



## **Site visit inspection report on compliance with HTA licensing standards**

### **ArroGen Forensics**

**HTA licensing number 12602**

**Licensed under the Human Tissue Act 2004 for the**

- **storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose**

**30 August 2018**

### **Summary of inspection findings**

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

Although the HTA found that ArroGen Forensics (the establishment) had met the majority of the HTA's standards, two major shortfalls and nine minor shortfalls were found against the Governance and Quality Systems, Traceability and Premises, Facilities and Equipment standards. These related to SOPs; audits; risk assessments; training; staff appraisals; incidents; slides sent off site for analysis and premises and equipment.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

## **The HTA's regulatory requirements**

Prior to the grant of a licence, the HTA must assure itself that the Designated Individual is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

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.

Its programme of site visit inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

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. They are grouped under four headings:

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

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, 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 provided.

HTA inspection reports are published on the HTA's website.

## Background to the establishment

ArroGen Forensics Ltd has been licensed by the HTA since December 2012. This report refers to the activities carried out at the establishment. The Designated Individual is the Operations Manager and the Corporate Licence Holder contact is the company Director. The service is coordinated by the Practice Manager and supported by a Biomedical Scientist. ArroGen Forensics Ltd is a Forensic Science company that provides a service to a network of private forensic pathologists who undertake post-mortem (PM) examinations on behalf of Coroners and the police. The establishment is licensed for the storage of a body of a deceased person or relevant material which has come from a human body for use for scheduled purposes.

The establishment receives wet tissue samples from pathologists undertaking forensic and coronial post mortems at various HTA licensed establishments throughout the UK. A security-cleared courier collects the samples on the day of the PM examination. A sample collection form is created in advance of the courier collection by the establishment and a unique identification code for the samples is generated. Once the samples are received by the establishment, they are processed into blocks and slides in the on-site laboratory (see shortfall against PFE1(a)). The blocks are stored at the establishment and the slides are sent to the relevant pathologist for examination. Staff follow a documented procedure for the dispatch, receipt and return of tissue slides. Once the pathologist has concluded their investigations, the slides are returned to the establishment where they are stored pending the end of coronial authority or under the Police and Criminal Evidence Act 1984 (PACE).

When Coronial authority for tissues has ended, the establishment contact the relevant Coroner's office, seeking information for relative's wishes regarding the fate of the tissue samples in storage. Tissue samples may be kept, if appropriate consent has been given for retention as part of the medical record or for use for scheduled purposes. However, the establishment do not use tissue for scheduled purposes (see *Advice*, item 11). The establishment are currently undertaking an audit of all PACE holdings to ensure that samples are not being retained longer than is necessary (see shortfall against T2(a)).

Key card access is required for the main entrance to the building. There is an intercom system to allow the on-site security team who operate 24/7, to confirm who is requesting access to the building. In addition, there is CCTV coverage of the storage areas. Laboratory areas are accessed by key codes and the Operations Manager keeps a record of who the codes have been distributed to. Storage areas are kept under key lock and the Practice Manager is the key holder who ensures only staff that need access are provided with the keys.

Blocks and slides stored at the establishment are recorded using excel spreadsheets to record the number of blocks and slides in storage, relatives wishes for samples, whether the tissue is being retained for scheduled purposes, disposed of, or returned to the family. Paper records are also kept on-site which includes the original consent forms (see *Advice*, item 2).

## Description of inspection activities undertaken

This was the second site visit inspection of the establishment with the previous inspection taking place in 2013. The inspection team carried out a visual inspection of the tissue storage areas and laboratory.

Roundtable discussions were undertaken with key members of staff and a review of the establishment's governance and quality systems, documentation and traceability audits were also undertaken. Audits were conducted for four Coroner's samples and two samples held under PACE. The audits included the number of blocks and slides retained or disposed, tissue consent forms, associated paperwork and cross-checking this information on the excel spreadsheets. In addition, the establishment's disposal records were reviewed for three cases to check disposal had occurred in line with the original consent given. No anomalies were found.

