Site visit inspection report on compliance with HTA licensing standards

James Cook University Hospital

HTA licensing number 12089

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**

14 & 15 November 2017

Summary of inspection findings

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

Although the HTA found that James Cook University Hospital (JCUH) had met the majority of the HTA's standards, four major shortfalls and eighteen minor shortfalls were found against the Consent, Governance and Quality Systems, Traceability and Premises, Facilities and Equipment standards. These predominantly related to the consent policy, training for paediatric/perinatal consent seeking, standard operating procedures, refresher training and competency assessments in relation to mortuary procedures, risk assessments, traceability of bodies, premises and equipment, fridge temperature monitoring and alarms.

Particular examples of 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

James Cook University Hospital (the establishment) is part of the South Tees NHS Foundation Trust. This report refers to the activities carried out in the mortuaries located at James Cook University Hospital (the hub site) and the Friarage Hospital (the satellite site). The mortuary and bereavement service is managed by Cellular Pathology; the DI is the Cellular Pathology Services Manager and the Corporate Licence Holder contact is the Medical Director for Clinical and Diagnostic Support Services. In summary, the establishment is licensed under the Human Tissue Act 2004 (HT Act) for: carrying out post-mortem (PM) examinations; removal from the body of a deceased person of relevant material (for scheduled purposes), 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 3300 bodies each year from the hospital and the community, and performs around 1200 PM examinations annually, the majority of which are conducted for two Coroners; HM Coroner for Teeside and HM Coroner for North Yorkshire. The total figure for PM examinations includes high-risk (up to category three), forensic and hospital ('consented') PM examinations. The hospital PM examinations are predominantly neuropathology cases and the establishment is a referral centre for Creudzfelt-Jacob Disease (CJD) PM examinations. Paediatric/perinatal PM examinations were conducted at the establishment until the retirement of the paediatric/perinatal pathologist in March this year; these cases are now transferred to another licensed establishment. However, consent for perinatal and paediatric cases is undertaken on site by clinicians at the maternity unit (see shortfall against C2(a)). Consent for adult hospital ('consented') examinations is sought by clinicians, supported by bereavement staff trained in PM consent (see *Advice*, item 5) and a Consultant Neuropathologist. Consent forms for adult hospital PM examinations are based on the HTA's model consent form. The consent form used for paediatric/perinatal PM cases is provided by the referring establishment and based on the SANDs consent form (see *Advice*, item 4); therefore, both forms are fully compliant with statutory and regulatory requirements.

The establishment has a total of 90 refrigerated body spaces, including eight bariatric spaces. Eight spaces can be converted to freezer spaces, for the storage of long-term bodies; there are 12 spaces within a Flexmort body storage system owned by the Trust. The permanent refrigerated body spaces are 'double-ended' for direct access in to the two PM rooms. There are dedicated fridge spaces for paediatric/perinatal cases and pregnancy remains (see *Advice*, item 30).

Swipe card access is required for both external doors in to the mortuary, as well as standard key locks and the mortuary has its own security alarm. In addition, there is a camera and intercom system at both doors so mortuary staff are able to verify who is requesting access.

Portering staff transfer and admit all hospital bodies to the mortuary. Bodies are transferred

from the wards using a concealment trolley via lifts to a staff/service corridor. The porters complete their own transfer record book and the mortuary register. Training in mortuary practice is provided by the mortuary manager to the portering supervisors. This training is then cascaded to the wider portering team (see shortfall against GQ3(a)). Perinatal cases, pregnancy remains and their associated documentation are transferred to the mortuary by porters, using a dedicated remains carrier, and are entered into a specific book.

