Site visit inspection report on performance against HTA quality standards
Kingston Hospital
HTA licensing number 12023

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**

2 February 2011

Executive Summary

A routine site-visit inspection of Kingston Hospital (the establishment) was carried out by the HTA on 2 February 2011.

The HTA's inspection highlighted areas of concern across the majority of licensing standards and regulatory requirements. Key findings included:

- poor governance and communication arrangements between the Designated Individual (DI) and staff working under the licence, which is likely to have contributed to a number of shortfalls identified across the HTA's licensing standards;
- poor traceability systems for blocks and slides containing samples of tissue taken during post mortem examination, including failure to define roles and responsibilities relating to the management of that tissue;
- damage to the body storage refrigeration units, which poses a risk to the health and safety of operators and to the dignity of the deceased; and
- significant discrepancies between the establishment's self-assessment against licensing standards submitted to the HTA in June 2010 and the inspection team's assessment.

Whilst the HTA found the governance arrangements in place for the DI to supervise activities under the licence to be unsuitable, it has not deemed the DI to be unsuitable to fulfil the role of DI. The HTA considers that strengthening the communication pathways and governance systems relating to licensed activities will significantly enhance the establishment's ability to meet the required standards.

Due to the high number of shortfalls identified across HTA standards, as well as the discrepancies between the establishment's self-assessment and the inspection team's

assessment, the HTA will return for a repeat site visit inspection by the end of the 2011 calendar year to ensure that sufficient improvements against standards are made.

Standards relating to records management, transportation and maintenance of equipment were not assessed during this inspection and will be addressed during the follow-up site-visit inspection. These standards are highlighted in Appendix 2: HTA standards.

All reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

The establishment is a medium-sized mortuary facility, undertaking approximately 300 adult post mortem examinations (PMEs) per annum. The vast majority are undertaken on behalf of HM Coroner (London – West) with a small number (~6 per annum) being consented hospital PMEs. Paediatric PMEs are not carried out at the establishment, although consent for these is obtained by Kingston Hospital staff. Known high risk cases are not carried out at the establishment.

PMEs are conducted twice a week. Usually a Home Office pathologist attends to carry out the PMEs, although there are three consultant histopathologists employed by the hospital who occasionally carry out PMEs (~12 per annum). If the PME is carried out by a Home Office pathologist (the vast majority of cases), any tissue taken for histopathology or toxicology is collected by a member of an HTA-licensed specialist organisation for analysis. In the small number of PMEs carried out by hospital-employed consultants, any tissue taken for histopathology is processed into blocks and slides on-site. Occasionally, organs are retained for specialist examination; however, no organs were being stored at the establishment at the time of the inspection. One piece of tissue was being retained for use for a scheduled purpose with consent.

This routine inspection was the establishment's first inspection by the HTA. In conducting the inspection, the team spoke to staff involved in the delivery of post mortem services, reviewed documentation informing the conduct of post mortem examinations and inspected relevant premises, including body store, post mortem suite and histopathology laboratory.

An audit trail was conducted of material taken during hospital consented PMEs to assess the robustness of the establishment's traceability systems. The audit trail highlighted a number of areas of concern about the management of tissue taken during PME when it is processed and stored on site. More detail is given against standard GQ6.

Meeting the HTA's regulatory requirements

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

The statutory duties of the DI are set down in Paragraph 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- that the conditions of the licence are complied with.

During the inspection it was apparent that the DI is operationally and practically removed from the work being carried out under the licence. In this situation, the HTA expects that strong communication channels are operating between staff working under the licence and the DI. This was not found to be the case, and the inspection team and the DI discussed

communication and governance at length. Although the HTA found the governance arrangements in place for the DI to supervise activities under the licence to be unsuitable, it has not deemed the DI to be unsuitable to fulfil this role because it considers that strengthening the communication pathways and governance systems relating to licensed activities will significantly enhance the establishment's ability to meet the required standards . The DI has acknowledged that changes must be made to strengthen communication and governance, and is currently considering whether to remain in the role as DI. Additionally, he has agreed to take immediate steps to strengthen governance and communication until such time as an alternative DI is assessed as suitable by the HTA.