## Inspection findings

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

## Compliance with HTA standards

Standard	Inspection findings	Level of shortfall
<b>GQ1 All aspects of the establishment's work are governed by documented policies and procedures</b>		
a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPATH.	<p>The SOP 'Outline of Histopathology Services' (FPS0002/05) references the HTA code of practice on disposal (Code of Practice 5) which is no longer in use.</p> <p>The SOP 'The Reporting of Human Tissue Act Reportable Incidents' (H008a) has not been reviewed since August 2013.</p> <p>In addition, a review of all SOPs relating to licensable activities is required to ensure that they are accurate and contain sufficient up-to-date detail of the procedures.</p>	<b>Minor</b>
d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use	Although SOPs are version controlled, there are no page numbers in some of the SOPs and many have not been ratified by someone other than the author.	<b>Minor</b>

e) There is a system for recording that staff have read and understood the latest versions of these documents	There is not a system for recording that staff have read and understood the latest versions of SOPs. This does not provide assurance that staff are aware of or conforming to SOPs that govern their work.	<b>Minor</b>
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	There are no formal governance meetings between staff and the DI. This means that HTA-related activities, any adverse events or other governance issues are not being discussed in a formal setting. This makes it difficult to identify areas for improvement and allocate tasks to staff to undertake improvements.	<b>Minor</b>

<b>GQ2 There is a documented system of audit</b>		
a) There is a documented schedule of audits	<p>The establishment does not have a documented schedule of audits for activities taking place under the licence.</p> <p>While some audits of activities had been performed by the establishment, these did not include process or observational audits, the establishment cannot therefore provide assurance that activities are conducted in accordance with documented procedures.</p>	<b>Major</b>
c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention	<p>The establishment have not undertaken regular audits of tissue in storage. There has been one audit of tissue blocks and slides since 2013.</p> <p>Although staff try to follow-up with the relevant Coroner's office or police force regarding relative's instructions for tissues, audits of tissues in storage have not been carried out frequently enough to establish if relatives instruction have been received.</p> <p>In addition, the DI cannot be assured that the processes and procedures in place for the retention and disposal of human tissue is robust.</p>	

<b>GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks</b>		
a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised	Staff receive some training in establishment procedures when they begin working for the establishment, however, the system for refresher training is poor and training is not documented for each member of staff.	<b>Minor</b>
d) Staff have annual appraisals and personal development plans	Staff do not have annual appraisals or personal development plans.	<b>Minor</b>

<b>GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored</b>		
a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis	The establishment have assessed a number of risks associated with licensed activities, although some key risks, for example, risks to the integrity of the tissue, have not been assessed. In addition, the risk assessments have not been reviewed since 2013.	<b>Major</b>
b) 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	Even though the risk assessments identify the control measures that are in place to mitigate each risk, many of these mitigating factors had not been finalised at the time of the assessment, therefore the effectiveness of mitigating factors could not be adequately assessed as they had not themselves been finalised.	

<b>T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.</b>		
a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete	<p>The establishment are currently experiencing issues with the return of slides sent off-site to pathologists for analysis.</p> <p>As pathologists may not return tissue slides in a timely fashion, once analysis has been completed, the establishment are not able to carry out the relatives wishes for tissues e.g. disposal, therefore pathologists are retaining tissue longer than is necessary.</p>	<b>Minor</b>

<b>PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.</b>		
a) The premises are clean and well maintained	The laboratory workbench surfaces and edges have areas of exposed wood. This damage makes the wood porous; therefore, the areas cannot be adequately cleaned or disinfected.	<b>Minor</b>
c) There are documented cleaning and decontamination procedures and a schedule of cleaning	There is a documented cleaning procedure with a cleaning schedule however, on inspection of the cleaning rota, the cleaning appears not to be completed when the cleaner is on holiday.	

<b>PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored</b>		
e) Where chemicals are used for preservation of tissue samples, there is adequate ventilation	The alarms on the ventilation tables in the cut-up laboratory were faulty and not working. This raises concerns that the ventilation may not be adequate for staff who regularly work with formalin.	<b>Minor</b>

