Site visit inspection report on compliance with HTA minimum standards

University Hospitals Coventry and Warwickshire NHS Trust

HTA licensing number

30018

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**

31st August - 1st September 2016

Summary of inspection findings

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

Although the HTA found that University Hospitals Coventry and Warwickshire had met the most of the HTA standards, three shortfalls were identified against standards GQ8 and PFE3. These were in relation to risk assessments of licensed activities taking place in both the tissue bank and the mortuary and body storage capacity.

Particular examples of strengths and good practice are included in the concluding comments section of the report.The establishment was provided with advice and guidance about areas that could be improved further.

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

This report describes the second site visit inspection of the University Hospitals Coventry and Warwickshire (the establishment), which is licensed to carry out post mortem (PM) examinations and the removal and storage of PM tissue for use for scheduled purposes under the Human Tissue Act 2004. PM tissue is stored under the governance of both the HTA licence and research tissue bank (RTB) ethics approval. The inspection took place over a period of two days, in which PM activities were reviewed on the first day and the storage of human tissue for research on the second day.

The establishment undertakes approximately 600 PM examinations a year under the jurisdiction of HM Coroner for Coventry and Warwickshire, including high risk cases up to category three. Very few adult hospital (consent) PM examinations are carried out. Consented paediatric cases are transferred to another licensed establishment for PM examination.

The inspection included a visual inspection of the mortuary and Arden Tissue Bank. Interviews were held with a Bereavement Officer, Mortuary Manager, Quality Manager, Histopathologist, Coroner's Officer, RTB Manager, Research & Development Manager, Desginated Individual and Corporate Licence Holder contact (CLHc).

The hospital's accident and emergency (A&E) department is an area in which samples may be taken in cases of sudden unexplained death in infancy (SUDI). Therefore, as part of the visual inspection, the HTA visited the A&E department and met with the Consultant Paediatrician responsible for this activity. They demonstrated an understanding of the requirements of the Human Tissue Act 2004 and explained the establishment's SUDI procedure. The HTA was satisfied with the arrangements in place covering this activity.

Porters are responsible for transferring bodies from the ward to the mortuary both during and out of hours, and are required to complete the 'Incoming Book' with their name, full name of the deceased and the date and time of transfer. Funeral Directors (FDs) are responsible for bringing in bodies from the community and also required to complete the 'Incoming Book'. For bodies that are brought in out of hours, the FDs must notify the portering department in order to gain access to the mortuary and all visitors to the mortuary, including FDs and porters, must sign in and out each time.

Each morning, mortuary staff are responsible for checking the identification and condition of bodies that have arrived out of hours. Bodies admitted from the hospital should be accompanied by a 'Deceased Patient Details Form', which is attached to the shroud of the deceased; mortuary staff check the identification of the deceased by reviewing the wrist and ankle bands containing their full name, date of birth and hospital number. Bodies admitted from the community have a wrist band attached, which includes the full name of the deceased, date of death and address.

On completion of their checks, mortuary staff are responsible for transcribing the details from the 'Incoming Book' to the Mortuary Register. Bodies of deceased with the same or similar sounding names are highlighted on the doors of the fridges by using a different colour pen and this is also highlighted in the register. It was noted during the inspection that a unique mortuary identification number is not assigned to bodies on arrival to the mortuary (advice item 3).

The mortuary has 98 storage spaces in the main body store. There are five freezer and five paediatric fridge spaces. There are two fridge banks that can be used for bariatric storage if required. There are also two temporary body storage units providing an additional 24 spaces; however, since January 2015, one of these have been set up in the high-risk PM suite, which is not currently in use as a result (see major shortfall, PFE3). An unlicensed body store at another Trust, with three freezer spaces and 18 fridge spaces, is used as an overflow under a contingency arrangement. All mortuary refrigeration units are connected to a continuous electronic monitoring system, which sends a notification to staff members in the event that a temperature excursion occurs. However, the fridge alarm system is not routinely tested by mortuary staff (advice item 6).

Because the post-mortem suite designated for high-risk PM examinations is not currently in use, these take place in the main PM suite after all other PM examinations are complete. This suite has five dissection tables each with its own dissection bench.

