Inspection report on compliance with HTA licensing standards
Inspection date: **12 January 2023**

UKHSA Colindale

HTA licensing number 12459

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 **UKHSA (Colindale)**	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 UKHSA Colindale ('the establishment') had met the majority of the HTA's standards, one major and three minor shortfalls were found against standards for, Governance and quality systems, Traceability and Premises, facilities and equipment.

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 standard

Major shortfalls

Standard	Inspection findings	Level of shortfall
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
a) Staff know how to identify and report incidents, including those that must be reported to the HTA	Persons designate were not fully aware of HTARI reporting categories. See advice and guidance re Updating SOP 090.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall

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).	There is no procedure in place to record the receipt of samples returned on the LIMS system	**Minor**

T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		
d) The method and date of disposal are recorded	The method of disposal is not recorded on the LIMS system.	**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.	GQ5	QO90 10-22 Whilst SOP provides a link to HTA HTARI reporting guidance. This is an old link and does not connect to website. The SOP should set out HTARI categories relevant to UKHSA to include disposal or retention of an organ or tissue against the express wishes of the family, loss of an organ or tissue, major equipment failure, serious security breach.

Background
UKHSA is licensed for the storage of bodies of the deceased and relevant material for use for scheduled purposes.

UKHSA has been licensed by the HTA since 2007. This was the third inspection of the establishment; the most recent previous inspection took place in April 2018.

Since the previous inspection, the establishment has changed name from Public Health England (PHE) to United Kingdom Health Security Agency (UKHSA).

Standards assessed against during inspection
44 out of the HTA's 72 standards were covered during the assessment. Standards covered at this inspection are listed in Appendix 3. As the establishment only store post-mortem samples for analysis on behalf of other establishments, standards relating to consent, post-mortem and body storage were not applicable. These standards have been deleted from the table.

Review of governance documentation
The Regulation Manager reviewed the establishment's self-assessment document provided by the DI in advance of the inspection and associated documentation including policies, procedural documents, audit documents and risk assessments.

Visual inspection
The Regulation Manager undertook a visual inspection of the premises which included the laboratories, sample storage and sample archive areas.

Audit of records
The Regulation Manager undertook audits of traceability for eight post mortem cases. Samples, records and consent documentation were crosschecked. No discrepancies were identified.

Meetings with establishment staff
The Regulation Manager met with staff carrying out activities under the licence. This included the Quality Manager, Laboratory Managers and the Designated Individual.

Report sent to DI for factual accuracy: 6 February 2023

Report returned from DI: 8 February 2023

Final report issued: 8 February 2023

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: 2 May 2023

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.

Appendix 3: Standards assessed during inspection

Governance and quality systems
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.
d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use.
e) There is a system for recording that staff have read and understood the latest versions of these documents.
f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity.
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework.
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff.
GQ2 There is a documented system of audit
a) There is a documented schedule of audits.
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these.

c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why to enable timely disposal of tissue where consent has not been given for continued retention.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks
a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised.
b) There are clear reporting lines and accountability.
c) Staff are assessed as competent for the tasks they perform.
d) Staff have annual appraisals and personal development plans.
e) Staff are given opportunities to attend training courses, either internally or externally.
f) There is a documented induction and training programme for new mortuary staff.
g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment’s policies and procedures.
GQ4 There is a systematic and planned approach to the management of records
a) There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.
b) There are documented SOPs for record management which include how errors in written records should be corrected.

c) Systems ensure data protection, confidentiality and public disclosure (whistleblowing).
GQ5 There are systems to ensure that all untoward incidents are investigated promptly
a) Staff know how to identify and report incidents, including those that must be reported to the HTA.
b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents.
c) The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.
d) Information about incidents is shared with all staff to avoid repeat errors.
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.
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.
c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register.

Traceability

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 traceability system ensures that the following details are recorded: i. material sent for analysis on or off-site, including confirmation of arrival ii. receipt upon return to the laboratory or mortuary iii. the number of blocks and slides made iv. repatriation with the body v. return for burial or cremation vi. disposal or retention for future use
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.
T2 Disposal of tissue is carried out in an appropriate manner an in line with the HTA's codes of practice.
a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete.
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary.
c) Disposal is in line with the wishes of the deceased's family.
d) The method and date of disposal are recorded.

Premises, facilities and equipment
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue
a) The premises are clean and well maintained.
c) There are documented cleaning and decontamination procedures and a schedule of cleaning.
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).
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access.
PFE2 There are appropriate facilities for the storage of bodies and human tissue
b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity.
d) Fridge and freezer units are in good working condition and well maintained.
e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper and lower set range.
f) Temperatures of fridges and freezers are monitored on a regular basis.
i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods.

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored
a) Items of equipment in the mortuary are in good condition and appropriate for use.
d) Staff have access to necessary PPE.
f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables are subject to regular maintenance and records are kept.