## Advice

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

No.	Standard	Advice
1.	GQ1(h)	The DI is advised to have meetings with Persons Designated (PDs) under the licence in order to help maintain oversight of licensable activities.
2.	GQ4(a)	The DI is advised to scan tissue forms and store them electronically as currently only paper records are being kept. Having electronic copies will ensure that this information is available in case of loss or damage of paper records.
3.	GQ5(a)	The DI is advised to ensure any issues with tissue received from establishments is recorded in the establishment incident log and to follow-up with the sending establishment.
4.	GQ5(a)	<p>There are currently two SOPs for staff to follow regarding incidents:</p> <ul style="list-style-type: none"> <li>- Incident and Complaints Reporting H008 (last reviewed 16/04/18) and</li> <li>- The Reporting of Human Tissue Act Reportable Incidents (last reviewed 9/8/13).</li> </ul> <p>The DI is advised to consider amalgamating the SOPs for continuity and ensure that all relevant HTARI categories are listed and that staff working under the licence read and acknowledge this SOP to improve awareness of HTARI incidents and reporting.</p> <p>In addition, the DI may wish to consider having the Biomedical Scientist as a PD who can access the HTARI portal on the HTA website, as they work directly with human tissue and will be aware of most incidents as they arise.</p>
5.	GQ6(a)	In addressing the shortfall that was identified against standard GQ6(a) the DI is advised to consider reviewing the HTA's publication 'Regulation of the Post Mortem Sector: What we have learned' (October 2016) which provides guidance and information in relation to risk assessments. This is available on the HTA's website.
6.	GQ6(b)	The DI is advised to re-assess the risk to staff who work out-of-hours and consider measures that could be implemented to help mitigate the risk to staff who may be working alone. For example, contacting security when they arrive and leave or the use of a personal alarm that will notify security in the event of an issue.
7.	T1(d)	The DI is advised to consider adding the process for same/similar names to the relevant SOPs, as there is a process in place, which was confirmed verbally, but this is not currently documented.
8.	T1(g)	The DI is advised to add the 'tissue type' to the electronic database rather than just the number of blocks and slides for the purposes of traceability. When slides are sent off-site to pathologists the establishment are currently only recording how many slides are due to be returned but if slides were to be lost, the establishment would not know what tissue types are missing. The current procedures for dispatch, receipt and return of tissue slides should be reviewed in light of these issues.

9.	T1(g)	The establishment stores a lot of tissue blocks and slides. The DI is advised to continue exploring options of a new electronic database and away from the various excel spreadsheets, which is a confusing system to navigate. The new system will also enable the establishment to upload tissue forms electronically, which will mitigate the risk of loss of paper records.
10.	PFE3(d)	DI is advised to ensure appropriate PPE is accessible for staff entering the laboratory area. Even though PPE is available, it is not in an easy place to reach.
11.	N/A	The DI is advised to refer to the Royal College of Pathologists (RcPath) document 'The retention and storage of pathological records and specimens' (5th edition, April 2015), for guidance in relation to the timescales for storing tissue blocks and slides, if consent has been given to retain them as part of a medical record. In addition, the DI may wish to consider contacting other licensed establishments who may be able to use tissue with consent for scheduled purposes, e.g. teaching and/or research, consider if it is appropriate to continue to store tissue that is not being used for the purpose for which it was retained, or if disposal of these tissues would be more appropriate.

### Concluding comments

The HTA observed some areas of strength and good practice during the inspection.

All staff involved in the inspection demonstrated a sensitive and dedicated approach to their work. Staff at the establishment are currently undertaking an inventory of police holdings focusing on one police force at a time in order to ascertain which tissue is no longer held under PACE and thus falling within the remit of the HTA.

There are a number of areas of practice that require improvement, including two major and nine minor shortfalls.

The HTA requires the Designated Individual to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, 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: 27 September 2018**

**Report returned from: 8 October 2018**

**Final report issued: 24 October 2018**

## 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: 23 June 2019**

## Appendix 1: HTA licensing standards

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

<b>Consent</b>
<b>C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice</b>
<p>a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice.</p> <p>b) There is a documented standard operating procedure (SOP) detailing the consent process.</p> <p><i>Guidance</i></p> <p><i>This should include who is able to seek consent, what training they should receive, and what information should be provided to those giving consent for post-mortem examination. It should make reference to the use of scanning as an alternative or adjunct to post-mortem examination.</i></p> <p>c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice.</p> <p><i>Guidance</i></p> <p><i>Information on consent should be available in different languages and formats, or there is access to interpreters/translators. Family members should be given the opportunity to ask questions.</i></p> <p>d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives.</p>

- e) Where consent is sought for tissue to be retained for future use, information is provided about the potential uses to ensure that informed consent is obtained.
- f) The deceased's family are given an opportunity to change their minds and it is made clear who should be contacted in this event and the timeframe in which they are able to change their minds.
- g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided.

