Site visit inspection report on compliance with HTA minimum standards

Darent Valley Hospital

HTA licensing number 12226

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**

1 July 2015

Summary of inspection findings

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

Although the HTA found that Darent Valley Hospital (the establishment) had met the majority of the HTA standards, two major shortfalls and four minor shortfalls were found in relation to the Consent and Governance and Quality standards. The major shortfalls relate to the lack of formal consent training and a documented procedure for seeking consent for perinatal post-mortem (PM) examinations, and risks associated with staffing levels in the mortuary. The minor shortfalls relate to the absence of a robust system for approving standard operating procedures (SOPs), the need to update SOPs in order to detail identity checks to be carried out on bodies and the lack of an induction plan for new mortuary staff.

In March 2013, the Clinical Lead for the Pathology Directorate took over the role of DI. Whilst he is removed from operations in the mortuary, he holds regular mortuary management meetings which the Mortuary Manager, APT and Quality Manager attend. In this way, he stays abreast of mortuary-related issues.

Following the previous inspection in 2011, in response to the HTA's findings, the establishment implemented a new system to identify each body with a unique identifier, installed an alarm system in the temporary storage area which is linked to the hospital switchboard and documented the procedure for reporting HTARIs to the HTA.

Particular 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 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

Darent Valley Hospital is licensed to carry out post mortem (PM) examinations, storage of bodies, and the removal and storage of PM tissue for use for scheduled purposes under the HT Act. The Dartford and Gravesham NHS Trust is the corporate licence holder and the corporate licence holder contact is the Chief Executive of the Trust.

Around 500 PM examinations are undertaken in the mortuary, almost all of them on behalf of the Coroner for West Kent. Until recently, the Trust had been working towards a merger with a neighbouring Trust, which included plans to integrate pathology services. However, the merger has been put on hold, which has resulted in some uncertainty about the future.

Coronial PM examinations are undertaken by visiting Pathologists based at another HTA-licensed establishment. Forensic PM examinations are undertaken by Home Office-registered pathologists. In all cases tissues and organs retained during PM examinations are transferred to other sites for analysis. Hospital, high risk or perinatal/paediatric PM examinations do not take place on site; babies, children and all identified high risk PMs are transferred to other HTA licensed mortuaries for PM examinations. Consent for perinatal PM examinations is taken by a consultant, who uses the consent form provided by the London Perinatal Pathology Network.

For the past two and a half years, the mortuary has been staffed by a Senior Anatomical Pathology Technologist (APT) who reports to the Mortuary Manager. The Mortuary Manager is in the Pathology Directorate, but is not directly involved in mortuary activities. The APT is supported by trained portering staff and has close working relationships with staff in Bereavement Services, the labour ward and visiting Pathologists. However, the HTA considers that the establishment's current level of resourcing of the mortuary, presents a risk which should be addressed as a matter of priority.

The Quality Manager for Pathology uses proprietary quality management software to help with document management, incident reporting and the scheduling of audits. The DI, Mortuary Manager and the APT attend formal mortuary management meetings, which are minuted.

Porters are trained in handling bodies and transferring them from the wards into fridges in the mortuary. Porters work in pairs and complete a mortuary booking in sheet when they bring bodies to the mortuary. Each morning, the APT checks bodies brought during the night and completes the mortuary register. When same or similar names have been identified, this is recorded in the mortuary register and on the fridge door where the deceased is stored. Two contracted Funeral Directors, who have received training, bring bodies from the community into the mortuary out of hours. They sign in at the main office in order to receive a pass which enables entry into the mortuary and complete a mortuary booking in sheet with details of the deceased. The APT is on call to receive bodies which are brought in by the Police out of hours and attends viewings out of hours.

The mortuary has 76 fridge spaces, including two bariatric spaces and three freezer spaces. Additional capacity is available in the form of a temporary storage unit with 27 spaces, including two bariatric spaces. All fridge and freezer temperatures are continuously monitored using a proprietary system. The fridges and freezers are linked to local alarms and the central switchboard. The alarms on the temporary storage units are activated when they are in use.

The main PM room has two down-draught tables and a viewing area; a second PM room, which is not currently in use, has one PM table.

Before coming on site, visiting Pathologists discuss cases scheduled for Coronial PM examinations with the APT, who follows their guidance on whether she can proceed to eviscerate the body before the Pathologist comes on site and undertakes an external body examination. The establishment does not provide histopathology services; all tissues removed during Coronial PM examinations are transferred by Courier to a neighbouring hospital which is licensed by the HTA.

The site visit inspection of Darent Valley Hospital was undertaken on 1 July 2015. This non-routine inspection was the third inspection of the establishment since they were first licensed under the HT Act, and was undertaken to review corrective actions and provide advice following an HTA reportable incicent.

