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**

8 and 9 February 2017

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, one major and four minor shortfalls were found in relation to Premises, facilities and Equipment, Consent and Governance and Quality Systems standards.

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 (LRI) is licensed to carry out Post Mortem (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, also in Leicester. The corporate licence holder is University Hospitals of Leicester NHS Trust, and the corporate licence holder contact is the Director of Clinical Governance. Mortuary services are managed by Empath Pathology Services, a regional pathology partnership.

The establishment undertakes approximately 2,000 adult post mortem (PM) examinations each year on behalf of a number of Coroners, including around 120 adult forensic PM examinations, and a further 140 paediatric PM examinations, which include coronial, forensic and hospital consented cases. Occasional hospital consented adult PM examinations are undertaken. High risk post mortems, up to category 3 are also performed. There has been an increase in PM activity of approximately 50% since the previous HTA inspection in 2013.

The mortuary at LRI is based on the ground floor of the main hospital building, with the entrance for porters and next of kin attending for viewings situated beside a busy reception and lift area. The viewing room is accessed via a short corridor from the main reception area and there is a further locked double door that porters use to gain access to the main body

store area. Porters bringing deceased patients from the wards use the public lifts; in consideration of others, they use a concealment trolley and staff and patients are not able to enter the lift at the same time. Mortuary staff try to ensure porters are not transferring a body to the mortuary while a family is arriving for or leaving a viewing (see advice item 5). The hospital plans to make the reception near the mortuary the main entrance to the hospital, which will increase the number of people using the area outside the mortuary entrance and the lifts that the porters use to bring bodies from the wards.

Bodies from the community are brought in by ambulance or the funeral director into a well-concealed, covered entrance area, which is blocked from public view by a shutter that is closed upon their arrival to ensure complete privacy. Release of bodies during normal working hours is undertaken by two members of staff, who check and confirm the paperwork and identity of the deceased. Out of hours releases are the responsibility of the Hospital Duty Manager.

LRI has 150 fridge and ten freezer spaces. There was only one free freezer space at the time of inspection. The number of fridges includes 24 outside fridges, which were originally added as contingency storage but now form part of the everyday storage. The outside fridges are in a well-concealed, secure area and are on the same temperature monitoring system as the indoor fridges. 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 18^0C for fridges and greater than 2^0C for freezers). Temperature trends are monitored manually by mortuary staff Monday to Friday (see shortfall against PFE3)

An audit trail was undertaken of five bodies at the LRI mortuary. Details in the mortuary register, name, storage location and identity tags were checked; no discrepancies were noted, however one body did not have a same/similar name wrist tag on, which was not in line with the SOP. In another case, a post-it note with the details of another deceased person was on the tray for someone else. Both cases were highlighted to the establishment on the day and rectified.

The PM suite at LRI has a main PM room which has seven stands that hold trays from the fridges for PM examinations. Dissection of organs takes place on small dedicated tables that sit over the end of the PM tray, which helps avoid any mix of organs. There is a separate forensic PM suite which has one downdraft, height-adjustable PM table. There is a viewing gallery for the forensic suite only. The condition of the flooring is poor throughout the PM suite (see shortfall against PFE1).

The mortuary at Leicester General Hospital (LGH) is in a separate building away from the main hospital. It consists of 68 fridges and provides the main contingency storage for LRI. The fridges line both sides of the body store; one side is used for hospital deaths and the other for any contingency storage required by LRI. This hospital does not receive any bodies from the community. The two sets of fridges were installed at different times. The inside of the older bank of fridges, used for contingency storage, was refurbished approximately eight years ago; however, the exterior was not changed and the wooden door trim and the fridge seals are showing signs of deterioration. There is separate storage for babies and products of conception. An audit of three bodies at LGH was undertaken; no anomalies were found.

The PM suite at LGH has two PM tables; it is occasionally used by the police for training but PM examinations are not undertaken there. The body store is manned by staff from LRI for 2.5 hours each afternoon, on a rota basis. As the building is remote from the rest of the hospital, staff who are called out of hours contact security to accompany them to the building.

