Site visit inspection report on compliance with HTA minimum standards

St Helier Hospital

HTA licensing number 12345

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 January 2017

Summary of inspection findings

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

The HTA found that St Helier Hospital (the establishment) had met all of the HTA standards.

Advice and guidance has been given in relation to standards on consent, governance and quality systems and premises, facilities and equipment.

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

The HTA's regulatory requirements

The HTA must assure itself that the DI, Licence Holder (LH), premises and practices are suitable.

The statutory duties of the DI 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 the activities carried out at St Helier Hospital (the establishment), whose licensing arrangements cover St Helier Hospital (the hub) and Epsom Hospital (the satellite). The Designated Individual (DI) is a Consultant Histopathologist; the Corporate Licence Holder (CLH) is Epsom and St Helier University Hospital NHS Trust, with the Chief Executive acting as the named contact (CLHc).

Epsom and St Helier University Hospitals NHS Trust is a large teaching hospital trust with a wide range of specialities and a 24-hour accident and emergency (A&E) department within each of its two hospitals. The pathology laboratory services at the Epsom site are operating under the Trust's pathology network, and provides services to Epsom and St Helier Hospitals.

St Helier Hospital – the hub

At the hub, licensable activities take place in the mortuary and the A&E Department.

The mortuary is staffed by four full-time Anatomical Pathology Technologists (APTs): the mortuary manager; deputy lead APT; senior APT; and one trainee APT, all of whom work across both sites. There is a member of mortuary staff on call at all times.

The main mortuary facility is located at St Helier's Hospital, where around 295 post-mortem (PM) examinations are undertaken per annum. The majority of these are conducted at the request of the HM Coroner for Sutton, including a number of Home Office/forensic examinations. In addition, around five consented adult PM examinations are undertaken each year. Perinatal/paediatric PM examinations are not conducted on site. Perinatal cases are sent to St George's Hospital and paediatric cases are sent to Great Ormond Street Hospital. High-risk PM examinations are not performed at the establishment.

The body store consists of 54 refrigerated spaces. There are eight permanent freezer spaces and 4 refrigerated spaces suitable for bariatric bodies, including four super bariatric spaces. In addition, there is a dedicated storage facility for six perinatal bodies. There are visual indicators on the fridges and fridge trays and a marker recorded in the mortuary register to indicate same/similar names, 'do not release' and if tissue is to be returned to a body before release.

A temporary cold storage system was purchased by the trust to provide additional storage capacity for up to 12 bodies, and this is located in the PM suite. The temperature is recorded manually every day in the morning and afternoon. In addition, there is an additional temporary storage system at the satellite site. Each evening, staff check that there are at least five spaces available in the hub (see Advice, item 9). In the event of both sites approaching capacity, a contingency plan is in place with two contracted funeral directors, subject to a formal contract, which is held by the chaplaincy service.

The body store is temperature monitored, with an alarm linked to the Trust's BOLD system, which connects to the switchboard when temperatures deviate outside the expected range. Switchboard then alerts the on-call technician along with the on-call maintenance staff. This system is subject to regular testing.

The post mortem suite consists of six PM tables and it is usual for four or five PM examinations to take place in one session. There is one dissection bench in the centre of the room and each case is completed before the next begins to mitigate the risk of organs being placed into the wrong body. The pathologist always undertakes an external examination of the body prior to evisceration for a consented adult PM; however, this is not always the case for routine coronial PMs (see advice item 5). However, there are procedures in place that set out the circumstances in which evisceration should not proceed without prior examination of the body by the pathologist.

Staff have access to personal protective equipment (PPE) when conducting routine PM examinations. The PM tables are not downdraft and the mortuary ventilation records were not available at the time of the inspection, however an official test was scheduled to take place after the inspection (see advice item 10).

The entrance to the mortuary used by funeral directors is screened from public view and CCTV monitors entry and exit points. Lone working does occur during and out of hours. However, there are procedures and security arrangements in place to provide protection for staff.

Checks, including condition of the body and identification of the deceased, are carried out on all bodies prior to PM examination, moving a body within the body store, the viewing of a

body or release of a body. When a body is received into the mortuary from the hospital, it is brought by the porters and checked in by mortuary staff using the patient's hospital number and other identifiers. When a body is received from the community, it is brought by funeral directors. All bodies are assigned a unique mortuary number when they are checked in.

