



Path Links (Grimsby)
 HTA licensing number 12310

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 Diana Princess of Wales Hospital	Not licensed	Licensed	Licensed
Mortuary	-	<i>Carried out</i>	<i>Carried out</i>
A&E	-	<i>Carried out</i>	-
Satellite site Scunthorpe General Hospital	Not licensed	Licensed	Licensed
Mortuary	-	<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.

The targeted non-routine site visit of Path Links (Grimsby) ('the establishment') found one minor shortfall against standards for 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

Minor shortfalls

Standard	Inspection findings	Level of shortfall
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	Although the establishment has a means to record some visitors to the mortuary, for example, those that book and attend for viewings, there is no visitor log to record the attendance of other persons.	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)	<p>The Mortuary Manager is advised to review and update relevant mortuary SOPs to ensure they reflect any changes in procedures as a result of the incident.</p> <p>In addition, the Mortuary Manager is advised to develop a documented 'end of day' procedure for staff to follow that includes actions and security checks they are required to undertake before they leave.</p>
2.	GQ6(a)	<p>The Mortuary Manager is advised to:</p> <ul style="list-style-type: none">• review and update the mortuary premises, security and access risk assessments to ensure they reflect the updated and additional security measures now in place.• include the deceased as potentially being at risk from relevant hazards identified in risk assessments.
3.	PFE1(d)	<p>The DI is advised to continue with the plan to:</p> <ul style="list-style-type: none">• remove the door to the viewing bay which is no longer used for viewings but houses a single fridge bank. This will mean the CCTV camera already installed in the body store will monitor access to this fridge bank as currently this area is obscured.• reposition existing CCTV cameras to help ensure all fridge doors can be monitored in all body store areas and there are no 'blind spots'.
4.	PFE1(e)	<p>The DI is advised to:</p> <ul style="list-style-type: none">• consider adding swipe card access to the internal doors in the mortuary to provide additional security and avoid having to use multiple keys for different doors.• continue with the plan to add a roller security door in front of the existing external mortuary door.• consider security options for the gate to the mortuary car park to better monitor and control access to this area, especially as staff work alone.• consider if fridge doors can be secured out of hours.

		<ul style="list-style-type: none"> • Increase the frequency of mortuary ‘end to end’ security audits from quarterly to monthly in line with existing swipe card and CCTV audits. The number of mortuary access records included in the audit should be representative for the level of activity.
5.	-	Path Links (Grimsby) is part of a pathology network with multiple mortuary premises which are licensed by the HTA. The HTA advises procedures and risk assessments relating to premises, security and access are reviewed across the network to provide assurance adequate measures are in place.

Background

Path Links (Grimsby) has been licensed by the HTA since August 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in May 2022

Since the previous inspection, the activity ‘making of a post-mortem examination’ has been removed from the licence in March 2024 at the request of the establishment as PM examinations no longer take place.

A decision to undertake a non-routine site visit was made by the Director of Regulation following a submission of a HTA Reportable Incident (HTARI) detailing a serious security breach at the mortuary of Diana Princess of Wales Hospital. Accordingly, this inspection focussed on the following standards relating to security: GQ1(a), GQ2(a), GQ6(a), PFE1(d) and PFE1(e). Scunthorpe General Hospital (the satellite site) was not inspected.

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:

Review of governance documentation

A review of governance documents relating to premises, security and access were reviewed following the site visit. A full review of the remaining governance documentation will be undertaken at the next routine inspection to be scheduled.

Visual inspection

The inspection team undertook a visual inspection of the premises which included the body store areas, office areas, viewing rooms and internal and external access points in to the mortuary.

Meetings with establishment staff

The inspection team met with the Designated Individual, the network Mortuary Manager, Group Director of Assurance, Director of Operations and the Chief of the Pathology Care Group.

Report sent to DI for factual accuracy: 16 April 2024

Report returned from DI: 28 April 2024

Final report issued: 1 May 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: 8 July 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.