The HTA also has concerns about the suitability of the refrigerated body storage units and does not consider that they are currently fit for purpose. Warping of the wooden frame of the units has caused issues with the doors that pose a risk to the health and safety of staff as well as the dignity of the deceased. Additional detail is provided against standard PFE1.

Meeting the HTA's licensing standards

The HTA developed its licensing standards with input from its stakeholders, in order to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA expects licensed establishments to meet these standards.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a licensing standard is not met, the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor' (see Appendix 3: Classification of the level of shortfall).

Unless otherwise advised, the establishment is required to inform the HTA within 28 days of the receipt of the final report of the corrective and preventative actions that will be taken to ensure that the improvements are addressed. A template for this purpose is provided as a separate Word document.

HTA standards not met

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.	The establishment's consent to examination or treatment policy does not fully reflect the requirements of the HT Act or Code of Practice on Consent for obtaining consent for PME. The establishment has recently implemented a standard operating procedure (SOP) for seeking consent for adult PMEs; however, it lacked sufficient detail to assist staff undertaking this task. Additionally, staff involved in obtaining consent for adult PMEs were not aware of the SOP. Specialist bereavement midwives obtain consent from parents for paediatric PMEs, which are carried out at another HTA-licensed establishment. The establishment does not have an SOP or policy for taking consent for paediatric PMEs.	**Major**
C2 Information about the consent process is provided and in a variety of formats.	The establishment provides persons giving consent with a Department of Health information leaflet. This leaflet was developed prior to the HT Act coming into force and does not meet the requirements for provision of information as set out in the Code of Practice on Consent. However, the establishment's consent form is based on the HTA's model consent form and provides additional detail on the consent process and options for the future use or disposal of retained tissue.	**Minor**
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	The establishment developed a training programme on consent for PME in 2007, which was delivered to a small core group of staff. Refresher training has not been offered; given the infrequency of staff obtaining consent for PMEs, refresher training is important to ensure skills and knowledge in this area are maintained. Training for obtaining consent for paediatric PMEs is not included in the programme. The establishment has recently audited consented PMEs and identified that, on a number of occasions, untrained staff have obtained consent for PMEs.	**Minor**

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.	Mortuary staff have recently commenced formal monthly meetings to discuss issues arising from work carried out under the HTA licences. One meeting has been held to date, which was not attended by the DI. There appears to be little communication between the DI and operational staff, potentially preventing the DI from being fully aware of issues relating to the delivery of post mortem services. SOPs reviewed by the HTA were found to be brief, with insufficient detail to support staff in carrying out operational activities. SOPs for the mortuary are written and authorised by the same person. Some existing systems (such as the recording of paediatric cases moving between the establishment and the premises where the PME will take place) could be streamlined to avoid duplication of effort by recording the same information in more than one place, a practice which may lead to transcription errors and inconsistencies. The systems and SOPs in place are limited to activities carried out in the mortuary. Whilst most of the tissue taken at PME is sent off-site for analysis, a small amount (blocks and slides from ~18 PMEs per annum) is retained at the establishment. The links between the mortuary and the laboratory are undefined and staff were not clear about who was responsible for managing the tissue upon arrival at the laboratory or for ensuring that it is disposed of or retained, in line with the wishes of the family. Anatomical Pathology Technologists (APTs) regularly eviscerate prior to the arrival of the pathologist and without the pathologist having performed an initial identification and inspection of the body. The HTA supports the professional guidelines of the Royal College of Pathologists, which recommend that the pathologist identifies the body and undertakes an external examination prior to commencement of the PME. The practice of APTs eviscerating without a pathologist present, contarary to RCPath guidelines, has not been risk assessed.	**Major**

