Site visit inspection report on compliance with HTA minimum standards

Central Manchester University Hospital

HTA licensing number 12554

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**

22-24 November 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 Central Manchester University Hospital (the establishment) had met the majority of the HTA standards, shortfalls were found against standards C1 and GQ6. These were in relation to consent procedures and tissue traceability, respectively.

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 improve 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 refers to activities carried out at two locations: Central Manchester University Hospital (the hub, for the purposes of HTA licensing) and Trafford General Hospital (the satellite). The hub is licensed to carry out post-mortem (PM) examinations, remove relevant material from the body of a deceased person and store bodies or relevant material; the satellite is licensed to store bodies or relevant material only.

The Designated Individual (DI) is a Consultant Paediatric Histopathologist. The Corporate Licence Holder is Central Manchester University Hospitals NHS Foundation Trust, and the Corporate Licence Holder contact (CLHC) is the Medical Director. There are 12 Persons Designated (PD) working under the licence.

Adult mortuary

The adult mortuary is staffed by nine Anatomical Pathology Technologists (APTs), including a senior APT, two trainee APTs, a mortuary assistant, and three locum APTs. The establishment is currently recruiting permanent staff who will replace the locum staff. There is an on-call rota for all staff, whose duties include attending the satellite site to book in or release bodies.

The body store consists of 104 fridge spaces, of which nine are bariatric, and there are an additional 12 spaces available in a Nutwell overflow unit. There is no freezer space available in the body store and bodies which require freezing are sent to a neighbouring Trust. A whiteboard is used to record details of all bodies in storage. Same/similar names are highlighted on fridge doors, as well as on the associated paperwork.

Fridge temperatures are monitored and linked to a remote call-out system, which alerts sodexo-employed fridge engineers and on-call staff to any temperature deviations. Temperature trends are monitored remotely as part of the alarm monitoring system but not by mortuary staff at present (see Advice, item 5).

Bodies are received in to the mortuary from the hospital and community. Hospital porters bring the deceased down from the wards and have been individually trained and competency assessed by mortuary staff on the correct procedures for putting a body into the fridge. Cases from the community are brought to the mortuary by funeral directors. Upon receipt in the mortuary, the identification details of the deceased are identified by two members of mortuary staff and the body is assigned a unique identifier.

When a body is released to a funeral director, at least three identifiers are checked. If there are any discrepancies, the body will not be released. Funeral directors also check the identification and are asked to confirm that any lines should be left in situ. Mortuary staff will remove if necessary.

Approximately 1,100 post mortem (PM) examinations take place per annum at the request of HM Coroner for Greater Manchester. Home office (forensic) PM examinations are sent to a neighbouring Trust.

Adult hospital consented PM examinations are not routinely performed. On the occasion that one takes place, consent is sought by the clinician who was treating the deceased (see shortfall identified against HTA standard C1).

The post mortem suite consists of four PM tables, which are not downdraft; however, there are 15 air changes per hour. Organs are dissected on an elevated platform on each table. There is no dedicated area for high risk PM examinations. When these are performed, no others take place in the mortuary and there is a 20-minute decontamination window after each one. The day before a PM examination, the pathologist performs a risk assessment for the cases due the following morning. Potential risks are identified and communicated with mortuary staff and other pathologists. The identity of the deceased is confirmed by both the APT and pathologist before evisceration. Material taken during PM examination is placed in cassettes in the mortuary, recorded on the pathologist worksheet and taken to histology by the APTs.

Paediatric mortuary

The paediatric mortuary has three full time APTs, including a senior APT, and a part-time assistant practitioner. A member of staff is on call at all times.

The body store consists of 12 fridge spaces, which can all be modified to hold more than one body. There are no freezer, or bariatric spaces available, however larger bodies can be moved to the adult mortuary if required. As with the adult mortuary, same/similar names are highlighted on the fridge door and the associated paperwork.

Fridge temperatures are monitored and linked to a proprietary remote call-out system which alerts on-call staff and Building Management Services to any temperature deviations. Temperature trends are monitored by the service provider company, and a daily reading is taken by mortuary staff.

Approximately 400 PM examinations take place each year. The majority of these are hospital consented perinatal or paediatric PM examinations; however, the mortuary is also a referral

centre for 18 hospitals in the North West region, as well as a coronial post mortem examination service for nine Coronial districts. Home office post-mortem examinations are also conducted in the mortuary.

