Site visit inspection report on compliance with HTA minimum standards

Medico-Legal Centre

HTA licensing number 12218

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**

5 April 2016

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 the Medico-Legal Centre had met the majority of the HTA standards, two minor shortfalls were found against standards GQ7 and GQ8, in relation to incident reporting procedures and risk assessments.

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 (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 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 the Medico-Legal Centre, Sheffield (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 is a public mortuary located in the same premises as the coroner's court and offices. It undertakes approximately 1,000 PM examinations a year, under the jurisdiction of HM Coroner for South Yorkshire (West). These include category 3 high-risk PM examinations and Home Office (forensic) PM examinations. Paediatric cases are transferred directly to other licensed establishments and the bodies of deceased infants or children are only occasionally stored in the mortuary, in forensic cases.

The establishment has a computerised tomography (CT) scanning facility located next to the mortuary, which is used to conduct digital PM examinations with authorisation of the Coroner or consent from the family. CT scanning is not a licensable activity under the HT Act and therefore this facitity was not within the scope of the inspection.

The mortuary has 87 storage spaces, comprising 78 fridges spaces and nine freezer spaces. Eight of the fridge spaces and four of the freezer spaces are bariatric storage. It provides a 24-hour service, with mortuary staff having responsibility for admitting and releasing bodies. A funeral director under contract to the Coroner is responsible for transporting bodies to the mortuary following deaths in the community.

When a deceased is admitted, a 'Declaration of Identification' form is completed and an ankle band with the deceased's full name, date of birth and a unique serial number assigned by

mortuary staff are added. The unique serial number is generated from the mortuary register. Bodies admitted from the community will also have a police toe tag, containing the deceased's full name, date of birth and address.

The mortuary fridges are connected to an audible alarm, which sounds if the fridge or freezer temperatures go outside of normal parameters. There is no auto dial-out system as staff are on-site 24 hours a day; however, staff monitor and record critical storage conditions and the DI informally reviews the temperature monitoring data to analyse trends (see advice item, 3).The establishment does not currently test the fridge alarms (see advice item, 3).

There are two PM suites, including a dedicated forensic suite. High-risk (category 3) PM examinations take place after all other cases have been completed; personal protective equipment is available to mortuary staff.

Visiting pathologists undertake all PM examinations. When tissue is retained, the wet tissue is cassetted during the examination and the blocks sent to another facility that processes them into blocks and slides and returns them to the establishment. Once the wishes of the family are known, mortuary staff arrange the storage, return or sensitive disposal of blocks and slides. Organs are fixed on site before they are sent away for specialist examination and repatriated with the deceased in line with the wishes of the family.

The HTA inspection included a documentation review and a visual inspection of the body store, post-mortem suites and viewing room. Interviews took place with a Pathologist, Anatomical Pathology Technologist (APT), the Medico-Legal Centre Manager and Lead APT (Designated Individual). A meeting was also held with the Coroner.

Traceability audits of three bodies were carried out. Both forward and reverse audits were carried out and bodies were identified by checking the full name, date of birth and serial number on the ankle bands and toe tags. A minor discrepancy was noted for one body, as the serial number had been noted incorrectly by one digit on the mortuary whiteboard;however, the ankle bands and corresponding paperwork had the correct unique serial number.

A tissue traceability audit was carried out using the paper and electronic records relating to samples taken during PM examination. One case was traced from the documented records to location of storage of blocks, and a set of blocks was identified in store and traced back through the documented records. No discrepancies were found.

Tissue samples and organs retained for police purposes 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/or 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.

Inspection findings

The HTA found the Designated Individual (DI) and theLicence 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 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly	Although the establishment has a procedure for dealing with HTA reportable incidents, in its current format the procedure does not: i) describe all types of incidents that must be reported; ii) specify the HTA reporting timeframes. Furthermore, the procedure documents the serious adverse event and reaction definitions under the Human Tissue (Quality and Safety for Human Application) Regulations 2007, which are not relevant to this establishment as it is only undertaking activities licensed under the HT Act.	Minor
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately	The establishment's risk assessments focus on risks to the health and safety of mortuary staff and do not consider the risks to bodies, organs and tissue.	Minor

Advice

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

No.	Standard	Advice
1.	GQ1	There are four items of advice in this section: 1. The DI should ensure that any amendments to the mortuary register are made with a single strike through using pen so that the text is still visible. Amendments should include the initials of the person making the change in order to improve the audit trail. 2. The DI is advised to review the procedure for viewing and identification of the deceased and consider including the practice of asking the relatives attending a viewing to confirm whom they have come to see. 3. The DI is advised to review the procedure MLC46 (freezing of the body) to include the length of time a body may be stored in refrigeration before it is transferred to the freezer. The HTA recommends a maximum of 30 days.

		4. The DI is advised to review admission and post-mortem procedures (i.e. MLC6, MLC9 and MLC12) as it was noted that most procedures refer to the 'name' as opposed to the 'full name' of the deceased.
2.	GQ2	The establishment carries out audits to assess its compliance against HTA standards. However, the audit reports do not make clear which areas of mortuary practice have been reviewed. The DI is advised to ensure that the content of the audits is clearly documented in the report.
3.	PFE3	There are four pieces of advice in this section: 1. Mortuary staff monitor and record the temperatures of fridges and freezers on a daily basis. The DI is advised to carry out trend analysis of the temperatures observed on a more formal basis and document this on the temperature logs. This will enable the establishment to plan preventative maintenance or servicing when the need arises. 2. Although mortuary staff attend the mortuary 24 hours a day and are available should an alarm sound locally, the fridge/freezer alarms are not subject to manual challenge to confirm if they are functioning correctly. The DI is advised to incorporate a regular schedule of alarm testing to ensure that they are functioning correcty. 3. Should the 24-hour service arrangements change in future, the DI should consider the out-of-hours arrangements for the notification of fridge or freezer alarms. 4. Bodies are not fully shrouded, with the head and feet being exposed. To ensure the dignity of the deceased is maintained, the DI is advised that all bodies, should be fully shrouded unless there are exceptional circumstances.
4.	D2	The DI is advised to review Disposal Procedure MLC15 so that it includes the HTA's requirement for the reason, method and date of disposal to be documented for all human tissue that is disposed of. The procedure should provide staff with instructions about how the reason, method and date of diposal should be documented in the mortuary register/computer. For example, currently, blocks and slides are placed in a yellow bin used for the disposal of human tissue only. Once the bin is full, a company responsible for incineration collects it. The procedure does not define whether the disposal date is the date: i) the tissue is physically placed in the bin; or ii) when it is collected by the company; or iii) the day on which the tissue is incinerated. Although there were no issues identified in regards to disposal, the DI is advised to review this to strengthen procedures as set out above.
5.	N/A	The DI is advised to add the Medico-Legal Centre Manager as a Person Designated (PD) under the licence and consider delegating them some responsibility. For instance, they could assist in the carrying out of HTA compliance audits.

Concluding comments

The establishment's staff work cohesively to ensure they achieve a high level of compliance with the HTA standards. Several areas of good practice were noted, including:

- a well thought-out staff competency process;
- the daily check of the condition of the deceased to ensure dignity is maintained;
- clear records of deceased with specific morphologies;
- schematic representation of the correct labelling of a deceased;
- a 24 hour service to ensure consistent and continuous care.

There are some areas of practice that require improvement, including two minor shortfalls in relation to standards GQ7 and GQ8. 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 shortfall 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: 26 April 2016

Report returned from DI: 26 May 2016 (with comments)

Final report issued: 8 June 2016

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: 07 July 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.

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 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.