

Site visit inspection report on compliance with HTA minimum standards

Manlove Forensics Ltd

HTA licensing number 12602

Licensed under the Human Tissue Act 2004 for the

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

8 August 2013

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 establishment had met the majority of applicable HTA standards, one minor shortfall was found in relation to the reporting of incidents to the HTA. However, this shortfall was resolved to the satisfaction of the HTA before the draft report was issued to the establishment.

Particular examples of 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

Manlove Forensics Ltd is a Forensic Science laboratory, which provides a service to pathologists undertaking post mortem examinations on behalf of the Police, Coroners and the Military. The pathology department receives wet tissue samples from a group of private pathologists undertaking forensic and coronial post mortems at various HTA licensed establishments around the country. The wet tissue is processed into blocks and slides, which are returned to the pathologist for examination. Once the pathologist has concluded their investigation, the slides are returned to Manlove Forensics Ltd where they are stored pending the end of coronial authority or under the Police and Criminal Evidence Act 1984 (PACE). In coronial cases, at the end of coronial authority the wishes of the family are carried out, with tissue either being returned to the family or their funeral director, sensitively disposed of or stored for use for a scheduled purpose depending upon the consent that is in place.

The establishment has been licensed since December 2012 and this routine inspection was its first site-visit inspection to assess whether it is continuing to meet the HTA's standards. The timetable for the site visit was developed in consideration of the establishment's licence application information, as well as pre-inspection discussions with the DI. During the site visit, a visual inspection of the premises, review of documentation and interviews with establishment staff were undertaken.

A tissue traceability audit was undertaken as part of the inspection. Four coronial cases were selected at random in the block and slide archive. In one of the four cases, the blocks and slides had been disposed of. In this case, the database on which the families' disposal wishes were recorded was checked. Additionally, the establishment's disposal records were reviewed and the disposal of the three blocks and slides for this case was correctly recorded. For the other three cases, the details of the retained tissue were cross checked with the establishment's electronic database records. No anomalies were found. The family wishes forms were also sought for the three cases where tissue is being retained. One case became a police case and the blocks and slides are now being held under PACE. The second case has a correctly completed wishes form indicating that the family wished for the tissue to be retained. The third case was more recent and the wishes forms were still awaited at the time of the inspection.

Details were also taken of two specimens of wet tissue that was being held at the establishment. A review of the establishment's records showed that the wet tissue is being held under PACE.

In summary, no anomalies were found during the tissue traceability audit.

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
GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	<p>The establishment has a procedure in place to record and investigate any adverse events that occur internally. However, this procedure does not cover the reporting of HTA reportable incidents (HTARIs) to the HTA. The establishment should have a procedure in place which aids the identification of HTARIs and details who should report them to the HTA, who reports them if the DI is absent, how to report them and within what timeframe they should be reported.</p> <p><i>Following the inspection, the establishment implemented a new procedure describing the HTARI reporting procedure. Additionally the DI has nominated a new Person Designated to the licence who is authorised to submit HTARIs to the HTA in his absence. The HTA has assessed this evidence as satisfactory to address the shortfall, and this standard is now met.</i></p>	Minor

Advice

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

No.	Standard	Advice
1.	PFE4	The establishment has a document (H001b) that sets out the responsibilities of the courier company used to transport tissue on its behalf. Although the courier has seen this document, there is no formal agreement between the two organisations. The DI is advised to put a contract in place with the courier company, so that the terms of the arrangement and the responsibilities of each party are clearly defined and understood.
2.	C1	<p>The establishment's practice is to verify that consent is sought from the highest ranking person in the hierarchy of qualifying relationships, as set out in the HT Act. In all cases, the relationship of the person signing the form is reviewed and where the person is lower than grandparent/grandchild in the hierarchy, enquiries are made with the coroner's office to establish whether there is a more appropriate family member in the hierarchy.</p> <p>This procedure may not fully mitigate the risk of tissue being retained without the consent of the person nearest the top of the hierarchy of qualifying relationships. The DI is therefore advised to consider, in consultation with the Coroner, whether checks should be undertaken wherever the person having signed the form is not the spouse or partner of the deceased. This will help avoid the establishment acting on the wishes of an adult child, who has completed the coroner's form without reference to their remaining parent.</p>

Concluding comments

Areas of good practice were found during the inspection. The establishment has systems to track tissue while it is on site. Additionally, these systems include tracking tissue sent off site either for review by pathologists or for specialist review in relation to particular pathologies. These systems help assure the DI that the establishment tracks all tissue including that which is held temporarily off site meaning that the tissue, if not returned within a defined timeframe can be requested to be returned so that the family's wishes can be carried out.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 6 September 2013

Report returned from DI: 9 September 2013

Final report issued: 10 September 2013

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
<ul style="list-style-type: none">• 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
<ul style="list-style-type: none">• Relatives are given an opportunity to ask questions.• Relatives are given an opportunity to change their minds and it is 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
<ul style="list-style-type: none">• 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.

<ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • 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.
GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail
<ul style="list-style-type: none"> • 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
<ul style="list-style-type: none"> • 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.