Inspection report on compliance with HTA licensing standards
Inspection date: **14 and 17 August 2023**

Musgrove Park Hospital

HTA licensing number 12083

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
Musgrove Park Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*

Summary of inspection findings

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

Although the HTA found that Musgrove Park Hospital ('the establishment') had met the majority of the HTA's standards, three minor shortfalls were found against standards for 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

Minor shortfalls

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits.	Audits of swipe card access into the mortuary are not included in the audit schedule.	**Minor**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	One of the cases where tissue was taken during PM examination that was selected for audit by the inspection team did not document the number of tissue blocks taken. Although blocks are stored in the mortuary, there is still a risk of blocks not being fully traceable.	**Minor**

PFE 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	The oscillating saws in the mortuary have some areas of rust which makes them difficult to clean and disinfect properly. In addition, the floor in the PM room has pooling of water on the surface which could get into the mortuary storage area also making these areas difficult to disinfect and clean properly.	**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.	GQ1(a)	The DI is advised to review and align procedures as much as possible between both hospitals within the same Trust as there may be a slight difference in practices. This will help mitigate the risk of errors, especially if staff are working at both hospitals. The DI is also advised to consider a system to be utilised across both hospitals in the Trust to reduce the amount of paperwork completed by staff.
2.	GQ2 (a)	The DI is advised to include audits of completed post-mortem consent forms in the audit schedule.
3.	GQ6 (a)	The DI is advised to risk assess the following:

		• The contingency storage room to determine if the size of the racking and temperature of the room is sufficient for licensable activities. • The fridge plant equipment to ensure it is secure from being accidently switched off

Background

Musgrove Park Hospital has been licensed by the HTA since August 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in January 2019.

Since the previous inspection, the establishment has merged with Yeovil District Hospital in April 2023 to form part of the Somerset NHS Foundation Trust. Prior to the inspection, a licence application was submitted to make changes to the licence arrangements. The application proposes that Musgrove Park Hospital would become the 'hub' site and Yeovil District Hospital the 'satellite site'. This application is currently being assessed.

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 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 relating to licensed activities, cleaning records, records of equipment servicing, audits, risk assessments, meeting minutes, temperature monitoring records, staff training records and reported incidents.

Visual inspection
The inspection included a visual inspection of the mortuary, body store, PM room and viewing room.

Audit of records
Audits were conducted for three bodies in refrigerated storage. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and electronic database. No discrepancies were found.

Audits were also conducted for tissue taken from PM examination. Information recorded on paper and computer records were reviewed and the location of blocks and slides stored in the mortuary. One discrepancy was found for a case where tissue was taken from PM examination (see minor shortfall against standard T1(g)).

Meetings with establishment staff

Interviews and discussions with staff carrying out processes under the licence were conducted including the DI, Anatomical Pathology Technologist, Porter and consent seeker for PM examinations.

Report sent to DI for factual accuracy: 01 September 2023

Report returned from DI: 06 September 2023

Final report issued: 08 September 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.