Site visit inspection report on compliance with HTA minimum standards

Wednesfield Public Mortuary

HTA licensing number 12285

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 and 11 June 2015

Summary of inspection findings

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

Although the HTA found that Wednesfield Public Mortuary (the establishment) had met the majority of the HTA standards, five shortfalls (two major and three minor shortfalls) were found with regard to the Governance and Quality Systems (GQS) and Premises, Facilities and Equipment (PFE) standards. The major shortfalls were in in relation to: (i) discrepancies in the traceability systems used; and (ii) inappropriate storage facilities at the hub site. The minor shortfalls were in relation to: (iii) use of inappropriate procedures and an absence of governance arrangements for all departments and sites covered by the licence; (iv) inconsistent procedures concerning the conduct of post mortem (PM) examinations; and, (v) inadequate environmental monitoring and control at the hub site. Advice has been given on matters across the range of standards and also into relation to licence management.

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 (DI), Licence Holder (LH), premises and practices are suitable.

The statutory duties of the DI 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 licenses 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 the activities carried out at Wednesfield Public Mortuary (the establishment), whose licensing arrangements cover the public mortuary itself (the hub site; owned by Wolverhampton City Council, WCC) and New Cross Hospital (part of the Royal Wolverhampton NHS Trust, and licensed as the satellite site). A separate body store is situated at Cannock Chase Hospital (part of the Royal Wolverhampton NHS Trust). Bodies there are either being held pending release to funeral directors or temporarily, pending a PM examination elsewhere. Since they are being transferred within seven days of arrival, storage at that site is considered by the HTA to be 'incidental to transportation' and so is exempt from licensing.

There are no nominated Persons Designated (PDs) at the hub site but there is one PD at the satellite site. This person was not available at the time of the inspection.

<u>Wednesfield Public Mortuary - the hub site</u>

At the hub site, approximately 450 PM examinations are carried out annually by four pathologists from the satellite site; the vast majority of these are under HM Coroner, Black Country. In addition, approximately five adult consented PM examinations are carried out each year. The establishment does not perform Home Office PM examinations. The mortuary is staffed by two qualified Anatomical Pathology Technologists (APTs) and one trainee.

Bodies arriving from the community are brought in by private ambulance or by a specific funeral director. Those arriving from the body store at the hospital satellite site are brought in

by the same funeral director (*see Advice item 9*).

The public mortuary hub site is purpose-built but steps should be taken to increase its security (*Advice item 7*). Although suitably staffed, lone working and out-of-hours unaccompanied access do occur.

The body store at the hub site contains 35 refrigerated spaces; ten of these can accommodate bariatric bodies. One bank of five spaces can be converted to freezer storage, if required. Refrigerator temperatures are recorded locally by mortuary staff and externally via an electronic signal sent to a contractor. Monthly temperature printouts are provided by the contractor. If temperatures exceed the set limits, a local audible alarm is sounded and an electronic signal is sent to the external contractor for action (*see Inspection findings against standard PFE3, below*). There is an on-call APT to arrange the movement of bodies to other units if required.

There is a separate storage area within the body store for formalin-fixed (wet) tissue specimens retained during the PM examination.

The PM room has three downdraught PM tables and two downdraught dissection benches, with adequate working space and good lighting. The inspection team was informed that cases up to Hazard Group 3 are managed within the facility, although this was not supported by documented evidence on ventilation within the PM room (*see Inspection findings against standard PFE2, below*).

There is a contingency plan for disaster recovery and individual plans for additional body storage demand depending upon the nature of the requirement.

Upon arrival, information about the deceased is entered into the Public Mortuary Register. If funeral directors bring in the body out-of-hours, they enter the details in the temporary register pending later transcription into the Public Mortuary Register. The location of the body is recorded in the temporary register but not in the Public Mortuary Register itself (*see Advice item 6*). Each body received is given a unique, sequential PM number.

The details of organs and tissue samples taken for analysis during PM examination are recorded on the histopathology request card and on the Coroners 'Next of Kin Statement'. These details are entered into the Tissue Retention and Disposal Register and on the TD-Web system, which can be accessed by staff in the public mortuary, the hospital body store and the Histopathology Department at the hospital satellite site. Organs and tissue samples are sent by hospital transport to the Histopathology Department.

