Site visit inspection report on compliance with HTA minimum standards

Kings College Hospital

HTA licensing number 12377

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**

30 September – 1 October 2014

Summary of inspection findings

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

Although the HTA found that Kings College Hospital (the establishment) had met the majority of the HTA standards, a shortfall was found in relation to the identity checks being performed on the deceased prior to a post-mortem examination taking place.

The HTA has given advice to the Designated Individual with respect to governance and quality systems and fridge/freezer temperature monitoring equipment checks.

Particular examples of good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

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

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

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

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

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

Background to the establishment and description of inspection activities undertaken

The licensed establishment consists of a body store, post mortem suite and laboratory facilities at King's College Hospital (KCH), the hub premises. The laboratory facility processes tissue taken during post-mortem examinations into blocks and slides. These are then reviewed by pathologists and stored until being archived, disposed of, or returned to the family, in accordance with the consent given. There is also a separate satellite site located at an industrial unit not far from the hub premises. Only storage of archive blocks and slides takes place at the satellite premises.

The laboratory facilities at the establishment consist of two separate laboratories for processing tissue which are selected depending upon the type of post-mortem case from which the tissue was removed. Routine post-mortem examination tissue samples go to the histopathology laboratory. Where cases involving neurological investigations, have the tissue sent to the neuropathology laboratory for processing.

The establishment undertakes around 400 adult post-mortem examinations each year, either on behalf of the Coroner, or with the consent of the deceased's family where there is clinical interest in a case. Paediatric cases are sent to other licensed establishments for examination.

Consent for post-mortem examination is sought by the clinician involved with the treatment of the deceased, who is supported by a member of the Trust's bereavement staff. The bereavement staff have been trained in the seeking of consent and also undertake refresher training. The bereavement staff seek consent for around 20 hospital post-mortem examinations per year.

Post mortem and histology activity is undertaken by staff working for a pathology partnership, Viapath, formed between KCH and other hospitals within London. Although the premises are owned by KCH, they are operated by staff working for the partnership. The DI is a KCH Trust employee and has no direct line management responsibility for staff working under the licence. Particular attention was given to understanding the governance arrangements under the licence and how the DI can effect change as required. The DI has regular meetings with staff at various levels working under the pathology partnership. These include senior managers, such as the Assistant General Manager and service delivery managers. The DI attends the partnership's monthly performance development group meetings, during which mortuary and laboratory issues are discussed. In addition the DI meets with the partnership's general manager on a weekly basis and in other meetings, the establishment's Corporate Licence Holder Contact who is the Trust's Associate Director of Governance and Assurance. The HTA was satisfied that the DI can effect change as required and has sufficient oversight of the licensable activities to discharge their duty.

During the inspection, the DI confirmed that removal of various tissue samples takes place in other areas of the hospital. This includes samples such as swabs and lavages from deceased children that have either arrived dead or die in the hub premises' Emergency Department (ED). The inspectors visited the ED and spoke with paediatric clinical staff. Although these staff thought that a document detailing the examinations that should be undertaken, including which tissue samples to take, was in existence, it could not be located during the inspection. It was thought that this document is stored with the paediatricians on the ward and would be brought to ED with the paediatrician who would be taking the samples. Additionally, at the time of the inspection, the DI had not appointed a Person Designated (PD) in the ED department to act as a point of contact in relation to the licensable activity. Advice has been given below with regards to formalising the process to follow when removing tissue from the deceased, and to appointing a PD.

In the Maternity department, the remains of stillborn infants or miscarriages may be stored prior to being moved to the mortuary so that, where appropriate, families have the opportunity to view the infants while on the ward. Remains are stored in a fridge that is kept in a small dedicated room, away from the main ward. Maternity department staff, namely the bereavement midwives, assist in the seeking of consent for paediatric post-mortem examinations. Staff have attended training at the licensed establishment undertaking the examinations and are using a version of a consent form developed by the Stillbirth and Neonatal Death charity (SANDS). Currently the storage fridge is not routinely temperature monitored, nor has there been a PD nominated within the department to act as a point of contact for the DI responsible for overseeing licensable activities. Again, advice has been given below with regards to these matters.

