Site visit inspection report on compliance with HTA minimum standards

Hemel Hempstead General Hospital

HTA licensing number 12082

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**

11 – 13 March 2014

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.

Hemel Hempstead General Hospital (the establishment) was found to have met all HTA standards.

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 Hemel Hempstead General Hospital, 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 their wishes.

There are also two separate satellite sites located at Watford General Hospital and Mount Vernon Hospital. Mount Vernon Hospital is part of another Trust; however, a laboratory facility there is operated by the establishment's Trust and therefore, for the purpose of HTA licensing, it is a satellite site. The satellite site at Watford General Hospital consists of a body store and post mortem suite. Fewer post mortem examinations are undertaken at the Watford General Hospital satellite site, with any tissue taken being transferred to the second satellite premises, Mount Vernon Hospital, for processing and review by the pathologists. The Mount Vernon laboratory stores, archives, disposes or returns tissue taken during post mortem examinations undertaken at the Watford General hospital satellite site in accordance with families' wishes.

Prior to the inspection, the DI confirmed that removal of various tissue samples takes place in other areas of the hospital, including blood, swabs and lavages from deceased children that have either arrived dead or die in the Watford General Hospital's accident and emergency

(A&E) department. This activity, which is licensable, does not take place at any of the other hospital sites within the Trust. During the inspection, the A&E department was visited and staff responsible for taking these samples were spoken with. Samples are taken in a dedicated room, which is private and is suitable for the procedure. Staff have guidance documents to follow, which detail the types of samples to be taken. The coroner has been made aware of what samples are being taken in such cases and has given 'blanket' approval. Nursing staff liaise with the parents of the deceased child and give information about coronial processes, explaining about the samples and how and why they are taken.

Paediatric post mortem examinations are not undertaken under the establishment's licence. Paediatric cases are transferred to other licensed premises for post mortem examination. The seeking of consent for hospital post mortem examination of babies is undertaken by the Watford Hospital's maternity department's consultant staff and is witnessed by a midwife who helps support the family through the process. Staff have attended training, and additional training sessions for staff have been organised by the external licensed establishment where the paediatric post mortem examinations are undertaken. This training will take place during the month following the inspection.

The establishment undertakes around 700 adult post mortem examinations each year, on behalf of the coroner. Around 500 of these examinations are undertaken at the hub premises, with the remaining 200 conducted at the satellite premises. On rare occasions, with the consent of the deceased's family where there is clinical interest in a case, a consented post mortem may be undertaken.

In the case of hospital consented adult post mortem examinations, consent is sought by the clinician who was involved in the treatment of the deceased prior to their death. These clinicians are supported by an anatomical pathology technologist (APT) who has received training in the consent process and who is also able to answer any questions that the family may have regarding the post mortem examination procedure. The trained APT has also provided suitable training to members of the Trust's bereavement service, who are now also able to support the clinicians in seeking consent for post mortem examinations.

Body storage fridges at the hub and satellite premises have remote alarm systems which alert the switchboard at another of the Trust's hospitals in the event of an equipment failure. The switchboard then contacts the estates department to attend the mortuary. There is an informal process, if the failure cannot be rectified; the estates department escalates the issue to a senior bed manager within the Trust. The bed manager then alerts pathology staff who, if necessary, contact the mortuary staff to assist in the moving of bodies.

This was the second site-visit inspection of the establishment and was a routine inspection to assess whether it continues 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 and coroner's office staff were undertaken.

An audit of bodies stored at the establishment's hub premises was undertaken during the inspection. Three bodies were chosen at random and identification details recorded on body tags were checked against details on the mortuary fridge doors and the mortuary register. Additionally, the same cross checks were undertaken on details from three randomly chosen bodies being stored at the satellite site. No anomalies were found during these audits.

