**Site visit inspection report on compliance with HTA minimum standards**

**Leeds General Infirmary**

**HTA licensing number 12231**

**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 - 11 November 2015**

## Summary of inspection findings

This inspection was conducted jointly with assessors from the United Kingdom Accreditation Service (UKAS), who assessed the mortuaries and histopathology laboratory against selected licensing standards on behalf of HTA.

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 Leeds General Infirmary had met the majority of the HTA standards, shortfalls were found, particularly in relation to standard GQ1 in that documented procedures for checking identification of the deceased, were not sufficiently detailed, and in relation to standard GQ3 as there was no record of training of Clinical Site Managers, and insufficient recording of training of portering staff, who carry out mortuary-related tasks.

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 (DI), 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 (the Act). They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

## Background to the establishment and description of inspection activities undertaken

This report describes the third routine site visit inspection of Leeds General Infirmary (the establishment), which was conducted jointly with the United Kingdom Accreditation Service (UKAS), who gathered evidence against selected licensing standards on behalf of HTA. The HTA inspectors met with staff involved with licensable activities, reviewed documentation and visited areas outside the mortuary where licensable activity was carried out.

The establishment consists of premises at the Leeds General Infirmary, the hub, and St James University Hospital, the satellite. Post-mortem (PM) examinations are undertaken at both the hub and satellite premises. The establishment undertakes adult and paediatric coronial PM examinations and adult, paediatric and perinatal consented hospital PM examinations.

Approximately 1,000 coronial, 12 adult hospital and 200 paediatric or perinatal hospital PM examinations are undertaken per year across both sites. Paediatric and perinatal PM examinations are all undertaken at the satellite site**.**

Consent for hospital PM examinations is sought by a trained nurse specialist or by clinicians involved in the care of the patient, following a documented standard operating procedure (SOP). Clinicians in key areas of the establishment, both medical and nursing, have been trained on seeking consent for hospital PM examination procedures by the nurse specialist, as have staff at hospitals referring paediatric cases to the establishment. The DI has recognised the key role undertaken by the nurse specialist and has put in place a plan to train the new full time bereavement support midwife and other relevant staff, such as mortuary APTs, in seeking PM consent in the event the nurse specialist is unavailable, and to provide for succession planning.

Facilities at both the hub and satellite premises have isolated examination suites used for performing known high-risk PM examinations. Removal of tissue consented for use in research also takes place within the mortuary. Forensic PM examinations are rarely undertaken, these being referred by the coroner to other local HTA licensed premises. The establishment does not currently store any samples taken under police authority, although procedures are in place to deal with such samples if required.

On each site the body store has space for 72 bodies in refrigerated spaces. The hub site also has four bariatric spaces and four freezer spaces. There is separate storage for 12 infants or babies. The paediatric storage at the hub site was not viewed during the inspection. The satellite site has 26 paediatric spaces, 12 bariatric spaces and one paediatric freezer space.

The establishment has another two body stores used for temporary storage of bodies prior to release or transfer for PM examination. These are also used as part of the establishment's contingency arrangements. They are not subject to HTA licensing and neither was visited as part of the inspection.

Prior to the inspection, the DI identified areas outside the mortuary where the licensable activity of removing tissue from the body of the deceased occasionally takes place. At the hub site these areas include the accident and emergency department (A&E), paediatric intensive care unit (PICU) and the neonatal intensive care unit (NICU). At the satellite site, removal activity takes place in A&E and NICU.

During the inspection the HTA met with staff from all areas where licensed activity takes place and visited the delivery suite and obstetrics and gynaecology ward where temporary storage of products of conception, foetuses and babies takes place before transfer to the histopathology or cytology laboratories for analysis, or to the mortuary. The DI visits each area periodically and has regular contact with staff working in those areas.

Under s39 of the HT Act, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, the 2012 report of the Association of Chief Police Officers' (ACPO) audit of tissue held under police authority contained a recommendation that police exhibits held on HTA-licensed premises should be included within the regular HTA inspection process. Therefore, procedures for Home Office PM examinations and the management of tissues and organs taken for criminal justice purposes were reviewed by HTA at this site visit inspection, though no storage of such samples was taking place at the time of inspection and had not taken place for the previous two years. 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.

Audits of traceability were carried out as part of the inspection, those in the body store being carried out by the UKAS inspectors on behalf of the HTA.

