Site visit inspection report on compliance with HTA minimum standards

Norfolk and Norwich University Hospital
HTA licensing number

11208

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**

1-2 December 2016

Summary of inspection findings

The establishment was found to have met most of theHTA standards. However, five minor shortfalls were identified, in relation to; consent procedures for the Biorepository (C1), incident reporting for both the Mortuary and Biorepository (GQ7), regular audits for the Biorepository (GQ2),the approach to maintaining traceability for the Biorepository (GQ6) and a risk assessment for mortuary evisceration practices (GQ8).

The HTA found the Designated Individual (DI), the Licence Holder (LH), the practices and all aspects of the premises to be suitable in accordance with the requirements of the legislation, subject to the identified shortfalls.

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 Paragraph 18 of the Human Tissue Act 2004. They are to secure that:

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

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

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

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

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

Background to the establishment and description of inspection activities undertaken

This report describes the third routine two-day site visit inspection of Norfolk and Norwich University Hospital (the establishment). The Histopathology Department is part of the Medicine and Clinical Support Division and the Directorate of Cellular Pathology. The Directorate forms part of the Norfolk & Waveney Cellular Pathology Service and includes a busy mortuary service.

The establishment has been operating under a hub-satellite licensing arrangement since 2015. There are two satellites; the Cotman Centre which is located on the Norwich Research Park site and the Biorepostory located on the hospital site. Both of these satellites are licensed for storage only. Post-mortem tissue blocks are stored at the Cotman Centre for use for research with consent from the family. Adult post-mortem slides pre-September 2014 and Fetal post-mortem slides pre-April 2014 are stored in the Biorepository.The Biorepository (the tissue bank) stores human tissue for research under the governance of the HTA licence and ethical approval from a recognised NHS Research Ethics Committee. Some post-mortem tissue is stored by the tissue bank and the vast majority of tissue there is from living people for specific projects that have ethical approval.

The inspection included a visual inspection of the body store, post mortem room, Accident and Emergency (A&E) department and Cotman Centre on day one and the Biorepository on day two. Formal interviews with the Desigated Individual, Mortuary Manager, Deputy Bereavement Services Manager, Chief BMS, Deputy Pathology Quality Manager, Biorepository Scientists and the Director of Biorepository were conducted over the two days. An interview with the Senior Coroner's Officer for Norfolk was conducted on the telephone pre-inspection. A document review of the establishment's policies and operational procedures was conducted and a series of traceability audits were also undertaken.

Mortuary

Post-mortem (PM) examinations are conducted under the jurisdiction of the Coroner for Norfolk. The vast majority of these, approximately 1,500-1,600 each year, are for the Coroner, with fewer than ten hospital consented PM examinations taking place each year. At the time of this site visit, forensic PM examinations were not taking place due to pressures on mortuary capacity, and were temporarily being referred to another establishment. Perinatal PM examinations take place at the establishment and are carried out by pathologists specialised in this area.

Bodies of patients who die in the hospital are brought to the mortuary by the porters, both during and out of hours. Each body has a wrist tag, which contains their name, hospital number, date of birth and NHS number. Bodies of those who die in the community are brought in by the Coroner's contracted funeral director, also during and out of hours, and each body has a wrist tag which contains the deceased's name, age, date of birth and address. If there is police involvement, a computer-generated number is also recorded. There are systems in place to identify bodies sharing a same or similar name, including red indicators on fridge doors and on paperwork. If tissue is to be repatriated, a 'Do not release' notice is placed on the fridge containing the deceased.

The body store provides for 104 fridge spaces, including five freezer spaces and 34 fridge spaces suitable for bariatric bodies. There are five fridge spaces allocated for forensic cases. There is a separate storage fridge for the bodies of infants, still births and fetuses, housed n a room adjacent to the main body store. There are also two Trust-owned Nutwell storage units on site, with a combined capacity of 30 spaces, for use during periods of reduced storage capacity in the main body store. The Nutwell storage units also provides three bariatric storage spaces. Furthermore, there are appropriate contingency arrangements in place with a local funeral director All fridges and freezers are connected to a continuous temperature monitoring system, which alarms when temperatures deviate from their expected range.