*Guidance*

*This may be based on the HTA's model consent form for adult post-mortem examinations available on the HTA website, or in relation to infants, the resources pack developed by the Stillbirth and neonatal death charity, Sands. The consent forms should record the consent given for the post-mortem examination and for the retention and future use of tissue samples.*

**C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent**

- a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice.

*Guidance*

*Refresher training should be available (for example annually).*

- b) Records demonstrate up-to-date staff training.
- c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual.
- d) Competency is assessed and maintained.

**Governance and quality systems**

**GQ1 All aspects of the establishment's work are governed by documented policies and procedures**

- a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPATH. These include:
  - i. post-mortem examination, including the responsibilities of Anatomical Pathology Technologists (APTs) and Pathologists and the management of cases where there is increased risk;

- ii. practices relating to the storage of bodies, including long term storage and when bodies should be moved into frozen storage;
- iii. practices relating to evisceration and reconstruction of bodies;
- iv. systems of traceability of bodies and tissue samples;
- v. record keeping;
- vi. receipt and release of bodies, which reflect out of hours' arrangements;
- vii. lone working in the mortuary;
- viii. viewing of bodies, including those in long-term storage, by family members and others such as the police;
- ix. transfer of bodies internally, for example, for MRI scanning;
- x. transfer of bodies and tissue (including blocks and slides) off site or to other establishments;
- xi. movement of multiple bodies from the mortuary to other premises, for example, in the event that capacity is reached;
- xii. disposal of tissue (including blocks and slides), which ensures disposal in line with the wishes of the deceased person's family;
- xiii. access to the mortuary by non-mortuary staff, contractors and visitors;
- xiv. contingency storage arrangements.

*Guidance*

*SOPs should reflect guidance contained in the HSE's document: Managing the risks of infection in the mortuary, post mortem room, funeral premises and exhumation.*

*Individual SOPs for each activity are not required. Some SOPs will cover more than one activity.*

- b) Procedures on evisceration ensure that this is not undertaken by an APT unless the body has first been examined by the pathologist who has instructed the APT to proceed.
- c) Procedures on body storage prevent practices that disregard the dignity of the deceased.

*Guidance*

*For example, placing more than one body on a tray, placing bodies unshrouded on trays, or storing bodies in unrefrigerated storage should not take place.*

*The family's permission should be obtained for any 'cosmetic' adjustments or other invasive procedures prior to release of bodies, for example, sewing the deceased's mouth to close it or the removal of a pacemaker. It is also good practice to discuss with the family any condition that may cause them distress, for example when viewing or preparing the body for burial, such as oedema, skin slippage of signs of decomposition.*

*If identification of the body is to take place before a post-mortem examination, if available, a Police Family Liaison or Coroner's Officer should have a discussion with the family about the injuries and let them know that reconstruction may be required.*

*However, the Pathologist should see the body without any changes being made, so if there is a need to reconstruct or clean a body before the post-mortem examination, it should be with the agreement of both the Pathologist and the Coroner. In Home Office cases, a viewing cannot normally take place until after the post-mortem examination.*

- d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use.
- e) There is a system for recording that staff have read and understood the latest versions of these documents.
- f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity.
- g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework.

*Guidance*

*These areas include maternity wards where storage of fetuses and still born babies takes place, areas where material is stored for research, the Accident and Emergency Department where removal of samples may take place in cases of sudden unexpected death in infancy. There should be an identified Person Designated in areas of the establishment remote from the main premises.*

- h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff.

*Guidance*

*Meeting minutes should be recorded and made available to staff.*

**GQ2 There is a documented system of audit**

- a) There is a documented schedule of audits.

*Guidance*

*As a minimum, the schedule should include a range of vertical and horizontal audits checking compliance with documented procedures, the completion of records and traceability.*

- b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these.

*Guidance*

*Staff should be made aware of the outcomes of audits and where improvements have been identified.*

- c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention.

*Guidance*

*Audits of stored tissue should include samples held under the authority of the police, where applicable.*

**GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks**

- a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised.

*Guidance*

*This includes portering staff, who have responsibility for bringing bodies to the mortuary out of hours and who may not be aware of the potential risks to the deceased during transfer into refrigerated storage, and unqualified mortuary 'assistant' staff.*

*APTs should be trained in reconstruction techniques to ensure that the appearance of the deceased is as natural as possible. APTs should be encouraged to work towards the achievement of the RSPH Level 3 Diploma in Anatomical Pathology Technology.*

- b) There are clear reporting lines and accountability.  
c) Staff are assessed as competent for the tasks they perform.

