Inspection report on compliance with HTA licensing standards
Inspection date: **26-27 January 2023**

Leicester Royal Infirmary

HTA licensing number 12337

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 **Leicester Royal Infirmary**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	*Carried out*	-
A&E	-	*Carried out*	-
Satellite site **Leicester General Hospital**	Not licensed	Licensed	Licensed

Mortuary	-	*Carried out*	*Carried out*
Satellite site **Glenfield Hospital**	Not licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*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 Leicester Royal Infirmary ('the establishment') had met the majority of the HTA's standards, six major and eight minor shortfalls were 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.

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 bodies is checked on release to the funeral service at all three sites. However, condition checks prior to this time are ad hoc, and there is no formal documented procedure to ensure these additional checks take place. In addition, an audit at Glenfield Hospital identified two bodies that required remedial actions, such as fresh sheeting.	**Major**
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	Although porters have been initially 'signed off' on completion of training, there is no on-going competency assessments. The establishment could not provide documentation showing that porters had received refresher training and competency (re)assessment. Furthermore, mortuary competency assessment intervals were inconsistent with the last assessment dates ranging from 2016 to 2021. The inspection team were therefore not assured that all staff had received up to date competency assessments.	**Major**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier	There are robust procedures of using three identifiers across activities at all three sites, with the exception of meeting families at the time of viewings. Whilst there are prompts to check three identifiers with families, the inspection team were not assured that this check takes place prior to the family entering the viewing room. This practice increases the risk of a family viewing the wrong body.	**Major**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		

a) The premises are clean and well maintained	**Leicester General Hospital** The age and subsequent deterioration of the mortuary transition areas at Leicester General Hospital means that there is a risk the areas cannot be maintained, cleaned and decontaminated effectively. Examples include: • Large areas of exposed plaster in the entrance and admission corridors. • Damaged wooden door frames with exposed wood. • Build-up of debris from outside, in the admission areas. • External doors are made of a porous material. **Glenfield Hospital** The post mortem room at Glenfield Hospital is for contingency only and does not form part of a regular cleaning schedule. The inspectors noticed areas where cleaning was not up to the expected standard. The area also included porous materials, which means there is a risk that the areas cannot be maintained, cleaned and decontaminated effectively. Examples include: • Build-up of debris in gullies and post mortem tables. • Broken porous cabinets and workbenches with exposed wood. • Storage of office equipment that are made of porous materials.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		

