Site visit inspection report on performance against HTA quality standards
City of Westminster Public Mortuary
HTA licensing number 12188

Licensed under the Human Tissue Act 2004 for the

- **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; and**
- **storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose**

3 August 2011

Executive Summary

A site visit inspection of City of Westminster Public Mortuary (the establishment) was carried out by the HTA on 3 August 2011.

The establishment was found to meet the majority of HTA standards across applicable areas: governance and quality; and premises, facilities and equipment. Consent and disposal standards are not applicable to the establishment's activity.

Three minor shortfalls were found in relation to governance and quality systems. The details of these are included in the report along with advice given to the Designated Individual (DI) on a number of the HTA standards relating to governance and quality. Examples of strengths or good practice are included in the concluding comments section of the report.

The HTA found the Designated Individual, the Licence Holder, the premises and the practices to be suitable in accordance with the requirements of the legislation.

All reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

The HTA licence (licensing number 12188) is held by Westminster City Council and covers the licensable activities which take place at the City of Westminster Public Mortuary (the establishment). Post-mortem (PM) examinations and removal of any tissue samples from the deceased at the establishment are undertaken on behalf of HM Coroner for Inner-West London Coroner's District.

A site visit inspection of City of Westminster Public Mortuary was undertaken on 3 August 2011. This was the second routine HTA inspection of the establishment; the previous inspection having taken place in August 2007. The inspection included interviews with the Pest Control and Mortuary Assistant Manager (DI), a consultant pathologist who carries out PM examinations at the establishment, a senior and a trainee anatomical pathology technician (APT) and the coroner's officer.

The establishment carries out approximately 550 coronial PM examinations each year, of which ten are Home Office cases. PM examinations are carried out by independent pathologists contracted by HM Coroner. Tissues removed for histological examination are done so under the authority of the Coroner and no human tissue is stored on the premises for future use for scheduled purposes under the HT Act.

The mortuary has the capacity to store 106 bodies (90 standard refrigeration spaces, six extra width spaces, five high risk spaces and five high risk freezer spaces). The refrigeration unit and the temperature monitoring system was replaced in 2008. Building refurbishment was also completed in 2008 and the mortuary now includes a dedicated high risk facility.

A traceability audit was carried out of two bodies stored at the mortuary. Identification tags were checked and all associated paper records were reviewed – no discrepancies were noted. In addition, records associated with tissues that were awaiting collection by the courier to be sent for histological analysis were reviewed. No anomalies were noted.

Meeting the HTA's licensing standards

The HTA developed its licensing standards with input from its stakeholders, in order to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA expects licensed establishments to meet these standards.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a licensing standard is not met, the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor' (see Appendix 3: Classification of the level of shortfall).

Unless otherwise advised, the establishment is required to inform the HTA within 14 days of the receipt of the final report of the corrective and preventative actions that will be taken to ensure that the improvements are addressed. A template for this purpose is provided as a separate Word document.

HTA standards not met

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	The Daily Operations Manual contains a comprehensive set of policies and standard operating procedures used in the mortuary. The documents were last reviewed in 2008 despite it being documented that review would take place annually. The manual is not currently being used as intended because staff are not confident that the information contained within documents is an up to date reflection of current procedures and practices in the mortuary. The HTA notes that the establishment views this as a priority and is in the process of updating the manual; therefore the shortfall has been assessed as minor.	**Minor**
GQ6 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	Staff have been trained in the requirement to report serious untoward incidents (SUIs) to the HTA. SUIs have also become a standing agenda item on mortuary team meeting agendas. The HTA identified both of these as good practice. It was however noted that the standard operating procedure for reporting incidents needs to be updated to include when and how to report SUIs to the HTA. This requirement has been identified by the establishment's staff and is included in the review of the Daily Operations Manual.	**Minor**
GQ7 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	The establishment has a comprehensive set of risk assessments in relation to risks associated with the health and safety of staff. However, risks relating to the safety of the deceased and the conduct of licensable activities are not assessed (see advice and guidance below).	**Minor**

Advice

Below are matters which the HTA advises the DI to consider.