Community bodies and bodies transferred from other hospitals are brought in to the mortuary via a service road. The access door to the mortuary is concealed but there is no CCTV coverage of this area (see shortfall against PFE1(d)). The mortuary has a dedicated vehicle used by mortuary staff to transfer bodies to JCUH for PM examination from the Friarage Hospital. Porters facilitate access to the mortuary for out of hours admissions from police and funeral directors. The police are responsible for identifying the bodies and completing the mortuary register (see shortfall against T1(c)). Mortuary staff work on-call and are contactable for help and the undertaking of community body viewings and identifications. All other viewings are conducted by portering and nursing staff (see *Advice*, item 15).

Mortuary staff complete body, identification and property checks of all bodies as soon as possible, or the next working day if the body was admitted out of hours (see shortfall against GQ1(a)). Reviewing the mortuary register is the only way mortuary staff are able to identify if a body has been admitted to the mortuary from the hospital or the community (see shortfall against T1(b)).

The establishment has a maternity unit, where there is a fridge for the storage of products of conception (POCs), fetuses and neonatal bodies prior to transfer to the mortuary (see shortfall against PFE2(e)). The fridge is located in a secure room with restricted access. Details of the bodies and specimens within the fridge, including transfer information, is recorded on the ‘Specimen transport log sheet’. All perinatal bodies are entered in to a dedicated book at the mortuary, then entered in to the mortuary register (in groups) to be signed for when released.

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

The PM service is fulfilled by three Consultant Histopathologists and one Consultant Neuropathologist. The majority of the pathologists are based at the establishment. PM tissue taken at post mortem is recorded in the mortuary register (to highlight tissue has been taken), a ‘specimen book’ and in a dedicated spreadsheet completed by the mortuary staff. All specimens are taken to the histopathology laboratory on site, where the specimen book is signed as confirmation of receipt by the laboratory staff. This book is also signed when

specimens are sent off site and a record of receipt is faxed/emailed to the mortuary by the receiving establishment.

The mortuary is staffed by the mortuary manager, a Senior Anatomical Pathology Technologist (APT), an APT and, more recently, a Trainee APT and a Mortuary Attendant.

The mortuary's main PM suite contains two downdraught PM tables and two dissection benches. A smaller, second PM room contains one downdraught table and one dissection unit. Although this room can be utilised as a high-risk suite and separate area to store bariatric and super-bariatric bodies, it is generally used during routine post mortem sessions (see *Advice*, item 31). The pathologist and APTs carry out identification checks of bodies prior to the external examination and evisceration of a body and a one-at-a-time system is used to avoid mix-up of organs and tissue samples removed during PM examination (see *Advice,* item 24).

The PM suite, body store and some mortuary equipment are showing signs of considerable wear that require attention (see shortfalls against PFE1(a) and PFE3(a)).

The Friarage Hospital Mortuary (the satellite site)

The Friarage Hospital (FH) is a district general hospital. The mortuary at FH is a body storage facility for the hospital and for community bodies from the North Yorkshire Coroner's district and is part of the contingency storage for JCUH. Bodies that require a PM examination, perinatal bodies, pregnancy remains and POCs are transferred to JCUH by mortuary staff (see *Advice*, item 26).

The satellite has a total of 23 refrigerated body spaces, including three bariatric spaces. One space can be converted to a freezer space for long-term body storage if required.

The mortuary is staffed by a hospital porter, whose primary role is to undertake mortuary activities; for example, the admission and release of bodies. Any viewings are arranged through JCUH and prepared by a member of the mortuary staff, who will travel from JCUH.

There is a concealed access door in to the mortuary which is secured by a key lock. There is a camera and intercom system to verify who is requesting access. However, there is no CCTV coverage of this area or the mortuary building (see shortfall against PFE1(d)).

Portering staff transfer and admit all hospital bodies to the mortuary. During normal working hours, the mortuary porter is one of two porters who undertake this task. Bodies are transferred from the wards using a concealment trolley, which is pushed the short distance from the main hospital building to the mortuary (see *Advice*, item 35).

