Site visit inspection report on compliance with HTA minimum standards

Royal Stoke University Hospital

HTA licensing number 12224

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**

19 April 2017 & 23-24 May 2017

Summary of inspection findings

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

During the HTA's inspection in September 2016, three shortfalls were identified; two major and one minor. The purpose of the later inspections was to review the corrective actions taken by the establishment in order to meet the HTA standards.

There are a number of areas of practice that require improvement, including the two major shortfalls which remain open. The HTA has also given advice to the Designated Individual with respect to tissue traceability and documented procedures.

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

The establishment has been licensed since May 2007 and was last inspected in September 2016. The establishment's HTA licence covers premises at two locations, Royal Stoke University Hospital (the hub, for the purposes of HTA licensing) and County Hospital, Stafford (the satellite). During the September 2016 inspection, two major and one minor shortfall were identified and the purpose of the later inspections was to review the corrective actions taken by the establishment in order to meet the HTA standards.

The 2017 inspection focussed on governance and quality systems; however, other areas were reviewed, including the satellite premises' body store, new fridge and freezer alarm system at the hub premises, new bariatric storage at the hub premises and changes to staffing at the establishment. The inspection also incorporated an unannounced element, during which an inspection of the hub premises on 19 April 2017 took place, without prior notification to the establishment staff. Findings from the unannounced inspection have been incorporated into this report. A detailed description of the activities being undertaken at the establishment under its HTA licence is documented in the inspection report relating to the inspection that took place on the 14-15 and 21-22 September 2016.

Unannounced inspection, 19 April 2017

During the unannounced inspection the HTA:

- Reviewed the procedures being undertaken during receipt, post-mortem (PM) examination and release of bodies;
- Assessed compliance with the new standard operating procedures (SOPs) provided to the HTA as part of the CAPA process following its routine inspection during September 2016;
- Assessed completion of the paperwork associated with receipt, PM examination and release of bodies;
- Conducted audits of forms and paperwork associated with these activities.

The 'Admissions to RSUH/County Mortuary' SOP referenced the use of a white board within the mortuary; however, it was not clear to the HTA whether a white board was still being used as part of the mortuary's procedures. The HTA gave advice to the establishment that it should review this SOP, and current practice, to ensure that the SOP reflects what is expected and that current practice is consistent with the SOP.

A discrepancy was also identified during the review of 'Post Mortem Duties' SOP (MORTSOPPM029) in that the SOP described the use of a form to record identity checks performed prior to the examination commencing but practice has changed and a different form was being used to record these checks.

The mortuary maintains an Excel spreadsheet containing details of PM examinations undertaken, including those cases where a whole organ is retained. The completion of the spreadsheet and associated paperwork is not governed by an SOP, for example with regards to the details that should be recorded about retained organs. During the review of the spreadsheet and associated documentation, not all of the hard copy organ retention sheets could be located.

The HTA audited nineteen examples of cases where the spreadsheet indicated that the pathologist had retained a whole organ. In nine of the cases from the nineteen which were audited, the location of the organ could not be identified. In each case, this may have been a failure to record that the organ was returned to the body prior to its release rather than the loss of the organ, there being no record that they were ever brought to the laboratory for processing or examination. However, the lack of robust records of traceability were considerd a risk to the Trust, both with regards to these cases and future cases where organs are retained. This was identified as a shortfall and the cases where traceability could not be established during the unannounced visit were investigated further during the site visit inspection on 23 – 24 May 2017 (see details below).

The HTA also conducted an audit of 195 set of records relating to bodies released from the mortuary between 14 December 2016 and 6 January 2017. A number of non-conformances were identified including cases where:

- Contrary to the establishment's SOP, the *Authority to remove a deceased patient form* did not contain either a disposal certificate number or a Coroner's release form reference.
- In nine of 19 cases where there had been a post-mortem examination, the identification of the deceased had been confirmed by one person prior to the PM examination, rather than two as required by the SOP.

- In four of the 19 post-mortem cases, the return to body storage section of the *mortuary post-mortem check list* had not been completed.

