Site visit inspection report on compliance with HTA minimum standards

City of Westmister 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**

30 September 2015

Summary of inspection findings

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

Although the HTA found that City of Westminster Public Mortuary (the establishment) had met the majority of the HTA standards, one minor shortfall was found against Governance and Quality Systems (GQS) standards in relation to standard operating procedures for carrying out regular audits and reporting the audit findings. Advice has been given on matters across the range of standards.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual 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.

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. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, 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 given to the DI.

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

City of Westminster Public Mortuary (the establishment) has been licensed by the HTA since January 2008 for the making of a post-mortem (PM) examination, removal of relevant material and storage of bodies of the deceased and relevant material for use for scheduled purposes. The corporate licence holder is the Local Authority, City of Westminster Council.

The establishment conducts approximately 600 adult PM examinations each year; the vast majority of which are under the authority of HM Coroner, Inner London West Cororner District, as well as Home Office and defence (second) PM examinations. The establishment also has Category III PM suite facilities on site.

Bodies are brought in by funeral directors instructed by the coroner's office. Bodies have wrist tags attached by the police or funeral director. The establishment uses a paper-based records system, which includes: a statistics records file; mortuary team case sheet and daily record diary to record the details of body admission; documentation relating to PM examinations; histology details and records of release to a funeral director.

The body store contains 106 refrigerated spaces; six of these can accommodate bariatric bodies. Twelve refrigerated spaces are designated holding fridges to store bodies brought in by funeral directors out of hours and 48 can be converted to freezers spaces for long-term storage and there are five high-risk freezer spaces. The Westminster Borough Council has a contingency arrangement via the Coroner's office with Hammersmith and Fulham mortuary..

Refrigerators are connected to an automated temperature monitoring and call out alarm system. In the event of fridge failure, the automated system sets off a local alarm and calls the monitoring company which then call the Westminster council security desk in the council office. The mortuary has a rolling contract with a maintenance company to attend to any

equipment failure within 2 hours to five days, depending on the criticality of the failure. The company also carries out monthly pre-emptive maintenance of all the equipment in the premises.

Upon arrival of a body, information about the deceased (including name, address, date of birth, fridge allocation and personal property details) is recorded on the funeral directors admission sheet by the funeral directors, in line with the standard operating procedure for funeral directors (See advice item 5). The mortuary staff check the details and a unique reference number is assigned when the deceased details are transcribed into the mortuary team case sheet. A unique ID is generated for each body, following a two-person identification check carried out by APTs.

Mortuary staff place colored magnets on the fridge door to highlight same/similar name or danger of infection. Similarly, if a family has requested repatriation of organs or tissue removed during PM examination, a ‘do not release’ magnet is placed on the fridge door. Same or similar names are also highlighted on the mortuary white board. Bodies are released to funeral directors after two mortuary staff have checked the name and unique reference number of the deceased on wrist tags. The body release forms are signed by the mortuary staff and funeral directors.

The PM room has six downdraught PM tables and dissection benches, with adequate working space and good lighting. Five visiting pathologists undertake PM examinations on a rota basis. There is a separate storage area within the PM room for formalin-fixed (wet) tissue samples retained during the PM examination. The tissue samples are sent to another HTA licensed establishment for toxicology and histopathology testing; transportation is by specific courier companies who have agreements in place with the coroner’s office.

Tissue samples may be stored temporarily at the establishment under police authority. There were few samples stored under police authority for fixing purposes at the time of the inspection.

The last HTA site visit inspection was in August 2011. This report describes the third routine site visit inspection, which included a visual inspection of the premises (body store, PM room and viewing area), interviews with staff working under the licence and document review.

A traceability audit of three bodies in storage was carried out. The locations of two of the three bodies were checked alongside the identification details on the wrist tag for each and corresponding paper records. Only the paper records for the third body were reviewed. No anomalies were identified. A tissue traceability audit was carried out on two of the bodies from which samples had been removed for toxicology purposes. Records pertaining to the collection of these samples by courier were seen. No discrepancies were identified.

Inspection findings

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

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of quality management and audit.	The senior APT (SAPT) carries out weekly audits of: cleanliness of the post mortem rooms, body reception and body storage areas; stock levels; maintenance logs; reported accidents or near misses; and fire alarm testing. The audit findings are recorded on the SAPT weekly inspection and assistant manager report. There is no evidence of regular audit of traceability of bodies stored, PM procedure, record keeping, collection of samples, tissues retained and body discharge. There is no system in place to document the name of the person responsible for follow up actions and the time frame for completing those actions. In addition, the standard operating procedure (SOP) 'SAPT weekly inspection' does not cover the procedure for carrying out and documenting these audits. *(See advice item 8)*	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	The DI is advised to ensure that the pathologists have read the SOPs relevant to the activities they carry out in the mortuary, and that they sign to confirm they have done so.
2.	GQ1	The HTA updated its guidance on HTA-Reportable Incidents shortly before the inspection. The DI is advised to refer to this guidance and review the establishment's policy and procedures in light of it. Further information on this guidance can be found on the HTA website: Post Mortem HTA reportable incidents
3.	GQ1	The SOP 'body reception' states that "the admission section of the case sheet must now be fully completed by the primary APT and signed off, as well as being signed and witnessed by the secondary APT." According to current practice in the mortuary, if short staffed, the two-person ID check is carried out by one APT and a funeral director or coroner's officer and it is not recorded on the mortuary team case sheet form, the section to be

