Inspection report on compliance with HTA licensing standards
Inspection date: **22 February 2024**

# 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**<br>**Stoke Mandeville Hospital** | Licensed | Licensed | Licensed |
| **Mortuary** | *Carried out* | *Carried out* | *Carried out* |
| **A&E** | - | *Carried out* | - |
| **Maternity** | - | - | *Carried out* |
| **Satellite site**<br>**Wycombe Hospital** | Licensed | Licensed | Licensed |
| **Mortuary** | - | - | *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.

The targeted unannounced site visit of Stoke Mandeville Hospital ('the establishment') found one major and two minor shortfalls against standards for governance and quality systems and premises, facilities, and equipment. These related to condition monitoring, recording of competency assessments and oversight of mortuary access.

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 |
|---|---|---|
| **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 | The mortuary at Stoke Mandeville hospital has two body store areas, the first is in the main building, and the second is a permanent external unit. Whilst the main mortuary has swipe card access, the external units require access via a key.<br><br>At the time of the inspection porters were required to sign for this key from main reception when completing transfers out of mortuary working hours. The inspection team noted that this key had been used, but not signed for, during the last nine mortuary out of hours transfers.<br><br>The current mortuary security audits do not routinely include review of CCTV footage or the use of the external unit key.<br><br>These findings highlight an increased risk of unauthorised access to the mortuary and external body store. The DI cannot provide assurance that all access is authorised and for a legitimate purpose.<br><br>*See advice item 1* | **Major** |

***Minor 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 | Procedures to monitor the condition of bodies are not always within a sufficient time period for mortuary staff to have oversight of any deterioration, and take appropriate action, as required.<br><br>The inspection team noted that condition checks were taking place on admission, following post mortem, and on release. Condition checks in between this time were ad hoc, and not always documented. | **Minor** |

| 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 | Whilst all staff had documented competency assessments, the inspection team noted that competency reassessment had not taken place since 2022. | **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(C) | The designated individual is advised to include the location of the CCTV cameras within the next security audit to ensure they have sufficient coverage of visitors within the restricted areas. |

**Background**

Stoke Mandeville Hospital has been licensed by the HTA since October 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in October 2022

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

A decision to undertake an unannounced visit was made by the HTA's Director of Regulation at a Regulatory Decision-Making meeting on 26 January 2024. This followed concerns relating to body storage and conditions that may impact dignity of the deceased. Accordingly, this inspection focused on the following standards: GQ1(c), GQ3(a), GQ3(c), GQ3(g), PFE1(e), PFE2(a), and PFE2(g).

**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 all staff training and competency assessments was undertaken. 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 both the main mortuary and external body storage areas. The inspection team completed an audit on the condition and postmortem reconstruction on six bodies within refrigerated storage. Further, the remaining 72 bodies from both refrigerator and frozen storage were visually checked. No concerns were identified.

*Meetings with establishment staff*

The inspection team met with staff carrying out processes under the licence. This included the Mortuary Manager, Anatomical Pathology Technologists, and Porter Supervisor. Feedback was discussed with the mortuary team, Head of Nursing Specialist Services, Designated Individual, and the Corporate Licence Holder contact.

**Report sent to DI for factual accuracy: 13 March 2024**

**Report returned from DI: 27 March 2024**

**Final report issued: 05 April 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: 1 August 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.