

Worcestershire Royal Hospital
 HTA licensing number 12079

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 Worcestershire Royal Hospital	Licensed	Licensed	Licensed
Mortuary	<i>Carried out</i>	<i>Carried out</i>	<i>Carried out</i>
Accident and Emergency Department	-	<i>Carried out</i>	-
Satellite site Alexandra Hospital, Redditch.	Not licensed	Licensed	Licensed
Mortuary	-	<i>Carried out</i>	<i>Carried out</i>
Accident and Emergency Department	-	<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.

Although the HTA found that Worcestershire Royal Hospital (the establishment') had met the majority of the HTA's standards, five major and four 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
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	Although systems and processes are in place to maintain the traceability of babies at Worcestershire Royal Hospital, the establishment does not currently obtain formal confirmation of receipt when babies are transferred to other establishments for post-mortem examination.	Major

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.

d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access)	The inspection team found that CCTV coverage is insufficient to effectively monitor access during out-of-hours periods at both the main viewing suite entrance door and the funeral directors' shutter entrance at Worcestershire Royal Hospital. This presents a significant risk of a serious security breach going undetected out of hours.	Major
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	<ul style="list-style-type: none"> Refrigeration plant equipment at Worcestershire Royal Hospital is located in an insecure outside area and power switches for the plant equipment are not fitted with tamperproof mechanisms. Security arrangements at Alexandra Hospital do not adequately prevent unauthorised access from the viewing suite to restricted areas. A door situated in the viewing suite is secured by bolt lock mechanism which, if unlocked from inside the viewing suite, provides direct access to the body store. <p><i>The establishment submitted sufficient evidence to address this shortfall before the report was finalised.</i></p>	Major

PFE2 There are appropriate facilities for the storage of bodies and human tissue.

a) Storage arrangements ensure the dignity of the deceased	<p>With regard to the external bank of fridges, located in the carpark at Worcestershire Royal Hospital, the inspection team was not assured that the location and access arrangements sufficiently safeguard the dignity of the deceased. As such, under the current set up, the use of this area for body storage is deemed unsuitable.</p> <p><i>See advice item 1</i></p>	Major
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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	<p>Outside refrigerator (pods four and five) at Worcestershire Royal Hospital have failed risk assessments by the Trust's Health and Safety team due to the uneven surface in the loading bay area. As a result, the mortuary have been advised not to use these units. However, mortuary staff have left the pods powered on, and they are still being used when deemed necessary. Although the units were not in use on the day of the inspection, the inspection team expressed concerns that they continue to be used despite the advisory notice. This poses the risk of accidental damage to a body.</p> <p><i>See advice item 6</i></p>	Major

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		

<p>d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use</p>	<p>Whilst most SOPs have been reviewed regularly, some SOPs have not been reviewed in line with the documented review date.</p> <p>This includes SOPs for:</p> <ul style="list-style-type: none"> • MOR_identicalSimilarName • Mor_Safe use of the Desoutter saw • WHAT-PAT mortuary assistance out of hours • MOR_Babytransfertoffrommortuary • Contingency Plans-Staffing, Spaces & Escalation <p>To fully address this shortfall, the establishment should undertake a comprehensive review of all SOPs related to mortuary activities to ensure they are current and within their documented review periods.</p>	<p>Minor</p>
<p>h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff</p>	<p>Whilst HTA meetings are held, they do not appear to be conducted in a consistent or structured manner. Attendance among Persons Designated is also inconsistent, and not all staff involved in licensed activities are invited to attend. Furthermore, meeting minutes are not routinely disseminated to relevant staff unable to attend.</p>	<p>Minor</p>

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored

<p>a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis</p>	<p>Although risk assessments are in place, several are outside of their documented review dates. This includes, but is not limited to, risk assessments for:</p> <ul style="list-style-type: none"> • Post-mortem procedures • Transfer of histology samples to external agencies • Displaying bodies for identification <p>To fully address this shortfall, the establishment should undertake a comprehensive review of all risk assessments related to mortuary activities to ensure they are current and within their documented review periods.</p>	<p>Minor</p>
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PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.