The PM suite consists of one downdraft PM table and two downdraft workbenches. A pathologist and an APT conduct the PM examinations together. Special measures are taken for high-risk PM examinations, and there is a 20-minute decontamination following each high risk case. A risk assessment is performed the night before the PM examination and the consent/authorisation is checked by the pathologist. The pathologist and the APT perform the identity checks prior to evisceration.

Bodies are received to the mortuary from Central Manchester University Hospital and other hospitals across the North West of the country. A bereavement midwife or a clinical coordinator performs the identity checks with mortuary staff. A unique number is assigned to each body. Bereavement midwives and clinical coordinators are trained by mortuary staff in mortuary procedures, including operating the trolley and appropriate handling of the deceased in the fridges.

Bodies are brought to and released from the hospital via a dedicated lift. Only mortuary staff have access to the lift, which cannot be operated without specific security permission. The mortuary is located on the third floor of the hospital and parents, accompanied by a bereavement midwife, a clinical coordinator, or nursing staff, may bring the deceased to the mortuary, if they so wish. There are two viewing suites which are used dependent on the age of the deceased. A charitable bid has recently been granted to further improve the standards and décor in both rooms. Mortuary staff will work together with designers to decorate the viewing rooms.

Trafford General Hospital

The premises at Trafford General Hospital operate solely as a body store. There are 60 spaces in the mortuary, of which 15 can accommodate bariatric bodies. There are no freezer spaces.

Fridge temperatures are monitored and linked to a proprietary remote call-out system which alerts on-call staff from the hub and Trafford estates to any temperature deviations. Temperature trends are monitored by the service provider company, who will notify the staff of any deviations.

A decommissioned post-mortem suite at the satellite site was inspected during the inspection. This has three downdraft tables and dedicated dissection areas, along with a separate high risk/forensic PM suite. The majority of the fridges in the body store are double sided and open into the relevant PM suite (see Advice, item 5).

Bodies are admitted to the mortuary from the hospital only and are brought by porters who admit the deceased to a designated bank of fridges. Porters leave the associated paperwork in the fridge room office in the mortuary and bereavement staff notify staff at the hub of any new admissions. A member of staff from the adult mortuary then travels to the satellite and formally admits the body, performing identity checks and completing the mortuary register. Bodies requiring hospital PM examination are transferred to the hub; however, this is not common, and usually bodies are released from the satellite site to the funeral director, with prior arrangement.

Viewings of bodies at the satellite are conducted by staff from the hub when required.

The Inspection

The establishment has been licensed since 2006. The timetable for this routine 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.

The inspection comprised of: a visual inspection of all three mortuaries; interviews with an adult and paediatric pathologist, an APT from the adult and paediatric mortuaries, the Corporate Licence Holder contact, two Coroner's Officers from different Coronial districts, the HTA Nominated Individual and the Designated Individual; and a review of governance documentation.

In addition, traceability audits were carried out on bodies and tissue samples in the mortuaries. A total of eight body audits were performed, two in the adult mortuary, two in the paediatric and two in the satellite. During the audits bodies were selected at random and details, including name, date of birth and hospital number were cross checked against paperwork and the mortuary registration form. One discrepancy was found at the satellite site between the details on the paperwork and the details on the wristband on the body, where the date of birth was recorded as November on the wristband and January in the paperwork.

A total of six tissue traceability audits, three in the adult mortuary and three in the paediatric mortuary in the hub were carried out. Documentation associated with a case was reviewed and the physical location of blocks and slides was sought to ensure the family's wishes had been respected. Two discrepancies were found in the adult mortuary relating to the location of paperwork detailing the number of blocks taken during the PM examination (see shortfall identified against HTA standard GQ6).

Under s39 of the Human Tissue Act 2004 (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."

