Inspection report on compliance with HTA licensing standards
Inspection date: **25 and 26 August 2026**

Stoke Mandeville Hospital

HTA licensing number 12245

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 Stoke Mandeville Hospital	Licensed	Licensed	Licensed
Mortuary	Carried out	-	-
Maternity	-	Carried out	Carried out
A&E	-	Carried out	-
Satellite site Wycombe Hospital	Not licensed	Not licensed	Licensed
Mortuary (satellite site)	-	-	Carried out

Pathology Lab	-	-	Carried out

Summary of inspection findings

The HTA found the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation; the suitability of the DI named on the licence could not be fully assessed as they were not available for the duration of the inspection.

Although the HTA found that Stoke Mandeville Hospital ('the establishment') had met the majority of the HTA's standards, 1 critical, 8 major and 1 minor shortfalls were found against standards for Consent, Governance and quality systems, and Premises, facilities and equipment.

The establishment took immediate action in response to concerns raised by the inspection team regarding the suitability of the body storage facility at Wycombe Hospital. The facility had been erected following the decision to decommission the mortuary. The Human Tissue Authority had not been informed of the decision to relocate the mortuary at that time. To maintain the dignity of the deceased and ensure their safe and appropriate care, the establishment decommissioned the facility and implemented alternative storage arrangements.

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

All applicable HTA standards have been assessed as fully met.

Critical 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.		

a) The premises are clean and well maintained	There are significant areas of damage to the structure of the building and equipment in use: At Wycombe Hospital • There are significant areas of exposed wood • The floor is constructed of unsealed concrete with excessive amounts of unidentified granular material covering it. • The walls of the unit are of unfinished wooden construction • There was damage to the screening used to provide ventilation and to prevent the risk of access to the area by birds, rendering it ineffective. At Stoke Mandeville Hospital • The floor in the PM suite is uneven leading to areas of pooled water after cleaning • A tool trolley and step ladders in the PM suite have some areas of corrosion • There are wooden door wedges in use, and the door between the body store and PM suite has sustained damage leading to areas of exposed wood This poses the risk of ineffective cleaning and decontamination.	**Critical (cumulative)**

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) e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The inspection team was not assured that security arrangements were sufficiently robust to protect against unauthorised access to mortuary facilities or to provide appropriate oversight of visitors and contractors with a legitimate right of access. At Wycombe Hospital, access to the body store is via an area of the hospital used for the storage and processing of hospital waste and faulty equipment. This area is in continual use, with delivery and waste collection vehicles and staff regularly undertaking operational activities. The door to the body store opens directly into the fridge room, providing an unrestricted view into this restricted area when accessed. In addition, the construction and screening of the external walls of the body store were insufficient to prevent observation of activities within the fridge room by staff working in the offices opposite. Oversight of activity could also be obtained from an external area that, although not intended for public use, was accessible and could be entered by members of the public. As a result, licensable activities undertaken within the body store could be viewed by individuals without authorised access. The inspection team was not assured that the location of the body store, its access arrangements, security measures, and the level of oversight from surrounding areas sufficiently safeguarded the dignity of the deceased. As such, under the existing arrangements, the use of this area for body storage was considered unsuitable. While regular security audits are undertaken, the audit does not include a review of the key sign-in/sign-out log for access to the body store. The log had not been completed for the transfer of bodies undertaken on the first day of the inspection. Additionally, while there is an intruder alarm in operation, the alerting system was not routinely tested, and it was unclear when the code was most recently changed or if it was routinely set on exiting the body store.	

	Following discussion during the inspection, immediate steps were taken to remove the facility from operational use and implement direct transfers of deceased individuals to an alternative storage location. (See Shortfall against standard PFE2(e)). At Stoke Mandeville Hospital property belonging to deceased individuals stored within the external unit was accessible to staff entering the area and was not secured within locked storage and documents containing personal and identifiable information were visible and accessible within the external unit. Whilst access to the unit was controlled by a coded padlock, this did not provide an auditable record of entry. Additionally, the external route used to transfer deceased individuals from the hospital to the external unit was insufficiently screened, allowing transfer activities to be observed and creating opportunities for unauthorised access to the unit during transfer operations. An unsecured gate provided direct access to the external body storage area at the time of inspection. Although immediate action was taken to secure the gate, the arrangement represented an additional weakness in the security of the facility. Furthermore, part of the material used to cover the external storage unit had become detached, exposing the compressor switch and compromising the tamper-proof integrity of the installation. Across both sites, the inspection team identified that, although CCTV systems were operational within the body storage areas, footage was not monitored outside normal working hours. Additionally, security audits relied on still images captured from CCTV footage to identify individuals accessing the mortuary. This approach does not provide sufficient oversight of activities undertaken within restricted areas or assurance regarding the suitability of access and activity within those areas.	

Major shortfalls

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
b) There is a documented standard operating procedure (SOP) detailing the consent process	Whilst there is an SOP in place detailing the consent process, it does not reflect the hierarchy of qualifying relationships for those giving consent and uses the term Next of Kin. Additionally, it does not specify what training consent seekers should receive, and the frequency of training and competency assessments.	**Major**
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice	Training is available for those responsible for seeking consent for adult post mortems. However, it does not fully address the requirements of the HT Act and HTA's codes of practice as there is no reference to the hierarchy of qualifying relationships.	**Major**
c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual	The Inspection team were not assured untrained staff involved in consent seeking for adult post mortems are always accompanied by a trained individual. The establishment submitted sufficient evidence to address this shortfall before the report was finalised.	**Major**
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		

