Site visit inspection report on compliance with HTA minimum standards

Worthing Hospital

HTA licensing number 12286

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**

6 – 7 April 2016

Summary of inspection findings

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

Worthing Hospital (the establishment) was found to have met all HTA standards.

The HTA has given advice to the Designated Individual with respect to the governance and quality standards and the premises, facilities and equipment standards. Specifically this advice mostly relates to procedural documentation, risk assessments and audit.

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

For the purposes of HTA licensing, the establishment consists of a hub site, Worthing Hospital, and two satellite sites at Southlands General Hospital and St Richards Hospital.

The hub site at Worthing Hospital consists of a body store and a post mortem suite. The body store has 84 refrigerated spaces in the main store, four of which can also operate as freezer storage if needed. There are also four permanent freezer spaces and four refrigerated spaces suitable for the storage of bariatric bodies. The hub premises include a separate cold room storage facility, which can accommodate a further eight bodies, eight bariatric bodies and a bariatric bed if needed. There is a dedicated storage fridge with for spaces for the storage of the bodies of infants. The main storage facility, the cold room and the separate infant storage are all temperature monitored with an alarm linked to the hospital's switchboard. Switchboard staff contact the estates department and, if needed, the on call mortuary staff if the temperature deviates from the expected range.

At the time of the inspection, the establishment was in the process of undertaking work to the entrance to the post mortem suite of the hub site, so that a bariatric table can be used to move bariatric cases between the body store and post mortem room, minimising manual handling. Included in the works is the addition of a new body hoist suitable for use when

handling bariatric bodies. The establishment indicated that these works will be completed within a few weeks of the inspection.

The St Richards hospital satellite site consists of a body store and laboratory facility. The body store's main storage consists of 42 standard spaces, 16 spaces capable of accommodating bariatric bodies, four freezer spaces and four spaces for infants. In addition there is a cold room storage facility providing an additional 45 spaces and room for a bariatric bed if necessary. All of the satellite site's storage facility is temperature monitored with an alarm linked to a third party specialist monitoring company, which contacts the hospital if the temperature deviates from the expected range. This alert is then passed on to the hospital's estates department and, if needed, the on call mortuary staff so that temperature deviations can be investigated.

At the establishment's Southlands Hospital satellite premises, the only licensable activity that takes place is storage of relevant material for use for scheduled purposes under the Human Tissue Act 2004 (HT Act). There are a number of tissue slides in storage that pre-date the HT Act and, therefore, the consent provisions of the HT Act do not apply; no audit was undertaken on this tissue. The tissue is being stored in a suitable and secure location. The establishment indicated that the majority of tissue from the deceased which had been stored at the satellite site has been sensitively disposed of and that there are plans to relocate the remaining stored tissue to the other satellite site (St Richard's hospital). The Southlands hospital premises will then not need to be licensed by the HTA (see advice item 5).

The establishment conducts around 860 post mortem examinations per year under the authority of the Coroner, including a small number of Home Office/forensic examinations. Only one or two hospital consented post mortem examinations are conducted each year. All post mortem examinations take place at the hub premises, with bodies requiring post mortem examination from the St Richards hospital satellite site being transferred to the hub.

Known high-risk post mortem examinations including HIV, Hepatitis B, Hepatitis C, Meningitis and Tuberculosis are undertaken. Staff have access to personal protective equipment when conducting both routine and high risk post mortem examinations.

Checks, including condition of the body and identification, are carried out on all bodies prior to post mortem examination, moving a body within the body store, the viewing of a body or releasing a body. However, during the inspection it emerged that a shortage in staffing is preventing bodies being checked on their receipt into the mortuary, unless the body arrives with personal property (about a third of bodies). Without identification and body condition checks upon arrival at the mortuary, there is a risk that any issues that may require immediate action, such as the lack of an identification label, mislabelling or the onset of decomposition, will not be detected until the body is being prepared for a post mortem examination, a viewing or release (see advice item 7).

