Site visit inspection report on compliance with HTA licensing standards

North Tyneside General Hospital

HTA licensing number 12261

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**

6 – 8 March 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 North Tyneside General Hospital had met the majority of the HTA's standards, twelve minor and five major shortfalls were found against the Consent, Governance and Quality systems, Traceability and Premises, Facilities and Equipment standards. These related to the consent form and training in seeking consent for hospital (consented) post mortem examinations; information for relatives; standard operating procedures (SOPs); audits; staff training and competency; lone working; traceability of tissue blocks; disposal of tissues and temperature alarms.

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

North Tyneside General Hospital (the establishment) is part of Northumbria Healthcare Foundation NHS Trust. This report refers to the activities carried out in the mortuaries located at North Tyneside General Hospital (the hub site), Hexham General Hospital (satellite site) and Northumbria Specialist Emergency Care Hospital (satellite site). The mortuary is managed by the Histopathology Department. The DI is a Consultant Histopathologist and the Corporate Licence Holder contact is the Executive Medical Director of the Trust. The establishment is licensed under the Human Tissue Act 2004 (HT Act) for: 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 scheduled purposes.

The establishment receives approximately 4000 bodies each year from deaths in the hospitals in the Trust and the community, and performs around 900 post-mortem (PM) examinations annually, the majority of which are conducted for HM Coroner for North Tyneside. The total figure for PM examinations undertaken includes high-risk (up to category three), forensic and around two hospital (consented) PM examinations. Paediatric/perinatal PM examinations are transferred to another HTA-licensed establishment. Consent for adult hospital PM examinations is sought by two Senior Anatomical Pathology Technologists (APTs) who have received some training in the seeking of consent (see shortfall against C2(a).

The establishment has a total of 88 refrigerated body spaces, including two bariatric spaces. All spaces can be converted to freezer storage but normally no more than four are used for this purpose, when required, for the storage of long term bodies (see shortfall against GQ1(a)(i)). Twenty-eight of the refrigerated body spaces are ‘double-ended’, providing direct access in to the PM room. There are dedicated refrigerated spaces for paediatric/perinatal cases and pregnancy remains (if required) in a dedicated storage area within the PM room.

Swipe card access is required for both external doors to the mortuary, which are covered by hospital CCTV. In addition, there is a camera and intercom system at both doors so mortuary staff are able to verify who is requesting access before opening the doors. Motion-activated, departmental CCTV covers mortuary access areas, corridors and the body store, and footage is reviewed daily by the senior APT.

Across all sites, portering staff transfer and admit all hospital bodies. They are also responsible for admitting community bodies in to the mortuaries at North Tyneside General Hospital (NTGH) and Hexham General Hospital (HGH). Hospital bodies are transferred from the wards using a concealment trolley. Upon admission, the mortuary register, body store location whiteboard and fridge door details are completed by the porters using the information on the ‘Notification of Death’ (NOD) form transferred with each body (see

shortfall against GQ1(a),(i)). Community bodies are brought to the mortuaries by contracted funeral directors. The mortuary staff complete body identification checks as soon as possible on the day, or the next working day if the body was admitted out of hours (see shortfall against PFE2(g) and *Advice*, item 18).

Training in mortuary practice and procedures is provided to all porters by the Senior APTs however, there is no refresher training being delivered (see shortfall against GQ3(a)).

Perinatal cases, pregnancy remains, products of conception (POCs) and their associated documentation, from all hospitals within the Trust, are recorded in dedicated registers and ultimately transferred to the mortuary at the hub site to facilitate the requested disposal option.

All bodies are entered on to a dedicated spreadsheet (for each mortuary) that can be accessed and updated from each of the establishment's sites. Bodies are released from the mortuaries using a standardised release form for this purpose (see *Advice*, item 19).

The PM suite at the hub site contains three downdraught PM tables, each with an associated dissection area. When removing bodies from refrigerated storage, APTs carry out initial identification checks against coronial or consent documentation and again with the pathologist prior to the external examination and evisceration commencing. Pathologists complete each PM examination before commencing the next case to help mitigate against any risk of a mix-up of organs and tissue samples between cases.

