Inspection report on compliance with HTA licensing standards
Inspection date: **22 October 2024 (Unannounced)**

Path Links (Lincoln)
HTA licensing number 12314
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 **Lincoln County Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	-	*Carried out*
A&E	-	*Carried out*	-
Satellite site **Pilgrim Hospital**	Not licensed	Licensed	Not Licensed

Paediatrics ward	-	*Carried out*	-
A&E	-	*Carried out*	-
Satellite site Grantham and District Hospital	Not licensed	Licensed	Not Licensed
Paediatric Ward	-	*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 Path Links (Lincoln) (the establishment) had met the majority of the HTA's standards, three major and two minor shortfalls were found against standards for Governance and quality, 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

Major Shortfalls

Standard	Inspection findings	Level of shortfall

GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
c) Procedures on body storage prevent practices that disregard the dignity of the deceased.	The condition of the deceased is checked on arrival by mortuary staff and regular checks are carried out, however staff do not consistently record these condition checks.	**Major**

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 bodies and tissue anywhere outside the mortuary, (such as to the lab or another establishment), including record-keeping requirements	The mortuary does not have a formalised process for confirming receipt of specimens in the histopathology laboratory.	**Major**

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	The external body storage unit (Portakabin) alarm is not tested and alarm tests for fridges within the mortuary are only conducted in hours.	**Major**

Minor shortfalls

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
b) Records demonstrate up-to-date staff training.	A staff member who seeks consent for adult PM examination informed the inspection team that they have not completed refresher training for several years.	**Minor**

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.	Competencies for porters do not include a section to test the porter's understanding of the types of incidents that need to be reported to the Human Tissue Authority.	**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 withing 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 (b)	The DI is advised to train additional staff in the consent seeking process for adult PM examinations to ensure there is adequate cover.
2.	GQ6 (b)	The risk assessments state ‘Adhere to SOP’ in the control measures section of the relevant risk, but do not specify the SOP they are referring to or list training and competency as a control measure in line with current procedures. The establishment is advised to include these as control measures under each risk.
3.	T1 (b)	The mortuary is advised to communicate with the wards to ensure outdated paperwork for admitting bodies to the mortuary is not used.
4.	PFE	The establishment is advised to do a gap analysis against HTA standards once the refurbishment works are complete to identify any security risks that need to be addressed. The DI is advised to contact the HTA once the works are completed as the HTA may conduct a follow up site visit inspection of the premises.

Background

Path Links (Lincoln) is licensed for the making of a PM examination, removal of relevant material from the deceased and storage of bodies of the deceased and removal of relevant material for use for scheduled purposes. The satellite sites at Pilgrim Hospital and Grantham and District Hospital are licensed for removal of relevant material from the deceased for use for scheduled purposes.

The establishment has been licensed by the HTA since August 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in May 2022.

Since the previous inspection, the establishment has started an upgrade and renovation of the mortuary storage facilities, and this was in progress during the site visit. Advice in relation to the upgrade has been given in this report (see advice item 4).

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) were assessed.

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 equipment servicing, audits, risk assessments, meeting minutes and reported incidents.

Visual inspection

The inspection included a visual inspection of the mortuary body store, external Portakabin storage unit, PM room, viewing room and fridge in maternity.

Audit of records

Audits were conducted for five bodies in refrigerated storage. Body location and identification details on bodies were crosschecked against the information in the mortuary database, mortuary register and relevant documentation. No discrepancies were found.

Audits were also conducted of records and tissue taken at PM examination for one hospital consented case and four coroner's cases. Relevant documentation was cross referenced and location of tissue in histology. No discrepancies were found.

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI, Mortuary Manager, Anatomical Pathology Technologist, consent seekers for PM examinations, Porter and Pathologist.

Report sent to DI for factual accuracy: 22 November 2024

Report returned from DI: 09 December 2024

Final report issued: 11 December 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: 15 April 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.