Site visit inspection report on compliance with HTA minimum standards

Salibury District Hospital

HTA licensing number

12047

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**

2 August 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 Salisbury District Hospital had met the majority of HTA standards, two minor shortfalls were found in relation to C1 and GQ6. These were in relation to a hospital consented post-mortem examination and the current practice for releasing bodies to funeral directors.

Particular examples of strengths and good practice are included in the concluding comments section of the report.The establishment was provided with advice and guidance about areas that could be improved further.

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 describes the third site visit inspection of the Salisbury District Hospital (the establishment), which is licensed to carry out post mortem (PM) examinations and the removal and storage of PM tissue for use for scheduled purposes under the Human Tissue Act 2004. The establishment undertakes approximately 400 PM examinations a year under the jurisdiction of HM Coroner for Wiltshire and Swindon. Very few adult hospital (consent) PM examinations are carried out, with only two having taken place in the last year. High risk cases, except tuberculosis (TB), are transferred to another HTA-licensed establishment. Consented paediatric cases are also transferred to another licensed establishment, after consent has been obtained by clinicians trained by staff from the receiving establishment using its consent forms.

During the inspection it was identified that the mortuary occasionally hosts surgical training courses, in collaboration with a local surgeon, which use bodies that have been donated for education and training related to human health. Advice has been provided to strengthen the governance surrounding this activity.

The inspection included a visual inspection of the mortuary, histopathaology laboratory, accident and emergency department (A&E) and maternity suite. The maternity suite was

visited to review the identification procedure for fetal remains and deceased infants. Interviews were held with a Bereavement Officer, Trainee Anatomical Pathology Technologist (APT), Laboratory Manager (Histology, Mortuary and Bereavement Services), Consultant Histopathologist, Medical Director (Desginated Individual).

This hospital's accident and emergency (A&E) department is an area where samples may be taken in cases of sudden unexplained infant death. Therefore, as part of the visual inspection, the area in the A&E department where removal of tissue takes place was visited and a brief discussion held with a Paediatric Nurse. The Paediatric Nurse demonstrated an understanding of the requirements of the Human Tissue Act 2004 and the establishment's governance systems, and the HTA was satisfied with the arrangements in place covering this activity. During the visual inspection a sudden infant death case was reviewed and samples removed had been documented in the medical notes.

The mortuary has 32 storage spaces in the main body store; which includes four freezer and four bariatric storage spaces. There is an overflow fridge area with racking which offers up to 12 spaces as well as super-bariatric storage. An additional unit offering up to 12 spaces is used primarily during the winter months. In a separate location near the body store, a further six spaces are available as both fridge and freezer storage. Fetuses and still born babies are transferred directly to the mortuary, which has a dedicated fridge for the storage of these.

Porters are responsible for transferring the bodies of adult and neonatal patients to the mortuary from hospital wards during and out of hours. On arrival, the porter completes the 'Hospital death register' for adults and the 'Neonatal Death Register' for fetuses and babies. The Coroner's contracted funeral directors transfer patients from the community to the mortuary during and out of hours, and complete the 'community death register', recording the full name of the deceased, date and time of arrival, valuables and address. Porters and funeral directors are required to print their initials against the relevant record in the respective register, to enable mortuary staff to identify who the deceased was transferred by in case of any problem. The identification of patients transferred out of hours is checked by mortuary staff the following day and measurements of height and weight are taken. The details of the deceased are transcribed from the register completed by the porter or funeral director into the mortuary register. All bodies are assigned a mortuary number and have a wrist band containing either the: full name, date of birth and hospital number (hospital patients) or full name, date of birth and address (community patients). A post mortem number is assigned to all patients undergoing a PM examination.

All mortuary refrigeration units, including the neonatal fridge, are connected to a continuous electronic monitoring system which sends a notification to staff members in the event that a temperature excursion occurs. However, the fridge alarm system is not tested and staff do not undertake daily check of temperatures and instead rely upon the electronic monitoring system to send a notification (advice item, 14). Bodies of deceased with the same or similar name are highlighted by placing a 'same or similar name' magnetic badge on the fridge door. A similar system is in place to alert staff if organs or tissue require repatriation with the body of the deceased.

The post-mortem suite has four dissection tables. Wet tissue and organs removed during the PM examination are placed in appropriate pots containing formalin. Organs for specialist examination are sent to other HTA-licensed establishments and wet tissue for histological examination is transferred by mortuary staff to the pathology laboratory, where it is placed into casettes. Staff working in the pathology laboratory receive notification of the wishes of the family once the Coroner's authority ends and ensure that tissue blocks and slides are disposed of sensitively; returned to the family or retained for a scheduled purpose. Mortuary

staff are informed if there are organs requiring repatriation with the body.

Traceability audits of three bodies were carried out; which included two adult and one padiatric body that had been released to the funeral director. Bodies were identified from the hospital and community registers and the mortuary register against the storage location of the patient. No discrepancies were identified. A further traceability audit was carried out of two bodies being stored for the scheduled purpose of education and training (advice item, 7). The consent forms for both cases were reviewed and demonstrated that appropriate consent was in place for their storage and use in education and training for human health.