Three Consultant Histopathologists, including the DI who is the only one based at the establishment, fulfil the PM service. The pathologists make a record of any tissue taken during a PM examination (see shortfall against T1(g)). All PM histology specimens retained by the DI are taken and processed at the histopathology laboratory on site, where they are signed for, as confirmation of receipt, by the laboratory staff. PM histology specimens taken by the visiting pathologists are transferred to, and processed, at another licensed establishment (see *Advice*, item 21).

Two Senior APTs, three APTs and one trainee APT work across all three of the establishment's sites. A Mortuary Assistant has recently been appointed (but is not yet in post) to help with non-technical duties and work across the satellite sites. Mortuary staff work on-call and provide cover for all of the establishment's sites during out of hours periods.

Traceability audits of body identifiers, storage locations, mortuary register details and associated documentation were carried out for four adult bodies (one hospital and three community bodies). Two minor anomalies were found:

- The fridge location of one body had not been updated in the mortuary register;

- The release section of the mortuary register had been completed for the same body but had been 'rubbed out' as it had been completed in error.

In addition, an audit of four cases where tissue had been removed for histological analysis during PM examinations was conducted. The inspection team visited the histopathology laboratory to review retained tissue and the associated traceability records. In addition, records of the relative's wishes regarding the fate of the tissue following its analysis were reviewed to determine if they had been acted upon appropriately. One anomaly was found:

- The 'Post Mortem Histology Request' form completed by the pathologist detailed the four types of tissue collected during the examination. While this was tracked appropriately in the electronic records, the details transcribed onto the Coroner's consent form, and discussed with the relatives, only noted two types of tissue collected during the PM examination.

  A review of the associated 'Post Mortem Histology Request' form and the 'Post Mortem of an Adult Ordered by the Coroner' form, showed that, although types of tissue are recorded, the quantities of each are not; for example, the number of blocks and/or pieces retained (see shortfall against T1(g)). In addition, the Coroner's form appears contradictory regarding the instructions for tissue when the Coroner's authority had ended (see shortfall against T2(a)).

Hexham General Hospital (satellite site)

Hexham General Hospital (HGH) mortuary is currently being used as a body storage facility only. PM examinations have not taken place at this site since November 2017. Community and hospital bodies admitted to the mortuary that require PM examination are transferred to the establishment's hub premises.

This mortuary has a total of 20 refrigerated body spaces, including four semi-bariatric spaces. These spaces can also be converted to freezer spaces for long-term body storage, if required. HGH mortuary can be used as part of the contingency storage plan for the hub premises during busy periods.

There is an external access door to the mortuary, for the admission and release of all bodies, which is secured by a key/thumb lock and covered by hospital CCTV externally and motion-activated departmental CCTV internally. There is an intercom system to speak to individuals requesting access (see shortfall against PFE1(d)(i)).

The mortuary is staffed, part-time, by an APT from the hub premises. Viewings are arranged and conducted by the APT on site (see shortfalls against GQ1(a)(ii), GQ6(a) and PFE1(d),(ii)).

The PM suite contains two downdraught tables and a dissection unit. Although not currently in use, the PM suite can be used as a contingency facility for post mortem services, providing the licence for this activity is maintained (see *Advice*, item 28).

Traceability audits of body identifiers, storage locations, mortuary register details and associated documentation was carried out for the three adult hospital bodies in storage. No anomalies were found.

Northumbria Specialist Emergency Care Hospital (satellite site)

Northumbria Specialist Emergency Care Hospital (NSECH) is a relatively new acute hospital, including Accident and Emergency and maternity care. This site has been licensed by the HTA since 2015. The mortuary at NSECH is a body storage facility for the hospital and is part of the contingency storage provision during busy periods at the hub premises. Bodies that require a PM examination are transferred to establishment's hub site.

The satellite has a total of 52 refrigerated body spaces, including eight bariatric spaces. There is no freezer storage; however, bodies requiring long-term storage are transferred to the hub site. There is a dedicated fridge for the storage of perinatal bodies, pregnancy remains and POCs.

Swipe card access is required for all external and internal doors within the mortuary; for example, into the body store and viewing area. There is a camera and intercom system at both external access doors and an electric access gate that funeral directors use meaning that mortuary staff are able to verify who is requesting access before allowing entry.

