Site visit inspection report on compliance with HTA minimum standards

Bradford Royal Infirmary

HTA licensing number 12244

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**

16 October 2012

Summary of inspection findings

Bradford Royal Infirmary (the establishment) was subject to a themed inspection focusing on consent, quality management and prevention of major equipment failures.

Although the HTA found that the establishment had met the majority of the HTA standards in these areas, some shortfalls were found. Two major shortfalls were identified in relation to consent to retention of tissues collected at PM examination or timely disposal of these samples and storage of paediatric cases. Non compliances relating to these issues were identified at the previous inspection in September 2009 and the HTA was subsequently assured that these had been addressed; however, during this inspection, continuing problems were identified. In addition, a number of minor shortfalls were found in relation to consent training, traceability audits, risk assessments and standard operating procedures (SOPs). Several of these minor shortfalls were also identified during the previous inspection, but the advice provided at that time had not been acted upon.

The DI and the Licence Holder were assessed and found to be suitable in accordance with the requirements of the legislation at the establishment's previous inspection. However, the discovery of a number of wet tissue samples, blocks and slides held beyond the time

necessary for the Coroner's purposes, and the continued, but temporary, storage of paediatric cases in an unmonitored fridge has called into question their understanding of the requirements of the Human Tissue Act 2004 and the HTA strongly advises the DI to undertake the HTA's e-learning programme.

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.

A themed inspection may be carried out at establishments which have been found previously to represent a lower risk of regulatory non-compliance. Themed inspections focus on standards against which the HTA has identified common shortfalls across the post mortem sector and areas of risk identified from analysis of serious untoward incidents reported to the HTA. The themes selected for 2012/13 business year are outlined in the table below.

Themes	**HTA Standards**
Appropriate consent is in place for post-mortem examinations not under the Coroner's jurisdiction and in the event that tissue is to be retained for future use. Where there is no consent for retention, tissue is disposed of.	
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.	C1
Information about the consent process is provided and in a variety of formats.	C2
Staff involved in seeking consent receive training and support in the	C3

implications and essential requirements of taking consent.	
Governance and quality systems promote robust traceability systems, reducing the risk of serious untoward incidents.	
All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process.	GQ1
There is a documented system of quality management and audit.	GQ2
A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	GQ6
There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	GQ7
Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	GQ8
Fridges and freezers safeguard the integrity of the deceased.	
There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.	PFE3

In addition to the standards listed above, the HTA will follow-up on any other issues that have arisen since the establishment's last inspection.

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

Bradford Royal Infirmary carries out only a small number of post-mortem (PM) examinations each year. Approximately six coronial cases, five adult hospital consented and thirteen paediatric hospital consented cases are undertaken each year. The majority of coronial cases are transferred to the local HTA-licensed public mortuary under the direction of the Coroner. However, all tissue samples collected during PM examinations at the public mortuary are brought to the establishment and transferred with those collected by the establishment itself to an HTA-licensed histology facility for processing. Following analysis, blocks and slides are stored at this facility for up to a year in case further analysis needs to be completed for the purposes of the Coroner. If after a year instructions have not been received from the Coroner, they are returned to the establishment for storage pending receipt of the disposal wishes of the deceased's family.

Staff at the establishment obtain consent for non-coronial paediatric PM examinations using its own form and patient information booklet, or those provided by the HTA licensed establishment to which paediatric cases are sent if the local paediatric pathologist is on annual leave. A contract is in place between the two establishments for this purpose.

Bradford Royal Infirmary's accident and emergency department is also licensed for removal of tissue from the deceased, which is occasionally necessary in cases of sudden infant death, and is carried out under the authority of the Coroner. During the inspection it was identified that storage of placentas for a research study is being carried out under the licence; however, only limited details were known about this study.

This was the second routine inspection of the establishment, the first one having been undertaken in 2009. The previous inspection identified non compliances with HTA standards in relation to the storage of paediatric cases in an unmonitored paediatric fridge, as well as the continued storage of tissues following the end of the Coroner's authority. Following that inspection, assurances were given by the DI that paediatric cases were now stored within the main body store, which is subject to temperature monitoring and alarms, and a disposal policy had been developed to ensure timely disposal of samples. However, the HTA has identified persistent problems in these areas which are detailed in the shortfalls against C1, GQ2 and PFE3.

The themed inspection comprised interviews with members of staff, a review of relevant documentation and visual inspections of the following departments: accident and emergency, mortuary, body store, the mortuary tissue store and histology laboratory blocks and slides storage. An audit was carried out in the body store, during which the details on the wrist bands of two of the deceased were compared with corresponding details in the mortuary register. No anomalies were found. Records in the mortuary of tissue taken at PM examination were traced to histology and checked against the computerized database. A record of tissue transferred offsite for processing and its subsequent return was reviewed and the corresponding blocks and slides were located in storage. No anomalies were found. Due to the time available, only a sample of the establishment's SOPs were reviewed. These covered key processes such as receipt and release of bodies from the mortuary, PM examination, reporting of incidents and recording fridge temperatures, as well as the quality manual.

