Site visit inspection report on compliance with HTA minimum standards

Gloucestershire Coroner's Court

HTA licensing number 12595

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**

7 February 2013

Summary of inspection findings

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

Although the HTA found that Gloucestershire Coroner's Court (the establishment) had met the majority of the HTA standards, three minor shortfalls were found against the governance and quality system standards and premises, facilities and equipment standards.

The shortfalls relate to body identification procedures, serious untoward incident reporting and fridge/freezer monitoring. In all three cases, the establishment has procedures governing the activity; however, these require further development in order to fully meet the HTA standards. Following the inspection and prior to the final inspection report being issued the establishment addressed two of the shortfalls relating to body identification procedures and serious untoward incident reporting to the HTA's satisfaction.

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

The mortuary and body store are located within the newly-built Gloucestershire Coroner's Court. They make up part of a purpose-built facility and are of a high standard. The rear of the establishment, where bodies are received and released, is slightly overlooked by neighbouring buildings; however, the establishment has taken measures to minimise the risk of observation. The rear entrance has a porch roof over the door and the establishment insists that all ambulances or funeral directors back their vehicles up to the door, so that only the front of the vehicle can be seen. All bodies are covered in sheets or contained in a body bag during receipt and release.

The establishment undertakes approximately 1,200 coronial post mortem (PM) examinations per year. Known high risk PM examinations of bodies with category 3 infections such as HIV, Hepatitis B and C are undertaken there, with higher risk infectious cases and paediatric cases transferred to other licensed establishments. No consented PM examinations are currently undertaken at the establishment.

Any tissue taken during PM examinations is sent to other licensed premises for processing into blocks and slides and review by the pathologist and there is a good system of traceability, which includes a system of faxing between the establishment and the premises where the tissue is sent. A pre-shipment fax is sent to the receiving establishment, which includes details of all the tissue that is due to be sent. On receipt, a fax is returned to the

establishment confirming that the tissue has arrived and matches the details contained within the pre-shipment fax. This system helps to assure the DI that there is a robust audit trail of tissue that is sent off site for analysis. Some advice has been given to the establishment on how this might be improved further (see Advice item 4 below).

The establishment has been licensed since March 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. In addition, a sample audit of bodies in refrigerated stored was undertaken. Four bodies were chosen at random and identification details recorded on body tags were checked against details in the mortuary register and on the mortuary fridge doors. No anomalies were found; however, in three of the four cases, the body identification tags only contained the forename and surname of the deceased (see shortfall below).

A tissue traceability audit was also undertaken. Details of three coronial PM examinations were taken and all records relating to tissue that had been taken and transported off site, including the traceability faxes, were reviewed. Again, no anomalies were found during this 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
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	During the sample audit in the body store, identification tags on three of the four bodies contained only the forename and surname of the deceased. Identifying the deceased using their name only, increases the risk of error if there are two or more individuals in the mortuary with the same or similar name. *The establishment provided documentary evidence to address this shortfall prior to the issue of the final report. The HTA has assessed this evidence as satisfactory to address the shortfall.*	**Minor**

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	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 Serious Untoward Incidents (SUIs) to the HTA. The establishment should have a procedure in place which aids the identification of SUIs 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. *The establishment provided documentary evidence to address this shortfall prior to the issue of the final report. The HTA has assessed this evidence as satisfactory to address the shortfall.*	**Minor**