The mortuary is staffed full-time during normal working hours by an APT from the hub premises. Viewings are arranged and conducted by the APT on site (see shortfalls against GQ1(a)(ii), GQ6(a) and PFE1(d)(ii)).

Paediatric/perinatal PM examinations are transferred to another HTA-licensed establishment. Consent for paediatric/perinatal PM examination is sought by clinicians who may not have received training in PM consent-seeking (see shortfall against C2(a)(ii). The consent form used for paediatric/perinatal cases and the information booklet is provided by the referring establishment and based on the SANDs documentation (see *Advice*, item 2).

In addition to the storage activities described above at all sites, the removal of tissue samples from the body of a deceased child occasionally only takes place in the Accident and Emergency Department at NSECH. The process and documentation for these cases was reviewed as part of the inspection and found to be compliant with current guidelines.

Traceability audits of body identifiers, storage locations, mortuary register details and associated documentation was carried out for three adult hospital bodies and one perinatal body. No anomalies were found.

Description of inspection activities undertaken

The establishment has been licensed by the HTA since August 2007. Previous routine site visit inspections took place in October 2010 and March 2014. This report describes the third routine site visit inspection in March 2018. Formal interviews were conducted with the DI, Mortuary Manager, mortuary staff, hospital porters, Coroner's Officer, Consultant Histopathologist and PM consent seekers (adult and perinatal). A visual inspection of all mortuaries was carried out, including body stores, viewing rooms and the PM suites at NTGH and HGH.

Material held for the police

Under s39 of the Human Tissue Act 2004, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' audit of tissue held under police authority, that police exhibits held on HTA licensed premises should be included within the regular HTA inspection process. Police holdings stored at the establishment were reviewed by the HTA during the inspection.

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
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) There is a documented standard operating procedure (SOP) detailing the consent process	The SOP 'Procedure for the Taking of Consent for an Adult Hospital Post Mortem' does not state that consent must be obtained in accordance of the 'hierarchy of qualifying relationships'. In addition, some of the wording does not reflect the HT Act or the HTA's codes of practice . For example: • paragraph 3.2 'Request for post mortem examination' states, 'The doctor will inform the family members that they will be required to give consent'. However, it may be clarified with additional text that consent should be given voluntarily; • Paragraph 3.8 'Retention of whole organs or large tissue slices' states 'in some cases it may be necessary to retain whole organs…' this should state 'with consent..'	**Minor**
c) There is written information for those giving consent, which reflects the requirements of the HT Act and theHTA's codes of practice.	The information booklet 'A Simple Guide to the Post Mortem Examination Procedure' refers to the 'next of kin' and 'properly interested persons' who can give consent for a PM examination. This implies that consent could be obtained from someone other than the person ranked highest in the hierarchy of qualifying relationships. (See *Advice*, item 1)	**Minor**

g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided	The consent form in use 'Consent to Hospital Post Mortem Examination on an Adult' (MF-HIS-MOR-G-018, version 1, 2009) does not reflect the requirements of the HT Act and the HTA's codes of practice. For example: • The signature of the 'next of kin' is required; • It refers to tissue blocks and slides being retained 'indefinitely' as part of the medical record. In addition, the reference for the 'retention of tissue samples' (in section 1) of the consent form is incorrect; it is actually in section 3. This may lead to confusion and misunderstanding. (see *Advice*, item 3)	**Major**

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	i) The senior APTs with responsibility for seeking consent for adult 'consented' PM examination have annual refresher training with the DI. However, this is predominantly based around the completion of the existing consent form, and does not include training on the requirements of the HT Act or the HTA's codes of practice. As a shortfall was identified in relation to the consent form, the lack of training increases a potential risk that consent may not be sought in accordance with requirements of the HT Act. ii) Clinicians with responsibility for seeking consent for paediatric/perinatal PM examination may have had PM consent training as part of their medical training, but there is no evidence they have received any refresher training. As a result, the consent standards C2(c) and (d) cannot be met for paediatric/perinatal consent seeking. (see *Advice*, items 4 and 5).	**Major**

