Site visit inspection report on compliance with HTA minimum standards

Croydon Public Mortuary

HTA licensing number 12081

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**

15 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 Croydon Public Mortuary had met the majority of the HTA standards; however, one minor and two major shortfalls were identified against standards GQ7, GQ8 and PFE3, respectively.

The HTA's consent standards do not apply, as the establishment is not involved in activities requiring consent under the Human Tissue Act.

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 Croydon 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 around 450 PM examinations a year under the jurisdiction of HM Coroner for South London. These include forensic post mortem examinations. High-risk and paediatric PM examinations are transferred to other HTA-licensed premises. The establishment is a designated 'emergency mortuary'.

Funeral directors bring in bodies out of hours and place them in the 'overnight' bank of fridges, which accommodates up to 16 bodies. They do not have access to the main body store, which provides 20 storage spaces, including four freezer spaces. Funeral directors are required to complete a 'details of deceased form' and place a tag on the fridge door to indicate the location of the deceased. Mortuary staff check the overnight bank of fridges for new admissions daily; they also check the identification of the deceased and their weight and height measurements, which are recorded in the 'heights, names and weights book' and review any property accompanying the deceased.

A unique identifier is allocated to each body; this is a sequential number, which is documented in the mortuary ledger and written onto a mortuary wrist tag placed on the deceased's wrist. Bodies are not transferred from the overnight bank of fridges until a post

mortem examination has taken place, unless the overnight bank of fridges are reaching their capacity (see advice and guidance item6). In order to increase the capacity in the body store, bodies may also be stored on trays at the bottom of the banks of fridges (see major shortfall, standard GQ8). The mortuary fridges are connected to an audible alarm, which sounds if the fridge or freezer temperatures goes outside of normal parameters, however, it is not subject to regular testing. The fridges are not connected to an auto dial-out system and mortuary staff rely on funeral directors to inform them of any issues that occur out of hours (see advice and guidance item, 6). Mortuary staff manually record fridge and freezer temperatures daily (see advice and guidance item 6).

The post-mortem suite has five dissection tables. PM examinations are conducted by visiting pathologists. Where tissue is retained, the wet tissue is placed in formalin pots and labelled in the PM room. The coroner's officers arrange for the Coroner's contracted courier to collect the specimens and transport them to a local hospital for histological examination. Organs are also fixed on site and transferred by courier to other centres for specialist examination. The courier is required to sign the 'Pathologists notification of material retained following autopsy form' to document the date the specimen was collected, the name of the person collecting it and the establishment to where the specimen will be transported.

The site visit included, a visual inspection of the viewing room, body store and post-mortem suite and interviews with a Pathologist, Coroner's Officer, Mortuary Manager, Anatomical Pathology Technologist (APT) and the Designated Individual, who is Head of Bereavement Services for Croydon Borough Council. A document review was also undertaken.

Traceability audits of three bodies were carried out. Bodies were identified by checking the full name and unique identifier of the deceased in the mortuary ledger against the paper records and the physical location of the deceased. No discrepancies were found. All three bodies had been subject to post mortem examination so a tissue traceability audit was also carried out using the paper records relating to the bodies. Toxicology samples had been removed from one body under coronial authority and no tissue had been removed from the other two bodies. All records 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.

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ7	The establishment's procedure to deal with HTA Reportable Incidents (HTARIs) has been copied from the HTA's 'Guidance for reporting HTARIs in the post mortem sector' document. In its current format, the SOP does not outline how mortuary incidents including, HTARIs, should be reported, managed, investigated and closed.	Minor
GQ8	Five minor shortfalls were identified against standard, GQ8. Taken together, the failure to adequately assess	Major

