Inspection report on compliance with HTA licensing standards
Inspection date: **19 November 2025**

Royal Devon and Exeter Hospital
HTA licensing number 12370

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 Devon and Exeter Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*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 Devon and Exeter Hospital ('the establishment') had met the majority of the HTA's standards, five major and two minor shortfalls were found against standards for Consent, Governance and quality systems, 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

Major shortfalls

Standard	Inspection findings	Level of shortfall
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 inspection team were not assured significant risks had been added to the corporate risk register. The Mortuary is accessed via a courtyard used to store hospital waste; and whilst significant work has been carried out to mitigate the risk of oversight of mortuary activity by staff and delivery drivers working in the courtyard. Refuse and delivery vehicles continue to come and go throughout the day causing congestion, affecting mortuary services by leading to delays to the collection of the deceased. Additionally, the risk of oversight of mortuary activities remains.	**Major**
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	There are significant areas of damage to the structure of the building and equipment in use. These include but are not limited to: • The PM suite and body store have areas of exposed plaster to the walls. • The floor in the PM is showing signs of significant wear, and cracking around the drainage grids increasing the risk of porosity, which may prevent effective decontamination. • One of the post mortem tables could no longer be used, as the base was unable to support the weight of the table due to corrosion. Furthermore, there were areas of corrosion on an electrical socket on another PM table. These issues were identified and plans put in place for rectification whilst the inspection team were onsite. • There were significant areas of exposed wood around the door frames in the PM suite and body store. Additionally, the shoe rack in the transitional area is of wooden construction. Furthermore, the dissection benches were supported by a wooden frame. • The sink attached to the dissection benches did not drain correctly, leaving debris in the ventilation system which cannot be adequately cleaned due to its construction. • The supporting structure of the dissection bench in the Forensic PM room is made of wood. Additionally, there is damage to the flooring which could prevent effective decontamination.	**Major**
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 chiller units for the fridge and freezer banks are in an area that could be accessed by the public. The switches have not been rendered tamper proof and the units could be switched off from outside. Additionally, the double door between the body store and viewing suite does not meet, leaving a small gap, which could lead to a risk of oversight of mortuary activity by those attending the mortuary for a viewing.	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
d) Fridge and Freezer units are in good working condition and well maintained	Whilst the fridge and freezer units are subject to regular maintenance, some of the fridge rollers are misaligned. Furthermore, some of the fridge trays have sustained damage which affects the smooth running of the tray into the fridge space.	**Major**
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 fridge and freezers used for storing tissue taken during PM located in the Crime Scene Investigation room are not alarmed or connected to the central monitoring system.	**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		
a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice	Whilst there is a system in place to assess staff competency and this is managed locally, the Trust consent policy states a framework is being developed.	**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	The inspection team are not assured regular meetings are carried out to discuss HTA licensed activities. The most recent meeting to discuss matters relating to HTA licensed activities was undertaken in January 2025. Prior to that a meeting was undertaken in May 2024.	**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.	PFE1(e)	Whilst all the entry points to the mortuary are covered by CCTV, the DI is advised to continue with existing plans to install an additional CCTV camera to provide additional oversight of the door leading from the PM suite. Additionally, the DI is advised to change the code for the intruder alarm on a regular basis.
2.	PFE3(a)	The DI is advised to continue with existing plans to replace the bases of the autopsy saws which have rusted and are difficult to decontaminate.
3.	General	The Licence Holder is advised to consider the governance structure pertaining to the DI role in terms of the time involved in maintaining everyday oversight of mortuary activity across two mortuaries in addition to the requirements of their full-time role.

Background

Royal Devon and Exeter Hospital has been licensed by the HTA since 2007. This was the sixth inspection of the establishment and

was unannounced; the most recent previous inspection took place in May 2023.
Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under the licence. However, there has been a change to the DI in July 2025.

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
Policies and procedural documents relating to licensed activities for the mortuary were reviewed. Traceability audits, risk assessments, meeting minutes, incidents, consent seeking procedures and information for relatives giving consent were also reviewed.

Visual inspection
The inspection included a visual inspection of the mortuary body store, viewing room and PM suite including the high-risk forensic room. The inspection teams observed the processes for admission and release of bodies within the mortuary.

Audit of records
Audits were conducted for three bodies in refrigerated storage and one body in freezer storage; an audit was undertaken of four bodies being released into the care of Funeral Directors. Body location and identification details on bodies were crosschecked against the information recorded on the electronic system and relevant documentation. No discrepancies were found.
Forward and reverse audits of traceability were conducted for tissue blocks and slides from six coronial and hospital consented PM cases, including audits of the consent documentation for the retention and disposal of these tissues. No discrepancies were found.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence, including the DI, Anatomical Pathology Technologists,

a porter, the bereavement Midwife, Pathologist, and consent seekers for PM examinations.

Report sent to DI for factual accuracy: 10 December 2025

Report returned from DI: 22 December 2025

Final report issued: 23 December 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.