Site visit inspection report on compliance with HTA minimum standards

University Hospital Lewisham

HTA licensing number 12266

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**

19-20 March 2014

Summary of inspection findings

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

Although the HTA found that University Hospital Lewisham (the establishment) had met many of the HTA standards, seven minor shortfalls were found in relation to consent, governance and quality systems, and premises, facilities and equipment. The shortfalls relate to aspects of the establishment's consent documentation, the approach to internal audit and risk assessment, staff training, mortuary cleaning, and the storage facilities in the maternity ward.

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 Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

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

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out by University Hospital Lewisham (UHL), part of the Lewisham and Greenwich NHS Trust, which has been licensed by the HTA since August 2007. It describes the second routine site visit inspection of the establishment, which took place on 19-20 March 2014.

University Hospital Lewisham performs a small number of consented, adult hospital post mortem (PM) examinations each year. Coroner's PM examinations are no longer undertaken at the hospital. Perinatal and paediatric PM examinations are transferred to other licensed premises.

The principal body store has been refurbished since the last inspection and now contains space for 52 bodies, including four spaces for bariatric bodies and spaces for perinatal cases pending transfer. A further six spaces are available for bodies in long term, frozen storage. All fridges and freezers are temperature controlled and alarmed. The PM examination suite has three examination tables with associated dissection areas.

The mortuary is currently staffed by two permanent Anatomical Pathology Technologists (APTs). Tissue samples taken during PM examination are sent to the Pathology Laboratory within the hospital, where they are processed and stored prior to disposal or retention in accordance with the family's wishes.

In November 2013, the Queen Elizabeth Hospital (QEH), Woolwich, became a satellite of UHL for the purposes of HTA licensing, when it became part of the Lewisham and Greenwich

NHS Trust. Prior to this, the QEH operated as a satellite site of the Princess Royal University Hospital, Bromley (licence number 12300), which was last inspected in April 2012. The QEH carries out approximately 100 consented, perinatal and paediatric hospital PM examinations each year, along with a small number of consented, adult hospital PM examinations. The principal body store at QEH has refrigerated space for 35 bodies, including four spaces for bariatric bodies. Additional overflow storage is also available within the PM examination suite in the form of a temporary, portable, modular system with 12 spaces (see advice below). The PM examination suite has two examination tables with associated dissection areas.

At the time of the inspection the mortuary at QEH was staffed by a locum APT, supported by APTs from UHL as needed. The hospital was in the process of recruiting a full time APT. Tissue samples taken during PM examination are sent to the Pathology Laboratory within the hospital for processing and storage.

The inspection included interviews with key members of staff working under the licence at both sites, including: the Designated Individual, who is the Head of Cellular Pathology at UHL; the two APTs at UHL; the Consultant Perinatal Pathologist at QEH; the Senior Bereavement Officer at QEH; and the Head of Cellular Pathology at QEH. A review of documentation relevant to the establishment's activities and a visual inspection of the premises were conducted as part of the inspection.

In addition, an audit of bodies stored in the mortuary fridges on both sites was undertaken. Two bodies were chosen at random from the mortuary registers on both sites and details of the deceased were cross checked with the information contained on the identification tags on the bodies. No discrepancies were noted. Where possible, tissue traceability audits were also carried out as part of this exercise. Paper records of the tissue taken during post mortem examination were cross-checked with the details stored on the establishment's electronic database, as were the number of blocks and slides held in storage. Hospital consent forms were also reviewed. Although no significant anomalies were found, a shortfall was noted in relation to the information contained in several of the completed consent documents and some advice has been given with respect to the transfer of data to the establishment's new laboratory information management system (see below).

