Site visit inspection report on compliance with HTA minimum standards

Miller House Mortuary
HTA licensing number 12125

Licensed under the Human Tissue Act 2004 for the

- **making of a post mortem examination;**
- **storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose**

2 July 2014

Summary of inspection findings

The HTA found the Designated Individual, the Licence Holder, the premises and the practices to be suitable in accordance with the requirements of the legislation.

Although the HTA found that Miller House Mortuary (the establishment) had met the majority of the HTA standards, three minor shortfalls were identified in relation to governance and quality standards. Existing standard operating procedures (SOP's) need to be strengthened to reflect working practice; no unique identifier is used in traceability records for samples taken at post mortem examination; and a more robust system needs to be in place for the recording of mortuary specific incidents, raising awareness of those reportable to the HTA.

Particular examples of strengths and good practice 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 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 refers to the activities that take place within the Miller House Mortuary, which conducts around 1,200 adult post-mortem (PM) examinations each year. The majority of these are routine coronial cases on behalf of HM Coroner from local areas, with approximately 40 being forensic cases. High risk cases are undertaken in a purpose-built PM suite within the establishment. The establishment does not carry out perinatal or paediatric PM examinations, or consented cases.

The mortuary is staffed by two qualified Anatomical Pathology Technologists (APTs). The fridge room has overall capacity for 98 adult bodies, and includes eight bariatric fridges and twenty spaces used as freezer storage. Temperature and alarm systems are monitored electronically. The main PM Suite contains five down-draught tables; including one in the the high risk suite.

During working hours, receipt and release of the deceased are overseen by the mortuary staff. Out of hours, admissions to the mortuary are carried out by a designated team of funeral directors, under the direction of the Coroner. There is an APT on-call for emergencies.

The mortuary register is completed for all community deaths. On arrival to the mortuary, bodies are assigned a unique identification number on a tag which is applied to the deceased's wrist. A capacity audit is carried out every five days to identify bodies that have been held in the mortuary for a long period. This highlights the potential need to move the deceased to freezer storage to help preserve the condition of the body.

The body is examined and the identity of the deceased is checked by the pathologist and the APT the day before the PM examination. Before evisceration, two APT's check the identification of the deceased again. A record of samples taken during the PM examination is

made in a specimen log book. Tissue, organs and toxicology samples taken at PM examination are transferred to other HTA Licensed establishments for analysis. The establishment does not dispose of PM tissue; therefore the standards relating to disposal do not apply.

This was a routine inspection brought forward following an incident that was reported to the HTA, and carried out to provide assurance that appropriate preventive measures are in place. Included in the one day inspection was a visual inspection of all facilities, a document review and interviews with key members of staff.

Traceability audits were completed as part of the inspection:

- Three bodies were selected from the white board and found to be in the specified location in the mortuary using the identification tag attached to the deceased by the funeral director. The information was also verified with the mortuary register.

- Three traceability audits of a PM examination under the authority of the Coroner, where tissue was removed for histology, were conducted. Tissue was traced from PM examination Histology request forms and the specimen log book. Coroner's forms were also reviewed.

Anomalies were found during the audit process. The identification toe tag which is placed on the body of the deceased by the funeral director on admission to the mortuary was missing from one of the deceased. There were no unique identifiers used for the traceability of tissue samples taken at PM examination. Advice and guidance has been given to strengthen these procedures.

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
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	Mortuary standard operating procedures, which set out activities taking place, do not cover some key aspects of mortuary work. For example, the following are not present: • Activity 1 & 19: The minimum number of identifiers that should be used for the identification of the deceased as part of the checks that take place on receipt and release of bodies; • Activity 1: The process of admission of bodies outside of working hours	Minor

	• Activity 53: Instructions on when to freeze a body and setting out circumstances in which it is unsuitable to move a body from refrigerated to frozen storage. • An SOP for the pre PM examination process, to include identification and external examination of the deceased prior to evisceration. • An SOP for the the Forensic PM examination procedure to include the recording and traceability of tissue samples. This is not an exhaustive list. To fully address the shortfall, the DI should review all SOPs relating to licensable activities to ensure they provide the necessary level of detail	
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	Tissue and organs taken at PM examination are recorded on the 'PM examination histology form' and in the specimen logbook. Traceability is maintained using the deceased person's name. There is no unique identifier used to trace samples to the deceased, such as a PM examination number. This creates a potential risk to traceability, for example, if tissues need to be reunited with the deceased's body following analysis. *(Refer to advice item 4)*	Minor
GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	The establishment has a corporate reporting system for health and safety incidents and a documented procedure for reporting HTA Reportable Incidents (HTARIs) to the HTA. However, mortuary incidents which don't require reporting through these systems are not recorded. This makes it difficult to monitor the occurrence of such incidents for any recurrent trends, and to track the completion of any necessary corrective and preventive measures.	Minor

