Inspection report on compliance with HTA licensing standards
Inspection date: **28-29 September 2021**

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	Licensed	Licensed	Licensed
Mortuary	-	*Carried out*	*Carried out*
Maternity	-	*Carried out*	-
A&E	-	*Carried out*	-

Summary of assessment 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 Consent, Governance and Quality systems, and Traceability. These related to governance documentation, staff competency assessments and traceability of bodies and tissues sent off-site.

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
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
d) Competency is assessed and maintained.	Competency has not been assessed and maintained for those seeking consent for perinatal post mortem (PM) examination.	**Minor**

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.	Standard operating procedures (SOPs) covering traceability of bodies lack sufficient detail of the checks performed and the types of identifiers of the deceased used. This includes but is not limited to: • SOP HH-03 Moving deceased between storage areas. This SOP does not include detail of the ID check performed before moving a body to another location within the department. • SOP HH-01 Receipt and release of the deceased. This SOP does not consistently state that three identifiers of the deceased are checked and agreed with the funeral director prior to release.	**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.	Out-of-hours site managers involved in licensed activities have no on-going competency assessments following initial training and sign-off.	**Minor**
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents.	The establishment's Human Tissue Authority reportable incident (HTARI) SOP does not detail the timeframe in which HTARIs are required to be reported to the HTA.	**Minor**
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.	Relevant material from the maternity department is sent off-site for analysis. The establishment was unable to provide assurance that they receive confirmation once this has arrived at its intended destination. In addition, the mortuary does not receive confirmation that bodies for Coroner PM examination have arrived at the intended destination.	**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.	C1(a)	The DI is advised to ensure the policy for seeking consent for perinatal PM examination includes detail of appropriate persons who can give consent, in the event the woman concerned is unable to be involved. The DI is advised to ensure that checklists used in conjunction with the SUDIC protocol clearly detail that removal of relevant material is only to be undertaken following discussion and authorisation from the Coroner.
2.	GQ2(a)	The DI is advised to increase the frequency of body traceability audits undertaken in the mortuary. Further advice was given to increase the number of bodies audited during the ‘patient pathway’ audits, so that findings are representative of more than one body.

3.	GQ5(a)	The DI is advised to review HTA requirements for the reporting of ‘Near-Miss’ HTARIs. This would ensure consideration is given as to whether an incident with no apparent adverse outcome requires reporting to the HTA.
4.	GQ6(a)	The DI is advised to include detail in risk assessments of the requirement to report incidents to the HTA, where this is applicable. The DI is further advised to review risk assessments to ensure there is adequate detail of control measures in place.
5.	PFE2(c)	The DI is advised to record the condition checks of bodies. This should include the date of the check, the condition of the body and include sufficient detail of actions taken in relation to expediting release from the mortuary and/or actions taken to prevent deterioration to the body.
6.	PFE2(f)	The DI is advised to introduce temperature monitoring during weekends and bank holidays. This would help to highlight any deviations from optimal temperatures and allow relevant action to be taken prior to any potential unit failures.

Background

The Hillingdon Hospital has been licensed by the HTA since September 2007. This was the third inspection of the establishment; the most recent previous inspection took place in August 2015.

Since the previous inspection, PM examinations are no longer undertaken at this establishment. The licence for this activity was revoked in 2018. Bodies requiring PM examination are now moved to another HTA licensed premises. Holdings of relevant material (blocks and slides) retained with appropriate consent from PM examinations prior to 2018 have been moved to another HTA licensed premises for storage and management.

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

Seven standards (GQ1(b), GQ2(a), T1(g), T2(a), T2(b), T2(c), T2(d)) out of the total 72 were **not** covered during the inspection. These standards were not applicable. The establishment does not undertake PM examination or store relevant material taken at PM examination.

Review of governance documentation

The assessment team reviewed the establishment's self-assessment document provided by the DI in advance of the inspection. Policies and procedural documents relating to licensed activities for the mortuary were reviewed. Ventilation reports, traceability audits, risk assessments, meeting minutes, incidents, consent seeking procedures and information for relatives giving consent were also reviewed.

Visual inspection

No visual inspection was undertaken as part of this inspection.

Meetings with establishment staff

The assessment team met with staff carrying out processes under the licence, including mortuary staff, portering staff, staff involved in the consent seeking process, some of the Persons Designated named on the licence and the DI.

Report sent to DI for factual accuracy: 27 October 2021

Report returned from DI: 11 November 2021

Final report issued: 16 November 2021

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 Virtual Regulatory Assessment Report.

Date: 4 May 2022

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 site visit 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 site visit.

   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 site visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine site visit inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.