Site visit inspection report on compliance with HTA licensing standards

Southend Hospital

HTA licensing number 11068

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**

13 – 14 September 2017

Summary of inspection findings

The HTA licence covers Southend Hospital (the establishment). The establishment was last inspected in March 2013. This report describes the first inspection of this establishment against the revised HTA licensing standards, which came into force on 3 April 2017.

One critical shortfall was found in relation to the condition of the premises. In addition, ten major shortfalls and six minor shortfalls were found across the range of standards.

Despite the shortfalls, the HTA found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation. However, there is significant work to be done to bring the establishment back up to an acceptable level of compliance.

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 (HT Act). 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

Southend Hospital (the establishment) has been licensed by the HTA since May 2007. It is licensed for the making of a post mortem (PM) examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes.

The mortuary is staffed by four Anatomical Pathology Technologists (APTs) and one Mortuary Assistant. The Mortuary Assistant undertakes admission, release and viewings of bodies but does not perform procedures for PM examination.

The establishment undertakes approximately 600 adult PM examinations each year. The majority of PM examinations are performed under coroner's authority. The establishment undertakes high-risk PM examinations (cases known or suspected to contain up to hazard group 3 biological agents). Home Office PM examinations are conducted at the establishment by visiting Pathologists. Perinatal and paediatric cases are transferred to another HTA-licensed establishment for PM examination.

Adult hospital consented PM examinations take place at the establishment very occasionally; the last hospital PM examination was in 2014. Consent for adult hospital PM examinations is sought by clinical staff who receive training from the Designated Individual (DI), who is a Consultant Histopathologist. Consent is sought using a consent form and information leaflet based on the HTA's model documentation (refer to Advice, item 4). Consent for perinatal PM examinations is sought by clinical staff using a consent form and information leaflet based on those provided by the Stillbirth and Neonatal Death (Sands) charity and modified by the establishment to which the cases are referred. Staff receive training in seeking consent for perinatal PM examinations which includes training provided by the specialist referral centre.

Mortuary facilities at the establishment are located in two areas: a body store in the basement of the hospital; and the main mortuary which is in a separate building and contains a body store, PM suite and viewing room. The HTA assessed these premises as requiring significant improvement (refer to critical shortfall against standard PFE1(a)). The body store and mortuary are secured by key code access and there is a lift to the mortuary which is in a corridor secured by electronic swipe card access. Doors to the mortuary are also locked with a key out-of-hours and there is a security alarm and closed-circuit television (CCTV) monitoring of the entrances (see Advice, item 17). Access control arrangements within the mortuary require strengthening (refer to minor shortfall against PFE1(e)).

In addition to these facilities, there is a contingency body store in a separate building on the hospital premises. This building is secured by key code access; however, the windows do not provide adequate security (refer to minor shortfall against standard PFE1(d)).

There is a service tunnel connecting the hospital and the basement body store to the mortuary via a lift. The tunnel is in a poor state of repair (refer to critical shortfall against standard PFE1(a)). At the time of the inspection, the lift was out of service for planned refurbishment, meaning bodies are transferred to the mortuary using concealment trolleys through public areas of the hospital, including outside areas (refer to Advice, item 18).

The mortuary and basement body store have 91 spaces for bodies, including four spaces for semi-bariatric bodies, four spaces for bariatric bodies and four freezer spaces. The establishment does not have sufficient capacity for refrigerated storage of bodies (refer to major shortfall against standard PFE2(b)).

The contingency body store has six temporary refrigerated storage units with space for 72 bodies in total during peak periods. Five of the temporary storage units were erected at the time of the inspection but were not in use (refer to Advice, item 19). The establishment has arrangements to hire two additional temporary storage units with space for a further 24 bodies. The establishment also has arrangements for storage of bodies at a funeral services premises, including storage of super-bariatric bodies (refer to Advice, item 22).

There is a storage temperature monitoring and alarm system for the fridges and freezers, including for the temporary storage units; however, this system has not been tested and the alarm trigger points do not provide assurance that storage temperatures are acceptable (refer to minor shortfall against standard PFE2(e)).