Again the establishment was given advice that the procedural documents should be reviewed with the aim of ensuring that they reflect practice and reference additional documents and forms correctly.

Inspection 23 – 24 May 2017

At the following inspection undertaken on 23-24 May, through a visual inspection and round table discussions, the establishment's body receipt, post mortem and release procedures were discussed with mortuary staff, including the mortuary manager, acting deputy mortuary manager, an anatomoical pathology technologist (APT) and a trainee APT. Procedural documents relating to the above activities were reviewed, as well as those governing HTA reportable incident reporting (HTARI) and capacity/contingency arrangements. The HTA also performed checks on bodies in storage.

The establishment was found to have made significant progress in improving the documented procedures relating to receipt and release of bodies since the unannounced inspection in April. Deviations from practice, for example, the use of a white board that was previously described in the procedure have been removed. Additionally, procedural documents now reflect the procedures as described by the staff and reference the supplementary documentation by the correct name and document identification number for example, the 'Porters and Funeral Directors Booking in Sheet' – Mortprof024.

The establishment has also revised its HTARI reporting procedure, which now includes the details of what type of incidents are reportable, who is responsible for reporting them to the HTA, the timeframe within whch incidents must be reported to the HTA and how they should be reported. However, the list of the types of incidents that are reportable does not include the most recent incident category defined by the HTA, and advice has been given to the DI below to incorporate this category within the document (see advice item 2). The new procedure, once updated to include the latest HTARI category, meets the requirements of the HTA standards and therefore the minor shortfall identified against GQ7 during the September 2016 inspection will be closed.

The newly created procedural document regarding condition checks made on bodies stored at the establishment after six days (MORTSOPWP047) reflects the process described by staff.

The documented procedure covering the PM examination process did not accurately reflect the procedure being undertaken during routine cases. It is not clear about which staff must undertake identity checks on the body prior to the PM examination and how these checks are recorded. In addition, although the procedure makes reference to the qualifying relationships set out in the Human tissue Act 2004 (HT Act), the consent section does not state that an individual may consent to a PM examination in life or may have nominated a representative to act on their behalf following their death and does not not rank the list of qualifying relationships, as required by the HT Act.

Although progress and improvements have been made with regards to the establishment's procedural documentation, a number of documents do not reflect the practices being undertaken at the establishment. The shortfall identified during the September 2016 inspection will therefore be kept open as it has not been fully met.

Audits

An audit of records relating to tissue and whole organs that were taken and retained during post mortem examinations was undertaken. In addition, the actual tissue samples - blocks, slides and organs - were sought and the numbers of each cross referenced against the establishment's records.

Initially, the HTA reviewed the nine cases identified during the unannounced inspection in April 2017 where records had indicated that whole organs had been taken and retained following post mortem examination but traceability could not be established. In all nine cases, the establishment had addressed the traceability issues following the unannounced visit and all organs were accounted for. In some cases, records of the organ being repatriated with the body had been located and filed appropriately. In other cases, by reviewing documentation relating to the post mortem examination, it had been determined that the entry within the establishment's organ tracking spreadsheet had been made in error and a whole organ had not been retained.

Further audits were conducted, as described below:

Records relating to four post mortem examinations that took place in 2017,and two in late 2016 were reviewed. Of the six cases selected, four included the removal and retention of a whole organ for further examination. For the 2017 cases, details were reviewed of tissue taken during post mortem examination, that had been recorded and scanned into the mortuary's electronic records as part of a new process. The laboratory records were also interrogated and the physical blocks and slides sought.

In the four cases where whole organs had been retained, evidence of each organ's repatriation to the body was seen.

In two cases, additional tissue blocks had been taken from organs; however, it was found that a supplementary H1 form, which details the tissue taken for further examination, had not been submitted to the relevant Coroner. The additional tissue was, however, recorded within the pathologists' post mortem reports sent to the Coroner.

All blocks and slides sought by the HTA were accounted for, matched laboratory records and where applicable, post mortem records. One of the recent post mortem cases had no post mortem record sheet scanned into the archive as per the establishment's procedure and was therefore not reviewed.

