

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	<i>Carried out</i>	<i>Carried out</i>	<i>Carried out</i>
Pathology lab	-	-	<i>Carried out</i>
A&E	-	<i>Carried out</i>	-

Summary of inspection findings

Although the HTA found that North Devon District Hospital ('the establishment') had met the majority of the HTA's standards, 1 major and 2 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.

Major shortfalls

Standard	Inspection findings	Level of shortfall
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	Tissue taken during post mortem examination (PM) is not fully traceable. The establishment does not have a system in place to identify when slides have been taken offsite for further examination by pathologists. This poses the risk of tissue being retained against the express wishes of the family.	Major (cumulative)
h) There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary, (such as to the lab or another establishment), including record-keeping requirements	There are no documented procedures in place for pathologists to follow when removing or returning slides analysed offsite.	

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
d) Competency is assessed and maintained	There were no documents available for review assessing staff as competent with the HTA requirements when seeking consent for adult and perinatal PM's. This includes those who have received consent training.	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	Whilst scheduled governance meetings do take place. There is no attendance by establishment staff from areas outside the mortuary and bereavement teams. Maternity and emergency department staff do not attend or receive the minutes of governance meetings discussing matters relating to HTA activity.	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(b)	Whilst consent seekers always offer a 24 hour cooling off period and this is reflected in consent forms, it is not explicit in the SOP The DI should consider adding the requirement for a cooling off period of at least 24 hours into the consent seeking SOP.
2.	GQ1(d)	The DI is advised to continue with the review and update of SOPs to reflect the new electronic mortuary records management system in place.
3.	GQ3(c)	The DI is advised to consider the implementation of a “train the trainer” system for the refresher training and competency checks for porters. This will help to relieve the workload of the mortuary manager and provide assurance for the portering managers that staff practice is satisfactory.
4.	PFE1(d)	Whilst the mortuary alarm code had recently been changed. The DI should consider adding the requirement to change the mortuary alarm access code on a regular basis to the security SOP.
5.	N/A	The DI is advised to inform the HTA of any short-term temporary changes to mortuary activity due to the building work being carried out.

Background

North Devon District Hospital has been licensed by the HTA since 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in February 2020.

Since the previous inspection, the hospital has merged with another hospital to become a single NHS Trust and there has been a change to the Corporate License Holder Contact (CLHc). There have been no changes to the licensed activity undertaken.

The establishment is currently undergoing a programme of refurbishment with plans in place to increase the footprint of the mortuary to provide additional capacity including bariatric fridge to freezer spaces and the refurbishment of the viewing suite and outside courtyard.

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 both the mortuary staff, site staff, midwives and porters.

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. The inspection team observed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records

Audits were conducted onsite of two bodies from refrigerated storage, and one body in long term frozen storage. Identification details on bodies were crosschecked against the information recorded in the register and associated paperwork. No discrepancies were identified.

The release of one body into the care of a funeral director was observed. Identification details on the body were crosschecked against the information recorded in the register and associated paperwork brought by the Funeral Director. No discrepancies were identified.

Audits of traceability were conducted for tissue blocks and slides from one hospital consented PM and two coronial cases. These included audits of the consent documentation for the retention of removed tissue. No discrepancies were identified.

Meetings with establishment staff

Staff carrying out processes under the license were interviewed including the DI, mortuary manager, trainee APT's, pathologist, mortuary porter, SUDIC lead, bereavement midwives and bereavement officers.

Report sent to DI for factual accuracy: 08/06/2023

Report returned from DI: 09/06/2023

Final report issued: 12/06/2023

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: 31 July 2023

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.