (PM) suite was not assessed as part of this inspection. A full review of the PM suite will be undertaken at the next routine inspection.

Audit of records
Audits were conducted onsite 10 bodies from refrigerated storage and two bodies from frozen storage across the hub and satellite sites, including adults and perinatal bodies. Identification details on bodies were crosschecked against the information recorded in the register and associated paperwork, in addition to information held on the mortuary whiteboard and in the electronic patient record system. No discrepancies were identified.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence at the hub and satellite sites. This included the Pathology Directorate Manager, Directorate Support Manager, Senior APT, APT, trainee APT, and Care After Death technicians.

Report sent to DI for factual accuracy: 05 December 2025

Report returned from DI: 19 December 2025

Final report issued: 02 January 2026

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

Post Mortem

Governance and quality systems
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. These include: i. post-mortem examination, including the responsibilities of Anatomical Pathology Technologists (APTs) and Pathologists and the management of cases where there is increased risk; ii. practices relating to the storage of bodies, including long term storage and when bodies should be moved into frozen storage; iii. practices relating to evisceration and reconstruction of bodies; iv. systems of traceability of bodies and tissue samples; v. record keeping; vi. receipt and release of bodies, which reflect out of hours arrangements; vii. lone working in the mortuary; viii. viewing of bodies, including those in long-term storage, by family members and others such as the police; ix. transfer of bodies internally, for example, for MRI scanning; x. transfer of bodies and tissue (including blocks and slides) off site or to other establishments; xi. movement of multiple bodies from the mortuary to other premises, for example, in the event that capacity is reached; xii. disposal of tissue (including blocks and slides), which ensures disposal in line with the wishes of the deceased person's family; xiii. access to the mortuary by non-mortuary staff, contractors and visitors; xiv. contingency storage arrangements.

Premises, facilities and equipment
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.
b) There are documented cleaning and decontamination procedures and a schedule of cleaning.
d)The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV

to monitor access).
e)Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access.
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.
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs.
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored
a) Items of equipment in the mortuary are in a good condition and appropriate for use: i. fridges / freezers ii. hydraulic trolleys iii. post mortem tables iv. hoists v. saws (manual and/or oscillating) *Guidance:* *Equipment should be made of material that is easy to clean, impervious, non-rusting, non-decaying and non-staining.*