Site visit inspection report on compliance with HTA licensing standards

Warrington Hospital

HTA licensing number 12024

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**

17-18 May 2017

Summary of inspection findings

The HTA found the Designated Individual (DI), the Licence Holder (LH) and the practices to be suitable in accordance with the requirements of the legislation.

Although Warrington Hospital met the majority of HTA standards, one major shortfall was found in relation to monitoring of fridges and one minor shortfall was found in relation to aspects of the mortuary premises.

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

The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the Designated Individual is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

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.

Its programme of site visit inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

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. They are grouped under four headings:

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

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, 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 provided.

HTA inspection reports are published on the HTA's website.

Background to the establishment

This report refers to the activities carried out at Warrington Hospital (the establishment), part of the Warrington and Halton Hospital NHS Foundation Trust. For HTA licensing purposes, Warrington Hospital is the 'hub' and the licence arrangements extend to the 'satellite' site at Data Space, where blocks and slides that pre-date the Human Tissue Act (HT Act) 2004 (existing holdings) are stored. The Designated Individual (DI) is a Pathology Manager. The Corporate Licence Holder (CLH) is the Hospital and the CLH contact is the Chief Executive

Officer for the Trust. The mortuary is staffed by a Mortuary Manager and two Anatomical Pathology Technologists (APTs). There are six in-house Consultant Histopathologists who conduct post-mortem (PM) examinations and two visiting trainee pathologists who work under the supervision of the Consultants.

Approximately 550 PM examinations are conducted at the establishment per year, the majority on behalf of the HM Coroner for Cheshire. Hospital consented PM examinations are rarely undertaken. High risk PM examinations (up to category 3) can be accommodated. Perinatal/paediatric cases are transferred to another HTA-licenced establishment for PM examination.

When they occur, a Matron or Senior Nurse seeks consent for adult hospital PM examinations using the establishment's consent forms. Registrars seek consent for paediatric/perinatal cases using the Stillbirth and Neonatal Death charity (SANDS) consent forms. All staff who seek consent are trained to do so.

The body store has refrigerated spaces for 79 bodies, five of which can hold bariatric bodies. There are also four spaces for super-bariatric bodies, which can be converted to freezers as a unit. Fetuses and products of conception (POCs) are stored on a dedicated fridge tray. There is contingency storage which can accommodate 16 bodies at another hospital within the same Trust.

Fridge temperatures are monitored and recorded during working hours only. The temperature monitoring system is situated in a corridor off the body store and displays a red LED light when the temperature goes outside of specification; however there is no audible alarm and no other alert system to ensure fridge failures are dealt with in a timely manor (see major shortfall against standard PFE2e).

Bodies are admitted to the mortuary at anytime. Deceased patients from the hospital are brought to the mortuary by security staff; community bodies are brought by funeral directors. There is CCTV outside the mortuary and an intercom system to alert mortuary staff of the arrival of funeral directors and visitors. Out of hours, funeral directors contact security staff who let them in to the mortuary. Security staff always work in pairs when admitting bodies. New security staff receive induction training on manual handling of mortuary equipment. They shadow experienced staff in mortuary procedures before being signed off to work in the mortuary unsupervised.

When a body is admitted, security staff/funeral directors fill out the mortuary 'booking in register, place the body in the fridge, and complete a mortuary ID card with the deceased person's details. The card is placed on the outside of the fridge door. It is the APT's responsibility to check the ID card on the fridge door against the 'booking in register', and transfer the information to the mortuary register. The APT also checks the condition of the

body and writes the deceased's name and the date of admission to the mortuary on the whiteboard. A unique mortuary number is assigned to each body and the APT records the number on the mortuary ID card. The same process is followed for paediatric/perinatal cases with a separate mortuary register for these.

At the start of each working day, two APTs cross-check the information on the whiteboard against the paperwork, conduct a body count and check for same/similar names. When a same/similar name is discovered, an asterisk is placed next to the name in the mortuary register and highlighted, and then a red asterisk is written on the whiteboard next to the names. In addition, an orange same/similar name magnet is placed on the corresponding fridge door and an orange wrist tag on the body.

Bodies are released between set hours, Monday to Friday. Upon release, mortuary staff must confirm the identity of the deceased with the funeral director by checking at least three identifiers on the identification tags against the release paperwork, ID card and mortuary register. The funeral director and APT both sign the register upon release. Bodies are only released if the appropriate release form is provided (e.g. Coroners or Hospital form). If there are any discrepancies, mortuary staff will not release the body until the correct ID details are confirmed.