Inspection findings

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

Compliance with HTA standards

Consent

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the Code of Practice.	Although an adult hospital-consented post mortem examination has not been performed in the past two years, the associated standard operating procedures (SOP) have not been kept up to date. The SOPs do not specify the appropriate person from whom consent should be sought. An SOP for seeking consent for a hospital-consented PM on a child was not seen on inspection. The SOP for a hospital-consented PM examination for the satellite site referred to seeking consent from a "family member", which increases the risk of consent being obtained from a person other than the person nearest the top of the hierarchy of qualifying relationships, as set out in the HT Act.	**Minor**

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	The number of blocks taken during PM examination is recorded on a worksheet, with one copy kept in the mortuary and a second copy filed in the patient notes stored in the office of the medical secretary. During the audit of the adult mortuary two worksheets were missing from patient files. Tissue taken during a PM examination is examined by the pathologist and returned to the histopathology laboratory, where it is stored or disposed of in line with the family's wishes. Current procedures do not require the slides to be checked when they are returned to the slide store, to ensure that all are accounted for.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	A number of the SOPs in place for mortuary and laboratory procedures require reviewing and updating. The DI is advised to review documents, particularly in relation to the satellite site, to ensure they are up to date and are reflective of current practices.
2.	GQ2	Mortuary staff perform robust audits in the mortuary, including audits of receipt and release procedures and an audit of the quality of reconstruction of bodies. However, traceability audits of tissue samples are not performed, where tissue is traced from the mortuary to pathology and through to the final paperwork from the Coroner. The DI is advised to implement these audits to ensure tissue can be traced throughout.
3.	GQ7	While the staff at the establishment are aware of the incident reporting systems, the establishment should have a documented procedure in place which specifies the type of adverse event or incident that is reportable to the HTA and the HTA's reporting requirements.
4.	PFE3	Fridge temperatures in all three mortuaries are monitored remotely by the alarm companies and by staff in the paediatric mortuary. Staff in the adult mortuaries in the hub and satellite are advised to regularly review temperature records for trends which may precipitate a fridge failure.
5.	PFE3	The mortuary is due to undergo refurbishment in 2017 in order to replace the fridges and plans are in place to adapt working arrangements whilst renovations are taking place. The DI is advised to risk assess these arrangements, with particular focus on how the work will impact on the deceased and the conduct of PM examinations during this time. The risk assessment should consider the HTARI categories, the PFE standards, as well as appropriate contingency arrangements. The DI may wish to consider transferring bodies to the satellite site for PM examination whilst work is ongoing.
6.	PFE4	There is a traffic light system in place to alert mortuary staff of any bodies that have been with them for longer than four weeks. A list is sent to bereavement staff on a weekly basis and they follow up with families. The HTA recommends that bodies should be moved to freezer storage after 30 days, or sooner depending on the condition of the body. As there are no freezers available in either the hub or satellite, the DI is advised to consider how the release of bodies may be expedited, for example, reviewing arrangements with local authorities and Coroners.
7.	D1	In both the adult and paediatric mortuaries, records of tissue disposal are maintained; however in the adult mortuary, the name of the person performing the disposal is not recorded. The DI is advised to document the person disposing of the tissue to maintain tissue traceability.

Concluding comments

During the inspection, a number of examples of good practice were observed. Both mortuaries in the hub are extremely busy, and the staff work well and efficiently together. The day before PM examinations, the Pathologist performs a risk assessment on the upcoming cases, highlighting any high-risk cases. The Adult and Paediatric Mortuary staff have a 'huddle' meeting every morning, where they discuss staff duties for the day, the number of PM examinations scheduled and any issues they need to be aware of. A robust same/similar name system is in place, with same/similar names highlighted on the fridge doors, the white board in the mortuary office and the associated documentation. Mortuary staff have a good working relationship and one of the Coroner's Officers interviewed commented on the exceptional communication between the mortuary and the Coroner's office. A training package has been developed for bereavement midwives who may not want to view a paediatric PM examination, which uses an animation to describe the process. Parents are provided with multiple opportunities to visit their baby or child in the paediatric mortuary. Mortuary staff are flexible with viewings and will ensure the viewing suite is set up as the parents left it, even drawing diagrams of the position of toys, should they wish to return.

There are a number of areas of practice that require improvement, including two minor shortfalls. The HTA has given advice to the Designated Individual with respect to audits, risk assessments, temperature monitoring and disposal records.

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: 19 December 2016

Report returned from DI: 23 December 2016

Final report issued: 19 January 2017

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: 13 April 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: o post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases o record keeping o receipt and release of bodies, which reflect out of hours arrangements o lone working in the mortuary o transfer of bodies and tissue (including blocks and slides) to other establishments or off site o ensuring that tissue is handled in line with documented wishes of the relatives o 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 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.