Premises, Facilities and Equipment

Standard	**Inspection findings**	**Level of shortfall**
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records. & PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.	The establishment has considered the possibility that a power failure may lead to the refrigerated units not maintaining appropriate temperatures for the storage of bodies. To mitigate this risk, on site temporary power generation equipment has been installed. The fridges and freezers in the mortuary are new and still covered by the manufacturer's warranty. An automated system monitors the temperatures and triggers an alarm if the temperature exceeds set limits. However, there are three elements of fridge/freezer monitoring that require attention: 1) The establishment was unaware of the upper or lower temperature limits which would cause the local alarm to trigger; 2) The establishment does not undertake regular testing of the alarm system to verify that it is operating as expected; 3) The establishment currently has no system in place that would alert staff that refrigerated units had deviated from set temperatures out of hours.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	The DI is advised to introduce a system that records that staff have read and understood standard operating procedures (SOPs) and policies, so that he can be assured that staff are following mortuary procedures.
2.	GQ2	The establishment undertakes a range of audits. On a monthly basis, the DI audits a sample of mortuary records to ensure that the electronic information management system reflects the information that has been entered into the establishment's mortuary register. In addition, audits of body release checks are undertaken. The DI is advised to expand the scope of the audits to include some procedural audits. As well as helping to assure him that staff are following the correct procedures, these will provide a means by which he can assure himself that the procedures remain fit for purpose.
3.	GQ3	The coroner's contracted funeral directors bring bodies to the mortuary out of hours and use the available mechanical lifting trolleys. The DI is advised to undertake some training with funeral director staff in the operation of these trolleys so that he can be assured the equipment is used properly and that the risk to funeral directors and to the bodies of the deceased by misuse is minimised. The DI is also advised to record this training.
4.	GQ6	The establishment has introduced a 'fax back' procedure which records when tissue sent for analysis arrives at the receiving premises. The DI is advised to develop this further so that couriers collecting tissue are required to sign to record that they have collected the tissue. This will provide the establishment with a traceability procedure that tracks every step of tissue and organ transfer.
5.	GQ6	Currently, establishment staff are alerted to the need for tissue to be repatriated with the body prior to release by marking the fridge or freezer door with a dry marker pen. The DI is advised to introduce a system where a notice is placed with the body indicating the need for tissue to be repatriated prior to release so that, in the event of the mark on the fridge/freezer door being accidentally removed, there will still be a means by which staff are alerted that tissue needs to be repatriated before releasing the body.
6.	D1	The establishment rarely needs to dispose of tissue, since tissue taken during PM examination is sent to other licensed premises for processing and analysis. However, it has developed a SOP to cover instances where tissue may need to be disposed of. This SOP does not reflect the practice of sending tissue to other licensed premises for disposal. The DI is advised to update the SOP to fully reflect the disposal procedure.

Concluding comments

This was the first inspection of this newly licensed establishment and it was clear that the DI is very involved in the day to day operation of the facility as well as being responsible for its overall management. In addition, the DI and his staff have developed systems which seek to ensure that they provide an effective service, and demonstrate a commitment to continuous

quality improvement.

Some examples of areas of good practice that were observed throughout the inspection are included below.

The establishment has undertaken a range of risk assessments that, as well as assessing various health and safety risks, assess the risks posed to the tissues and bodies at the establishment.

The establishment is currently training a new member of staff and has developed a thorough training program which records competencies and progress towards becoming fully trained.

The 'fax-back' system to confirm that tissue sent for analysis has been received helps to assure the DI that there is a robust audit trail for tissue that is transported off-site.

There are a number of areas of practice that require improvement, including three minor shortfalls. The HTA has also given advice to the Designated Individual with respect to governance and quality system standards and disposal standards.

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.

Before the draft inspection report was finalised, the establishment submitted revised standard operating procedures addressing the shortfall relating to body identification. The establishment now use a three point identification system which includes, forename, surname and unique mortuary number to identify bodies during body receipt, viewing, undertaking a post mortem examination and body release procedures. A new serious untoward incident reporting standard operating procedure was also provided. This information was assessed by the HTA as satisfactory to meet the shortfalls. Consequently there is no longer a need to address these two shortfalls through the CAPA process.

Report sent to DI for factual accuracy: 7 March 2013

Report returned from DI: 18 March 2013

Final report issued: 2 April 2013

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: 26 June 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
• 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.

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

- 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.