The body store at Glenfield Hospital (GH) forms part of the main hospital building and can accommodate 32 bodies. The bodies there are mainly deceased patients from the hospital, with occasional transfers from LRI when they have reached capacity. Staff from LRI attend the body store for 2.5 hours each morning, again on a rota system. An audit of two bodies was undertaken comparing the details on the paperwork to the details on the identity tags; no anomalies were found.

All three sites are linked to the same electronic mortuary register. The register tracks each body throughout its time in the mortuary and records what tissue has been taken as part of a PM examination. There is also a tissue retention book, which has different colour carbon copies to assist in traceability of tissue.

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 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 LRI and the LGH site.

This was the fifth inspection of the establishment since it was 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, a Coroner's Officer, the Quality Manager and Mortuary Manager and an APT.

A document review was carried out. The documents reviewed included standard operating procedures (SOPs) and policies relating to mortuary activities, computer records of bodies booked into the mortuary, tissues removed during PM examinations and disposal records. Other governance documents reviewed included incident reports and investigations, audit records, equipment maintenance record, training records and a review of records relating to receipt and transportation of tissues received for specialist examination.

A body release was observed during the visual inspection at the LRI and the release procedure was followed by staff. In addition, details of tissue taken during three PM examinations were traced from the mortuary register, through to written and computer records to the records of stored blocks or disposal records as appropriate. All blocks and slides had been stored or disposed of in line with the wishes of the family.

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 establishments work are supported by ratified documented policies and procedures as part of the overall governance process	Standard operating procedures (SOP) are in place for all mortuary procedures and on the whole they are of a good standard and reflect the activities carried out. However, the establishment has fallen behind with the implementation of some planned audits and review of some SOPs.	**Minor**
	The Mortuary Manager sends a monthly list to the bereavement office identifying the bodies that have been in the mortuary for over 30 days. However, there is no formal process in place to manage these bodies once they are identified to ensure they are placed into freezer storage at the appropriate time. In addition, there is no system in place that can readily identify exactly how long each body has been in the mortuary. Additionally, bodies that may have been in the mortuary for up to four weeks but not a full month at the time of the check may not be identified until the following month. *(See advice item 4)*	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE1 The premises are in reasonable condition (structure and cleanliness of floors, walls, entranceways)	The floor in the PM suite has a number of large cracks, which have become holes in some places; this allows for water to build up below the surface during cleaning and makes decontamination of the area impossible. Although this is acknowledged to be a health and safety risk to staff working in the area, and has been on the Trust risk register for over six months, at the time of inspection there were no plans to have the necessary work undertaken. The HTA is referring this matter to the Health & Safety Executive for consideration.	**Major**
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records	The alarms triggers for the fridges are set at 0 and 18 degrees, the latter being higher than sector norms. This, combined with the fact that temperatures are not checked at the weekend, means that the fridges could run at an inappropriately high temperature for some time without the awareness of staff, posing a risk to the integrity of bodies.	**Minor**
PFE4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues an cells during transport and delivery	A shortfall was identified during the HTA's previous inspection that the establishment does not have a documented procedure in place governing the transfer of bodies from the mortuary to another area of the hospital where scanning for post-mortem radiology (cross sectional imaging) takes place. Following that inspection, in order to address the shortfall, the establishment provided a checklist that covered the release and return of bodies following post mortem radiology, including 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. However, during this inspection staff appear to be unaware of this checklist and have not changed practice since the last inspection. Furthermore, they appear to have no involvement in the release of bodies, including checking the identity of the deceased, prior to their transfer to the radiology department.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	There was a discrepancy in the Hospital consent policy in the description of who can consent to a PM examination; the DI is advised to ensure this is updated in line with HTA Codes of Practice.
2.	GQ3	There has been a large increase in the number of PM examinations undertaken at the establishment but a comparatively small increase in the number of staff, which impacts on their ability to attend training due to workload. The DI is advised to assess the impact of the increased workload on staff training.
3.	GQ1	The SOP for PM examination gives details of when evisceration may take place before the pathologist verifies the identity of the deceased and examines the body. This practice is contrary to the Royal College of Pathologist's guidelines on the conduct of a PM examination. The DI is advised to ensure that the identity of the deceased is checked and a thorough external examination of the body is carried out by the pathologist prior to evisceration in all cases. This will be mandatory from 3rd April 2017, when the HTA's revised codes of practice and licensing standards come into effect.
4.	GQ1	The DI is advised to implement a system that enables staff to easily identify how long a patient has been in the mortuary. This information should feed in to a process to update the bereavement offices more frequently for hospital deaths and for the Coroner. It is advised that the DI puts a policy in place to formalise when a body will be transferred to freezer storage, which should be inline with HTA's guidance of after 30 days. Such a policy will be mandatory from April 2017, when the HTA's revised codes of practice and licensing standards come into effect.
5.	-	There is a lit sign at the entrance funeral directors use to let them know that there is a viewing in progress; however, there is nothing on the hospital entrance side for porters to indicate that additional care should be taken. Whilst acknowledging the sensitivies in this area, the DI should consider putting a system in place to inform porters when a viewing is taking place.
6.	-	At the time of the last inspection, it was noted that the Deputy Laboratory Manager had temporarily taken on the role of 'HTA co-ordinator' to ensure that tissue is disposed of in accordance with the wishes of the next of kin. This role has continued to fall under the Deputy Laboratory Manager, even though there has been a significant increase in the number of PMs undertaken and subsequently the amount of tissue to be managed. The DI is advised to consider adding additional resource to support this work.
7.	GQ8	Staff working at the satellite sites can be quite isolated, particularly at LGH. Currently, staff check in with the hub when they arrive but the DI is advised to consider the risk of not having a personal alarm for staff working at the satellites.
8.	PFE1	The DI is advised to have the PM suite assessed by the hospital Infection Control lead.