The hospital's accident and emergency (A&E) department is an area in which samples may be taken in cases of sudden unexplained death in infancy (SUDI). Therefore, as part of the visual inspection, the HTA visited the A&E department and met with the Consultant in Paediatric Emergency Medicine responsible for this activity. They demonstrated an understanding of the requirements of the Human Tissue Act 2004 and explained the establishment's SUDI procedure. The HTA was satisfied with the arrangements in place covering this activity.

A number of traceability checks were conducted. The identification wrist tags of three bodies stored in the mortuary, including two from the hospital and one from the community, were checked and all associated records, including the notification of death form and electronic records, were reviewed. No discrepancies were found.

Forward and reverse audits were carried out where histology had been taken during coroner's and hospital consented PM examinations. All paper and electronic records were reviewed and the number of blocks and slides stored in the Cotman Centre were also checked. A minor discrepancy was noted in relation to a hospital consented PM examination. It had been documented on the laboratory's records that the tissue blocks and slides, following PM examination were being stored as part of the medical record and for research; however, the consent form indicated that the consent giver had consented for the tissue blocks and slides to be stored as part of the medical record only (see Advice, item 1). All tissue blocks and slides were in storage and had not been used for research in error.

Tissue samples and organs retained for police purposes are sent to other establishments for analysis. Under s39 of the HT Act, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, the 2012 report of the Association of Chief Police Officers' (ACPO) audit of tissue held under police authority contained a recommendation that police exhibits held on HTA-licensed premises should be included within the regular HTA inspection process. Therefore, procedures for Home Office PM examinations and the management of tissues and organs taken for criminal justice purposes were reviewed by HTA at this site visit inspection. Any findings will be shared with the Home Office but are not contained in this report.

Biorepostory

The Biorepository (the tissue bank), formally called the 'Partners in Cancer Research Tissue Bank', was given ethical approval (08/H0304/85/5) by the East of England Research Ethics Committee in 2014. The ethical approval also enables tissue from the diagnostic archive to be used for research; this diagnostic archive is co-located in the Biorepository. The tissue bank has been under-staffed for some time and, new staff have recently been recruited to manage the operation of the facility. A Biorepository Manager is now in post and has responsibility for reviewing and streamlining processes and improving the tissue bank's governance systems.

The tissue bank stores healthy and diseased tissue under specific studies approved by a local University Ethics Committee, which is responsible for reviewing each research proposal before tissue can be stored within the tissue bank or released from the tissue bank. Biorepostory Technicians are involved in seeking consent in some studies and are responsible for receiving samples into the tissue bank.

All samples are received into the tissue bank by the Biorepository Technicians and must be accompanied by a consent form, which is reviewed by Technicians to ensure it is complete. Consent forms are stored at the Cotman Centre and the Biorepository for all samples stored in the tissue bank. Once samples are received and labelled at the Cotman Centre they are then placed into -80^{0}C freezer storage. Samples are identified using a unique computer-generated identification number; however, there is a lack of consistency in how these are assigned (see minor shortfall, GQ6).

The Biorepository is located in the Bob Champion Building on the hospital Site. It houses five -80^{0}C freezers to accommodate the tissue from the bank and has a transit freezer in which samples are stored temporarily if there is an issue with the sample. The transit freezer can also be used as a contingency freezer in the event of freezer failure.
The Biorepository freezers are all managed under a continuous temperature monitoring system. In the event of a critical storage failure, the system will alert a member of staff. The Biorespository also accommodates freezers for research groups that store tissue under the

governance of project-specific ethical approvals; however, these freezers are monitored under separate temperature monitoring systems.

Forward and reverse traceability audits were carried out on seven samples at the Cotman Centre and the Biorepository (Norwich Research Park). A sample that had been received at the Cotman Centre was being stored without being assigned a unique identifier (see Minor Shortfall, GQ6). Furthermore, a minor discrepancy was identified during the audits, in relation to a consent form: unlike for the other clauses, the first clause of the consent was not initialled by the participant. No further discrepancies were identified. An audit of tissue that had been released from the diagnostic archive to an external establishment was also carried out (see Advice, item 8). No discrepancies were noted.

