Site visit inspection report on compliance with HTA minimum standards

Queen Elizabeth II Hospital

HTA licensing number 12110

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**

13 and 14 February 2013

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 Queen Elizabeth II Hospital (the establishment) had met the majority of the HTA standards, eight minor shortfalls were found in relation to the Governance and Quality Systems (GQS) and Premises, Facilities and Equipment (PFE) standards. The Trust has recently re-organised the provision of post mortem (PM) services, such that where PM examination used to take place across the hub and satellite premises of this establishment, all PM examinations now take place at the satellite site, which has recently undergone some refurbishment. Several of the PFE shortfalls relate to this site.

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, the Licence Holder, the premises and the 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 the activities carried out by Queen Elizabeth II (QE II) Hospital (the establishment). This was the second site-visit inspection of the establishment since it was issued an HTA licence in 2007 (the first was in November 2009). It was a routine inspection to assess whether the establishment is continuing to meet the HTA's standards. The establishment's post mortem (PM) licence currently covers all three licensable activities at both the QE II Hospital (the hub) and the Lister Hospital (the satellite). At the time of the previous inspection, PM examinations were being performed on both sites. Now, owing to Trust rationalisation, PM procedures are only performed at the Lister site.

The QE II mortuary consists of a body store for deaths occurring within the QE II Hospital. When a death reported to the Coroner requires a PM examination, the deceased is transferred to the Lister mortuary within 24 hours. For community deaths from the QE II district, the deceased are transported directly to the Lister mortuary. The QE II body store has fridge capacity for 37 bodies, with separate fridge storage facilities for fetuses (products of conception, non-viable fetuses) and fetal tissues pending cremation, burial or disposal, and stillbirths, neonates and children pending burial or cremation or for transfer to other HTA-licensed premises for PM examination. The Histopathology Department is also based at the QE II site.

The Lister mortuary consists of a body store with a fridge capacity for 65 bodies (including four bariatric shelves), freezer capacity for four bodies and separate fridge storage facilities for foetuses, stillbirths, neonates and children. The mortuary also has a PM suite, changing rooms, viewing room and office.

On average, around 860 routine adult PM examinations are undertaken at the Lister mortuary each year. These are under the authority of HM Coroner for Hertfordshire. In addition, about 12 consented adult PM examinations are performed at the Lister site each year and 22 forensic PM examinations. Although there is storage space for four bariatric bodies, transport restrictions do not permit PM examination on such bodies. Therefore, bariatric cases under Coronial authority are transferred to other HTA-licensed premises. There is a Service Level Agreement (SLA) governing this arrangement but this does not extend to consented PM examinations (*see Advice item 1*).

Known high risk (hazard group 3 pathogen) cases are performed. However, very high risk cases are transferred to other HTA-licensed premises for PM examination.

Tissue samples and whole organs are frequently sent off-site for examination at other HTA-licensed premises. These include hearts and brains for specialist examination, brains and spinal cords donated for research, and toxicological samples. These arrangements, and those with the local Funeral Director, are all subject to formal agreements (*see Advice item 2*).

The Emergency Department at the Lister Hospital has procedures for dealing with cases of sudden unexpected death in infants (SUDI) under Coronial authority. Therefore, samples for analysis are removed there, including blood, cerebrospinal fluid, swabs from identifiable lesions, nasopharyngeal aspirates and skin biopsies (*see Advice item 3*).

The site-visit inspection included a visual inspection of both the hub and the satellite sites. At the hub, the mortuary and histopathology laboratory were inspected. The visual inspection of the satellite included the mortuary and A&E Department. Interviews were conducted with the DI, the Mortuary and Bereavement Services Manager, an Anatomical Pathology Technologist (APT), a Bereavement Officer, a Consultant Histopathologist, the Coroner's Office Manager and a Senior Coroner's Officer, the Pathology Quality Lead and the Histopathology Laboratory Manager. A documentation review and audit trails were also carried out. Details of the audits are provided below, there were no discrepancies noted.

As part of the site-visit inspection, two audit trails were carried out at the establishment. The first tested arrangements for labelling and storage of bodies in the Lister mortuary fridges. Three bodies were chosen (two with the same surname) and identification details on body tags were checked against the mortuary register and on the mortuary fridge doors; no anomalies were found. The second was a vertical audit of tissue removed at PM examination for histological analysis. Three Coronial cases were selected at random. Details of the tissues retained were cross checked between the mortuary and histopathology records. Additionally, the blocks and slides were checked against the histopathology records. No anomalies were found. The wishes of the relatives (for one set to be disposed of, one set retained for education/training and one set returned to the Funeral Director for cremation) had been followed.