*Guidance*

*Assessment of competence should include the standard of APTs' reconstruction work.*

- d) Staff have annual appraisals and personal development plans.  
e) Staff are given opportunities to attend training courses, either internally or externally.

*Guidance: attendance by staff at training events should be recorded.*

- f) There is a documented induction and training programme for new mortuary staff.  
g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures.

*Guidance*

*The qualifications of locum staff should be checked prior to them commencing work in the mortuary and their competency to undertake each task should be assessed.*

*Contractors, visiting and temporary staff and funeral service staff bringing bodies out of hours should be required to read relevant standard operating procedures and sign to confirm their understanding.*

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

- a) 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.

*Guidance*

*Records include mortuary registers, PM examination records, tissue retention forms and records of transfer and return of organs/tissue sent elsewhere for examination.*

- b) There are documented SOPs for record management which include how errors in written records should be corrected.
- c) Systems ensure data protection, confidentiality and public disclosure (whistle-blowing).

#### **GQ5 There are systems to ensure that all untoward incidents are investigated promptly**

- a) Staff know how to identify and report incidents, including those that must be reported to the HTA.

*Guidance*

*HTA-reportable incidents must be reported within five days of the date of the incident or date of discovery.*

*Incidents that relate to a failure of hospital staff to carry out end of life care adequately should be reported internally and the incidence of these monitored.*

- b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents.
- c) The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.
- d) Information about incidents is shared with all staff to avoid repeat errors.
- e) The establishment adopts a policy of candour when dealing with serious incidents.

#### **GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored**

- a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis.

*Guidance*

*Risks to the dignity and integrity of bodies and stored tissue should be covered. The HTA's reportable incident categories provide a good basis for risk assessments. Risk assessments should be reviewed at regular intervals, for example every 1-3 years or when circumstances*

*change. Staff should be involved in the risk assessment process.*

- b) 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.

*Guidance*

*Relevant staff should have knowledge of risks and the control measures that have been taken to mitigate them.*

- c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register.

## **Traceability**

### **T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail**

- a) Bodies are tagged/labelled upon arrival at the mortuary.

*Guidance*

*The condition and labelling of bodies received in body bags should always be checked and their identity confirmed. They should be labelled on the wrist and/or toe. Body bags should not be labelled in place of the body.*

- b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records).

*Guidance*

*Body receipt and release details should be logged in the mortuary register, including the date and name of the person who received/released the body and, in the case of release, to whom it was released. This includes bodies sent to another establishment for PM examination or bodies which are sent off site for short-term storage which are subsequently returned before release to funeral service staff.*

- c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier.

*Guidance*

*Identification details should not be written on bodies. Where bodies are moved off site for contingency storage the DI should ensure that suitable systems are in place to identify same or similar names.*

- d) There is system for flagging up same or similar names of the deceased.

- e) Identity checks take place each time a body is moved whether inside the mortuary or from the mortuary to other premises.

*Guidance*

*Mortuary white boards containing the names of the deceased give potential for error if wiped clean (such as when visitors attend for reasons of confidentiality), and should not be relied upon as the sole source of information about the locations of bodies.*

*Fridge/freezer failures that require bodies to be moved temporarily whilst repairs take place present a risk to traceability. Full identification checks should be made when they are placed back into normal storage.*

- f) There are procedures for releasing a body that has been in long term storage and is therefore not in the current register.
- g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings). The traceability system ensures that the following details are recorded:
- i. material sent for analysis on or off-site, including confirmation of arrival
  - ii. receipt upon return to the laboratory or mortuary
  - iii. the number of blocks and slides made
  - iv. repatriation with the body
  - v. return for burial or cremation
  - vi. disposal or retention for future use.

*Guidance*

*Consent information which covers retention/disposal of tissues should be made available to the other site, as appropriate.*

- h) There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary, (such as to the lab or another establishment), including record-keeping requirements.

*Guidance*

*Formal written agreements with funeral services are recommended. Coroners usually have their own agreements for transportation of bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases.*

**T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.**

- a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete.

- b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary.
- c) Disposal is in line with the wishes of the deceased's family.