Inspection findings

The HTA found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation, though advice has been provided to the DI with respect to completion of the HTA e-learning programme.

Compliance with HTA standards

Consent

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the Code of Practice & C2 Information about the consent process is provided and in a variety of formats	Wet tissues and some frozen PM samples, some dating back as far as 2005 are being kept pending notification of the disposal wishes of the relatives from the Coroner's officer. On review of the coroner's form in use, it was evident that relatives are not given the option to retain tissues, only to have them repatriated with the body, returned to the family for their own disposal, or sensitively disposed of by the hospital. Even though this tissue is not actively being used for scheduled purposes, the long-term storage of tissue samples is not considered appropriate and steps must be taken to ensure that this practice ceases. The Coroner notifies the relevant pathologist when his authority has ended and informs them of the wishes of the next of kin regarding disposal. In turn the pathologist then notifies mortuary staff if tissues can be disposed of. However, in several cases the instructions from the Coroner have not been forthcoming and, mortuary staff remain unclear about whether these samples are still required for Coroner's purposes or whether consent had been obtained for their continued retention. A research study has commenced involving placentas, which are stored in the paediatric fridge. Consent documentation for the use of one placenta was reviewed. The details on the form were very brief, stating only the identification of the paediatric case and parent, and the name of the study. It did not outline what the placenta would be used for or how long it will be stored, so it is not clear exactly what the parent has consented to and whether this includes storage and use for a scheduled purpose under the HT Act. In addition, it was not clear what information about the study has been given to parents to inform their consent. The Women's Services department has produced a bereavement guideline document, which outlines the procedure for taking consent in paediatric cases; however this refers to the indefinite retention of blocks and slides, which does not comply	**Major**

	with the requirement for consent to be obtained for storage for a scheduled purpose. The consent form and information booklet for Paediatric PM examinations carried out at Bradford has not been reviewed since 2004 and the information booklet for adult consented PM examinations was implemented in 2002. All of these documents detail the consent that is required to retain whole organs and the disposal options for whole organs, but there is no reference to blocks and slides. The consent forms in use for adult and paediatric cases are not subject to document control.	
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	Bereavement staff who are involved in the consent process for paediatric and adult cases have received thorough training in obtaining consent; however, consent is not always sought in the presence of these staff. It is unclear when clinicians who are involved in taking consent received training and what the training incorporated. No training records were available for review.	**Minor**

Governance and Quality

Standard	**Inspection findings**	**Level of shortfall**
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	SOPs which require the identification of the deceased to be checked do not specify what details are checked to prevent errors in identification. In addition, the process for highlighting same or similar names is not contained in the admissions SOP. The lack of detail increases the risk of inconsistent practice and may result in errors.	**Minor**

GQ2 There is a documented system of quality management and audit.	The establishment carries out several procedural audits each year; however, traceability audits of key areas are not conducted. In particular, there is a store of wet tissues, blocks and slides, the majority of which are awaiting instructions from the Coroner in order that they can be disposed of (see advice against D1 below). Whilst a catalogue of this material is maintained, it is not audited to show compliance with the wishes of the relatives with regard to retention or disposal, or notification from the Coroner that their authority has ended. Regular audit of these tissues would ensure tissues are disposed of in a timely manner. Staff transfer deceased persons' identification details from the mortuary register onto an electronic database, however no checks are made for transcription errors.	**Minor**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	The establishment has carried out thorough risk assessments on the premises and processes that relate to health and safety. Risks of non-compliance with regulatory requirements and risks to the safety and security of bodies and tissue samples, such as loss of traceability, have not been considered.	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.	Paediatric cases are brought from the ward by porters and placed in a domestic fridge/freezer outside the main body store, which is not subject to temperature monitoring, either electronic or manual, or alarmed. Mortuary staff periodically check for bodies which have been brought in and move paediatric cases to the main body store, which is temperature monitored and alarmed. If the paediatric fridge were to fail out of hours or during a weekend, this may not be discovered until mortuary staff return to work. There is a risk that paediatric cases brought to the mortuary on a Friday afternoon would begin to decompose before discovery of the fault, compromising the outcome of a PM examination. The paediatric fridge/freezer is also used	**Major**

	for storage of products of conception and placentas, which are wrapped and labelled but not placed in containers; this was noted on the last inspection to be inappropriate.	

