Site visit inspection report on compliance with HTA minimum standards

St Mary's Hospital, London

HTA licensing number 12553

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**

12-14 May 2014

Summary of inspection findings

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

Although the HTA found that St Mary's Hospital, London (the establishment) had met the majority of the HTA standards, minor shortfalls were found in relation to standards GQ1 and GQ3. The HTA found that a documented procedure was required to maintain traceability during transfers between locations in the body store and that training of some staff carrying out licensed activities was inconsistent, presenting a potential for reputational risk to the establishment should an HTA reportable incident occur as a result.

Since the last inspection the establishment has acted on many of the items of advice given. Consent procedures have been reviewed and training improved. The quality management system has been well considered and documentation and procedures standardised across all sites, with only minor local differences.

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

HTA post mortem licence number 12553 covers licensable activity at the hub site at the St Mary's Hospital in Paddington, London (St Mary's) and four satellite sites at Hammersmith Hospital (Hammersmith), Charing Cross Hospital (Charing Cross), Chelsea and Westminster Hospital (Chelsea and Westminster) and Samaritan Hospital for Women (Samaritan). Of these hospitals, four form part of Imperial College Healthcare NHS Trust, with Chelsea and Westminster being part of Chelsea and Westminster NHS Foundation Trust.

During initial discussions in preparation for the inspection, establishment staff confirmed that no licensable activity has taken place at Samaritan for some time. Accordingly, this site did not form part of the inspection, and its licence will be revoked. Staff also confirmed that longer term storage of post mortem material only takes place at St Mary's and that removal of tissue from the deceased does not take place on any site other than St Mary's. It was agreed that the inspection team would seek to clarify the licensing requirements in light of the activities carried out, during the inspection.

Hospital consented, and some coronial post-mortem (PM) examinations take place at the main hub site at St. Mary's. Hospital PM examinations have also been carried out at Chelsea and Westminster; however, none have been carried out there for over a year. At the time of

the inspection, the PM room at Chelsea and Westminster had been decommissioned as recent maintenance work had uncovered an issue with the ventilation system. The Chelsea and Westminster NHS Foundation Trust is considering whether the facility should be made good so that PM examinations may be carried out, or if the space could be re-utilised for another purpose.

Consideration was given to whether Charing Cross required to be licensed. Although any tissue storage is carried out under another HTA licence, the HTA reviewed body storage records and it was clear that bodies are occasionally stored for periods exceeding a week before being transferred to St Marys for PM examination. Accordingly, Charing Cross requires to be licensed for storage, as the incidental to transportation exemption does not apply.

With regard to Hammersmith Hospital, there is storage of adult deceased, but also babies and fetal products from a neighbouring maternity wing. No temporary storage takes place within the maternity unit, with fetal products and perinatal deceased being transferred to the laboratory or mortuary as soon as possible. In the main, bodies for PM examination are transferred to St Mary's for onward transfer to a specialist centre within a few days. However, there may be the occasional case where a deceased baby is stored for longer than seven days prior to the mother deciding on a hospital PM examination. Accordingly, at present, Hammersmith requires to be licensed for storage.

At all sites, trained portering staff deal with the collection of bodies from the wards and receipt into the mortuary. They complete patient details within the mortuary register and put the body in an available refrigerator space. Copies of the relevant notification of death forms are then placed on a clipboard or wall mounted folder for subsequent access by patient affairs, bereavement officers and mortuary staff. Mortuary staff then check that identity details, location and patient property have been recorded correctly before logging the details of the deceased onto an electronic database. The process followed is largely uniform across all sites, with only minor local differences.

At this time, any same or similar names are identified. If same or similar names are found, a warning card is placed on each relevant refrigerator door space and, where present, the whiteboard marked accordingly.

Traceability of bodies within the mortuaries and to the PM suite at St Mary's is maintained by the use of sequential body numbers, unique to each site, and a sequential St Mary's PM examination number, which number also traces tissues retained at PM examination to the laboratory. As blocks and slides are processed, the electronic database is updated.

Twelve hospital, consented PM examinations were performed in 2013. In that year, over 100 perinatal cases were also carried out but these are now referred to a specialist HTA licensed establishment. Accordingly, only adult PM examinations are now carried out. It is anticipated that 12 to 15 adult PM examinations will be carried out in 2014.

Consent for hospital PM examinations is taken by members of a core consent team, who have all attended training carried out by a consultant histopathologist. If the patient's attending clinician is not a member of this core team, then a core team member takes the lead in the consent process. In advance of the PM examination, the pathologist checks the consent form to confirm it has been completed correctly and also to confirm that consent has been taken by a trained member of the core team.