Inspection findings

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

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.	Porters transport bodies to the mortuaries during and out of working hours. New porters receive local induction training by senior porter colleagues and records of such training are kept by the head porter. Mortuary staff are not involved in the development or delivery of this training and therefore the DI is not assured of porters' competency in performing mortuary activities.	**Minor**
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.	The establishment has a Trust level procedure in place to record any untoward incidents that occur; however, this does not cover the reporting of Serious Untoward Incidents (SUIs) to the HTA (*see Advice item 11*).	**Minor**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	Although risk assessments are in place for several procedures, these do not cover the range of activities taking place under HTA licences and do not sufficiently reflect the potential risks to the bodies in the care of the mortuary. In particular, risk assessments of the following activities have not been undertaken: evisceration of the deceased before the pathologist arrives, the rapid release of bodies out of hours or the possibility of the occurrence of a SUI (*see Advice item 12*).	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE1 The premises are fit for purpose.	The Lister mortuary has recently been refurbished. Maintenance of the body store refrigeration plant compressors (situated on the floor above the body store) is carried out by the Trust's Quality Control Department. The DI	**Minor**

	does not have access to records demonstrating that there are regular maintenance checks of the mortuary premises and that actions resulting from such checks are acted on within an appropriate timeframe. During the visual inspection, the HTA observed that the refrigeration plant system was leaking into the fridges, which mortuary staff were having to free of ice.	
PFE2 Environmental controls are in place to avoid potential contamination.	The changing rooms at the Lister are situated on the opposite side of the corridor to the PM suite. There is a small transition area within the PM suite. Since the establishment is performing high risk (hazard group 3) PM examinations, there is the possibility of airborne transmission and infection. However, there has been no risk assessment of the use of this transition area to ensure that there is minimal contamination when PPE is removed and the door to the PM suite is opened.	**Minor**
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.	The temperatures of some of the fridges in the Lister body store (those containing foetuses and the newly acquired fridges) are not regularly monitored by staff. In addition, these fridges are not linked to the to the switchboard temperature monitoring system.	**Minor**
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.	The testing of the fridge and freezer alarm system is not routine practice at the establishment.	**Minor**
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.	Maintenance of the body store refrigerators and freezers (on both sites) is undertaken by an external company. During a recent visit it was noted that new fridge and freezer parts would be required as the existing ones were in poor condition. Maintenance of the PM tables is reportedly carried out by the Trust Quality Control Department. However, the HTA observed that one PM table was leaking fluid onto the floor of the PM suite and a ceramic PM table was chipped, exposing the porous interior and presenting an infection risk. The PM suite contains two respirators for high risk PM examinations. There was no maintenance contract for this equipment.	**Minor**

Advice

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

No.	**Standard**	**Advice**
1.	N/A	The establishment has an SLA with an HTA-licensed establishment for carrying out bariatric PM examinations under Coronial authority. The DI is advised to extend this to incorporate bariatric cases requiring a consented PM examination.
2.	N/A	The DI is advised to ensure that signed copies of all agreements with external organisations are retained in the mortuary files.
3.	N/A	Licensable activities are undertaken in the Emergency Department at the Lister Hospital. The DI is advised to appoint a Person Designate (PD) to oversee such activities in this Department in order to facilitate communication about HTA relevant issues and the prompt reporting of SUIs.
4.	C1	The hospital PM consent form is based on the HTA template, which has been adapted for local use. The DI should remove the HTA logo from this form.
5.	C2	The information booklet given to families prior to consent being sought does not contain information about the family's options for retention or disposal of blocks and slides produced following the PM examination. The DI is advised to modify the information booklet so that options for the families and information about what blocks and slides are and the various ways in which they may be retained as mementos is included. The DI may wish to refer to the HTA model information booklet which can be found on the HTA website: http://www.hta.gov.uk/_db/_documents/Post-mortem_examination_-_your_choices_about_organs_and_tissue_FINAL_v3_0_201201255642.pdf
6.	C3	PM consent training currently consists of trained bereavement staff passing on their experience of attending an external bereavement training course, augmented by observation of the consent taking process. The DI is advised to formalise the consent training process internally into a consent training course. Those who have attended this internal course and observed the process can then go on to take consent themselves. Use of such internal training will also enable recorded refresher training.
7.	GQ1	The DI is advised to update the SOP for blocks and slide traceability to include the procedure involved when the family request that, if possible, they are returned with the body before the funeral.
8.	GQ1	Because of staff shortages, recent governance meetings have not taken place. The DI is advised to ensure that governance meetings involving HTA activities (e.g. Mortuary and Bereavement Team meetings, Pathology Senior Management Team meetings) should occur regularly and that there is a standing item at these meetings for HTA-related matters. This will ensure that nominated Persons Designate (PDs) and other staff can discuss and feedback on issues such as untoward incidents, changes to SOPs, audits, risk assessments, HTA training and updates from the HTA (e.g. e-newsletter items).

