Site visit inspection report on compliance with HTA minimum standards

East Ham Public Mortuary

HTA licensing number 12032

Licensed under the Human Tissue Act 2004 for the

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

18 June 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 East Ham Public Mortuary (the establishment) had met the majority of the HTA standards, four minor shortfalls were found with regard to the Governance and Quality Systems (GQS) and Premises, Facilities and Equipment (PFE) standards. The shortfalls were in relation to: (i) the absence of an audit schedule; (ii) incomplete incident reporting procedures; (iii) incomplete risk assessments; and (iv) lack of routine testing of refrigerator and freezer alarm system.

As no consented post-mortem (PM) examinations take place at this establishment, and the mortuary does not retain any tissue samples outside the authority of the Coroner, the consent standards do not apply.

Particular examples of good practice are included in the concluding comments section of the report.

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

This report refers to the activities carried out at East Ham Public Mortuary (the establishment), where approximately 450-500 post mortem (PM) examinations are undertaken each year by independent pathologists under the instruction of the HM Coroner for East London. This includes a small number of forensic and defence PM examinations. Known high risk cases (Hazard Group 3 and above) are sent to The Royal London Hospital for specialist examination. The establishment does not carry out PM examinations of neonatal or paediatric cases, or consented PM examinations.

The establishment has two full time Anatomical Pathology Technologists (APTs). The DI is the Registration and Cemetery Services Manager for the Newham Registration and Nationality Service in the London Borough of Newham. She is based off site, but is close by and visits regularly. The corporate licence holder is the Local Authority.

The mortuary has 29 refrigerated spaces for bodies. Ten of these fridges can be converted to freezer storage if needed. Four of the spaces can accommodate bariatric bodies. The facilities are dated, however on the day of inspection they were clean and appeared well maintained.

The PM suite has three designated workstations, each with a set of height-adjustable stands that hold the mortuary trays on which the PM examinations are performed. There is a dedicated dissection bench at the foot of each station.

The PM room has a ventilation system that is switched on at the beginning of each day (*see advice item 5)*. Formalin and fixed histological specimens are stored in a well-ventilated cabinet. There is also a formalin dispensing station.

Histology and toxicology samples retained during PM examination are transferred by contracted courier to the chosen establishment of each independent Pathologist. The Coroner's Office conveys the disposal wishes of the family directly to the Pathologist, who then communicates these wishes to the hospital. The hospital carries out the family's wishes, once they have received notification that coronial authority has ended. Paperwork relating to the wishes of the family is kept by the Pathologist who carried out the PM examination.

This was the third site visit inspection of the establishment since it was issued an HTA licence in 2007 (the last inspection was in 2011). It was a routine inspection to assess whether the establishment is continuing to meet the HTA's standards. It comprised of a visual inspection of the mortuary, PM suite, body store and viewing/ID room. Interviews with members of staff and a review of documentation were undertaken.

The release of one body from the body store was observed during the inspection. The procedure was compared with the respective standard operating procedure (SOP). No anomalies were found. Collection of toxicology samples by a contracted courier was also observed and compared with the respective SOP. There were no discrepancies.

Audit trails were conducted on three bodies in the refrigerators. Body location and identification details on wrist tags of the bodies were cross referenced against the whiteboard and the patient register records. No anomalies were found.

An audit trail was also conducted on three PM cases where tissue was taken and sent to other establishments for analysis. In the first case, an organ was taken for analysis and later reunited with the body prior to the release. The records relating to this were reviewed and no anomalies were found. In the second and third cases, tissue had been sent to another establishment for analysis. No anomalies were found in the records of the first of these, but in the other, a discrepancy was found relating to a sample of liver tissue (*see advice item 2*). To complete the traceability audit, the HTA followed up with the establishment that received the tissue.