A tissue traceability audit was carried out using the paper and electronic records relating to a hospital consented PM examination and a coroner's case. In the first case, 14 tissue blocks and 15 slides were created and retained for use for scheduled purposes in line with the family's wishes. However, upon review of the consent form, it became apparent that the family had consented to retention of the histology tissue blocks and slides, whilst also indicating that they should be disposed of (minor shortfall and advice item, 2).

In the second case, a whole brain and heart, were removed during the post-mortem examination and transferred for specialist examination. Evidence that the heart and brain were released to the funeral director in line with the family's wishes was seen. 12 tissue blocks and 16 slides were created following the coroner's PM examination; evidence of the family's wishes for the sensitive disposal of these samples were seen. However, a minor discrepancy was noted with regards to the number of blocks recorded on the electronic system in comparison to the paperwork for the case. This was a transcription error and all other records were traceable and confirmed that 12 tissue blocks had been created. At the time of the inspection, the establishment was awaiting confirmation that disposal of the tissue blocks and slides had taken place.

Inspection findings

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

Compliance with HTA standards
Consent

Standard	Inspection findings	Level of shortfall
C1	Upon review of a hospital PM consent during the HTA tissue traceability audit, it was identified that consent had been given for both retention of tissue blocks and slides for scheduled purposes and their disposal. There was no evidence that clarification was sought from the consent giver that they had given their consent to the retention of the blocks and slides. See advice item 2.	Minor

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail	The establishment's procedures require that funeral directors collecting the bodies of patients who have died in hospital must bring an 'authority to release' form before the patient can be released. However, funeral directors collecting bodies of those who have died in the community do not present any paperwork to mortuary staff, stating the body they have come to collect. Furthermore, mortuary staff and funeral directors rely on confirming the full name of the deceased only, and no unique identifiers are used, which increases the risk of releasing the wrong body.	Minor

Advice

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

No.	Standard	Advice
1.	C1	The DI is advised to devise a 'consent checklist' which could be referred to by staff seeking consent for a hospital PM examination. This checklist may contain key information that the staff member should inform the family member during the consent process.
2.	C1	The consent form for adult PM examination should be reviewed and the following should be added: 1) On page 2 under section '*Your choices for disposal of tissue blocks and slides'*, it should be made clear that tissue samples will be disposed of by the hospital once used for a scheduled purpose. 2) On page 3. clause four should be reworded. The statement: 'I want the hospital to lawfully dispose of any blocks and slides (this would be by incineration)' should be replaced with 'I do not consent to the samples being kept and I want the hospital to lawfully dispose of any blocks and slides (this would be by incineration)'. The DI is advised that staff seeking consent should undertake a thorough review of completed consent forms, which is carried with paediatric consent forms, to ensure there is no ambiguity surrounding the consent given. Clarification should be sought if the consent form has not been completed clearly.
3.	C3	Bereavement staff and a core group of clinicians are trained in seeking consent for adult hospital PM examinations. The DI is advised to consider annual refresher training for staff members to ensure that their skills in seeking consent for a hospital PM examination are kept up-to-date. This is particularly important, given the low number of hospital consented PM examinations.
4.	GQ1	The DI may wish to add the post mortem number to the mortuary register to enable staff to easily identify which patients have had a PM examination.
5.	GQ1	The DI is advised to review all procedures that involve identification of the deceased (i.e. receipt of a body, PM examination, release of a body, head and neck surgical training) to ensure that the procedures specify which identifiers should be checked. The HTA recommends a minimum of three identifiers, one of which should be unique to the deceased.
6.	GQ1	Viewings may ocassionally take place out of hours. A Clinical Site and Duty Mananger would be responsible for managing this process. The DI is advised to review this procedure to ensure it includes the procedure that the Duty Manager must follow during an out of hours viewing.
7.	GQ1	At the time of the inspection, two bodies with consent for storage and use for 'education and training relating to human health' were being stored in the mortuary for use in surgical training undertaken by surgeons attending a formal course which will take place in the PM suite. The procedure 'Organising Head and Neck Dissection', CP-M-MSOP-001, should set out who is responsible for identifying the deceased and removing them from storage.

