Site visit inspection report on performance against HTA quality standards
Waltham Forest Public Mortuary
HTA licensing number 12420

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**

29 September 2011

Executive Summary

A site visit inspection of Waltham Forest Public Mortuary (the establishment) was carried out by the HTA on 29 September 2011.

The establishment was found to meet many of the HTA standards across the areas of: governance and quality; premises, facilities and equipment; and disposal, although some shortfalls were found in relation to all of these. The consent standards are not applicable as all post-mortem (PM) examinations are carried out under the authority of the Coroner or the police and no tissue is retained by the establishment for future use for scheduled purposes.

Overall, the HTA found the Designated Individual, the Licence Holder and the practices taking place at the establishment to be suitable in accordance with the requirements of the legislation. However, the HTA has significant concerns about the condition of the premises and the security of the site. The layout of the mortuary and the lack of space in the PM room make it difficult for staff to follow Health and Safety Executive (HSE) guidelines on safe working in the mortuary and PM room, and the worn flooring in the PM room and the lack of suitable equipment to monitor exposure to formaldehyde may present a health and safety risk. It is noted that these shortfalls do not impact on the dignity of the deceased who are well cared for by staff working in the establishment. However, the HTA recommends strongly that the establishment commissions an external review of health and safety compliance by the HSE, or an equivalent independent expert, as a matter of urgency.

Some examples of strengths and good practice were observed during the inspection and these are included in the concluding comments section of the report.

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

Waltham Forest Public Mortuary (the establishment) carries out between 430-450 post-mortem (PM) examinations each year. All PM examinations are carried out under the authority of the coroner; some are Home Office PM examinations. No consented PM examinations are carried out on site and therefore the consent standards are not applicable to this establishment. Once the PM examination is completed, any tissue or fluid samples removed from the deceased are taken off site by the visiting pathologist for processing and analysis elsewhere, with the exception of some toxicological samples which are kept in refrigerated storage in case additional testing is required. If additional testing is not required, these samples are sensitively disposed of. The establishment carries out PM examinations on some high risk cases, which are known to have infectious diseases such as tuberculosis. The lungs of known tuberculosis cases are perfused overnight with formalin before the body is subjected to a PM examination.

This was the second routine inspection of the establishment; the first one having been undertaken in 2007.

The inspection comprised a visual inspection of the mortuary and body store, interviews with members of staff and review of relevant documentation. Audit trails were conducted using paper records of two deceased persons received into the mortuary, the records of tissues samples collected at PM examination for analysis and the subsequent repatriation of tissue samples with the deceased in line with the wishes of the bereaved. One anomaly was found when carrying out the audit in the body store, where a digit was missing from the unique identification number that had been recorded on the wrist tag of the deceased. All of the paper records reviewed were compared against the details held in the electronic mortuary register; no anomalies were found.

The fridges and freezers within the body store were replaced in 2009; however the remainder of the mortuary has not undergone any significant renovation in the last twenty years. During the visual inspection, the inspection team noted that the floor of the PM examination room was badly worn and the stainless steel tables were corroded. In addition, it was noted that PM examinations are routinely carried out on trolleys as well as on the two fixed PM tables in order to complete the daily case load, demonstrating that there is insufficient space for the volume of activity taking place at the establishment. There is a lack of clear demarcation of clean, dirty and transitional zones and staff have to walk through the reception and body storage areas to access the changing rooms.

Staff are aware of the shortcomings of the premises and have addressed some of the issues in the short-term through their operational procedures. In addition, security measures were improved following a recent attempt to break into the mortuary office, and metal roller blinds have been installed. However further steps will be necessary as council staff who reside at two nearby premises will be vacating during the next few months, leaving the facility isolated and more vulnerable. The HTA noted that the establishment has submitted plans to the local council to address the long-term need to renovate the mortuary as a whole.