Toxicological and asbestos fibre analyses are performed off site; samples for such analysis are transported by specific courier companies.

Tissue and organs are occasionally sent off site for specialist examination; they are taken by a specific courier company to either King's College Hospital NHS Foundation Trust or Royal Brompton and Harefield NHS Foundation Trust.

New Cross Hospital - the satellite site

At the hospital satellite site, licensable activities occur within the Emergency Medicine, Histopathology, and Obstetrics and Gynaecology Departments. The hospital satellite site also contains a body store but no licensable activity takes place here (see below).

Emergency Medicine Department. Tissue is removed from minors in cases of sudden unexpected death in infants and children (SUDIC) by paediatric consultants in a secure area which ensures the dignity of the deceased. Samples removed (whole blood and urine for biochemical analysis, and skin biopsies for cytogenetic analysis) are sent by courier to University Hospitals Birmingham NHS Foundation Trust. The DI was not aware of their responsibilities under the licence for the activity taking place in this Department (*see*

Inspection findings against standard GQ1 (1), below).

Histopathology Department. Pregnancy remains of all types are transferred to the Histopathology Department for analysis and disposal, accompanied by the relevant paperwork (*see Advice item 10*).

This Department also receives, processes and stores all tissues and organs removed during PM examination at the public mortuary hub site.

Obstetrics and Gynaecology Department. Stillbirths and neonatal deaths are stored in a refrigerator pending transfer to the hospital body store. Pregnancy remains are stored in the same refrigerator pending transfer to the Histopathology Department. The refrigerator temperature is recorded manually by the Department's staff during the working week only (*see Advice item 8*). The DI was not aware of their responsibilities under the licence for the activities taking place in this Department (*see Inspection findings against standard GQ1 (1), below*).

New Cross Hospital Body Store. This is used to store around 1,500 bodies each year. Approximately 80 of these are transferred to other sites for PM examination. All other bodies are stored pending release to a funeral director for burial or cremation; this is not storage for a scheduled purpose and is not licensable.

Bodies transferred include around 50 adults each year moved to the hub site for PM examination and around ten infants or children sent to Birmingham Women's NHS Foundation Trust or Birmingham Children's Hospital NHS Foundation Trust (depending upon the age of the child) for PM examination. Stillbirths and neonatal deaths are transferred to Birmingham Women's NHS Foundation Trust (approximately 20 cases each year). There was no evidence of ratified Service Level Agreements (SLAs) in place governing the provision of PM examination services by these parties (*see Advice item 1*).

Stillbirths, neonates and deceased minors requiring PM examination are transported from and to the hospital body store by a specific funeral director. Adult bodies requiring PM examination are also transported to and from the public mortuary hub site by a specific funeral director (*see Advice item 9*).

All bodies held temporarily in the body store pending a PM examination elsewhere are transferred within seven days of arrival and are therefore exempted from storage licensing.

The inspection process

This was the third site visit inspection of the establishment since it was issued a HTA licence in August 2007 (the last inspection was in July 2011). It was a routine inspection, to assess whether the establishment is continuing to meet the HTA's standards.

The timetable for the site visit inspection was developed after consideration of the establishment's previous inspection report, compliance update information and discussions with the DI. The site visit inspection included a visual inspection of the public mortuary hub site (body store, PM room, viewing area) and the Hospital Body Store (including the viewing area), the Emergency Medicine, Histopathology, and Obstetrics and Gynaecology Departments of the hospital satellite site.

Meetings were held with staff working under the licence. They were: the DI (Head of Operational Services, WCC); the Corporate LH contact (CLH contact; Bereavement Services Manager, WCC); the Cellular Pathology Quality Lead; the Pathology Office Manager; the Divisional Medical Director; a Consultant Pathologist; a Consultant Obstetrician and Gynaecologist; and, HM Coroner's Office Team Leader.

