Site visit inspection report on compliance with HTA licensing standards

Worcestershire Royal Hospital

HTA licensing number 12079

Licensed under the Human Tissue Act 2004 for the

- **making of a post mortem examination (hub site only);**
- **removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation; and**
- **storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose**

6 – 8 June 2017

Summary of inspection findings

The HTA licence covers Worcestershire Royal Hospital (the hub site) and Alexandra Hospital (the satellite site). This is 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 premises. Eight major shortfalls and ten minor shortfalls were found in relation to the standards for governance and quality systems, traceability, and premises, facilities and equipment.

Despite the shortfalls, the HTA found the Designated Individual and the Licence Holder 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.

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

Worcestershire Royal Hospital (the hub) and Alexandra Hospital (the satellite) are part of Worcestershire Acute Hospitals NHS Trust. Both hospitals have been licensed by the HTA since June 2007, but separately until Alexandra Hospital became a satellite of Worcestershire Royal Hospital and its licence was revoked in May 2017.

The Designated Individual (DI) has been overseeing licensed activities taking place at both hospitals since January 2014. In July 2016, pathology services across the Trust merged, including management of the mortuaries at Worcestershire Royal Hospital and Alexandra Hospital. Since this time, the mortuaries have been managed by a single Mortuary Manager and mortuary practices have been aligned across both sites.

The mortuaries are staffed by six Anatomical Pathology Technologists (APTs) – the Mortuary Manager, four experienced APTs and one trainee. The establishment increased the number of staff to seven by employing locum staff in the months preceding the inspection; however, prior to this, the mortuary had been significantly understaffed at times and, despite this, the establishment has plans to return the staffing level to six APTs in the coming months (see Advice, item 23).

The Mortuary Manager and experienced APTs work across both sites. The mortuary at Alexandra Hospital is usually staffed by one APT, whilst the other APTs staff the mortuary at Worcestershire Royal Hospital (see Advice, item 3).

Worcestershire Royal Hospital – hub site

Worcestershire Royal Hospital is licensed for the making of a PM examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes.

Approximately 900 adult PM examinations are conducted there each year; this is a significant increase from approximately 500 PM examinations that took place there before the closure of the PM suite at Alexandra Hospital in 2016. The majority of PM examinations are performed under Coronial authority. High-risk (cases known or suspected to contain hazard group 4 biological agents), Home Office, perinatal and paediatric cases are transferred to other HTA-licensed establishments.

Adult hospital consented PM examinations take place very occasionally; no cases were undertaken in 2016 and two cases had been undertaken in 2017 up to the date of the inspection. Consent for adult hospital PM examinations is sought by trained mortuary staff, in conjunction with clinical staff, using a consent form and information leaflet based on the HTA's model documentation (see Advice, item 1). Consent for perinatal PM examinations is

sought by clinical staff in the Labour Department, using a consent form and information leaflet based on those provided by the Stillbirth and Neonatal Death (Sands) charity (see Advice, items 1 and 6). Staff receive training in seeking consent for PM examination as part of their clinical training and from the HTA-licensed establishment to which perinatal PM examinations are referred.

The mortuary at Worcestershire Royal Hospital is located in a separate building on the hospital site. The building is secured by locked doors with swipe card access, except for one door which is secured by a key lock only (see Advice, item 16). There is closed-circuit television (CCTV) monitoring inside the mortuary and at some entrances (see Advice, item 16). Overall, the mortuary security and access control arrangements are inadequate (see major shortfalls against standard PFE1(d).

The mortuary has 77 spaces for bodies, including seven spaces for bariatric bodies and five spaces for perinatal or paediatric cases. One fridge unit with five spaces can be used for frozen storage where bodies require long-term storage. The mortuary also has a separate fridge with six spaces for fetuses and babies; however, this is not currently in use and has not been connected to an electrical supply (see Advice, item 20). Perinatal and paediatric cases are transferred directly to the mortuary and are not stored elsewhere in the hospital.

The establishment has contingency arrangements for storage of bodies at Alexandra Hospital (see Advice, item 20). At the time of the inspection, it was employing two temporary storage units with space for 24 bodies in the mortuary at Worcestershire Royal Hospital. These units were intended for use during periods of peak activity as contingency storage; however, because the mortuary does not have adequate fridge storage capacity, they have been in near constant use for extended periods over at least the past 18 months (see major shortfalls against standards PFE2(b) and PFE2(i)). The units are sited in the viewing room (requiring an alternative viewing room to be set up) and PM suite (see critical shortfall against standard PFE1(a)). The establishment has previously also hired an external temporary storage unit to be erected outside the mortuary to provide additional refrigerated storage capacity. It has struggled with capacity in recent months and has not documented or assessed the risks of the contingency arrangements for storage of bodies (see major shortfall against standard PFE2(i)).