- Two bodies were retrieved from the body store and the identification details contained on wrist bands checked against those held in mortuary records.
- The details of one body held in store were noted within mortuary records and compared against those contained on the wristband attached to the deceased.
- Details of three cases where tissue had been retained at PM examination were selected from electronic records held. The corresponding consents or coronial authorisations for PM examination were reviewed, together with the families' wishes for disposal, retention or return of tissues retained. Related traceability records were also reviewed. In one of these cases, all blocks and slides were to be returned to the funeral director acting for the family. The traceability records detailing this were reviewed, as was the file slip in the block storage drawer, which recorded the removal of blocks from storage. In the second case, there was consent for retention of the brain and tissue blocks and slides for use for research or teaching. All retained tissues were located in the wet tissue store and block and slide store. In the third case, the blocks and slides were located in store, in accordance with the consent given, which had been for retention for use for teaching and research.
- One brain was selected from tissues stored in the wet tissue store, identification details recorded, and the corresponding consent records retrieved.

In all cases no discrepancies were found.

**Inspection findings**

The HTA found the DI 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. | Identification procedures detailed within various key SOPs used by staff when receiving, releasing or preparing deceased bodies for viewing are not sufficiently detailed. They do not provide staff with clear guidance on what identifiers should be used, the minimum number of recorded details to ensure correct identification or what documentation those details should be checked against.<br><br>While the HTA recognises that staff working at the establishment are experienced and familiar with identification practises, the lack of clear, documented instructions as to how and what identification details need to be checked, presents a reputational risk to the Trust and a risk of distress to others, in the event the wrong body is released particularly if inexperienced or locum staff are involved in identification procedures or at times when staff are working under time pressure.<br><br>By addressing this shortfall, the DI will help to mitigate those risks. | **Minor** |
| GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills. | There is no evidence that Clinical Site Managers, who are involved in the release of the deceased to funeral directors out of normal mortuary hours, have been trained in mortuary procedures for release of bodies. Similarly, training records for porters involved in out-of-hours release are insufficiently detailed.<br><br>The involvement of non-mortuary staff in the release of bodies presents a risk to the establishment, which can be mitigated by training and the use of clearly documented procedures, in particular the identification procedures to be followed when dealing with the deceased.<br><br>By addressing this shortfall, the DI will ensure that only trained staff are involved in the release of bodies out of mortuary hours and this will help to mitigate the risk of wrongful release. | **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 have consent for PM examination referred to in the Trust "Consent to Examination and Treatment" policy.<br>By doing so, he will help to raise awareness of the availability of trained staff and support documentation should clinicians consider requesting a hospital PM examination. |
| 2. | GQ1 | The DI is advised to risk assess the procedures detailed in the SOPs used at the satellite site (HPSOP PMJ 023.07 and HPSOP PMJ 024.06) to govern receipt and release of fetuses, neonates and stillbirths, which rely on the mothers' or babies' name and babies' date of birth.<br>This assessment should consider whether there are any further mitigating steps which might be taken, in situations where parents of one baby have differing surnames to minimise risk of release of another baby. |
| 3. | GQ1 | The DI is advised to review the governance documentation used across both sites with a view to standardising elements of it, taking into account any differences required by local practice or infrastructure.<br>The HTA notes that staff work across both sites and by standardising documentation, in particular SOPs, the DI will help to minimise staff confusion as to procedures in place and simplify review procedures. |
| 4. | GQ2 | The DI is advised to have reference to the mortuary included within the establishment's Quality Manual and to include details of the body and tissue storage facilities within the relevant sections of that document, so that the mortuary is considered in any review of overarching quality procedures. |
| 5. | GQ2 | The DI is advised to audit release of bodies outside mortuary working hours to ensure that only trained staff are involved in the release of the deceased to funeral directors.<br>This will help to assure the DI that required procedures are being followed and mitigate the risk of wrongful release. |
| 6. | GQ3 | The DI is advised to review the induction and on-going training plans for mortuary staff to ensure that any new staff are fully trained on mortuary procedures and current staff maintain their knowledge. |
| 7. | PFE1 | The DI is advised to institute a visitors book to allow visitors to sign in to the mortuary, to accord with local policy which states this should take place. |
| 8. | PFE2 | The DI is advised to ensure that cleaning and decontamination records of the fridges and freezers are retained on site for review, to ensure that the relevant SOP and schedule are being followed. |
| 9. | PFE3 | The DI is advised to review the current temperature monitoring arrangements at the hub and satellite, with particular reference to those fridge units which are not alarmed remotely and for which daily temperature recording is carried out by staff on working days.<br>The HTA is aware that the lack of remote alarms has previously been risk |