GQ2 There is a documented system of quality management and audit.	The HTA considers the establishment's quality management system (QMS) to be limited, with little evidence of using available tools (e.g. risk assessments, audits, document control) to assist in continual improvement, and a lack of staff involvment. The establishment has an audit schedule in place, but this does not include audit of retained material or vertical audits. Findings from previous audits did not document responsibility for follow up actions and associated timeframes, with the result that necessary improvements may not have been made.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.	APTs are trained by shadowing experienced staff members. The establishment does not have a training programme or competency checklist to ensure that training specific to their work as an APT follows a full and systematic progression.	**Minor**
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	The establishment's traceability systems do not provide a robust audit trail from receipt of a body to its release, including the tracking of tissues, blocks and/or slides. The establishment uses numerous logs, many involving duplication of information, to track bodies and tissue removed during PME. Duplication of information between logs can give rise to transcription errors and discrepancies in records. The inspection team observed the following errors: • in one case, tissue taken during PME was not recorded in the PM suite log book but was in the office log book; • an incorrect number of slides made from a single block of tissue was recorded in the laboratory register; and • an incorrect name was transcribed from the porter's log book into the formal mortuary register, indicating that staff had not checked the identity of the deceased before recording this information. The establishment's system for tracing tissue once it has left the mortuary is not robust. Tissue is taken into the histopathology lab by either an APT or pathologist following a PME; however, the processes for receiving the tissue into the laboratory was not clear, nor were the roles and responsibilities of staff involved. There is a separate handwritten register for the small amount of tissue processed on site, which is filled in by a laboratory secretary. This log does not include information about: • additional slides prepared (e.g. for alternative	**Major**

	staining); the HTA found evidence to suggest that one pathologist was in possession of an additional 10 slides, the existence of which had not been recorded; • information that would assist staff in knowing what tissue should be repatriated/retained/or otherwise disposed of; or • any information recording the disposal/ return of blocks or slides. The inspection team conducted an audit trail on four hospital consent PMEs and the following discrepancies were found: • as described above, in two cases additional slides for alternative staining had been made but not recorded; • in one case, one block could not be located.	
GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	The Trust has a general incident reporting procedure that all staff must use for reporting any incidents. There is no mortuary-specific SOP or guidance on reporting incidents that take place in the mortuary, including the requirement to report these to the DI, the process for determining which incidents are serious, and the requirement to report any serious incidents to the HTA. Review by the HTA of a recent incident report demonstrated a lack of awareness by staff about the management of incidents and escalation procedures.	**Major**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	Some SOPs have been informed by a brief risk assessment associated with the procedure. The inspection team was provided with a small number (~6) of additional risk assessments, which were dated 2006 and had not been subject to review. Individual assessments focussed on health and safety risks relating to the working environment and use of equipment; they neglected to take into account other factors, e.g. risks to the bodies and tissue, risks of lone working, or risks of failure to comply with regulatory requirements. Risk assessments did not include the allocation of staff to take forward identified actions, or relevant timeframes in which to do so.	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE1 The premises are fit for purpose.	The establishment's refrigerated storage units are in poor condition and are not currently fit for purpose. The wooden frame of the refrigeration units has warped, leading to: • injury to a staff member when a door came off its hinges and fell onto them (prior to the inspection all hinges were replaced, however attention has not been given to the frame); • some fridge doors coming open, which may compromise storage temperatures and the condition of bodies; • some fridge doors no longer being able to be opened properly. Failure to rectify the issues with the refrigeration units could prevent body trays being moved safely in and out of the units, posing a risk to the health and safety of staff and to the safety and dignity of the deceased. As the mortuary staff have been able to work around these issues so far, this has not been assessed as a critical shortfall; however, this issue does have the potential to become critical if left unresolved.	**Major**
PFE2 Environmental controls are in place to avoid potential contamination.	Cleaning of the mortuary is a shared responsibility between staff and contract cleaners; however cleaning undertaken by mortuary staff is not documented. The cleaning SOP does not provide detail on specific areas which should be cleaned, how often and with what type of decontaminant. The cleanliness of the mortuary was highlighted in a recent SUI reported to the HTA, which indicated that cleaning of the mortuary had not been undertaken to an acceptable level following a PME. Recent inspection by the establishment's infection control team found that cleaning in the mortuary had been improved since the SUI. As part of the internal SUI investigation, a recommendation was made to review the service specifications for cleaning the mortuary to ensure that the quality of cleaning is monitored and documented regularly. This action was to be taken forward by September 2010. However, records of the contracted cleaning provided to the HTA do not provide detail on the areas cleaned within the post mortem suite and body store and therefore do not provide assurance that cleaning of relevant areas is being carried out appropriately.	**Major**

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.	See comments against PFE1 above	**-**

