Site visit inspection report on compliance with HTA minimum standards

University Hospital of North Durham

HTA licensing number 12461

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**

23 – 24 March 2016

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.

Although the HTA found that University Hospital of North Durham (the establishment) had met the majority of the HTA standards, three minor shortfalls were found against the governance and quality system standards.

The shortfalls relate to the need for appropriate documented procedures for some of the establishment's activities, systems to report incidents to the HTA and risk assessments. The HTA has given advice to the Designated Individual with respect to consent documentation, documented procedures, risk assessments and temperature monitoring.

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's HTA licence covers premises at two locations, a hub site at University Hospital of North Durham and a satellite site at Darlington Memorial Hospital.

The hub site consists of a body store, post mortem room and a histopathology laboratory. The body store has 48 storage spaces, eight of which can be operated as freezer spaces if needed. Twenty three of the spaces are suitable for the storage of bariatric bodies. The establishment experienced some pressure with regards to storage spaces over the winter period and at the time of the inspection, a temporary storage facility providing an extra twelve spaces was in use in a secure side room of the mortuary. A second temporary unit had been installed in the PM room however this was not in use at the time of the inspection as it was awaiting repair.

The satellite premises consist of a body store and post mortem room. Any tissue taken for histological analysis during a post mortem examination is sent to the hub site to be processed into blocks and slides and review by the pathologist. The body store at the satellite site consists of 33 storage spaces in the main store, three of which can operate as freezers. In addition, there is a separate cold room, which has spaces for twelve bodies and a bariatric bed, which is available if needed. The establishment has portable racking, which can be placed into the cold room to provide an additional six spaces. The satellite site also has

access to a temporary storage facility located within the mortuary complex, which was in use at the time of the inspection.

At both hub and satellite premises, the main storage facility is temperature monitored and connected to an alarm which is connected to switchboard. Switchboard staff alert the engineers, and if necessary mortuary staff, should the temperature deviate from the appropriate range. At the satellite site, the separate cold room storage area is also linked to the alarm system. The alarm systems at both premises are tested regularly by the establishment's estates department. The estates department also maintains mortuary equipment, for example bone saws and post mortem examination tables in addition to the mortuary's air handling systems.

At both the hub and satellite sites, the temporary storage units are not linked to an alarm system and therefore there is no automatic system for alerting staff to an equipment failure or deviation in the storage temperature. Although the temperatures of the units are monitored and recorded by mortuary staff during normal working days, and they are connected to the hospital's emergency power supply, the lack of a system which would alert staff to an equipment failure or storage temperature deviation increases the risk to the bodies stored in these units should there be an equipment failure. Advice has been given to the DI with regards to the monitoring of the temporary storage units.

The establishment's hub and satellite sites conduct adult post mortem examinations, either under the authority of the Coroner or with appropriate consent where there is a medical interest in the case. At the hub site, approximately 800 post mortem examinations are undertaken under the authority of the Coroner every year, alongside a very small number, three or four, consented, hospital post mortem examinations. At the satellite premises, approximately 270 coronial and around one to two consented hospital post mortem examinations take place every year.

At both the hub and satellite sites, consent for adult hospital post mortem examinations is sought by the clinician who was treating the deceased, with the support of an anatomical pathology technologist (APT) who has received training in the appropriate seeking of consent and use of the consent forms. The APT can answer any questions that the person giving consent may have about the procedure. In addition, a pathologist may also participate and support the consent seeking process.

Neither the hub nor satellite site undertakes paediatric or infant post mortem examinations. These are referred to and conducted at another HTA licensed premises after consent taken by staff at the establishment.

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

During the inspection the HTA was informed that APTs routinely eviscerate bodies prior to the arrival of the pathologist. There are some circumstances in which the APT awaits the arrival of the pathologist prior to commencing the post mortem examination, for example, where the death is the result of a road traffic accident or a suicide and where anything unusual or suspicious is identified. This is contrary to guidance issued by the Royal College of Pathologists. Furthermore, the circumstances in which an APT may and may not commence a post mortem examination are not documented in the establishment's standard operating procedures (see shortfall against standard GQ1 and advice item 5).

Removal of various tissue samples may take place in areas outside of the mortuary at both the hub and satellite hospitals. These samples include blood and swabs which are removed from deceased children who are brought to the hospital or die in the accident and emergency (A&E) department, in line with procedures governing sudden unexpected death in infants.

At the hub premises any deceased children are transferred to a paediatric ward where the removal of tissue is undertaken by a paediatrician in a room which is private and is suitable for the procedure. The paediatricians follow documented guidance, which detail the types of sample to be taken. At the satellite premises removal of these samples takes place in a dedicated bay of the paediatric resuscitation area within the emergency department, which again is private and is suitable for the procedure. As at the hub, paediatricians remove these samples and work to the same guidance.