Advice

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

No.	Standard	Advice
1.	GQ1	There is a system in place to ensure that staff have read and understood the latest versions of the SOPs. However, this is not recorded for mortuary staff. The DI is advised to maintain records to verify that mortuary staff have read and understood new and updated SOPs, for example, through a 'read and sign' sheet
2.	GQ4	The DI is advised to introduce a consistent documented procedure for correcting errors in the mortuary register and other important written records. Such an approach, which could include striking through errors with a single line and initialling and dating corrections, would facilitate audit. The use of correction fluid within written records should be avoided.
3.	GQ6.	Deceased persons who have the same or similar sounding names are highlighted in the mortuary register with a red dot. The DI is advised that the risk of errors in identification could be reduced further by, for example, highlighting persons with the same or similar names on the white board. The DI may also wish to consider placing a coloured sticker onto wrist tags or attaching a notice to shrouds/clothes as additional visual reminders. The DI is also advised to consider a similar procedure for the repatriation of organs and tissues to the deceased. Any changes to working practice should be reflected in the relevant SOP.
4.	GQ6	Tissue taken at PM examination are recorded in the Specimen Log Book as 'Histology'. The DI is advised to strengthen the traceability of samples by recording the type and amount of tissue that is taken exactly as it is stated on the Histology request form. Any changes to working practice should be reflected in the relevant SOP
5.	GQ7.	The policy on the management of HTA reportable incidents covers the procedure for reporting an incident to the HTA. The DI is advised to expand the current policy to include the HTA Reportable Incident classifications. The DI is also advised to identify a second Person Designated to report incidents via the portal and to update the SOP with the names and contact details of those PDs that can report incidents to the HTA via the portal. The HTA has produced guidance on HTARI reporting, which the DI may find useful when revising the procedure: http://www.hta.gov.uk/_db/_documents/Guidance_for_reporting_HTARIs.pdf
6.	GQ8	The DI is advised to review the format of the establishment's risk assessments to ensure there is a clear distinction between existing control

		measures and any additional measures that need to be implemented to further mitigate identified risks. For example, risks associated with the admission of a deceased person to the mortuary are to be mitigated by providing training funeral directors in the correct procedures. However, as no records of any such training have been kept, it is difficult to verify this control measure has been implemented and the risk reduced. The DI is also advised to extend the suite of risk assessments to cover all of the HTA reportable incidents classifications.
7.	PFE2	The DI is advised to ensure that the daily temperature logging of the fridges and freezers in the mortuary takes place before they have been accessed in order to ensure that temperatures are stable, allowing for trend analysis.
8.	-	Mortuary staff carry out a high volume of PM examinations. To ensure they have sufficient protected time to strengthen quality management systems and address the shortfalls identified, without impacting on mortuary service provision, the DI is advised to keep under review the administrative support available to them.

Concluding comments

During the inspection, examples of good practice were observed. Miller House Mortuary is a clean, well-kept facility with a small dedicated team of staff who maintain a high level of dignity and respect for the deceased. Systems of quality management and governance have been greatly strengthened since the last inspection and new processes around the identification of deceased who require long term storage are now embedded into mortuary procedures. The mortuary carries out an audit that identifies the length of time bodies have been in storage and a robust process to move bodies into freezer storage to preserve their condition.

The establishment ais currently facing difficulty with capacity of long term storage due to the high volume of bodies requiring a local authority cremation or burial. The HTA endorses the continued efforts of the establishment in strengthing communication with HM Coroner's Office and Local Authority staff to address this situation.

There are a number of areas of practice that require improvement, including three minor shortfalls. The HTA has given advice to the DI with respect to some elements of governance systems and the traceability of tissue.

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: 18 July 2014

Final report issued: 31 July 2014

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: 19 October 2014

Appendix 1: HTA standards

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

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• There is a documented policy which governs consent for post-mortem examination and the retention of tissue and reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent. • There is a documented SOP detailing the consent process (including who is able to take consent, what training they must receive, and what information must be provided to those giving consent for post-mortem examination). • There is written information about the consent process (provided to those giving consent), which reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.
C2 Information about the consent process is provided and in a variety of formats
• Relatives are given an opportunity to ask questions. • Relatives are given an opportunity to change their minds and is it made clear who should be contacted in this event. • Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use). • Where consent is sought for tissue to be retained for future use, information is provided about the potential uses in order to ensure that informed consent is obtained. • Information on the consent process is available in different languages and formats, or there is access to interpreters/translators.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• There is a training programme for taking consent for post-mortem examination and tissue retention which addresses the requirements of the HT Act and HTA code of practice on consent. • Refresher training is available (e.g. annually). • Attendance at consent training is documented. • If untrained staff are involved in consent taking, they are always accompanied by a trained individual.

Governance and quality system standards
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process

• Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include:
  ○ post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases
  ○ record keeping
  ○ receipt and release of bodies, which reflect out of hours arrangements
  ○ lone working in the mortuary
  ○ transfer of bodies and tissue (including blocks and slides) to other establishments or off site
  ○ ensuring that tissue is handled in line with documented wishes of the relatives
  ○ disposal of tissue (including blocks and slides)
(Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)
• Policies and procedures are regularly reviewed (for example, every 1-3 years).
• There is a system for recording that staff have read and understood the latest versions of these documents.
• Deviations from documented SOPs are recorded and monitored.

GQ2 There is a documented system of quality management and audit
• There is a quality manual which includes mortuary activities. • Policies and SOPs are version controlled (and only the latest versions available for use). • There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits). • Audits include compliance with documented procedures, records (for completeness) and traceability. • Audit findings document who is responsible for follow up actions and the timeframe for completing those actions. • Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why. • There is a complaints system in place.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills
• Staff are appropriately trained/qualified or supervised. • Staff have annual appraisals. • Staff are given opportunities to attend training courses, either internally or externally. • Attendance by staff at training events is recorded.

- There is a documented training programme for new mortuary staff (e.g. competency checklist).

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

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

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

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

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.
- 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.