The mortuary uses an electronic register to record details of bodies, including admission, release and viewings of bodies. Staff have computer access to the electronic register in each of the body stores (including a portable computer for use in the contingency body store) and the Bereavement Office. The electronic register includes a system to automatically flag bodies with same or similar names (see Advice, item 12).

Bodies from the community are transferred to the mortuary by the contracted funeral services organisation. Details of bodies admitted from the community out-of-hours are recorded on a paper form and entered onto the electronic register by mortuary staff at the start of the next working day. Bodies are transferred from hospital wards to the body stores by portering staff. Perinatal and paediatric cases are transferred directly to the body stores and are not stored elsewhere in the hospital. Bodies are released from the mortuary only by mortuary staff.

The PM suite has four tables and one dedicated bench for preparation of organs and tissue samples. Each PM table is assigned a number as part of the establishment’s system to ensure traceability of samples during PM examination. Tissue samples are transferred to cassettes in the PM suite so that only minimal tissue is taken during PM examination.

Material taken at PM examination may be transferred to the establishment's Pathology Laboratory for histological analysis or to other establishments for toxicology or other tests. Pathology services at the establishment have been provided as part of a joint venture between NHS and private sector partners since October 2014. Organs and tissue samples may be kept, with consent, for use for scheduled purposes. The establishment does not routinely store organs for use for scheduled purposes. At the time of the inspection the establishment was storing only PM blocks and slides. Samples are stored in the Pathology Laboratory, which is within the main hospital building and is secured by key code access.

The establishment uses paper records and electronic databases to record sample details, including storage location, details of transport where samples are sent to other organisations for analysis, and the family's wishes for the fate of the samples. Paper records are scanned and stored electronically (refer to Advice, item 9). The establishment's procedures for traceability of PM slides are not sufficiently robust (refer to major shortfall against standard T1(g)).

Sampling of tissues from deceased children in cases of sudden unexpected death in infancy (SUDI) is performed in the mortuary and not in any other area of the hospital premises.

Home Office PM examinations are conducted at the establishment. Under section 39 of HT Act, 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, the 2012 report of the Association of Chief Police Officers' (ACPO) audit of tissue held under police authority contained a recommendation that police exhibits held on HTA-licensed premises should be included within the regular HTA inspection process. Therefore, procedures for Home Office PM examinations and management of tissues and organs taken for criminal justice purposes were reviewed by the HTA at this site visit inspection. At the time of the inspection, there were no samples stored under police authority at the establishment.

Description of inspection activities undertaken

This report describes the third, routine HTA site visit inspection of Southend Hospital. The inspection team interviewed staff involved with licensable activities, reviewed documentation and conducted visual inspections of the mortuary, basement and contingency body stores, and the Pathology Laboratory.

A traceability audit was conducted for three adult bodies and three paediatric cases. These audits included checks of storage locations and identifiers recorded in the electronic register for bodies in fridge and freezer storage. The following discrepancies were found:

- The names on the fridge door labels for two bodies were spelled incorrectly.
- Traceability of one body in freezer storage could not be confirmed because the identification tag was not accessible (refer to Advice, item 13).

The establishment was not storing any whole organs or wet PM tissue at the time of the inspection. Audits of traceability were conducted for tissue blocks and slides from three PM cases, including checks of the consent documentation for storage of samples and disposal records where consent had not been given for storage or use of samples after the end of the coroner's authority. The following discrepancies were found:

- Fifteen additional slides which were not recorded on the paper or electronic traceability records were being stored for one case.
- The consent form for storage and use of samples after the end of coroner's authority was blank for one case. The establishment does not know whether coroner's authority for storage of the samples has ended and so they cannot evidence that these samples are stored with appropriate authority or consent. The HTA did not find evidence that these samples have been used for a scheduled purpose without consent.
- Records of disposal do not detail the number of tissue blocks and slides disposed of.