Community bodies are admitted to the mortuary by the mortuary porter during normal working hours or by hospital security staff out-of-hours. Identification and property checks are carried out of all bodies as soon as possible, or the next working day if the body was admitted out of hours.
All bodies are entered in to the mortuary register on admission to the mortuary and their last names entered on to the designated fridge door whiteboard (see *Advice*, item 34).

Training in mortuary practices to the wider portering and security teams was originally provided by the Portering and Security Supervisor but this has now been delegated to the mortuary porter (see *Advice*, item 14).

Description of inspection activities undertaken

The establishment has been licensed by the HTA since June 2007. Previous routine site visit inspections took place in July 2011 and January 2014. This report describes the third routine site visit inspection in November 2017. Formal interviews were conducted with the DI, Mortuary Manager, mortuary staff, hospital porters and security staff, Coroner's Officer, Consultant Neuropathologist and PM consent seekers (adult and perinatal). A visual inspection of both mortuaries, including body stores, viewing rooms and the PM suite at JCUH.

Traceability audits of body identifiers, storage locations, mortuary register details were carried out for four adult bodies (two hospital and two Coroner's cases) and one perinatal body. Some anomalies were found; both Coroner's cases were identified using only two points of identification on both identification bands. In addition, one hospital body stored within the Flexmort body store was leaking and had been in refrigerated storage for longer than the recommended 30 days (see *Advice*, item 32).

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. Any findings in relation to police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the HT Act.

Inspection findings

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

Compliance with HTA standards

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.	The general policy G49 'Post Mortem Consent and the Retention and Disposal of Tissues Thereafter' requires updating to refer to the HTA's updated codes of practice implemented in April 2017 and ensure the links to external guidance are up to date. In addition, section 5.7, paragraph two, refers to research on PM residual tissue; this information is incorrect as it only applies to tissue from the living . Consent is required for the use of any tissue from the deceased for research. Residual PM tissue ('wet trimmings') should be disposed of via clinical waste. The DI is required to audit all PM tissue in storage to ensure it does not contain any PM residual tissue and that it is not being used for a scheduled purpose without appropriate consent.	**Minor**

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	Clinicians receive consent training during their clinical qualification but receive no formal training, or refresher/update training, in obtaining consent specifically for paediatric/perinatal consented PM examinations.	**Minor**
b) Records demonstrate up-to-date staff training	Records for adult (consented) PM examinations show staff were last trained over two years ago (see *Advice*, item 5).	**Minor**

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) The SOP for the storage of long-term bodies was written the week prior to the inspection and is awaiting approval. ii) There is no SOP for lone working in the mortuary at JCUH or the FH mortuary although there are procedures in place. ii) SOPs do not always reflect current practice. Examples include, but are not limited to: SOP S_CP_MBS_SOP001 'Admission of Cadavers to JCUH and FHN Mortuary' does not state that the identification of bodies and body condition is checked by mortuary staff. SOP S_CP_MBS_SOP0011 'Viewing of Cadavers' refers to a ritual washing facility that is no longer there. iii) Where identification checks are referred to in SOPs they do not always detail what or how many identifiers should be checked. There should be a minimum of three, including at least one unique. First and last names are considered a single identifier. All SOPs require review to provide assurance they reflect correct procedures and current practices for mortuary tasks.	**Minor**
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	Some SOPs are past their review date. Examples include but are not limited to: S_CP_MBS_SOP0001 'Admission of Cadavers' (July 2016) S_CP_MBS_SOP0009 'Capacity Contingency Plan' (August 2017) J_CP_MPM_SOP0018 'Post Mortem Room Procedures' (August 2017) All SOPs require review to ensure they are up to date.	**Minor**
e) There is a system for recording that staff have read and understood the latest versions of these documents	Not all mortuary staff are included in the Q-Pulse document distribution lists for SOPs and none are included in the distribution lists for risk assessments in relation to their work. Staff external to the mortuary who have responsibility for undertaking mortuary procedures, for example, the admission of bodies and preparation of viewings should also be aware of relevant mortuary SOPs. It is important that <u>all</u> staff acknowledge SOPs and other relevant documents in a timely manner to demonstrate they have read and understood them.	**Minor**