There is a storage temperature monitoring and alarm system for the mortuary fridges and freezers at Worcestershire Royal Hospital, including for the temporary refrigerated storage units; however, this system has not been tested and mortuary staff do not all have access to the monitoring system (see major shortfall against standard PFE2(e)).

The PM suite at Worcestershire Royal Hospital has three downdraft tables and two dedicated benches for the preparation of tissue samples. Some items of equipment in the PM suite are not fit for purpose (see minor shortfall for standard PFE3(a)).

Material taken at PM examination may be transferred to the establishment's Pathology Department for histological analysis or to other establishments for toxicology or other tests. Organs and tissue samples may be kept, with consent, for use for scheduled purposes. The establishment does not routinely store samples for use for research. Samples are stored in a dedicated area in the mortuary. The mortuary uses paper and electronic registers 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. The establishment's procedures for traceability of PM tissues are not sufficiently robust (see 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 Accident and Emergency (A&E) Department. Licensed activities in this department are not incorporated within the establishment's governance framework for the HTA licence (see minor shortfall against standard GQ1(g)).

Alexandra Hospital – satellite site

Alexandra Hospital is licensed for the removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes.

The mortuary at Alexandra Hospital is located in the main hospital building. It is secured by locked doors with key code and key lock access, except for one door which is secured by a key lock only (see Advice, item 16). There is CCTV monitoring inside the mortuary and of some of the building entrances (see Advice, item 16). The HTA assessed the body store premises at this site as requiring significant improvement (see critical shortfall against standard PFE2(a)).

The mortuary has 47 spaces for adult bodies, including four spaces for bariatric bodies and three for super bariatric bodies. One fridge unit with five spaces is located in an isolation room and can be used for storing bodies which pose a health and safety or environmental risk, or for frozen storage where bodies require long-term storage. The mortuary also has a separate fridge with four spaces for fetuses and babies (see major shortfall against standard PFE2(a)). The fridge units, with the exception of the isolation fridge, are not connected to a temperature monitoring alarm (see major shortfall against standard PFE2(e)).

The establishment has two temporary storage units at this site with space for 24 bodies; these units were erected but not in use at the time of this inspection (see Advice, item 20).

The PM suite at Alexandra Hospital was decommissioned in 2016 and the site is no longer licensed for the making of a PM examination. Bodies are transferred elsewhere for PM examination; adult cases are transferred to Worcestershire Royal Hospital and high-risk

(cases known or suspected to contain hazard group 4 biological agents), Home Office, perinatal and paediatric cases are transferred to other HTA-licensed establishments.

At the time of the inspection, the establishment was storing organs, with Coronial authorisation or consent, from four PM examination cases undertaken at Alexandra Hospital. These organs are stored in a dedicated area in the isolation room in the mortuary, and records of the samples and Coronial authorisation/consent for their storage are maintained in the establishment's paper and electronic registers.

Sampling of tissues from deceased children in SUDI cases is performed in the A&E Department by a core team of staff, under pre-emptive Coronial authorisation.

Description of inspection activities undertaken

This report describes the HTA's third, routine site visit inspection of each of Worcestershire Royal Hospital and Alexandra Hospital and the first inspection since pathology services at the sites merged and Alexandra Hospital became a satellite of this licence. The inspection team interviewed staff involved with licensable activities, reviewed documentation and conducted visual inspections of the mortuaries at both sites and the A&E Department at Alexandra Hospital. The HTA was not able to assess the conduct of licensed activities in the A&E Department at Worcestershire Royal Hospital because staff in the department were not available during the inspection; licensed activities in this department will be assessed as part of the corrective and preventative action plan for the minor shortfall against standard GQ1(g).

A traceability audit was conducted for seven adult bodies and one paediatric case, which included checks of storage locations and identifiers recorded in the paper and electronic records. Transport records were audited for two bodies which had been transferred from Alexandra Hospital to and from Worcestershire Royal Hospital for PM examination. There were no discrepancies in traceability of these bodies. There were no bodies in frozen storage at either mortuary at the time of the inspection meaning that an audit of frozen storage could not be conducted.

Audits of traceability were conducted for organs, tissue blocks and slides from four PM cases, including checks of the consent documentation for storage of the samples. A discrepancy in sample traceability was identified in one case, where the establishment was storing an additional slide that had not been recorded on the paper or electronic records (see major shortfall against standard T1(g)). Consent forms for one adult and one perinatal PM examination were reviewed. The date of completion recorded on the perinatal PM examination consent form was incorrect (see Advice, item 1). Disposal records were reviewed for disposed PM tissue blocks and slides. No discrepancies in disposal records were found.