In some circumstances, bodies scheduled for a post mortem examination early the following day are left, fully shrouded, overnight in the post mortem suite. The post mortem suite is secure from other areas of the mortuary, with lockable doors, CCTV covering the body store and entrances to the mortuary and an alarm. However, there are no steps taken to chill the area. This practice is not documented and there is no guidance for staff on when it should not take place, for example, in the warmer summer months when there may be an increased risk of deterioration of the bodies (see advice item 1).

Any tissue taken during post mortem examination for further analysis is placed into cassettes and transported to the St Richards hospital satellite premises for processing into blocks and

slides. Once the slides have been examined by the pathologist, the blocks and slides are returned to the hub site for storage pending receipt of the family's wishes from the Coroner and the end of Coronial authority. Once notified by the Corner that the body can be released, the establishment acts upon the family's wishes and either sensitively disposes of the tissue, returns the samples to the family or transfers them to the St Richards hospital satellite site for long term storage.

Consent for hospital post mortem examinations is sought by the clinician who was treating the deceased in life. The clinician first discusses the request for a post mortem examination with a pathologist, who can advise on its scope and answer any questions they may have. When seeking consent from the family of the deceased, the clinician is supported by a member of the Trust's bereavement team, who are familiar with the forms used to record consent and patient information leaflets used to support the consent seeking process.

The bereavement staff are familiar with the requirements of the Human Tissue Act 2004 (HT Act) and have a documented consent seeking procedure to follow, which reflects legal requirements. It describes who can give consent under the HT Act and recognises that before approaching anyone in a qualifying relationship to the deceased, a person may consent themselves in life or nominate a representative to act on their behalf after death. The person giving their consent is allowed the opportunity to change their mind and is asked to call the bereavement office to confirm that they still wish the post mortem examination to take place prior to it starting. In the absence of this phone call, it will be suspended until the bereavement staff have confirmed with the person giving their consent that they still wish it to proceed.

The establishment maintains detailed records of the disposal of pregnancy remains. If a family wishes to enquire about disposal that has taken place in the past, the establishment can provide details including the time and date of cremation, the chaplain present and where the ashes were scattered.

Post mortem examinations of infants from both Worthing and St Richard's hospitals are undertaken at another HTA licensed establishment; consent for these is sought by consultants or senior registrars in the maternity department with the support of a lead midwife who has received training in seeking consent and use of the appropriate forms. Consent seeking training has also been cascaded to all midwives in the department so that they are available to support the consent seeking process if needed. A pathologist from the licensed establishment where infant post mortems take place periodically visits the staff at Worthing and St Richard's hospitals to train staff on the use of the forms used to record consent and other aspects of seeking consent.

The maternity departments at both the hub and satellite premises may store the bodies of stillborn babies or fetuses in cold cots prior to them being moved to the mortuary so that, where appropriate, parents have the opportunity to spend time with them on the ward. Longer term storage does not take place within the maternity department and remains are transferred to the mortuary for storage prior to release to the family or for post mortem examination. At the time of the inspection the DI had not nominated a member of staff in the maternity department to act as a Person Designated and oversee licensed activities of removal (see advice item10).

Removal of various tissue samples from bodies of the deceased may take place in areas outside of the mortuary at both the Worthing hospital hub and St Richard's hospital satellite site. These samples include blood and swabs which are removed from deceased children

who are brought to the hospital or die in the accident and emergency (A&E) department, in line with procedures governing sudden unexpected death in infants.

Removal of these samples takes place in a dedicated bay of the paediatric resuscitation area at both the hub and St Richard's hospital satellite site's emergency departments. Both of these areas are private and suitable for the sampling procedure, which is undertaken by a paediatrician. Documented guidance detailing the types of sample to be taken is available for the paediatrician to follow.

The Coroner has been made aware of the potential samples that may be taken in such cases and has given their approval for this to occur; however, establishment staff also inform the Coroner of sampling prior to each case.