Wet tissue and organs removed during PM examination are placed in appropriate pots containing formalin. Organs for specialist examination are sent to other HTA-licensed establishments and wet tissue for histological examination is transferred by mortuary staff to the pathology laboratory, where it is placed into cassettes. The pathology laboratory returns tissue blocks and slides to the mortuary for storage, and mortuary staff carry out the wishes of the family when they receive notification of these from the Coroner. They ensure that tissue blocks and slides are disposed of sensitively; returned to the family or retained for a scheduled purpose in line with the wishes of the family.

Traceability audits were carried out by reference to two adult bodies and one fetus. Bodies were identified from the mortuary register to the fridge location and against the wrist/ankle bands of the deceased. The fetus was identified from the paediatric mortuary register to the fridge location and against the label on the casket. All bodies were fully traceable, however a minor discrepancy was identified in relation to the records associated with the fetus. This was in relation to hospital number which was recorded on a local spreadsheet but not in the relevant mortuary register. No other discrepancies were identified.

A tissue traceability audit was carried out using the paper and electronic records in relation to two bodies that had been subject to a PM examination, in which human tissue was stored in the tissue bank. The family's wishes form and a hospital PM consent form were reviewed and demonstrated that consent had been given for human tissue blocks and slides to be stored for research. The locations of the blocks and slides were identified by checking the electronic database. All tissue blocks and slides were fully traceable and there were no discrepancies.

Tissue samples and organs retained for police purposes are sent to other establishments for analysis. Under s39 of the HT Act, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, the 2012 report of the Association of Chief Police Officers' (ACPO) audit of tissue held under police authority contained a recommendation that police exhibits held on HTA-licensed premises should be included within the regular HTA inspection process. Therefore, procedures for Home Office PM examinations and the management of tissues and organs taken for criminal justice purposes were reviewed by HTA at this site visit inspection. Any findings in relation to Home Office PM examinations and/or police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the HT Act.

Arden Tissue Bank

The Arden Tissue Bank (the tissue bank) is a research ethics approved tissue bank, located in the pathology department's diagnostic archive, in which tissue from the deceased is stored under the governance of both a research tissue bank (RTB) ethical approval and HTA licence. Tissue and whole organs removed during PM examination are stored in the tissue bank for research in line with the wishes of the family. Occasionally, tissue blocks and slides from the diagnostic archive are also released for use in research and this activity is controlled under the governance and oversight of the tissue bank manager (advice item, 17). All tissue and organs (from the living and the deceased) stored in the tissue bank are given a unique identification number, which is generated by the electronic database. All samples are assigned a label containing the unique identification number. Hospital PM consent forms, families' wishes forms from the coroner and instructions from the police demonstrating consent for storage for research are stored separately in the tissue bank and labelled w`ith the unique identification number in each case.

The tissue bank receives, from another HTA-licensed establishment, whole hearts which have been deemed unsuitable for transplantation but for which consent has been given for use for research. When these become available, a courier is responsible for collecting the heart from the HTA-licensed establishment and transferring it to the tissue bank. On its arrival, the whole heart and any sections taken, are logged on the electronic database and given a unique identification number. The remaining heart tissue is then transferred immediately by courier, to a researcher granted approval to receive tissue from the tissue bank. Ocassionally the hearts are stored for surgical training purposes under the anatomy

licence held by the establishment.

The majority of tissue samples, including surgical resections of lung and endometrial tissue, are stored in the tissue bank under the governance of project-specific NHS research ethics approval. Although these fall outside the scope of the HTA's licensing remit, advice was provided in relation to the consent requirements under the HT Act (Advice item, 10). In future, the tissue bank plans for tissue to be collected and stored from donors prospectively.

The tissue bank has 12 -80^{0}C freezers including a back-up freezer to be used in the event of a mechanical failure. There are also contingency arrangements in place with other HTA-licensed establishments (advice item, 15). There is a temporary freezer located in the diagnostic archive area, where temperature-sensitive tissue samples are stored temporarily whilst tissue bank staff log the material into the bank; these tissue samples are then transferred to freezers located in a separate building on the hospital site, for long-term storage. The freezers, which are locked at all times, can only be accessed by tissue bank staff with swipe card access. Wet tissue from the deceased is also stored in this building in a locked cabinet. All freezers are subject to continuous temperature monitoring using an electronic system which is checked on a daily basis. In the event of a temperature excursion, the electronic monitoring system sends a notification to members of staff both during and out of hours.