9.	GQ2	The establishment has a detailed audit schedule in place. The DI may wish to add the following to this schedule: horizontal audits to ensure that SOPs accurately reflect the practices being carried out; an audit of retained tissue and the family's wishes; an audit of length of stay in body store fridges. The results of all audit findings, and actions taken, should be formally recorded.
10.	GQ6	The DI is advised to ensure that, when stillbirths, neonates and children are transferred to another establishment for PM examination, all paperwork is included with the body to ensure full traceability.
11.	GQ7	The DI is advised to include the following in the SOP for SUIs: examples of SUIs, details of who should report them to the HTA, who should report them if the DI is absent, how to report them and within what timeframe they should be reported.
12.	GQ8	As a starting point for risk assessments of the potential for an SUI to occur, the DI may wish to consider the following examples from the HTA Guidance Document: http://www.hta.gov.uk/_db/_documents/Guidance_Document_-_SUI_Notification_201112192847.pdf
13.	PFE2	The DI is advised to ensure that formalin levels in the PM suite are maintained below 1 ppm (see link 1, below).
14.	PFE2	The transition zone links the PM suite directly to the corridor. The DI is advised to demarcate this area with coloured tape and signage.
15.	PFE3	The establishment has contingency plans for body storage capacity problems. These include: use of the QE II body store; use of a temporary, mobile facility; use of a body store at a nearby HTA-licensed establishment, and use of Funeral Director premises. However, these have not been formalised and would benefit from being set out in agreed plans.
16.	D2	The method and reason for disposing of tissue are the same for all cases. The DI is advised that these could be incorporated into the SOP on disposal of human tissue.

Link 1:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4119258

Concluding comments

Staff working in the mortuary are very committed to good practice. However, there are several problems with the premises, facilities and equipment, as highlighted by shortfalls in this report, which are causing operational difficulties. Whilst the HTA does not consider there to be a risk to the dignity of deceased individuals, it is concerned that adequate steps do not appear to be being taken to keep the premises, facilities and equipment to a reasonable standard of maintenance.

During the inspection of Queen Elizabeth II Hospital, several areas of good practice were noted:

- The consent meeting for hospital consented PM examinations always involves the treating clinician, a bereavement officer and a pathologist. This helps to ensure that any

questions that the family may have can be answered and that the person giving consent is fully informed.

- There is a comprehensive audit schedule which includes 'satisfaction surveys' of the service by families and funeral directors, and audits against CPA standards

- Staff are enthusiastic, hardworking and knowledgeable, and are encouraged to further their careers by attending relevant courses (e.g. APTs are encouraged to attend a wide variety of courses on bereavement).

- There is excellent communication with the Coroner's Office:

    - The nominated person at the establishment (Histopathology Laboratory Manager) is in frequent communication with the Coroner's Office concerning the end of an inquest and the family's wishes (and records all this data on a spreadsheet).
    - There is a dedicated person within the Coroner's Office to handle HTA issues.
    - The induction training of new mortuary staff includes time in the Coroner's Office.
    - The induction training for new Coroner's Officers includes time in the mortuary.
    - The Coroner's Officers hold local workshops on consent/the role of the Coroner's Officer/post mortems (several of which are held with HTA staff).

There are eight areas of practice which require improvement and these constitute minor shortfalls. The HTA has also given advice to the Designated Individual in several areas, including consent, governance and quality systems, premises facilities and equipment and disposal, as well as licence management and use of agreements.

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: 12 March 2013

Report returned from DI: 8 April 2013

Final report issued: 16 April 2013

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: 07 June 2013

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• There is a documented policy which governs consent for post-mortem examination and the retention of tissue and reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent. • There is a documented SOP detailing the consent process (including who is able to take consent, what training they must receive, and what information must be provided to those giving consent for post-mortem examination). • There is written information about the consent process (provided to those giving consent), which reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.
C2 Information about the consent process is provided and in a variety of formats
• Relatives are given an opportunity to ask questions. • Relatives are given an opportunity to change their minds and is it made clear who should be contacted in this event. • Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use). • Where consent is sought for tissue to be retained for future use, information is provided about the potential uses in order to ensure that informed consent is obtained. • Information on the consent process is available in different languages and formats, or there is access to interpreters/translators.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• There is a training programme for taking consent for post-mortem examination and tissue retention which addresses the requirements of the HT Act and HTA code of practice on consent. • Refresher training is available (e.g. annually). • Attendance at consent training is documented. • If untrained staff are involved in consent taking, they are always accompanied by a trained individual.

