Site visit inspection report on compliance with HTA minimum standards

Royal United Hospital Bath NHS Trust

HTA licensing number 12250

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**

10 June 2014

Summary of inspection findings

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

Although the HTA found that Royal United Hospital Bath NHS Trust (the establishment) had met the majority of the HTA standards, minor shortfalls were found in relation to standards C3 and GQ2. Consent for paediatric post mortem examinations is taken by Consultant Paediatricians or Obstetricians. They have been trained on the consent procedure and use appropriate consent forms and information, but that training has not been recorded or updated. In addition, there is no formal governance meeting in relation to licensed activities at which the DI attends with persons designated or others carrying out licensed activities.

Since the last HTA inspection, the previous DI has retired and the activities are now carried out in new, purpose-built premises on the same hospital site. At the time of the inspection, the mortuary and histopathology laboratory had recently moved to the new premises and processes were in the course of being embedded, with staff training on amended procedures on-going. Some of the systems, including the building monitoring system, were in the course

of being commissioned. Review and update of governance documentation was also being carried out.

Particular examples of strengths and 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 Royal United Hospital Bath NHS Trust (the establishment) carries out licensed activities in relation to its function as a hospital and public mortuary. The body store receives approximately 2,000 bodies annually, and Pathologists at the establishment carry out some 350 adult post mortem (PM) examinations. The majority of these are on the instruction of the coroners for the Eastern Somerset and Avon districts

Three adult hospital (consented) PM examinations were carried out in the year of the inspection. No forensic cases are carried out; these being referred to a nearby mortuary. PM examinations for prenatal, perinatal and paediatric cases are also referred elsewhere. Fetal tissue samples and products of conception are received into the mortuary and these are traced through the mortuary system using the same systems as for bodies of adult deceased.

Staff from tissue banks access the mortuary for retrieval of tissues for transplant and there are service level agreements or third party agreements in place governing this activity.

The recently installed body store has space for 80 bodies, including four freezer spaces and 16 bariatric spaces. In addition, a modular contingency store is in place allowing the storage of an additional 12 bodies, or six larger bariatric bodies, where size would not permit storage on body store trays. The establishment no longer stores any relevant material held under police authority.

Bodies are received into the mortuary from the hospital and the community. At all times, bodies are placed into the body store by trained hospital portering staff, or by the coroner's contracted undertakers, working to a defined procedure provided to them by the establishment. The procedure followed outside office hours differs only in that hospital security staff are contacted in advance of arrival to allow the contracted undertakers access to the secure areas of the mortuary.

Bodies are placed in an available body store slide, and a notice is placed on the door of the body store space, alerting mortuary staff. Mortuary staff then check identity and other details and log these onto the electronic mortuary register. This forms part of the software system used to trace the body, and any tissues retained from it, through the mortuary, PM examination and laboratory, and is accessible to staff in both the mortuary and laboratory areas. Each body is allocated a unique identification number when logged in.

Mortuary staff carry out a daily check of all body store spaces, noting details of any patients with same or similar names. Other staff are alerted to this by the placing of stickers on fridge doors.

Bodies that undergo PM examination are allocated a further 'PM' number, which is used in turn to trace tissues through the laboratory to eventual disposal, return or storage with consent.

Authority for a coronial PM examination is faxed from the coroner's office. Where the pathologist deems it necessary to retain organs or tissues for further examination into the cause of death, a form containing details of this is faxed to the coroner. Subsequently, the wishes of the next of kin are provided to the establishment by return of that form, duly completed. Details of tissue retained and the wishes of the family are entered onto a specific 'Tissue Retention' spread sheet.

The procedure for obtaining consent for adult hospital PM examination had been changed shortly prior to the inspection. Consent is taken by one of two trained consultant histopathologists who discuss the clinical aspects of the case with the deceased's clinician.

Details of tissue retained for further examination are entered onto the Tissue Retention spread sheet, as are wishes of the relatives, in line with the consent given.

If tissues or organs are sent elsewhere for specialist examination, this is recorded on a separate spreadsheet, and a faxback system is used to maintain traceability and confirm receipt.

The spreadsheets recording tissue retention and sending for specialist examination can be accessed to run monthly reports of cases where relatives' instructions in relation to return, storage or disposal of tissue are outstanding, or where the establishment awaits confirmation of the closure of inquests from the coroner. Letters are sent to the coroner for updates where

necessary. Similarly, secretarial staff can check for those cases where receipt of faxback forms is awaited.