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.	i) Controlled SOPs do not always reflect current practices or include sufficient and/or correct information. Examples include, but are not limited to: • SOPs that require body identifiers or identification checks do not always state what is required to be checked; for example, full name, DOB and address; • SOP-LP-HIS-MOR-G-040, version 3, 'Procedure for the Reception and Storage of bodies in the Mortuary' does not state that the NOD form from the wards will indicate that a body is, or potentially could be, an infection risk. In addition, this SOP states that surnames can be same or similar names, but does not refer to first names. Mortuary staff are not following the documented procedure for managing these bodies; • SOP-LP-HIS-MOR-G-018, version 8, states that the porters are responsible for the completion of the mortuary register when a body is admitted out-of-hours. However, funeral directors have been routinely undertaking this task; • SOP-LP-HIS-MOR-G-013, version 10, 'Procedure for Release of Bodies to Funeral Directors' states Coroner's bodies can be released unless instructions have been received to the contrary (section 8A, iii). In practice, bodies cannot be released from the mortuary until the Coroner has sent a release form. In addition, this SOP states that identity checks are undertaken before a body is physically removed from a refrigerated space (Section 8B, iii); • SOP-LP-HIS-MOR-G-010, version 7, 'Procedure for Post Mortems with High Risk Infection Hazards' states that blood can be obtained to test for category three pathogens. Where such an infection is unlikely to be a factor in the cause of death, the testing cannot be authorised by the Coroner. Consent from the person ranked highest in the hierarchy of qualifying relationships is therefore required for any additional removal of relevant material for testing. In addition, the results of these tests would not preclude the PM examination from happening.	**Minor**

	This practice was discussed with the DI during the inspection who assured the inspection team this would not happen unless appropriate consent is sought. • SOP-LP-HIS-MOR-G-038, version 3, 'Guidelines for Long Term Storage' does not cover the process of identifying which bodies may require long-term storage or the process to be followed when transferring bodies for long term storage (see *Advice*, item 8) All SOPs require review to provide assurances that they reflect correct procedures and current practices for mortuary activities. ii) Currently there is no SOP for staff who work alone at the satellite sites and the unlicensed body store. The arrangements and procedures will need to be considered separately for each site.	

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The 2018 audit schedule and reporting has been improved with the appointment of a Quality Manager to oversee audit activities. However, the current schedule of audits focusses primarily on the activities at the hub site, including traceability of tissues, bodies and procedures. The schedule does not currently include relevant audits at the satellite sites, for example, procedural and body audits, including the transfer of bodies to the hub site.	**Minor**
b) Audit findings document whom is responsible for follow-up actions and the time frame for completing these	The schedule of audits for 2017 was completed but the scope of the audits were limited. An 'observation' was identified in the audit AUD960, 'Consent to hospital PM on an Adult' (19/12/2017); two tissue slides were identified as missing. This finding should have been raised as a 'non-conformance' for action. The inspection team highlighted this with establishment staff during the inspection and they were able to locate the missing slides (they had been mis-filed).	**Minor**

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	Porters have received training in mortuary related tasks from mortuary staff but there is no evidence of regular refresher training. (see *Advice*, item 13)	**Minor**

c) Staff are assessed as competent for the tasks they perform	Mortuary staff have not undergone any competencies assessments for the mortuary tasks they undertake.	**Major**
g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures	The 'Policy for 3rd Party Pathologists (LP-HIS-MOR-G-042, version 1) states that visiting pathologists will abide by the Trust policies and procedures. However, visiting pathologists have not read and acknowledged the mortuary SOPs that are relevant to their work. (see *Advice*, item 14)	**Minor**

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	Risk assessments are not in place for lone working at the satellite sites. Safeguards that are currently in place do not ensure the safety of staff working alone.	**Major**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
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	The establishment uses a 'Mortuary Checklist for Viewings/Identifications' form (MF-HIS-MOR-G-043, version 1) to record the identification details of a deceased when viewings or formal identifications are arranged. However, only one or two identifiers are checked with relatives when they attend for a viewing; this varies depending on the member of staff involved in the viewing process. (see *Advice*, item 20)	**Minor**
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The quantity of tissue blocks retained at PM examination are not recorded, only the type of tissue taken, therefore tissue records are not detailed enough. Recording the quantities of blocks taken will ensure accurate traceability records are maintained and can be audited.	**Minor**

