Inspection report on compliance with HTA licensing standards
Inspection date: **09 & 10 November 2023**

Morriston Hospital
HTA licensing number 30015

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 **Morriston Hospital**	Licensed	Licensed	Licensed
Mortuary	*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.

Although the HTA found that Morriston Hospital ('the establishment') had met the majority of the HTA's standards, one major and six minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities and equipment. These related to capacity for long term storage of the deceased, mortuary maintenance, standard operating procedures and risk assessments, staff competency assessment and the reporting of near-miss incidents to the HTA.

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

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	Whilst the premises were clean at the time of the inspection, the post mortem (PM) room floor was showing signs of heavy wear and tear and in some areas, this appeared down to the concrete layer. This presents a risk of ineffective cleaning and decontamination of the floor.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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.	Whilst Standard Operating Procedures (SOPs) detailed that staff must use three points of identification of the deceased during identification procedures, some SOPs were not fully clear that it is the three identifiers on the body that must be used to match against documentation in the relevant procedure. To fully address this shortfall the establishment should review all SOPs relating to traceability of bodies to ensure they contain sufficient details of identification checks performed.	**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 staff have been trained and have completed previous rolling programmes of competency assessment, some staff were not up to date with the current cycle of competency assessment in key tasks.	**Minor**
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	Whilst staff know how to identify and report incidents, some incidents falling within the HTA reportable incident (HTARI) categories had not been reported to the HTA as the establishment had determined them to be a near miss.	**Minor**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed	Whilst risk assessments are embedded into individual SOPs and there are mitigations in place to reduce identified risks to a minimum, the risk assessments did not always contain sufficient information of the control measures in place.	**Minor**

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
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)	The PM room has an external emergency exit door to the rear of the room. This door is on a key lock. At the time of the inspection there was no assurance as to how many keys were in operation for this door. The establishment, however, have mitigated the risk of access to the deceased as the body storage doors are locked internally within the PM room following completion of PM examinations with keys being stored in the safe in the mortuary office. Furthermore, there is CCTV monitoring access to this door and regular audits of CCTV are undertaken.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	Whilst the establishment had mitigations in place to manage freezer capacity at the time of the inspection, freezer capacity was on the risk register as it had been identified current capacity is likely to be insufficient to meet increasing demands long term.	**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.	C1	The DI is advised to liaise with the Coroner service regarding the form in use for the recording of families wishes as to the fate of material retained at PM examination. Currently there are less than three identifiers of the deceased on the form which may present a risk of mismanagement of tissue where bodies have a same or similar name. Furthermore, the option to retain tissue for research is given, however, the establishment do not currently undertake any research. The form should reflect the establishment's practice that where suitable use for research cannot be identified, the tissue will be sensitively disposed of.
2.	GQ3(a)	The DI is advised to review the resilience arrangements in place to provide porter training as this was being provided by one individual alone.
3.	T1(c)	The DI is advised to review and update the viewing form in place to include written confirmation of the three-point identification check that is completed at the point of arrival of visitors.
4.	PFE1(d)	Whilst the external fridge condenser units are secured in a locked and gated area, the DI is advised to consider fully enclosing this area to reduce the risk of tampering with the units to a minimum.
5.	PFE2(b)	The establishment has undergone internal changes with some hospital wards moving from unlicensed hospital sites to Morriston Hospital. The DI is advised to monitor body storage capacity at this site to ensure there is no adverse impact on the mortuary from the changes.
6.	PFE3(a)	Whilst regularly serviced and operational, the hydraulic mortuary trolleys were showing some minor areas of rusting. The trolleys were on the departmental risk register for replacement at the time of the inspection. The DI is advised to progress these plans to ensure mortuary equipment remains fit for purpose.
7.	PFE3(c)	Whilst the ventilation system to the PM room is regularly serviced and provides the necessary 10 air changes per hour, the recent service report provided to the inspection team detailed there were some

		elements of the system that required additional maintenance. The DI is advised to ensure this maintenance is completed (if not done so already) to mitigate the risk of the ventilation system degrading further.

Background

Morriston Hospital has been licensed by the HTA since July 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in June 2019.

Since the previous inspection, there has been a revocation of a satellite site in June 2020, with this site now under the management of another Health Board within Wales. Changes to Persons Designate under the licence have occurred in November 2019, April 2021, January 2023, September 2023, and November 2023.

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).

The inspection team also undertook advisory inspections of the unlicensed body stores at Singleton Hospital and Neath Port Talbot Hospital which are used by the establishment as part of contingency storage arrangements. The unlicensed body stores are under the same staffing and governance structure as the hub site. The sites are not licensed as no licensable activity is undertaken. Only standards relating to body storage and conditions that may impact dignity of the deceased were assessed on an advisory basis. Accordingly, the advisory inspection focused on the following standards: GQ1(c), T1(a), T1(b), T1(c), T1(d), T1(e) T1(f), PFE1(a), PFE1(c), PFE1(d), PFE1(e), PFE2(a), PFE2(b), PFE2(c), PFE2(d), PFE2(e), PFE2(f), PFE2(g), PFE3(a), PFE3(b), PFE3(d) and PFE3(f).