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

The maternity departments at both the hub and satellite premises have dedicated fridges where the remains of stillborn babies or fetuses may be stored temporarily prior to being moved to the mortuary so that, where appropriate, parents have the opportunity to spend time with them on the ward.

At the satellite site, the storage fridge on the maternity department is checked daily by the maternity department's staff during the routine checks of critical equipment. This means that staff would be alerted to an equipment failure within 24 hours of it occurring which helps to minimise the risk of a failure going undetected.

At the hub premises however, the storage fridge is not routinely checked, which increases the risk that an equipment failure may not be detected by maternity department staff. Advice has been given to the DI below (see advice item 8).

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

As part of the inspection planning it came to light that the establishment's previous DI had been absent from work for several months before the establishment had applied for a change of DI. During the inspection both the DI and Corporate Licence Holder Contact (CLHC) were reminded of the importance of having a DI in place to ensure that licensable activities are being undertaken appropriately. Having a suitable DI in place to oversee licensable activity is also a statutory licensing requirement and the DI and CLHC were reminded of this during the inspection.

An audit of bodies stored at both the establishment's hub and satellite premises was undertaken. At the hub premises, five bodies were selected at random: three bodies that were being stored in the establishment's main body store and two stored in a temporary storage unit. Details from the identification tags and the physical location of the bodies were cross checked against the establishment's records on the location white board, the body's associated paperwork and the establishment's electronic database. No anomalies were found in relation to the three bodies stored in the main body store. An anomaly was found in relation to the two bodies stored in the temporary storage unit. In both cases the paper work associated with the bodies had been updated with the new location details when the bodies were moved from the main store to the temporary storage unit; however, the establishment's electronic record of body location had not been updated.

At the satellite unit, three bodies were selected at random and included one from the main store, one from the walk-in cold room and one from the temporary storage unit. Again, no anomalies were found in the cases where bodies were being stored in the main storage unit; however, in relation to the body stored in the temporary unit, neither the paperwork or the establishment's electronic record of body location had been updated. The DI is advised to implement a system whereby the location of the bodies is recorded when they are moved within the establishment's mortuaries (see advice item 6).

A tissue traceability audit was also undertaken during the inspection. Three coronial post mortem examination cases from both the hub and satellite sites were selected at random. In all six cases, the physical blocks were sought and their details cross checked against the mortuary records and the establishment's laboratory's electronic tracking database. In all six cases the blocks and slides were being retained at the establishment's histopathology laboratory and the physical numbers of each matched the laboratory's electronic records. During the tissue traceability audits the coronial family wishes forms were also reviewed. In one case, the family's wishes had not yet been received from the Coroner's office. In five cases the family's wishes had been received and in four of these the families had consented to the retention of tissue. In the final case, the family had requested that at the end of coronial authority they wished the tissue to be disposed of. Establishment staff indicated that the coronial authority had not yet ended and the blocks and slides were being retained under the authority of the Coroner, pending their instruction. In summary, no anomalies were found during the tissue traceability audits initiated at both the hub and satellite sites.

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.	The establishment does not have documented procedures for all of the activities taking place under the licence. Examples of procedures which are not in place include, but are not limited to:- • A procedure describing the circumstances in which APTs can eviscerate a body prior to the arrival of a pathologist and those in which the APT should wait for the pathologist to arrive prior to commencing the post mortem examination. • A procedure to identify and highlight bodies with same or similar names within the mortuary. • A procedure to describe the reconciliation of retained tissue with the coronial family wishes forms and what actions to take to ensure that families' wishes are acted upon appropriately, • A procedure to describe the completion of the paperwork associated with bodies in the mortuary and the use of the unique barcode identifiers. Advice has also been given to the DI below (see advice items 3 and 5).	**Minor**
GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	The establishment has procedures to follow for the reporting of adverse events using the Trust's incident reporting system and uses the HTA reportable incident guidance document which gives details about reporting incidents to the HTA. However, there is no mortuary-specific standard operating procedure setting out what constitutes an HTA-reportable incident, the timeframe within which it must be reported to the HTA, who has responsibility for reporting the incident to the HTA and who reports incidents to the HTA in the absence of this person.	**Minor**

