Inspection report on compliance with HTA licensing standards
Inspection date: **3 and 4 September 2025**

Royal Glamorgan Hospital
HTA licensing number 12338

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 **Royal Glamorgan Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Satellite site **Prince Charles Hospital**	Licensed	Licensed	Licensed
Mortuary (satellite site)	*Carried out*	*Carried out*	*Carried out*

Satellite site **Princess of Wales Hospital**	Licensed	Licensed	Licensed
Mortuary (satellite site)	*Carried out*	*Carried out*	*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.

Royal Glamorgan Hospital ('the establishment') was found to have met all HTA standards.

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.

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

Number	Standard	Advice
1.	GQ2(c)	The DI is advised to continue his review of arrangements for the ongoing storage of blocks and slides.
2.	GQ4(a)	The DI may wish to investigate the introduction of an electronic register system. This will reduce the use multiple paper documents across three sites, reduce the risk of transcription errors and aid traceability.
3.	PFE1(a)	The DI is advised to monitor the condition of bench legs, and the autopsy saw at the hub site. These items are showing early signs of deterioration but were compliant with HTA standards at the time of

		inspection.
4.	PFE1(d)	The DI should undertake a review of power supplies to the outside storage units and consider actions to enhance the security of plant equipment at Royal Glamorgan Hospital.
5.	PFE3(c)	The DI is advised to monitor the condition of the ventilation unit at the hub site. A recent engineers report has noted at the time of inspection it is functional but at end of its serviceable life.
6.	PFE2(e)	The DI is advised to arrange for testing of temperature alarms out of hours to ensure the documented escalation process is embedded.
7.	General	The DI may wish to review the current arrangements for primary mortuary service provision at the Royal Glamorgan. Whilst the Mortuary is in serviceable condition, the facilities are limited and will require future investment to maintain compliance with HTA standards.
8.	General	The Mortuary at Princess of Wales site has discontinued post mortem service provision. The DI may wish to review licencing arrangement for this site.

Background

Royal Glamorgan Hospital and it's two satellite sites, Prince Charles Hospital and Princess of Wales Hospital, are 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.

Royal Glamorgan Hospital has been licensed by the HTA since November 2007. This was the seventh inspection of the establishment; the most recent previous inspection took place in February 2023.

Since the previous inspection, post mortem services have ceased at the Princess of Wales Hospital.

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 documentation on site and submitted after the inspection. Standard operating procedures, risk assessments and policies were reviewed. Audit schedules, competency records, cleaning record forms and meeting minutes were inspected as part of the review process.

Visual inspection
The inspection included a visual assessment of the body storage areas in the mortuary, PM room, viewing room, and tissue storage areas at the hub site. The inspection team observed the processes for release of bodies within the mortuary. Visual assessments of the body storage areas in the mortuary and viewing room were made at both satellite sites.

Audit of records
A traceability audit of four bodies in storage was undertaken at the hub site. The audit included bodies from both the community and hospital with same and similar names and one in long-term storage. Details were cross-checked against identity bands and the mortuary register. No discrepancies were found.

A traceability audit of three bodies in storage was undertaken at the Prince Charles Hospital satellite site. This included bodies from the hospital including those with same and similar names and one in long-term storage. Details were cross-checked against identity bands and the mortuary register. No discrepancies were found.

A traceability audit of four bodies in storage was undertaken at the Princess of Wales Hospital satellite site. This included bodies from the hospital including those with same and similar names. Details were cross-checked against identity bands and the mortuary register. No discrepancies were found.

Audits were conducted of tissue taken at post mortem examination for ten cases. Information was cross-checked between the mortuary electronic database, Coroner's paperwork, family wishes forms, the laboratory database, and tissue blocks and slides being stored. No discrepancies were found.

Meetings with establishment staff
The inspection team conducted interviews with staff carrying out processes under the licence. This included the Designated Individual, Trainee APT, Quality Manager, Bereavement Midwife and Porter.

Report sent to DI for factual accuracy: 16 September 2025

Report returned from DI: 16 September 2025

Final report issued: 16 September 2025

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.