It was also learned during the inspection that the establishment removes, with appropriate consent, liver biopsies from some deceased patients for use in research in connection with the liver. This area was not visited during the inspection due to time constraints; however, the DI stated that there was a consent procedure in place and samples are stored under the governance of an appropriate HTA research licence.

This was the third site-visit inspection of the establishment and was a routine inspection to assess whether it is continuing to meet the HTA's standards. The timetable for the site visit was developed in consideration of the establishment's last self-assessed compliance information, as well as pre-inspection discussions with the DI and review of the previous

inspection findings. During the site visit, a visual inspection of the premises, review of documentation and interviews with establishment staff were undertaken.

An audit of bodies stored in the establishment's fridges was undertaken during the inspection. Four bodies were chosen at random and identification details recorded on body tags were checked against details on the mortuary fridge doors, the notice of death on the body and the electronic and paper mortuary body records. One of the cases chosen had the same name as another body being stored. In this case, in addition to the above checks, the details written on the office's white board were also reviewed. There was a minor discrepancy in the recording of a body's location and the deceased's date of birth on the office white board; however, details recorded in the mortuary registers and on the body correlated.

Tissue traceability audits were also undertaken during the inspection. Details of five post-mortem examinations were taken, consisting of two coronial histopathology cases, two coronial neuropathology cases and a consented case. Details of tissue taken at post-mortem examination were cross checked between mortuary records, histology request sheets and the laboratory traceability records. The physical blocks and slides were also sought and cross checked. Where applicable, consent forms and coronial family wishes forms were also reviewed. In two cases coronial family wishes forms had not yet been returned to the mortuary. The mortuary holds tissue in cases where there are no known family wishes for twelve months following the end of the coronial inquest, after which time any retained tissue is disposed of sensitively. This course of action is agreed with the Coroner. In summary, no anomalies were found during the audit of tissue.

In addition to the above tissue traceability audit, two cases were chosen at random from the archive tissue store at the satellite premises. Details of retained tissue were again cross checked as above at the hub premises. One of the cases chosen was tissue from the living and therefore not being stored under the establishment's post mortem licence. The second case was tissue from the deceased; no anomalies were found.

Inspection findings

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

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	The establishment's procedure on verifying the identity of the deceased prior to post-mortem examinations taking place is not sufficiently detailed. The standard operating procedure (SOP) does not specify who is responsible for undertaking identity checks. The establishment has risk assessed the identity checking procedure; however, the risk assessment identified points of identification to be checked on the deceased's identity tag in order to minimise the risk of performing a post-mortem examination on the wrong body. This points of identification are again, not reflected in the SOP. This results in a risk that the deceased may be incorrectly identified prior to a post-mortem examination commencing. *The establishment provided documentary evidence to address this shortfall prior to the issue of the final report. The HTA has assessed this evidence as satisfactory to address the shortfall.*	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1 GQ2	The establishment has put in place a new DI and new mortuary manager since the last inspection. Some new procedures have been implemented and other existing procedures have been amended and updated. The DI is advised to review all procedural documents to help ensure that the SOPs reflect the current practices taking place under the licence. When performing the review, the DI may wish to consider undertaking some process audits of staff against the relevant SOPs. This may help identify where the procedure has changed but the documents have not been updated to reflect the changes.
2.	GQ1	It is understood that the pathologist is not always present when identity checks are conducted and that evisceration is routinely undertaken by mortuary staff without the pathologist being present. Current guidance from the The Royal College of Pathologists (RCPath) published in February 2014, requires the

