Inspection report on compliance with HTA licensing standards
Inspection date: **23 April 2024**

Royal Surrey County Hospital
HTA licensing number 12222

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
Royal Surrey County 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 Royal Surrey County Hospital ('the establishment') had met the majority of the HTA's standards, seven major and 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
All applicable HTA standards have been assessed as fully met.

Major shortfalls

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of audit		
c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention	Whilst an audit schedule is in place and audits have been completed. The inspection team were not assured tissue audits contain a sufficient sample size for the establishment to assure themselves any non-conformances are identified and follow up action taken in a timely manner.	**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	The Inspection team were not assured all staff who undertake activities under the licence are appropriately trained. No training records were available for review to indicate relatives officers who facilitate viewings have received training. This poses the risk of the viewing of the wrong body. Furthermore, there were no records available for review pertaining to the training of site staff who facilitate out of hours releases, which poses the risk of the release of the wrong body. *(as a result standard GQ3(c) cannot be assessed)*	**Major**
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 risks are assessed on a regular basis, the mitigating controls used by staff are not reflected in the risk assessments.	**Major (cumulative)**
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 inspection team were not assured significant risks had been added to the corporate risk register. There are insufficient numbers of permanent staff available to manage the volume and complexity of mortuary activity. This poses the risk of reduced capacity to undertake administrative tasks including activity relating to the review and updating of key documents.	
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	Viewings are facilitated by relatives officers. The inspection team were not assured information provided by families is checked against the ID bands on the body prior to being shown into the viewing room. This poses the risk of the viewing of the wrong body. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Major**
T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary	Whilst there is a process in place for slides for analysis to be booked out, they are not always returned to the establishment in a timely manner when they are no longer needed. This poses the risk of a loss of tissue slides.	**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)	The access used by porters and the door to the viewing suite are not covered by CCTV. Whilst there is an audio visual doorbell in place the access corridor is poorly lit which may prevent staff from seeing clearly who is seeking entry. This poses the risk of a serious security breach.	**Major (cumulative)**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	Security arrangements do not ensure oversight of visitors and contractors who have a legitimate right of access. Maintenance staff who are authorised to carry out work out of hours are not required to sign in and out of the mortuary. This poses a risk to the dignity and security of bodies.	
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 the fridges and freezers have an audible alarm and there is a monitoring system in place, the temperature monitoring system for one bank of fridges is faulty and does not alert switchboard personnel in the event of a temperature excursion out of hours. Furthermore, temperature trend analysis is not routinely undertaken to identify trends and the extent of any variations in storage temperatures. This poses the risk of an incident pertaining to the accidental damage to a body.	**Major (cumulative)**
f) Temperatures of fridges and freezers are monitored on a regular basis	Whilst there is a system in place for the daily recording of fridge and freezer temperatures at the weekend and Bank Holidays, there were several days where fridge and freezer temperatures had not been documented. This poses the risk of an incident pertaining to accidental damage to a body.	

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.	The Standard Operating Procedure (SOP) detailing the transfer of post mortem specimens to the pathology laboratory is not reflective of staff practice and suggests two identifiers can be used to maintain traceability. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors	Bodies are transferred on hydraulic trolleys from the post mortem room to the body store to return to refrigerated storage. No cleaning or decontamination of the trolley takes place between the movement of bodies from dirty to transitional areas in the mortuary unless it is visibly contaminated. As the body store is in constant use by porters and Funeral Directors this poses the risk of cross contamination.	**Minor**
PFE3 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	There was significant rusting to the hydraulic mortuary trolleys used in the body store and contingency storage areas. This poses the risk of ineffective cleaning and decontamination. Whilst the inspection team were provided with an approved business case for the replacement of this essential equipment, there was no indication of when the equipment would be ordered or delivered.	**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(c)	The DI is advised to liaise with the third party responsible for the production and governance of the leaflet relating to minimally invasive post mortem examinations. The document currently states “2017” which suggests this was the last review date.
2.	GQ1(d)	Whilst SOPs had been recently reviewed and updated, the DI is advised to ensure there is a system in place to ensure reviews are undertaken within the establishment governance framework.
3.	T1(b)	The DI is advised to consider discontinuing the use of the paper mortuary registers as there is an electronic system in place and the use of more than one mortuary tracking system increases the risk of a transcription error.
4.	T1(g)	The DI is advised to add the date organs are transferred offsite for analysis to the electronic records in addition to paper records. Additionally, consideration should be given to the use of paper slips to indicate when blocks and slides have been disposed of or removed from storage for analysis. This will provide an additional level of assurance tissue blocks and slides have not been misplaced and support the auditing process.
5.	T2(d)	The DI is advised to add the method of disposal of tissue to the electronic tissue spreadsheet in addition to paper records.

6.	PFE1(a)	The DI is advised to expedite the existing plans in place for the replacement of equipment and refurbishment of the mortuary.
7.	PFE2(b)	The DI is advised to consider withdrawing the use of scoops for the storage of bodies when the planned refurbishment of the mortuary has been completed, due to the risk presented to staff of musculoskeletal injury and the risk of accidental damage to a body.
8.	PFE2(h)	The DI should consider moving the fridge location used for storage of perinatal losses until the fault in the out of hours temperature alerting system has been resolved.

Background

Royal Surrey County Hospital has been licensed by the HTA since 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in November 2021.

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under the licence. However, a business case has been approved for a major refurbishment of the mortuary to include additional storage, an updated temperature monitoring system and new hydraulic mortuary trolleys.

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 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 for the mortuary, records of servicing of

equipment, audits, risk assessments, meeting minutes, reported incidents and training records for staff undertaking activity under the licence.

Visual inspection
The inspection included a visual assessment of the establishment including the post mortem suite, body storage areas and viewing rooms. Areas outside the mortuary carrying out licensed activity were also visited including the Pathology department and tissue storage room. The inspection team observed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records
Audits were conducted onsite of four bodies in refrigerated storage and one body in long term frozen storage. The release of one body into the care of the Funeral Director was observed. Identification details on bodies were crosschecked against the information recorded in the register and associated paperwork in addition to information held electronically. No discrepancies were identified. Audits of traceability were conducted for six cases of histology samples. The inspection team identified a discrepancy in recording for one case, and paperwork relating to tissue taken and family wishes could not be located for two cases from 2018 and 2019. (see shortfall against GQ2(c) for further information).

Meetings with establishment staff
Staff carrying out processes under the licence were interviewed including the DI, Senior APT, Quality Manager, Trainee APT, Biomedical Scientist, Porter, Porter Supervisor, Bereavement Midwife, Perinatal/Paediatric Consent Seeker, Adult Pathologist and Adult Consent Seeker.

Report sent to DI for factual accuracy: 16/05/2024

Report returned from DI: 01/06/2024

Final report issued: 03/06/2024

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: 6 January 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.