A forward traceability audit was carried of a whole heart and relevant sections stored in the tissue bank freezer. The heart was identified using the electronic database and corresponding consent form. All heart tissue sections were fully traceable and there were no discrepancies. The electronic database demonstrated that the remainder of heart tissue was transferred to the local University.

A reverse traceability audit was carried out of tissue stored in the tissue bank temporary freezer that was originally retained by the mortuary on behalf of the police. A review of the family's wishes form was undertaken and demonstrated consent for research was in place. A minor discrepancy was noted, as the two pots containing tissue had been labelled with an incorrect unique identification number. This was a minor transcription error and the pots were re-labelled with the correct unique identification number immediately. There were no further discrepancies.

Inspection findings

Overall, the HTA found the Licence Holder to be suitable in accordance with the requirements of the legislation.

Whilst the Trust has expanded in size over the years, mortuary fridge and freezer capacity has remained the same and temporary storage units are in constant use to provide additional storage. As a result, the mortuary's reduced storage capacity relative to the number of bodies that need to be accommodated has been identified as a 'red risk' on the Trust's corporate risk register, with monitoring of capacity being undertaken by mortuary staff on a daily basis. The HTA's view is that this presents a significant risk to the integrity of bodies stored in the mortuary, as well as a reputational risk to the Trust.

Compliance with HTA standards

Governance and Quality Systems

Standard	Inspection findings	Level of shortfall
GQ8 Risk assessment of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately	Although a comprehensive range of risk assessments was in place considering health and safety risks, there were no risk assessments of activities taking place under the HTA licence at the Arden Tissue bank (see advice item 13 below).	Minor
GQ8 Risk assessment of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately	Mortuary staff occasionally use the bottom of the fridges for additional storage, when the fridges are reaching capacity. Smaller bodies are placed in body bags and stored on the bottom of the fridge, without trays. Staff rely on estimating the size of the body before placing it in the lower-most space, which poses a risk of accidental damage if the body is larger than estimated or has an unusual morphology (e.g. curvature of the spine). There has been no risk assessment of this practice to consider risks to the deceased or to staff in respect of manual handling. Furthermore, there has been no assessment of risk to the deceased as well as mortuary staff in respect of how often bodies need to be moved around in order to make space.	Major

Premises Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissue and cells, consumables and records	Body storage arrangements are insufficient to meet the needs of the mortuary. Temporary body storage units are in constant use and during periods of increased demand, such as in the winter months, bodies are placed on the floor of the fridges. Furthermore, the Isolation room, which is used to carry out high risk PM examinations, has been out of service since January 2015 as it used to accommodate a temporary storage unit.	Major

Advice (Mortuary)

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

No.	Standard	Advice
1.	C3	Consent for hospital consented PM examinations is sought by clinicians and bereavement staff, who are present during the process. The DI has provided consent training to all bereavement staff; however, refresher training is not being provided. The DI is advised that refresher consent training should be provided as hospital consented PM examinations are infrequent.
2.	GQ1	The DI is advised to review all procedures that involveidentification of the deceased (i.e. receipt of a body, PM examination, release of a body)) to ensure that the procedures specify which identifiers should be checked. The HTA recommends a minimum of three identifiers, one of which should be unique to the deceased.
3.	GQ6	Whilst three points of identification are checked for each body entering the mortuary, to strengthen tracability systems, the DI may wish to consider assigning a unique identifier each time a body is admitted to the mortuary.
4.	GQ8	In relation to the mortuary, the DI is advised to review the risk register and update it to include risks associated with storing bodies on the bottom of the fridges and their increased manual handling.
5.	PFE2	The DI is advised to document cleaning of the mortuary in a cleaning log.
6.	PFE3	Although the mortuary fridges and freezers are subject to continuous temperature monitoring, the DI is advised to consider a manual challenge of the alarm notification system to ensure that it is functioning correctly. The DI is advised to document routine alarm tests.
7.	D1	The DI is advised to review the disposal of pregnancy remains policy and ensure that it is in line with the HTA's pregnancy remains guidance, as it does not currently offer sensitive incineration or cremation.
8.	N/A	The DI is advised to identify a Person Designated (PD) in A&E and inform the HTA in writing.
9.	N/A	The DI is advised to hold regular meetings with the Coroner's Officers, particularly as the Coroner's Office has had some change in staff. This will strengthen the working relationship as well as improve the lines of communication between mortuary staff and Coroner's officers.

