Site visit inspection report on compliance with HTA minimum standards

Central Mortuary, Birmingham

HTA licensing number 12194

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 May 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 Central Mortuary, Birmingham ('the establishment') had met the majority of the HTA standards. Three minor shortfalls were found in relation to: documented risk assessments; testing of mortuary fridge and freezer alarms; and the ventilation system in the main post mortem (PM) examination suite.

HTA consent standards do not apply to this establishment. All PM examinations are performed under the authority of HM Coroner, and no PM tissues are stored for use for scheduled purposes when coronial authority has ended.

Examples of strengths 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. 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

Central Mortuary, Birmingham ('the establishment') admits bodies from the community and local hospitals. Over 1,700 post mortem (PM) examinations are performed each year on adults and on children over two years of age, including high risk cases up to Category 3. All PM examinations are performed under authority of HM Coroner for Birmingham and Solihull by pathologists from local HTA-licensed establishments. No Home Office or hospital (consented) PM examinations, or PM examinations of children under two years old, are carried out.

Organs, tissues and fluids taken at PM examination are transported from the establishment by a contracted courier to local hospitals and toxicology laboratories for analysis. In line with the family's instructions, the hospitals dispose of or retain organs and tissues when coronial authority has ended. Organs or tissues may also, occasionally, be returned to the establishment for repatriation with a body prior to release to a funeral director. Toxicology samples are returned to the establishment following analysis for disposal by incineration once coronial investigations are complete. Disposal records are maintained.

The mortuary has 107 refrigerated storage spaces, including 27 in deep freeze. Paediatric cases are stored on dedicated trays in these fridges. There are two PM examination suites,

one of which is routinely used. This suite has four PM tables. The other suite is not currently used for PM examinations.

The establishment has been licensed by HTA since September 2007. Two previous site visit inspections have taken place (October 2007 and December 2010). This report describes the third, routine, site visit inspection of the establishment. The HTA inspectors met with staff involved with licensable activities and reviewed documentation. In addition, traceability audits were conducted. The storage locations and identifiers of two deceased persons with the same surname were audited. In each case, 'check' was written by the deceased's name on the whiteboard as a reminder to staff. However, 'check' had not been written in the mortuary register against either name, or on the body bag of one deceased person, which is out of line with the establishment's routine practice (refer to advice items 2, 6). For one case, part of the deceased's address had been written incorrectly by the funeral director on their identity tag, and hence was incorrect in the mortuary register. The correct address, as confirmed by the Coroner's Office, appeared in all other mortuary records (refer to advice item 7). Three cases where an organ, tissues or fluids were taken for analysis at PM examination were audited. Records of transfer of material to other establishments for analysis were seen. In one case, the toxicology samples had been returned following analysis and were stored in a -20 ^{o}C freezer pending disposal. For the other two cases, no material had been returned to the establishment for repatriation with the body or disposal, in line with the families' wishes. No anomalies were found in any of these audits.

Consent standards do not apply to this establishment, as all PM examinations are performed under the authority of HM Coroner, and relevant material is not stored for use for scheduled purposes once coronial authority has ended.

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.	There is a comprehensive documented risk assessment of the premises, facilities and equipment. However, there are no documented risk assessments of the admission, viewing, release or PM examination processes, or transportation of samples for analysis. *(Refer to advice item 8)*	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE1 The premises are fit for purpose.	The ventilation system in the PM suite requires upgrade to increase the number of air changes to the recommended level of ten per hour This is a longstanding problem, about which the HTA provided advice in 2013. The DI has discussed upgrade work with contractors, but plans for such work are yet to be finalised. The failure to provide adequate air changes is contrary to accepted good practice and may have a negative impact on the working environment. *(Refer to advice item 10)*	**Minor**
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.	There is no documented procedure, or schedule, for testing mortuary fridge and freezer alarms.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	The DI is advised to discuss with HM Coroner whether retention for the purpose of future diagnosis for the benefit of the family can be added to the list of options on the 'Retention and disposal of tissue' consent form for adults and older children. This option is given on the 'Retention and disposal of tissue' consent form for babies and young children.
2.	GQ1	Regarding standard operating procedures (SOPs), the DI is advised; • the 'Viewing of bodies' SOP (4.2) should specify which details are used to identify a deceased person prior to a viewing, such as their full name, date of birth and address; it should ensure that more than one identifier is used to mitigate the risk of preparing the wrong body for a viewing; • the 'Body receipt and handling' SOP (4.1) should state that bodies with the same, or similar sounding, names are highlighted with the word 'check' on the mortuary whiteboard, in the mortuary register and on the body bag (refer also to advice item 6), and; • SOPs should have a formal review process whereby a second person, other than the author, reviews the document.
3.	GQ1	The DI is advised to maintain written records to verify all pathologists have read, and will follow, relevant SOPs.
4.	GQ2, GQ3	The DI is advised that audits of processes such as admission, viewing and PM examination of bodies can be used to confirm ongoing staff competence in