Advice

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

No.	Standard	Advice
1.	C1/C2/C3	The Sudden and Neonatal Death Charity (SANDS) will be publishing a model consent form, guidance for consent takers and information for bereaved parents in January 2013. The DI is advised to review the establishment's paediatric consent procedures in light of these, and make adjustments as appropriate.
2.	GQ2	The DI is advised that the checklist for SUDI cases, which is used to ensure various information has been gathered and all necessary samples have been collected, needs to be document controlled.
3.	GQ2	The DI is encouraged to involve staff from different departments, who do not normally carry out the activity, to audit processes. Staff who do not carry out a process on a day to day basis are more likely to identify discrepancies and aid continuous improvement.
4.	GQ2/ GQ6	The form used to record transfer of samples between the mortuary and histology laboratory has been photocopied and as a result has lost the details of version control contained in the footer. The DI is advised to ensure that only authorised versions of forms are used and photocopying is avoided. The DI is also advised that the number of cassetted pieces of tissue is recorded on the form, so that on arrival in histology staff can check that all samples have been received.
5.	GQ3	Staff training records were not reviewed as part of this inspection. Concerns were expressed over making changes to processes in the mortuary due to the difficulties associated with retraining portering staff. The DI is advised to review the staff allowed access to the mortuary to ensure only those competent in the transfer of bodies and completion of paperwork carry out these duties.
6.	GQ7	The establishment has an SOP for reporting serious untoward incidents to the HTA. The DI is advised to ensure the SOP includes the requirement to report SUIs within five working days.
7.	GQ8	The DI is advised to use the HTA serious untoward incident notification list as a basis for risk assessing processes where serious incidents could occur.
8.	PFE3	Discussions have taken place with the local public mortuary to act as a contingency for body storage should there be a fridge failure or lack of capacity at the establishment. The DI is advised to ensure this agreement is formalised as soon as practicable.
9.	D1	The DI is advised that consent is not required to dispose of relevant material, though attempts should be made to follow the wishes of the relatives wherever possible.

10.	-	The DI is advised to revisit the HTA e-learning training to ensure he is fully aware of Human Tissue Act 2004 consent requirements.

Concluding comments

A number of strengths and areas of good practice were noted during the inspection and examples are given below.

Since the establishment only has one paediatric pathologist, arrangements have been made and formalised in a contract, for paediatric PM examinations to be completed by another HTA licensed establishment when this pathologist is on leave. Consent forms and patient information booklets have been provided by that establishment and a member of the bereavement staff has participated in consent training and can guide staff who may have questions about the documents or transferring the paediatric cases to the other hospital. Where religious reasons require a PM examination to be completed within a short time frame, this is communicated with the establishment and where this is feasible, an assurance is given to the parents that the PM examination will not delay the funeral arrangements before the consent process is completed in full.

The monitoring of the main body store fridges is done comprehensively. Temperatures are recorded manually on a daily basis by mortuary staff, as well as by electronic sensors which relay the temperature information to the estates department, which provides a monthly summary of the temperature readings to the mortuary staff for their review. The process of monitoring fridge temperatures is described in two SOPs, one for manual and one for the electronic system; these documents also outline the action to be taken if the fridge temperature is outside the 2-8 degrees Celsius range.

An audit template has been developed for the various procedural audits that are completed. This consists of a checklist of areas which the auditor should observe and ask questions about and a summary sheet for the key audit findings. A ‘follow up’ sheet is also completed where the non-conformances are listed and appropriate actions identified and their completion recorded.

The establishment has implemented a quarterly ‘Human Tissue Management Group’ meeting, which has representatives from the mortuary, bereavement office, accident and emergency department, women’s services, research group as well as the Coroner. The consent process and use of human tissue is discussed at the meeting as well as any issues which relate to the HTA licence.

Following the previous inspection, two conditions were applied to the licence and a third was proposed but met before the finalisation of the report. Whilst evidence was submitted and accepted to demonstrate compliance with these conditions, the inspection has revealed key aspects which remain outstanding. These include the use of an unmonitored fridge for temporary storage of paediatric cases and long-term storage of foetus, products of conception and some PM tissue samples, as well as failures to dispose of PM tissue samples in a timely manner. A number of areas of advice have been implemented, but equally a number of areas have not been progressed, such as updates to consent documentation, risk assessments and audit of written and electronic records, which have been reported here as shortfalls. In total, two major and four minor shortfalls were identified during the inspection. The HTA has also given advice to the Designated Individual on a range of issues, including updates to documentation, disposal of tissues and completion of the HTA e-learning course.

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: 06/11/12

Report returned from DI: 16/11/12

Final report issued: 13/12/12

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: 26 May 2013

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.