Site visit inspection report on compliance with HTA minimum standards

Haringey Public Mortuary

HTA licensing number 12263

Licensed under the Human Tissue Act 2004 for the

- **making of a post mortem examination; 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**

26 August 2015

Summary of inspection findings

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

Although the HTA found that Haringey Public Mortuary (the establishment) had met the majority of the HTA standards, five minor shortfalls were found against standards on Governance and Quality Systems (GQS), Premises Facilities and Equipment (PFE) and Disposal (D). The minor shortfalls were in relation to: (i) the practice of eviscerating the body prior to the arrival of the pathologist; (ii) documenting audit findings; (iii) documenting non – compliances and follow up procedures (iv) contingency plans for the storage facilities; and (v) disposal of post mortem tissue. Advice has been given on matters across the range of standards.

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 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

Haringey Public mortuary (the establishment) has been licensed by the HTA since February 2009 for the making of a post-mortem (PM) examination and storage of bodies of the deceased and relevant material for use for scheduled purposes. The corporate licence holder is the Local Authority, Haringey Council.

The establishment conducts approximately 500 adult PM examinations each year; the vast majority of which are under the authority of HM Coroner, North London, as well as Home Office and defence (second) PM examinations. The establishment has recently upgraded the mortuary facilities to support Category III PM examinations and carries out approximately one high-risk PM examination a week.

Bodies are brought in by funeral directors instructed by the coroner's office. Bodies have wrist tags attached by the police or funeral director. The establishment uses a series of forms and maintains a database to record the details of body admission, PM examination, histology details and release to a funeral director.

The body store contains 41 refrigerated spaces; five of these can accommodate bariatric bodies. The coroner's office has a contingency arrangement with a local funeral director in case of fridge failure. There are 12 freezers spaces for long-term storage. At the time of inspection, it was noted that the freezers were reaching capacity and there were no contingency arrangements in place for long-term storage of bodies (minor shortfall, PFE3).

Refrigerators are alarmed and in the event of failure the alarm will sound locally. Refrigerator and freezer temperatures are monitored and recorded by mortuary staff on working days only. There is no out-of-hours temperature monitoring or call-out alarm system in place, and the establishment depends on the funeral directors bringing the bodies in the mortuary over

the weekend to notify the on-call APT in the event of a fridge failure. At the time of inspection, the establishment was in the process of installing an automated temperature monitoring and out-of-hours call-out alarm system.

Upon arrival, information (such as name, address, date of birth, fridge allocation and personal property details) about the deceased is recorded on the Case admission form and property form by the funeral directors. The mortuary staff checks the details and a unique reference number is assigned when the deceased patient's details are transcribed into the mortuary register. Mortuary staff put red wrist tags on high-risk bodies and a yellow magnet is put on the fridge door. Same or similar names are also highlighted by colored wrist tags and fridge magnets on doors. Bodies are released to funeral directors after two APTs check the identification on wrist tags before the release takes place.

The PM room has two downdraught PM tables and dissection benches, with adequate working space and good lighting. Three visiting pathologists are on weekly rota to undertake PM examinations. There is a separate storage area within the body store for formalin-fixed (wet) tissue samples retained during the PM examination. The tissue samples are sent to another HTA licensed establishment for toxicology and histopathology testing; transportation is by specific courier companies who have agreements in place with coroner's office. Tissue samples may be stored temporarily at the establishment under police authority. There were no samples stored under police authority at the time of the inspection.

The last HTA site visit inspection was in August 2012. This report describes the fourth routine site visit inspection, which included a visual inspection of the premises (body store, PM room and viewing area), interviews with staff working under the licence and document review.

Audits of traceability records were conducted for bodies stored in the fridges and documentation of histology samples taken during PM examination. Vertical audits of the removal of tissue during PM examination from three bodies revealed full traceability in the paper and electronic records. In each case, the blocks and slides produced had been treated in line with the family's wishes. No discrepancies were identified.

