Site visit inspection report on compliance with HTA minimum standards

Poplar Public Mortuary

HTA licensing number 12087

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**

22 July 2015

Summary of inspection findings

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.

Although the HTA found that Poplar Public Mortuary had met the majority of the HTA standards, three minor shortfalls were found in relation to GQ1, GQ7 and PFE3. The establishment's standard operating procedures (SOPs) were not reflective of current practice and lacked the detail needed to ensure staff work in a consistent way (minor shortfall against, standard GQ1). The establishment does not keep an incident log and does not have a documented procedure on how to manage incidents, including those that should be reported to the HTA (minor shortfall against, standard GQ7). During the inspection, it was noticed that the temperature display on the alarm unit in the mortuary office was indicating a fridge temperature which was outside the lower limit of temperatures according to the mortuary SOP. The mortuary staff were unaware of this or what might have caused it (minor shortfall against, standard PFE3).

Particular examples of strengths and good practice are included in the concluding comments section of the report.The establishment was provided with advice and guidance about areas that could be improved further.

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 describes the third site visit inspection of Poplar Public Mortuary (the establishment), which is licensed to carry out post mortem (PM) examinations and the removal and storage of PM tissue for use for scheduled purposes under the Human Tissue Act 2004. The establishment undertakes between 300-400 PM examinations a year under the jurisdiction of HM Coroner for Inner London North. These include forensic and category 3 high-risk PM examinations.

The mortuary has 53 storage spaces, consisting of 12 freezer spaces, 24 fridge spaces in the main body store and 17 fridge spaces in the 'night bank' of fridges. If bodies are received out of hours, the Coroner's contracted funeral directors are only able to access the night bank of fridges and not those in the the main body store. The funeral directors are required to log any admissions that occur out of hours in the establishment's night register, and mortuary staff check the bodies, and identification details, the next day and move them into the main body store fridges. The mortuary fridges are connected to an audible alarm which sounds in the office if the fridge or freezer temperatures goes outside of normal parameters. Mortuary staff manually record fridge and freezer temperatures daily and review data for trend analysis once every six weeks.

The alarm display in the mortuary office shows the temperature of the four banks of

fridges/freezers. During the inspection, it was noticed that the temperature for 'bay three' on the alarm display was reading 0c. Bays one, two and four were all within normal limits, according to the alarm display. The temperature readings of the fridges and freezers in the body store itself also indicated that the temperatures of all four bays were within the normal range. According to the establishment's documented procedure, the lower alarm set point is 1.5°C. At the time of the inspection mortuary staff were unaware that the alarm display temperature was reading 0°C and could not provide a reason for the discrepancy (*minor shortfall, PFE3*).

The post mortem suite has three dissection tables. High risk PM examinations take place after all other cases have been completed and personal and protective equipment is available to mortuary staff. Visiting pathologists undertake all the PM examinations and, where tissue is retained, the wet tissue is placed in formalin pots and labelled in the PM room. The coroner's officers arrange for a courier to collect the specimens and transport them to a local hospital for histology purposes. Organs are also fixed on site and transferred by courier to other centres for specialist examination. All organs or tissue to be collected by courier are documented in the specimen register by mortuary staff. Mortuary staff record: the full name of deceased, the coroner's reference number, specimen type, date of collection, signature of the courier upon collection and recipient establishment.

Traceability audits of three bodies were carried out. Bodies were identified by checking the full name of the deceased on the fridge door against the mortuary register. One body had an ankle band, provided by the local hospital, with the wrong year of birth.The wrist band provided by the establishment had the correct year of birth. Mortuary staff confirmed that they would only check the mortuary wrist band for identification purposes. No other discrepancies were found. All three bodies underwent a post mortem examination. A tissue traceability audit was carried out using the paper records relating to two of the bodies where tissue had been retained under coronial authority. All records were checked and no discrepancies were found.

Two further cases were reviewed during the tissue traceability audit. In the first case, an organ had been retained under coroner's authority and the family's wishes form indicated that the organ should be repatriated with the deceased. Documentary evidence indicated that repatriation had taken place. In the second case, tissue had been retained under coroner's authority and the family's wishes form indicated that the tissue should be retained for use for a scheduled purpose under the HT Act. All records, including the specimen register, were checked and no discrepancies were found.

Inspection findings

The HTA found the Licence Holder to be suitable in accordance with the requirements of the legislation. The current Designated Individual is leaving the establishment on the 19 August 2015 and a new application has been made by Mr Stuart McGregor, Registered Safety Practitioner. The HTA Considers Mr McGregor suitable to act in this capacity.

The shortfalls identified below, particularly, in relation to GQ1 indicate that there has been little improvement since the last inspection in 2012. The new Designated Individual needs to take a more proactive approach to supervision of licensed activities, and should have proteceted time, and support from the senior team, to enable him to carry out this role and fulfil his statutory duty to ensure suitable practices are being carried out.