Disposal

Standard	Inspection findings	Level of shortfall
D2 The reasons for disposal and the methods used are carefully documented.	The majority of tissue taken during PME is sent off-site for analysis and this is documented. For the small amount of tissue that is analysed at the establishment, there is no procedure that captures the requirements for maintaining traceability of tissue when it is disposed of, including documenting the reasons for disposal. It is therefore not possible to determine whether tissue is disposed of in accordance with the documented wishes of the family. Within the laboratory log book, there is no logical place for the disposal of any tissue to be recorded. Due to the low risk of tissue being retained without consent, and the findings against standard GQ6 (traceability), the HTA has assessed this shortfall as minor.	**Minor**

Advice

Below are matters which the HTA advises the DI to consider.

No.	Standard	Advice
1.	GQ1	The DI is advised that any errors made in the formal registers should be crossed out and initialled, rather than overwritten. This will ensure that the reason for any change, as well as the change itself, is clear and made by an appropriate person.
2.	GQ1	The DI is advised to consider whether training should be provided to hospital porters who have access to the mortuary, to ensure that they are working appropriately under the establishment's governance and quality systems.
3.	GQ2	The DI is advised to ensure that all actions arising out of audits and SUIs are taken forward in a timely manner and evidence is available to demonstrate how these actions have been carried out.
4.	GQ6	The DI is advised to consider using a single unique identification number, assigned at the point of entry to the mortuary, to track and trace all bodies and tissue. This ID could be written onto the identification tags of the deceased to help strengthen traceability and identification prior to PME.

5.	N/A	The DI is advised to review the HTA's communication flowchart and consider how it could be used to continue to improve communications with the Coroner's office, including identification of a nominated person to facilitate communication.

Concluding comments

Significant improvements are required across the majority of HTA standards, which will be facilitated by strengthening of governance systems and improved communication between staff and management.

Although a high number of shortfalls against standards were identified through the inspection, the HTA was reassured by the willingness of staff working under the licence to take on board the inspection findings in order to increase performance against standards. As mentioned earlier in this report, the establishment is required to inform the HTA within 28 days of the receipt of the final report of the corrective and preventative actions that will be taken to ensure that the necessary improvements are made, and a follow up site visit inspection will take place by the end of 2011 to ensure that standards are appropriately raised.

Report sent to DI for factual accuracy: 28 February 2011

Report returned from DI: 10 March 2011

Final report issued: 22 March 2011

Appendix 1: HTA inspection process

The Human Tissue Authority regulates the removal, storage, and use of human bodies, body parts, organs and tissue for activities such as research, transplantation, and education and training. The legal requirements for establishments which carry out such activities are set out in the Human Tissue Act 2004 and The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006.

We license establishments in England, Wales and Northern Ireland that carry out these activities, and inspect them to make sure legal requirements are met.

Inspections

We use the term 'inspection' to describe when we:

- visit an establishment to meet with staff, view premises and facilities, and review policies and procedures (a site-visit inspection); or
- assess written information we have requested from an establishment (a desk-based assessment / inspection).

We carry out inspections to assess if the Designated Individual (DI) is suitable to supervise the activity covered by the licence, as it is their responsibility to ensure that:

- other staff working under the licence are suitable;
- suitable practices are used when carrying out the activity; and
- the conditions of the licence are met.

We also need to be satisfied that the licence applicant or holder, the establishment's premises, and the practices relating to licensed activities, are suitable.

To help us reach our decisions, we have developed standards under four headings: Consent; Governance and Quality; Premises, Facilities and Equipment; and Disposal.

After every site visit inspection, we write a report documenting our findings. Where we find a particular standard is not fully met, we will describe the level of the shortfall as 'Critical', 'Major' or 'Minor'. In most cases, it will be the responsibility of the DI to seek the HTA's agreement on how they will address the identified shortfalls. More information about the classification of shortfalls can be found in Appendix 3.

The majority of our site-visit inspections are announced. If we have concerns about an establishment, we can also undertake an unannounced site visit inspection.

You can find reports for site visit inspections which took place after 1 November 2010 on our website.

Appendix 2: HTA standards

Standards which are not applicable to this establishment have been highlighted.

