Site visit inspection report on compliance with HTA minimum standards

Princess Alexandra Hospital

HTA licensing number 12458

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**

03 November and 14 December 2016

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 Princess Alexandra Hospital (the establishment) had met the majority of the HTA standards, a shortfall was found against standard GQ1. This was in relation to standard operating procedures.

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

This report refers to activities carried out at Princess Alexandra Hospital (the establishment), which has been licensed since 2007 and was last inspected in 2012. The inspection was conducted in two parts. The first site visit, on 3 November, was to assess the condition of the mortuary facility and, in particular, the suitability of refrigerated body storage. The decision to bring forward inspection of the premises resulted from a report published by the Care Quality Commission (CQC) in October 2016, which made reference to the poor state of the fridges and aspects of the post mortem suite, giving rise to concerns about the suitability of the premises and compliance with HTA's standards. The second site visit was conducted on the 14 December.

Approximately 600 post mortem (PM) examinations take place at the request of HM Coroner for Essex and HM Coroner for Hertfordshire. Forensic PM examinations are occasionally performed and paediatric PM examinations are sent to other HTA licensed mortuaries.

The Designated Individual (DI) is a Consultant Pathologist. The Corporate Licence Holder is The Princess Alexandra Hospital NHS Trust, with the Trust's Medical Director as the named contact (Corporate Licence Holder contact, CLHC). There are four Persons Designated (PD) working under the licence (see Advice, item 12).

HTA inspection, part 1

The November inspection comprised: a visual inspection of the body store, the contingency storage unit and the post mortem suite; review of documentation relating to management of the facilities, particularly temperature records; and discussions with the Mortuary Manager, Anatomical Pathology Technologist, Designated Individual and Corporate Licence Holder contact.

Body store

The mortuary facility consists of a body store and a post mortem room. The body store has 80 storage spaces, of which 72 are standard fridge spaces, two are bariatric and six are freezer spaces. There is a separate bariatric fridge, which can hold two bodies weighing up to 75 stone. The bariatric fridge is also used to store products of conception, which are individually packaged and placed together on a single tray.

There are 20 further spaces available in a temporary mobile storage unit, provided under a rental agreement. At the time of the first site visit, funding to allow the purchase of a similar unit had been secured.

The mobile unit is located at the back of the mortuary building, next to offices whose windows have been darkened, and is over-looked by wards. When a body is being placed in the unit or removed, sheeting is used to reduce visibility of the deceased to people within the adjacent buildings. The unit is locked at all times and the keys are kept by mortuary staff (see Advice, item 7).

During the CQC inspection, particular concern was raised about the oldest bank of fridges in the mortuary, which is used to store bodies due for post-mortem examination. This bank has six fridges, each with six body storage spaces and six freezer spaces; it is the most frequently used bank, as the fridges are double-sided and can be accessed from the post mortem suite. CQC's report highlighted the condition of the fridge doors, which were reported as being not fit for purpose, with significant rusting on the hinges, and two that could not be securely closed. In addition, the CQC found that the freezer was not functioning efficiently, with a significant build-up of ice preventing the removal of two trays.

The establishment responded promptly to the CQC's report and, prior to the HTA's first site visit inspection, the doors and the chiller units of the bank were replaced. The HTA examined the new doors and reviewed temperature records since their installation. The records indicated that the new doors and chiller units are functioning as expected and the bank is maintaining correct temperatures. The freezer was also examined; the ice buildup noted during the CQC visit was not present and the top two trays could be removed easily. A review of historical temperature data indicated that the freezer had not been operating at maximum efficiency, although the temperature was still low enough (-10˚C to -12˚C) to keep stored bodies frozen. Following the refurbishment, the temperature records showed that the freezer unit now operates at around -20˚C.

One of the banks of fridges in the body store is used for bodies that are not subject to post-mortem examination; another is used for the storage of bodies that are awaiting release following post-mortem examination. Both of these banks of fridges had been installed within the last ten years. The doors showed signs of general wear and tear; however, the seals of all doors remained fully intact and did not raise any concerns. Temperature records were reviewed and confirmed that the fridges were functioning as expected.