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 establishment has a range of SOPs covering relevant procedures; however several of these documents are limited in the detail they contain and could result in new members of staff being unaware of important steps in each of the procedures. For example, the SOP on the post-mortem examination of known infectious cases does not detail which cases can be carried out on site and the additional precautionary measures to be taken when dealing with these cases, or which infectious cases must be transferred.	**Minor**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	The establishment has completed a range of health and safety risk assessments; however, other risks such as misidentification of bodies and loss of traceability of tissues have not been undertaken.	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE1 The premises are fit for purpose.	Space within the PM examination room is limited. PM examinations are regularly carried out on two fixed tables and two trolleys which are taken into the PM room. This practice has not been risk assessed. The flooring in the mortuary is worn and the porous surface beneath the protective coating is exposed. Since known high risk PM examinations are undertaken at the mortuary, there is a risk that the floor cannot be effectively decontaminated following PM examinations. The mortuary is relatively isolated and council staff who live adjacent to the mortuary will shortly be vacating their homes. This will result in the mortuary being less secure out of working hours. The mortuary has already been the victim of theft, the lead roofing having been stolen, and attempts have been made to break into the building. Steps should be taken to make the facility more secure.	**Major**
PFE2 Environmental controls are in place to avoid potential contamination.	The layout of the reception, body store and changing areas does not lend itself to a logical progression from clean to dirty areas. This increases the risk of contaminating clean areas. There are no demarcations or signs to indicate which areas are designated clean, transitional or dirty. The lungs of known tuberculosis cases are perfused overnight with formalin before the body is subjected to a PM examination. This practice has not been risk assessed. In addition, staff are not aware of safe working limits for formaldehyde and there is no monitoring equipment or system of monitoring personal exposure to formaldehyde to ensure that it is within safe levels.	**Major**

Disposal

Standard	Inspection findings	Level of shortfall
D1 There is a clear and sensitive policy for disposing of human organs and tissue.	The SOP on the disposal of clinical waste does not explain how to dispose of samples, mostly taken for toxicological purposes, that are no longer required, or how disposal should be recorded.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ2	The establishment has a spreadsheet which details the authorisation and review dates of the documents in use; however these details, particularly the version number, need to be on the document itself so that staff are aware which version they are reading to ensure it is the most up to date. All signs, forms and procedures should be subject to document control. In addition, the establishment would benefit from an SOP detailing the document control process, how documents are accessed and by whom, and how to generate the completed histology form from the Access Database
2.	GQ2	The establishment carries out several records audits, but does not undertake audits of compliance with operational procedures. The DI is advised to include these in the audit schedule, as they will help to provide assurance that new staff and locum staff are working in accordance with standard procedures.
3.	GQ5	Since the establishment works with Independent Pathologists, it is advisable to put an agreement in place to set out roles and responsibilities, particularly with regard to evisceration of the deceased and disposal of any tissue samples taken. Alternatively, this could be written within a suitable SOP which all relevant parties would sign to acknowledge they had read it.
4.	GQ8	The DI may find it helpful to risk assess the likelihood of serious untoward incidents occurring, as defined by the HTA and available on the HTA website.
5.	PFE1	There are significant problems with the premises, as indicated above. The HTA recommends strongly that the DI commissions an external review of health and safety compliance as a matter of urgency, to assure herself that there is no significant health risk to staff working in the mortuary.
6.	PFE2	The establishment is advised to refer to the Health and Safety Executive handbook ‘Safe working and the prevention of infection in the mortuary and post-mortem room’ (paragraph 59) for guidance on the safe working levels for formaldehyde, and the Department of Health publication HBN20 ‘ Facilities for mortuary and post mortem services’, sections on risks arising from the use of formalin and ventilation.

Concluding comments

During the inspection of Waltham Forest Public Mortuary, two major and three minor shortfalls were identified by the inspection team. A number of strengths and areas of good practice were also noted.

The establishment has developed its own computerised mortuary register, which enables the recording of all information relating to the deceased, including unique reference number, PM date, tissue samples collected, repatriation or disposal requirements and the date disposal is completed. A histology form is generated automatically from the information recorded in the mortuary register, and the pathologist verifies the tissue samples taken against a print out of the histology form and signs to confirm that the tissues have taken off site for processing and analysis.

When the new body storage fridges were installed, the establishment had an additional ceiling chiller installed in one half of the body storage area, which can be closed off using an internal door. In the event that bariatric cases are received into the mortuary that do not fit in the bariatric fridges, or fridge breakdown, this area provides a contingency and can be used for short-term storage of the deceased.

The establishment provides services to and interacts with a number of different professional groups including independent pathologists, coroner's officers and undertakers. Feedback forms have been distributed to these individuals to gather any comments on their service in order that improvements can be made. The new DI and mortuary staff work well together as a team.

Report sent to DI for factual accuracy: 21 October 2011

Report returned from DI: No factual accuracy comments received from DI.

Final report issued: 29 November 2011

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: 04 January 2013

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 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 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 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.