On release of bodies, mortuary staff must confirm the identity of the deceased by checking the identification tags, which contain the unique mortuary identifier and name, against the release paperwork before releasing the body (see advice item 4). The funeral directors do their own independent check. If there are any discrepancies, mortuary staff will not release the body until the correct identification details are confirmed.

Consent for adult hospital PM examinations is sought primarily by the clinician who was treating the deceased before they died. They first discuss the request for a PM examination with a pathologist, who can advise on its scope and answer any questions they may have. All those involved in seeking consent are sufficiently trained and are familiar with the forms used to record consent and the patient information leaflets used to support the consent seeking process.

Tissue and organs are occasionally sent offsite for specialist examination. Specimens are taken by a specific courier company to either King's College Hospital NHS Foundation Trust (brains) or St George's University Hospital NHS Foundation Trust (hearts). Samples sent for toxicological analysis are transported by specific courier companies once a week to Imperial Healthcare NHS Trust (Charing Cross).

Stillbirths are transferred from the maternity department to the mortuary as soon as possible, but in consideration of the needs and wishes of the parents. The bereavement midwives are familiar with the requirements of the Human Tissue Act 2004 (HT 2004) and have a documented consent procedure to follow, which reflects legal requirements. The person giving their consent is allowed the opportunity to change their mind within a 24-hour window and can call the bereavement services on a direct line if they change their mind.

Epsom Hospital – the satellite

The premises at the satellite site operate solely as a body store. The mortuary contains refrigerated storage, a viewing room and a decommissioned PM room, which currently holds a temporary storage unit; this is usually unused but is available should the need arise. One member of staff is located permanently at the body store with the four remaining staff members shared across both sites.

The body store consists of 60 refrigerated spaces. There are no bariatric spaces but two chiller blankets suitable for bariatric bodies are available. One bank of fridges can be converted into four freezer spaces. There is a designated bank of fridges for paediatric/perinatal bodies. Temperature monitoring is similar to that of the hub, with an alarm linked to the Trust's BOLD system.

The Epsom site only receives bodies from the hospital wards or from the St Helier site when the mortuary has reached capacity. The procedures for receipt and release of bodies are common across the sites.

The inspection process

This was the first inspection of the establishment since its licensing arrangements were changed. Epsom and St Helier Hospitals previously held separate HTA licences but, following the merger of pathology services in 2012, Epsom became a satellite site on the St Helier

licence in 2013. (Previous inspections of the St Helier site took place in 2009 and 2012 and of the Epsom site in 2010). This was a routine inspection to assess whether the establishment is continuing to meet the HTA's standards and to provide the HTA with assurance about the suitability of the premises and facilities.

The inspection timetable was developed after consideration of the establishment's previous inspection reports, compliance update information and discussions with the DI. It included a visual inspection of the body store at both sites, PM suite, viewing areas, and the A&E departments. Interviews were held with the DI; Persons Designated (Mortuary Manager/APT and Consultant Obstetrician); a trainee APT; a senior APT, Pathology Quality Manager and the Coroner's Officer. A thorough review of governance and quality documentation was also undertaken.

During the inspection, the release of three bodies to contracted funeral directors was observed. Processes were checked against SOPs and no discrepancies were found. However there were some inconsistencies with identification checks that have not been properly documented in the SOPs (see advice item 6).

The HTA also conducted audit trails on three bodies stored in the refrigerators at the St Helier Hospital site and two bodies stored at the Epsom Hospital site. Body location and identification details on body tags were cross-referenced against the information on the fridge doors and whiteboard and in the mortuary book (St Helier site) and mortuary admissions book (Epsom site). No discrepancies were found.

Vertical traceability audits were carried out on tissue removed during three PM examinations (one adult hospital consented and two adult Coronial). Paper records (adult hospital consent form, Coroner's form for wishes of the deceased and PM histology request forms), were compared to the number of blocks and H&E-stained slides held at the St Helier site (coronial PM) and at the Epsom site (hospital consented PM). A traceability audit was also conducted on a whole organ that was sent from the hub for analysis and disposal at another HTA licensed establishment. No discrepancies were found.

The A&E Department at both St Helier Hospital and Epsom Hospital has procedures for dealing with cases of sudden unexpected death in infants (SUDI) under coronial authority. There are robust procedures in place and a thorough SUDI pack, including a checklist of all necessary actions (e.g. removal of blood, CSF, biopsies), is present in the resuscitation areas where SUDI removal takes place. The resuscitation areas are spacious, secure and ensure the dignity of the deceased.