Immediately in advance of the inspection, the establishment disposed of PM tissue blocks and slides from a number of coronial PM examinations dating back to 2011. The establishment's procedures to ensure timely disposal of PM samples and communication with the coroner had not been followed for many of these cases (refer to major shortfalls against standards GQ2(c) and T2(a)).

Consent forms for hospital PM examinations for one adult and one perinatal case were reviewed. Discrepancies were found in completion of the adult hospital PM examination consent form:

- The details of the consent information leaflet had not been completed.
- The timeframe for withdrawing consent for the PM examination was less than 24 hours and there was no explanation recorded on the consent form for this deviation from the establishment's consent seeking procedure.

Inspection findings

Although the HTA found the Licence Holder and the DI to be suitable in accordance with the requirements of the legislation, the number and severity of shortfalls identified is of significant concern. With regard to the DI, whilst he was deemed to be a suitable person for this role, he had not ensured that suitable practices are used in the course of conducting activity under the licence.

There is significant work to be done to bring the establishment back up to an acceptable level of compliance. The HTA will monitor progress on this through the corrective and preventative action (CAPA) plan to be completed by the establishment (see below).

An application from the establishment to change the DI was approved by the HTA following the inspection.

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	SOPs do not accurately reflect the consent requirements of the HT Act. • The SOP for seeking consent for hospital PM examinations describes that consent for storage and use of samples for scheduled purposes once coroner's authority has ended should be sought from the person named as next of kin on the coroner's paperwork. • The SOP for PM examination describes that consent for a hospital PM examination should be sought from the next of kin or executor of the will. The HTA did not find evidence that the establishment has undertaken a PM examination, stored or used tissue with consent from a person who is not the appropriate person under the HT Act; however, these procedures, if followed, have the potential to result in a statutory breach of the HT Act. *Refer to Advice, item 1.*	**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.	Many of the SOPs do not accurately reflect current practice and do not contain sufficient detail for staff on the procedures that must be followed. Particular examples include: • SOPs describing identification of the deceased do not include details of the minimum identifiers and records that must be checked, how the identification checks should be performed and the procedures to follow in the event of discrepancies being identified; • the SOP describing labelling of unidentified bodies does not include sufficient details of the procedure to follow and does not accurately reflect current practice; • SOPs describing storage of bodies do not include details of the procedure to transfer bodies to frozen storage, including identification checks and records of the transfer; • SOPs for portering staff describing activities they undertake in the mortuary do not contain sufficient details of the procedures that must be followed for admission of bodies; and • SOPs describing storage of PM samples do not include sufficient details of traceability records. This means the establishment cannot be assured that procedures are undertaken in a consistent manner and in line with the requirements. This is not an exhaustive list of the amendments required to SOPs, and to fully address this shortfall, the establishment should review all SOPs relating to licensed activities to ensure that they are accurate and contain sufficient details of procedures.	**Major**

e) There is a system for recording that staff have read and understood the latest versions of these documents	Whilst there is a system for staff to record that they have read and understood the policies and SOPs relevant to the activities they undertake, these records are not complete for all staff. For example, Pathologists undertaking PM examinations had not recorded that they have read and understood the SOP describing the procedures for undertaking PM examinations. This poses the risk that some staff are not aware of the procedures they must follow, including updates to procedures, and may not carry out their duties in accordance with the requirements.	**Minor**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Although some governance meetings are held by departments engaged with licensed activities, these meetings do not cover all matters relating to the HTA licence.	**Minor**