The inspection included interviews with: the DI (the Clinical Lead for Pathology); a visiting Consultant Histopathologist, who undertakes PM examinations; the Mortuary Manager; Bereavement Midwives; the Consultant who seeks consent for perinatal PM examinations; a

member of the Bereavement Service who is responsible for disposing of fetal tissue; a Coroner's Officer and the Senior APT. Discussions were also held with the Quality Manager for Pathology. The HTA team visited the Labour Ward to discuss the pathway followed in cases of stillbirth, miscarriage or terminations. The team also visited Accident and Emergency to discuss protocols relating to sudden infant death.

A document review was carried out of policies, procedures and governance documentation. These included: mortuary SOPs on the admission of bodies, recording details in the mortuary register, allocating a unique ID to the deceased, infection risks and documenting fridge/freezer temperatures; PM examinations; reporting HTA reportable incidents; training records; meeting minutes; audit schedules; disposal of fetal remains; coroner's forms documenting the wishes of the next of kin; forms used to record tissues removed during PM examinations; cleaning records; and maintenance of mortuary equipment. Computer records in the proprietary quality management system relating to non-conformances and corrective actions were reviewed, as well as the process for managing documents, audits and scheduling audits.

Several audit trails were undertaken. Three bodies in storage, two community deaths and one hospital death, were traced from the mortuary registers to the storage location. Details in the mortuary register, name, storage location and identity tags were checked; no discrepancies were noted.

Paper records relating to two coroner's PM examinations were traced from the mortuary register, written records of tissue removed during the PM examination and records of the wishes of the next of kin. In one case a whole heart and spleen was sent to another HTA licensed establishment, returned to the mortuary and repatriated. This was evidenced by the traceability records, in this case a fax back to confirm receipt of the organ and tissue. In the second case blocks of lung tissue and pleura tissue were retained. Evidence was obtained that the tissue was transferred to the histopathology laboratory at another HTA licensed establishment. The inspection team also reviewed actions taken following the previous HTA inspection in January 2011.

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

Consent

Standard	Inspection findings	Level of shortfall
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. C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	The establishment does not have a documented procedure for seeking consent for perinatal PM examinations which outlines information to be provided to parents and states that consent must be sought by trained staff or in the presence of staff who have received training in how to seek consent. Bereavement Midwives and the Beareavement Officer follow a checklist, which covers the care pathway for miscarriages and terminations. Bereavement Midwives provide information about PM examinations to parents and the Bereavement Officer checks completed consent forms and communicates with staff at the site where PM examinations take place. However, these established procedures are not documented. Training in seeking consent for perinatal PM examinations is not provided. The Consultant Obstetrician/Gynaecologist described the process for seeking consent. However there is no system to ensure that all clinicians who seek consent for perinatal PM examinations have received training and have observed a PM examination or are supported by staff who have received training in seeking consent. Unfamiliarity with the HT Act and Code of Practice on Consent poses a risk that valid, informed consent may not be obtained for PM examinations and retention of tissue following PM examinations (see Advice item 2).	**Major**

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.	In most cases, evisceration of the body takes place before the pathologist has made a full examination of the external surface of the body. This arrangement is not formally documented, does not operate within an agreed framework and has not been risk assessed (see advice item 3). There is no documented procedure to cover the transfer of babies from the mortuary to the Labour ward for viewings. *Following the inspection the HTA was informed that the establishment changed its practice; evisceration takes place after the pathologist undertakes an external examination of the body.*	**Minor**
GQ2 There is a documented system of quality management and audit.	Standard operating procedures (SOPs) which cover activities taking place in the mortuary are drafted and approved by the same member of staff. This practice, which is the result of having only one member of staff in the mortuary, does not allow for a robust system for reviewing and updating SOPs. *Following the inspection the HTA was informed that the establishment has recruited an APT who is due to start work in September 2015.*	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.	The establishment is currently recruiting for an APT. There is no documented mortuary induction and training programme for new staff (see advice item 7).	**Minor**
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	SOPs do not state that bodies must be checked to confirm the identity of the deceased using three points of identification before post-mortem examinations, viewings and before bodies are released by the mortuary. Release procedures do not detail the checks that should be completed in order to ensure that any tissue or organ to be repatriated with the body have been re-united before the body is released. The absence of robust checking procedures increases the risk of misidentification of bodies, PMs being undertaken on the wrong bodies, release of the wrong bodies and disposal which is not in accordance with the relative's wishes.	**Minor**

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	The establishment has not sufficiently addressed the risk posed by having a single APT. The establishment is seeking to recruit an APT. In the meantime, steps should be taken by the establishment to ensure that risks to mortuary activities, which are currently being undertaken by a single member of staff, have been adequately mitigated. *Following the inspection the HTA was informed that the establishment has recruited an APT who is due to start work in September 2015.*	**Major**