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	The 'Post Mortem of an Adult Ordered by the Coroner' form (MF-HIS-MOR-G-005, version 3) has been developed by the establishment with approval of the Coroner. It is a lengthy document and appears to give contradictory options for tissue once the Coroner's authority has ended. Discussions with the Coroner's Officer during the inspection clarified that section 4 of the form ('Disposal of Tissue and Whole Organs') relates to disposal of tissues once they are no longer needed for the scheduled purposes detailed in section 3.2. However, while this is explained to the relatives by the Coroner's Officer, this is not clear from the form and may lead to relatives believing tissue will be retained indefinitely or disposed of immediately after the PM examination. In the majority of cases, the establishment is storing tissue which is not being used for the purpose for which it was retained (e.g. for the scheduled purpose of research) and is not disposing of these tissues either. (see Advice, item 31)	**Minor**

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
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)	i) Although there is an intercom at each access door to HGH mortuary, staff are unable to visually verify who is requesting access at the body store door. Staff do not have immediate access to the hospital CCTV that covers this area. This increases the risk of this door being opened to unauthorised people, potentially causing a security and/or safety issue for staff who work alone. (see *Advice*, item 22) ii) The personal panic alarms in use within the mortuaries will not to alert anyone externally to the mortuary if an issue arises. The fixed panic alarms within the mortuary at NTGH are not suitably placed for staff to activate them if required. (see *Advice*, item 23)	**Minor**

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

a) Storage arrangements ensure the dignity of the deceased	The upper alarm trigger point for refrigerated storage across all sites is 15°C. The upper alarm limit means that a temperature deviation from the advised storage temperature of around 4°C may not trigger an alarm and alert establishment staff to the deviation within an appropriate timescale. Any delay in alerting establishment staff to a deviation of the storage temperature from the expected range poses a risk to the integrity of the stored bodies and to the dignity of the deceased. The refrigerated body storage at HGH has two temperature monitoring systems that display quite significant temperature differences. The DI is required to: • ensure the storage temperature is maintained around 4 °C and alarms are triggered at appropriate limits; • establish which system is recording accurate temperature readings; • ensure this system is connected to the alarm; • remove the system that is not required. (see Advice, item 24)	**Major**
g) Bodies are shrouded or in body bags whilst in storage	Bodies admitted from the community are not routinely placed in body bags. This could potentially pose a hazard to staff responsible for admitting these bodies in to the mortuary. In addition, pertinent information regarding infection risk and circumstances of death of bodies admitted out-of-hours is not readily available for mortuary staff to undertake an appropriate assessment of risk during body admission checks.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(c)	In addressing the shortfall identified against standard C1(c), the DI is advised to include the relevant contact details for NSECH within the information given to consent givers. In addition, the DI may wish to consider having the supporting information in a format that can be printed as required rather than producing multiple copies in booklet form. This may mean that should the information require updating, new versions of the information is easier to produce. Finally, the DI may wish to use some of the wording from the HTA's model information leaflet which is available on the HTA's website.
2.	C1(c)	The maternity unit at NSECH use an information leaflet for paediatric/perinatal PM examinations from the licensed establishment undertaking these PM examinations. The DI is advised to liaise with them and implement a system through which the DI is assured that the maternity unit are using the most recent version of the leaflet.
3.	C1(g)	In addressing the shortfall identified against standard C1(g), the DI is advised to consider using the model PM consent form available to download, amend and use from the HTA's website.
4.	C2(a)	The DI is advised to consider sourcing external training for the senior APTs who are responsible for seeking consent for adult consented PM examination. This will provide assurance their knowledge is up-to-date and they have sufficient understanding of the consent requirements under the HT Act. This training would need to be refreshed periodically.
5.	C2(a)	The DI is advised to source external consent training for the clinicians who are responsible for seeking consent for paediatric/perinatal PM examination at NSECH. Alternatively, the bereavement midwives and some other midwives have undertaken training in seeking consent for PM examination. The DI may wish to consider developing a procedure through which these trained staff could accompany the clinicians during the consent seeking process. The midwives attendance during consent seeking would need to be recorded and their training refreshed periodically.
6.	GQ1(a)	The DI is advised to continue updating the SOPs to a standardised format.
7.	GQ1(a)	The DI may wish to consider implementing a form to be completed for bodies admitted out-of-hours to ensure that information regarding these bodies is communicated efficiently to mortuary staff; for example, when there is a risk of infection. This is especially important as currently bodies from the community are not always received in body bags and the mortuary staff may not receive information for a few days.
8.	GQ1(a)	The DI is advised to liaise with the senior APTs to develop a more detailed SOP for the management of long-term bodies that require frozen storage. The SOP should include how these bodies are identified, who is responsible for following these cases up and when they should be frozen. The HTA's guidance states that bodies should be frozen after 30 days if there is no indication they are soon to be released or further examined, or before, depending on the condition of the body.