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

Consent

Standard	Inspection findings	Level of shortfall
C2 Information about the consent process is provided and in a variety of formats.	The wording of the consent form in use at QEH is such that the family's wishes for the retention or disposal of tissue taken during the PM examination could be misconstrued depending on how fields in sections 'C', 'D' and 'E' are completed. As a result, there is a risk that the establishment may retain tissue beyond the PM examination without valid consent.	**Minor**

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of quality management and audit.	Although evidence of internal audits was seen during the course of the inspection, there is an inconsistent approach to this practice across both sites, both in terms of the range of activities that are being audited, and the manner and rigor with which audits are being documented and the findings acted upon. In particular, although QEH had a comprehensive audit schedule in place for 2011/12, which included, amongst other things, audits of consent documentation, temperature monitoring records, staff training, and risk assessments, a similarly robust schedule of audits has not been conducted since then.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.	Although the establishment has procedures in place to provide training to hospital porters on both sites, a review of training records and mortuary logs revealed that a number of porters working within the mortuaries in the months leading up to the inspection had not received formal, documented training.	**Minor**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	Although the establishment has a wide range of risk assessments in place relating to the licensable activities being carried out at the UHL, comparable documents are not in place at the QEH. Those risk assessments that are in place at QEH focus solely on health and safety issues and do not consider risks in relation to the licensed activity, such as accidental damage to a body or release of the wrong body for burial or cremation.	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE1 The premises are fit for purpose.	The room and fridge in the maternity ward at QEH used to store products of conception (POCs), fetuses and stillborn babies on a temporary basis lack appropriate security measures to prevent unauthorised access.	**Minor**

PFE2 Environmental controls are in place to avoid potential contamination.	The establishment's procedure for cleaning the storage facility at QEH stated that a weekly clean of the fridges should be performed on a rotational basis. However, cleaning records are not consistent with such a schedule having been adhered to.	**Minor**
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.	Although the storage facilities in the main mortuary at QEH are appropriately alarmed and monitored, the equipment used to store POCs, fetuses, and stillborn babies on a temporary basis in the maternity ward lack equivalent safeguards.	**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 update the UHL SOP relating to paediatric post mortem examinations (MO20) to include links to the HTA's current Codes of Practice. The DI should also review references within this document to the retention of tissue as part of a baby's medical record, to make sure it is clear to those reading this procedure that under the Human Tissue Act 2004 consent is needed to store relevant material for use for a scheduled purpose, which would include determining the cause of death or obtaining scientific or medical information about a living or deceased person which may be relevant to any other person.
2.	GQ1	The DI is advised to appoint Persons Designated in each area of the two hospitals where relevant material is stored under the authority of the establishment's HTA licence, including, for example, the maternity ward at QEH.
3.	GQ1	The DI is advised to review and update any service level agreements that the organisation has with third parties, such as the agreement between UHL and St Thomas' Hospital for paediatric and perinatal PM examinations, to ensure that those that remain important for service provision are current.
4.	GQ1	The DI is advised to formalise the contingency plans for storage of POCs and fetal material in the maternity ward at QEH. Procedures for the routine use and monitoring of storage equipment should also be documented.
5.	GQ1	The DI is advised to update the consent policy at QEH to include appropriate reference to PM consent. The document should be updated to include details of the current DI.
6.	GQ2	The DI is advised to incorporate the UHL form entitled 'Removal of a deceased out of hours checklist' into the establishment's document control system, either as a stand-alone document or as an appendix to an associated SOP as is currently done for forms such as the 'Mortuary out of hours tissue retrieval checklist'.
7.	GQ2	The DI is advised to audit the information contained on the laboratory