h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	There are no formal meetings between the DI and staff who oversee activities in areas covered by the licence (see *Advice*, item 12). As a result, the DI cannot assure herself that she has sufficient awareness and oversight of the activities in those areas and is unable to share HTA-related information with those staff.	**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	i) A plan for training or on-going training records were not provided for the recently appointed mortuary attendant or trainee APT, who had been in post for four weeks at the time of inspection. ii) Training in mortuary tasks has initially been provided by the mortuary manager to the senior portering staff who cascade this training to the wider portering team. However, there is no practical refresher training for the senior porters (see *Advice*, item 14). ii) Portering staff at FH have only received initial training in mortuary tasks. There is no evidence of refresher training.	**Minor**
c) Staff are assessed as competent for the tasks they perform	The mortuary attendant is undertaking key mortuary tasks independently; for example, the checking and releasing of bodies, but has not been assessed as competent in these tasks in the short time he has been in post (see *Advice*, item 15).	**Major**

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	Although the mortuary porter at the FH is aware that he should report any incidents to the mortuary manager at JCUH, he was unaware of HTA reportable incidents (HTARIs) and the types of incidents that would require reporting to the HTA, for example, accidental damage to a body.In addition, a review of the incident log highlighted an incident at JCUH that should have been reported to the HTA. (see *Advice*, item 17)	**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	There are risk assessments relating to health and safety matters, and some in relation to licensed activities and the potential risks to the deceased and tissue (see *Advice*, item 18).	**Minor**

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

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)	The mortuary register is the only record of all the bodies admitted to the mortuary at JCUH. This is completed by the person(s) responsible for admitting the body to the mortuary; for example, the porters or police officers. If the details of the body are omitted from the mortuary register, mortuary staff are unaware that a body is in the mortuary, and the identification and admission procedures cannot be completed. After reviewing the incident record, there have been two occasions this year where bodies have been omitted from the mortuary register. Mortuary staff were made aware of the presence of these bodies by external sources; for example, in one case, the post mortem authority form sent by the Coroner's Office. The mortuary does not use a whiteboard to indicate where bodies are located or write names on to the numbered fridge doors. Fridge numbers are documented in the mortuary register but review of these is difficult as they may be on numerous pages. Names of the deceased are currently entered into a computer system when the body is released from the mortuary, unless they are subject to a PM examination. This retrospective logging of bodies in to the mortuary does not lend itself well to the traceability of bodies while in the care of the establishment and is not fit for purpose. The computer system in use does not have the capacity to display an 'overall' record of who and how many deceased persons are in the mortuary at any one time, making it difficult for mortuary staff to locate bodies, identify same or similarly named individuals, monitor storage capacity and bodies that have been in prolonged refrigerated storage. Bodies from both mortuaries are released using the 'Authority for Removal Of Deceased' form, which is completed at the mortuary by the funeral staff using information from the mortuary register. Additional documentation may be brought by the funeral staff but this may not include the three required identifiers. Coroner's bodies are not released from the mortuary without documented authority from the Coroner. There is currently a potential serious risk to the traceability of bodies in the mortuary not only because of the practices highlighted above, but due to the high throughput of bodies. There should be a robust and consistent system in place to ensure traceability of all bodies from admission to release.	**Major**

	(see *Advice*, item 19)	
. 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	Bodies are not consistently identified using three identifiers, one being unique. This is a particularly the case for community bodies (see *Advice,* item 21)	**Minor**