9.	GQ1(a)	The DI is advised to ensure that the procedure for identifying same or similar surnames is amended to state same and similar names to help mitigate the risk of release of a wrong body.
10.	GQ1(a)	The DI is advised to ensure that any changes to SOPs and documentation are implemented across all sites (where possible) for consistency and for staff who work across sites.
11.	GQ1(g)	The DI is advised to appoint a suitable Person Designated (PD) in the maternity unit located at NSECH to be a point of contact and help provide assurance that suitable activities are taking place.
12.	GQ1(h)	The DI is advised to implement regular meetings with the PDs and/or include them in existing meetings that cover HTA-related activities. This will help the DI to maintain oversight of the activities in those areas.
13.	GQ3(a)	In addressing the shortfall identified against standard GQ3(a), the DI is advised to ensure that the senior APTs responsible for porter training in mortuary tasks, schedule and record periodic refresher training; including, for example, when equipment is changed or when there has been an incident. This training should also cover HTA reportable incidents (HTARIs), to ensure the portering staff have an awareness of these types of incidents.
14.	GQ3(g)	The DI is advised to develop an SOP signatory sheet for visiting staff (pathologists and locum APTs, if required) to sign, demonstrating they have read and understood the SOPs relevant to the work they are undertaking. This should include the SOP title, number and version number.
15.	GQ6(a)	The DI is advised to reference the risk assessment for HTA licensed activities (RA-HIS-MOR-G-003, version 3) within the other relevant health and safety risk assessments to demonstrate those risks have been considered.
16.	T1(b)	Current practice involves the yellow sequential mortuary register number stickers being entered into the mortuary register, prior to a body being admitted. These stickers are provided in duplicate,the first sticker added in advance into the mortuary register and the second sticker remaining on the reel and being added to the identification band of a body when it is admitted to the mortuary. The DI is advised to ensure that the first and second stickers are only taken from the reel at the time of admission. There is currently a risk that the incorrect sticker could be selected on admission of a body, leading to issues with misidentification and traceability.
17.	T1(b)	To further strengthen traceability of bodies while in the care of the mortuary, the DI may wish to consider implementing the following: • Using the full name and mortuary register number of the deceased on the fridge door and body store whiteboard. The mortuary register number is unique to that body, acting as an additional identifier while in the care of the mortuary; • Extending the lines on the whiteboard at NTGH to ensure that names of bodies are written against the correct fridge number; • Printing the yellow mortuary register stickers in triplicate so this number can also be added to admission documentation.
18.	T1(c)	The DI is advised to contact the Coroner's contracted funeral directors that bring bodies to the mortuary out-of-hours to reiterate the importance of bodies being identified with three identifiers, one being unique. Although issues with