		information management system that has been recently introduced into UHL's pathology department to ensure that records of blocks and slides prepared as part of PM examinations are complete. The DI is also advised to review the information that is captured on specimen transit log forms at QEH to ensure that all mandatory fields, such as 'received date' and 'received by', are completed.
8.	GQ2 and GQ3	The DI is advised to review the documents contained within the 'Mortuary out of hours information' folder used in the UHL mortuary to ensure that it contains only current versions of SOPs and forms. The DI should also consider whether having similar reference material in the QEH mortuary would support staff, such as porters and funeral directors, who use the facility out of hours.
9.	GQ3	The DI is advised to review the approach to staff appraisal following the recent organisational changes, to ensure that all staff involved in the carrying out of licensable activities have annual appraisals.
10.	GQ6	The DI is advised to update the mortuary registers used in both mortuaries at the earliest opportunity to ensure that the printed column headings on each page reflect the information that should be documented. As an interim measure, the DI should consider whether the column headings in the registers used at UHL should be changed manually, as is current practice at QEH. Although there was no evidence that the current format results in inaccuracies, the potential exists and the use of amended registers would ensure consistency of data entry and reduce the risk of error.
11.	GQ7	The DI is advised to update the establishment's incident reporting SOP (MO18) to include examples of HTA Reportable Incidents (HTARIs). Although the document contains examples of clinical incidents that should be reported both internally and externally, it lacks mortuary-specific examples that are relevant to the activities taking place under the authority of the establishment's HTA licence. The DI is also advised to ensure that Persons Designated at both sites are able to access the HTA's Portal for the purposes of reporting HTARIs in the DI's absence. At the time of the inspection, this was true for staff at the QEH, not at the UHL.
12.	GQ7	The DI is advised to remind staff of the need to record any incidences of bodies being received into the mortuary without appropriate identification on the Trust's incident management system, as stipulated in the establishment's SOP on admission of bodies into the mortuary. This will help ensure that there is appropriate investigation of any such incidents and that the root causes are identified and addressed.
13.	GQ8	The DI is advised to review the system used to review and authorise risk assessments at the UHL. In particular, the requirement for the area manager to sign completed risk assessments, as indicated on the current risk assessment template, should be reviewed in light of current practice. If needed, additional members of staff who can authorise risk assessments should be identified and the templates updated accordingly. The DI also advised to consider whether the risk assessments embedded within SOPs can be used more effectively to further develop working practices, especially where they identify risks that are catagorised as 'high'.
14.	PFE3	The DI is advised to review the information contained in the mortuary escalation plans for UHL and QEH to ensure that they provide sufficient clarity as to the

		trigger points that should prompt the taking of further action, such as the moving of bodies into contingency storage or the need to contact the Bereavement Office or funeral directors.
15.	PFE3	The DI is advised to review, and subsequently formalise, the circumstances under which bodies are moved from refrigerated storage into frozen storage. Consideration should be given to the specific procedures for adults, babies and fetuses.
16.	PFE3	The HTA endorses the steps that the establishment is taking, together with its maintenance contractor, to try to establish an appropriate methodology for challenging the body store alarm systems on a periodic basis. The DI is advised to consider similar options for the storage facilities at the QEH.
17.	PFE3	The DI is advised to audit and review the routine use of contingency storage equipment at QEH with a view to determining whether additional, permanent storage capacity is needed. Furthermore, although the temperature of this equipment is routinely monitored when in use, the unit lacks a high temperature alarm. The DI is therefore advised to formally risk assess the use of this equipment to ensure that existing control measures are adequate to safeguard any bodies stored within it, particularly out of hours.
18.	D2	The DI is advised to review the establishment's current practices relating to the storage and disposal of POCs to ensure that they are sufficiently robust to ensure timely disposal of tissue. In particular, the DI should consider implementing a maximum storage time for POCs which, if reached, would trigger appropriate disposal of the tissue irrespective of the number of POCs in storage at that time.

Concluding comments

The HTA saw several examples of good practice during the course of the inspection, including the approach to risk assessment at UHL and the carrying out of external audits at both sites. Even though there is more to do, the DI has taken steps to align working practices on both sites, where appropriate, and to share examples of best practice since the incorporation of QEH into the Lewisham and Greenwich NHS Trust. Regular cross site meetings have also been instigated which should help in this regard going forward.

The establishment has given careful consideration to how best to ensure that informed consent is given by relatives considering a hospital PM examination in light of the low number of such procedures that are carried out at both sites each year. This has resulted in the establishment having a core group of trained staff members on both sites who are able to support untrained members of staff in the seeking of consent as needed. This helps ensure consistency, but also that staff are involved in the consent process frequently enough to remain familiar with the procedure. Training material relating to the consent process is generally of a high standard, in particular that used to support staff involved in the seeking of consent for paediatric PM examinations.

Seven areas of practice were identified during the course of the inspection that require improvement, each resulting in a minor shortfall. These relate to certain aspects of the establishment's governance and quality systems, such as risk assessment, audit and training. Shortfalls were also noted in relation to the establishment's consent forms and the storage

facilities in the maternity ward at QEH. The HTA has given advice to the Designated Individual with respect to a number of the establishment's procedures, documents and working practices with a view to helping the organization further develop working practices at both sites.

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: 6 May 2014

Report returned from DI: 20 May 2014

Final report issued: 26 June 2014

Inspection CAPA Plan Closure Statement:

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: 29 October 2014

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).

PFE2 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.

PFE4 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.