Materials held for the police

Under s39 of the Human Tissue Act 2004, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' audit of tissue held under police authority, that police exhibits held on HTA licensed premises should be included within the regular HTA inspection process, police holdings stored in the PM suite were reviewed by the HTA during the inspection. Any findings in relation to police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the HT Act.

Inspection findings

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

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
1.	C1	The HTA logo currently appears on the hospital's consent form for PM examinations. The HTA does not permit the use of its logo, as it may imply the involvement of the HTA in the creation of an establishment's documents, policies and procedures or be incorrectly construed as endorsement by the HTA or an indicator of quality. It should, therefore, be removed from the form.
2.	C1	The current consent policy refers to "the highest ranking family member" (paragraph 5.5 of the policy); this is not an accurate reflection of the legal requirements relating to consent, and should be amended to refer to the hierarchy of qualifying relationships.
3.	GQ1	There are currently no Persons Designated in either A&E department. To enable the DI to maintain oversight of licensed activities taking place in those areas, the DI is advised to identify a suitable person to act in this capacity, to keep staff up to date on HTA-related matters and to report back to the DI on any issues or concerns. The HTA should be notified of their contact details.
4.	GQ1	Currently, the identifiers that are checked by mortuary staff on receipt and release of bodies are not consistent and are not fully documented in the mortuary SOPs. The DI is advised to include in procedural documentation the details of the identifiers that must be routinely checked, to ensure consistent practice across the team.
5.	GQ1	In some cases, evisceration takes place before the pathologist has undertaken an external examination of the body. This practice is contrary to professional guidance issued by the Royal College of Pathologists on the conduct of PM examinations ('Standards for Coroners' pathologists in post-mortem examinations of death that appear not to be suspicious'). https://www.rcpath.org/resourceLibrary/standards_coronerspost-mortem_feb14-pdf.html External checking by a pathologist prior to evisceration will be mandatory from 1st April 2017 when the HTA's revised standards come

		into force, and the DI is advised to incorporate this into documented SOPs and into practice with immediate effect as planned.
6.	GQ4	Throughout its documentation, the unique identifier used by mortuary staff is referred to by different names: the unique mortuary number and the mortuary admission number. The DI is advised to settle on a term and adopt it throughout for consistency.
7.	GQ7	It is currently unclear if porters are aware of what kind of incidents are reportable to the HTA and the internal reporting process should one of these occur. The DI is advised to ensure that porters are fully trained in incident reporting so that they recognise when and to whom to report an HTA-reportable incident.
8.	GQ8	There is a wide range of risk assessments of mortuary activities; however, not all risks to the deceased have been considered. The DI is advised to review the current suite of risk assessments to ensure they contribute to the prevention of an HTA reportable incident and include risk assessments for all HTARI classifications.
9.	PFE1	Mortuary capacity at the hub, although currently being managed, poses a major risk. The DI is advised to escalate mortuary capacity to senior management, with a view to its inclusion in the Trust's corporate risk register.
10.	PFE2	During the inspection, staff were unclear about whether the ventilation in the post mortem room was subject to regular checks to ensure that it is working effectively. The DI is advised to determine whether tests on air changes rates have been undertaken and to review the results of these tests to ensure that the number of air changes remains appropriate. If they have not been undertaken, the DI is advised to make the necessary arrangements.

Concluding comments

The mortuary team are committed and conscientious. They take great pride in their work and have the interests of the bereaved and care of the deceased as their priority. Many areas of good practice were observed throughout the inspection, some examples of which are given below.

- The mortuary at St Helier Hospital and the body store at Epsom Hospital both have a mortuary grid to indicate occupancy, which is an effective method of maintaining oversight of storage capacity. It is updated every time a body is received or released.
- There are extensive monthly audits of mortuary practices.
- The quality manager offers a 'Pathology Audit Workshop' for all Trust staff, along with an 'Induction to Quality' course teaching individuals and teams how to conduct appropriate and efficient audits and the importance of quality with regards to risk and audit.

- There is a very strong relationship between the mortuary team and portering staff, which has resulted in overall efficient procedures and low incident numbers.

The HTA has given advice to the Designated Individual with respect to Governance and Quality Systems and Premises, Facilities and Equipment standards.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 06/02/2017

Report returned from DI: 20/02/2017

Final report issued: 21/02/2017

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below/. 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.