		As course partcipants will have access to the mortuary, a code of conduct should be provided to them prior to the course so that they understand their responsibilities whilst working in the mortuary.This could also be provided to embalmers attending the mortuary.Separate risk assessments should also be carried out which consider health and safety risks for course participants as well as any mortuary staff present during the embalming of bodies.
8.	GQ2	The establishment is involved in carrying out audits to assess their compliance against HTA standards. A vertical audit had been carried out which followed a body from receipt through to release; however, the audit report did not provide sufficient evidence about what was reviewed or the findings. The DI is advised to ensure that the information that is being audited is clearly documented in the report.
9.	GQ3	The DI should consider providing refresher training to mortuary staff involved in releasing bodies to ensure that they understand procedure, CPM SOP 018, particularly, in relation to repatriation of organs to the body of the deceased.
10.	GQ3	Porters are trained in mortuary procedures and each porter has a competency checklist which is signed off by the APT providing the training. The current training for new porters does not include out of hours viewings and there is a reliance on more experienced porters being available during these times. Although out of hours viewings are rarely conducted, the DI is advised to consider including training for all porters to ensure they are aware of their responsibilities, particularly with regards to the identification of the deceased and transfer of the body to the viewing room.
11.	GQ7	During the review of the establishment's incident logs, two incidents were identified that should have been reported to the HTA. The DI is encouraged to contact the HTA if unsure whether a particular incident requires reporting, and to reports these, and any others that have occurred within the last 12 months.
12.	GQ8	The establishment has carried out a range of risk assessments taking into account health and safety risks as well as risks to the bodies and tissue in storage. The DI is advised to extend the scope of risk assessments to include other HTARI categories.
13.	PFE1	During the visual inspection of the body store and PM suite, cracks were noted in the flooring. Staff confirmed that the cracks were due to be filled and in future there are plans for the floor to be replaced. The DI is advised to monitor the condition of the floor once the cracks have been filled and to assess the infection risk for staff working in the mortuary.
14.	PFE3	Although the mortuary fridges and freezers are subject to continuous temperature monitoring, the DI is advised to consider the following: 1) Manual challenge of the alarm notification system to ensure that it is functioning correctly. The DI is advised to document routine alarm tests. 2) The temperature monitoring system is only checked if there is a temperature excursion. The DI is advised that temperature monitoring system should be reviewed regularly to ensure it is functioning correctly; this could be carried out daily.

Concluding comments

The establishment's staff comprises a small team that have a good working relationship. Several areas of good practice were noted including:

- The management and care of mothers who have suffered pregnancy loss. The maternity suite has dedicated rooms to accommodate bereaved families following a pregnancy loss. Mortuary, maternity and portering staff work together to arrange for parents to view their baby in the maternity suite.

- The bereavement team are located in the mortuary, which means that staff work closely and effectively with one another.

- Actions arising from audits have a robust follow up as part of the Trust's clinical effectiveness review.

- The Lead APT reviews all paediatric consent forms to ensure that they have been completed properly before babies or fetuses are transferred for PM examination to another HTA licensed establishment.

There are some areas of practice that require improvement, including two minor shortfalls in relation to standards C1 and GQ6. The HTA has given advice to the Designated Individual on a range of issues to make further improvements.

The HTA requires that the Designated Individual addresses the shortfall 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: 16 August 2016

Report returned from DI: 23 August 2016

Final report issued: 2 September 2016

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: 20 October 2016

Appendix 1: HTA standards

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

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

Governance and quality system standards
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process
• Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include: 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 or tissue taken during post mortem examination are fully traceable, including blocks and slides. The traceability system ensures that the following details are recorded:
    - material sent for analysis on or off-site, including confirmation of arrival
    - receipt upon return to the laboratory or mortuary
    - number of blocks and slides made
    - repatriation with a body
    - return for burial or cremation
    - disposal or retention for future use.
- Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.

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

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

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

- All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed.

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

Premises, facilities and equipment standards
PFE1 The premises are fit for purpose
• There is sufficient space for the activities to be carried out. • Refrigerated storage units are in good working condition and well maintained. • Surfaces are made of non-porous materials. • The premises are in reasonable condition (structure and cleanliness of floors, walls, entranceways). • The premises are secure (e.g. there is controlled access to bodies, tissue, equipment and records).
PFE 2 Environmental controls are in place to avoid potential contamination
• There is clear separation of clean, transitional and dirty zones (e.g. doors, floor markings, signs). • There is appropriate PPE available and routinely worn by staff. • There is adequate critical equipment and/or PPE available for high risk post mortems. • There are documented cleaning and decontamination procedures. • There are documented cleaning schedule and records of cleaning and decontamination.
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.
• There is sufficient capacity for storage of bodies, organs and tissues. • Temperatures of fridges and freezers are monitored on a regular basis. • There are documented contingency plans in place should there be a power failure, or overflow. • Bodies are shrouded whilst in storage. • There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary (e.g. lab, other establishment), including record-keeping requirements.
- There are written agreements in place with any external parties (e.g. undertaker, or courier) who transport bodies and/or tissue behalf of the establishment (laboratory or mortuary).

  (Note that coroners usually have their own agreements with external parties for transportation bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases.)

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

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

(Note: These records may be held by the mortuary or centrally by the Trust, e.g. Estates Department.)

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- There is a documented Trust or mortuary/laboratory policy for the disposal of human tissue, which reflects the requirements of the HTA code of practice on disposal.
- There are documented procedures for disposal of human tissue, including blocks and slides.

D2 The reason for disposal and the methods used are carefully documented

- There are systems in place that ensure tissue is disposed of in accordance with the documented wishes of the deceased person's family.
- Disposal records include the date, method and reason for disposal.
- Tissue is disposed of in a timely fashion.

  (Note: this means that tissue is disposed of as soon as reasonably possible once it is no longer needed, e.g. when the coroner's or police authority ends or consented post-mortem examination is complete.)

Appendix 2: Classification of the level of shortfall

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

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

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.