Tissue traceability audits were also undertaken during the inspection. Details were taken of three coronial cases where tissue was taken during post mortem examinations performed at the hub premises. The blocks were sought and the establishment's tissue records relating to the blocks were reviewed. Records of blocks processed and disposal, where applicable, are recorded in a post mortem tissue database. During this audit it was found that the

establishment did not record the number of slides cut from tissue blocks. Usually the establishment staff assumes that one slide for H&E staining is cut from each block; however, the establishment's system did not provide a mechanism through which this could be verified. As a result, the establishment had no process for tracking when extra slides are cut for special stains, which presented a risk to traceability and that tissue samples may be retained without consent. The HTA identified this as a shortfall against HTA standard GQ6.

The lack of an effective system was addressed by the establishment during the three day inspection. A new system was developed whereby any slides cut are recorded on the histopathology request form. The establishment's standard operating procedure (SOP) was also amended to reflect this change. As a result, the establishment was determined to have met the tissue traceability standard GQ6 in full.

To complete the audit at the hub site, signed coronial family wishes forms were reviewed.

A second tissue traceability was undertaken at the Watford General Hospital satellite site. Details were taken of three coronial cases where tissue was taken during post mortem examination. In addition, details were taken of a consented hospital post mortem examination. At the second satellite site, Mount Vernon Hospital's histopathology laboratory, the tissue blocks and slides relating to the four post mortem examinations were sought. The number of blocks matched the records in the mortuary and the laboratory. In two of the coronial cases no 'family's wishes forms' had been returned as the inquest was still on-going; however, in the third case, a signed family's wishes form was reviewed. In the consented post mortem case, a signed consent form for the post mortem examination and the retention of tissue was reviewed.

In all seven post mortem cases reviewed at the satellite sites, 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

All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
1.	C1	A member of the establishment's patient services team telephones the person who has given consent for a post mortem examination (who has already been determined to be the highest ranking person in the list of qualifying relationships) to verify that the consent giver has not changed their minds prior to the examination starting. This is considered to be good practice; however, this practice is not reflected in the Trust's consent policy. The DI is advised to amend the policy to reflect the verification procedure.
2.	C3	The establishment's consent policy does not state that a member of staff who has been trained in seeking consent for post mortem examination must be present during the seeking of consent process and therefor does not reflect the

		wording of the 'Hospital PM Procedure' standard operating procedure (SOP). The DI is advised to amend the policy to clarify that a trained member of staff must be present so that the two documents are aligned. The DI may wish to use wording similar to that in the establishment's 'Hospital PM Procedure' SOP which does clearly identify the need for trained staff to be present when consent is being sought.
3.	C3	The establishment is currently training new members of staff in the patient services team in seeking consent for post mortem examination. The DI is advised to offer the opportunity for these staff to observe a post mortem examination to help increase their understanding of the process and enable them to better answer any questions raised by families.
4.	GQ1	The establishment's body release SOP refers to 'checking the wristband ID' on the deceased when releasing bodies to funeral directors. The DI is advised to update this SOP to detail which points of identification must be checked and which documents they are checked against. This detail is particularly important as senior Trust staff, bed managers, may be called upon to release a body out of hours without mortuary staff assistance.
5.	GQ1	The DI is advised to update all three of the establishment's post mortem examination SOPs to include the steps to take if a previously unknown tuberculosis infection is found during a post mortem examination.
6.	GQ1	The DI is advised to invite pathologists who undertake post mortem examinations to the mortuary meetings. This will help to ensure that they are aware of any current issues facing the mortuary and will mean that they are able to input into the decisions being taken regarding the mortuary and its practices.
7.	GQ1	The DI is advised to appoint Persons Designated (PD) in the accident and emergency department and maternity departments where removal of tissue and storage take place. The PDs will act as a point 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.
8.	GQ2 GQ6 D2	During the inspection it was found that there was no system to record the number of slides cut from a particular block. During the inspection the establishment introduced a new procedure whereby the number of slides cut from a block is recorded on the histopathology request form. These forms are archived by the establishment by attaching them onto the post mortem report. The form will serve as a record of the number of slides being cut and therefore provide a mechanism through which, when acting upon with wishes of the deceased's family, the establishment can assure itself that all tissue from a particular case can be identified. The DI is advised to schedule audits of the newly amended histopathology request forms to verify that they are being completed as expected and in accordance with the appropriately amended SOP.
9.	GQ3	Some mortuary procedures such as performing viewings, responding to fridge alarms and releasing bodies are undertaken by the Trust's bed managers during out of hours periods. The bed managers received training in these procedures some time ago. The DI is advised to provide refresher training to bed managers to help ensure that these procedures are being undertaken appropriately.

