Site visit inspection report on compliance with HTA minimum standards

Leicester Royal Infirmary

HTA licensing number 12337

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**

13 and 14 November 2013

Summary of inspection findings

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

Although the HTA found that Leicester Royal Infirmary (the establishment) had met the majority of the HTA standards, three minor shortfalls were found in relation to Consent and Governance and Quality Sysems standards.

Since the previous inspection the establishment has expanded its services in relation to perinatal PM examinations. Consent for perinatal post mortem (PM) examinations is taken at the labour wards in Leicester Royal Infirmary and Leicester General Hospital. The establishment has an on-line training package, which was developed following the inspection in 2010. However, this training is not mandatory for staff who take consent.

The establishment has taken forward its plans to validate the use of post mortem radiology (cross sectional imaging). However, there are no documented procedures governing the

movement of bodies from the mortuary to the areas in the hospital where scanning takes place and the return of bodies from those areas.

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

Leicester Royal Infirmary is licensed to carry out PM examinations and the removal and storage of PM tissue for use for scheduled purposes under the HT Act. The establishment has two satellite sites, one at Leicester General Hospital and the other at Glenfield Hospital. The corporate licence holder is University Hospitals of Leicester NHS Trust, and the corporate licence holder contact is the Director of Clinical Governance. Pathology services at University Hospitals of Leicester NHS Trust and Nottingham University Hospitals Trust have recently merged to form a new pathology service 'empath'.

The establishment undertakes around 1300 PM examinations each year and has a close working relationship with the East Midlands Forensic Pathology Unit based at the University of Leicester. Staff from this unit attend the mortuary to undertake forensic PM examinations. The mortuary is staffed by five Anatomical Pathology Technologists (APTs) and two Medical Technical Officers. The Medical Technical Officers rotate between the hub and the two

satellite sites. APTs also undertake activities on behalf of other HTA licensed establishments including taking blood samples, if the deceased person is to be a bone donor, and retrieval of eyes.

Around 80% of PM examinations are undertaken on behalf of the coroner for Leicester City and South Leicestershire District and another 20% on behalf of the coroner for Rutland & North Leicestershire District. Around 100 forensic PM examinations and over 100 paediatric PM examinations are also undertaken each year. High risk PM examinations take place in the forensic PM suite. Staff are trained to handle such cases and are provided with appropriate protective equipment. The two satellite sites function as body stores. PM examinations do not take place at those satellite sites though rooms are available where PM examinations can potentially take place in the event of an emergency.

Porters receive induction training in the mortuary. Mortuary staff check the bodies using three points of identification, complete the 'mortuary register' and log details of the deceased in the i-LAB computer system. When same or similar names have been identified with other deceased in the mortuary, this is recorded in the mortuary register and on the fridge door where the deceased in stored. Hospital Porters and/or the Duty Manager arrange for supervised access to the mortuary when bodies are delivered out of hours.

The establishment has 252 fridge spaces, including bariatric spaces, and ten freezer spaces across all three sites. The fridges and freezer temperatures are monitored and linked to local alarms and to the central switchboard. The alarms are activated in the event of deviation of normal operating temperature for more than 30 minutes (less than 0^0C or greater than 8^0C for fridges and greater than 10^0C for freezers).

The Coroner's officer faxes authorisation for a PM examination to the mortuary.Two members of staff check the identity of the deceased and document the check before any examination takes place. Experienced APTs undertake an external examination of the body and follow guidance on when they can proceed with evisceration of the body in the absence of a Pathologist. The Pathologist is responsible for ensuring that all tissues and organs removed are noted on the Tissue Retention Form (TRF) which consists of four duplicate sets of forms. The white, yellow, pink and blue duplicate TRF forms are used, as required, for record keeping by the Pathologist, as a request form which accompanies tissue samples sent to the histopathology laboratory, attached to the deceased if tissues are to be returned to the body before it is released and by the mortuary for record keeping, respectively.

Release of bodies during normal working hours is undertaken by two members of staff who check and confirm the the paperwork and identity of the deceased. Out of hours releases are the responsibility of the Hospital Duty Manager.