Details of the advisory inspection findings can be found in appendix 3 of this report.

Review of governance documentation
The inspection team reviewed the establishment's self-assessment document provided by the DI in advance of the inspection. Policies and procedural documents relating to licensed activities were reviewed. This included cleaning records for the mortuary and PM room, records of servicing of equipment, fridge and freezer alarm testing records, ventilation reports, body and tissue traceability audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents and staff training and competency records. Consent seeking policies and procedures, information for relatives giving consent and current consent forms in use for both adult and perinatal PM examination were also reviewed.

Visual inspection
The inspection team undertook a visual inspection of the premises at the hub site and the unlicensed body store sites which included the mortuary body storage areas, the viewing rooms, and the PM room at the hub site. Also inspected was the storage area for tissue retained at post mortem examination at the hub site.

Audit of records
The inspection team undertook audits of traceability for four bodies in storage at the hub site and three bodies at the unlicensed body store site at Singleton Hospital. This included bodies with same / similar names and a body in frozen storage. Traceability details were crosschecked between the identification bands on the body, information on the mortuary whiteboard, associated records of the deceased, the mortuary electronic database and the mortuary register. No discrepancies with traceability were identified. There were no deceased in storage at the Neath Port Talbot Hospital site at the time of the advisory inspection.

Audits were conducted of tissue and organs taken at PM examination for five cases. Information was crosschecked between the mortuary traceability documentation, Coroner's paperwork, family wishes forms, the tissue spreadsheet and the tissue blocks and slides being stored. Three cases were identified as being stored for a scheduled purpose with appropriate consent. One case had been disposed of in line with the wishes of the family with a further case to be disposed of once no longer under the authority of the Coroner. No discrepancies with traceability were identified.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence including members of mortuary and pathology staff, the mortuary manger, the regional mortuary manager, a member of the portering staff, staff involved in the consent seeking process for perinatal and adult PM examination, the quality manager, and the DI who is also a pathologist undertaking PM examination.

Report sent to DI for factual accuracy: 05 December 2023

Report returned from DI: 02 January 2024

Final report issued: 03 January 2024

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: 8 November 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: Advisory inspection of the unlicensed body stores at Singleton Hospital and Neath Port Talbot Hospital

Advice

The HTA advises the DI to consider the following to further improve practice at the unlicensed body stores:

Number	Standard	Advice – Singleton Hospital
1.	PFE1(a)	The establishment are advised to ensure that cardboard boxes are not stored directly on the floor of stock cupboards to allow effective decontamination of the rooms.
2.	PFE1(d)	A padlock was used directly to the internal body store 'sliding doors' to prevent unauthorised access to this area out of hours, however, there was no mechanism in place to prevent the doors from being lifted outward from the bottom which could potentially allow access. The establishment are advised to review the security of this door to ensure security methods are robust.
3.	PFE1(e)	The establishment are advised to review the security arrangements between the viewing suite, the care after death team office and the main mortuary to mitigate the risk of unauthorised access to the body store should manual locks on doors between the areas not be deployed. Furthermore, the establishment are advised to consider that the viewing room did not have a system in place for staff to be able to raise an alarm should this be required. This may pose a risk of visitors accessing the rest of the mortuary if staff security is compromised.
4.	PFE3(a)	The internal racking system of the body store was showing signs of rusting due to age. The establishment are advised to have this inspected to ensure the integrity of the framework has not been compromised which could lead to a failure of the racking. Furthermore, these areas may be difficult to effectively clean and decontaminate.
5.	N/A	The establishment are advised to review the form which gives options to women for the disposal of pregnancy remains under 24 weeks gestation. Some pregnancy remains tissue, dependant on the amount of tissue present, may be retained fully as part of the women's medical record following analysis. This means there would be no tissue available for disposal. The form should reflect that this may, on occasion be a possibility for understanding of those making disposal decisions.

Number	Standard	Advice – Neath Port Talbot Hospital
1.	PFE1(a)	Whilst the premises were clean at the time of the advisory inspection, there were several ceiling tiles in the body store that had been broken as part of some recent upgrading to the area. The establishment are advised to replace the broken tiles.
2.	PFE1(d)	The establishment are advised to screen the rear of the body store at this site. This is to prevent oversight of activity in the body store as the rear body store doors open out directly into an area which is frequented by passing Health Board staff.
3.	N/A	This site is not routinely staffed due to the very low number of deceased arriving from the hospital for storage. Currently a member of staff travels to this site daily to check for routine admissions, meaning the staffing number at the busier site is reduced. The establishment may wish to consider whether the recent implementation of CCTV into the body store of this site may allow remote monitoring to negate the requirement for staff to travel if no bodies have been received.