Inspection findings

Overall, the HTA found the Licence Holder to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards (Post-Mortem)

Governance and Quality Systems

Standard	Inspection findings	Level of shortfall
GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly	Although the mortuary has an incident reporting procedure in place, it does not state the five working days HTA reporting timeframe. The document uses the old terminology (serious untoward incidents) throughout instead of referring to HTA reportable Incidents (HTARIs) and does not include the HTA's incident classification list.	Minor
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately	The APTs routinely eviscerate bodies in the absence of the Pathologist. Prior to evisceration, identification checks are carried out by the APTs. Evisceration in the absence of the pathologist is contrary to RcPath's Standards for Coroners' pathologists in post-mortem examinations of deaths that appear not to be suspicious (Feb, 2014). There establishment had not undertaken a risk assessment of this practice. *Following the site visit inspection, the DI confirmed that this practice has now ceased and that no evisceration takes place prior to an external examination of the body by a Pathologist.*	Minor

Compliance with HTA standards (Research)

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	At the time of the inspection, the Biorepository did not have an SOP governing the seeking of informed consent for the use of tissue for research. Although one was understood to be in draft, it was not available to Biorepository Technicians or Clinicians who are involved in seeking consent or involved in the informed consent process.	Minor

Governance and Quality Systems

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of quality management and audit	The establishment is not carrying out audits for the Biorepository and does not have in place a schedule of audits.	Minor
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail	The Biorepository's approach to assigning unique identifiers to samples is inconsistent. Some researchers collecting samples are given a batch of labels containing unique identifiers which requires Biorepository Technicians do keep a log of these numbers so each time samples are received into the tissue bank, they can be accounted for. There are occasions where not all labels are used by researchers, which leads to some labels becoming redundant. This was observed in practice during the tissue traceability audit, as a batch of samples received into the tissue bank had not been assigned a unique identifier. The researcher for this study had been provided with identification labels by Biorepository staff ahead of the tissue collection.	Minor

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly	The Biorespository does not have a procedure in place which describes how to manage and address incidents involving human tissue samples.	Minor

Advice

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

Mortuary (Advice)

No.	Standard	Advice
1.	C1	The Adult PM consent form provides the following options in regards to histology samples: 1) retain as part of the medical record; 2) retain as part of the medical record and use in research; 3) dispose of; 4) return to body; or 5) return to the family. The DI is advised to consider re-wording options one and two, so that there is clear distinction between keeping tissue samples as part of the deceased's medical record in case they may be of future benefit to the family and keeping samples for use for a scheduled purpose under the HT Act. The DI should also consider other scheduled purposes for which the tissue could be used, such as clinical audit, performance assessment and quality assurance.
2.	GQ8	The DI is advised extend the scope of risk assessments to include HTARI categories, so that that the risk of any of these occurring is assessed.
3.	PFE5	The Estates Department is responsible for arranging the annual servicing and maintenance of the mortuary ventilation system, however, there are no records of air changes. The DI is advised to obtain records pertaining to the ventilation system to ensure it function appropriately.
4.	D1	Post mortem tissue is rarely used for research; however, where consent has been given for its use for this purpose, it is stored in the Cotman Centre. The DI is advised to consider disposing of any samples that are unlikely to be used and to establish a disposal policy for PM samples that have consent for research.
5.	N/A	The DI is advised to identify a Person Designated in the A&E Department This will help the DI maintain oversight of licensed activities taking place in the department.

Biorepository (Advice)

No.	Standard	Advice
6.	C1	The DI is advised to formally document the approach, in a procedure, to obtaining consent for the storage and use of tissue for research that is taken over the telephone, including what details should be consistently recorded.
7.	GQ4	To monitor the effectiveness and consistency of consent procedures, the DI is advised to implement a system which requires Biorepository staff to review all consent forms to ensure that they are complete. This could be included as part of regular auditing against HTA standards.
8.	GQ6	Although the diagnostic archive is under the governance of both the ethical approval and HTA licence, details of tissue blocks and slides stored and subsequently distributed for research are currently held in a separate system. The DI should consider storing this information centrally so that it is accessible to Biorepository staff.

9.	GQ7	The DI is advised to draft a standard operating procedure (SOP) which outlines the types of incidents that need to be reported and investigated, staff groups that must be informed immediately and the process that must be followed to identify and implement corrective and preventative actions. Incidents may include, but are not limited to: • receiving and/or storing specimens without evidence of appropriate consent; • storing or using human tissue after consent has been withdrawn; • storage failure or other damage affecting human tissue quality; • loss of human tissue; • sample mix-up or loss of traceability; • incorrect disposal. This information will give staff a better understanding of the types of incidents involving human tissue that must be reported and investigated.
10.	PFE3	The DI is advised to include a regular manual challenge of the alarm system in the Biorepository to ensure the alarm notification system is functioning correctly and to expected specifications.
11.	D1	The DI is advised that Biorepository staff should also record the date of disposal on the traceability database to evidence full traceability. The disposal SOP should be amended to include this requirement.