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	The body store and PM room floor is showing significant signs of wear, including cracking and pitting of the surface. This compromises mortuary staff's ability to clean and disinfect the post mortem suite sufficiently. In addition, the edges and corners of the floor in both areas appear to be dirty and require attention. There is damage to walls and more significant damage (cracking) to the plastic protective casings (on corners) within the body store and PM room. The observation area for the PM room is immediately above the dissection units and is fully screened. The paint is flaking from the wooden frame and there are cracks exposing bare wood. This is an area that will become heavily contaminated during PM sessions. Mortuary staff will not be able to sufficiently decontaminate and disinfect this area. The inspection team noted that two of the three PM tables were contaminated with organic material after the room had been cleaned and disinfected. The issues identified above, in addition to poor cleaning and disinfection routines, pose a potential health and safety risk to mortuary staff and others who work in the mortuary.	**Major**
c) There are documented cleaning and decontamination procedures and a schedule of cleaning	The cleaning schedule displayed in the JCUH body store is wiped clean at the end of each week, therefore there is no permanent record of cleaning activities (see *Advice* item 28).	**Minor**
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)	There is no CCTV coverage of the mortuary at JCUH or FH. This could compromise the security of staff and premises, especially out-of-hours.(see *Advice*, item 29).	**Minor**

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

a) Storage arrangements ensure the dignity of the deceased	i) JCUH Mortuary: the upper alarm trigger point for the main fridges in the body store (9°C) will not ensure the alarms are triggered at appropriate temperatures to optimally maintain bodies stored in there. Mortuary staff are not aware of the lower trigger point and are unsure of the time period that elapses before the alarm will trigger. The smaller PM room is occasionally used to store bariatric and super-bariatric bodies. An air-conditioning unit is used to reduce the temperature of the room and ice packs are used around the body to help reduce and maintain the body at a suitable temperature. The room temperature is not monitored when being used for this purpose (see *Advice*, item 31). ii) FH Mortuary: the alarm trigger points for the main fridges in the body store (below 1°C and 10°C) will not ensure the alarms are triggered at appropriate temperatures to optimally maintain bodies stored in there. Mortuary staff are unsure of the normal temperature ranges, the alarm trigger points of the freezers and the time period that elapses before the alarm will trigger.	**Minor**
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	i) The fridge on the labour ward and the Flexmort body storage system at JCUH do not have a local alarm and are not connected to an alarm system. ii) The main fridges and freezers at JCUH and FH are alarmed but not routinely tested (see *Advice* item 33).	**Minor**
f) Temperatures of fridges and freezers are monitored on a regular basis	Fridges and freezer temperatures in the mortuary (at both sites) are not routinely monitored or reviewed for trends. The temperatures of the fridge on the labour ward at JCUH are manually monitored weekly.	**Minor**

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

a) Items of equipment in the mortuary are in good condition and appropriate for use	The body hoists, the base of the dissection unit and the electric saw are showing areas of rust (see *Advice*, item 37). Two of the three body hoists have been identified as 'poor' or 'recommended for upgrade' in the maintenance company's inspection reports (no comment has been made on the third hoist). In addition, the latest inspection reports (October 2017) stated two hoists couldn't be inspected, one due to its location and the other due to a flat battery and blown fuse.	**Major**
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	The establishment has not provided the ventilation service records for JCUH mortuary to provide assurance the ventilation system is working to the required standard and is regularly maintanied	**Minor**
f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept	The establishment has not provided the following maintenance records for: Friarage Hospital • fridges and freezer • Body hoists James Cook University Hospital • PM tables and dissection units The DI is required to to submit these records for review.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(a)	Although the consent policy refers to the hierarchy of qualifying relationships for obtaining consent for post mortem, the policy also refers to 'next of kin', which implies that consent could be obtained from someone other than the person ranked highest. The DI is advised to avoid using the term 'next of kin' (NOK) in the consent policy.
2.	C1(d)	While the information given to relatives regarding PM examinations is printed directly from the HTA's website, the DI is advised to use this information to develop their own post mortem information for relatives, displaying the Trust logo. Pertinent information should be included, for example, tissue retained with consent for research and education will be disposed if not used for either of these scheduled purposes within a specified time frame. In addition, the Coroner's Offices should be made aware of this for their PM cases to ensure they are appropriately informing relatives.
3.	C1(g)	The DI is advised to amend the hospital (consented) PM forms to include a section for the signature of bereavement staff involved in the consent process. This will demonstrate that a person with knowledge of the HT Act 2004, and