Viewings are arranged between the family and mortuary staff and are usually conducted in the afternoon. In exceptional cases (e.g. for religious reasons or to accommodate families traveling from far distances), they will be take place at other times, including outside normal working hours, and arranged ahead of time with mortuary staff. Staff carry a personal phone and there is a panic alarm in the event that they feel threatened or in danger if attending unaccompanied by a colleague.

The PM suite has three down-draft tables, two of which are height-adjustable. Each morning, before a PM examination takes place, the APT removes the bodies from the fridge and checks the identification details on the wrist tags against relevant paperwork. Once the Pathologist arrives, they carry out another identification check along with the APT. The Patholoigst conducts a thorough external examination of each body and records their findings, before giving permission to the APT to go ahead with evisceration of the first body.

Organs are dissected on a bench at the end of the table where the PM examination is conducted. This mitigates the risk of organs being returned to the wrong body. High-risk cases are conducted at the end of the day to limit exposure. The air-handling unit for the PM suite is serviced regularly and servicing records were observed to be up to date.

Histology samples taken during PM examination are cassetted in the mortuary and taken to the histology department by mortuary staff for analysis. After the analysis is completed, they are kept, reunited with the body or disposed of, according to the wishes of the family. In the

case of an organ for repatriation, the register book is marked and a ‘do not release’ magnet is put on the corresponding fridge door to mitigate the risk of a body being released with the organ having been returned.

Description of inspection activities undertaken

This was the third site visit inspection of the establishment (the last inspection took place in 2012). At the hub site, the inspection included a visual inspection of the body store, PM suite, viewing area, histology laboratory and satellite site where existing holdings of blocks and slides of PM tissue are stored.

Interviews with members of staff, a review of governance and quality documentation and traceability audits were also undertaken, as described below.

Audit trails were conducted on two hospital and one community body stored in the refrigerators. Body location and identification details on body tags were cross-referenced against the information in the booking in register, mortuary register, mortuary ID card, whiteboard location and paper records. Same/similar name processes were also checked.

An audit trail was also undertaken on three Coroner’s cases where histology samples had been retained following PM examination, one of these cases also removed a whole heart to be sent for specialist analysis. Relevant paper records, consent forms, and location of samples in histology were checked, as well as the procedures for recording disposal of samples.

The satellite site is a purpose-built archive facility. A review of the premises security, storage and traceability systems was undertaken which included an audit trail of archived blocks and slides taken from PM examination on their electronic management system. Details from tissue in storage were also taken and crosschecked against the information held on the database ordering system at the hub site.

No discrepancies were found during any of the audits conducted by the HTA.

A release of three bodies to funeral directors was observed during the inspection and processes were checked against SOPs. No discrepancies were found.

Inspection findings

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

Compliance with HTA standards

Premises, facilities and equipment

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and integrity of human tissue		
a) The premises are clean and well maintained	It was observed during inspection that the walls of the mortuary changing rooms and an area of the body store wall is peeling. Staff are unable to clean/disinfect the peeling walls effectively and despite repairs, the dampness continues to spread. **See, Advice item 7**	Minor

PFE2 There are appropriate facilities for the storage of bodies and human tissue		
e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of the upper or lower set range.	The establishment has purchased an alarm system, but this has not yet been installed; staff are monitoring temperatures during working hours to check they are in the required range. There is a risk that a fridge or freezer failure could occur out of hours and not be discovered in time to prevent decomposition of bodies. **See, Advice item 5**	Major

Advice

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

No	Standard	Advice
1.	C1 (d) and C2 (a)	The DI should consider updating the consent form for hospital PM examinations to include separate sections for organs and tissue, in case families wish to choose different disposal or retention options (see the HTA