PM examinations under the jurisdiction of the coroner rarely take place at the establishment

as in the main deaths in the community are dealt with at the local public mortuary. However, in cases where a patient suffering from trauma is admitted to the St Mary's trauma unit, and subsequently dies, a coronial PM examination may be carried out. The appropriate authority for this is faxed to the establishment by the coroner.

Storage of tissues (where consent is in place), as well as disposal, is managed by the histopathology laboratory at St Mary's, acting in conjunction with the mortuary. Products of conception, non viable fetuses and pre 24 week fetuses are disposed of sensitively, according to parents' wishes.

Viewings are managed by patient services or bereavement staff. These staff may also attend viewings to support relatives, as may nursing staff from the ward, site operation or duty managers (who are generally senior members of nursing staff), or midwives in the case of perinatal deaths. Bodies for viewing are prepared by mortuary staff in office hours, or by porters, nursing staff or site operation or duty managers, out of hours.

Release of bodies during office hours is carried out by a member of mortuary staff in conjunction with the attending undertaker, following a defined process, with both signing the register to confirm a dual check of identity. Out of hours release, which occurs rarely, is by site operation managers or duty managers acting in conjunction with undertakers**.**

This, the second inspection of the establishment, was a routine scheduled inspection, the previous one having been carried out in 2010. This three day site visit comprised visual inspections of the premises, including the mortuary suite and histopathology laboratories at St. Mary's, the mortuary suite at Chelsea and Westminster, the body store at Hammersmith and the body store at Charing Cross hospital. The inspection also included interviews with key staff and a review of governance documentation, consent and authorisation documentation, and traceability records.

On each site, an audit of traceability was carried out:

- At Charing Cross, the details of one body were selected from the mortuary register and the corresponding body located in store. The relevant paper records and database entries were located and checked for accuracy. Only a minor discrepancy was found, in that the notification of death form detailed the presence of only a wrist band, when there was also an ankle band.

  The electronic database was reviewed and details of one deceased reviewed. The corresponding paper records were located, and the body located in store and identification confirmed. There were no discrepancies.

- At Chelsea and Westminster, a similar procedure was followed for two cases, one of which was in freezer storage. The HTA found that the body in freezer storage had been moved from a refrigerator space and, although the paperwork attached to the door of the freezer was in order, the mortuary register had not been updated to show the change of location. A further check in relation to a baby stored in the freezer awaiting cremation disclosed the same issue. As this presents an increased risk of wrongful release, it has been classified as a minor shortfall.

- At Hammersmith, one perinatal and one adult case were selected. The relevant identification tags were checked against the corresponding paper records and no discrepancies were found.

- At St Mary's, one fetal sample was selected within the mortuary register and located in the fetal refrigerator. Identity details were confirmed and the relevant paperwork, being a "sensitive disposal" form confirming consent for disposal by cremation, was reviewed.

  Two adult bodies were selected from the mortuary register, located within the body store and identity details checked against the paper records and the electronic database.

  One patient record, relating to a case where a limited hospital PM examination had been carried out, was accessed on the electronic database and the blocks and slides traced through the laboratory to store. The original consent form and traceability paperwork completed during the PM examination were reviewed, as was the electronic record confirming the number of blocks and slides produced. The blocks and slides were then located in store.

  Blocks from a PM examination case were located in store and the corresponding slides found. The original consent documentation was reviewed to confirm consent for storage for scheduled purposes, and the electronic database reviewed.

  No discrepancies were found.

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	There is no specific guidance to staff on how to amend the mortuary register in the event that a body is moved from one location within the body store to another. This happens occasionally when a body is transferred to frozen storage. If the mortuary records are not amended to indicate the change in location, traceability is affected and the risk of wrongful release is increased.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.	The establishment uses site operation managers or duty managers, who are members of staff from departments not related to the pathology directorate, to carry out some licensed activities outside office hours. These activities include the viewing of bodies and, occasionally, the release of bodies to undertakers. These staff members are provided with, and acknowledge, the relevant Standard Operating Procedures, but it has been difficult for the DI to arrange face to face training and this has therefore not been carried out for all members of staff. As the out of hours activities are ones which risk causing distress to families of the deceased and reputational risk to the establishment in the event they are not properly carried out, it is important that staff training is completed and refreshed periodically.	**Minor**

Advice

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

No.	Standard	Advice
1.	C2	The DI is advised to amend the wording of the “Guide to the Post Mortem process” information leaflet provided to family members, as it contains a statement suggesting blocks and slides will always be kept permanently as part of the medical record, which contradicts other consent information made available to relatives and does not reflect the underlying legislation. This will help to ensure that relatives are receiving consistent information.