Fridge temperatures are monitored and linked to a remote-call out system, which alerts the hospital switch board and on-call staff to any temperature deviations from the expected range. In addition, temperature trends are monitored manually on a daily basis to identify trends.

Contingency storage

The establishment reported that the rented portable temporary storage unit, referred to above and soon to be replaced with a unit purchased by the Trust, is considered by the Trust to

provide sufficient body storage capacity, including during peak periods, as the mortuary rarely reaches full capacity. At the time of the first visit however this contingency storage was being used, meaning that contingency spaces may not have been available if needed (see Advice, item 9).

Post mortem suite

The post-mortem suite has three fixed post-mortem tables, each with a dedicated dissection area where the pathologist examines the organs. There are approximately 17-19 air changes per hour, although evidence of this is held by the Trust's estate department and was not reviewed during the visit. Post-mortem examination of bariatric bodies is conducted on a bed taken into the suite for this purpose. High-risk bodies (below category 3) are dissected in a body bag and personal protective equipment is used; however, no respirators were available for staff. Adequate and suitable respiratory protective equipment should be used for post-mortem examinations where there is a risk of exposure to airborne infectious agents (see Advice, item 6).

The post-mortem suite floor had significant lime-scale build up, due to the hardness of the water. This porous lime-scale may prevent effective cleaning and decontamination of the mortuary suite. The HTA was informed that a request to replace the floor had been submitted to the Trust Board (see Advice, item 5).

HTA inspection, part 2

During the December inspection visit, the HTA assessed compliance with HTA standards not considered during the earlier visit. The inspection comprised: a visual inspection of the mortuary; interviews with the Mortuary Manager, the CLHC, the Chief Executive, a Coroner's Officer for the Essex Coroner, the Child Death Lead, the Senior Bereavement Advisor, the Maternity lead, the Pathology Quality Manager and the Designated Individual; a review of governance documentation; and a number of traceability audits of bodies and stored tissue samples.

The mortuary is staffed by two Anatomical Pathology Technologists (APTs) and a Mortuary Manager. A mortuary support worker has recently been recruited, who will assist mortuary staff with booking-in and releasing bodies, as well as undertaking viewings.

Bodies are received into the mortuary from the hospital and the community. Hospital porters bring the bodies of patients who have died in the hospital; the bodies of those who die in the community are brought by the Coroners' contracted funeral directors. Individual training for porters on the correct procedure for admitting a body and competency assessment has been performed by the Mortuary Manager. Upon receipt of the deceased, identification details are verified by mortuary staff and, as part of the checking procedure, the body is assigned a unique identifier which is written on a new wristband and placed on the body.

When a body is released to a funeral director, a 'Coroner's authority to release form' must be provided. If the form is not available, the body will not be released. The identity of the deceased is checked by the collecting funeral director and an APT.

The HTA performed three body audits, where bodies were selected at random and details, including name and hospital number, were cross checked against paperwork, the mortuary register and the electronic recording system. No anomalies were found. In addition, four tissue traceability audits were carried out, where documentation associated with a case was

reviewed and the physical location of the blocks and slides was sought to ensure the family's wishes had been acted upon appropriately. 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 establishments work are supported by ratified documented policies and procedures as part of the overall governance process	Standard operating procedures (SOP) are in place for all mortuary procedures; however, a number do not reflect current working practices. For example, the SOP for APTs performing a PM examination states that the identity of the deceased should be checked by one APT, when current mortuary practice is that two APTs perform the identity checks with one signing the PM chart to record that the check has taken place. Examples where practice is not reflected in the SOPs include, but may not be limited to the following documents: (i) LP-770-002 Lodging and releasing of bodies (ii) LP-770-004 SOP for Pathologists (iii) LP-770-001 SOP for APT	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	In some cases, following the pathologist's review of documentation, evisceration may take place before the pathologist verifies the identity of the deceased and examines the body. This practice is contrary to the Royal College of Pathologist's guidelines on the conduct of a PM examination. The DI is advised to ensure that the identity of the deceased is checked and a thorough external examination of the body is carried out by the pathologist prior to evisceration in all cases. This will be mandatory from 1st April 2017, when the HTA's revised codes of practice and licensing standards come into effect.