The Deputy Laboratory Manager has temporarily taken on the role of 'HTA co-ordinator' and ensures that tissues are disposed of in accordance with the wishes of the next of kin. There are procedures in place to ensure that all blocks and slides are accounted for and pathologists return all slides to the laboratory. Paper records such as the Tissue Retention Form and computer records (i-LAB) are updated as appropriate once disposal takes place. The establishment has an extensive archive of retained blocks and slides, which are stored in secure areas at the Leicester Royal Infirmary and at the two satellite sites.

The site visit inspection of Leicester Royal Infirmary and its two satellite sites was undertaken on on 13 and 14th November 2013. This was the fourth inspection of the establishment since they were first licensed under the HT Act, and included interviews with the Clinical Lead for Histopathology (DI), Pathologists who undertake adult and paediatric PM examinations, Consultant Obstetrician and Clinical Lead for Perinatal Mortality who takes consent for

perinatal PM examinations, Coroner's Officer, Quality Manager and Mortuary Manager and an APT.

A document review was carried out. The documents reviewed included standard operating procedures (SOPs) relating to PM examinations, Quality Manual, policies, computer records of bodies booked into the mortuary, tissues removed during PM examinations and disposal records, as well as paper records of incident reports and investigations, audit records, equipment maintenance record and training records. The inspection did not include a review of records relating to receipt and transportation of tissues received for specialist examination.

An audit trail was undertaken of two bodies stored in the mortuary. Details in the mortuary register, name, storage location and identity tags were checked; no discrepancies were noted. The release procedure followed when a body is released was also observed. Computer (i-LAB) and paper records relating to a coroner's PM examination and a perinatal PM examination were traced from the mortuary register, check lists, written and computer records and records of stored blocks or disposal records as appropriate. The number of blocks relating to each case was checked against the paper and i-Lab computer records. The consent form for one adult consented PM examination was also reviewed. It was noted that the relationship to the deceased was not documented in the consent form. Advice relating to this finding is provided in advice section in this report. There were no other discrepancies.

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
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.	The hospital consent forms for perinatal PM examinations do not document whether consent has been obtained for the continued storage of blocks and slides for use for scheduled purposes, as required by the Human Tissue Act 2004. Consent forms for perinatal PM examinations state that “Blocks and slides are kept indefinitely as part of the medical record…may also be used for medical education and audit.” It is not clear if parents are given the option to decline to give consent for retention of blocks and slides following perinatal PM examinations. Advice against this standard is provided in the section below. Unlike in the case of perinatal PM examinations, consent forms for adult PM examinations document whether consent is in place for continued storage of tissue samples. The guidance within the form explains that tissue samples can be processed using wax.	**Minor**
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	The DI is not able to assure himself that consent is only taken by staff who have received formal training in taking consent. Consent for perinatal PM examinations is taken by clinicians based in the labour wards at Leicester General Hospital and Leicester Royal Infirmary. Staff who take consent attend study days where consent may be discussed. The Trust has an on-line module – Caring for Patients after Death – which provides training in taking consent for hospital PM examinations, but this is not part of mandatory training. In addition, records are not kept for staff who attend training in taking consent.	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process	Bodies are transferred from the mortuary to areas of the hospital where scanning for post-mortem radiology (cross sectional imaging) takes place. The HTA team was informed that scanning takes place out of hours and takes around 30 minutes, that it is undertaken by dedicated forensic radiographers and that Porters wait with the body and return the body back to the mortuary. However, the establishment does not have a documented procedure to ensure sufficient oversight of this process. The procedure should cover the release and return of bodies from the mortuary following receipt of a request for post mortem radiology, and include procedures to ensure that the dignity of the deceased is maintained during the time when the bodies are away from the mortuary and in the areas where scanning takes place.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	The DI is advised to consider adopting the consent forms issued by the Stillbirth and neonatal death (SANDs) charity, which includes detailed guidance for clinicians who seek consent and for parents who give consent for perinatal PM examinations.
2.	C3	The DI is advised to consider reviewing and updating the on-line consent training module – Caring for Patients after Death – in order to emphasise that appropriate consent must be in place for the continued storage of tissues and blocks and slides for use for scheduled purposes under the HT Act. Terms such as retention and storage are not defined and this can result in some confusion. Guidance on the use of the SANDs consent form could also be included in this module.
3.	GQ1	The DI is advised to strengthen governance arrangements with the Accident and Emergency Department and Labour wards in the hub and satellites sites. This could include the appointment of PDs and ensuring that they attend regular governance meetings.
4.	GQ1	The DI is advised to consider revoking the licensable activity - making of a post mortem examination- from the licences held by Leicester General Hospital and Glenfield Hospital as PM examinations are not currently undertaken at those satellite sites. In the event of an emergency, the establishment can apply to the