*Guidance*

*Organs and tissue returned to the body prior to its release should be contained in clear viscera bags, which prevent leakage, are biodegradable and pose no issues for crematoria in relation to emissions and pollution. Clinical waste bags or household bin bags should not be used for this purpose.*

*Tissue blocks and glass slides should not be placed inside the body for the purpose of reuniting tissues with the deceased. Blocks and slides should be placed in a suitable container and transported with the body should the family wish to delay the funeral until the slides are returned.*

- d) The method and date of disposal are recorded.

**Premises, facilities and equipment**

**PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue**

- a) The premises are clean and well maintained.

*Guidance*

*Floors, walls and work surfaces should be of non-porous construction and free of cracks and chips. The premises should be subject to a programme of planned preventative maintenance, which ensures that the premises, facilities and equipment remain fit for purpose.*

- b) There is demarcation of clear, dirty and transitional areas of the mortuary, which is observed by staff and visitors.
- c) There are documented cleaning and decontamination procedures and a schedule of cleaning.
- d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access).

*Guidance*

*Relatives who visit for a viewing should not be able to access the body store area. Security systems and lone working arrangements should take into account viewings which take place out of hours.*

- e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access.

## PFE2 There are appropriate facilities for the storage of bodies and human tissue

- a) Storage arrangements ensure the dignity of the deceased.

*Guidance*

*Refrigeration of bodies should be at a temperature of approximately 4 degrees Celsius. The optimal operating temperature for freezer storage is around -20 Celsius, +/- 4 degrees.*

- b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity.

*Guidance*

*Capacity should be regularly reviewed, particularly if contingency arrangements are used for an extended period.*

- c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs.

*Guidance*

*There should be sufficient frozen storage for the long-term storage of bodies; the HTA advises that bodies should be moved into frozen storage after 30-days in refrigerated storage if there is no indication they are soon to be released or further examined, or before, depending on the condition of the body. Where there is insufficient freezer storage to meet needs, there should be arrangements with other establishments, or other contingency steps, to ensure that bodies can be stored appropriately.*

*Bodies in long-term storage should be checked regularly; this should include confirmation of their identity and the reason for their continued storage.*

*Where new fridges are installed, these should measure 24"-26" in width and consideration should be given to the proportion that should be larger to accommodate bariatric bodies.*

- d) Fridge and freezer units are in good working condition and well maintained.
- e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range.
- f) Temperatures of fridges and freezers are monitored on a regular basis.

*Guidance*

*Temperature monitoring should enable the establishment to identify trends and may mitigate the risk of a possible fridge failure.*

- g) Bodies are shrouded or in body bags whilst in storage.
- h) There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.
- i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods.

*Guidance*

*Where contingency arrangements involve the transfer of bodies to other premises, these should be assessed to ensure that they are suitable and that traceability systems are of the required standard. Stacking bodies on the same fridge tray is not considered suitable practice.*

*Establishments should have documented agreements with any funeral services that they may use for contingency storage. Consideration should be given to whether the funeral service provides contingency storage for other mortuaries. SOPs should address issues such as risk assessments and same/similar name systems.*

*The hire of temporary storage units should not be the sole contingency arrangement for an establishment. Establishments should put in place other formally agreed arrangements for contingency storage. Where the hire of temporary storage facilities*

*forms part of establishments' contingency arrangements, consideration should be given well in advance and steps taken to ensure availability of funds, and of units for hire.*

*Establishments should consider entering in to Mutual Aid Agreements*

*with neighbouring organisations in order that they can provide and obtain support during periods of capacity shortages.*

**PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored**

a) Items of equipment in the mortuary are in a good condition and appropriate for use:

- i. fridges / freezers
- ii. hydraulic trolleys
- iii. post mortem tables
- iv. hoists
- v. saws (manual and/or oscillating)

*Guidance*

*Equipment should be made of material that is easy to clean, impervious, non-rusting, non-decaying and non-staining.*

b) Equipment is appropriate for the management of bariatric bodies.

c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually.

*Guidance*

*COSHH requires a thorough examination of the ventilation system at 14-month intervals, and sets out what the examination should cover.*

- d) Staff have access to necessary PPE.

*Guidance*

*Where face masks should be worn, they should be face fitted.*

- e) Where chemicals are used for preservation of tissue samples, there is adequate ventilation.

- f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept.

*Guidance*

*This includes fridges in Maternity where fetuses or still born babies are stored prior to examination. Maintenance records may be held by the mortuary or centrally by the Trust, such as the Estates Department. They should be available for review during inspection by the HTA.*

## 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.