2.	GQ1	The DI is advised to amend the Standard Operating Procedure (SOP) dealing with receipt of bodies to include a review by staff of the body store inventory to identify same or similar names, in order to fully reflect the current practice.
3.	GQ1	The DI is advised to review the SOPs dealing with viewings, in and out of office hours, to ensure they are consistent with regard to procedures to be followed by staff, particularly with regard to identification procedures. This will ensure that staff are guided to undertake identical checks on release.

4.	GQ1	The DI is advised to amend the “Routine Hours Mortuary Procedures” SOP to detail that the daily check of bodies in store incorporates a check of the mortuary register, confirming the body slide location as well as identity and property details. This will help identify any circumstance where a body has been moved and the register not updated.
5.	GQ1	The DI is advised to ensure, on review, that SOPs and protocols reflect current practice. In particular, reference is made to the procedures relating to the filing of Notification of Death forms, where there are slight differences in procedures across each site. Achieving uniformity of process will aid those staff working across various sites.
6.	GQ1	The DI is advised to add a section to the out of hours release SOP to flag up the need to check the refrigerator door paperwork for the indicator card indicating a body is awaiting the return of organs or tissues.
7.	GQ3	The DI is advised to consider whether a formal refresher session on consent procedures should be scheduled for members of the core consent team to provide for updating of those team members who do not seek consent for prolonged periods. This will ensure that staff who have not sought consent for some time are fully updated on current procedures.
8.	GQ3	The DI is advised to ensure that, after porter training has been completed and recorded by the lead or head porter, a member of mortuary staff signs off the records, in accordance with planned procedures.
9.	GQ4	The DI is advised to remind staff of the establishment’s policy and procedures relating to how amendment of records is to be carried out, including the need to initial and date changes. This will help to ensure that changes are traceable to the individual carrying out the change.
10.	GQ6	The DI is advised to consider the two systems currently in use to track transfer of babies for PM examination to determine which best suits the needs of the establishment, and to roll that system out to all sites involved in those transfers. This will aid staff working across various sites and help ensure uniformity of approach, minimising the risk of error.
11.	GQ7	The DI is advised to ensure that an incident report is raised for any failure of ward staff to follow personal care after death procedures, including where bodies are received into the mortuary with only one identity band attached where Trust policy may require two. This will help to inform ward staff of the importance of following Trust identification policies.
12.	N/A	The DI is advised to consider the activities carried out at each site, in particular Charing Cross and Hammersmith, in light of the current licensing arrangements. As part of this, the DI is advised to risk assess the possibility of bodies being held in storage for a period in excess of seven days before being transferred to

		St Mary’s for PM examination. This will help the DI decide whether the current licensing structure is suitable or necessary.

13.	N/A	The DI is advised to ensure the continuation of the current policy whereby no PM examinations are carried out at Chelsea and Westminster, until the ventilation system has been repaired and validated as suitable for purpose.

Concluding comments

The HTA found various examples of good practice during the inspection. Consent training has been well considered and the procedures for checking that consent is sough by trained staff appear to be robust.

The establishment uses a proprietary electronic quality management system to control documentation, record staff acknowledgement of new documents and schedule audits and risk assessments. Audits are well managed and comprise a mix of vertical and horizontal audits with a full audit against the HTA standards being carried out every six months.

Risk assessments are reviewed annually, on process change or following incidents, and evidence was seen of risk assessment being carried out as part of change control and in relation to the drafting of new documentation.

The incident reporting SOP is particularly comprehensive, providing guidance to staff on the types of incidents which fall into the classification of HTA reportable incidents. Examples are provided, having been selected from documentation published by the HTA and an example incident is worked through in the SOP itself, to guide staff on the practical aspects of reporting.

The establishment has a well developed contingency plan, particularly in relation to capacity for frozen storage or bariatric cases, both of which it has risk assessed and incorporated on the Trust risk register.

The system of daily checks of identification of deceased also includes a check on condition. Staff grade the condition of the deceased on receipt to inform decisions on allowing viewing of bodies. As the daily check includes a further grading of body condition, any deterioration is noted. Similarly, the daily checks prompt actions to deal with any deceased who have remained in store pending decisions on burial or cremation.

There are areas of practice that require improvement, resulting in two minor shortfalls. The HTA has given advice to the Designated Individual with respect to some elements of documentation and the licensing arrangements.

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 shortfall identified during the inspection.

Report sent to DI for factual accuracy: 3 June 2014

Report returned from DI: No comments on factual accuracy received

Final report issued: 17 June 2014

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: 15 September 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.