		with the appropriate PM consent training, was involved in the consent seeking process.
4.	C1(g)	The paediatric/perinatal consent form in use refers to the HTA's former 'Code of Practice 3: Post Mortem Examination' (2009). The DI is advised to liaise with the referring establishment to ensure they are referencing and using the most recent version of the consent form.
5.	C2(a)	The training material used by the DI and Consultant Neuropathologist to provide PM consent training refers to the HTA's former codes of practice. It therefore requires updating and was last conducted in July 2015. The DI is advised to formally schedule this training to occur at least every two years. In addition, it would be prudent to develop an SOP for bereavement staff to refer to as consent seeking is undertaken infrequently. They should also be familiar with the HTA's codes of practice covering consent (Code A) and PM examination (Code B).
6.	GQ1(a)	The SOP S_CP_MO_SOP0048 'Guidance for reporting HTARIs in the PM Sector' appears incomplete, with some references missing (in red text). The DI is advised to review this SOP to ensure the correct version is available.
7.	GQ1(a)	The SOP J_CP_MPM_SOP0018 'Post Mortem Room Procedure' refers to the 'Consent to a post mortem examination' (page 1). The consent form currently in use is titled 'Consent for post-mortem examination of an adult'. Page 6 of the SOP refers to the consent form as being a triplicate booklet, when it is actually a single copy document.
8.	GQ1(a)	The DI is advised to review all policies and SOPs to ensure they refer to the HTA's updated codes of practice.
9.	GQ1(a)	The SOP for the viewing of bodies should include viewing of bodies in long-term storage by relatives and others, such as the police.
10.	GQ1(a)	The DI may wish to consider a formal way of recording visitors and activities in the mortuary; for example, tissue retrieval teams and when viewings have taken place out of hours. Currently tissue retrieval teams leave their paperwork for staff in the mortuary and this is the only record that they have used the facility. A formal visitor record will help monitor activities and if any incidents occur, who was present, especially as mortuary staff do not routinely attend out of hours.
11.	GQ1(d)	To maintain consistency, all forms used within the mortuaries at both sites should be subject to the same document control as the SOPs.
12.	GQ1(g)	The DI is advised to appoint Persons Designated (PDs) in areas where licensable activities are taking place. This includes the labour ward and Accident and Emergency department.
13.	GQ2(b)	The DI is advised to ensure that the most appropriate person is responsible for following up the actions of audits to ensure they are completed.
14.	GQ3(a)	The mortuary manager is advised to formally schedule and record refresher training for the mortuary porter at FH and the senior portering team at JCUH at least every two years, or when necessary. For example, when equipment is changed or when there has been an incident. This training should also include HTA reportable incidents (HTARIs) to ensure the portering staff have an awareness of these types of incidents. Any training provided to the porter and security teams at FH by the mortuary porter, should be recorded, dated, and signed by both the trainee and trainer.

