Site visit inspection report on compliance with HTA minimum standards

Public and Forensic Science Centre

HTA licensing number 12046

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**

10 October 2012

Summary of inspection findings

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

Although the HTA found that the Public and Forensic Science Centre (the establishment) had met the majority of the HTA standards, one shortfall was found in relation to Serious Untoward Incident (SUI) reporting.

The establishment had addressed the majority of the advice items from the previous inspection, and improvement was noted particularly in the area of governance and quality systems. Specific examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual are set down in Paragraph 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 establishment was built in 2009 and is the largest public mortuary in England. The establishment was built in order to become a regional hub for Coronial and forensic post mortem (PM) examinations, and activity has increased as these plans have begun to be put into place. In 2009, approximately 400 PM examinations were carried out at the establishment, increasing to around 1600 at the time of the inspection. There are two main mirror-image PM suites, each with 3 tables. The establishment has the capacity to store 250 deceased patients. In general, the establishment operates a system of only storing those deceased for which a PM has been ordered by the Coroner. The establishment has agreements with two funeral directors, each of whom store the deceased on behalf of the Coroner until such time as a PM is ordered. Once a PM has been ordered, the funeral director transports the deceased to the establishment. The two appointed funeral directors have access to the body store when establishment staff are not present through secure swipe card access. Individual employees of the funeral directors have been trained in the relevant establishment policies and procedures and have signed all relevant standard operating procedures (SOPs). The DI, an experienced mortuary manager, supervises five anatomical pathology technicians (APTs) and there is another APT vacancy to be filled. There are ten pathologists who carry out PM examinations regularly at the establishment.

The establishment is a major centre for forensic PM examinations in the region, and there are dedicated forensic facilities available. Dedicated double-sided forensic refrigeration units link directly to a dedicated forensic PM suite, which has a separate windowed viewing area and audio-visual links to an on-site conference room.

A routine scheduled site-visit inspection was carried out at the establishment. The visual inspection included the delivery area, body store, 2 main PM suites, the forensic PM suite and storage areas. Family viewing areas were also visited. An audit trail was carried out in two phases. First, identification details (name, address and date of admission) were taken from wrist bands of three of the deceased in refrigerated storage. The details were traced through the mortuary register, admission forms and electronic database. No anomalies were found. During the second phase of the audit, identification details were recorded from three forensic samples being stored temporarily (awaiting transport, as routine) in a small refrigerator with a storage area. The details were traced to the mortuary register, where a circular red sticker was present within each record to indicate that tissue had been taken, in accordance with the SOP. Identifiers were traced through the electronic database as well as admission forms and tissue traceability forms. No anomalies were found.

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.	Details were found in the establishment's incident reporting log for three incidents occurring in 2010 which, although reportable as Serious Untoward Incidents (SUIs), were not in fact reported to the HTA. In addition, the SOP for incident reporting fails to state the 5-day timeframe in which SUIs should be reported to the HTA nor does it give any examples of the types of incidents that should be reported to the HTA. ***Please note:*** *In the interim period between the issue of the draft report and issue of the final report, the establishment proactively addressed this shortfall, resulting in standard GQ7 being fully met prior to publication of the final report.*	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ5	The establishment currently uses a system of chronological numbering to assign mortuary numbers to the deceased based on the order in which they were

		admitted to the mortuary. The numbering system restarts annually, thus allowing for duplication. As deceased are sometimes kept for several months in deep freeze, this system could result in two patients with the same mortuary number being present in storage at the same time. The DI is advised to consider adding the year to the mortuary numbering system in order to further guard against misidentification and aid traceability by making each mortuary number unique.
2.	GQ7	The DI explained that filming for television has occasionally taken place at the establishment. Whilst formal agreements were in place with film crews, it was noted that their presence was not risk assessed with regard to issues relevant to the Human Tissue Act 2004, such as security and dignity of the deceased. The DI is advised to ensure that any such activity is risk assessed should it be planned to take place again in the future.
3.	GQ7	The HTA has been made aware of several instances of inappropriate images of the deceased being broadcast on social media sites through the inappropriate use of mobile phone within establishments. The DI is advised that the use of electronic communication devices, such as mobile phones, by visitors to the establishment should be risk assessed.
4.	PFE1	The DI is advised to replace the wooden-handled mallet in the PM storage area with a non-porous alternative.
5.	PFE1	The DI is advised to continue with plans in place to solve the damp issue with flooring in PM suite 2.
6.	PFE3	A detailed plan is in place for overflow, as the establishment is part of an emergency mortuary planning group. The DI is advised to also put in place a contingency plans should there be a power failure or natural disaster resulting in the need for operations to cease at the establishment.
7.	PFE4	The DI is advised to ensure that the Third Party Agreement with organ retrieval teams is reviewed with the new Coroner and signed by all appropriate parties.

Concluding comments

Several areas of strength and good practice were noted throughout the inspection. During the visual inspection, it was noted that the facilities were well-equipped and clean. Security measures were thorough and well thought-out, including 24-hour CCTV monitoring (outdoor and indoor), individual swipe card access and panic buttons. Through support from the local council, the lone working scheme had recently been reviewed and improved through the addition of individual personal attach alarms. In terms of governance, the establishment benefits from a dedicated administrator with knowledge of working practice within the mortuary. It was widely acknowledged on the day of the inspection by those working with the establishment that the administrator is a key member of staff, especially considering the high volume of activity taking place. During the inspection, the establishment's plans for implementing a facility for minimally-invasive PM examination were discussed. Funding has been secured and plans are underway for the construction of the facility as an extension to the current building. The centre would be the first of its kind in Europe, and plans to build this state-of-the-art facility indicate the desire of the establishment to be a model of good mortuary practice.

Policies and procedures around SUI reporting require improvement, and this should be accomplished by addressing the shortfall against standard GQ7. In the interim period between the issue of the draft report and issue of the final report, the establishment proactively

addressed the only shortfall identified, resulting in all HTA standards being fully met prior to publication of the final report.The HTA has given advice to the Designated Individual in several areas where current practice should be further improved.

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

Report sent to DI for factual accuracy: 29 Oct 2012

Report returned from DI: 13 Nov 2012

Final report issued: 7 Dec 2012

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.