Inspection report on compliance with HTA licensing standards
Inspection date: **27 June 2024**

Forensic Access

HTA licensing number 12602

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 **Forensic Access**	Not licensed	Not licensed	Licensed
Pathology lab			*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 Forensic Access ('the establishment') had met the majority of the HTA's standards, two cumulative major, two major and two minor shortfalls were found against standards for Governance and quality systems and Premises, facilities and equipment. Five of the shortfalls (one cumulative major and three major) relate to findings from the last inspection in 2018. The HTA is concerned that adequate steps were not taken to address these findings in the intervening period and to embed suitable practices at the establishment.

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
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.	Some SOPs relating to activities are not reflective of current practice or do not contain sufficient details of procedures. For example: • Control of clinical material; • Returns process; and • Histology – incident complaint reporting HTARIs. *This shortfall was identified at the previous inspection in 2018.*	**Major**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	There are no formal governance meetings between staff and the DI. This means that HTA-related activities, any adverse events or other governance issues are not being discussed in a formal setting. This makes it difficult to identify areas for improvement and allocate tasks to staff to undertake improvements. *This shortfall was identified at the previous inspection in 2018.*	**Major**
GQ2 There is a documented system of audit		

a) There is a documented schedule of audits	The scope of the audit schedule for licensed activities conducted under the licence is limited. The audit schedule does not include sufficient audits to check compliance with documented procedures, the completion of records or security of the premises. The establishment cannot therefore provide assurance that activities are conducted in accordance with documented procedures. *This shortfall was identified at the previous inspection in 2018.*	**Cumulative Major**
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	The audit template used for audits does not cover all areas of the procedure, or record sufficient detail to ensure that the audit is robust.	
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis	Not all procedures relating to licensed activities have been risk assessed. These include but are not limited to: • major equipment failure. • incidents leading to unplanned closure of mortuary/inability to deliver services. • serious security breach. This is not an exhaustive list of the risks not assessed and, to fully address this shortfall, the establishment should review all risk assessments relating to all licensed activities to ensure that all risks have been identified. *This shortfall was identified at the previous inspection in 2018.*	**Cumulative Major**
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	Not all mitigating controls have been included in the risk assessment. *This shortfall was identified at the previous inspection in 2018.*	

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity	Deviations from documented SOPs are not recorded or monitored.	**Minor**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept	Key items of equipment are not regularly serviced.	**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.	GQ2(c)	The DI is advised to increase the robustness of the returns procedure by recording the confirmed number of blocks and slides and the initial of the staff member on the form. The DI is advised to add to the histology form an area for pathologists to tick that the standard panel of tissue types have been removed during post mortem examination, so that staff can check that the correct number of tissue has been received.

2.	GQ3(c)	The DI is advised to include in staff competency assessments how to identify HTA reportable incidents (HTARIs). The DI is advised to include more detail in the competency assessment of what staff have been assessed against for example, which SOP. The competency assessments should also include the month that the assessment took place and staff initials.

Background

Forensic Access has been licensed by the HTA since December 2012. This was the third inspection of the establishment; the most recent previous inspection took place in August 2018.

Since the previous inspection, the establishment have ceased all coronial work.

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

Standards C1 a-g, C2 a-d, GQ1 b and c, T1 a-b and d-f, T2 (b), PFE1 b and c, PFE2 a-h, PFE3 b, c and e were not assessed as the establishment do not seek consent or store the deceased. The remaining 40 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 laboratories, records demonstrating the servicing of equipment, audits, risk assessments, ventilation record, reported incidents and staff training records.

Visual inspection

The inspection included a visual inspection of the laboratories.

Audit of records

Audits of traceability were conducted for tissue blocks and slides from five cases, including audits of the returns documentation of these tissues. Whilst two minor discrepancies were found, this was not sufficient to amount to a shortfall but oral advice was given to the establishment at the time of the inspection.

Report sent to DI for factual accuracy: 7 August 2024

Report returned from DI: 20 August 2024

Final report issued: 23 August 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: 20 January 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.