15.	GQ3(c)	The DI is advised to ensure that the competence of all staff involved in mortuary procedures (at both sites) is regularly assessed and this is recorded. Staff that have not been deemed competent should not be working unsupervised. In addition, competency records should be signed by the assessor and not just the staff member.
16.	GQ3(g)	Although the mortuary does not currently have any locum staff, they should sign a signatory sheet to record they have read and understood the SOPs relevant to the work they will be undertaking.
17.	GQ5 (a)	The DI is advised to ensure that all staff working under the licence are aware of the HTA reportable incidents (HTARIs) and any incidents are reported within five days of discovery.
18.	GQ6(a)	The DI is advised to ensure that the licensed activities outlined in GQ1 and the HTARI categories are risk assessed to provide a comprehensive set of risk assessments. In particular, risks to the dignity and integrity of bodies and stored tissue should be covered. In addition, it is important that risk assessments contain sufficient and relevant information. For example, the risk assessment for the 'Identification of Cadavers' (F_CP_MHS_BS_RAS0009) does not mention misidentification of bodies but does mention hazardous substances. The HTA's publication 'Regulation of the Post Mortem Sector: What we have learned' (October 2016) provides guidance and information in relation to risk assessments. This is available on the HTA's website.
19.	T1(b)	The DI is advised to explore different options to improve the traceability of bodies and may wish to consider the following: • Using a mortuary register number (sequential) as bodies are admitted to the mortuary. This number would be unique to that body, acting as an additional identifier while in the care of the mortuary; • Using a whiteboard to record the full names of bodies next to the relevant fridge number; • Adding the full name and other identifier (e.g. the mortuary register number suggested above) to the relevant fridge door or whiteboard; • The use of a different coloured pen on the whiteboard or fridge door for out of hours admissions would highlight to mortuary staff which bodies are new admissions that require checking. • Introduce a form that can be completed for all admissions to the mortuary, completed by the porters or police, that can be used by the mortuary staff when undertaking body checks. This form can then be used by mortuary staff to complete the mortuary register, ensuring consistency and neatness; • Introduce a standardised release form for funeral directors that is completed by them prior to arrival at the mortuary and brought in addition to any other requested documentation outlined in the existing release SOP. This form should contain the required three identifiers to release a body; for example, full name, DOB and address. It should also be signed by the relatives; • Use of an IT system that is better suited for recording all the mortuary activities. For example, the details of all bodies on admission to the mortuary and their subsequent release, details of bodies for post mortem, when tissue is retained at post mortem and other relevant information.

20.	T1(d)	Same or similar names are checked by looking through the mortuary register and are subsequently highlighted. An additional red identification band placed on bodies was used as a visual cue but this has ceased. The DI is advised to include when same or similar name checks are carried out in the relevant SOPs and additional steps that should be taken when releasing a body with a same or similar name. In addition, the DI is advised to reinstate the use of coloured identification bands to highlight these cases and consider the use of a visual cue on body store doors, for example, a coloured magnet. This principle can also be applied for other pertinent information; for example, 'Danger of infection', 'Implant device' or 'Do not release'.
21.	T1(c)	The DI is advised to liaise with the relevant parties to ensure that all bodies brought in from the community are identified with a minimum of three points of identification, one being unique. Currently the majority of these bodies are identified with two points of identification.
22.	T1(f)	The DI is advised to include the procedure for the release of bodies in long-term storage within SOP S_CP_MBS_SOP0012 'Release of Cadavers'.
23.	T1(g)	The mortuary manager is advised to ensure all tissue retained at PM is accurately recorded on the PM tissue spreadsheet. For example, when a brain **and** dura has been retained at PM examination, the dura is not omitted from the spreadsheet.
24.	T1 (g)	The DI is advised to consider the current practice of labelling specimen containers with body identifiers prior to a PM examination taking place. Depending on how securely this is done, there is a risk that tissue could be placed in incorrect containers.
25.	T1(g)	The spreadsheet used by mortuary staff to record PM cases that have had tissue retained is altered to the preference of the member of staff using the spreadsheet at the time; for example, in date order or alphabetically. To prevent confusion and potential omission of important information, the mortuary manager is advised to decide how the spreadsheet data will be viewed.
26.	T1(h)	The DI is advised to ensure that perinatal cases and pregnancy remains transferred to JCUH from the FH for group funerals are signed for in the dedicated book for this purpose at FH.
27.	T2 (a)	There is currently a system in place for the follow–up and recording of specimen disposal instructions for routine Coroners' PM cases. However, staff are unclear who is responsible for following up specimens retained in forensic cases. The DI should consider who is best placed to periodically follow-up these cases, recording the details of any communications to ensure they are not retained longer than necessary. Any instructions given for disposal of tissues should be recorded.
28.	PFE1(c)	The mortuary manager is advised to keep a permanent copy of the body store cleaning records to demonstrate which cleaning activities have been undertaken and when.
29.	PFE1(d)	The DI is advised to explore options with the Trust to provide adequate CCTV coverage of the access areas of each mortuary to ensure there is adequate security in the event of any incidents.
30.	PFE2(h)	Where possible, the mortuary manager is advised to store paediatric/perinatal bodies and pregnancy remains separate to adult bodies. When body store