GQ2 There is a documented system of audit		
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	The establishment had not followed its procedure for auditing and following up when coroner's authority for storage of PM samples has ended and whether samples should be disposed of. As a result, the establishment had built up a store of PM tissue blocks and slides from some PM examination cases dating back to 2011. The establishment undertook an audit of PM samples immediately in advance of the inspection and disposed of samples where coroner's authority had ended and consent had not been given for continued retention. The establishment also identified some cases where it is not known whether coroner's authority has ended or whether consent has been given for continued retention. These samples are stored pending either disposal or, where consent can be evidenced, storage for use for a scheduled purpose. The establishment is following up these cases and has a plan to ensure timely disposal of samples where coroner's authority has ended and consent has not been given for continued retention. The HTA did not find evidence that samples have been used for a scheduled purpose without consent. *Refer to shortfalls against standards T2(a) and T2(b).*	**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	Some staff demonstrated a lack of awareness of the reporting requirements for HTA Reportable Incidents (HTARIs). The establishment's SOP for HTARIs does not reflect accurately the establishment's procedures for reporting HTARIs to the HTA. The establishment's procedure for reporting and investigating incidents does not ensure that all HTARIs, including near-misses, are reported to the HTA. The HTA found an incident recorded on the incident log which was a near-miss HTARI but had not been reported to the HTA. *Refer to Advice, item 10.*	**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	Whilst the establishment has documented risk assessments of the risks related to the licensed activities, many of these do not contain sufficient details of the risks and mitigating actions.	**Minor**

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's procedures for identification of bodies do not always use a minimum of three identifiers. Identification checks for viewings are conducted by checking only one identifier provided by the family against the identification label on the body. The SOPs describing procedures for identification of bodies do not include details of the minimum identifiers that should be used, how the identification checks should be performed and the procedures to follow in the event of discrepancies being identified. This presents a significant risk of misidentification of the deceased. *Refer to Advice, item 11.*	**Major**

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The establishment's procedures do not provide for full traceability of PM slides: • The establishment does not record on the sample traceability database when additional slides are made. • The establishment does not record when slides are returned from Pathologists to the laboratory. This means that when slides are not stored in the laboratory, the establishment does not know whether the slides are being stored by the Pathologist in another location or are lost. Even in cases where the number of slides in storage is the same as the number of slides recorded on the sample traceability database, the establishment cannot be assured that all the slides are accounted for, since it is possible that additional slides were made that were not recorded on the database. The establishment could not demonstrate full traceability of slides for one case where slides were audited by the HTA.	**Major**

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 establishment had not followed its procedure for following up when coroner's authority for storage of PM samples has ended and whether samples should be disposed of. As a result, the establishment had built up a store of PM tissue blocks and slides from some PM examination cases dating back to 2011. The establishment identified this immediately in advance of the inspection and disposed of samples where coroner's authority had ended and consent had not been given for continued retention. The establishment also identified some cases where it is not known whether coroner's authority has ended or whether consent has been given for continued retention. The establishment is following up these cases and has a plan to ensure timely disposal of samples where the coroner's authority has ended and consent has not been given for continued retention. *Refer to shortfall against standard T2(b).*	**Major**

b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary	Although the establishment has a procedure for following up when coroner's authority has ended and what the families' wishes for the fate of PM samples are, this procedure had not been followed. This means that the establishment cannot provide assurance that tissue has not been kept for longer than necessary. *Refer to shortfall against standard GQ2(c).*	**Major**
d) The method and date of disposal are recorded	The establishment's SOP describing the procedure for disposal of PM samples does not include details of the records of disposal that should be made. The establishment records only that tissue blocks and slides have been disposed of and does not record the number of samples disposed of. This is particularly important given the weaknesses in the establishment's procedures for traceability of PM tissue blocks and slides. *Refer to shortfall against standard T1(g).*	**Major**

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	A number of major shortfalls were found against this standard, which together constitute a critical shortfall because of the risk to the dignity of the deceased and the health and safety of the staff. ***Body store facilities*** The condition of the basement body store presents a risk to the dignity of the deceased and health and safety of staff: • There are areas of exposed porous concrete on the floor and the step in front of the fridges and an exposed drain in the basement body store. These areas cannot be cleaned effectively and appeared to be dirty. • There is a large area of exposed plaster and brick on one wall and extensive damage to the other walls in the basement body store, including deep scratches and areas of exposed plaster. This means that the room is dusty and is difficult to clean. There are also areas of damage to the walls in the mortuary body store, including areas of exposed plaster. Whilst this damage is less severe, if not addressed it has the potential to	**Critical**