2.	GQ1	The identity of the deceased is checked by two APTs in advance of evisceration; however only one APT signs the PM chart. The DI is advised to record the details of the two people who confirm the identity of the deceased.
3.	GQ2	The completion of annual mortuary procedural audits is proving difficult to achieve, given the number of mortuary staff. The DI is advised to review the schedule and ensure that appropriate quarterly targets are defined.
4.	GQ6	The DI is advised to review the process for following up with the Coroner's office to establish the status of cases and for notifying the laboratory, where tissue samples are held. Being notified of the end of an inquest, and passing this information on to the laboratory, will help ensure families' wishes are acted on in a timely manner.
5.	PFE1	The post-mortem suite floor has significant build-up of lime scale, which contributes to water pooling and may cause difficulties when moving the trolley or carrying out cleaning and decontamination procedures. The Trust is advised to continue with its plans to replace the floor, which can only get worse and may increase the risk of adverse events occurring.
6.	PFE2	The mortuary does not provide respirators for staff. The Designated Individual should review the requirements for appropriate personal protective equipment and ensure that appropriate equipment is available for mortuary staff to use when needed.
7.	PFE3	The mobile body storage unit is overlooked by offices and wards. Although sheeting is used to reduce visibility, the DI is advised to continue with the plan to erect a screen, which will shield the entrance of the mobile unit and reduce the potential for the movement of bodies to be seen by anyone in the adjacent buildings, thereby protecting the dignity of the deceased. The portable unit is on wheels. Although secured by a hitch lock, the DI should consider adding a wheel lock to mitigate the risk of the unit being moved.
8.	PFE3	The mobile body storage unit is not currently linked to the temperature monitoring system and remote call-out system. When the permanent unit is installed, the DI is advised to ensure that it is subject to the same level of monitoring as the other storage. In the meantime, the DI should put in place a procedure whereby the temperature of the portable unit is regularly checked, especially during out of hours periods so that any malfunctions of the unit can be detected and mortuary staff alerted.
9.	PFE3	The DI is advised to review contingency storage and should assure herself that there is adequate contingency storage and procedures in place to deal with extra bodies should they be required, and keep this under review.
10.	D1	The record of material disposed of is currently stored with the Coroner's office. The DI should continue with plans to alter this system to that ensure a record of all tissue disposed of is kept on site.
11.	N/A	In line with the HTA's Code of Practice on post-mortem examination, the DI is advised to suggest to the Coroner that material should be disposed of within an agreed period of time if the family does not make their wishes known. The consent form should be revised accordingly.

12.	N/A	As removal of relevant material occurs in A&E and Maternity, the DI is advised to nominate a PD in both of these areas, who should be well versed in HTA procedures and able to oversee the activity taking place in these areas.

Concluding comments

Following the site visit inspection, the HTA is satisfied that the concerns raised by CQC have been adequately addressed and that, overall, the establishment is continuing to meet HTA standards.

Areas of good practice were noted throughout the inspection, particularly in relation to the consent procedures. A hospital consented post mortem has not been performed for a number of years; however, staff involved in seeking consent attend refresher training on a yearly basis. In addition, simulated tissue blocks and slides are used as visual aids for families during the consenting process, so that they are fully informed about the size of any tissue that may be taken for histological examination.

A further example is the use by mortuary staff of an action sheet for all bodies in the mortuary, which tells staff the status of the body, whether it is awaiting PM examination, or if all documents have been received from the Coroner to release the body.

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 audits, the post mortem suite floor, the contingency storage unit and external body checks by pathologists prior to evisceration.

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: 6 January 2017

Report returned from DI: 12 January 2017

Final report issued 16 January 2017

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: 21 April 2017

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: o post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases o record keeping o receipt and release of bodies, which reflect out of hours arrangements o lone working in the mortuary o transfer of bodies and tissue (including blocks and slides) to other establishments or off site o ensuring that tissue is handled in line with documented wishes of the relatives o 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 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.