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| | | assessed, resulting in the current temperature monitoring arrangements, but noted that records of temperature monitoring are incomplete, with gaps during holidays and periods of staff absence. Although no issues relating to equipment failure have arisen, the DI is advised to consider what other arrangements could be put in place to ensure consistent recording of temperatures on a daily basis, to help more accurately trend for equipment failure and mitigate the risk of damage to the deceased, in the absence of more comprehensive alarm arrangements. |
| 10. | PFE3 | While the HTA does not consider there to be a risk to the safety of bodies in the contingency body store, the poor quality of the environment in which the fridges are located contrasts significantly with that of the main body store.<br><br>The DI is advised to assess the sufficiency and appropriateness of the current contingency storage arrangements at the hub site, taking into account the high level of use of that store over many months in the last year.<br><br>The DI should also consider the remoteness of the store from the mortuary. Whilst security of the store appears to be robust, the DI should also consider the condition of the corridor leading to it, which has a steep incline and is in poor condition. This means that two members of staff have to be absent from the mortuary for an extended period for each transfer and there may be health and safety issues for staff associated with transfer of bodies to the store. |

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| 11. | PFE5 | The DI is advised to ensure that, where possible, he, or the relevant persons designated (PD), obtain copies of all maintenance and service records relating to equipment within the mortuary, including those with details of calibration of temperature probes of the fridges and the efficiency of air handling units.<br>By doing so the DI will be assured that equipment is functioning as required by HTA standards, and help to trend for possibility of equipment failure. |
| 12. | PFE5 | The DI is advised to institute a procedure for routine alarm testing of the storage units. By doing so he will help to identify possible alarm failure and minimise risk of damage to bodies in storage. |

**Concluding comments**

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

- Regulatory risks, including all of the HTARI categories, have been assessed, as have risks in the carrying out of licensed activity in other areas of the hospital. The risk of untrained staff being involved in seeking consent for a hospital PM examination has been assessed and various mitigating steps put in place.

- The DI has nominated PDs in all areas where licensable activity is carried out, including portering services. Each PD is required to produce an annual "Assurance Report" detailing what activity has taken place in their area of work and how each relevant HTA standard is being met. This document is used as the basis of discussion with the DI and the HTA Manager at the Trust, to identify risks and areas for improvement.

- HTA matters are discussed at HTA group meetings involving the DIs for all licenses held by the Trust, ensuring sharing of learning and cross pollination of good practice. In addition, PM specific activity is discussed at meetings of the HTA PM sub-group and relevant information shared with staff.

- A comprehensive suite of audits, both vertical and horizontal is in place, covering documentation and traceability. In particular, there is regular audit of tissue held within the wet tissue store, including an annual audit of all wet tissue stored.

- The establishment regularly collates a list of coronial cases in which tissues have been retained and seeks instructions from the coroner as to their disposal.

- Communication with the coroner is robust and key instructions, such as authority for PM examination and details of families' wishes, are provided to the establishment only by means of a secure fax transmission with automatic confirmation of receipt.

- Good working relationships and processes between the GIFT project research team, the mortuary and prospective donors and their family has helped the establishment build up a valuable research resource for a range of projects.

There are a number of areas of practice that require improvement, including two minor shortfalls. The HTA has given advice to the DI with respect to amendments of the Trust consent policy, review of some elements of governance documentation, assessment of risks in relation to contingency storage arrangements, training of staff in relation to identification

procedures and documentation relating to maintenance and service of critical mortuary equipment.

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: 23 November 2015**

**Report returned from DI: 4 December 2015**

**Final report issued: 10 December 2015**

**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: 01 April 2016**

## 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 |
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| **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.<br>• 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).<br>• 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.<br>• Relatives are given an opportunity to change their minds and is it made clear who should be contacted in this event.<br>• 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).<br>• 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.<br>• 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.<br>• Refresher training is available (e.g. annually).<br>• Attendance at consent training is documented.<br>• 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.