	pose a risk to the dignity of the deceased and health and safety of staff. The fridges and freezers in the mortuary and basement body store are in poor condition, including: • extensive damage to the door panels; • rust on some of the hinges; and • failure of the seals between floor panels inside the units. Whilst the storage units appeared to be clean at the time of the inspection, it is difficult for them to be cleaned effectively and this presents a risk to the health and safety of staff. ***PM suite*** The seals between the floor and the bases of the PM tables have failed. There are areas of rust on a cabinet and storage trolley in the PM suite. Although these areas appeared to be clean at the time of the inspection, it is difficult for staff to clean these areas effectively and this presents a risk to the health and safety of staff. This is particularly important given that the establishment undertakes high-risk PM examinations. ***Service tunnel*** The service tunnel used for transport of bodies from the hospital and basement body store to the mortuary is in poor condition: • the floor is uneven and slippery in places; and • there are areas of pooled water as a result of leaks from the building service systems and external environment. The condition of this area poses risks to the dignity of the deceased and of incidents occurring resulting in damage to bodies. This also presents a risk to the health and safety of staff.	
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)	The windows of the contingency body store do not have adequate security restrictors and were unlocked and open at the time of the inspection. Although this body store was not in use at the time of the inspection, the inadequate security arrangements for this facility present a risk of unauthorised access.	**Minor**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The door between the PM observation gallery and the mortuary entrance area for staff is routinely unlocked and open. This poses a risk of unauthorised viewing of a PM examination.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity	The establishment does not have sufficient capacity for refrigerated storage of bodies and has had to make use of eight temporary storage units for extended periods during the winter months. When the contingency body store is in use, bodies are transferred using concealment trolleys through an outside public area of the hospital which is in close proximity to the visitors' entrance to the mortuary. This presents risks to the dignity of the deceased and causing distress to families. Whilst there is an SOP describing use of the contingency body store, this does not include details of the procedure for transporting bodies to and from the facility.	**Major**
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	The temperature monitoring and alarming arrangements for the storage units are inadequate: • The temperature alarm for the fridges does not have a lower limit. • The temperature alarm upper limit for the fridges is set a 17°C, which is too high. The temperature alarm system is not tested regularly. This poses the risk that failure of the fridges or freezers or deviation from the acceptable storage temperatures may go unnoticed for a period of time, impacting on the integrity of the bodies stored in these units. The temperature alarming arrangements are particularly important given the age of the storage units and the number of faults which have occurred recently. *Refer to Advice, items 20 and 21.*	**Major**

Advice

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

No.	Standard	Advice
1.	C1(b)	The establishment must ensure that appropriate consent under the HT Act is given for retention of samples for use for scheduled purposes. The next of kin or the personal representative of the deceased, with whom the coroner's officer liaises with may not be the person highest in the list of qualifying relationships under the Section 27 (4) of the HT Act. Further information on the consent requirements of the HT Act can be found in the HTA's Codes of Practice. Code of Practice A – Guiding Principles and Fundamental Principle of Consent: www.hta.gov.uk/sites/default/files/Code%20A%20-%20Principles%20and%20consent%20Final_0.pdf. Code of Practice B – PM Examination: www.hta.gov.uk/sites/default/files/Code%20B%20-%20PM%20Final_0.pdf.
2.	C1(b)	Removal of relevant material from the body of a deceased person for use for a scheduled purpose is a licensed activity and must take place on licensed premises and with appropriate consent. The DI is advised to refer to the HTA's Code of Practice B for further information regarding removal of relevant material from the body of a deceased person for testing for infection status.
3.	C1(f)	The DI is advised that once consent has been given for a hospital PM examination, the family should be given the opportunity to change their minds or to change the scope of the PM examination. The time relatives have to reflect on their decision and the point up to which they may withdraw their consent should be clearly stated and should not be less than 12 hours. The HTA recommends no less than 24 hours.
4.	C1(g)	The DI is advised to remind staff seeking consent for adult hospital PM examinations of the importance of completing consent forms in a consistent manner. This will help to ensure that the establishment can evidence that appropriate consent for hospital PM examination and storage of PM samples has been given in accordance with the requirements of the HT Act. Consent forms should be audited to ensure that they are completed in a consistent manner and identify any additional training requirements for staff seeking consent. The DI is also advised to add document control information to the consent form for adult hospital PM examinations to help ensure that only the most up-to-date version is used.
5.	GQ1(a)	The DI is advised to ensure that references to documents in the establishment's procedures are up-to-date. The DI is further advised to include references to the HTA's Codes of Practices in these documents to help ensure that staff are aware of the requirements of the HT Act and the HTA's advice and guidance.