		model consent form: https://www.hta.gov.uk/policies/post-mortem-model-consent-forms). The DI is also advised to update the PM consent training presentation to bring it into line with the revised codes and standards that were published on the 3rd April 2017, prior to conducting training /refresher training for staff.
2.	GQ1 (a)	Some mortuary standard operating procedures (SOPs) do not contain sufficient detail: the following SOPs should be amended to reflect current practice: **SOP HC-AC-48 :** include all definitions of HTARI categories, definition of a near-miss and update link in SOP to most recent HTA HTARI guidance: Guidance for reporting HTA Reportable Incidents (HTARIs) in the post mortem sector ; **SOP HC-MO-4.5 and SOP HC-MO-28.4**: state that a minimum of three identifiers must be checked (at least one unique) against release paperwork before releasing a body; **SOP HC-MO-6.4**: state that a thorough external examination of the body is carried out by the Pathologist prior to evisceration taking place.
3.	PFE1 (d)	The viewing room door leads to a storage area with a bank of fridges. This door is not lockable and presents a risk of visitors gaining access to the fridges and patient information. The DI is advised to assess this risk and take any mitigating actions that are identified.
4.	PFE2 (c)	It is rare that a body needs storage in the mortuary for more than 30 days; however, when this does occur, staff follow a documented procedure for moving the body into the 'isolation fridge'. This procedure does not state when bodies should be moved into long-term freezer storage. The HTA recommends that bodies should be moved into freezer storage at 30 days or sooner, depending on the condition of the body. The DI is advised to align procedures with the HTA's guidance set out on page 7 (paragraph 24) of its report on storage capacity and contingency arrangements in mortuaries: https://www.hta.gov.uk/sites/default/files/Capacity%20and%20Contingency%20Report%20Nov%2015.pdf In the event that a body cannot be moved into long-term freezer storage within the 30 days, the DI is advised to log the reason, make a note of the condition of the body and keep the situation under review in case alternative

		arrangements have to be made.
5.	PFE2 (e)	The DI is advised to incorporate regular documented fridge temperature checks out of hours to identify a fridge failure and mitigate the risk of accelerated decomposition of bodies. Training should be provided to staff responsible for checking the fridges. Once the new fridge alarms are installed, mortuary staff are advised to conduct regular documented tests of all fridges/freezers to ensure that the call out systems are working properly.
6.	PFE3 (a)	One of the instruments used for PM examination has a wooden handle. The use of porous material, such as wood can easily become contaminated and difficult to disinfect. Mortuary staff are advised to replace the wooden instrument with a more suitable one.
7.	PFE3 (a)	In relation to the shortfall above (PFE1 a), the DI is advised to liaise with the Trust's Estates Department to achieve the necessary repairs to the walls. He is also advised to monitor the dampness in the mortuary and take steps to prevent it from spreading to other areas if the repairs are delayed.
8.	PFE3 (a)	The trolley used in the body store is very heavy and difficult for staff to manoeuvre. Although the risk of manual handling injuries to staff using the trolley has been identified, it should be kept under review in case the risk increases.

Concluding comments

Staff at the establishment are committed and take pride in their work. They appear to have good communication with the Coroner, which helps mitigate any delays to release of bodies.

Despite the shortfalls, areas of good practice were identified:

- The DI has put together a very thorough consent training presentation on adult PM examinations, which includes reference to statutory and regulatory requirements.

- There is a section on the reverse of the body ID card for funeral directors/security staff to note any issues relating to the body they need to communicate to mortuary staff.

- To further mitigate the risk of releasing the wrong body, funeral directors must sign off paperwork one at time when collecting more than one body. There is also an SOP that details special arrangements for different faiths.

There are some areas of practice that require improvement, including one minor shortfall in relation to mortuary premises and one major shortfall in relation to monitoring of fridges. Advice was also given in regards to consent documentation, governance and quality systems, and premises, facilities and equipment.

The HTA requires the Designated Individual to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfall will be addressed, 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: 8 June 2017

Report returned from DI: 16 June 2017

Final report issued: 20 June 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: 12 September 2017

Appendix 1: HTA licensing standards

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

Consent

C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice

a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice.

b) There is a documented standard operating procedure (SOP) detailing the consent process.

c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice.

d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives.

e) Where consent is sought for tissue to be retained for future use, information is provided about the potential uses to ensure that informed consent is obtained.

f) The deceased's family are given an opportunity to change their minds and it is made clear who should be contacted in this event and the timeframe in which they are able to change their minds.

g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided.

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent

a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice.

b) Records demonstrate up-to-date staff training.

c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual.

d) Competency is assessed and maintained.

