Inspection report on compliance with HTA licensing standards
Inspection date: **24 April 2024**

The Hillingdon Hospital
HTA licensing number 12328

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
The Hillingdon Hospital	Not licensed	Licensed	Licensed
Mortuary	-	*Carried out*	*Carried out*
Maternity	-	*Carried out*	-
A&E	-	*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 The Hillingdon Hospital ('the establishment') had met the majority of the HTA's standards, five minor shortfalls were found against standards for, governance and quality systems, and security.

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

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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.	The establishment does not have an SOP for release of bodies from the maternity unit. Whilst there is an established process for release from the maternity unit there is no documented procedure to support this. *(See advice item 1)*	**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	Maternity staff do not have competency assessments for viewing or releasing on the maternity ward.	**Minor**

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	Risk assessments do not include details of responsible individual for each action, deadlines for completing actions and confirmation that actions have been completed.	**Minor**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The maternity unit send specimens to external laboratories. Whilst there is an audit trail to the point of dispatch, there is no confirmation of receipt. The DI is advised to introduce a system to ensure specimens have been received.	**Minor**

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	Porters are required to sign for a key and swipe card from the security office when completing transfers out of mortuary working hours. The inspection team noted that this key had been used, but not signed for on three occasions. Whilst audits of swipe access and CCTV confirm the entry and exit times of individuals the establishment does not audit the security key log.	**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.	GQ1a	Whilst SOPs are well written some steps in processes lack detail. The DI is advised to consider introducing greater detail into SOPs for clarity.
2.	T1b	The mortuary uses a combination of paper and electronic records to track bodies. The electronic system holds a unique identification number for each record. The electronic record can only be accessed on the computer in the mortuary office and requires the use of an additional written document to transfer data between the fridge room and computer. The DI is advised to consider installation of a computer in the fridge room to enable the electronic system and its unique identification number to strengthen traceability. The establishment use individual trays for babies which are not individually numbered. The DI is advised to number these trays to strengthen traceability.
3.	T1c	The DI is advised to specify which three identifiers should be used in every SOP relating to the movement and transfer of bodies
4.	PFE1d	The DI is advised to relocate the magnetic locking mechanism from the external aspect of the viewing room door to the internal aspect. This will strengthen security provisions.

Background

The Hillingdon Hospital is licensed for the removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes.

The Hillingdon Hospital has been licensed by the HTA since September 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in September 2021.

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

Six standards (GQ1(b), T2(a), T2(b), T2(c), T2(d), PFE3(c)) out of the total 72 were **not** covered during the inspection. These standards were not applicable as the establishment does not undertake PM examination or store relevant material taken at PM examination.

Review of governance documentation

The inspection team reviewed the establishment's self-assessment document provided by the DI ahead of inspection. Standard operating procedures, risk assessments and policies, audit schedules, cleaning record forms and meeting minutes were inspected as part of the review process.

Visual inspection

The site visit included a visual assessment of the mortuary, viewing facilities and post mortem room.

Audit of records

A traceability audit of four bodies in storage was undertaken. This included a body in long term storage. Details were cross checked against identity bands, the mortuary register and an electronic database. No discrepancies were found.

Meetings with establishment staff
The assessment team met with staff carrying out activities under the licence, including the DI, the Mortuary Manager, a Porter, a Consultant Paediatrician and midwifery consent takers.

Report sent to DI for factual accuracy: 30 April 2024

Report returned from DI: 7 May 2024

Final report issued: 7 May 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: 22 July 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.