6.	GQ1(a)	The DI is advised to review signage in the mortuary to include details of: • the requirements and procedures for reporting incidents, including near-miss incidents; • the temperature monitoring and alarm arrangements and actions to be taken in the event of the temperature alarm sounding; and • when storage units are turned off and not in use, so that staff are aware of where bodies can be placed. This will help to raise awareness of, and ensure compliance with, the establishment's procedures for undertaking activities in the mortuary. The DI is also advised to introduce larger labels on the storage unit doors for the names of the deceased to be recorded so that these can be more easily read. The DI is further advised to consider introducing a whiteboard for communication of non-urgent issues between staff, including mortuary staff and porters. This may be of particular benefit when staff are working in the different body stores or out-of-hours. The HTA has seen this in use at other establishments where it has been reported to work well to improve communication between porters and mortuary staff.
7.	GQ2(a)	The DI is advised to strengthen audits of mortuary activities by ensuring that they cover all mortuary procedures in sufficient detail. This is particularly important given that the establishment uses standard laboratory audit template forms for undertaking and recording mortuary audits and not all sections of these forms are relevant to mortuary activities or reflect the HTA's licensing standards.
8.	GQ3(a)	The DI is advised that in the event of portering staff and Nursing Managers recommencing viewings, the DI should first ensure that they are appropriately trained in the procedures or are supervised by trained staff.
9.	GQ4(b)	Whilst the establishment uses some electronic registers and databases for traceability of bodies and samples, some paper records are still used. The DI is advised to ensure that SOPs describing management of paper records include details of how written amendments to records should be made.
10.	GQ5(a)	The DI is advised that further information on HTARIs, including the up-to-date HTARI categories can be found on the HTA website: www.hta.gov.uk/policies/post-mortem-hta-reportable-incidents.
11.	T1(c)	To address the shortfall against standard T1(c), the DI should ensure that a minimum of three identifiers, including at least one unique identifier, are used to identify bodies. SOPs describing the procedures for checking the identification of bodies should describe, as a minimum: • what records or information are required for the identification check; • the minimum number of identifiers that must be used and what these identifiers are expected to be, including for cases where the identity of the deceased is not known at the time of admission to the mortuary; • how the identification check should be performed, including what records the identification tag on the body should be checked against; and • the actions to take in the event of any discrepancies in the identifiers. The DI should ensure that the procedure for viewings of bodies describes details of what information the family are required to provide to mortuary staff so that the