		these procedures.
5.	GQ6	Identity tags applied to bodies of the deceased by funeral directors prior to their transfer to the mortuary are of variable quality and may become faded, damaged or unattached. The DI is advised to attach waterproof identity tags, such as those used in hospitals, to bodies upon their admission, to ensure traceability and minimize the risk of errors in identification.
6.	GQ6	The DI is advised that current systems for highlighting the presence of deceased persons with the same or similar sounding names, or cases where tissues or organs are to be returned to the body prior to release to a funeral director, can be further enhanced by, for example, placing a laminated card on the shroud of the deceased or applying a wrist tag stating this.
7.	GQ7	Minor non-conformances are discussed at bi-monthly HTA meetings, but are not formally logged. The DI is advised to keep written records of errors and non-conformances in the mortuary and of corrective and preventive measures taken. This will enable him to identify any possible trends in non-conformances which might indicate wider problems.
8.	GQ8	The DI is advised to assess the potential risk of contamination by bodily fluids or infective agents when bodies pass between transitional and clean areas at admission and release in the 'HTA compliance of premises, facilities and equipment' risk assessment.
9.	PFE1	The main suite which is used for PM examinations does not have a protective underfloor membrane. As a result, ground water from underneath the building has caused the linoleum flooring to bubble in places, creating an uneven surface. This bubbling does not at present affect cleaning or drainage, or pose a health and safety risk to staff. However, the floor will continue to become more uneven unless a membrane is fitted. The establishment has been in discussion with a contractor to have such a membrane installed. The HTA endorses the establishment's commitment to address this problem. Once plans for installation of an underfloor membrane in the main PM suite are finalised, the DI should notify HTA whether PM examinations will be performed in the second PM suite whilst the work is undertaken, or bodies transferred to other licensed establishments for PM examination.
10.	PFE2	Until the ventilation system is upgraded, the DI is advised to ensure: • that all staff working in the mortuary have necessary immunisations against infectious diseases; • personal protective equipment for known, or suspected, high risk cases continues to be available, and; • airflow in the PM suite is monitored regularly in the PM suite. The Health and Safety Executive may also be able to provide advice.

Concluding comments

Despite the shortfalls, areas of strength were identified. Staff have a good working relationship with HM Coroner's Office, and there are regular meetings between the Coroner, her officers and mortuary staff. A wide range of premises and procedural audits is performed, and findings are discussed at bi-monthly meetings. SOPs are generally clear and well written.

A number of areas of practice require improvement, including three minor shortfalls. The HTA has given advice to the DI with respect to documented procedures and traceability systems, and the mortuary premises.

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: 12 June 2015

Report returned from DI: 26 June 2015

Final report issued: 26 June 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: 03 September 2018

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:
    - 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 and tissue samples taken during PM examination are fully traceable.
- Details of organs retained and the number of wax blocks and tissue slides made are recorded.
- The traceability system includes the movement of tissue samples between establishments.
- Details are recorded of tissue that is repatriated or released with the body for burial or cremation.
- Regular audits of tissue storage and traceability are undertaken to ensure compliance with operational procedures; tissue samples found which are not being stored with consent are disposed of with reference to the family's wishes.
- Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly

- Staff are trained in how to use the incident reporting system.
- Staff know how to identify incidents and near-misses which must be reported, including those that must be reported to the HTA
- The incident reporting system clearly outline responsibilities for reporting, investigating and follow up for incidents.
- The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.

- Information about incidents is shared with all staff (including the reporter) to avoid repeat errors.

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed.
- Risk assessments include risks associated with non-compliance with HTA standards as well as health and safety risks.
- Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years.
- Risk assessments include how to mitigate the identified risks; this includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- There is sufficient space for the activities to be carried out.
- Refrigerated storage units are in good working condition and well maintained.
- Surfaces are made of non-porous materials.
- The premises are in reasonable condition (structure and cleanliness of floors, walls, entranceways).
- The premises are secure (e.g. there is controlled access to bodies, tissue, equipment and records).

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:
  - fridges / Freezers
  - hydraulic trolleys
  - post mortem tables
  - hoists
  - saws (manual and/or oscillating)
  - PPE for high risk cases (e.g. respirators)
- The use of porous materials is kept to a minimum and has been risk assessed
- Maintenance/service records are kept for equipment, including fridges/freezers, trolleys, post mortem tables (if downdraught) and post mortem suite ventilation.

(Note: These records may be held by the mortuary or centrally by the Trust, e.g. Estates Department.)

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- There is a documented Trust or mortuary/laboratory policy for the disposal of human tissue, which reflects the requirements of the HTA code of practice on disposal.
- The policy states the position with regard to the retention and use of microscope slides, and in particular that tissue slides must be disposed of or returned to the family in accordance with their wishes if consent is not obtained for their continued storage and future use once the PM has concluded.

D2 PM tissue is disposed of if consent is not given for its storage and use for scheduled purposes
• There are documented procedures for disposal of human tissue, which include methods of disposal for whole organs, wet tissue, wax blocks and microscope slides. • Tissue is disposed of in accordance with the documented wishes of the deceased person's family. • Disposal details of organs and tissue blocks are recorded, including the date and method of disposal. • There is a rolling programme of tissue disposal that ensures that tissue, including microscope slides, is disposed of in a timely fashion when it is no longer needed for the purposes of the Coroner or to determine the cause of death.

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   (1) A notice of proposal being issued to revoke the licence

   (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or
   - indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
   - has the potential to become a critical shortfall unless addressed

   or

   A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

   In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.