Tissue disposal occurs on a monthly basis, within a defined period after the closure of inquests. A list of tissues for disposal is produced from the Tissue Retention spreadsheet, this is checked by the relevant pathologist for each case, and a member of mortuary staff arranges for and records disposal, which is by incineration separately from clinical waste in line with the HTA's code of practice on disposal.

Disposal of products of conception and fetal tissues is according to the wishes of the parents. Where burial is not chosen, the establishment arranges for cremation of all such tissue in conjunction with the bereavement office and local crematorium.

Release of bodies only takes place during office hours and is carried out by establishment staff acting together with the attending undertaker. Release follows verbal confirmation of instructions from the coroner, or by the undertaker delivering a documented form of authority to release.

This inspection was a non-routine inspection, scheduled as a result of the change of DI and the moving of the facilities to the new pathology building. It comprised a visual inspection of the premises, taking in the body store, PM examination room, laboratory and block and slide storage. A review of documentation was carried out by accessing the electronic document management system and paper copies of records were examined where available. Key staff, including the DI, a Histopathologist, mortuary technicians, and members of the quality management team, were interviewed.

During the visual inspection, an audit of traceability was carried out:

- Two bodies were located in the body store, and identity details checked against those on the paper notices of death and information held within the electronic mortuary record.

- A product of conception sample was selected from those stored awaiting cremation and traceability details checked against the electronic register.

- Two cases where PM examinations had been carried out were selected from the database. The corresponding coronial authorities were retrieved, as were documents detailing tissue retained at PM examination and the wishes of the relatives.

  For one of these cases the traceability records for organs sent for specialist examination were also reviewed. For both cases, the laboratory section of the database was searched to confirm details of tissue blocks retained at PM examination, and these were then located within the block and slide store. The Tissue Retention spread sheet was also reviewed to check the accuracy of recording of tissues retained and wishes of the relatives.

No discrepancies were found.

- A patient file relating to a hospital, consented PM examination was reviewed for the presence of the appropriate consent documentation. This was noted to be an out of date NHS consent form, but this case pre-dated the change to consent procedures undertaken following the appointment of the current DI.

Inspection findings

The HTA found the DI and the Licence Holder to be suitable in accordance with the requirements of the legislation. The suitability of the DI was discussed with him during the inspection. The DI is slightly remote from the licensed activity as he works within a different directorate of the Trust, though his role as a Consultant Obstetrician means he has involvement with the mortuary and laboratory staff in relation to fetal tissue and products of conception. He also appears to be well supported in his role by the staff working under the licence. Advice has been provided to help further support the DI in his role.

Compliance with HTA standards

Consent

Standard	Inspection findings	Level of shortfall
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	Consultant Obstetricians or Consultant Paediatricians have been trained to take consent for paediatric cases using appropriate consent forms and information. However, this training was not recorded and has not been refreshed since being carried out three years ago. By refreshing and updating this training, the DI will help to ensure that those giving consent are provided with information which is up to date, accurate and in line with current requirements of the underlying legislation and HTA Codes of Practice. Advice has also been provided under this standard.	**Minor**

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of quality management and audit.	There are no formal governance meetings attended by the DI and persons designated at which all aspects of the licensable activities may be discussed, including issues arising, incidents, audit results and suggestions for quality improvement. By having regular meetings, subject to a formal agenda and minuted, the DI may be better supported in his role, and be able to maintain awareness of any issues related to the licensed activity. Such meetings will also provide a format for shared learning, the discussion of incidents or issues arising and help promote continuous quality improvement.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	The DI is advised to finalise the adaptation of the HTA model consent form, currently referred to and hyperlinked in the electronic version of the SOP 'Consent for Adult Post Mortem Examination', to produce a Royal United Hospitals Bath NHS Trust document attached to the SOP. This will ensure staff taking consent use the correct consent form at all times.
2.	C3	The DI is advised to adapt the training materials used in training staff to take consent for adult PM examinations, for use in the training of staff taking consent for paediatric cases. Specialist input to this training should be provided by someone familiar with the technical aspects of paediatric PM examination. This will minimise the work needed to implement such training and help to ensure consistency in the way consent taking is carried out.
3.	GQ1	The DI is advised to record the daily checking of the bodies in store as a method of recording body store audit, check on condition of the deceased and the checking for same or similar names. This will help to ensure that such procedures form part of the daily routine of the mortuary.
4.	GQ1	Following the move to the new facility, the DI is advised to continue the review of SOPs to ensure they reflect the practices now been carried out. As an example, the 'Maintenance and Monitoring of the Mortuary' SOP makes reference to the previous system used to monitor body store fridge temperatures. Also, the SOP detailing steps to be taken in advance of PM examination, 'Procedure prior to undertaking an Autopsy', does not detail the procedure followed by establishment staff to stamp and sign coroners authority forms confirming identity has been checked by two people prior to commencement of examination.
5.	GQ7	The DI is advised to modify the text of the incident reporting SOP to clarify the requirement to report HTARIs to the HTA within the required five working day period as provided for in the document's accompanying flowchart. This will aid staff in understanding the reporting requirements.
6.	GQ7	The DI is advised to review the current incident reporting SOP and related error log to ensure that all current HTARI classifications are detailed. This will help staff understand the types of incident which must be reported to the HTA.
7.	GQ7	The DI is advised to arrange for all persons designated to be linked to the licence to allow them access to the HTA portal and to have a procedure in place governing how HTARIs may be reported to the HTA in his absence. This will help to ensure consistent and timely reporting of HTARIs when the DI is absent.
8.	GQ8	The DI is advised to update the risk assessment of the body release procedure. The current risk assessment is out of date and does not include the risk control measures currently in place. By updating this risk assessment, including consideration of how authorisation for release is documented, the DI will be informed on whether the current control measures maximise the mitigation of any risks of this procedure, which, if carried out incorrectly, has reputational risk for the Trust.