		HTA for a licence to cover the activity of making a PM examination.
5.	GQ2	The DI is advised to consider audit consent forms in order to ensure that all sections on the form have been completed, Such audits will help to provide assurance to the DI that staff who take consent are aware of the need to accurately document taking of consent,
6.	GQ8	The DI is advised to undertake a risk assessment of the practice of evisceration of bodies by APTs before the arrival of the pathologist. The current practice is for APTs to undertake a risk assessment of each case before making a decision to eviscerate a body. A senior member of staff will be retiring from service and so the DI may find it helpful to review this practice in order to satisify himself that unsupervised evisceration is only undertaken by experienced APTs.
7.	PFE2	During routine maintenance in April 2013, it was observed that airflow in the main post-mortem room did not meet the requirements of Health Building Note (HBN20) standards. Airflow in the adjacent Forensic PM room was found to meet the requirements when the controls were set to 'hazardous', but not during 'normal' settings. It was also found that the door seals on the access door to the main PM room were worn and in need of replacement. The DI is advised to ensure that these findings are followed up and acted upon. Airflow measurements should be undertaken to ensure that the number of air changes in the main PM room are at least 10 air changes per hour as stated in HBN20.

Concluding comments

The DI, Pathologists, Deputy Laboratory Manager and staff in the mortuary and histopathology laboratory work well together as a team. Mortuary Management meetings take place each month and daily ten minute 'Mortuary Huddle' team meetings are used to ensure two way communication between staff and management.There were several examples of good practice.

The mortuary register consists of individual forms for each deceased patient and is used to capture information about each case, including infection risks, anomalies etc. The use of checklists for each critical step, e.g. in relation to receipt of bodies, PM examination, and release of bodies, prompt staff to ensure that procedures are followed.

Access to the mortuary for teaching purposes or viewing a PM examination must be authorised by the mortuary manager or clinical lead for the mortuary. A set of 'Model rules for the UHL Mortuary' for visitors are displayed throughout the mortuary. A documented procedure covers police officers using the mortuary and there are notices for Funeral Directors and for the East Midland Ambulance service, who deliver bodies from the community or transfer bodies from other mortuaries out of hours. The notices cover the requirements for identity bands, provide guidance on when body bags should be used and which fridges should be used to store bodies from the community

There are robust systems in place to track bodies and tissues. Porters, Funeral Directors and Ambulance services personnel complete a 'Patient reception register' when delivering bodies to the mortuary. The use of 'Body transfer forms' for bodies transferred to Leicester Royal Infirmary from the satellite sites, 'Tissue tracking forms' for tissues sent away for specialist examination, and information recored in the i-LAB computer system help to maintain

traceability. The Deputy Laboratory Manager has good oversight of blocks and slides stored in the archives at the satellite sites.

The establishment uses ‘Cellular Pathology Action’ forms following reports of incidents, audits, complaints or feedback. Headings such as: ‘what happened?’; ‘why did it happen?’; ‘what was the root cause?’; ‘what immediate action was taken?’; ‘what was done to prevent it happening again?’; and ‘how this has been assessed to ensure it is effective?’; prompt users and help to ensure that the investigation and corrective and preventative actions are appropriate.

There are a number of areas of practice that require improvement, including three minor shortfalls. The HTA has given advice to the Designated Individual with respect: to adopting the SANDs consent form for perinatal PM examinations; updating the on-line consent training module; strenghthening governance arrangements; auditing consent forms and undertaking a risk assessment of the practice of evisceration in the absence of a pathologist. During the inspection the HTA observed that airflow measurements in the main PM room were not sufficient and has advised the DI to take the necessary steps to ensure that the number of air changes meets HBN20 requirements.

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: 11 December 2013

Report returned from DI: 2 January 2014

Final report issued: 14 January 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.

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.