Advice

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

No.	Standard	Advice
1.	C2	Bereaved parents are usually provided with printed versions of the booklet "Deciding about a post mortem examination: Information for parents" issued by the Stillbirth and Neonatal Death Society (SANDS). During the inspection, the HTA was informed that the establishment had run out of these and was currently providing parents with "A guide to the post mortem examination procedure involving a baby or child", an obsolete NHS publication dated 2003, before the commencement of the Human Tissue Act 2004. This booklet states that blocks and slides will be kept as part of the medical record and does not mention that they can only be kept with consent. The DI is advised to use the SANDS booklet, which can be accessed via the following link: https://www.hta.gov.uk/policies/sands-perinatal-post-mortem-consent-package#sthash.IAGvuZWw.dpuf.
2.	C3	The DI is advised to consider training a core group of staff who will be available to seek consent or support clinical staff who seek consent. The core group could include Consultants, Bereavement Midwives and the Bereavement officer. A member of the core group would be able to sit in and support clinicians who have not attended training in seeking consent for PM examinations.
3.	GQ1	The DI is advised to risk assess the procedure currently taking place, where the APT eviscerates before the pathologist undertakes an external examination of the body, and implement an agreed framework which states situations where it would not be appropriate for evisceration to take place in the absence of a pathologist. The DI is advised that the practice of evisceration before the pathologist has completed an external examinaion of the body is not in accordance with the guidance issued by the Royal College of Pathologists in February 2014 - 'Standards for Coroners' pathologists in post-mortem examinations of deaths that appear not to be suspicious'.
4.	GQ1	The DI is advised to appoint Persons Designated under the HTA licence in areas such as the Labour Ward, A&E Department and Bereavement services. The DI is also advised to formalise the arrangements with visiting pathologists in order to clarify their roles and responsibilities, including feeding back to the DI any concerns relating to staff and the premises. Persons Designated and visiting

		Pathologists should be encouraged to attend governance meetings so that they keep up to date with mortuary issues.
5.	GQ1	The mortuary follows a procedure for checking same and/or similar name. Bodies with same or similar names are highlighted in the mortuary register and on the fridge door. The DI is advised to ensure that the SOPs for admission of bodies and release of bodies are updated to include this procedure, which helps to ensure that the wrong body is not released or subjected to a PM examination.
6.	GQ2	The establishment has an audit schedule covering mortuary activities, which refers to HTA standards. The DI should remove reference to standards under the Human Tissue Quality and Safety Regulations 2007, which do not apply to the post mortem sector. The DI is encouraged to establish links with the HTA licensed establishment where visiting pathologists are based, in order to enable shared learning and explore the possibility of cross site audits.
7.	GQ3	The DI is advised to implement a training programme for new staff in the mortuary. The programme should cover the skills required, competency assessments and identify persons responsible for mentoring the new member of staff. This will help to ensure that the new recruit is trained in the most time efficient manner.
8.	GQ8	The DI is advised to extend the range of risk assessments to include the risk of an HTA reportable incident occurring. These include: the risk of a body being released without all tissue being returned in accordance with the family's wishes, the risk of the wrong body being released, the risk of a PM on the wrong body, etc. This will ensure that all practices relating to licensable activities have been risk assessed and help to reduce the risk of a HTARI.
9.	PFE3	The DI is advised to set up a system to check fridge and freezer alarms on a regular basis and monitor the response of staff who work on the switchboard. This will help to assure the DI that staff who man the switchboard are aware of the steps to take should an alarm be activated out of working hours.
10.	D2	The Coroner's form documents the wishes of the next of kin in relation to tissues, blocks and slides. It does not specifically document the wishes in relation to organs which are removed during a post mortem examination. The DI is advised to consider entering into discussions with the Coroner in order to ensure that the pathway for communication between the family, coroner's officer and the mortuary are formalised so that organs are repatriated or disposed/retained in accordance with the family's wishes.

Concluding comments

There were several areas of good practice. There are regular team meetings which are minuted. Issues such as contingency arrangements, bodies in long term storage are regularly reviewed. The DI has excellent links with the senior management team, who provide support and help to implement improvements to the service. There are effective systems in place to ensure that the premises and equipment are well maintained. All porters receive training as part of the induction programme and staff provide input into the training.

Staff at the establishment deal with bereaved families with respect and sensitivity. The Bereavement Officer and Bereavement Midwives follow a detailed checklist, which covers the care pathway in cases of miscarriage or terminations. The checklist identifies the roles and

actions for key members of staff, whether or not a PM is to be undertaken, and ensures that key steps, including maternal care, transfer of the baby to the mortuary, funeral arrangements and disposal /retention of tissues and organs, are completed in a satisfactory manner and in accordance with the wishes of the parents. The Labour Ward has a dedicated bereavement suite, where viewings of babies take place and all fetal remains irrespective of gestational age are disposed of by cremation. In 2013, staff at the establishment received an Excellence in Bereavement Award from the Royal College of Midwives.

There are a number of areas of practice that require improvement, including two major shortfalls and several minor shortfalls. In addition, the HTA has given advice to the Designated Individual with respect to strengthening governance arrangements, extending the range of risk assessments and documenting communication with the Coroner's office to cover the disposal/retention of organs following PM examinations.

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

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 29 July 2015

Report returned from DI: 14 August 2015

Final report issued: 17 August 2015

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: 15 February 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.