Governance and quality systems

GQ1 All aspects of the establishment's work are governed by documented policies and procedures

a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath. These include:

   i. post-mortem examination, including the responsibilities of Anatomical Pathology Technologists (APTs) and Pathologists and the management of cases where there is increased risk;

   ii. practices relating to the storage of bodies, including long term storage and when bodies should be moved into frozen storage;

   iii. practices relating to evisceration and reconstruction of bodies;

   iv. systems of traceability of bodies and tissue samples;

   v. record keeping;

   vi. receipt and release of bodies, which reflect out of hours arrangements;

   vii. lone working in the mortuary;

   viii. viewing of bodies, including those in long-term storage, by family members and others such as the police;

   ix. transfer of bodies internally, for example, for MRI scanning;

   x. transfer of bodies and tissue (including blocks and slides) off site or to other establishments;

   xi. movement of multiple bodies from the mortuary to other premises, for example, in the event that capacity is reached;

   xii. disposal of tissue (including blocks and slides), which ensures disposal in line with the wishes of the deceased person's family;

   xiii. access to the mortuary by non-mortuary staff, contractors and visitors;

   xiv. contingency storage arrangements.

b) Procedures on evisceration ensure that this is not undertaken by an APT unless the body has first been examined by the pathologist who has instructed the APT to proceed.

c) Procedures on body storage prevent practices that disregard the dignity of the deceased.

d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use.

e) There is a system for recording that staff have read and understood the latest versions of these documents.

f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity.

g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework.

h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff.

GQ2 There is a documented system of audit

a) There is a documented schedule of audits.

b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these.

c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks

a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised.

b) There are clear reporting lines and accountability.

c) Staff are assessed as competent for the tasks they perform.

d) Staff have annual appraisals and personal development plans.

e) Staff are given opportunities to attend training courses, either internally or externally.

f) There is a documented induction and training programme for new mortuary staff.

g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures.

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

a) 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.

b) There are documented SOPs for record management which include how errors in written records should be corrected.

c) Systems ensure data protection, confidentiality and public disclosure (whistle-blowing).

GQ5 There are systems to ensure that all untoward incidents are investigated promptly

a) Staff know how to identify and report incidents, including those that must be reported to the HTA.

b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents.

c) The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.

d) Information about incidents is shared with all staff to avoid repeat errors.

e) The establishment adopts a policy of candour when dealing with serious incidents.

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored

a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis.

b) 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.

c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register.

Traceability

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail

a) Bodies are tagged/labelled upon arrival at the mortuary.

b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records).

c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier.

d) There is system for flagging up same or similar names of the deceased.

e) Identity checks take place each time a body is moved whether inside the mortuary or from the mortuary to other premises.

f) There are procedures for releasing a body that has been in long term storage and is therefore not in the current register.

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings). The traceability system ensures that the following details are recorded:

   i. material sent for analysis on or off-site, including confirmation of arrival

   ii. receipt upon return to the laboratory or mortuary

   iii. the number of blocks and slides made

   iv. repatriation with the body

   v. return for burial or cremation

   vi. disposal or retention for future use.

h) There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary, (such as to the lab or another establishment), including record-keeping requirements.

T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.

a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete.

b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary.

c) Disposal is in line with the wishes of the deceased's family.

d) The method and date of disposal are recorded.

Premises, facilities and equipment

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue

a) The premises are clean and well maintained.

b) There is demarcation of clear, dirty and transitional areas of the mortuary, which is observed by staff and visitors.

c) There are documented cleaning and decontamination procedures and a schedule of cleaning.

d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access).

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access.

PFE2 There are appropriate facilities for the storage of bodies and human tissue

a) Storage arrangements ensure the dignity of the deceased.

b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity.

c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs.

d) Fridge and freezer units are in good working condition and well maintained.

e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range.

f) Temperatures of fridges and freezers are monitored on a regular basis.

g) Bodies are shrouded or in body bags whilst in storage.

h) There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods.

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored

a) Items of equipment in the mortuary are in a good condition and appropriate for use:
    i. fridges / freezers
    ii. hydraulic trolleys
    iii. post mortem tables
    iv. hoists
    v. saws (manual and/or oscillating)

b) Equipment is appropriate for the management of bariatric bodies.

c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually.

d) Staff have access to necessary PPE.

e) Where chemicals are used for preservation of tissue samples, there is adequate ventilation.

f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept.

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.