Inspection report on compliance with HTA licensing standards
Inspection date: **02 April 2025**

Royal Shrewsbury Hospital

HTA licensing number 12184

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 Shrewsbury Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
A&E	-	*Carried out*	-
Satellite site **Princess Royal Hospital**	Not licensed	Licensed	Licensed
Mortuary (satellite site)	-	-	*Carried out*

Maternity	-	-	*Carried out*
A&E	-	*Carried out*	-

Summary of inspection findings

This was an announced targeted site visit to inspect the progress of the corrective and preventative actions taken by the establishment in response to the shortfalls identified during the last previous inspection carried out 8 and 9 October 2024. The HTA found the Licence Holder (LH) and Designated Individual (DI) to be suitable in accordance with the requirements of the legislation.

The targeted announced site visit of Royal Shrewsbury Hospital ('the establishment') found one major and one minor shortfall against standards for Premises, facilities and equipment.

Whilst a significant amount of work has been undertaken to implement corrective and preventative actions to address the findings from the HTA Inspection in October 2024, the two shortfalls found at this inspection relate to elements of two of the major shortfalls from the previous inspection. During the inspection feedback meeting, the HTA inspector identified there was further work needed to fully address the shortfalls.

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
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
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	Whilst most of the fridges are monitored centrally and there is an alerting system in place, the following units do not have external alerts for temperature excursion: • the toxicology fridge and freezer at the hub site, • the specimen freezer at the satellite site, • the fridge used for the storage of fetal remains at the satellite site, and • the temporary storage units at the satellite unit. This poses the risk of accidental damage.	**Major**

Minor shortfalls

Standard	Inspection findings	Level of shortfall
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	Whilst the establishment has taken action to prevent oversight of activities, the risk of observing transfer of bodies from the main mortuary into the bariatric storage unit has not been fully mitigated.	**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.	GQ3(c)	The DI is advised to consider the addition of a column in the database used to log the training of non-mortuary staff to indicate the date they were assessed as competent.
2.	T1(d)	The DI is advised to review and strengthen the process relating to same or similar names. Consideration should be given to the addition of an alert sticker to the patient journey form in addition to the mortuary register.
3.	T2(d)	The DI is advised to consider recording the number of slides disposed of on the paper based disposal forms retained in the mortuary. This will support the auditing process and support the identification of any discrepancies.
4.	PFE1(d)	The DI is advised to expedite the existing plans in place to upgrade the centrally monitored intruder alarm alerting system and electronic access system.
5.	PFE3(a)	The DI is advised to monitor and rectify the minimal rusting to the hydraulic trolleys within the body store, to ensure there is no further deterioration.

Background

Royal Shrewsbury Hospital has been licensed by the HTA since 2007. This was the sixth inspection of the establishment; the most recent previous inspection took place in October 2024. During this targeted follow up inspection, we identified two shortfalls that have not been fully addressed in standards PFE2(a)(e), these were identified during the last previous inspection.

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

11 out of the HTA's 72 standards were covered during the announced targeted inspection. Standards covered at this inspection are listed in Appendix 3. The inspection focused on areas of concern, seven of which were identified during the most recent previous inspection; the remaining 61 standards will be assessed during the next routine inspection.

Review of governance documentation

The inspection included a review of some of the establishment's governance documentation relating to licensed activities. This included training and competency records for mortuary and non-mortuary staff who undertake activity under the licence, fridge temperature monitoring records and records relating to the traceability of tissue taken at PM.

Visual inspection

The inspection included a visual assessment of both establishments including, body storage areas in the mortuaries and in the maternity department, PM room, viewing rooms and tissue storage areas. The inspection teams observed the processes for admission of bodies within the mortuary

Audit of records

Audits were conducted onsite of three bodies in refrigerated and one body in frozen storage at the hub site and two bodies in refrigerated and one body in frozen storage at the satellite site. 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.

Audits of traceability were conducted for tissue blocks and slides from three coronial cases, these included audits of the consent documentation for the retention of these tissues. No discrepancies were identified.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence, this included the Corporate Licence Holder contact (CLHc), the DI, Pathology Operations Manager, Quality Lead, Mortuary Manager, APT, Mortuary Assistant, Estates Manager, and Bereavement Midwife.

Report sent to DI for factual accuracy: 08/04/2025

Report returned from DI: 14/04/2025

Final report issued: 14/04/2025

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.

Appendix 3: Standards Assessed

Governance and quality systems
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.
c) Staff are assessed as competent for the tasks they perform.

Traceability
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail
c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier.
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings). The traceability system ensures that the following details are recorded: i. material sent for analysis on or off-site, including confirmation of arrival ii. receipt upon return to the laboratory or mortuary iii. the number of blocks and slides made iv. repatriation with the body v. return for burial or cremation vi. disposal or retention for future use.

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
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.
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.
f) Temperatures of fridges and freezers are monitored on a regular basis.
i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods.
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.*