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	Although the establishment has risk assessments covering some of the key mortuary activities such as receipt of bodies, release of bodies and post mortem examination, these risk assessments are predominantly health and safety based and do not sufficiently assess the risks to the deceased or any tissue removed from the deceased (see advice item 4 below).	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	The establishment's consent form includes wording which states that blocks and slides are retained following a post mortem examination as part of the deceased's medical record; although there are appropriate options for families to select and record their wishes with regards to tissue taken during the post mortem examination, the wording on the form does not make it clear that tissue can only be retained with appropriate and valid consent. The DI is advised to review this form and amend the wording to reflect other establishment documentation so it is clear that tissue may only be retained if appropriate and valid consent is in place. The DI may wish to review and adapt the HTA model consent form for use at the establishment. https://www.hta.gov.uk/policies/post-mortem-model-consent-forms
2.	C2	Different information leaflets are available to support the bereaved. These include two information leaflets for families considering post mortem examination. The different leaflets contain varying detail regarding the post mortem process and the options open to those giving consent pertaining to tissue taken during the post mortem examination. The DI is advised to review the process for providing information to families to ensure that they have the level of detail that they need in order that they can make the decision that is right for them.
3.	GQ1	In addressing the shortfall relating to the lack of documented procedures for some activates taking place at the establishment, the DI is advised to conduct a gap analysis to identify all procedures which are not fully described in the establishment's standard operating procedures.
4.	GQ8	Although the establishment has risk assessments covering some of the key mortuary activities such as receipt of bodies, release of bodies and post mortem examination, these risk assessments are predominantly health and safety based and do not sufficiently assess the risks to the deceased or any tissue removed from the deceased. The DI is advised to use the HTA reportable incident categories as an initial guide and risk assess the establishment's procedures to ensure they mitigate the risk of a reportable incident occurring.

5.	GQ1 & GQ8	APTs routinely eviscerate bodies prior to the arrival of the pathologist. There are some circumstances in which the APT awaits the arrival of the pathologist prior to commencing the post mortem examination, for example, where the death is the result of a road traffic accident or a suicide. This is contrary to guidance issued by the Royal College of Pathologists which states in the "Standards for coroners' pathologists in post-mortem examinations of deaths that appear not to be suspicious" that 'the pathologist will ensure that the body is that for which the pathologist has authorisation to make a post-mortem examination' and that 'the pathologist will ensure that no evisceration takes place before the pathologist has made a full examination of the external surface of the body.' https://www.rcpath.org/resourceLibrary/standards_coronerspost-mortem_feb14-pdf.html The DI should consider whether it is appropriate for APTs to eviscerate a body before the arrival of the pathologist in any circumstances.
6.	GQ1 & GQ8	There are currently two different systems operating at the hub and satellite sites with regards to recording the positions of bodies that have been moved within the establishment's storage facility. At the hub site, the new location of the body is updated on the relevant paperwork and in the electronic records; however, at the satellite site, the paperwork and electronic records are not updated. The DI Is advised to risk asses the process of moving bodies within the establishment's storage facility and how body location is recorded on the establishment's paperwork and in the electronic system. Once risk assessed, the DI is advised to implement a procedure for recording body location and standardise how location is recorded between the two sites.
7.	PFE3	The DI is advised to devise and implement a procedure to monitor the functioning of the temporary body storage facilities to ensure that establishment staff would be made aware of an equipment failure or deviation from the desired temperature during out of hour periods.
8.	PFE3	At both University Hospital of North Durham and Darlington Memorial Hospital, the bodies of stillborn babies or fetuses may be stored temporarily prior to being moved to the mortuary so that, where appropriate, parents have the opportunity to view and spend time with them on the ward. At Darlington Memorial Hospital, the fridge temperature is checked daily during the ward's routine essential equipment checks however at University Hospital of North Durham the fridge temperature is not monitored. The DI is advised to implement a system whereby checks are undertaken of the fridge in maternity at University Hospital of North Durham to ensure that it continues to operate as expected and through which staff would be made aware of an equipment failure.
9.	General	The DI is advised to appoint a Person Designated in the emergency departments and the maternity departments at both the hub and satellite sites to act as points of contact in relation to the activity taking place in these areas. This will facilitate the DI being made aware of any issues that arise, who will in turn, be better able to disseminate any licensing updates or information to staff in these areas. The DI is also advised to invite the PDs to governance meetings so that information regarding licensable activity can be shared.

Concluding comments

Despite the three minor shortfalls, areas of good practice were observed during the inspection, examples of which are set out below.

At the paediatric department at the University Hospital of North Durham site, the clinicians were planning to undertake an exercise simulating a sudden unexpected death of an infant. The aim of this exercise was to familiarise new clinical staff with the procedures around sampling in such cases, liaising with the Coroner, family and hospital staff and the associated paperwork. Undertaking such training exercises helps to ensure that all relevant clinical staff are appropriately trained for such events and are aware of the correct procedures to follow.

The establishment's estates department's checks on the body storage facilities at the hub and satellite sites help to assure the DI that alarm systems are operating appropriately and that staff who receive the alarm calls respond appropriately to them.

There are a number of areas of practice that require improvement, including three minor shortfalls. The HTA has given advice to the Designated Individual with respect to consent documentation, documented procedures, risk assessments and temperature monitoring.

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 / subject to compliance with the additional conditions applied to the licence.

Report sent to DI for factual accuracy: 25 April 2016

Report returned from DI: 12 May 2016

Final report issued: 24 May 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: 03 March 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.