9.	PFE3	The DI is advised to monitor the body store fridge temperatures during the on-going commissioning of the facility's systems to monitor trends. This should continue until the system allowing staff to review temperatures recorded by the building management system is fully rolled out. By doing this, any failure of the newly installed cooling equipment or alarm system may be identified at an early stage, which will help mitigate any damage to the deceased in store.
10.	PFE3	The DI is advised to challenge the alarm system on a regular basis, to ensure that the automatic call out to building management staff functions as it should and to record the result of that process. This will help to mitigate any failure in the alarm system going un-noticed, minimising the risk of damage to stored bodies in the event of failure of the body store cooling equipment.
11.	D2	The DI is advised to introduce a procedure for staff to review coroners' forms where relatives' wishes are for retention for use for a scheduled purpose, to ensure that the properly interested persons providing such instructions are the appropriate persons in the hierarchy of qualifying relationships. This will help to ensure that appropriate consent for retention is in place and help to assure the DI that the requirements of the legislation have been met.
12.	N/A	The DI is advised to appoint persons designated working in the various areas of licensed activity to feedback to him on a regular basis, in order to help maintain his oversight of the licensed activities. By having persons designated in the areas of pathology, tissue retention administration, quality management and mortuary and laboratory management, and by having regular communication with them, the DI will be supported in his role and better informed on how the licensed activities are being carried out.

Concluding comments

The HTA saw various examples of good practice during the inspection.

The establishment has employed a quality manager dedicated to the pathology department and this, together with well-considered use of an electronic management system, has resulted in improvements to management of governance documentation related to the activities carried out and a drive for continuous quality improvement.

A wide ranging schedule of audits is in place and this has included a vertical audit encompassing all HTA standards, with the exception of those relating to consent, which are scheduled audit for later this year. Results of audits are reviewed and actions taken to address issues identified.

The establishment has modified its consent procedure to make it more robust, with two trained Consultant Histopathologists carrying out all consent for adult hospital PM examinations.

A database of tissue retained at post mortem is maintained and a staff member is specifically tasked to maintain this. Reports detailing cases for which the establishment awaits familys' wishes are produced monthly, and where appropriate, letters are sent to the coroner seeking confirmation of these.

Similarly, a monthly schedule of tissues for disposal is produced and, following review by the relevant pathologist, a staff member checks all relevant documentary and electronic records to ensure all tissues for disposal are located and disposal recorded.

In advance of carrying out a PM examination, two members of staff check identity of the deceased and this check is recorded by a stamp being applied to the coronial authority and signed by the identifying staff members.

There are excellent contingency arrangements in place for storage of bodies at times of high demand. Modular storage facilities are in place within a dedicated area of the body store and these can be activated to provide additional storage for up to 12 bodies, or can be used in cases where a bariatric body cannot be stored within any of the permanent body store spaces.

There are areas of practice that require improvement, resulting in two minor shortfalls. The HTA has given advice to the DI with respect to elements of documentation, risk assessments and the use of persons designated to support him in his role.

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: 18 June 2014

Report returned from DI: 03 July 2014

Final report issued: 03 July 2014

Inspection CAPA Plan Closure Statement:

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: 3 March 2015

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.