	the potential risks to bodies and tissues associated with routine mortuary activities and the ongoing pressures on storage capacity, as well as identifying effective mitigating actions to address these risks, represents a major shortfall against this standard. i. Although the establishment has carried out health and safety risk assessments, no consideration has been given to the risks to the bodies or tissue in storage (See advice and guidance item 3). ii. The APTs routinely eviscerate bodies in the absence of the Pathologist, following a risk assessment of each case and receipt of an email from the Pathologist that the evisceration can proceed. Prior to evisceration, identification checks are carried out by the APTs. Evisceration in the absence of the pathologist is contrary to RcPath's *Standards for Coroners' pathologists in post-mortem examinations of deaths that appear not to be suspicious* (Feb, 2014). This practice has not been formally risk assessed, despite advice to this effect from the HTA following a HTARI in 2013 under the category 'Post mortem on the wrong body'. iii. Mortuary staff occasionally use the bottom of the fridges for additional storage, when the fridges are reaching capacity. Smaller bodies are placed on trays and staff rely on estimating the size of the body before placing in the lower most space.This poses a risk of accidental damage if the body is larger than estimated or has an unusual morphology (e.g. curvature of the spine). There has been no risk assessment to consider risks to the deceased or to staff in respect of manual handling. iv. The mortuary fridges are alarmed but there is no call-out system, which means that funeral directors are relied upon to notify the APT if an alarm is sounding when they attend to bring a body. There has been no risk assessment to consider the likelihood of a fridge failure occurring and not being identified by a funeral director. v. Risk assessments have not considered the pressures on freezer storage capacity. Pressures on storage capacity should also be reflected in the Council's corporate risk register (see advice and guidance item 6).	

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3	At the time of the site visit inspection, the last freezer space was due to be occupied leaving no additional capacity for any bodies requiring long-term storage or that are already in a state of decomposition on arrival to the mortuary. There is a need for freezer storage capacity to be reviewed and for contingency arrangements to be considered as a matter of priority.	Major

Advice

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

No.	Standard	Advice
1.	GQ1	There are a five pieces of advice under GQ1: i. The DI should consider updating the body receipt and release SOPs, as they do not highlight the process to be followed for highlighting bodies of the deceased with the same or similar names. ii. The DI should consider updating the receipt procedure' (1 & 1a) to reflect that an appropriate assessment of the size of the deceased should be made before placing them at the bottom of the fridge. The DI should also consider placing signage in the over night fridge area so that funeral directors are aware not to use the bottom of the overnight fridge spaces. iii. Identification checks are made by APTs prior to evisceration of the body. The establishment updated its identification check procedure following an HTARI involving PM on a wrong body. The DI is advised to ensure that staff undertaking identification checks document that they have done so. iv. The DI is advised to ensure that all staff, including visiting pathologists, sign and date SOPs to demonstrate that they have been read and understood. v. Currently, SOPs only state the date the document was last reviewed. To improve document control, all SOPs should be version and date controlled. Furthermore, the date by which the document will require review should be stated on each document.
2.	GQ3	There are occasions when mortuary staff work alone and, at other times, are assisted by staff from the Crematorium to assist with specific mortuary activities, i.e. manual handling of bodies. The DI should consider drafting a lone working procedure.The DI should also consider recording the competence of staff involved in mortuary activities and risk assess their involvement in mortuary duties.