<p>a) The premises are clean and well maintained</p>	<ul style="list-style-type: none"> • The inspection team identified that one refrigerator (pod one) at Worcestershire Royal Hospital was in an unclean condition and requires a thorough deep clean to meet expected standards. <i>The establishment submitted sufficient evidence to address this shortfall before the report was finalised.</i> <i>See advice 6</i> • The floor in the body store at Worcestershire Royal Hospital has two small areas where the flooring has split and lifted by the rear shutter entrance. This presents a potential route for water ingress and thereby increasing the risk of ineffective decontamination. <i>The establishment submitted sufficient evidence to address this shortfall before the report was finalised.</i> • The inspection team observed multiple doors across both sites exhibiting small areas of exposed wood, which inhibits decontamination. • A leak was identified in the ceiling of the body store at Alexandra Hospital. 	<p>Minor</p>
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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.	PFE2 a	The DI is advised to either explore alternative plans for a more suitable and appropriate location for the external fridge bank, or fully enclose its entrance to ensure that the dignity of the deceased is fully maintained during transfer and release.
2.	T1 c	The inspection team identified weaknesses in maternity processes for viewings and releases. Therefore, to strengthen protocols and mitigate the risk of a body being viewed or released in error, the HTA advises that maternity staff align their identity check procedures for these processes with those of the mortuary.
3.	C2 b	Adult consent training was scheduled to take place on the day of the unannounced inspection but was subsequently cancelled. The DI is advised to ensure that a new date is promptly arranged so that staff receive appropriate training.
4.	C1 a	The DI is advised to remove incorrectly used references to the 'Next of Kin' during the next document review.
5.	C1 a/b	The establishment is currently exploring the option of disposing of tissue not used for research purposes after a three-year period. The DI is advised to ensure that, if this change is adopted, the new procedure is incorporated into the relevant consent policy and SOPs, and that all staff involved in obtaining consent are updated and trained on the revised process.
6.	PFE3 a	<p>The DI is advised to reassess the suitability of the following to ensure ongoing safety, hygiene, and operational effectiveness:</p> <ul style="list-style-type: none">• The uneven surface in the loading bay area at Worcestershire Royal Hospital, to confirm that it provides a suitably level and stable platform for the safe transfer of the deceased to external storage.• The roof over pod one at Worcestershire Royal Hospital, to ensure it is adequately maintained and capable of preventing water runoff onto the fridge doors. Observations during the inspection

		<p>indicate a potential for water ingress, which may affect the structural integrity and hygiene of the storage area.</p> <ul style="list-style-type: none"> • The wooden plinths are located beneath the external pods at Worcestershire Royal Hospital, assessing their long-term suitability and identifying any maintenance or replacement needs. Regular checks should be undertaken to confirm they remain structurally sound. • The metal gates in the exterior storage area at Worcestershire Royal Hospital, to determine their effectiveness and appropriateness for their intended function, particularly with regard to staff safety. Consideration should be given to whether these gates pose a risk to staff safety during high winds.
7.	GQ3 a	Whilst funeral directors are only involved in the transportation element of the transfer to the external unit at Worcestershire Royal Hospital, the DI is advised to introduce training and competency assessments to ensure this is in place should their support be required in the process.
8.	GQ3 a	Although a process exists for out-of-hours (OOH) viewings, it is not currently implemented due to a lack of staff training. The DI is advised to ensure appropriate training is provided so that trained staff are available should an OOH viewing be required, or to formally remove this option if it cannot be supported.
9.	PFE3 b	The DI is advised to continue with plans to install a bariatric post-mortem table in the post-mortem room. This will ensure appropriate facilities are in place for the care and examination of bariatric cases.
10.		During the inspection, the temperature in the viewing suite at Worcestershire Royal Hospital was found to be excessively high. The DI is advised to consider appropriate adjustments to ensure this does not negatively affect families attending the mortuary for viewings.

Background

Worcestershire Royal Hospital has been licensed by the HTA since June 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in September 2022. Since the previous inspection, there has been a change to the Corporate Licence Holder Contact (CLHC) as of June 2024.

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 team undertook an unannounced visual inspection of the mortuary body storage areas, the post mortem room and the viewing suites at Worcestershire Royal Hospital and Alexandra Hospital. The inspection team also observed the process for release within the mortuary.

Audit of records

Audits were conducted for eight bodies from refrigerated storage across both sites. Identification details on bodies were crosschecked against the information recorded in the mortuary electronic register and associated paperwork. The inspection team identified no discrepancies. Audits of tissue traceability were also undertaken for four histology cases; the inspection team identified

no discrepancies.

Meetings with establishment staff

The inspection team met with staff carrying out activities under the licence, including the Mortuary Manager, a Senior APT, a Porter, a Pathologist, a consent seeker, and the Designated Individual.

Report sent to DI for factual accuracy: 24/06/2025

Report returned from DI: 08/07/2025

Final report issued: 11/07/2025

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.