Site visit inspection report on compliance with HTA minimum standards

Pathlinks
(in relation to the United Lincolnshire Hospitals Trust)

HTA licensing number 12314

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**

27-28 July 2016

Summary of inspection findings

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

Although the HTA found that Pathlinks (the establishment) had met the majority of the HTA standards, a minor shortfall was found, in relation to consent documentation.

Advice has also been given to the establishment with respect to some procedural documents, governance meetings, traceability systems and risk assessments.

Particular examples of 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 (DI), 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

Pathlinks currently holds two HTA post mortem (PM) sector licences covering four hospital sites within two separate NHS Trusts. The first licence covers the Lincoln County Hospital, Pilgrim Hospital in Boston and the Grantham and District hospital (licensing number 12314) and the second covers the Diana, Princess of Wales Hospital in Grimsby (licensing number 12310). Activities across the sites are overseen by the same Designated Individual (DI) with the Corporate Licence Holder Contacts being the Medical Directors of the respective Trusts.

Both sets of premises for which were inspected separately; however the inspections reflected the fact that many procedures are aligned and shared. In cases where findings were similar, the same advice and guidance has been offered to the DI in both inspection reports. This report relates to the inspection of the Lincoln County Hospital, the hub premises, and the two satellite premises, Pilgrim Hospital and Grantham and District hospital, which was carried out over two days (27 and 28 July 2016).

Pathlinks (the establishment) has been licensed since August 2007 and this was its third routine site-visit inspection to assess whether it continues to meet the HTA's standards. The timetable for the site visit was developed in consideration of the establishment's latest self-assessed compliance information, in addition to a review of the previous inspection findings and pre-inspection discussions with the DI and Person Designated (PD). During the site visit, a visual inspection of the premises, review of documentation and interviews with

establishment staff were undertaken, in addition to audits of bodies and retained tissue. No discussions were held with staff from the Coroner's office; however, the HTA met with a Coroner's Officer from the jurisdiction during the inspection of the Pathlinks licence at Grimsby (licence number 12310) and the coronial PM examinations taking place at the Lincoln establishment are performed under the authority of the same Coroner as those performed at the Grimsby establishment.

Both coronial and adult hospital (consented) PM examinations take place at the establishment's hub premises located at the Lincoln County Hospital. Paediatric and infant cases are transferred to another HTA licensed establishment for PM examination. The mortuary at the hub premises consists of a body store with 36 refrigerated spaces and four spaces providing frozen storage. In addition, there is a dedicated overflow storage facility providing a further 36 refrigerated spaces and space for up to two bariatric storage beds. All of the storage spaces at the hub have their temperature monitored electronically and should the temperature deviate from the expected range, an alarm sounds in the hospital's switchboard and staff alert the mortuary or the on-call Anatomical Pathology Technologist if the alarm sounds out of hours via an on-call mobile phone.

Hospital portering staff bring bodies to the mortuary outside of normal working hours and record their details in the establishment's mortuary register. Mortuary staff verify the details in the register against the details on the body during the next working day and also record details on the establishment's electronic database. The mortuary is appropriately secure with controlled access via a swipe card security system. Release of bodies to funeral directors is always undertaken by the mortuary staff.

The PM examination suite at the hub has three PM stations, although routinely only two of these are used, with the third being used occasionally by trainee pathologists so that they can work under the supervision of a senior. High risk PM examinations take place on bodies with known blood born infections including Hepatitis and HIV. Any bodies with known infections which are airborne are transferred to the Grimsby establishment and are undertaken in the dedicated high-risk PM suite.

The establishment carries out approximately 190 PM examinations at the hub premises, under the authority of the Coroner from the North Lincolnshire and Grimsby jurisdiction, and around six hospital, consented PM examinations each year. It updated the consent procedure and associated documentation following the last HTA inspection and although the standard operating procedure (SOP) reflected this update, the Trust's consent policy referred to and included an old version of a consent form produced by the Department of Health (DH) in 2003. Consent is sought by the clinician who was treating the deceased. The clinician is either supported throughout the consent seeking process by a member of staff trained in the seeking of consent or can receive training in the seeking of consent prior to the meeting with the family. Despite the establishment having a procedure where all consent forms are reviewed by the mortuary manager to check that they have been correctly completed prior to any PM activity being undertaken, having an out of date form referenced in the Trust's consent policy does pose a potential risk that the incorrect form could be used by a clinician seeking consent. Therefore, a shortfall has been identified against the consent standards.

If any tissue is taken during the course of adult PM examinations, it is placed into tissue cassettes in the PM suite and sent to the laboratory, which is also located within the hub site, for processing into blocks and slides. Following the review of the slides by the pathologist, blocks and slides are stored within the laboratory until the wishes of the deceased's family are received and the Coroner's authority has ended. Once the wishes of the deceased's family are received and coronial authority has ended, the establishment acts upon the wishes

of the family and either sensitively disposes of the tissue, returns the samples to the family or stores the tissue for future use with appropriate consent.