3.	GQ8	The DI is advised to extend the scope of risk assessments to include, the risks of the occurrence of an HTARI using the HTARI categories as a reference point, and the risks associated with lone working in the mortuary. Furthermore, the current template could be re-drafted to include a risk matrix system. This would enable the levels of risks and the likelihood of an incident occurring to be defined clearly.
4.	PFE1	Currently, only police officers are required to complete the visitors sign in book. To ensure good security arrangements are in place, the DI should consider requesting that all visitors to the mortuary sign in, e.g. crematorium staff, contractors,pathologists and funeral directors.
5.	PFE2	The fridges, freezers and PM suite are subject to maintenance by an external contractor. The DI is advised that the air changes in the PM room should be recorded by the contractor during maintenance visits, as although these are measured, the records do not provide evidence to support this.
6.	PFE3	There are four pieces of advice under this standard: i. Funeral directors using the night bank of fridges have been informed not to use the lower most fridge spaces. The DI is advised to provide signage to remind them. ii. Mortuary staff are responsible for recording fridge and freezer temperatures on a daily basis (except weekends). Although evidence of temperature monitoring was seen, mortuary staff were using a 'tick' system to demonstrate the temperature had been checked, as opposed to recording the temperature observed.The DI is advised that staff should record the temperature seen. iii. Although the fridges and freezers are connected to an alarm system, there is no dial-out system to notify members of staff of an alarm out of hours. Mortuary staff are reliant on funeral directors bringing in bodies out of hours and on weekends to notify them if an alarm is sounding. The DI should consider placing the fridge alarms on a dial-out system and to ensure that the alarms are subject to manual challenge to test they are working. As an immediate solution, the DI may wish to consider placing a visual reminder in the area accessed by funeral directors, so that they are aware of what to do should the alarm sound. iv. The DI should review the establishment's procedure on the use of freezer storage and when bodies should be moved to a freezer. In relation to the long-term storage of bodies, the HTA advises that bodies should be placed into frozen storage 30 days after the date of death, unless their release is imminent, or a second post-mortem examination.
7.	D1/2	At present, no human tissue disposal takes place at the establishment; however, 'Procedure Four, Removal of Histology Samples', contains the following sentence, 'should samples be returned to the Mortuary for disposal, these will be bagged separately and incinerated along with

		other clinical waste'. The DI is advised to consider updating this procedure so it captures information about the third party responsible for collecting human tissue and the systems used to capture the reason, method and date of disposal.

Concluding comments

The establishment's staff demonstrated a good working relationship and are keen to ensure that they are continuously improving. Some examples of good practice were noted during the inspection. The DI is responsible for scheduling and carrying out horizontal and observational audits that assess the establishment's compliance against HTA standards. Mortuary staff have good communication with the coroner's office to ensure that bodies are not released to funeral directors without the appropriate forms. Each body received is recorded on a 'body risk assessment' sheet, where details of height/weight/external observations upon arrival are noted. There is robust traceability of samples to other sites using a courier, faxback system.

There are some areas of practice that require improvement, including one minor shortfall and two major shortfalls in relation to standards GQ7, GQ8 and PFE3, respectively. The HTA has given advice to the Designated Individual on a range of issues to make further improvements.

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: 10 November 2015

Report returned from DI: 25 November 2015

Final report issued: 26 November 2015

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 16 May 2016

Appendix 1: HTA standards

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

Governance and quality system standards
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process
• Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include: o post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases o record keeping o receipt and release of bodies, which reflect out of hours arrangements o lone working in the mortuary o transfer of bodies and tissue (including blocks and slides) to other establishments or off site o ensuring that tissue is handled in line with documented wishes of the relatives o disposal of tissue (including blocks and slides) *(Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)* • Policies and procedures are regularly reviewed (for example, every 1-3 years). • There is a system for recording that staff have read and understood the latest versions of these documents. • Deviations from documented SOPs are recorded and monitored.
GQ2 There is a documented system of quality management and audit
• There is a quality manual which includes mortuary activities. • Policies and SOPs are version controlled (and only the latest versions available for use). • There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits). • Audits include compliance with documented procedures, records (for completeness) and traceability. • Audit findings document who is responsible for follow up actions and the timeframe for completing those actions. • Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why.

- There is a complaints system in place.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Staff are appropriately trained/qualified or supervised.
- Staff have annual appraisals.
- Staff are given opportunities to attend training courses, either internally or externally.
- Attendance by staff at training events is recorded.
- There is a documented training programme for new mortuary staff (e.g. competency checklist).

GQ4 There is a systematic and planned approach to the management of records

- There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.
- There are documented SOPs for record management.

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).
- Organs 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.