		pathologist who will be performing the post-mortem examination to undertake identity checks and perform an external examination on the deceased prior to evisceration taking place. The DI is advised to consider this guidance when developing a clearer procedure and associated SOP regarding verifying the identity of the deceased prior to post-mortem examinations taking place. In accordance with the RCPath guidance this procedure should include a check of the identity and an external examination of the deceased by the pathologist prior to the post-mortem examination commencing.
3.	GQ2 GQ6	There is a large amount of archive blocks and slides currently stored at the establishment's satellite premises. The DI is advised to undertake periodic audits of stored tissue in order to assure himself that traceability is being maintained and that associated documentation stored at the hub premises is also being appropriately managed and can be located.
4.	GQ8	The establishment has a range of risk assessments in place, including some in relation to risks to the bodies and tissues. The DI is advised to review these risk assessments with a view to expanding their scope to cover more of the risks posed to the bodies and tissues. The DI may wish to consider using the HTA reportable incident categories as a basis of risks to be addressed in future risk assessments.
5.	GQ2	The DI is advised to appoint a PD in the accident and emergency and maternity departments to act as points of contact in relation to the licensed activity taking place in these areas. In this way, the DI will be made aware of any issues that arise and will, in turn, be better able to disseminate any licensing updates or information to staff in these areas. The DI is also advised to invite the PDs to governance meetings so that information regarding licensable activity can be shared. In addition, in the accident and emergency department, the DI is advised to formalise the documentation relating to the taking of samples from deceased children brought into, or who die unexpectedly in, the accident and emergency department. In formalising the documents, the DI should ensure that copies of the required documentation which guide staff on which samples to take are available to accident and emergency staff. The DI may wish to consider, as suggested by the accident and emergency staff during the inspection, placing some of the documentation on the department's electronic document portal. Finally, in the maternity department, the DI is advised to put in place regular checks on the storage fridge which is used to store the bodies of deceased infants before they are transferred to the mortuary. The DI is advised to implement a procedure whereby the maternity department staff verify that the fridge is operating as expected during staff shift changes when other essential equipment within the maternity department is also checked.
6.	GQ3	The mortuary manager has recently started a program of porter training whereby existing and new portering staff will receive training on the use of mortuary trolleys, body placement within the storage fridges and the handling of the deceased. The DI is advised to consider adding guidance to portering staff about what type of adverse incidents represent an HTA reportable incident. In addition, the DI should consider specific training and guidance regarding moving the deceased and manual handling. This is to alert porters to matters specific to the deceased, such as the deceased being potentially prone to injury during manual handling procedures.

7.	GQ6	The establishment is currently investigating a sensitive disposal route for material originating from pregnancy terminations of less that 24 weeks gestation. In the meantime, the mortuary is storing tissue from terminations, but this in not recorded in any register and the mortuary has no other means of knowing how much material of this nature they are holding. The DI is advised to audit the stored material and to record details of what is being held pending sensitive disposal. This audit should be undertaken at the earliest opportunity to avoid a further increase of unrecorded material. In addition, any new material received by the mortuary should be recorded. Maintaining a record of what is being held pending sensitive disposal will help mitigate the risk of any tissue being lost and provide a means by which the DI can assure himself that all tissue has been disposed of once the disposal procedure has been established.
8.	PFE3	The DI is advised to continue with plans to implement a fridge and freezer alarm testing procedure (currently in draft). The DI is advised to amend the procedure to incorporate two types of alarm test, the first where the establishment verifies that the alarm has triggered and sounded at switchboard following alerting the switchboard staff of the test; the second, similar but not alerting switchboard staff of the test. This will verify that switchboard calls the relevant members of establishment staff when the alarm was triggered.

Concluding comments

Good practices were observed during the inspection, some examples of which are included below.

Examples were seen of advice given by the HTA during the previous inspection being considered and practices changed as a result. Additionally, the recently appointed Mortuary Manager and DI have identified and implemented several improvements to processes within the establishment. There appeared to be good working relationships between staff at the establishment who also demonstrated a desire to continuously improve practice and the service given to the hospital and the families of the deceased.

From descriptions of the arrangements given during the inspection, the DI has also formed suitable governance links with both the Trust and the service delivery partnership. These links should give him suitable oversight of the activity and mechanisms by which he can effect change, if required.

A system to record the identity checks and who has undertaken them when the deceased are released to the undertaker has been developed and helped to provide the DI assurance that the risk of misidentification and release of the wrong body has being mitigated.

There are a number of areas of practice that require improvement, including one minor shortfall. The HTA has given advice to the Designated Individual with respect to governance and quality systems and fridge/freezer temperature monitoring equipment checks.

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: 29 October 2014

Report returned from DI: 24 November 2014

Final report issued: 4 December 2014

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: 29 December 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
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.