The establishment's two satellite premises are body stores only with no post mortem activity taking place at either site. At the Pilgrim Hospital satellite site there are a total of 61 storage fridge spaces with three for bariatric cases. There is also a dedicated fridge for the storage of paediatric and infant bodies. Mortuary staff carry out most duties; however, portering staff and the hospital's site managers have been trained in some mortuary procedures such as body receipt and undertaking body viewings out of hours. At the time of the inspection it was noted that there were two bodies with the same surname and a third with a similar name all being stored in the satellite's storage facility. Although staff were aware of the presence of three bodies with similar names, the documented same/similar name procedure where coloured markers are placed on the body store's doors was not being followed. The DI has been given advice below regarding the establishment's same/similar name procedure (see advice item 3).

At the establishment's Grantham and District Hospital satellite site there are a total of 24 refrigerated body store spaces. The alarm is monitored via an alarm which is linked to the building's burglar alarm and then onto the switch board which would notify establishment staff in the event of a fridge failure out of hours.

As part of the inspection, the Emergency Department of each hospital was visited to determine whether removal of relevant material from the body of a deceased person takes place in relation to the management of cases of sudden unexpected death of an infant or child (SUDIC).

Staff within the departments at Lincoln County Hospital and the Grantham and District Hospital reported that no samples are taken in such cases.

Staff from the department at Pilgrim Hospital were unclear whether samples are removed from the bodies of deceased infants or children in the department. Removal of relevant material from the body of a deceased infant or child is a licensable activity under the Human Tissue Act 2004 and, if occurring, would be taking place under the authority of the satellite licence. The DI must determine what, if any, samples are removed in such cases (see advice item 4).

Although paediatric and infant cases are transferred to another HTA-licensed establishment for PM examination, consent for these cases is sought by clinicians working in the maternity departments of the establishment premises at Lincoln County and Pilgrim hospitals. Staff use the consent and information forms provided by the licensed establishment where the PM examinations are undertaken. During the inspection of the hub premises at Lincoln County Hospital it was found that two folders held in the maternity department, containing blank consent forms to record consent, were available to staff seeking consent. The forms in each folder were different and it appeared that one set of forms was older and had been superceded by an updated version. The DI currently has not identified a PD in the maternity department to oversee the seeking of consent occurring there (see advice item 1).

At the Pilgrim Hospital satellite site's maternity department, the inspection team discussed the seeking of consent for PM examination of infants by department staff. PM examinations of infants do not take place under the establishment's licence and are undertaken at another HTA licensed establishment. Currently, it appears that an old version of the consent form is being used to record the consent given. It is important that the most up to date from is used to record consentand that the person giving consent is given up to date information. The out of

date consent forms being used to record consent for infant PM examinations at the satellite and the hub premises have been identified as a risk, which has resulted in a shortfall relating to consent (see also advice item 1).

There are no maternity services at the establishment's Grantham and District Hospital satellite site.

During the inspection several traceability audits were undertaken. Firstly, an audit of bodies that were stored at the establishment's hub premises at Lincoln County Hospital was performed, with details being taken from the identification bands on two bodies and cross checked against the details in the mortuary register and the establishment's electronic database.

An audit of the bodies in storage at the Pilgrim Hospital satellite site was undertaken. Firstly, two bodies that had been received in to the mortuary overnight by portering staff had their name, date of birth, hospital number and physical location cross checked against the paperwork, the storage fridge door and the mortuary register. Secondly, one body was removed from the storage fridge and the identity details, specifically name, date of birth and hospital number, were taken from the body ID tag. These details and the body's physical storage location were cross checked against the associated paperwork, the mortuary register and the establishment's electronic database.

An audit of the bodies in storage at the Grantham and District Hospital satellite site was also undertaken. One body was removed from the storage fridge and the identity details including name, date of birth and hospital number were taken from the body's ID tag. These and the body's physical storage location were cross checked against the associated paperwork, the mortuary register and the establishment's electronic database. No anomalies were found during any of the audits undertaken at any of the hub or satellite sites.

Finally, an audit of tissue taken during PM examination was undertaken. Details of tissue taken during two coronial PM examinations and one hospital, consented PM examination were noted. The laboratory records relating to the three PM examinations were reviewed, the physical blocks and slides sought and family wishes and consent forms relating to the tissue were reviewed. In all three cases, the laboratory records matched the details taken from the mortuary's tissue records and the physical number of blocks and slides also matched these and the laboratory's records. In the two coronial cases, the family's wishes had been received and indicated the family's wishes with regards to the retained tissue. In the consented case, a correctly completed consent form was reviewed, which indicated that consent had been given for retention of the tissue for future use. In summary, no anomalies were identified during the tissue traceability audit.

