HTA
Human Tissue Authority

Site visit inspection report on compliance with HTA minimum standards

Fulham Public Mortuary

HTA licensing number 12489

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**

14 October 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.

The HTA found that Fulham Public Mortuary had met the majority of the HTA standards. A major shortfall was found in relation to assessment of risk associated with licensable activities. Of particular concern is the number of bodies requiring long term storage in deep freeze, which often exceeds the number of freezer spaces available. This situation has been ongoing for some time but has not been captured in a risk assessment. In addition, a minor shortfall was found regarding procedures for disposal of post-mortem tissue samples.

HTA consent standards do not apply to this establishment, as all post-mortem examinations are performed under authority of HM Coroner.

Examples of strength 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 (DI) are set out in Section 18 of the Human Tissue Act 2004 ('the HT Act'). 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 licenses 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

Up to 700 adult post mortem (PM) examinations are carried out each year at Fulham Public Mortuary (the establishment), including Home Office (forensic) and high risk PM cases, all of which are under authority of HM Senior Coroner for West London. The establishment does not carry out paediatric or consented PM examinations.

Bodies are admitted from local hospitals and the community by HM Coroner's contracted funeral director. For community deaths, the funeral director attaches identity tags to the deceased at the place where their body was found. Bodies that are transferred from hospitals have NHS identification tags. Upon arrival at the mortuary, the funeral director completes an admission sheet listing the deceased person's identification details and the date and address of collection of the body. Bodies are placed into a specified bank of fridges by the funeral director, and mortuary staff assign each body a unique, sequential, admission number. There is no on-call APT for bodies which are admitted outside of core working hours.

The mortuary has 54 fridge spaces and freezer storage for a further twelve bodies. Fridges and freezers have automatic temperature controls and alarms, which are tested regularly. The high-risk PM suite can be chilled to enable storage of a superbariatric body.

Changes in practice at the Coroner's Office have contributed to a slowing down in throughput of bodies in the mortuary in recent months, which is placing increased pressure on storage capacity. The situation is particularly acute for bodies in long-term storage that need to be frozen (refer to shortfall against standard GQ8).

PM examinations are performed by visiting pathologists who work to a rota three days each week (refer to advice item 1). The main PM suite has facilities to conduct up to ten PM examinations, and on some occasions up to ten bodies will undergo PM examination in one day. There is one organ dissection board. To prevent any likelihood of organs being returned to the wrong body, an organ bowl is not taken to the dissection board until the organs that were dissected prior to that are returned to the correct body. Organs, tissues and toxicology samples retained during PM examination are normally collected from the establishment by courier and transferred to other HTA-licensed premises for processing and examination. Tissues and organs may, at the request of the family, be returned to the establishment to be reunited with a body prior to its release (refer to advice item 5).

Body release takes place during working hours only (refer to advice item 1).

The establishment stores some historic tissue and toxicology samples (one sample dates from 2007), pending instruction from HM Coroner on retention for coronial purposes or disposal. The establishment has sought instruction from HM Coroner about some of these samples and is awaiting further information (refer to shortfall against standard GQ8).

The establishment has been licensed by HTA since May 2008. Two previous site visit inspections have taken place (in August 2009 and November 2012). This report describes its third, routine, site visit inspection. The HTA inspectors met with staff, visually inspected the mortuary and reviewed documentation. HM Coroner was invited to contribute to the inspection process, and did not respond to this request. Release of two bodies to funeral directors was observed. Traceability records were audited for:

- one body in long term storage;
- two PM examinations at which histology and toxicology samples were taken;
- ten tissue samples in storage;
- a body transferred to another HTA-licensed establishment for temporary storage in July 2015 and subsequently returned to this establishment;
- an organ which had been returned to the establishment for repatriation with the body.

Three anomalies were found. In relation to the body in long term storage, the deceased’s surname was mis-spelt by the funeral director on the admission sheet when they were admitting the body, however all other records had the correct spelling. In the case of one of the PM examinations audited, a deviation from local procedures meant that samples were not transferred from the establishment by the courier, hence the histology and toxicology register had been completed retrospectively by the APT. Of the ten tissue samples checked by the HTA, one label was illegible and unaccounted for in records (refer to shortfall against standard GQ8).

Home Office PM examinations are performed at this establishment by Home Office registered forensic pathologists. Organs and tissue samples are sent to other establishments for analysis. Under s39 of the HT Act, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, the 2012 report of the Association of Chief Police Officers’ (ACPO) audit of tissue held under police authority contained a recommendation that police exhibits held on HTA-licensed premises should be included within the regular HTA inspection process. Therefore, procedures for Home Office PM examinations and the management of tissues and organs taken for criminal justice purposes were reviewed by HTA at this site visit inspection. Any findings in relation to Home Office PM examinations and police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the HT Act.

Consent standards do not apply to this establishment; all PM examinations are performed under authority of HM Coroner.