Advice (Arden Tissue Bank)

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

No.	Standard	Advice
10.	C1	The DI is advised to review arrangements for the traceability of tissue samples which are being stored under the governance of project-specific ethical approval. The tissue bank currently receives these samples without evidence that consent has been given for their use in research. The DI should assure himself that all material stored in the tissue bank has consent.
11.	C3	National Institute for Health Research (NIHR) informed consent training is provided to researchers involved in ethically-approved research. Although, there is no prospective human tissue collection into the tissue bank, moving forward the DI is advised to incorporate consent training which covers the requirements of the Human Tissue Act 2004 (HT Act 2004). This will ensure that all tissue stored under the licence has consent obtained by staff trained in seeking consent.
12.	GQ7	There is a laminated poster in the tissue bank which provides information to tissue bank staff about the reporting process for adverse incidents involving human tissue samples. The DI is advised to draft a standard operating procedure (SOP) which outlines the types of incidents that need to be reported and investigated, staff groups that must be informed immediately, the CAPA process that must be followed, the follow up of actions and closure of investigations. Incidents may include, but are not limited to: • receiving and/or storing specimens without appropriate consent documentation; • storing or using human tissue after consent withdrawal; • storage failure or other damage affecting human tissue quality for useful research; • loss of human tissue; • sample mix-up or loss of traceability; • transport of specimens to and from the establishment; • security arrangements; • incorrect disposal. This information will give staff a better understanding of the types of incidents involving human tissue that must be reported and investigated.
13.	GQ8	In addressing the tissue bank's minor shortfall against this standard, the DI is advised to include an assessment of risk for the incidents laid out in advice item, 12, above.
14.	PFE2	The DI is advised to document cleaning of the mortuary in a cleaning log.
15.	PFE3	In the event of a freezer failure in the tissue bank, there are arrangements with other HTA-licensed premises to store human tissue. There is an SOP (TB EP01) which outlines the process for dealing with freezer failure; however, it does not include the off-site contingency arrangments. The DI is advised to review the SOP to include this information.

16.	PFE3	Although the tissue bank fridges and freezers are subject to continuous temperature monitoring, the DI is advised to consider the following: 1) Manual challenge of the alarm notification system to ensure that it is functioning correctly. The DI is advised to document routine alarm tests. 2) Regular review of the temperature monitoring system to ensure it is functioning correctly (e.g. daily). The temperature monitoring system for the mortuary fridges is only checked if there is a temperature excursion.
17.	N/A	The DI is advised to consider including the diagnostic archive under the governance of the NHS REC approval. This may be particularly helpful if the diagnostic archive is accessed frequently and will help the NHS REC take into account any ethical considerations surrounding the use of diagnostic tissue.

Concluding comments

As referred to earlier in this report, the HTA is concerned that the lack of sufficient storage space for bodies poses a significant risk to the Trust, and has therefore been identified as a major shortfall against the HTA's licensing standards.

Despite the pressure on mortuary staff, they continue to provide an efficient service and several areas of good practice were noted during the inspection, in respect of:

- the last offices audit, which was initiated by mortuary staff to identify problems in relation to the way in which wards manage the process and its impact on the mortuary;
- the monitoring of ambient room temperatures of both the mortuary body store and tissue bank storage areas;
- the approach taken to storing human tissue in a dedicated area and ensuring that all tissue, regardless of whether it is subject to the HTA licensing requirements, is handled in a consistent manner;
- the sensitive approach taken in respect of families attending viewings.

There are some areas of practice that require improvement, including one minor and two major shortfalls in relation to standards GQ8 and PFE3. The HTA has given advice to the Designated Individual on a range of issues in relation to standards, C1, C3, GQ1, GQ6, GQ7, GQ8, PFE2, PFE3 and D1 to make further improvements.

The HTA requires that the Designated Individual addresses the shortfall 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: 19 October 2016

Report returned from DI: 07 December 2016 (with comments)

Final report issued: 07 December 2016

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: 10 November 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.

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 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.
- 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 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.