Although the number of blocks and slides stored matched laboratory records, there were examples where additional special stained slides, mega blocks or the total number of blocks had been recorded on the usual page in the establishment's laboratory information management system (LIMS), the tissue retention page. Further interrogation of the LIMS found that the page used to record the cassettes and slides created did correlate with the correct number of blocks and slides (although mega blocks and slides were not recorded by this system). The discrepancies between the tissue retention page and the numbers of blocks and slides created were thought to be due to operator error during manual data entry into the LIMS. Advice has been given to the establishment to investigate if the page used to record the number of blocks and slides created, rather that the tissue retention page, could be interrogated to provide details of all tissue retained following post mortem examination (see advice item 1).

A reverse audit of retained tissue was also undertaken where details of three post mortem cases where tissue had been retained were taken by locating the blocks and slides in the

tissue archive. The LIMS was then interrogated and mortuary records of tissue taken during PM examination were reviewed both on the post mortem spread sheet and the scanned post mortem records. In one case, the LIMS' tissue retention page recorded that only six blocks and slides had been taken; however, seven had been made. The mortuary records for this case correctly recorded that seven pieces of tissue had been taken during the examination. No other discrepancies were found during the review of the other two cases.

The establishment has streamlined the retained tissue archive since the inspection in September 2016 and mortuary staff now scan and archive the records of tissue taken during post mortem examination. In addition, responsibility for completion of the histopathology request cards in the mortuary has been taken on by the APTs, who cross check the number of tissue pieces taken against the post mortem records when completing the request form.

The changes that the establishment has made to its traceability systems have helped to improve organ and tissue traceability since the September 2016 inspection. However, the discrepancies found between the laboratory LIMS' retained tissue page and the actual numbers of blocks and slides made still represents a potential risk to the traceability of retained tissue. In addition, there are examples of staff not following the establishment's procedures governing retained tissue, including the requirement to send the Coronial H1 forms and 'scaning in' the post mortem record sheets, which also pose a potential risk to tissue traceability. The shortfall identified during the September 2016 inspection will therefore be kept open. The establishment will have the opportunity to make further changes to its traceability systems to strengthen them in order to ensure that laboratory records reflect the numbers of organs, blocks and slides retained following post mortem examinations. Changes to the establishment's changes to its traceability systems will be reviewed by the HTA to determine if the standard is fully met or not.

In addition to tissue traceability audits, audits of bodies within the body store at both the hub and satellite premises were also undertaken. At the hub premises, four bodies were selected at random and five selected at the satellite. Details from the body's identification wristband and the body's location details were cross checked between the body, paper records and electronic records. No anomalies were found during the audit.

Finally, an audit to verify that electronic records of bodies in the mortuary database matched the numbers of bodies indicated by the mortuary paperwork was undertaken. Paper-based records indicated that 70 bodies were currently being stored at the mortuary which correlated with the active records within the electronic mortuary database.

The establishment has installed and activated a new temperature monitoring system at the hub premises. This system monitors the fridge and freezer temperatures and, should these deviate from the expected range, triggers an alarm at the establishment's estates department, which, in turn, alerts the on-call mortuary staff.

The establishment has also completed the installation of a new bariatric body storage unit within the body store, which accommodates an additional three bariatric bodies using a racking system. This racking can also be removed meaning that a larger body on a bariatric bed can be accomodated.

Finally, the establishment has appointed a permanent mortuary manager. Reporting to the mortuary manager is an acting deputy mortuary manager, two APTs and two trainee APTs.

