Site visit inspection report on compliance with HTA minimum standards

Lister Hospital

HTA licensing number 12110

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**

15 November 2016

Summary of inspection findings

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

Although the HTA found that Lister Hospital (the establishment) had met the majority of the HTA standards, one minor shortfall was found in relation to autopsy practice and one minor shortfall was found in relation to the management of licensed activities taking place in the Maternity and A&E Departments.

Particular examples of strengths and 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, 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

Lister Hospital – the establishment

For the purposes of HTA licensing, the establishment is Lister Hospital. It was previously a satellite site of the Queen Elizabeth II Hospital; however, there have been no mortuary services there since 2014. The DI is a Consultant Histopathologist; the LH is East and North Hertfordshire NHS Trust with the Chief Executive Officer (CEO) acting as the named corporate licence holder contact (CLHC). The Persons Designated (PDs) on the licence are the Mortuary and Bereavement Services Manager and the Histopathology Laboratory Manager.

Lister Hospital offers general and specialist medical services. The pathology laboratory services are operating under The Pathology Partnership, which is a joint venture between six NHS Trusts in the East of England (including the East and North Hertfordshire NHS Trust). Licensable activities take place in the mortuary, Histopathology Laboratory, Maternity and Accident and Emergency (A&E) Departments.

The mortuary has a body store, post mortem (PM) suite, changing facilities, sluice, viewing room and mortuary office which is shared between the mortuary and bereavement services. There is a small transition area between the changing rooms and the PM suite which has been risk assessed following a shortfall identified on a previous HTA inspection.

The body store contains a fridge with capacity for 69 bodies (including four bariatric bodies), freezer capacity for four bodies and a designated fridge storage area for fetuses, stillbirths, neonates and children. There is also a separate fridge storage facility for products of conception.

All fridges and freezers in the body store are centrally temperature monitored. An alarm linked to the hospital's switchboard alerts the estates department, which then contacts the mortuary or the Anatomical Pathology Technologist (APT) on call if the temperature goes outside the set range. The temperature of the fridges and freezers is also monitored manually during the working week. There is regular testing of the fridges and freezers, demonstrated by the test record sheet.

The PM suite is suitable for cases up to category 3 (category 4 high-risk cases are transferred to UCLH Foundation Trust for PM examination), and contains two downdraft tables. The mortuary ventilation system provides 13 air changes per hour, demonstrated by maintenance records. There is also a ceramic PM table, which is in good condition.

The entrance to the mortuary used by contracted funeral directors is screened from public viewing and CCTV monitors entry and exit points. Despite the mortuary being suitably staffed, lone working does occur, both during normal working hours and out of hours. However, there are procedures and security arrangements in place to provide protection for staff and these have been risk assessed.

The mortuary is staffed by three full time APTs and a trainee APT. There is a member of mortuary staff on call at all times.

On average, around 500 routine coronial adult PM examinations are undertaken each year under the authority of HM Coroner for Hertfordshire. In addition, second (defence) PM examinations, Home Office PM examinations and, very rarely, consented adult PM examinations are performed at the establishment each year. Paediatric and perinatal cases are referred to Addenbrookes Hospital, but consent is obtained by staff at Lister Hospital.

Before a PM examination, bodies are placed in the fridge bays that are connected to the PM suite. There is a running order, so tissue is not removed from more than one body at a time. The cause of death form is used as a record of consent from the coroner and the mortuary has implemented a two-person check of the identity of the deceased before evisceration takes place. 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 shortfall against standard GQ1*).

Tissue samples taken during PM examination are sent to the Histopathology Laboratory for processing and analysis. Whole organs and tissue samples are frequently sent off-site for examination at other HTA-licensed premises. These include hearts (sent to St George's University Hospital NHS Foundation Trust) and brains (sent to King's College Hospital NHS Foundation Trust) for specialist examination. Toxicology samples are sent to Northern General Hospital in Sheffield.

Checks of the condition of the body and the identification of the deceased are carried out 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 in by mortuary-trained porters and checked in by mortuary staff using the electronic mortuary database ('MortBase') and a pro forma is placed on the front of the fridge in which the deceased is placed. If a body is received overnight by the porters, their name is written in red on the mortuary board and they are formally checked in by mortuary staff in the morning. When a body is received into the mortuary from the community, it is brought in by contracted funeral directors and checked in by the mortuary staff using a blue form. A unique PM

identification number is allocated if a body is due to have a PM examination; however, neither hospital nor community deaths are allocated a unique mortuary ID *(see advice item 1*).

Mortuary staff use visual indicators on the body store whiteboard to highlight same/similar name, 'do not release', danger of infection, the presence of an implanted device and if tissue is to be returned to the body before release. These visual indicators have corresponding coloured wrist tags, which are placed on bodies.

On release of bodies, mortuary staff must confirm the identity of the deceased with the funeral directors by checking at least three identifiers on the identification tag against the release paperwork before releasing the body. Funeral directors rarely collect bodies out of hours and bodies are always released by APTs. If there are any discrepancies, mortuary staff will not release the body until the correct identification details are confirmed.

