Inspection report on compliance with HTA licensing standards
Inspection date: **7 December 2023**

Salisbury District Hospital
HTA licensing number 12047

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
Salisbury District Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab			*Carried out*
A&E		*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 Salisbury District Hospital (‘the establishment’) had met the majority of the HTA’s standards, six major and six 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.

Major shortfalls

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Whilst there is a schedule of audits there is no security audit including the checking of CCTV against records of mortuary access. (See *Shortfall* against standard PFE1(e))	**Major**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised	Staff who undertake mortuary duties do not receive regular competency assessments. There were no documents available to review relating to mortuary staff, site managers and porters being assessed as competent for tasks undertaken under the licence.	**Major**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register	The number of staff employed at the establishment is not currently present on the Trust risk register. There may be insufficient technical staff to support the level of activity undertaken. The establishment have submitted a number of reportable incidents and have cited staff shortages as contributing factors. This poses a further risk that could lead to the unplanned closure of the establishment and impact its ability to deliver services.	**Major**
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)	Most doors to the Mortuary are fitted with key operated locks and not swipe card access systems. There is CCTV coverage of access and egress points of the main entrances of the department however the fire escape door is not covered. There is no CCTV coverage of internal areas in the Mortuary. CCTV images cannot be viewed in the Mortuary. The existing security arrangements do not employ sufficiently effective mechanisms to control access to the Mortuary.	**Major (cumulative)**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The access used by funeral directors is controlled by a domestic key operated lock. Keys are held in the Hospital switchboard and signed out. During the inspection it was apparent that the access logs were not audited, and names of individuals were not recorded. This system does not give effective oversight of persons entering the Mortuary.	
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity	The establishment uses a variety of contingency storage solutions to deal with capacity issues. The soft-shell contingency units are in continuous use and have been for several years.	**Major (cumulative)**
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	There is limited refrigerated, and no long-term storage facilities for bariatric bodies at the establishment.	
e) Fridge and freezer units are alarmed, and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range	The external fridge units are not remotely alarmed and rely on manual temperature checks. These checks are not undertaken at weekends and bank holidays. This presents a risk of undetected failure which could result in accidental damage to bodies.	**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.	SOPs relating to contingency storage arrangements lack sufficient detail for the use of Funeral service premises. There are few formalised lone working arrangements for staff in place and no panic devices. Lone working has the potential for greater risks to staff and the dignity of the deceased.	**Minor**
g) All areas where activities are carried out under a HTA licence are incorporated within the establishment's governance framework.	There is no Persons Designated named on the licence covering the removal activities undertaken in the Emergency department. (See *Advice* item 2)	**Minor**
GQ2 There is a documented system of audit		
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	Whilst the establishment undertake comprehensive audits, they do not document who is responsible for follow-up actions and the time frame for completing these.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		

d) Staff have annual appraisals and personal development plans	Staff do not routinely receive annual appraisals and personal development plans.	**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	Risk assessments do not give deadlines for actions to be implemented and confirmation of completion. This presents a risk of mitigations not being completed.	**Minor**
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 are clean, some items require maintenance: • The seals at the base of the PM tables are broken. • There are shelves in the PM room made of porous material which prevents effective 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.	C1(f)	The Maternity unit advises parents to call the Labour ward should consent for post mortem be withdrawn. The Bereavement Midwife is advised of the withdrawal of consent when in the office and is the single point of contact to the Mortuary. The DI is advised to review this system to determine if a more direct notification method to the Mortuary can be employed.
2.	GQ1(g)	The DI may wish to consider adding a member of Mortuary technical staff to the cohort of Persons Designate.
3.	T1(c)	The establishment have introduced a form to be used for bodies in long term storage. The DI is advised to introduce a statement on the form reflecting that it should not be used as a method of identification to facilitate release of bodies. Various documents are supplied by Funeral Directors to facilitate the release of a body. The DI may wish to consider the use of a hospital release form only which requires three identifiers to be completed and provided. This may further mitigate any risks associated with the use of differing forms which may contain differing identifiers.
4.	T1(d)	The DI is advised to consider the reintroduction of a magnet alert system to further highlight the deceased with same and similar names.
5.	T1(e)	The DI is advised to incorporate the movement of bodies to other premises into risk assessments relating to transfer and storage.
6.	PFE1(a)	The facia around the freezer door in the Post mortem room consists of several panels. These panels have separated and require repositioning. The DI is advised to arrange repair before bringing the freezer back in to service.

Background

Salisbury District Hospital is 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.

Salisbury District Hospital has been licensed by the HTA since 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in September 2021.

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 3 April 2017).

Review of governance documentation

The inspection team reviewed the establishment's self-assessment document provided by the DI ahead of inspection. Standard operating procedures and policies were reviewed. Risk assessments, audits, cleaning records, meeting minutes and a ventilation report were inspected as part of the review process.

Visual inspection

The inspection included an on-site visual assessment of the security arrangements, body storage areas in the mortuary, PM room, viewing room and tissue storage areas. The processes for release of bodies within the mortuary was observed during the inspection.

Audit of records
A traceability audit of four bodies in storage was undertaken. This included bodies from both the community and hospital including those with same and similar names and one in long term storage. Details were cross checked against identity bands and the mortuaries' electronic database. No discrepancies were found.

Audits were conducted of tissue taken at PM examination for five cases. Information was crosschecked between the mortuary documentation, 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, APT, Bereavement Midwife, Porter, Quality Manager, Pathologist and Consultant Paediatrician.

Report sent to DI for factual accuracy: 2 January 2024

Report returned from DI: 12 January 2024

Final report issued: 15 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: 20 September 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.