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

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	**Finding September 2016** During the inspection it was found that many of the establishment's procedural documents had passed their review date and had not been updated to reflect changes in practice. Additionally, recently updated procedures did not accurately reflect practice as they referred to incorrect documentation such as 'mortuary ledger' and previous procedures such as an out of date same/similar name procedure. As the establishment has experienced significant changes in staffing and has brought in locum staff to help with workloads, it is important that accurate documentation is available for staff to be trained in and follow. **Finding May 2017** Although progress and improvements have been made with regards to the establishment's procedural documentation, there are still documents that do not reflect the practices being undertaken at the establishment. The shortfall identified during the September 2016 inspection will therefore be kept open.	**Major**

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	**Finding September 2016** During an audit of tissue taken and retained during post-mortem examinations, it was found that there is some tissue that could not be accounted for and therefore, traceability has been lost. Additionally, there are no procedures relating to the 'teaching set' of tissue to ensure that tissue is not retained for longer than to the consent allows. No tissue has been stored for longer than it should have been; however, the lack of an appropriate procedure to keep this tissue under review, creates a risk that this may occur in the future. **Finding May 2017** Although progress and improvements have been made with regards to the establishment's traceability procedures, there remains a potential risk to tissue traceability. The shortfall identified during the September 2016 inspection will therefore be kept open.	**Major**

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	**Finding 19 April 2017** The HTA audited nineteen examples of cases where the spreadsheet indicated that the pathologist had retained a whole organ. In nine of the cases from the nineteen which were audited, the location of the organ could not be identified. In each case, this may have been a failure to record that the organ was returned to the body prior to its release rather than the loss of the organ, there being no record that they were ever brought to the laboratory for processing or examination. However, the lack of robust records of traceability were considerd a risk to the Trust, both with regards to these cases and future cases where organs are retained. **Finding May 2017** In all of the above nine cases, the establishment had addressed the traceability issues following the unannounced visit and all organs were accounted for. In some cases, records of the organ being repatriated with the body had been located and filed appropriately. In other cases, by reviewing documentation relating to the post mortem examination, it had been determined that the entry within the establishment's organ tracking spreadsheet had been made in error and a whole organ had not been retained. As a result, the shortfall identified in April 2017 regarding organ traceability has not been applied to the establishment's licence.	~~**Major**~~ **Fully met**

Advice

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

No.	Standard	Advice
1.	GQ6	The DI is advised to investigate if the laboratory database page which records the numbers of cassettes and slides made could be interrogated to determine the numbers of blocks and slides retained following post mortem examination. This is due to the

		tissue retention page, which is currently used to trace retained tissue, being shown to contain discrepancies between records and the actual numbers of blocks and slides in storage. The DI is also advised to ensure that mega blocks and slides are recorded within the laboratory's traceability systems, as they are not currently recorded electronically. Finally, the DI is advised to ensure that all pathologists who take tissue samples from whole organs retained following post mortem examinations are recorded on an appropriate coronial form which is then sent to the Coroner.
2.	GQ7	The establishment's new procedure relating to HTA reportable incidents (HTARI) does not include details of the latest HTARI category. The DI is advised to review the HTARI categories in the HTA's guidance at the link below, and include all categories within the document. https://www.hta.gov.uk/sites/default/files/HTARI%20Guidance%20for%20establishments%20Feb16_0.pdf

Assessment of existing conditions/shortfalls against standards

Two shortfalls identified during the inspection in September 2016 remain open following a review of the actions taken by the establishment during this inspection. In both cases, improvements to the establishment's systems have been made but the standards to which the shortfalls relate have been assessed as being unmet.

The shortfall against standard GQ7 identified in September 2016 relating to HTA reportable incident reporting was determined to have been met subject to the advice given above regarding upate of relevant procedural documentation.

More detail regarding the findings relating the shortfalls identified during the September 2016 inspection is included above in the 'Background' and 'Compliance with HTA Standards' sections.

Concluding comments

The establishment has made some changes to procedures which were considered to represent good practice, examples are included below:

- The establishment has restricted visits by funeral directors bringing or collecting bodies at the mortuary between 8am – 9am. This provides an uninterrupted period during which mortuary staff can undertake identity checks of bodies received during the previous evening and to record them in the mortuary database.

- The establishment has also formalised the process through which condition checks are undertaken of bodies that have been in the mortuary for six days or more. This procedure has been included as part of the establishment's documented procedures.

There are a number of areas of practice that require improvement, including two major shortfalls. The HTA has given advice to the Designated Individual with respect to tissue traceability and documented procedures.

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: 22 June 2017

Report returned from DI: 12 July 2017

Final report issued: 26 July 2017

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.