A documentation review and five separate procedural, horizontal and vertical audits were carried out at the public mortuary hub and hospital satellite site. Discrepancies were found in

two sets of audits at the public mortuary hub site (*see Inspection findings against standard GQ6, below*). No discrepancies were found in the remaining three audits, summarised below:

- Vertical audits at the hospital satellite site of two stillbirth cases sent for external PM examination revealed full traceability between the Obstetrics and Gynaecology Department, the Hospital Body Store and Birmingham Women's NHS Foundation Trust.
- Procedural audits at the public mortuary hub site on the receipt of one body and release of one body indicated no discrepancies when compared with the respective standard operating procedures (SOPs).
- Vertical audits at the public mortuary hub site on the removal of tissue during PM examination from three bodies (two coronial cases and one consented case) revealed full traceability in the paper and electronic records. In each case, the blocks and slides produced had been treated in line with the family's wishes.

Inspection findings

Although the HTA found the DI and the CLH to be suitable in accordance with the requirements of the legislation, the current CLH contact reports to the DI and is not senior enough to be in a position to replace the DI if required. A person with greater accountability needs to be identified to act as the CLH contact.

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	(i) The following SOPs do not reflect current working practices: o 'Removal of samples for histological analysis' (which should include the current procedure used for repatriation of blocks and slides). o 'Repatriation of organs and tissues with the body prior to release'. o 'HTARI reporting' (which should include information about reporting HTARIs to the HTA within five working days). o 'Refrigerator maintenance'. o 'Demarcation of areas of clean and dirty zones within the mortuary'. (ii) There is no regular forum where staff working under the licence can discuss regulatory issues. *See Advice item 3*.	**Minor**

GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	The APTs perform evisceration prior to the pathologist checking the body. This activity has not been risk assessed and there is no formal agreement or formalised procedure which sets out the circumstances in which this can happen, and the circumstances in which the APT should not proceed without the pathologist having first examined the body. *See Advice item 4*.	**Minor**
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail	(i) The results of the HTA's horizontal audit of three bodies in the refrigerator indicated that: - The body storage locations are not written in the Public Mortuary Register. - One of the deceased was a known 'high risk' case but this had not been highlighted in the Public Mortuary Register or on the refrigerator door. (ii) A vertical audit of a formalin-fixed tissue sample removed as part of PM examination and temporarily stored in the public mortuary body store revealed that there was no paperwork associated with the sample.	**Major**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE2 Environmental controls are in place to avoid potential contamination.	(i) The recommended minimum number of air changes in a PM room is ten per hour for the management of cases up to Hazard Group 3; formaldehyde concentrations should be maintained below 2 ppm. The inspection team saw no evidence that air changes or formaldehyde concentrations are being measured in the PM room and there was no preventative maintenance programme for the PM room in place. (ii) There are no policies and procedures governing cleaning and decontamination for the public mortuary hub site and no records that cleaning and decontamination have taken place in the PM room, body store, refrigerators or freezer.	**Minor**

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.	(i) The refrigerators in the public mortuary body store are not maintaining the temperature within the normal operating range. The electronic temperature monitoring chart showed a high degree of temperature variation within the previous month. Although call-outs had been actioned, the uncertainty about the reliability of the refrigerators presents a significant risk to the integrity of the bodies stored. (ii) The temperature limits for the call-out process for the refrigerators and freezer in the body store are not known and there is no routine testing of the temperature alarm system. (iii) There is no preventative maintenance programme for the refrigerators and freezer in the public mortuary and hospital body stores, or for the Obstetrics and Gynaecology refrigerator.	**Major**

Advice

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

No.	Standard	Advice
1.	N/A	For consistency in service, the DI is advised to put in place SLAs with organisations providing non-Coronial PM examination services.
2.	C1	The DI is advised to liaise with the Coroner and his officers with a view to modifying the 'Next of Kin statement' by amending the option 'retained as part of the deceased's medical records' so that it concludes with 'for the future use and benefit of the family'.
3.	GQ1	In other establishments, governance meetings cover items such as adverse incidents, standardisation of documents, changes to SOPs, audits and their findings, risk assessments, HTA training, the setting up of agreements with other establishments and updates from the HTA (e.g. e-newsletter items). It is advised that these meetings are governed by an agenda and that minutes are recorded and circulated. The minutes should include timelines for identified actions and there should be a standing agenda item for discussing progress against actions identified at previous meetings. To ensure consistent governance across the Emergency Medicine and Obstetrics and Gynaecology Departments, the DI is advised to appoint Persons Designated (PDs) in these Departments to attend these meetings and to oversee licensable activities taking place.
4.	GQ1	The Royal College of Pathologists document 'Standards for Coroners' pathologists in post-mortem examinations of deaths that appear not to

