

Royal Cornwall Hospital
HTA licensing number 12208

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 Cornwall Hospital	Licensed	Licensed	Licensed
Mortuary	<i>Carried out</i>	<i>Carried out</i>	<i>Carried out</i>
Maternity		<i>Carried out</i>	<i>Carried out</i>
A&E		<i>Carried out</i>	
Neonatal unit		<i>Carried out</i>	
Paediatric ward		<i>Carried out</i>	
Pathology Lab			<i>Carried out</i>

Satellite site West Cornwall Hospital	Licensed	Licensed	Licensed
Mortuary (satellite site)	<i>Carried out</i>	<i>Carried out</i>	<i>Carried out</i>

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 Cornwall Hospital ('the establishment') had met the majority of the HTA's standards, seven major and three 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.

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Major shortfalls

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
b) There is a documented standard operating procedure (SOP) detailing the consent process	The establishment does not have a detailed SOP for taking consent for adult post mortems, a policy is used instead. The policy lacks detail on what training must be undertaken in advance of consent being sought. This presents a risk of untrained individuals undertaking the process of seeking consent.	Major
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
d) Competency is assessed and maintained	The maternity department do not have a formal competency assessment process in place. (See <i>Shortfall</i> against standard GQ3(c)).	Major
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 maternity unit does not have an SOP for viewing on the ward. This presents a risk of misidentification when undertaking this process. (See <i>Advice</i> item 1)	Major
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	Maternity staff do not have competence assessments for viewing or release on maternity ward.	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)	Refrigeration plant equipment is located in an insecure outside area at Royal Cornwall Hospital. Power switches for the plant equipment are not fitted with tamperproof mechanisms.	Major
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	Multiple areas of extensive corrosion are present on the stacking trolley in the post mortem room at Royal Cornwall Hospital. This prevents effective decontamination.	Major
f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept	The fridge in the maternity ward is not regularly serviced and a schedule of cleaning is not present.	Major

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice	Whilst the establishment utilises the video "Respect for the dead, care for the living - a guide to the post mortem procedure" it does not have written information available for those giving consent.	Minor
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Issues relating to licensed activities are discussed in Pathology governance meetings. This meeting does not however include PDs from all areas working under the licence.	Minor
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis	The establishment do not have a risk assessment for accidental damage to a body.	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 remove the term “Next of kin” from SOPs relating to the retention and disposal of tissue following Coroner's post mortem.
2.	GQ6(a)	The DI is advised to add the review of trends in fridge temperatures as a mitigation to risk assessments relating to equipment failure.

Background

Royal Cornwall Hospital and the satellite site at West Cornwall 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.

Royal Cornwall Hospital has been licensed by the HTA since November 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in January 2022.

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, risk assessments and policies were reviewed. Staff training records, competency records 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 body storage area, PM room and viewing room at West Cornwall Hospital were visually assessed. The processes for release of bodies within the mortuary was observed during the inspection.

Audit of records

A traceability audit of five bodies in storage Royal Cornwall Hospital was undertaken. This included bodies from both the community and hospital including those with same and similar names, one in long term storage and a perinatal body. Details were cross checked against identity bands and the mortuaries' electronic database. No discrepancies were found.

A traceability audit of three bodies in storage West Cornwall Hospital was undertaken. This included bodies from both the community and hospital. Details were cross checked against identity bands and the mortuaries' electronic database. 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, Mortuary Manager, Trainee APT, Bereavement Midwife, Porter, Quality Manager and Pathologist.

Report sent to DI for factual accuracy: 18 June 2024

Report returned from DI: 20 June 2024

Final report issued: 20 June 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: 3 October 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.