		identification check of the body is conducted in line with the required standards. The DI may wish to consider introducing a form to record this information. Where the identity of the deceased is not known at the time of admission to the mortuary, the DI is advised to consider recording the police log number on the identification tag on the body and in the electronic register, in addition to the identifiers used currently.
12.	T1(d)	The DI is advised to further evaluate the potential limitations of the electronic register for flagging bodies with same or similar names. The DI is advised to strengthen the procedure for management of bodies with same or similar names by introducing a manual check to identify bodies with same or similar names as part of the establishment's daily mortuary checks.
13.	T1(e)	The DI is advised to ensure that when a body is transferred to frozen storage the identification tag on the body is positioned so that it can be easily read. This will help to ensure that the identification of bodies in frozen storage can be checked periodically and for release from the mortuary.
14.	T1(g)	The DI should ensure that the traceability system for PM samples ensures that the following details are recorded: • material sent for analysis on or off-site, including confirmation of arrival; • receipt upon return to the laboratory or mortuary; • the number of blocks and slides made; • repatriation with the body; • return for burial or cremation; and • disposal or retention for future use.
15.	T1(h)	The DI is advised to remind staff of the procedure for transfer of samples from the mortuary to the Pathology Laboratory to ensure that the 'PM Tissue Request Form' is sent with the samples, in line with the establishment's procedure.
16.	T2(b)	As part of the corrective and preventative actions to address the shortfall against standard T2(b), the DI should ensure that staff at the establishment are fully aware of what samples are held and why, to enable timely disposal of tissue where consent has not been given for continued retention. The HTA recommends that a nominated person is identified to handle the communication channels between the Pathology Laboratory and the coroner's office. The nominated person should ensure that decisions are passed to and within the Pathology Laboratory and there is no uncertainty about tissue disposal or retention when the coroner's authority has expired. The HTA has published a model communication flowchart to support good communication between coroners and HTA-licensed establishments; this can be found in Code of Practice B (Annex B, pages 39-40): www.hta.gov.uk/sites/default/files/Code%20B%20-%20PM%20Final_0.pdf.
17.	PFE1(d)	In addition to the corrective and preventative actions to the address the shortfall against standard PFE1(d), the DI is advised to consider whether further security arrangements and CCTV monitoring may be required for the mortuary and body store premises. This should be undertaken as part of the risk assessment of the security of these premises.

18.	PFE2(a)	During periods when the mortuary lift is out of service, bodies are transferred to the mortuary using concealment trolleys through public areas of the hospital, including outside areas. Whilst this procedure has been documented and risk assessed, the DI is advised to keep under review the suitability of this arrangement to ensure that the dignity of the deceased is protected.
19.	PFE2(d)	The DI is advised to ensure that the temporary storage unit ventilation ducts are appropriately sited to ensure that there is sufficient air flow for the units to work correctly.
20.	PFE2(d)	Whilst the fridge and freezer units are maintained, a number of faults have occurred recently and these units may be nearing the end of their useful working life. The DI should keep the suitability of these units under regular review to ensure that they function as required and plans are made for their replacement.
21.	PFE2(f)	The DI is advised to review the storage temperatures of the fridge unit in the mortuary body store which is operating at temperatures of 5°C to 6°C. The HTA advises that optimal fridge temperature is approximately 4°C. The DI is further advised to introduce a regular formal review of the storage temperatures of the fridges and freezers. This may help to identify issues with the function of the storage units.
22.	PFE2(i)	The DI is advised to review the establishment's contingency arrangements for storage of bodies at funeral services premises to assure themselves that procedures at these premises are sufficiently robust and in line with the standards expected by the establishment. For further advice on contingency storage arrangements, the DI is advised to refer to the HTA's guidance document 'Storage capacity and contingency arrangements in mortuaries: Guidance for DIs in HTA-licensed establishments': www.hta.gov.uk/sites/default/files/Capacity%20and%20Contingency%20Report%20Nov%2015.pdf.
23.	PFE3(d)	The DI is advised to review the availability of personal protective equipment for staff undertaking PM examinations for known or suspected high-risk cases (up to hazard group 3 biological agents).
24.	PFE3(f)	The establishment's Estates Department manages servicing and maintenance of the mortuary facilities and equipment. The DI is advised to ensure that the mortuary receives copies of servicing and maintenance records. This will help mortuary staff to ensure that maintenance schedules are appropriate.

Concluding comments

This reports describes the third site visit inspection of Southend Hospital. Despite the significant shortfalls against the HTA standards, the HTA observed some areas of strength:

- Staff involved in the inspection, including mortuary staff and the bereavement midwife seeking consent for perinatal PM examinations, demonstrated a sensitive approach to their work and dedication to providing a good service.

- Mortuary staff demonstrated that they work hard under difficult conditions with ageing

mortuary facilities. The overall cleanliness of the mortuary facilities in spite of these challenging conditions demonstrates their hard work and dedication.

