



Stepping Hill Hospital
 HTA licensing number 12031

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 Stepping Hill Hospital	Not licensed	Licensed	Licensed
Mortuary	-	<i>Carried out</i>	<i>Carried out</i>
Pathology lab	-	-	-
Maternity	-	<i>Carried out</i>	<i>Carried out</i>
A&E	-	<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.

Stepping Hill Hospital (“the establishment”) was found to have met all the HTA standards. The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

The HTA advises the DI to consider the following to further improve practice:

Number	Standard	Advice
1.	GQ1(a)	The DI is advised to include lone working measures for mortuary staff when they attend for out of hours paediatric viewings in the on-call standard operating procedure.
2.	GQ2(a)	The DI is advised to increase the number of randomly selected out of hours mortuary access events in security audits.
3.	GQ6(a)	The DI is advised to detail the only circumstance in which staff would work alone i.e. paediatric viewings in the lone working risk assessment.
4.	PFE1(d)	The DI is advised to: <ul style="list-style-type: none">• continue with the plans to install additional CCTV cameras inside the mortuary to provide effective oversight of access to the body store fridges.• confirm that CCTV footage from the mortuary is not readily viewable by security staff.• change any security alarm or key pad door codes on a regular basis.

5.	PFE1(e)	<p>The DI is advised to:</p> <ul style="list-style-type: none"> • close and secure the gates to the mortuary yard out of hours to control access, especially as the establishment’s external body storage is located in this area. • find out who has key access to the gate at the side of the mortuary to help ensure this gate is not used to access the rear of the mortuary and yard area without authorisation. • continue with the plans to secure the fridge condenser units to mitigate the risk of these being tampered with.
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Background

Stepping Hill Hospital has been licensed by the HTA since September 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in July 2023.

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under the licence.

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

A decision to undertake an announced visit was made following a sector wide direction to all establishments to submit an Evidential Compliance Assessment (ECA) relating to security and access arrangements. The information provided by the establishment raised concerns relating security measures and processes. Accordingly, this inspection focused on the following standards: GQ1(a), GQ2(a), GQ6(a), GQ6(c), PFE1(d) and PFE1(e).

Review of governance documentation

The inspection team reviewed the establishment's ECA document provided by the DI ahead of inspection. Standard operating procedures, risk assessments and policies were reviewed. Audits relating to security and access were inspected as part of the review process.

Visual inspection

The inspection of the facility included a visual assessment of the mortuary, viewing facilities and external body storage areas.

Audit of records

No audits were conducted during the inspection process.

Meetings with establishment staff

No audits were conducted during the inspection process.

Report sent to DI for factual accuracy: 22 November 2024

Report returned from DI: 9 December 2024

Final report issued: 10 December 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.