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
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	Documented risk assessments for mortuary activities consider health and safety issues, but do not address potential risks to traceability and storage of bodies and tissues, such as the misidentification of a body for release or for PM examination, or the storage of PM samples without coronial authorisation or valid consent. Risk assessments should result in mitigating actions which ensure robust traceability of bodies and samples. At the time of the inspection, there were more bodies requiring frozen storage than there were freezer spaces, and some of these bodies had been in storage for more than one year. The establishment is managing this situation by rotating some bodies into and out of frozen storage, which poses risks to traceability and the physical condition of bodies. While mortuary staff and the Borough Council are proactively engaging with HM Coroner to expedite the release of bodies and closely monitor storage capacity, the 'Risk Assessments for Fulham Public Mortuary 2014' has not been updated to reflect the increased pressures on storage capacity and, in particular, freezer space. Pressures on storage capacity should also be reflected in the Council's corporate risk register. Taken together, the failure to adequately assess the potential risks to bodies and tissues associated with routine mortuary activities and the ongoing pressures on storage capacity, and to identify effective mitigating actions to address these risks, represents a major shortfall against this standard. *(Refer to advice item 8)*	**Major**

Disposal

Standard	Inspection findings	Level of shortfall
D2 PM tissue is disposed of if consent is not given for its storage and use for scheduled purposes.	Histology and toxicology samples that are no longer required for coronial purposes are disposed of, but there is no documented standard operating procedure (SOP) describing how this is performed or recorded.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	Regarding SOPs, the DI is advised: • to specify the personal identifiers, such as the full name of the deceased, which must be confirmed prior to PM examination and release of a body to a funeral director; • the 'Fixation of a brain' SOP should explain how a brain is packaged and labelled prior to collection; • pathologists should sign to confirm they have read, and will abide by, local SOPs.
2.	GQ1, PFE4	The establishment may be required to act as an emergency mortuary in the event of a mass fatality incident. It is not the intention that bodies already in storage are moved, unless circumstances dictate the need for this. The DI is advised to develop a documented SOP setting out the procedure for the temporary transfer of bodies to other establishments, where this becomes necessary. As a minimum, the SOP should describe: • the information to be given about the condition of each body, for example if a body is badly decomposed or oedematous, to inform the handling and storage of bodies by staff at the receiving establishment(s); • the information about whether a body requires a PM examination, or is awaiting repatriation of organs or tissues, to be provided; • how the movement of bodies between establishments is recorded; • responsibilities for arranging transport of bodies between establishments; • who is responsible for notifying the HTA of an HTA reportable incident (HTARI) once a body has left the establishment. The DI is also advised to involve relevant parties in the development of the SOP, including: HM Coroner; the receiving establishments; funeral directors; the relevant borough councils; and the Metropolitan Police.
3.	GQ2	Regarding audits, the DI is advised: • the 'Audit of licensable activities' SOP should provide clearer instruction on how procedural audits are to be carried out, specifying whether they should include, for example: observation of mortuary procedures; review of SOPs; auditing of traceability records, and; storage of bodies and tissues; • to regularly review the contents of fridges where toxicology and histology samples are stored, to mitigate the risk of samples being overlooked; • to inform auditors to provide greater detail in their audit reports about the process they followed and the evidence they reviewed.
4.	GQ4	The DI is advised to develop a more structured filing system for paperwork in the body store, such as use of trays or boxes, to mitigate potential risks of key documents being mislaid. Similar advice was given in the HTA's 2012 inspection report.
5.	GQ6	The DI should be informed by HM Coroner's Office if a family has requested return of organs or tissues to a body prior to release to a funeral director. To

		mitigate the risk of a family's instructions not being followed, the DI is advised to formalise communication channels with the Coroner's Office.
6.	GQ6	The DI is advised to enhance procedures to highlight bodies with the same or similar sounding names, for example by use of signage on the shroud of the deceased or application of an additional wrist tag.
7.	GQ7	Regarding HTA Reportable Incidents (HTARIs), the DI is advised: • to nominate other persons who can report a potential HTARI to the HTA in his absence. This will ensure the requirement to report a potential HTARI within five working days of its discovery can be met, and; • the 'HTA Reportable Incidents' SOP and the 'Risk Assessments for Fulham Public Mortuary 2014' should refer to the HTA online portal for HTARI submissions.
8.	GQ8	The DI is advised to use the HTARI reporting categories as a basis for potential risks to be assessed. In addition, when undertaking risk assessments in relation to receipt, storage and release of bodies, the Coroner's Office should be involved to make sure that all parts of the PM process are considered and appropriate mitigating steps to reduce risks are taken. This is particularly important in relation to the long-term storage of bodies, which often relies on the actions of other parties to expedite the timely release of these bodies.
9.	PFE3	Bariatric bodies are placed in standard sized fridges with their arms folded inwards, to reduce the width of the body and enable placement into the fridge. This process is well understood by staff, but is not documented in an SOP, and a risk assessment of the placement of bariatric bodies in standard sized fridges has not been completed. There is a potential risk that if, for example, the arms fold outwards whilst in storage, the body could be damaged when it is removed from the fridge.

Concluding comments

Despite the shortfalls, strengths were identified. The mortuary receives good administrative support from the corporate licence holder, London Borough of Hammersmith and Fulham Council. Staff showed a strong commitment to the dignity and care of the deceased. Locum anatomical pathology technologists (APTs) are usually previous employees of the establishment, and hence familiar with local processes.

A number of areas of practice require improvement, including one major shortfall and one minor shortfall. The HTA has given advice to the DI with respect to strengthening governance and quality systems.

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: 29 October 2015

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 15 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.

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 audittrail
• 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 thatneed 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).
PFE2 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.

PFE4 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: o fridges / Freezers o hydraulic trolleys o post mortem tables o hoists o saws (manual and/or oscillating) o 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 Dept.)*

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.