a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath.	There is no reference in the storage SOP to the frequency of condition checks for adult bodies in refrigerated storage. Additionally, there is a discrepancy between the SOP and staff practice.in the frequency condition checks are carried out for perinatal losses.	**Major**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised	There were no documents available to review indicating Porters and Funeral Directors who undertake activity under the licence have received regular refresher training. Additionally, for some records reviewed the date training was carried out had not been completed. This means Standard GQ3(c) cannot be assessed for these staff groups. The establishment submitted sufficient evidence to address this shortfall before the report was finalised.	**Major**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed	Some risk assessments did not provide sufficient detail on the actions taken to mitigate risks to bodies associated with an HTA reportable incident. Additionally, it is not always clear what actions need to be taken, who is responsible for each action or the timeline for completing these. This means identified risks may not be mitigated in a timely way. The establishment submitted sufficient evidence to address this shortfall before the report was finalised.	**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	The doors of the refrigerated storage units at Stoke Mandeville Hospital have sustained damage and are dented with areas of exposed metal. This was identified by the establishment before the inspection and there are plans in place for a refurbishment of the mortuary including the body store. The storage unit at Wycombe Hospital has areas of corrosion on the interior floor.	**Major (cumulative)**
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 refrigerated storage unit at Wycombe Hospital, and the fridge and freezer units used for storing tissue samples at Stoke Mandeville Hospital are not alarmed. Additionally, the fridge within the maternity department at Stoke Mandeville Hospital did not have remote monitoring and alarm systems in place. This limited the ability to provide timely notification to staff if storage temperatures fell outside the acceptable range. The establishment was instructed to suspend use of the fridge until appropriate monitoring arrangements could be implemented and compliance with the required standards demonstrated. Furthermore, there is no testing of the lower set range or testing of the alerting system out of hours in all storage areas across both sites.	
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	The plastic stretchers used in the external body store do not appear to be the correct size for the racking. Additionally, the stretchers are not compatible for use with the hydraulic trolleys and cannot be suitably anchored during the transfer of bodies. Posing the risk of accidental damage to a body. Furthermore, one of the tables used for post mortem examinations is not functioning, and the measuring sticks are broken.	**Major**

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.		
c) There are documented cleaning and decontamination procedures and a schedule of cleaning.	There were no cleaning records available to review for the fridge used to store bodies on maternity.	**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.

DI and CLH/LH suitability
The inspection team were unable to fully assess the suitability of the DI as they were not available for the duration of the inspection.

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

Number	Standard	Advice
1.	GQ1(c)	The DI is advised to review the body condition check documentation and consider incorporating recognised condition descriptors or an objective scoring system to support consistent recording and assessment of body condition over time.

2.	GQ1(h)	Govenance meetings with Persons Designated to discuss HTA business have recently been commenced, the DI is advised to continue with existing plans to increase the frequency of these to quarterly.
3.	GQ2(c)	Whilst stored tissue is regularly audited and includes a suitable sample size. The DI is advised to extend the audit of tissue to include the adherence with the SOP relating to the insertion of tracer slips when tissue is removed from storage for further analysis. Additionally, consideration should be given to the addition of older tissue samples in storage to the audit.
4.	GQ3(a)	Whilst porters were able to describe HTA reportable incidents (HTARI's), and there is signage within the mortuary, the DI is advised to add HTARI's to the existing training package.
5.	PFE1(a)	The DI is advised to continue with existing plans in place for the refurbishment of the mortuary at the hub site
6.	PFE1(c)	The DI is advised to add a list of areas cleaned to the cleaning log in the PM Suite
7.	PFE1(d)	The fridge used for the storage of pregnancy losses on maternity is in a secure area with restricted access. However, the DI is advised to consider if the fridge should be fitted with a locking mechanism.
8.	N/A	The DI is advised to review the procedure in place for the transfer of bariatric bodies from the ward to the mortuary to ensure it maintains the dignity of the deceased and adheres to best practice guidance.

Background

Stoke Mandeville Hospital has been licensed by the HTA since 2007. This was the sixth inspection of the establishment; and was unannounced. he most recent previous inspection took place in February 2024 and was focussed on a small selection of standards. The most recent inspection of all the standards took place in October 2022.

Since the previous inspection, there have been no significant changes to the licence arrangements or activities carried out under the licence. However, the has been a change to key personnel with a change to the CLHc and the DI in 2025. The establishment has plans in place for the refurbishment of the mortuary facilities, which are due to start in the next few weeks.

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, records of equipment servicing, audits, risk assessments, meeting minutes, temperature monitoring records, staff training records and reported incidents.

Visual inspection

At Stoke Mandeville Hospital (the hub site) the inspection included a visual inspection of the mortuary body store, viewing room, external storage unit, PM suite and the body storage area on maternity. The inspection team observed the processes for the transfer and release of bodies within the mortuary.

At Wycombe Hospital (the satellite site) the inspection included a visual inspection of the body store and the histopathology laboratory.

Audit of records

Stoke Mandeville Hospital

Audits were conducted for 7 bodies, Body location and identification details were crosschecked against the information recorded on the electronic system and relevant documentation. No discrepancies were found.

Wycombe Hospital
A body audit was not undertaken as there were no bodies in store.
Audits of traceability were conducted for tissue blocks and slides from 11 cases, including audits of the consent documentation for the retention and disposal of these tissues. At the time of the audit tissue blocks could not be located for two cases, these were located after the inspection team had left site.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence at the hub and satellite sites, including the Care Group Director, and lead for Pathology, the lead Nurse for the directorate, the interim Mortuary Manager, Deputy Mortuary Manager, APTs, trainee APT, Porters, and the Midwifery team including a bereavement midwife.

Report sent to DI for factual accuracy: 28 September 2026

Report returned from DI: 13 October 2026

Final report issued: 14 October 2026

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.