No.	Standard	Advice
1.	GQ2	The HTA recommends that the DI considers introducing an audit of records. Some records are audited as part of the weekly audit carried out by the senior APT, however, given that unique identifier number and other information is transcribed every week from the daily work diary, the inspection team considered it would be good practice to carry out a more thorough audit of records periodically. This may include both vertical and horizontal audits.
2.	GQ3	There have recently been a number of new pathologists carrying out PM examinations at the mortuary, either as a result of annual leave cover or for other reasons. There is currently no induction for new pathologists in order to familiarise them with the procedures and practices at the mortuary. The pathologists are not under the direct control of the mortuary and as such, it was suggested that the DI introduces an induction to mortuary procedures & practices that could be offered to new pathologists and this recorded in mortuary documents.
3.	GQ5	The form used by the Coroner to record the wishes of the relatives when organs or tissues are removed for histological examination to determine the cause of death in a coroners PM examination has been very recently amended. The new form combines the options of archive and disposal. These forms accompany organs and tissue when they are sent from the mortuary for histological analysis and are used to inform staff at the histopathology laboratories what the relatives wishes are when the case has concluded. The HTA is concerned that having these two options combined makes it difficult to interpret the relatives' wishes and therefore to carry out their wishes appropriately. It is recommended that the DI discuss the possibility of amending the form with the Coroner's office to separate the options for: - disposal - retention for use in research or education / training.
4.	GQ6	The establishment is advised that in the unusual event that tissues from the same patient are sent separately for histopathological examination, a copy of the Coroner's form detailing the relative's wishes should accompany both sets of tissues. This will prevent tissues that arrive separately having no associated documentation that outlines the relative's wishes. The DI should consider maintaining a log of incidents that occur in the mortuary in order to identify any trending
5.	GQ7	The DI is encouraged to consider risks associated with the mortuary's practices using the list of reportable serious untoward incidents (SUIs) as a starting point. This will help to identify any potential risks to the safety and dignity of the deceased, allowing preventative measures to be identified and put in place to militate against these. Anatomical pathology technicians (APTs) carry out external examination of bodies prior to evisceration and findings are discussed with the pathologist, usually by telephone, before proceeding with the evisceration. It is

		recommended that APTs document the detail of these conversations and that the SOP on post-mortem examination is updated to reflect this practice. Furthermore, the HTA advises that, for the avoidance of doubt, staff are provided with written guidance on the circumstances in which they should not proceed with evisceration and instead wait for the arrival of the pathologist.
6.	PFE2	It is advised that the map of restricted areas is updated to include transitional zones.
7.	PFE3	The refrigeration units were temperature monitored and alarmed. However, during the inspection, the HTA discovered that despite an audible alarm sounding locally, there is no provision for an out of hours response. The DI is advised to consider the risks associated with the lack of out of hours provision and take appropriate action to mitigate these.

Concluding comments

The establishment has made significant progress since the last inspection four years ago. During this time, the mortuary has overcome staffing issues and undergone significant building work. The mortuary now has a dedicated high risk PM suite and the refrigerated body storage units have been replaced. The HTA was particularly impressed with the support and training offered to the trainee anatomical pathology technician and the establishment's contingency plans in case of a mass fatality. The HTA found the establishment's staff work together as a cohesive team and have clear systems of communication in place with the Coroner's office.

Report sent to DI for factual accuracy: 22 August 2011

Report returned from DI: no factual accuracy comments were made by the DI

Final report issued: 29 September 2011

Appendix 1: HTA inspection process

The Human Tissue Authority regulates the removal, storage, and use of human bodies, body parts, organs and tissue for activities such as research, transplantation, and education and training. The legal requirements for establishments which carry out such activities are set out in the Human Tissue Act 2004 and The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006.

We license establishments in England, Wales and Northern Ireland that carry out these activities, and inspect them to make sure legal requirements are met.

Inspections

We use the term 'inspection' to describe when we:

- visit an establishment to meet with staff, view premises and facilities, and review policies and procedures (a site-visit inspection); or
- assess written information we have requested from an establishment (a desk-based assessment / inspection).

We carry out inspections to assess if the Designated Individual (DI) is suitable to supervise the activity covered by the licence, as it is their responsibility to ensure that:

- other staff working under the licence are suitable;
- suitable practices are used when carrying out the activity; and
- the conditions of the licence are met.

We also need to be satisfied that the licence applicant or holder, the establishment's premises, and the practices relating to licensed activities, are suitable.

To help us reach our decisions, we have developed standards under four headings: Consent; Governance and Quality; Premises, Facilities and Equipment; and Disposal.

After every site visit inspection, we write a report documenting our findings. Where we find a particular standard is not fully met, we will describe the level of the shortfall as 'Critical', 'Major' or 'Minor'. In most cases, it will be the responsibility of the DI to seek the HTA's agreement on how they will address the identified shortfalls. More information about the classification of shortfalls can be found in Appendix 3.

The majority of our site-visit inspections are announced. If we have concerns about an establishment, we can also undertake an unannounced site visit inspection.

You can find reports for site visit inspections which took place after 1 November 2010 on our website.

Appendix 2: HTA standards

Standards which are not applicable to this establishment have been highlighted.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• There is a documented policy which governs consent for post-mortem examination and the retention of tissue and reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent. • There is a documented SOP detailing the consent process (including who is able to take consent, what training they must receive, and what information must be provided to those giving consent for post-mortem examination). • There is written information about the consent process (provided to those giving consent), which reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.
C2 Information about the consent process is provided and in a variety of formats
• Relatives are given an opportunity to ask questions. • Relatives are given an opportunity to change their minds and is it made clear who should be contacted in this event. • Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use). • Where consent is sought for tissue to be retained for future use, information is provided about the potential uses in order to ensure that informed consent is obtained. • Information on the consent process is available in different languages and formats, or there is access to interpreters/translators.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• There is a training programme for taking consent for post-mortem examination and tissue retention which addresses the requirements of the HT Act and HTA code of practice on consent. • Refresher training is available (e.g. annually). • Attendance at consent training is documented. • If untrained staff are involved in consent taking, they are always accompanied by a trained individual.