		space is limited, it may be easier to move the paediatric/perinatal cases and pregnancy remains to the smaller spaces within the Flexmort body store.
31.	PFE2(a)	The DI is advised to ensure storage of bariatric and super-bariatric bodies within the small PM room does not occur for prolonged periods, especially in the absence of temperature monitoring.
32.	PFE2(c)	The DI is advised to move bodies into frozen storage after 30 days in refrigerated storage (or before, depending on the condition of the body) if there is no indication they are soon to be released or further examined..
33.	PFE2(e)	The DI is advised to ensure that fridges and freezers are regularly tested to ensure alarms will trigger when temperatures deviate from the required ranges. In addition, the DI may wish to consider linking the Flexmort body storage system at JCUH mortuary to the existing remote alarm system to ensure staff are alerted to any temperature deviations.
34.	PFE3(a)	The white boards used on the fridge doors (at FH) are stained from the pens used on them. The DI is advised to clean these (if possible) or replace them to ensure body identification details can be clearly read.
35.	N/A	The DI is advised to consider alternative options for the transfer of bodies from the main hospital building at FH to the mortuary. This transfer occurs outside of the hospital building, and concerns have been raised about people seeing the concealment trolley in transit. A risk assessment should be considered. In addition, obscuring the windows of the contractor portacabins currently overlooking the mortuary access door may help to reduce the risk of the dignity of the deceased being compromised.
36.	N/A	The establishment is currently storing tissue for research. The DI is advised to consider if it is appropriate to continue storing this tissue if it is not being used for the purpose for which it had been retained, or if disposal of these tissues would be more appropriate. Tissue being stored for any scheduled purposes should be regularly reviewed. The rationale for the disposal of any tissues should be recorded, including the date and method of disposal. The DI is advised to have a process in place for the regular audit and review of tissue retained from Coroner's cases for civil or legal proceedings to ensure that each case is considered on an individual basis, that there is a documented reason for retaining tissue and that tissue is not retained for longer than necessary.
37.	N/A	The disinfectant of choice for the mortuary is sodium hypochlorite (bleach). The use of bleach is likely to have had an impact on the condition of mortuary equipment due to its prolonged use. The DI is advised to consider the use of other disinfectants to prevent the further deterioration of equipment. Further advice and information can be found in the HSE guidance 'The Safe Working and Prevention of Infection in Mortuaries and Post Mortem Rooms'.

Concluding comments

The qualified APTs in the mortuary at JCUH have worked together for a number of years and are experienced members of staff. In the last three years workload has increased and they have helped to ensure the continued provision of the mortuary service. The recent addition of a trainee APT and a mortuary attendant undertaking non-technical duties will relieve some workload pressures and provide support to the existing mortuary team.

There some areas of good practice:

- The spreadsheet used to record tissue taken at post mortem is colour-coded depending on disposal instructions for the tissue, e.g. rows highlighted brown are for disposal.
- The mortuary porter at FH has implemented a 'log' which records pertinent information in relation to each body and is an easy reference for the bodies being stored or released from the mortuary.

There are a number of areas of practice that require improvement, including 4 major shortfalls and 18 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: 12/12/2017

Report returned from DI: 21/12/2017

Final report issued: 03/01/2018

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: 19/11/2018

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.