Bereavement officers are trained to take consent for adult hospital PM examinations as well as paediatric and perinatal PM examinations. Consent for paediatric and neonatal PM examinations is taken within the Maternity Department by bereavement midwives. Cascade training is in place to train mortuary staff to enable them to take consent. The clinician who was treating the deceased is also involved; they first discuss their request for a PM examination with a pathologist, who can advise on scope and can answer any questions the family 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 booklet used to support the consent seeking process.

Stillbirths and pregnancy remains are transferred from the Maternity Department to the mortuary as soon as possible, in consideration of the needs and wishes of the parents. Products of conception are stored in a fridge in the department pending transfer to the mortuary within 24 hours. The temperature of the fridge is recorded manually by a max and min thermometer and logged. The set temperature range of the fridge is set out in the Maternity fridge SOP (*see advice item 7*). The bereavement midwives are familiar with the requirements of the Human Tissue Act 2004 and have a documented consent procedure to follow, which reflects legal requirements. Maternity Department staff are aware of the HTA's guidance on the disposal of pregnancy remains following pregnancy loss or termination and have implemented this guidance in their practice.

The A&E Department at Lister 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 area where SUDI removal takes place. The resuscitation area is spacious, secure and ensures the dignity of the deceased.

The inspection process

This was the first inspection of the establishment since it became the main licensed premises rather than a satellite of Queen Elizabeth II Hospital; as a satellite, it was inspected in 2009 and 2013. It was a routine inspection, to assess whether the establishment is continuing to meet the HTA's standards and also 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. The inspection included a visual inspection of the mortuary, the PM suite, the viewing area, the Histopathology Laboratory, the Maternity Department and A&E Department. Interviews were conducted with the DI, the Mortuary and Bereavement Services Manager (PD), an APT, a Coroner's Officer, Histopathology Laboratory Manager (PD) and the CLHC. A thorough review of governance and quality documentation was also undertaken.

The HTA conducted identification audit trails on three bodies stored in the fridges within the mortuary. Body location and identification details on body tags were cross referenced against the information on the fridge doors, whiteboard and electronic mortuary register. No discrepancies were found.

Vertical traceability audits were carried out on tissue removed as part of three coronial adult PM examinations. Paper and electronic records (coroner's form for wishes of deceased, PM histology request forms, MortBase data entries) were compared to the number of blocks and stained slides in the Histopathology Laboratory. Discrepancies were noted in two out of three cases. In one case, the number of samples removed had been entered onto the histopathology request form but not into the database. In another case, the number of samples recorded on the histopathology request form was different from the number of samples on the database (*see advice item 3*).

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

Two shortfalls were found in relation to governance and quality systems and premises, facilities and equipment.

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1	In some cases, evisceration takes place before the pathologist has undertaken an external examination of the body. This practice has been 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'). External checking by a pathologist prior to evisceration will be mandatory in the HTAs new codes and standards from April 2017.	**Minor**

Standard	Inspection findings	Level of shortfall
GQ1	The DI does not have sufficient oversight of all areas where licensable activities are occurring as there are currently no PDs in the Maternity and A&E Departments.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	The DI is advised to consider assigning a unique identifier for each body that enters the mortuary. Currently, only bodies undergoing post mortem receive a unique identifier.
2.	GQ1	The DI is advised to appoint a Persons Designated (PD) to oversee licensable activities undertaken in the Maternity and A&E departments. The appointment of new PDs will facilitate communication about HTA relevant issues, reporting back to the DI on any issues and concerns and prompt reporting of HTARIs.
3.	GQ2	The DI is advised to add a vertical traceability audit of tissue taken during PM examination to the internal audit schedule.
4.	GQ7	The establishment works to the Trust's procedure for reporting untoward incidents, which contains a section on reporting HTA reportable incidents (HTARI). The DI is advised to develop guidance for staff, or a mortuary-specific SOP, outlining who can report an incident, the types of incident to report, the process that should be followed, who should report in the absence of the DI and within what timeframe they should be reported (five days).
5.	GQ7	Local incident reporting and recording had only just been set up. The DI is advised to identify all 'local' incidents (outside the DATIX system) and discuss these at meetings.
6.	GQ8	The DI is advised to standardise the current suite of risk assessments and remove duplication.
7.	PFE3	The temperature of the fridge in the Maternity Department is manually recorded from Monday to Friday and checked for trends. The DI is advised that staff on duty should monitor the temperature of the fridges at weekends to mitigate any risk resulting from temperature fluctuations. In addition, the DI is advised to modify the maternity SOP and to include this in the mortuary quality manual to reflect current practice in the Maternity Department.
8.	PFE3	The DI is advised, if possible, to obtain printouts of temperature charts from Estates on a regular basis to identify trends and signs of potential fridge/freezer failure. The Estates Manager could also be included at meetings.