Concluding comments

Staff working in the Mortuary and Biorepository have a good working relationship and are working hard to achieve compliance with the HTA's standards. The Biorepository is a invaluable resource and is accessed by a multidisciplinary team of researchers that are located on the Norwich Research Park site.

There were a some areas of good practice that were observed during the inspection:

- The Mortuary Manager monitors and records the capacity of the mortuary on a daily basis, to ensure that capacity is sufficient at all times;
- The mortuary offers a particularly sensitive service to bereaved mothers, which includes photography and keepsakes.

As highlighted above, there are some areas of practice that require improvement, including four minor shortfalls against C1, GQ2, GQ6, GQ7 and GQ8 and the HTA has given advice in respect of, C1, C2, GQ4, GQ6, GQ7, GQ8, PFE3 and D1 to the DI.

The HTA requires that the DI addresses the identified shortfall 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: 05 January 2017

Report returned from DI: 12 January 2017 (with comments)

Final report issued: 12 January 2017

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: 27 July 2017

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• There is a documented policy which governs consent for post-mortem examination and the retention of tissue and reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent. • There is a documented SOP detailing the consent process (including who is able to take consent, what training they must receive, and what information must be provided to those giving consent for post-mortem examination). • There is written information about the consent process (provided to those giving consent), which reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.
C2 Information about the consent process is provided and in a variety of formats
• Relatives are given an opportunity to ask questions. • Relatives are given an opportunity to change their minds and is it made clear who should be contacted in this event. • Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use). • Where consent is sought for tissue to be retained for future use, information is provided about the potential uses in order to ensure that informed consent is obtained. • Information on the consent process is available in different languages and formats, or there is access to interpreters/translators.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• There is a training programme for taking consent for post-mortem examination and tissue retention which addresses the requirements of the HT Act and HTA code of practice on consent. • Refresher training is available (e.g. annually). • Attendance at consent training is documented. • If untrained staff are involved in consent taking, they are always accompanied by a trained individual.

Governance and quality system standards

GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process

- Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include:
    - post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases
    - record keeping
    - receipt and release of bodies, which reflect out of hours arrangements
    - lone working in the mortuary
    - transfer of bodies and tissue (including blocks and slides) to other establishments or off site
    - ensuring that tissue is handled in line with documented wishes of the relatives
    - disposal of tissue (including blocks and slides)

  (Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)
- Policies and procedures are regularly reviewed (for example, every 1-3 years).
- There is a system for recording that staff have read and understood the latest versions of these documents.
- Deviations from documented SOPs are recorded and monitored.

GQ2 There is a documented system of quality management and audit

- There is a quality manual which includes mortuary activities.
- Policies and SOPs are version controlled (and only the latest versions available for use).
- There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits).
- Audits include compliance with documented procedures, records (for completeness) and traceability.
- Audit findings document who is responsible for follow up actions and the timeframe for completing those actions.
- Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why.
- There is a complaints system in place.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Staff are appropriately trained/qualified or supervised.
- Staff have annual appraisals.
- Staff are given opportunities to attend training courses, either internally or externally.
- Attendance by staff at training events is recorded.

- There is a documented training programme for new mortuary staff (e.g. competency checklist).

GQ4 There is a systematic and planned approach to the management of records

- There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.
- There are documented SOPs for record management.

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).
- Organs or tissue taken during post mortem examination are fully traceable, including blocks and slides. The traceability system ensures that the following details are recorded:
    - material sent for analysis on or off-site, including confirmation of arrival
    - receipt upon return to the laboratory or mortuary
    - number of blocks and slides made
    - repatriation with a body
    - return for burial or cremation
    - disposal or retention for future use.
- 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.
- There are documented procedures for disposal of human tissue, including blocks and slides.

D2 The reason for disposal and the methods used are carefully documented

- There are systems in place that ensure tissue is disposed of in accordance with the documented wishes of the deceased person's family.
- Disposal records include the date, method and reason for disposal.
- Tissue is disposed of in a timely fashion.

  (Note: this means that tissue is disposed of as soon as reasonably possible once it is no longer needed, e.g. when the coroner's or police authority ends or consented post-mortem examination is complete.)

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.