10.	GQ3	The portering staff have been trained in body handling and body receipt, but, again, this training took place some time ago. Refresher training has been offered by the establishment, but take up has been limited. The DI is advised to consider making this training mandatory and/or providing training to portering staff during their induction as this may help to ensure that all porters have received appropriate training. The DI is also advised to risk asses the procedures undertaken by the porters, as this may help identify areas of risk and therefore inform any training that is given.
11.	GQ8	Some mortuary procedures such as performing viewings, responding to fridge alarms and releasing bodies are undertaken by the Trust's bed managers during out of hours periods. The DI is advised to risk asses the processes that are undertaken by the bed managers during out of hours periods. These risk assessments will help to assure the DI that the potential risks associated with non-mortuary staff undertaking mortuary procedures are identified so that suitable measures to mitigate against these risks can be identified and put in place.
12.	PFE1	The establishment has identified that there are some operational issues with the drainage and air handling systems at both the hub and satellite post mortem suites. At the hub site, the air changes per hour are currently measured at four, which is well below the recommended rate of ten. The establishment has risk assessed this issue and has put in place measures, such as wearing masks while conducting post mortem examinations. At the satellite site, the post mortem suite has an air change rate of 64 changes per hour, which is resulting in the premature failure of plant equipment. The floors at both premises have issues with pooling water caused by the poor location of drains. All of these issues have been reported to the Trust's health and safety supervisor who has assisted in assessing the risks. The establishment has further investigations scheduled in the weeks following the inspection to determine how these issues may be addressed. The DI is advised to keep the floor drainage and air handling issues under close review to assure herself that these issues do not worsen and that any measures which are put in place to address the issues are effective.
13.	PFE1	Out of hours, the establishment has trained bed managers to respond to fridge and freezer equipment failure alarms. An alarm triggers a call to the bed manager on duty. The bed manager then alerts the estates department to investigate and, if necessary, mortuary staff are notified via a senior pathology department manager if the issue cannot be rectified. Although this procedure has been agreed, it is not documented in a formal procedure, and there is a risk that appropriate steps may not be taken in the event of mortuary equipment failure. The Di is advised to produce an appropriate procedure for bed managers to follow in the event of an equipment failure and have this procedure incorporated in to the bed manager's pack, which is referred to by them when working out of hours.

Concluding comments

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

The establishment has developed good procedures for transporting tissues and organs to external centres for specialist review. These require the receiving centre to forward a fax confirming receipt to the establishment, helping it to maintain full traceability records.

In the mortuary, the names of the deceased are written on the mortuary white board and fridge/freezer doors using different coloured pens. A different coloured pen is used each week on a four week rotation to alert the mortuary staff to any bodies that have been in the mortuary for long periods. Mortuary staff can then follow up any cases that have been in the mortuary for longer than is usual and, if necessary, transfer the body to the freezer.

The active role played by patient services in seeking consent and communicating with the family in order to confirm whether or not they have changed their minds prior to a post mortem examination taking place helps assure the DI that the post mortem examination is undertaken in accordance with their wishes.

The HTA has given advice to the Designated Individual with respect to consent, governance and quality systems and premises facilities and equipment standards.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 17 April 2014

Report returned from DI: 23 April 2014

Final report issued: 22 May 2014

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.