		be suspicious' (page 6) states that: 'The pathologist will ensure that no evisceration takes place before the pathologist has made a full examination of the external surface of the body'. The DI should consider whether it is appropriate for the APT to eviscerate before the arrival of the pathologist in any circumstances.
5.	GQ2	To ensure consistent governance across all areas working under the licence, the DI is advised to extend the audit schedule to cover licensable activities in the Emergency Medicine and Obstetrics and Gynaecology Departments.
6.	GQ4	During the audits at the hub site the HTA noticed that the storage location in the temporary register did not always match the storage locations in the refrigerators, since refrigerator breakdown had resulted in bodies being moved and the temporary register had not been updated. The DI is advised to ensure that body location is always included in the Public Mortuary Register.
7.	GQ8, PFE1	The public mortuary hub premises are only accessible by a key system and there is no CCTV monitoring of entry and exit points, no electronic access control and no out-of-hours intruder alarm system. The DI is advised to formally risk assess the security of the public mortuary hub premises and to review this risk assessment on an annual basis.
8.	PFE3	To ensure consistent temperature monitoring throughout the establishment, the DI is advised to the link the Obstetrics and Gynaecology refrigerator to the electronic call-out system used in the hospital body store.
9.	PFE4	To ensure a consistent service for the transport of bodies, organs and tissues, the DI is advised to enter into formal agreements with funeral directors and couriers for the transport of bodies and samples when not under Coronial authority. The DI is referred to the 'Model agreement between mortuaries and funeral directors for the removal of bodies' on the HTA's website.
10.	D1, D2	The Trust form 'Consent for Pathological Examination and Disposal of Tissue following early Pregnancy Loss' currently states that 'the hospital will make arrangements for the disposal of tissue in a respectful manner'. The Trust default policy is for incineration. In line with the HTA's 'Guidance on the disposal of pregnancy remains following pregnancy loss or termination', the woman should be offered burial, cremation and incineration as disposal options. Incineration may be used only where the woman makes this choice or does not want to be involved in the decision.

Concluding comments

The licensing arrangements, whereby a neighbouring NHS Trust is a satellite site of a Local Authority Public Mortuary, are unusual and present some challenges for the DI, who is not based at either site and has a broad remit within his role as Head of Operational Services for the Local Authority.

Although he has a good understanding of his statutory role, he needs to have support to cover all the varying activities under the licence. The HTA has given advice to the DI into how he can better oversee these activities (*see, for example, Advice item 3*) and consideration should be given by WCC into whether the DI should have more dedicated time to be able to carry out his role effectively.

In addition, the CLH contact needs to be a senior member of the Local Authority, who would then be in a position to replace the DI should that ever become necessary.

During the site visit inspection of the establishment, it was noted that there is good communication between the establishment and Birmingham Women's NHS Foundation Trust in relation to consent for PM examination, and the transfer and return of stillbirths and neonatal deaths. There is also a comprehensive list of risk assessments covering licensable activities.

There are a number of areas of practice that require improvement, including two major and three minor shortfalls. The HTA has given advice to the DI with respect to the Consent, Governance and Quality Systems, Premises, Facilities and Equipment, and Disposal standards, as well as to licence management.

The HTA requires that the DI 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.

Report sent to DI for factual accuracy: 22 July 2015

Report returned from DI: 5 August 2015

Final report issued: 13 August 2015

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: o post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases o record keeping o receipt and release of bodies, which reflect out of hours arrangements o lone working in the mortuary o transfer of bodies and tissue (including blocks and slides) to other establishments or off site o ensuring that tissue is handled in line with documented wishes of the relatives o disposal of tissue (including blocks and slides) 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 outlines 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).

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.

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 inspection.

   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.

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: 22 April 2016