Standards which were not assessed during this inspection have been highlighted.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• There is a documented policy which governs consent for post-mortem examination and the retention of tissue and reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent. • There is a documented SOP detailing the consent process (including who is able to take consent, what training they must receive, and what information must be provided to those giving consent for post-mortem examination). • There is written information about the consent process (provided to those giving consent), which reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.
C2 Information about the consent process is provided and in a variety of formats
• Relatives are given an opportunity to ask questions. • Relatives are given an opportunity to change their minds and is it made clear who should be contacted in this event. • Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use). • Where consent is sought for tissue to be retained for future use, information is provided about the potential uses in order to ensure that informed consent is obtained. • Information on the consent process is available in different languages and formats, or there is access to interpreters/translators.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• There is a training programme for taking consent for post-mortem examination and tissue retention which addresses the requirements of the HT Act and HTA code of practice on consent. • Refresher training is available (e.g. annually). • Attendance at consent training is documented. • If untrained staff are involved in consent taking, they are always accompanied by a trained individual.

Governance and quality system standards

GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process

- Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include:
    - post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases
    - record keeping
    - receipt and release of bodies, which reflect out of hours arrangements
    - lone working in the mortuary
    - transfer of bodies and tissue (including blocks and slides) to other establishments or off site
    - ensuring that tissue is handled in line with documented wishes of the relatives
    - disposal of tissue (including blocks and slides)

  (Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)
- Policies and procedures are regularly reviewed (for example, every 1-3 years).
- There is a system for recording that staff have read and understood the latest versions of these documents.
- Deviations from documented SOPs are recorded and monitored.

GQ2 There is a documented system of quality management and audit

- There is a quality manual which includes mortuary activities.
- Policies and SOPs are version controlled (and only the latest versions available for use).
- There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits).
- Audits include compliance with documented procedures, records (for completeness) and traceability.
- Audit findings document who is responsible for follow up actions and the timeframe for completing those actions.
- Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why.
- There is a complaints system in place.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Staff are appropriately trained/qualified or supervised.
- Staff have annual appraisals.
- Staff are given opportunities to attend training courses, either internally or externally.
- Attendance by staff at training events is recorded.

- There is a documented training programme for new mortuary staff (e.g. competency checklist).

GQ4 There is a systematic and planned approach to the management of records

- There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.
- There are documented SOPs for record management.

GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).
- Organs or tissue taken during post mortem examination are fully traceable, including blocks and slides. The traceability system ensures that the following details are recorded:
    - material sent for analysis on or off-site, including confirmation of arrival
    - receipt upon return to the laboratory or mortuary
    - number of blocks and slides made
    - repatriation with a body
    - return for burial or cremation
    - disposal or retention for future use.
- Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly

- Staff are trained in how to use the incident reporting system.
- Staff know how to identify incidents and near-misses which must be reported, including those that must be reported to the HTA
- The incident reporting system clearly 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).

  (Note that coroners usually have their own agreements with external parties for transportation bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases.)

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Items of equipment in the mortuary are in a good condition and appropriate for use:
  - fridges / Freezers
  - hydraulic trolleys
  - post mortem tables
  - hoists
  - saws (manual and/or oscillating)
  - PPE for high risk cases (e.g. respirators)
- The use of porous materials is kept to a minimum and has been risk assessed
- Maintenance/service records are kept for equipment, including fridges/freezers, trolleys, post mortem tables (if downdraught) and post mortem suite ventilation.

(Note: These records may be held by the mortuary or centrally by the Trust, e.g. Estates Department.)

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- There is a documented Trust or mortuary/laboratory policy for the disposal of human tissue, which reflects the requirements of the HTA code of practice on disposal.
- There are documented procedures for disposal of human tissue, including blocks and slides.

D2 The reason for disposal and the methods used are carefully documented

- There are systems in place that ensure tissue is disposed of in accordance with the documented wishes of the deceased person's family.
- Disposal records include the date, method and reason for disposal.
- Tissue is disposed of in a timely fashion.

  (Note: this means that tissue is disposed of as soon as reasonably possible once it is no longer needed, e.g. when the coroner's or police authority ends or consented post-mortem examination is complete.)

Appendix 3: 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.

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.

Follow up actions

A template corrective and preventative action plan is available as a separate Word document. 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.