Governance and quality system standards
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process

• Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include:
  • post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases
  • record keeping

- receipt and release of bodies, which reflect out of hours arrangements
- lone working in the mortuary
- transfer of bodies and tissue (including blocks and slides) to other establishments or off site
- ensuring that tissue is handled in line with documented wishes of the relatives
- disposal of tissue (including blocks and slides)

(Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)

- Policies and procedures are regularly reviewed (for example, every 1-3 years).
- There is a system for recording that staff have read and understood the latest versions of these documents.
- Deviations from documented SOPs are recorded and monitored.

GQ2 There is a documented system of quality management and audit

- There is a quality manual which includes mortuary activities.
- Policies and SOPs are version controlled (and only the latest versions available for use).
- There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits).
- Audits include compliance with documented procedures, records (for completeness) and traceability.
- Audit findings document who is responsible for follow up actions and the timeframe for completing those actions.
- Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why.
- There is a complaints system in place.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Staff are appropriately trained/qualified or supervised.
- Staff have annual appraisals.
- Staff are given opportunities to attend training courses, either internally or externally.
- Attendance by staff at training events is recorded.
- There is a documented training programme for new mortuary staff (e.g. competency checklist).

GQ4 There is a systematic and planned approach to the management of records

- There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.
- There are documented SOPs for record management.

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).

- Organs or tissue taken during post mortem examination are fully traceable, including blocks and slides. The traceability system ensures that the following details are recorded:
    - material sent for analysis on or off-site, including confirmation of arrival
    - receipt upon return to the laboratory or mortuary
    - number of blocks and slides made
    - repatriation with a body
    - return for burial or cremation
    - disposal or retention for future use.
- Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly

- Staff are trained in how to use the incident reporting system.
- Staff know how to identify incidents and near-misses which must be reported, including those that must be reported to the HTA
- The incident reporting system clearly outline responsibilities for reporting, investigating and follow up for incidents.
- The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.
- Information about incidents is shared with all staff (including the reporter) to avoid repeat errors.

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed.
- Risk assessments include risks associated with non-compliance with HTA standards as well as health and safety risks.
- Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years.
- Risk assessments include how to mitigate the identified risks; this includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- There is sufficient space for the activities to be carried out.
- Refrigerated storage units are in good working condition and well maintained.
- Surfaces are made of non-porous materials.
- The premises are in reasonable condition (structure and cleanliness of floors, walls, entranceways).
- The premises are secure (e.g. there is controlled access to bodies, tissue, equipment and records).

PFE 2 Environmental controls are in place to avoid potential contamination
• There is clear separation of clean, transitional and dirty zones (e.g. doors, floor markings, signs). • There is appropriate PPE available and routinely worn by staff. • There is adequate critical equipment and/or PPE available for high risk post mortems. • There are documented cleaning and decontamination procedures. • There are documented cleaning schedule and records of cleaning and decontamination.
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.
• There is sufficient capacity for storage of bodies, organs and tissues. • Temperatures of fridges and freezers are monitored on a regular basis. • There are documented contingency plans in place should there be a power failure, or overflow. • Bodies are shrouded whilst in storage. • There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.
PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination
• There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary (e.g. lab, other establishment), including record-keeping requirements. • There are written agreements in place with any external parties (e.g. undertaker, or courier) who transport bodies and/or tissue behalf of the establishment (laboratory or mortuary). *(Note that coroners usually have their own agreements with external parties for transportation bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases.)*
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

• Items of equipment in the mortuary are in a good condition and appropriate for use:
  • fridges / Freezers
  • hydraulic trolleys
  • post mortem tables
  • hoists
  • saws (manual and/or oscillating)
  • PPE for high risk cases (e.g. respirators)
• The use of porous materials is kept to a minimum and has been risk assessed
• Maintenance/service records are kept for equipment, including fridges/freezers, trolleys, post mortem tables (if downdraught) and post mortem suite ventilation.
(Note: These records may be held by the mortuary or centrally by the Trust, e.g. Estates Department.)

Disposal Standards
D1 There is a clear and sensitive policy for disposing of human organs and tissue
• There is a documented Trust or mortuary/laboratory policy for the disposal of human tissue, which reflects the requirements of the HTA code of practice on disposal. • There are documented procedures for disposal of human tissue, including blocks and slides.
D2 The reason for disposal and the methods used are carefully documented
• There are systems in place that ensure tissue is disposed of in accordance with the documented wishes of the deceased person's family. • Disposal records include the date, method and reason for disposal. • Tissue is disposed of in a timely fashion. *(Note: this means that tissue is disposed of as soon as reasonably possible once it is no longer needed, e.g. when the coroner's or police authority ends or consented post-mortem examination is complete.)*

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

- **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:

  - A notice of proposal being issued to revoke the licence
  - 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.
  - A notice of suspension of licensable activities
  - Additional conditions being proposed
  - Directions being issued requiring specific action to be taken straightaway

- **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.

- **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.