- Mortuary staff have been monitoring deviations in procedures for labelling of bodies from the hospital and community and working with the relevant staff to address these.

- Staff demonstrated a willingness for continual improvement and compliance with the regulatory requirements, and were open to the advice given by the HTA.

Staff at the establishment had been aware of a number of the issues raised during the inspection and had been trying to rectify these.

Although the HTA found that the establishment had met some of the HTA's standards, significant shortfalls were found against the range of standards, with one shortfall assessed as critical and ten as major (see Appendix 2 for information about the HTA's classifications of shortfalls). There is significant work to be done to bring the establishment back up to an acceptable level of compliance.

Although the DI was deemed to be a suitable person, he had not ensured that suitable practices are used in the course of conducting activity under the licence. An application from the establishment to change the DI was approved by the HTA following the inspection.

The HTA has written to the Medical Director, who is the corporate licence holder contact for the purposes of HTA licensing, the Chief Executive and the DI outlining the actions that must be taken as a matter of urgency to address the critical and major shortfalls identified.

All shortfalls will be managed through the HTA's process for agreeing and overseeing CAPAs. The HTA requires the DI to submit a completed 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: 25 October 2017

Report returned from DI: 8 November 2017

Final report issued: 13 November 2017

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: 11 March 2020

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 they are placed back into normal storage.

f) There are procedures for releasing a body that has been in long term storage and is therefore not in the current register.

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings). The traceability system ensures that the following details are recorded:

i. material sent for analysis on or off-site, including confirmation of arrival

ii. receipt upon return to the laboratory or mortuary

iii. the number of blocks and slides made

iv. repatriation with the body

v. return for burial or cremation

vi. disposal or retention for future use.

Guidance

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

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

Guidance

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

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

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

b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary.

c) Disposal is in line with the wishes of the deceased's family.

Guidance

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

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

d) The method and date of disposal are recorded.

Premises, facilities and equipment

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

a) The premises are clean and well maintained.

Guidance

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

b) There is demarcation of clear, dirty and transitional areas of the mortuary, which is observed by staff and visitors.

c) There are documented cleaning and decontamination procedures and a schedule of cleaning.

d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access).

Guidance

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

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

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

a) Storage arrangements ensure the dignity of the deceased.

Guidance

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

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

Guidance

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

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

Guidance

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

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

Where new fridges are installed, these should measure 24"-26" in width and consideration

should be given to the proportion that should be larger to accommodate bariatric bodies.

d) Fridge and freezer units are in good working condition and well maintained.

e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range.

f) Temperatures of fridges and freezers are monitored on a regular basis.

Guidance

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

g) Bodies are shrouded or in body bags whilst in storage.

h) There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods.

Guidance

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

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

The hire of temporary storage units should not be the sole contingency arrangement for an establishment. Establishments should put in place other formally agreed arrangements for contingency storage. Where the hire of temporary storage facilities forms part of establishments' contingency arrangements, consideration should be given well in advance and steps taken to ensure availability of funds, and of units for hire.

Establishments should consider entering in to Mutual Aid Agreements with neighbouring organisations in order that they can provide and obtain support during periods of capacity shortages.

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

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

   i. fridges / freezers

ii. hydraulic trolleys

iii. post mortem tables

iv. hoists

v. saws (manual and/or oscillating)

Guidance

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

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

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

Guidance

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

d) Staff have access to necessary PPE.

Guidance

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

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

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

Guidance

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

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. Critical shortfall:

A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

or

A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

A critical shortfall may result in one or more of the following:

(1) A notice of proposal being issued to revoke the licence

(2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

(5) Directions being issued requiring specific action to be taken straightaway

2. Major shortfall:

A non-critical shortfall that:

- poses a risk to human safety and/or dignity, or
- indicates a failure to carry out satisfactory procedures, or
- indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
- has the potential to become a critical shortfall unless addressed

or

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

   This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

   In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.