		insufficient identifiers are addressed when they are identified, this may help reduce the frequency of occurrence and prevent delays.
19.	T1(c)	When releasing bodies from the mortuary to the funeral director, the DI is advised to ensure that mortuary staff consistently use the address of the deceased as a third identifier, stated on the release form brought by the funeral directors, and not the mortuary register number. This will ensure that bodies are being identified using information independent from that which the mortuary has generated.
20.	T1(c)	The DI may wish to consider strengthening the procedure for viewings by introducing a form to be completed by relatives when they attend for viewings. This can include relevant information to check the identification on the deceased, before the viewing takes place. In addition, the DI is advised to include the address and date of death of the deceased on the checklist for viewings and identifications to enable this to be cross-referenced with the information the mortuary have and the identification details on the body, especially for community cases
21.	T1(h)	One of the visiting pathologists transfers their own histology specimens after each PM session they undertake. The DI is advised to have the specimens formally signed 'out' of the establishment in addition to signing for their 'receipt' at the recipient histology laboratory to maintain robust records of traceability.
22.	PFE1(d)	The DI is advised to explore options to enable staff to visually verify who is requesting access to the HGH bodystore. For example, a 'spyhole' could be put in the door.
23.	PFE1(d)	The DI is advised to consider additional options with regards to the safety of staff who work alone at the satellite sites. For example, personal alarms carried by staff that will notify security teams if there is an issue.
24.	PFE2(a)	The DI is advised to ensure fridge temperatures are maintained at approximately 4°C, with appropriate alarm trigger points and time delay before the alarm triggers. The optimal operating temperatures for mortuary freezers is -20°C, +/- 4 degrees; the trigger points and time delays for the freezer alarms should allow for this. It is important that all staff are aware of the acceptable fridge and freezer temperature ranges to be able to recognise potential equipment failures before they occur.
25.	PFE2(g)	On a few occasions, bodies were not completely covered whilst in refrigerated storage. The DI is advised to ensure that all bodies in storage are fully covered to maintain their dignity and that those in body bags are fully contained within the bags, to prevent potential leakage of fluids and exposure to infection risks.
26.	PFE3(a)	The DI is advised to continue with plans to replace hydraulic hoists at NTGH as they are starting to show signs of age-related wear and damage.
27.	PFE3(d)	Although most staff within the mortuary have been face-fitted for the FFP3 masks, this has not been done for some time. The DI is advised to repeat this for all staff. If any staff have facial hair, the use of fully ventilated hoods is required.
28.	PFE3(f)	The DI is advised to maintain the servicing of the HGH PM suite equipment and ventilation system while it is still considered a PM contingency facility.

29.	N/A	The DI is advised to ensure that when refrigerated storage has been converted to freezer storage, signs are used on the doors to alert all staff to prevent accidental freezing of bodies.
30.	N/A	The establishment is currently using infection notification forms to provide funeral staff with information about the infection status of a body. These forms detail a short list of what the infection could be. The route of infection transmission may be disclosed (i.e. inoculation or inhalation) to ensure the appropriate PPE is used; however, details of the potential infection should not be included. The DI is advised to review the use of these forms to assure themselves that information relating to deceased patients is treated in confidence. In addition, the infection status of a body should not be displayed on body store whiteboards or fridge doors. The DI is advised to consider the use of coloured signs or magnets for use on body store doors stating 'Danger of Infection', rather than naming the infection. This approach could also be applied for other pertinent information; for example, 'Tissue retained', 'Implant device' or 'Do not release'.
31.	N/A	The DI is advised to consider if it is appropriate to continue storing tissue that is not being used for the purpose for which it had been retained, for example, teaching or research, or if disposal of these tissues would be more appropriate. Any tissue being stored for scheduled purposes should be regularly reviewed. The rationale for the disposal of any tissues should be recorded, including the date and method of disposal. Discussions with relatives, who wish to consent to tissues being stored for use for scheduled purposes, should include the information that if the tissues are not used for these purposes within a specified timeframe that they will be sensitively disposed of.

Concluding comments

The mortuary team appear to work well together, demonstrate enthusiasm, and care for the work they undertake. Mortuary staff received praise from different people interviewed throughout the inspection and have good relationships with service users. They are supported by a senior team who work closely with the mortuary staff. There are some areas of strength and good practice:

- The consent PM information booklet contains an 'explanation of terms' section to help relatives to understand information and references;
- Documentation for the transfer and receipt of bodies between sites is a particular strength, demonstrating identification checks on release and subsequent admission into the receiving site;
- The spreadsheet used to record mortuary admissions is accessible across all sites to allow staff to access information and assess capacity at all sites;
- Whiteboards are located in each body store to communicate pertinent information to porters and funeral directors who have access to the area. In addition, at NSECH, there is a dedicated book that the porters can use to communicate relevant information to mortuary staff.

There are a number of areas of practice that require improvement, including five major shortfalls and twelve 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: 09/04/2018

Report returned from DI: 24/04/18

Final report issued: 10/05/18

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: 21/11/18

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.

Consent

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

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.

b) There is a documented standard operating procedure (SOP) detailing the consent process.

Guidance

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.

c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice.

Guidance

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.

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.

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 injures 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 theyare 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 forthese 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.