The establishment has been licensed since August 2007 and this was its third routine site-visit inspection to assess whether it continues to meet the HTA's standards. The timetable for the site visit was developed in consideration of the establishment's latest self-assessed compliance information, in addition to a review of the previous inspection findings and pre-inspection discussions with the DI and Person Designated. During the site visit, a visual inspection of the premises, review of documentation and interviews with establishment and Coroner's office staff were undertaken.

An audit of bodies stored at both the establishment's hub and St Richard's hospital satellite premises was undertaken. At the hub premises, three bodies were selected at random: two bodies that were being stored in the establishment's main body store and one stored in the walk in cold room. Details including forename, surname, date of birth and hospital number (if applicable) from the body identification tags and the physical location of the bodies were cross checked against the establishment's records; these included records on the storage fridge door and cold room whiteboard, the body's associated paperwork and the establishment's electronic database. One of the deceased's names had one letter mistyped while it had been entered into the establishment's electronic register and which was corrected by establishment staff during the audit. Apart from this one minor typographical error, no anomalies were found.

At the satellite premises, three bodies were again selected at random: two from the main body store and one from the walk in cold rooms. Details from the identification tags and the physical location of the bodies were cross checked against the establishment's records on the whiteboards, the body's associated paperwork and the establishment's electronic database. No anomalies were found during this audit.

Tissue traceability audits were also undertaken during the inspection. Firstly, details were taken of three sets of blocks and slides being held at Worthing hospital's mortuary. Coronial, traceability forms and electronic records were reviewed. In all cases the families had opted for disposal but Coronial authority had not yet ended. These slides were appropriately stored in a secure area of the mortuary pending their disposal once the Coronor's authority ends. No anomalies were found.

A subsequent audit of tissue looked at three further cases where blocks and slides were being retained at the St Richards Hospital site. In one of the three cases, the family had asked for tissue to be returned to their funeral director and records showed that the tissue had been released. In the remaining two cases where blocks and slides were being retained, the details held on the electronic records matched the physical number of blocks and slides stored and the families' wishes forms confirmed that consent for retention had been given. No anomalies were found during the audit.

Inspection findings

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

Compliance with HTA standards

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 & GQ8	The DI is advised to produce a documented procedure governing the practice of leaving bodies in the post mortem suite overnight prior to a post mortem examination. This procedure should include details of when it is not appropriate to leave bodies out overnight, such as in the warmer summer months. It should be informed by a risk assessment of the practice, to ensure that any risks have been considered and addressed. The risks that the DI should consider include risks relating to suitable storage conditions for bodies in the PM room and whether the PM room requires chilling if it is routinely used to store bodies overnight prior to post mortem examination.
2.	GQ1	The establishment has a standard operating procedure (SOP) detailing the process of undertaking a post mortem examination. The procedure states that identification checks on the deceased are undertaken by the anatomical pathology technologist (APT) and the pathologist prior to commencing the examination. The SOP however does not contain details of the points of identification that should be used. The HTA advises that three points of identification should always be used whenever bodies are identified, one of which should be unique; for example name, date of birth/address, hospital number. The DI is advised to review this SOP and all SOPs where body identification is part of the procedure to ensure that they reflect the three point identification process to be used.
3.	GQ3 & GQ7	The establishment delivers training to portering staff and funeral directors, attendance at which is recorded. The DI is advised to include awareness of the HTA reportable incident (HTARI) categories in this training. This will help to assure the DI that if any of these staff are involved in an adverse event in the mortuary while no mortuary staff are present, they know that the incident is reportable to the HTA and will report it appropriately to mortuary staff at the earliest opportunity. In addition, the DI is advised to include a link to the HTARI reporting portal in the establishment's HTARI SOP so that staff have a quick reference guide to finding the portal if needed.
4.	GQ6	Occasionally, bodies are received into the mortuary without any identification tags. The establishment reminds all relevant staff of the importance of correct identification being in place. In addition, the DI may wish to add the risk of mis-identification in this way to the establishment's risk register so that the issue can