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1	Although the establishment has made some improvements since the last inspection, SOPs and other documents need further attention. In their current format, SOPs do not provide the comprehensive and detailed information about mortuary procedures that is required by staff working to them, and some SOPs provide inaccurate information. For example, one SOP made reference to a 'viewing gallery' which the establishment does not have.	Minor
GQ7	The establishment does not have an incident reporting system to enable staff to record any internal incidents or HTA Reportable Incidents (HTARIs). Furthermore, there is no SOP outlining how to deal with incidents, including HTARIs. Without a formal reporting procedure and system, incidents are not subject to formal investigation and the establishment is unable to provide evidence of any improvements made or learning gained as a result of incidents.	Minor

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3	At the time of the inspection, the digital display of the fridge alarm system in the mortuary office showed a temperature reading of 0°C for the bay three fridge. However, the temperature reading at bay three in the body store was within range. According to the establishment's SOP, a temperature below 1.5°C is outside normal parameters. The discrepancy between the fridge alarm system reading and the fridge temperature reading could not be explained and calls into question whether the alarm monitoring system is functioning correctly. *Advice and Guidance, item 6*	Minor

Advice

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

No.	Standard	Advice
1.	GQ1	There are four pieces of advice under GQ1: 1. Although the establishment has made improvements as a result of a minor shortfall identified against this standard during the previous site visit inspection, further work is required to improve governance systems further. Where SOPs had been revised, it was not clear if staff had read the latest versions. A document with names and signatures of staff confirming that they had read the SOP were attached to the SOPs; however, the signature dates preceded the revision date. The DI should ensure that all staff have read and understood revised procedures and that there there is an up to date record of this. 2. The DI should consider implementing a document control system, to capture all current and archived SOPs and policies relevant to the mortuary. This will give ready access by staff to current and past governance documentation. 3. The DI should also ensure that names of any previous authors of SOPs, no longer employed at the establishment, are removed from any documents and replaced with the name of the current author. 4. The DI attends the mortuary and meets with the mortuary staff once a month. Currently, these meetings are not minuted. Going forward, the DI is advised to ensure that an agenda is in place for all meetings and that they are formally documented.
2.	GQ2	A good range of audits have been carried out by the establishment's council-employed Health and Safety team. However, some audit reports did not clearly indicate actions taken as a result of issues being identified. The DI is advised to ensure that audit reports provide evidence that actions have been addressed and closed when completed. Further improvements to the audit process can be made by carrying out additional types of audits for example, observational and procedural audits of mortuary practices.
3.	GQ3	The establishment does not have a mortuary-specific induction programme in place. The DI is advised to consider developing a formal induction programme in the mortuary for new staff that are appointed to work in the mortuary.

4.	GQ6	Currently, mortuary staff use the deceased's full name and coroner's reference number to identify bodies. To strengthen traceability systems further, the DI is advised to consider using a minimum of three identifiers, including one that is unique to the deceased.
5.	PFE2	Mortuary staff are responsible for cleaning the mortuary body store and post mortem suite, however do not currently document this. The DI is advised to ensure that all cleaning and decontamination is recorded in the form of a cleaning log.
6.	PFE3	There are three pieces of advice: 1. Although the mortuary fridges are subject to regular servicing and maintenance, during which the alarms are tested, the DI is advised to incorporate regular testing of the alarm system. 2. The DI should liaise with the maintenance company to review the alarm set up in regards to the fridges and freezer to ensure that: i) all correct temperatures for corresponding bays are reflected in the alarm display; and ii) the alarm is functioning in respect of all fridge and freezer bays. In addition, mortuary staff should check the display on a daily basis in conjunction with their normal fridge and freezer temperature monitoring duties. 3. The DI is advised to draft a documented procedure for mortuary staff so that they understand the trigger point at which the contingency arrangements may need to be considered. For example, reference should be made to the maximum number of bodies in storage, particularly during busy periods, that could impact the operation of the mortuary.
7.	N/A	The mortuary fridge door labels, where the names of the deceased are written, must be replaced. The inspection team found it difficult to read the names due to excessive staining from the ink used.
6.	N/A	The DI is advised to add the APTs in the mortuary as Persons Designated (PDs) under the licence for HTARI reporting purposes.

Concluding comments

The establishment's staff demonstrated a good working relationship and are keen to ensure that they are continuously improving. The new Designated Individual is keen to improve mortuary practices further.The establishment also has a very good working relationship with Poplar's Coroner's Court which is situated next to the Mortuary.

There are some areas of practice that require improvement, including three minor shortfalls in relation to standards GQ1, GQ7 and PFE3. The HTA has given advice to the Designated Individual on a ranage of issues to make further improvements.

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.

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: 17 August 2015

Report returned from DI: 2 September 2015

Final report issued: 2 September 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: 26 November 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.

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 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.

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.
- 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 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.