d) Fridge and freezer units are in good working condition and well maintained	**Leicester Royal Infirmary.** One bank of fridges at the Leicester Royal Infirmary have doors at both the post mortem room and body store ends of the units. When these trays are placed back into the fridges, the inspection team noted occasions where these would cause the other side to open. This is because the trays come into contact with the internal side of the doors, there are insufficient seals, and the fridges are not locked. This poses a risk to fridges being accidently left open with no oversight by mortuary staff. **Glenfield Hospital** The main bank of fridges is old, has rust patches and the seals on the doors have perished. Furthermore, the floors of the fridges are exposed, porous, concrete which means there is a risk they cannot be cleaned and decontaminated effectively.	**Major**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	Air flow within the post mortem room at Leicester Royal Infirmary was recorded as 8.67 air changes per hour in the most recent ventilation report. This was identified as a shortfall at the previous inspection, and whilst remedial actions were taken at the time, this has again fallen below the required 10 air changes per hour. This presents a risk to staff if there are undiagnosed infections.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework	There are no persons designate for areas other than the mortuary or laboratory. The inspection team is therefore not assured that the DI has oversight of regulated activities within the accident & emergency department or on maternity wards.	**Minor**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Matters relating to HTA-licensed activities are only discussed at high level mortuary meetings. There are no formalised governance meetings involving the designated Individual, persons designate or staff working under the licence. This means staff do not have the opportunity to attend HTA meetings relevant to them.	**Minor**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Whilst there is a documented schedule of audit, with plans to include extensive mortuary specific audits, at the time of inspection these were not in place and mortuary audits submitted were out of date.	**Minor**
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
a) Staff know how to identify and report incidents, including those that must be reported to the HTA	Non mortuary staff working in regulated areas, such as bereavement midwifes and porters, are unable to identify those incidents that are reportable to the HTA. However, adequate processes are in place to ensure the DI is made aware of all incidents from these areas, and that they would be reported or escalated as required.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	Whilst contingency arrangements are in place, Glenfield Hospital is currently using temporary units on a permanent basis to store bariatric bodies.	**Minor**
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 inspection team identified a single unit fridge, used for storing relevant material, in the mortuary at Leicester Royal Infirmary. Whilst this is temperature monitored, it is not connected to any alarm systems.	**Minor**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) Items of equipment in the mortuary are in good condition and appropriate for use	Hydraulic trolleys at Leicester General Hospital mortuary have large areas of exposed metal and rust. This presents a risk of ineffective decontamination.	**Minor**
d) Staff have access to necessary PPE	Staff do not have access to adequate PPE within the post mortem room at Glenfield Hospital. These facilities are not currently in use, however, to meet this standard, processes should be in place to ensure staff have suitable PPE if required.	**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)	Whilst staff were appropriately trained to take consent, the training events attended varied between individuals. The DI is advised to standardise this process to ensure they have approved these courses.
2.	GQ1(a)	The DI is advised to document the arrangements for setting up and using the contingency post mortem room at Glenfield Hospital to ensure it is fully equipped and safe for staff to use at short notice.
3.	GQ2(a)	Whilst mortuary access is audited as required, the DI is advised to include access to the mortuary as a regular review on the mortuary audit schedule.
4.	GQ6(b)	The DI is advised to audit and expand the risk assessment for lone working arrangements, to ensure the mechanisms currently in place, to contact security, are suitable and being used.
5.	PFE1(d)	Whilst the premises are secure, the DI is advised to lock any unused rooms adjacent to the Leicester General Hospital mortuary working areas to further minimise the risk of unauthorised access.
6.	PFE1(e)	Attendance to the mortuary is fully auditable by both CCTV and swipe card access. The DI is advised that the porter's key log includes a time the key is returned to further assist with this traceability.
7.	PFE1(e)	The DI is advised to assess the slow door closing mechanisms to restricted areas to further mitigate against the risk of unauthorised access.
8.	PFE3(a)	The DI and mortuary manager are advised to explore additional equipment options to aid patient transfer, and to ensure this is consistent across sites.

Background

Leicester Royal Infirmary has been licensed by the HTA since January 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in October 2018.

Since the previous inspection, there has been a change of designated individual. The mortuary at Leicester General Hospital has been decommissioned and facilities have been relocated to an existing external building, including two new body store areas, which has increased capacity. All post mortem examinations are now conducted at the hub site, of Leicester Royal Infirmary. The post mortem licence remains at Glenfield Hospital, and the facilities are used for contingency plans only.

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 all mortuary body storage areas at all three sites, the post mortem rooms at Leicester Royal Infirmary and Glenfield hospitals, viewing rooms and tissue storage areas. The inspection teams observed the processes for admission, release and viewing of bodies within the mortuaries.

Audit of records

Leicester Royal Infirmary (Hub site)

Audits were conducted for four bodies from refrigerated storage and one from freezer storage. Identification details on bodies were crosschecked against the information recorded in the mortuary electronic register and associated paperwork. Whilst one minor discrepancy was found regarding the address of a patient, this was not sufficient to amount to a shortfall and oral advice was given

to the establishment at the time of the inspection. Audits of traceability were conducted for tissue blocks and slides from five coroners consented cases. These included audits of the consent documentation for the retention of these tissues. No discrepancies were identified.

Leicester General Hospital (Satellite site)
Audits were conducted for four bodies from refrigerated storage. Identification details on bodies were crosschecked against the information recorded in the mortuary electronic register and associated paperwork. No discrepancies were identified.

Glenfield Hospital (Satellite site)
Audits were conducted for four bodies from refrigerated storage. Identification details on bodies were crosschecked against the information recorded in the mortuary electronic register and associated paperwork. No discrepancies were identified, however the inspection team noted that the condition of two bodies required attention and remedial actions had not been taken. *See shortfall GQ1c.*

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI, mortuary manager, APT, assistant technical officer, pathologist, mortuary porter, bereavement officer and bereavement midwifes.

Report sent to DI for factual accuracy: 15 February 2023

Report returned from DI: 27 February 2023

Final report issued: 08 March 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: 30 August 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.