		signed by the second APT being left blank. This gives the impression that the ID check was not carried out by two individuals. The DI is advised to modify the mortuary team case sheet to record all two-person checks during the body receipt process. In addition, the DI is advised to update the SOP to reflect the current practice when the mortuary is short staffed.
4.	GQ1	The establishment serves as a contingency mortuary for storage of bodies for Hammersmith and Fulham public mortuary. In addition, the mortuary serves as contingency storage for Guy's and St. Thomas' Hospital and St. Georges' NHS Healthcare trust. The establishment is advised to develop a SOP for the body receipt process as part of these contingency arrangements. The SOP should include the information required before the receipt of the deceased, the process of external examination and ID check carried out at the time of receipt, details of PM and release of the deceased to the funeral directors.
5.	GQ1	The establishment has developed a 'Code of Conduct for funeral directors', which serves as an SOP for bringing in bodies during out of hours. This was last reviewed in 2008. The DI is advised to review and ratify the SOP to ensure that it is in line with the current practices carried out at the mortuary.
6.	GQ1	In addition to the checks of the name and unique reference number of the deceased, the establishment may wish to consider using a third identifier, unique to the deceased, such as date of birth as part of three point checks carried out before the release of the body.
7.	GQ1	It was noted during the inspection that the fridge location number on the body tags of the deceased is not frequently updated to show the correct storage location of the body in the fridge. The DI is advised to put systems in place to record the correct fridge/freezer location on the body tag and wrist bands. If location of bodies is subject to change frequently, the DI may wish to consider not recording body location on the body tags. The DI is also advised to ensure that any changes in the location of the deceased are made and initialed in the paper records to indicate a robust audit trail of movement of the deceased in the mortuary.
8.	GQ2	The DI should ensure the audits SOP describes the checks carried out as part of the audits, the procedure to documenting the audit findings and the name of the person responsible for following up actions and the time frame for completing those actions.
9.	PFE2	The 'Housekeeping' SOP describes daily cleaning procedures of the mortuary. The weekly cleaning rota is displayed on the white board and audited by senior APT during weekly audits. Records of these cleaning schedules are not kept for future review to demonstrate an up to date cleaning of the mortuary in line with the SOP. The DI is advised to introduce a system to keep the records of cleaning to demonstrate the above practice. The DI is also advised to update the SOP to include the cleaning procedure for the fridge and freezers in the body store.
10.	PFE3	The DI is advised to schedule manual checks of the storage temperature alarms to ensure that they are operating as expected. This should include checks that the system notifies the council security desk as expected and that

		alarm notifications are responded to appropriately. These checks and any resulting actions should be documented.

Concluding comments

This report outlines the third HTA site visit inspection of City of Westminster Public Mortuary. Despite the shortfall identified, areas of strength were observed.

The DI and senior APT have a good working relationship with HM Coroner's Office, and there is regular contact between the Coroner, his officers and mortuary staff. The DI is well supported by colleagues in the local council in the management of the mortuary. The establishment has a robust approach to health and safety and has introduced a system of external audits of the mortuary, which is carried out by members of council.

The coloured markers used to record the deceased's details on the whiteboard are changed every month, which highlights bodies stored for longer than four weeks. The mortuary has a good system of visual markers to identify same or similar names, high-risk bodies and bodies awaiting repatriation of tissue.

There is a robust system for the identification of the deceased for PM. ID checks are carried out by the APT when the deceased is removed from the fridge and by the pathologist prior to the PM commencing and after the PM is complete.

There are a number of areas of practice that require improvement, including one minor shortfall. In addition, the HTA has given advice to DI on a range of issues, including governance documents, traceability systems and mortuary facilities.

The HTA requires that the Designated Individual addresses the shortfall by submitting a completed corrective and preventative action (CAPA) plan 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.

Report sent to DI for factual accuracy: 28 October 2015

Report returned from DI: 10 November 2015

Final report issued: 15 November 2015

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: 30 August 2016

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

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: o post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases o record keeping o receipt and release of bodies, which reflect out of hours arrangements o lone working in the mortuary o transfer of bodies and tissue (including blocks and slides) to other establishments or off site o ensuring that tissue is handled in line with documented wishes of the relatives o 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.

GQ6 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 and tissue samples taken during PM examination are fully traceable.
- Details of organs retained and the number of wax blocks and tissue slides made are recorded.
- The traceability system includes the movement of tissue samples between establishments.
- Details are recorded of tissue that is repatriated or released with the body for burial or cremation.
- Regular audits of tissue storage and traceability are undertaken to ensure compliance with operational procedures; tissue samples found which are not being stored with consent are disposed of with reference to the family's wishes.
- 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.

GQ7 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.

GQ8 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.
- The policy states the position with regard to the retention and use of microscope slides, and in particular that tissue slides must be disposed of or returned to the family in accordance with their wishes if consent is not obtained for their continued storage and future use once the PM has concluded.

D2 PM tissue is disposed of if consent is not given for its storage and use for scheduled purposes

- There are documented procedures for disposal of human tissue, which include methods of disposal for whole organs, wet tissue, wax blocks and microscope slides.
- Tissue is disposed of in accordance with the documented wishes of the deceased person’s

family.

- Disposal details of organs and tissue blocks are recorded, including the date and method of disposal.
- There is a rolling programme of tissue disposal that ensures that tissue, including microscope slides, is disposed of in a timely fashion when it is no longer needed for the purposes of the Coroner or to determine the cause of death.

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 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.

   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 or site visit.

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. 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.