Inspection findings

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

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	The APTs perform evisceration prior to the pathologist checking the body. This activity has not been risk assessed and there is no formal agreement or formalised procedure governing the circumstances in which they are authorised to do this, nor the circumstances in which they should not proceed without the pathologist having first examined the body. *(Refer to advice item 2)*	**Minor**

GQ2 There is a documented system of quality management and audit.	Although the establishment undertakes and documents regular audits of bodies stored, PM procedure, record keeping, collection of samples, tissues retained and body discharge, there is no system in place to document the name of the person responsible for follow up actions and the time frame for completing those actions. *(Refer to advice item 8)*	**Minor**
GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	The establishment has a documented procedure on incident reporting and recording non compliances with operational procedures and how these should be followed up. This includes guidance on when to report an incident to the HTA. However, at the time of inspection it was noted that minor mortuary incidents and non-compliances identified from regular audits are not recorded and shared with all staff in line with the SOPs. In addition, the adverse incident record book has not had a new entry since 12 September 2012. (*Refer to advice item 10*)	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.	At the time of inspection it was noted that the freezers were reaching capacity. In the absence of effective contingency arrangements, this poses a risk for long-term storage of bodies at the establishment. *(Refer to advice item 12)*	**Minor**

Disposal

Standard	Inspection findings	Level of shortfall
D2 PM tissue is disposed of if consent is not given for its storage and use for scheduled purposes.	The establishment is responsible for disposal of PM tissue returned from the histopathology laboratory. Although there are documented procedures in place for disposal of human tissue, the method and date of disposal are not recorded. *(Refer to advice item 15)*	**Minor**

Advice

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

No.	Standard	Advice
1.	N/A	Further to the discussions held during the inspection, the DI is advised to identify Persons Designated (PD) to support him in overseeing licensed activities in the mortuary and reporting HTARIs within five working days. The HTA should be notified of the names of the PDs.
2.	GQ1	At present, in cases deemed to be low-risk, the APTs eviscerate bodies prior to the arrival of the pathologist, who does not undertake an external examination of the body beforehand. The DI should implement a procedure by which confirmation from the pathologist that they wish the body to be eviscerated prior to their arrival is documented, and provide written guidance for the APTs on the circumstances in which they should not proceed with evisceration. In addition, the DI is advised to update: • SOP (B1.3) 'Preparation of the deceased for and during a Post Mortem examination', which should specify the details used to identify the body prior to PM examination. The SOP should ensure that more than one identifier is used, to mitigate the risk of preparing the wrong body. • HPM4 'Histology and Toxicology datasheet' should be modified to record if evisceration has taken place prior to checks from the pathologist.
3.	GQ1	The agreements with visiting pathologists state that the pathologists are aware of the procedures and SOPs in the mortuary. The DI is advised to ensure that the pathologists have read the SOPs relevant to the activities they carry out in the mortuary, such as SOP B 1.3, and that they sign to confirm they have done so.
4.	GQ1	The procedure for Home Office PM examinations that take place out-of-hours is different from PM examinations carried out during working hours. During working hours two APTs are responsible for removing the body from the fridge, carry out evisceration, reconstructing the body and returning it to the fridge. When Home Office PM examinations takes place out of hours, one APT assists and is left to undertake reconstruction and return the body into storage unassisted. The DI is advised to update the current SOP to update this information. The DI is also advised to risk assess this lone-working arrangements and provide guidance for staff should they require additional assistance to carry out these procedures during out of hours.
5.	GQ1	The mortuary uses two tools, to monitor activities carried out at the establishment and maintain traceability of tissues and organs removed during the PM examination: Haringey Access database and Haringey public mortuary Excel spreadsheet. The DI is advised to risk assess and document the procedure for managing records, which should describe the process for updating the database and the person responsible for maintaining it.
6.	GQ1	The HTA updated its guidance on HTA-Reportable Incidents shortly before the inspection. The DI is advised to refer to this guidance and review the establishment's policy and procedures in light of it. Further information on this guidance can be found on the HTA website:

		Post Mortem HTA reportable incidents
7.	GQ1	The SOP B1.15 'Fridge and freezer monitoring' states that fridge monitoring is undertaken daily. This is not the normal procedure in the mortuary, as the fridge temperatures are only checked and recorded during working hours. The DI is advised to update the SOP to reflect the current practice in the mortuary. In addition, the DI should include the details of the corrective and preventative actions to be undertaken in case of non-compliance and fridge/freezer breakdown.
8.	GQ2	The establishment has a system of internal and external procedural audits in place. The DI is advised to update the current SOP B1.10 'Internal & External Audits ' to describe the purpose and method of carrying out each audit; the document should also include information about who is responsible for carrying out these audits, reporting of non-conformances, corrective and preventative actions taken and time frames for addressing non-conformances. Non-conformances, can be discussed during governance meetings to promote shared learning.
9.	GQ2	The establishment carries out horizontal audits. To strengthen governance further, the DI is advised to introduce a system of vertical audits to review the procedures from admission of bodies into the mortuary to their release to funeral directors.
10.	GQ7	The establishment has a document system for recording and reporting non compliances and near misses incidents in the mortuary. For example, • SOP HPM 1.10 Internal and External Audits mention "If you find a non-compliance then you must find out why this happened, rectify and document what remedial action was required"; and, • SOP HOM 1.19 Deviation of procedure mentions "If a non-conformity or deviation from procedure happens (see examples) a Deviation from procedure form (HPM 14) needs to be filed. Complete the form as soon as possible and deliver it to your line manager." The DI is advised to keep records of minor incidents, errors and non-conformances in the mortuary, and of corrective and preventive measures in line with SOP 1.10 and 1.19.
11.	PFE1	The door between the viewing gallery and access to the mortuary body store and PM suite does not have a lock. This presents a security risk as there is no means of preventing unauthorised access to these areas via the viewing room.
12.	PFE3	At the time of the inspection, the freezers at the establishment were reaching capacity. The establishment is advised to have contingency agreements in place for frozen body storage and to put a documented procedure in place which includes details of the agreements with other mortuaries, and actions to be taken by staff before the mortuary reaches capacity.
13.	PFE3	The DI is advised to schedule regular manual challenge of the fridge and freezer alarms to ensure that they are operating as expected. In addition, the automated temperature monitoring system due to be installed should be checked periodically to ensure that it notifies the APT as expected and that alarm notifications are responded to appropriately. These checks and any resulting actions should be documented. The DI is advised to amend the current SOP B1.15 'Fridge and Freezer

		monitoring' to reflect these changes.
14.	PFE3	The bodies stored in the body store are subject to weekly body audit. This is a sampling exercise to check the condition and review the documents associated with three bodies in the fridge. Storage conditions of the bodies which are not part of the audit are not checked on a regular basis. The establishment is advised to conduct more frequent checks on the condition of bodies, for example, daily checks of the condition of bodies stored in the fridges for signs of decomposition or fluid leaks. This will help to assure the DI that the establishment's storage arrangements ensure that the dignity of the deceased is maintained.
15.	D2	The tissue disposed of by the mortuary is recorded as a note on HPM 4 'Histology and Toxicology datasheet' and mortuary database excel sheet. The DI is advised to update the SOP 1.6 'Repatriation and Disposal of Human Tissue' to include the procedure for recording the method and date of the tissue disposed of by the establishment. The documented procedure should include methods of disposal for whole organs, wet tissue, wax blocks and microscope slides. The DI is advised to ensure that the method and date of disposal are recorded for all the tissues disposed of by the mortuary.

Concluding comments

This report outlines the fourth HTA site visit inspection of Haringey Public Mortuary. Despite the shortfalls identified, areas of strength were observed.

The DI has a good working relationship with HM Coroner's Office, and there is regular contact between the Coroner, his officers and mortuary staff. The DI has good support from the local council towards day to day management of the mortuary.

The establishment has introduced a system of external audits of the mortuary, which is carried out by members of council. The establishment has developed a list of rules and regulations for funeral directors accessing the mortuary out-of-hours. This list is displayed in the body store and print outs are given to all the funeral directors visiting the mortuary.

The mortuary has a good system of visual markers to identify same or similar names, high-risk bodies and bodies awaiting repatriation of tissue.

There are a number of areas of practice that require improvement, including four minor shortfalls. In addition, the HTA has given advice to DI on a range of issues, including governance documents, traceability systems, mortuary facilities and disposal.

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.

Prior to finalising the report, the establishment started to work on addressing the outstanding shortfalls. These were not completely addressed by the time the inspection report was finalized.

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 / subject to compliance with the additional conditions applied to the licence.

Report sent to DI for factual accuracy: 24 September 2015

Report returned from DI: No factual accuracy comments were made by the DI

Final report issued: 29 October 2015

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: 4 March 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:
    - 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.

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.