

State Pathologist 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
Hub site State Pathologist Department	Licensed	Licensed	Licensed
Mortuary	<i>Carried out</i>	<i>Carried out</i>	<i>Carried out</i>
Pathology lab			<i>Carried out</i>

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.

State Pathologist Department ('the establishment') was found to have met all HTA standards.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

The HTA advises the DI to consider the following to further improve practice:

Number	Standard	Advice
1.	GQ1(a)	The DI is advised over the next review period of the standard operating procedures to ensure that current practice is reflected e.g., any errors found or non-completeness of the admission sheet to contact the appropriate person to correct or collect the information.
2.	GQ2(a)	The DI is advised to add to the audit schedule a security audit to interrogate the swipe card access of authorised staff.
3.	GQ3(c)	The DI is advised to add to the Coroner's contracted funeral director's competency assessment template how to identify and report HTA reportable incidents to appropriate staff.
4.	GQ5(a)	The DI is advised to create an aide memoire of applicable HTA reportable incidents and who to report incidents to, for displaying in the body store as a reminder for Coroners contracted funeral directors.
5.	T1(a)	The DI is advised to use the body bag insert to store the toe tag that is created when admitting deceased into the mortuary to prevent any potential loss of tag prior to the body bag being opened.
6.	T1(b)	The DI is advised to record the movement of deceased e.g., from fridge to freezer either in the mortuary register or electronic system for audit traceability purposes.
7.	T1(d)	The DI is advised to indicate same/similar name in either the mortuary register or electronic system as well as on the fridge door as an additional visual aide for staff.
8.	T1(h)	The DI is advised to look at implementing a timeframe on when to contact the external establishment for return of organs in a timely manner once the report is received.

9.	T2(d)	The DI is advised to record in the blocks and slides boxes the date of disposal.
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Background

The State Pathologist Department is licensed for the making of a PM examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes.

The State Pathologist Department has been licensed by the HTA since July 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in January 2020.

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

Standards C1a-g and C2a-d were not assessed as they are not applicable.

This was a focussed inspection on staff training and traceability of bodies and tissue. Standards GQ3a-g, T1a-h and T2a-d were assessed

Review of governance documentation

The inspection included a review of the establishment's governance documentation relating to admission and release of deceased. This included procedural documents relating to admission and release of deceased and staff training records.

Visual inspection

The inspection included a visual inspection of the mortuary body store, PM room and viewing room.

Audit of records

Audits were conducted for three bodies in refrigerated storage and one in long term freezer storage. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and electronic database. No discrepancies found.

Audits of traceability were conducted for tissue blocks and slides from six PM cases (four forward and two reverse), including audits of the consent documentation for the retention of these tissues and organs. No discrepancies found.

Materials held for the police

Under section 39 of the HT Act, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. Any information provided by the establishment in relation to police holdings have been shared with the Home Office, but do not appear in the report as they are outside the scope of the HT Act.

Report sent to DI for factual accuracy: 21 September 2022

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 28 October 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 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.