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**

28 September 2016

Summary of inspection findings

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

Gloucestershire Coroner's Court (the establishment) was found to have met all the standards.

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

This report refers to licensed activities carried out at Gloucestershire Coroner's Court, where a mortuary and body store are located. This was the second routine site visit inspection of the establishment (the last inspection took place in 2013). The inspection included a visual inspection of the body store, post mortem (PM) room, viewing area and areas where tissue taken from PM examination is stored. Interviews with members of staff and a review of documentation was also undertaken.

The mortuary is staffed by a Centre Manager, who is the Designated Individual under the HTA licence, a senior Anatomical Pathology Technologist (APT), two further APTs and a Mortuary Technician. The Corporate Licence Holder (CLH) is Gloucestershire County Council. There is a team of Coroner's Officers based on site.

The establishment carries out approximately 1,000 PM examinations each year, predominantly on behalf of HM Coroner for Gloucestershire; these include forensic, defence and high risk PM examinations up to category 3. Paediatric cases are sent to other licensed establishments for PM examination. There are eight contracted Pathologists who undertake the PM examinations. Hospital consented PM examinations are rarely undertaken, but when they are, it is under an agreement with the referring hospital and consent is sought by the deceased person's clinician and the hospital's bereavement team..

The body store has 62 spaces for bodies, which includes nine freezer and 53 fridge spaces. There are dedicated fridge bays which can accommodate bariatric bodies. On the rare occasion that the establishment receives a paediatric body, it is stored on a separate fridge tray. There is a web-based alarm system that monitors the fridge and freezers 24 hours a day and sends an email directly to mortuary staff on call in the event of a fridge failure. There is secure swipe card access to the mortuary, and CCTV inside the body store and outside the building.

There is contingency storage at other licensed establishments and funeral homes nearby, all of which have an agreement with the establishment.

The mortuary receives bodies from the community and the local hospital. The areas of the body store where bodies are received and released is fenced in and has a roof over the door to keep the area secluded from view. The establishment has also taken measures to minimise the risk of observation from neighbouring buildings by requiring funeral directors and ambulances to back their vehicles up to the door in order to block the view. During working hours, mortuary staff admit bodies into the mortuary and write the identification details in the mortuary register. At least three identifiers are used, which include first name, last name, and a unique mortuary ID. In some cases, there will be additional information such as date of birth, date of death or address.

Out of hours, the Coroner's contracted funeral directors admit bodies to the mortuary. They are trained in mortuary procedures and must be signed off by mortuary staff as competent, before being allowed to admit bodies. They will write the identification details in the out of hours mortuary log, place ID tags on the body, place the body into the fridge and then write the name of the deceased on the outside of the fridge door. Mortuary staff perform dignity and identification checks of the bodies the next morning and transfer identification information into the mortuary register. The body is then assigned a unique mortuary ID, which is written on the wrist tag. There are identifying magnets with different colours that are placed on the outside of the fridge door to highlight particular issues such as same/similar name, risk of infection and do not release. The bodies are also given a corresponding coloured wristband so staff have an additional visual indicator.

Mortuary staff must confirm the identity of the deceased with the funeral director by checking at least three identifiers on the identification tags against release paperwork before releasing the body. If there are any discrepancies, mortuary staff will not release the body until the correct identification details are confirmed.

The PM suite has five down-draft height-adjustable tables, each with a set of rollers that allow easy transfer of the body onto the tray on which the PM examination is performed. There are three dissection benches, which the pathologist uses for examination of organs. PM examinations are done one at a time. Advice was given to the establishment to further mitigate the risk of returning organs to the wrong body (see advice item 5). There is a designated area for forensic and defence PMs with a viewing area for police and other professionals. High risk cases are conducted in a separate area and, when possible, at the end of the day to limit exposure. The air handling unit for the PM suite is serviced regularly and servicing records were observed to be up to date.

Tissue retained during the PM examination is cassetted in the mortuary, sent to another licensed establishment for processing and analysis, and then stored or disposed of according to the consent provided. It is the responsibility of the receiving establishment to ensure that consent wishes are met and tissue rarely comes back to the mortuary for storage. There is a cabinet in a separate room where tissue samples are held waiting for collection. Tissue is collected every Thursday by a contracted courier, who must sign a log book confirming receipt of each item. The receiving establishment then sends a fax to the mortuary to confirm that tissue has been received.

The HTA conducted identification audits on three bodies stored in the refrigerators, two of which had the same surname. Body location and identification details on wrist tags were cross referenced against the information on the fridge doors, paper records and the computer

system. Systems for same/similar names were also checked against relevant SOPs. No discrepancies were found.

Audit trails was conducted on two coronial cases where histology samples had been retained during the PM examination and on a hospital consented case from a referring hospital. Relevant paper records, computer records and consent forms were checked. No discrepancies were found.

A release of a body to funeral directors was also observed. Processes were checked against SOPs and no discrepancies were found.

Materials held for the police

Under s39 of the Human Tissue Act 2004, 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, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' audit of tissue held under police authority, that police exhibits held on HTA licensed premises should be included within the regular HTA inspection process, police holdings stored in a separate room within the PM room and the freezer in the body store were reviewed by the HTA during the inspection. Any findings in relation to 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 and the Licence Holder to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

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

No	Standard	Advice
1.	GQ1	The DI is advised to include in the same /similar name SOP the practice of putting an asterisk in red pen in the mortuary register next to the name of bodies with same/similar names in order to reflect current practice.
2.	PFE3	There is a documented procedure in place setting out the reasons why bodies should be moved into long-term freezer storage. However, it does not state a timeframe. The HTA recommends that bodies should be moved into freezer storage at 30 days or sooner, depending on the condition of the body. The DI is advised to align procedures with the HTA's guidance set out on page 7 (paragraph 24) of its report on storage capacity and contingency arrangements in mortuaries: https://www.hta.gov.uk/sites/default/files/Capacity%20and%20Contingency%20Report%20Nov%2015.pdf

		In the event that a body cannot be moved into long-term freezer storage within the 30 days, the DI is advised to log the reason, make a note of the condition of the body and keep the situation under review in case alternative arrangements have to be made.
3.		The DI is advised to display notices in the mortuary with contact details of mortuary staff, so funeral directors know whom to contact in case an incident occurs out of hours.
4.		Viewings are conducted by on-site coroner's officers, who usually stay in the viewing room with the family. The viewing room has a door that leads into the body store of the mortuary. Although staff are in the room with the family, there is a chance that a family member could inadvertently open this door and enter the body store. The DI is advised to reverse the lock on the door so it only unlockable from the side of the body store to mitigate this risk.
5.		The DI is advised to consider implementing a colour coding system in the PM room, matching organ bowls with with PM tables to further mitigate the risk of organs being returned to the wrong body.

Concluding comments

Many areas of good practice were observed. These included:

- there is good communication between coroners officers and mortuary staff, which ensures a quick turnaround time for PM examinations;
- the team of pathologists has a designated spokesperson who meets with the DI to discuss any issues that may arise;
- audits are conducted monthly of the entire PM process, from receipt to release of bodies, which include checking records for accuracy and legibility, observational practices in the body store and PM room to see if staff are following SOPs and procedural audits of the body release process; and
- the use of colour-coded wrist bands to identify the bodies of deceased with same/similar names; bodies that should not be released and those with an implanted device.

The HTA has given advice to the DI on a range of issues relating to governance and quality systems and premises, facilities and equipment.

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

Report sent to DI for factual accuracy: 21 October 2016

Report returned from DI: 25 October 2016

Final report issued: 25 October 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 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.