Governance and quality system standards

GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process

- Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include:
    - post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases
    - record keeping
    - receipt and release of bodies, which reflect out of hours arrangements
    - lone working in the mortuary
    - transfer of bodies and tissue (including blocks and slides) to other establishments or off site
    - ensuring that tissue is handled in line with documented wishes of the relatives
    - disposal of tissue (including blocks and slides)

  (Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)
- Policies and procedures are regularly reviewed (for example, every 1-3 years).
- There is a system for recording that staff have read and understood the latest versions of these documents.
- Deviations from documented SOPs are recorded and monitored.

GQ2 There is a documented system of quality management and audit

- There is a quality manual which includes mortuary activities.
- Policies and SOPs are version controlled (and only the latest versions available for use).
- There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits).
- Audits include compliance with documented procedures, records (for completeness) and traceability.
- Audit findings document who is responsible for follow up actions and the timeframe for completing those actions.
- Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why.
- There is a complaints system in place.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Staff are appropriately trained/qualified or supervised.
- Staff have annual appraisals.
- Staff are given opportunities to attend training courses, either internally or externally.
- Attendance by staff at training events is recorded.

- There is a documented training programme for new mortuary staff (e.g. competency checklist).

GQ4 There is a systematic and planned approach to the management of records

- 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.
- There are documented SOPs for record management.

GQ5 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).
- Organs or tissue taken during post mortem examination are fully traceable, including blocks and slides. The traceability system ensures that the following details are recorded:
    - material sent for analysis on or off-site, including confirmation of arrival
    - receipt upon return to the laboratory or mortuary
    - number of blocks and slides made
    - repatriation with a body
    - return for burial or cremation
    - disposal or retention for future use.
- Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.

GQ6 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly

- Staff are trained in how to use the incident reporting system.
- Staff know how to identify incidents and near-misses which must be reported, including those that must be reported to the HTA
- The incident reporting system clearly outline responsibilities for reporting, investigating and follow up for incidents.
- The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.
- Information about incidents is shared with all staff (including the reporter) to avoid repeat errors.

GQ7 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed.
- Risk assessments include risks associated with non-compliance with HTA standards as well as

health and safety risks.

- Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years.
- 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.

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- There is sufficient space for the activities to be carried out.
- Refrigerated storage units are in good working condition and well maintained.
- Surfaces are made of non-porous materials.
- The premises are in reasonable condition (structure and cleanliness of floors, walls, entranceways).
- The premises are secure (e.g. there is controlled access to bodies, tissue, equipment and records).

PFE 2 Environmental controls are in place to avoid potential contamination

- There is clear separation of clean, transitional and dirty zones (e.g. doors, floor markings, signs).
- There is appropriate PPE available and routinely worn by staff.
- There is adequate critical equipment and/or PPE available for high risk post mortems.
- There are documented cleaning and decontamination procedures.
- There are documented cleaning schedule and records of cleaning and decontamination.

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.

- There is sufficient capacity for storage of bodies, organs and tissues.
- Temperatures of fridges and freezers are monitored on a regular basis.
- There are documented contingency plans in place should there be a power failure, or overflow.
- Bodies are shrouded whilst in storage.
- There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary (e.g. lab, other establishment), including record-keeping requirements.
- There are written agreements in place with any external parties (e.g. undertaker, or courier) who transport bodies and/or tissue behalf of the establishment (laboratory or mortuary).

  (Note that coroners usually have their own agreements with external parties for transportation bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases.)

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Items of equipment in the mortuary are in a good condition and appropriate for use:
  - fridges / Freezers
  - hydraulic trolleys
  - post mortem tables
  - hoists
  - saws (manual and/or oscillating)
  - PPE for high risk cases (e.g. respirators)
- The use of porous materials is kept to a minimum and has been risk assessed
- Maintenance/service records are kept for equipment, including fridges/freezers, trolleys, post mortem tables (if downdraught) and post mortem suite ventilation.

(Note: These records may be held by the mortuary or centrally by the Trust, e.g. Estates Department.)

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- There is a documented Trust or mortuary/laboratory policy for the disposal of human tissue, which reflects the requirements of the HTA code of practice on disposal.
- There are documented procedures for disposal of human tissue, including blocks and slides.

D2 The reason for disposal and the methods used are carefully documented

- There are systems in place that ensure tissue is disposed of in accordance with the documented wishes of the deceased person's family.
- Disposal records include the date, method and reason for disposal.
- Tissue is disposed of in a timely fashion.

  (Note: this means that tissue is disposed of as soon as reasonably possible once it is no longer needed, e.g. when the coroner's or police authority ends or consented post-mortem examination is complete.)

Appendix 3: 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 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 Human Tissue Act 2004 (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:

   (1) A notice of proposal being issued to revoke the licence

   (2) 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.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) 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 CoPs, 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.

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 or site visit.

Follow up actions

A template corrective and preventative action plan is available as a separate Word document. You 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 desk-based or site-visit inspection.

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