Inspection findings

The HTA found the DI and the Licence Holder to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

Consent

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the Code of Practice.	Despite the establishment's SOP regarding the seeking of consent referencing an up-to-date consent form and information leaflet, during the inspection it was found that the Trust's consent for PM examination policy refers to and includes a copy of an out of date Department of Health consent form. This out of date form does not reflect the requirements of the HT Act with regards to consent. During a review of the consent documentation used for recording consent for infant post mortem examinations, which are undertaken at another licensed establishment, different versions of the consent forms were available to staff. It appeared that some older versions of the consent forms were still in circulation and despite being superceded, could be used in error by establishment staff.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	The DI is advised to review the consent forms being used to record consent for infant PM examinations and to ensure that only the most up to date version is in use at the establishment. Additionally, the DI is also advised to appoint a PD in the maternity department where consent for infant PM examination is sought. Although these examinations take place at another HTA licensed establishment and consent is recorded using that establishment's consent procedure, having a point of contact will facilitate the DI being made aware of any changes to the consent procedures so that he may assure himself that they remain appropriate.
2.	GQ1	The establishment's SOPs referring to receipt, release and PM examinations of bodies all include reference to identity checks that are performed on the bodies prior to critical steps being undertaken. However they do not always detail which points of identification must be checked, such as name, hospital number, place of death or date of birth must be checked and what they should be checked against. The DI is advised to review all of the establishment's SOPs referencing identity checks, and where appropriate, amend them so that details of the points of

		identification that should be checked and what they are checked against are explicitly detailed.
3.	GQ1	The establishment has a procedure to highlight when two or more bodies with the same or similar names are being stored within the establishment's fridges and freezers. The procedure indicates that bodies with same or similar names will have a coloured sticker affixed to the storage fridge or freezer door. Although the same/similar name procedure covers all Pathlinks licensed premises, during the inspection a differing approach to identifying bodies with same or similar names was seen, and not all sites are using the coloured stickers to help identify such cases. The DI is advised to review compliance with the establishment's same/similar name procedure across all licensed premises to assure himself that the procedure is being followed as he expects, and either amend the procedure to reflect practice or retrain staff working at the establishment in the documented procedure.
4.	GQ1	As part of the inspection, the establishment's Emergency Departments at the hub and both satellite sites were visited. This was to determine if in SUDIC cases,where infants or children die in the establishment's emergency department or en-route to the emergency department, any samples are taken post mortem by department staff or paediatricians for analysis. Although most staff reported that such samples are not taken in SUDIC cases, during the visit to one of the Emergency Departments it was thought that some sampling may occur, following authorisation by the Coroner, with samples being taken by paediatricians. The DI is advised to liaise with the emergency and paediatric departments to determine whether or not any post mortem samples are taken in SUDIC cases. If samples are taken, he is also advised to ensure that the procedures around the sampling are appropriate and to appoint a PD to act as a point of contact regarding this activity, which is subject to licensing under the HT Act. This will facilitate the DI being made aware of any issues that arise, who will in turn, be better able to disseminate any licensing updates or information to staff in these areas. The DI is also advised to invite the PD to governance meetings so that information regarding licensable activity can be shared.
5.	GQ1	The DI is advised to review the frequency and format of governance meetings which include staff from the satellite premises and the other liensed site in Grimsby. The DI may wish to consider other forms of engagement (such as a standing monthly email communication) which could be used to supplement face to face meetings, meaning that the requirement for establishment staff to travel would be reduced. This may help to assure the DI that matters pertaining to licensable activity are being documented and shared with other staff, management and the DI working under Pathlink's.
6.	GQ6	The DI is advised to ensure that any corrections made to written records should be made by striking through the error with a single line and the correct entry added, rather than overwriting the original record or covering it with correction fluid or stickers.
7.	GQ8	The establishment has a good range of risk assessments which address not only health and safety risks but also risks to the bodies and tissues stored at the establishment. The DI is advised to review these risk assessments to ensure that all of the HTA reportable incident categories have been considered as risks and any procedures to mitigate the risk of them occurring are identified.

Concluding comments

Despite the minor shortfall identified, good practice was also observed during the inspection.

The establishment is introducing competency based training for hospital staff that undertake some procedures within the mortuary; for example, porters bringing the deceased to the mortuary. The training involves a review of the trainee's performance of certain tasks such as dealing with bariatric cases, which is undertaken and recorded by a trained member of staff. Only once a trainee is deemed competent are they signed off as authorised to carry out an activity. This competency based training helps to assure the DI that any staff undertaking work in the mortuary have been appropriately trained.

There are a number of areas of practice that require improvement, including one minor shortfall. The HTA has given advice to the DI with respect to some procedural documents, governance meetings, traceability systems and risk assessments.

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: 1 September 2016

Report returned from DI: 16 September 2016

Final report issued: 29 September 2016

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: 20 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: o post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases o record keeping o receipt and release of bodies, which reflect out of hours arrangements o lone working in the mortuary o transfer of bodies and tissue (including blocks and slides) to other establishments or off site o ensuring that tissue is handled in line with documented wishes of the relatives o 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 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.