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.	Although audits of tissue do take place, these are not documented. There is no documented schedule of audits relating to HTA licensed activities. (*see advice item 2*)	**Minor**

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	The establishment has an overarching SOP, which states that HTARIs must be reported to the HTA. However, this does not state: • the categories of HTA reportable incidents; • who can report the incident; • the five day timeframe for reporting the incident, once discovered. In addition, the establishment does not appear to be reporting and investigating mortuary incidents which do not need to be reported to the HTA but which do warrant investigation. (*see advice item 3*)	**Minor**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	The establishment has assessed the risks relating to some of its activities, but these mostly relate to health and safety considerations and do not extend to risks to the bodies in the care of the mortuary. Risk assessments do not contain sufficient detail of: • evaluation of the risk (likelihood of occurrence and severity of risk) or • actions taken to mitigate the risk. (*see advice item 4*)	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.	There is no documented schedule or testing of fridge and freezer alarms. The maintenance contract for servicing of equipment in the mortuary has expired. (*see advice item 8 and 9*)	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	Even though the DI visits the mortuary often to meet with mortuary staff, she is advised to:

		• set up quarterly formal scheduled meetings; • include HTA-related issues as a standing agenda item at these meetings; • minute the meetings. These meetings can also include locum staff and pathologists when/if available.
2.	GQ2	The traceability audit conducted by the inspection team identified an anomaly in the information recorded about a tissue sample retained for histology. Details of retained tissue were recorded in three separate places: the patient register record; the mortuary database; and the Pathologist's histology sheet. The information on the patient register record and the mortuary database stated that a liver sample had been retained; however the Pathologist histology sheet had no record of this information. A regular audit of records would help ensure that errors are rectified. As well as audits of records, the DI is advised to set up a regular schedule of audits of the following activities: • PM examination procedures; • receipt and release of bodies, which reflect out of hours arrangements; • transfer of bodies and tissue off site. The DI is also advised to have more than one person participate in audits of licensable activities. This will enable trend analysis to be carried out on non-conformances that may be identified.
3.	GQ7	The DI is advised to ensure mortuary staff routinely use the local incident reporting system should a (non-HTARI) incident occur. Incidents should be investigated and follow up actions identified.
4.	GQ8	The DI may wish to consider using the HTARI classifications as a basis for undertaking risk assessments. She may also wish to liaise with other establishments develop her understanding of mortuary risks.
5.	PFE2	The establishment is currently waiting for the air filters of the ventilation system in the PM suite to be replaced. The DI is advised to make sure there is regular monitoring of the air flow and assessment of risks to staff, to ensure they take adequate precautions (i.e. wearing appropriate PPE).
6.	PFE3	With respect to contingency arrangements, the DI is advised to formalise verbal agreements with local funeral homes or other establishments. Currently, there is dependence on the provision of Nutwell storage units, hired during the busy periods, and these may not always be available when needed.
7.	PFE3	The DI is advised to define high and low temperatures for the fridges and the freezers in the mortuary. This will give staff an indication if the current temperature is approaching a level at which action may need to be taken. The DI is advised to set up a system to test and document fridge and freezer temperatures.
8.	PFE5	The maintenance contract for equipment in the mortuary has expired and the DI is in the process of getting a new contract with a different company. The DI is advised to secure new contracts which cover all equipment as soon as possible. This will help ensure that everything is in working order.
9.	PFE5	Alarm systems are in place for the fridge and freezers; staff are encouraged to

		test the alarm monthly to make sure they are in full working order. Details of tests should be documented.

Concluding comments

Despite the shortfalls, many areas of good practice were observed throughout the inspection, some of which are included below.

East Ham Public Mortuary provides a valuable service to HM Coroner for East London. The staff are experienced and committed to their work. They have effective systems of communication with the Coroner and Pathologists, and good working relationships with each other.

PM examinations are conducted by visiting Pathologists. The APTs are flexible in their working arrangements to accommodate those of the Pathologists and never eviscerate a body before it has been examined by the Patholgoists.

The establishment has a robust identification procedure for labelling bodies and documenting identification information, including a system of identifying same or similar names.

Since taking on the role in March, the DI has worked with mortuary staff to significantly improve the premises and working environment in the mortuary, including identifying training opportunities so staff can develop and keep their skills up to date. She is aware of her statutory duty under the HT Act and is making time to fulfil this role effectively.

There are a number of areas of practice that require improvement, including four minor shortfalls. The HTA has given advice to the Designated Individual with respect to undertaking and documenting audits and risk assessments, incident reporting and routine testing of refrigerator and freezer alarms.

The HTA requires that the Designated Individual addresses the shortfalls 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.

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.

Report sent to DI for factual accuracy: 15 July 2015

Report returned from DI: 13 August 2015

Final report issued: 18 August 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: 23 September 2015

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:
    - 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 There are documented procedures for donor selection and exclusion, including donor criteria.

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.