Inspection report on compliance with HTA licensing standards
Inspection date: **11 June 2025**

State Pathologist's Department
HTA licensing number 12493

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
State Pathologist Department	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
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 State Pathologist's Department ('the establishment') had met the majority of the HTA's standards, one major and six minor shortfalls were found against standards for CCTV access, and governance and quality systems.

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.		
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)	Whilst processes are in place for continued monitoring, staff working under the licence, including the designated individual, do not have direct access to recorded CCTV footage. The inspection team, therefore, did not receive evidence of regular audits that use CCTV to monitor access to the regulated areas of the mortuary or laboratory. This poses a risk to staff not having oversight of who has accessed the mortuary and laboratory out of hours.	**Major**

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.	Documented policies and SOPs cover the majority of mortuary activities; however, they lack sufficient detail, and do not reflect procedures observed on site. These include, but are not limited to: • Transferring of bodies internally between fridges and freezers. • Techniques, and recording of, limited post mortem reconstruction at the request of the funeral service.	**Minor**
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	The condition of bodies is checked on a regular basis, however there is no formal process of recording the condition and any required follow up actions.	**Minor**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Whilst the mortuary team have daily discussions, there are no regular documented governance meetings that discuss HTA-licensed activities.	**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	All mortuary and laboratory staff have documented competency assessment. However, this does not extend to contracted funeral staff employed by the Coroners Service to transfer bodies into the mortuary. Contracted funeral staff have not received any competency assessment since their initial induction training in 2021.	**Minor**
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	The majority of risk assessments have not been reviewed since 2022. Mortuary risk assessments lack sufficient detail, and have inconsistent risk scoring, that does not reflect the risk or control mitigations in place.	**Minor**
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	All areas of the mortuary are cleaned on a regular basis, however whilst all areas appeared clean, this cannot be evidenced with a completed schedule of cleaning.	**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(a)	The mortuary manager is advised to review all SOPs to ensure they contain all relevant steps in the procedures they outline.
2.	GQ1(c)	The designated individual and mortuary manager are advised to document all requests from families and funeral staff where the release procedure would deviate from the SOP. This includes that of limited reconstruction following a post mortem.
3.	GQ1(d)	The designated individual is advised to review the templates used for SOPs and risk assessments. The layouts are currently inconsistent and do not always include key version control information.
4.	GQ5(a)	The mortuary manager is advised to report all incidents relating to the transfer of bodies into the mortuary to the HTA for oversight, to determine if they meet the criteria for an HTA reportable incident.
5.	PFE1(a)	The mortuary floor currently has cracks and signs of wear, necessitating specialised decontamination and cleaning methods. The designated individual is advised to monitor the floor's condition, as further deterioration may result in a shortfall to standard PFE1 (a).

Background
State Pathologist's Department has been licensed by the HTA since July 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in September 2022.

Since the previous inspection, there has been a change to the corporate licence holder contact in June 2025.

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
61 out of the 72 HTA licensing standards were covered during this inspection (published 3 April 2017). Standards regarding consent were not applicable, as the establishment does not seek consent for, or undertake, consented post mortem examinations.

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, cleaning records for the mortuary, records of servicing of equipment, audits, risk assessments, meeting minutes, reported incidents, and training records for staff.

Visual inspection
The inspection included an unannounced visual assessment of the laboratory and mortuary including the access points, mortuary fridge rooms, post mortem room, contingency storage areas, viewing facilities and tissue storage areas. The inspection team observed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records
Audits were conducted for three bodies from refrigerated storage and one from frozen storage. Identification details on bodies were cross-checked against the information recorded on the electric mortuary register and associated paperwork. No discrepancies were identified.

Audits of traceability were conducted for tissue blocks and slides from five coronial cases. These included audits of the consent documentation for the retention of these tissues. No discrepancies were identified.

Meetings with establishment staff
Staff conducting processes under the licence were interviewed including the Designated Individual, Mortuary Manager, Pathology Manager, and Anatomical Pathology Technologist.

Feedback was provided on 29 July 2025 to the Corporate Licence Holder Contact, Designated Individual, Mortuary Manager, Laboratory Manager, Administration Manager and Biomedical Scientist.

Report sent to DI for factual accuracy: 07 August 2025

Report returned from DI: 12 August 2025

Final report issued: 13 August 2025

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: 15 January 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.