Inspection report on compliance with HTA licensing standards
Inspection date: **20 November 2025**

North Devon District Hospital
HTA licensing number 12401

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 **North Devon District Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
A&E	-	*Carried out*	-

Summary of inspection findings

Although the HTA found that North Devon District Hospital ('the establishment') had met the majority of the HTA's standards, four major and one minor shortfall was 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.

Major shortfalls

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	There is an audit schedule that includes vertical and horizontal audits in the mortuary; however, the establishment could not provide evidence that body and tissue traceability audits have taken place for 2025. Additionally, the frequency of tissue traceability audits is not sufficient.	**Major**

Standard	Inspection findings	Level of shortfall
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
h) There are documented procedures for transportation of the bodies and tissue anywhere outside the mortuary, (such as to the lab or another establishment), including record-keeping requirements.	Mort-SOP-10 does not detail how receipt is documented and communicated to the mortuary.	**Major**

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.	Fridges and freezers are alarmed and monitored; however, tests of the lower and upper set range have not been carried out.	**Major**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
d) Staff have access to necessary PPE.	Although face masks are available for staff to use in the PM suite, there is no record to demonstrate that staff have received up-to-date face fit testing for the use of this personal protective equipment.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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.	There were no documents available to review indicating one member of staff received an up-to-date annual appraisal and personal development plan.	**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.	C2(a)	The establishment may wish to consider training additional staff in seeking consent for adult PM examinations to ensure there is adequate cover.
2.	GQ1(a)	The establishment is currently in the process of transferring ownership of tissue traceability for PM blocks and slides from histology to the mortuary and are undertaking a review of their tissue disposal and retention SOP. The DI is advised to continue with their plans to update the relevant procedures.
3.	GQ1(a)	The establishment is advised to remove references to the next of kin in the procedure for recording tissue disposal or retention of PM material in line with guidance document.
4.	PFE(e)	The DI is advised to ensure that the temporary contingency fridges are on the same system as the

		mortuary fridges for temperature monitoring and alarms prior to use.
5.	PFE3(d)	The establishment may wish to consider training additional staff in conducting high risk PM examinations to ensure there is appropriate contingency should the staff member who conducts these is not available.
6.	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

North Devon District 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 May 2023.

Since the previous inspection, there has been a change in the Corporate Licence Holder Contact (CLHc) and additional Persons Designated (PD) added to the licence. The mortuary has also had a refurbishment of the body store and viewing room.

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, ventilation reports, audits, risk assessments, meeting minutes, reported incidents and training records for staff.

Visual inspection
The inspection included a visual assessment of the establishment including, the body storage area, the PM room, viewing room and tissue storage areas.

Audit of records
Audits were conducted onsite of six bodies from refrigerated storage. At the time of the inspection there were no bodies in long term storage. Identification details on bodies were crosschecked against the information recorded in the electronic system. No discrepancies were identified.

Audits of traceability were conducted for tissue blocks and slides from six coronial PM cases. These included audits of the consent documentation for the retention of removed tissue and location of blocks and slides in histology. No discrepancies were identified.

Meetings with establishment staff
Discussions were held with staff working under the licence including the DI, Anatomical Pathology Technologist (APT), Mortuary Bereavement Lead, Pathologist, Porter, Quality Manager and consent seekers for post-mortem examinations.

Report sent to DI for factual accuracy: 10 December 2025

Report returned from DI: 22 December 2025

Final report issued: 05 January 2026

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.