9.	PFE2	There are cleaning schedules for the mortuary and PM suite; however, the inspection team noted cases where appropriate attention to detail had not been made in terms of cleaning, for example a cobweb near the door of a fridge and debris on the floor at LGH. The DI is advised to ensure that comprehensive checklists are developed to ensure all sites are appropriately cleaned and that cleaning records are added to the audit schedule.
10.	PFE2	The last time the air ventilation system was checked and serviced was in 2015. The DI is advised to ensure annual checks take place.
11.	PFE3	The DI is advised to risk assess the sufficiency of freezer storage.
12.	PFE3	Following PM examination, some bodies are covered loosely up to the neck. It is considered good practice to shroud bodies fully whilst in storage and the DI is advised to ensure that full shrouding becomes routine and that this is reflected in mortuary procedures.

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 communications between staff and management.There were several examples of good practice:

- The annual Porter refresher training includes the full induction programme for the mortuary.
- There is a strong ethos of sharing learning from incidents involving porters; in addition to an update in training and induction documents, a 'Toolbox Talk' is also developed to share with all portering staff.
- The Day Book is a good reminder for staff of everything that needs to be done and requires confirmation that each activity has been taken.
- There are 'Danger of Infection' stickers that given funeral directors all the information they need in relation to appropriate precautions without specifying exactly what the infection is, which helps maintain patient confidentiality.
- Stickers for tissue traceability have been designed to indicate the wishes of the next of kin, when they were acted upon and by whom. These are stuck to the back of the tissue tracking form.
- The mortuary register is a duplicate book, which details and records all the information required for the admission and release of the deceased. One copy is kept by the establishment and the other is given to the funeral director. This is a well structured and easy to follow document which helps to mitigate the risk of errors.
- The tissue retention log is a triplicate book; copies are kept by the pathologist, sent with the tissue and placed with the body which highlights to staff they need to check before release of a body.

There are a number of areas of practice that require improvement, including a major and four minor shortfalls. The HTA has given advice to the Designated Individual with respect to governance and quality systems and premises, facilities and equipment.

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: 7 March 2017

Report returned from DI: 15 March 2017

Final report issued: 12 April 2017

Completion of corrective and preventative actions (CAPA) plan

Some actions in the CAPA plan were still outstanding when the establishment was inspected in October 2018, they will now be managed as part of the CAPA plan following that inspection.

Date: 7 November 2018

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.