		be escalated at the various governance meetings which are attended by him and the mortuary staff. This may help to alert a wider group of staff within the Trust to the issue and encourage greater compliance.
5.	GQ6	The establishment indicated that the majority of tissue from the deceased which had been stored at the Southlands hospital satellite site has been sensitively disposed of and that the remaining historical tissue slides stored there, and the tissue currently being held at the St Richard's hospital satellite site, is the only tissue being stored outside of coronial authority, and there is consent for its storage. Once the final historical tissue has been moved from the Southlands satellite site, the DI is advised to undertake an audit of stored tissue and disposal records to assure himself that all tissue has been moved or disposed of as expected.
6.	GQ8	The establishment may be moving to a new electronic register system in line with other areas of the department. The mortuary currently uses a bespoke system developed by mortuary staff to record details of the deceased within the mortuary. This system is also used to track and record various notes and alerts about the deceased, for example, where tissue or organs should be repatriated with the body prior to release. The system also lists all names alphabetically, which helps mortuary staff to identify bodies with the same or similar names. The DI is advised to risk asses the introduction of the new electronic register system to identify any risks associated with the change of system and ensure that the change will not introduce risks in relation to the management of bodies.
7.	GQ8	During the inspection, the inspection team were informed that a shortage in staffing had led to reduced checks of bodies received into the mortuary. The DI is advised to risk asses the practice of not undertaking checks on bodies as they arrive in the mortuary so that all associated risks can be identified and procedures implemented to militate against these risks. In addition, the DI may wish to add the risk of delaying the checks undertaken on bodies in this way to the establishment's risk register so that the issue can be escalated at the various governance meetings which are attended by him and the mortuary staff. This may help to alert a wider Trust staff within the Trust to any issues relating to staffing within the mortuary.
8.	GQ8	The St Richard's hospital site has been a satellite to the main licence since September 2014. Prior to this it was separately licensed with its own procedures in place. Since becoming a satellite site, the mortuary staff have been reviewing procedures at the satellite and aligning them with the processes at the hub premises. At the satellite site, porters undertake viewings without the presence of mortuary staff. Although the establishment indicated that they planned to align this practice with the hub site and always have a member of mortuary staff present for body viewings, in the interim period, the DI is advised to risk assess the porters undertaking viewings so that all associated risks can be identified and procedures implemented to mitigate these risks
9.	PFE3	Although the establishment's storage facility is alarmed to alert staff to any deviation from the required storage temperatures, the DI is advised to periodically review fridge and freezer temperature records to identify any trends which may indicate a gradual decline in performance or future failure of equipment.
10.	General	The DI is advised to appoint a Person Designated in the maternity department who would cover both the hub and satellite sites and act as a point of contact in relation to the activity taking place in these areas. This will facilitate the DI being

		made aware of any issues that arise, who will in turn, be better able to disseminate any licensing updates or information to staff in these areas. The DI is also advised to invite the PDs to governance meetings so that information regarding licensable activity can be shared. In addition, the DI is advised to periodically involve staff in the bereavement team responsible for supporting the seeking of consent for post mortem examination in governance meetings so that information regarding licensable activity can be shared.

Concluding comments

Areas of good practice were observed during the inspection, examples of which are set out below.

The process whereby the bereavement team ask families who have consented to a post mortem examination to telephone the establishment back to confirm that they still wish the examination to proceed helps ensure that families have sufficient time to consider the issue and make the decision that is right for them.

A pathologist from the licensed establishment where infant post mortems take place visits to train staff on the use of the forms used to record consent and other aspects of seeking consent.

The establishment has a good range of documented risk assessments which cover both health and safety risks and risks to the deceased. These have been produced for the majority of the establishment's standard operating procedures and have helped to identify the risks associated with those procedures.

The HTA has given advice to the Designated Individual with respect to some procedural documentation, risk assessments and audit.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

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

Report sent to DI for factual accuracy: 6 May 2016

Report returned from DI: 20 May 2016

Final report issued: 25 May 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.

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 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.