Concluding comments

There were many areas of good practice that were observed throughout the inspection:

- There are many different meetings in place such as governance, bereavement and mortuary meetings, which incorporate various departments and whose agendas often include items taken from HTA newsletters.
- Good working relationships are in place between the mortuary and the coroner's office, due largely to the approach taken by the Coroner, who has established a system whereby APTs and coroner's officers can observe each others' work in their respective workplaces. There is also frequent communication between the coroner's office and the Histopathology Laboratory, with regard to tissue samples.
- The coroner's office keeps its own register of all samples retained at PM examination, so this can be regularly matched against the mortuary register.
- The coroner's office sends the original family's wishes forms to the Histopathology Laboratory and keeps its own copy for reference, helping to minimise the risk of error.
- The products of conception pathway is clearly displayed in the Maternity Department and in the mortuary.
- There is extensive external training available for mortuary staff on a variety of topics related to mortuary and bereavement services.
- The Trust's CEO takes and active interest in the mortuary and is very supportive of the work it undertakes.

There are a number of areas of practice that require improvement, including two minor shortfalls. The HTA has given advice to the Designated Individual with respect to Governance and Quality Systems and Premises, Facilities and Equipment standards.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

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

Report sent to DI for factual accuracy: 13 December 2016

Report returned from DI: 12 January 2017

Final report issued: 13 January 2017

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 27 February 2017

Appendix 1: HTA standards

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

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

Governance and quality system standards

GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process

- Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include:
    - post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases
    - record keeping
    - receipt and release of bodies, which reflect out of hours arrangements
    - lone working in the mortuary
    - transfer of bodies and tissue (including blocks and slides) to other establishments or off site
    - ensuring that tissue is handled in line with documented wishes of the relatives
    - disposal of tissue (including blocks and slides)

  (Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)
- Policies and procedures are regularly reviewed (for example, every 1-3 years).
- There is a system for recording that staff have read and understood the latest versions of these documents.
- Deviations from documented SOPs are recorded and monitored.

GQ2 There is a documented system of quality management and audit

- There is a quality manual which includes mortuary activities.
- Policies and SOPs are version controlled (and only the latest versions available for use).
- There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits).
- Audits include compliance with documented procedures, records (for completeness) and traceability.
- Audit findings document who is responsible for follow up actions and the timeframe for completing those actions.
- Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why.
- There is a complaints system in place.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Staff are appropriately trained/qualified or supervised.
- Staff have annual appraisals.
- Staff are given opportunities to attend training courses, either internally or externally.
- Attendance by staff at training events is recorded.

- There is a documented training programme for new mortuary staff (e.g. competency checklist).

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

- There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.
- There are documented SOPs for record management.

GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).
- Organs and tissue samples taken during PM examination are fully traceable.
- Details of organs retained and the number of wax blocks and tissue slides made are recorded.
- The traceability system includes the movement of tissue samples between establishments.
- Details are recorded of tissue that is repatriated or released with the body for burial or cremation.
- Regular audits of tissue storage and traceability are undertaken to ensure compliance with operational procedures; tissue samples found which are not being stored with consent are disposed of with reference to the family's wishes.
- Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.

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

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

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

- All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed.
- Risk assessments include risks associated with non-compliance with HTA standards as well as health and safety risks.
- Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years.
- Risk assessments include how to mitigate the identified risks; this includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- There is sufficient space for the activities to be carried out.
- Refrigerated storage units are in good working condition and well maintained.
- Surfaces are made of non-porous materials.
- The premises are in reasonable condition (structure and cleanliness of floors, walls, entranceways).
- The premises are secure (e.g. there is controlled access to bodies, tissue, equipment and records).

PFE 2 Environmental controls are in place to avoid potential contamination

- There is clear separation of clean, transitional and dirty zones (e.g. doors, floor markings, signs).
- There is appropriate PPE available and routinely worn by staff.
- There is adequate critical equipment and/or PPE available for high risk post mortems.
- There are documented cleaning and decontamination procedures.
- There are documented cleaning schedule and records of cleaning and decontamination.

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.

- There is sufficient capacity for storage of bodies, organs and tissues.
- Temperatures of fridges and freezers are monitored on a regular basis.
- There are documented contingency plans in place should there be a power failure, or overflow.
- Bodies are shrouded whilst in storage.
- There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

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

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

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

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

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

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

Disposal Standards

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

- There is a documented Trust or mortuary/laboratory policy for the disposal of human tissue, which reflects the requirements of the HTA code of practice on disposal.
- The policy states the position with regard to the retention and use of microscope slides, and in particular that tissue slides must be disposed of or returned to the family in accordance with their wishes if consent is not obtained for their continued storage and future use once the PM has concluded.

D2 PM tissue is disposed of if consent is not given for its storage and use for scheduled purposes

- There are documented procedures for disposal of human tissue, which include methods of disposal for whole organs, wet tissue, wax blocks and microscope slides.
- Tissue is disposed of in accordance with the documented wishes of the deceased person’s

family.

- Disposal details of organs and tissue blocks are recorded, including the date and method of disposal.
- There is a rolling programme of tissue disposal that ensures that tissue, including microscope slides, is disposed of in a timely fashion when it is no longer needed for the purposes of the Coroner or to determine the cause of death.

Appendix 2: Classification of the level of shortfall

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

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

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   (1) A notice of proposal being issued to revoke the licence

   (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or
   - indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
   - has the potential to become a critical shortfall unless addressed

   or

   A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

   In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.