Inspection findings

Although the HTA found the Licence Holder and the Designated Individual to be suitable in accordance with the requirements of the legislation, the number and severity of shortfalls identified is of significant concern. The HTA will be maintaining oversight of the actions taken to address these shortfalls, to ensure that they are rectified promptly and appropriately. A follow-up site visit inspection will be undertaken to provide the necessary assurance.

Assessment of existing shortfalls against standards

Four minor shortfalls identified at the last inspection of Alexandra Hospital remained open at the time of this inspection. The HTA assessed three of these as having been addressed since the PM suite at Alexandra Hospital has been decommissioned and the main fridge unit has been replaced. One minor shortfall relating to governance meetings remains outstanding and will be addressed by the corrective and preventative action plan for standard GQ1(h).

Compliance with HTA standards

Standard	Inspection findings	Level of shortfall
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 currently in place 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; • the SOP for long-term storage of bodies does not detail the process for switching storage units to freezer mode and changing the temperature alarm parameters; • the SOP for storage and temperature alarm arrangements does not detail the acceptable temperature ranges and alarm trigger points; • the SOP for lone working in the mortuary at Alexandra Hospital does not accurately reflect the arrangements and is not accordance with the Trust's lone working policy;	**Major**

	and • the SOP for HTA reportable incidents (HTARIs) does not detail the processes for investigating and following up incidents, references a previous version of the HTA's 'Guidance for Reporting HTARIs', and does not include a complete list of the HTARI categories. 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 mortuary activities to ensure that they are accurate and contain sufficient details of procedures. *Refer to Advice, items 2 and 3.*	
e) There is a system for recording that staff have read and understood the latest versions of these documents	Although the establishment has a system for recording that all mortuary staff have access to and have read and understood the SOPs and policies relevant to the activities they undertake, these records are not complete for all mortuary staff. This poses the risk that staff are not aware of updates to procedures, and may not carry out their duties in accordance with the requirements.	**Minor**
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework	The establishment does not have Persons Designated (PDs) in each department where activities are conducted under the licence. There are no PDs for the A&E Departments at either site and the Labour Department at Worcestershire Royal Hospital. The DI visits these departments infrequently and so cannot oversee activities in these departments effectively without PDs to support him. The DI does not have sufficient oversight of removal of relevant material under the licence in the A&E Department at Worcestershire Royal Hospital. The DI could not identify staff overseeing this activity until immediately prior to the inspection. Staff from this department have not attended the establishment's HTA governance meetings. *Refer to shortfall against standard GQ1(h) and Advice, item 6.*	**Minor**

h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Although the establishment has held some governance meetings relating to licensed activities, these have been infrequent. This is particularly important given the changes to the establishment's pathology services and mortuary processes and that activities are taking place in several different departments and across two sites.	**Minor**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The establishment does not have a documented schedule of audits for activities taking place under the licence. Although the establishment has undertaken audits of stored tissue samples, regular audits have not been undertaken of compliance with mortuary procedures, traceability of bodies, and mortuary records. *Refer to Advice, item 7.*	**Minor**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised	Porters at Worcestershire Royal Hospital who undertake activities in the mortuary have not been trained in all mortuary procedures they perform.	**Minor**
c) Staff are assessed as competent for the tasks they perform	Although the establishment has a procedure for assessing the competency of mortuary staff, competency assessments have been undertaken immediately in advance of HTA inspections only.	**Minor**

GQ4 There is a systematic and planned approach to the management of records		
b) There are documented SOPs for record management which include how errors in written records should be corrected	The establishment's SOP for management of mortuary records does not cover the creation, review and amendment of records. The HTA observed inconsistent approaches to written amendments, including use of correction fluid in the mortuary register and PM record book.	**Minor**

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	Porters undertaking activities in the mortuary lack of awareness of the establishment's incident reporting procedures and the reporting requirements for HTA Reportable Incidents (HTARIs). *Refer to Advice, items 4 and 9.*	**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	The establishment's risk assessments of procedures related to licensed activities do not include sufficient details of the risks and actions in place to mitigate these risks. In particular, the following risks have not been assessed in sufficient detail: • misidentification of bodies; • accidental damage of bodies; • integrity of bodies and long-term storage arrangements; • mortuary security; • major equipment failure; and • lone working in the mortuary at Alexandra Hospital. *Refer to Advice, item 10.*	**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 three identifiers. The procedures for identification of bodies for viewings and release of bodies from the mortuary to funeral services rely on only one or two identifiers. This poses a significant risk of misidentification of the deceased.	**Major**

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The establishment's procedures for traceability of PM tissues are not sufficiently robust. The mortuary at Worcestershire Royal Hospital contains two dedicated benches for the preparation of tissue samples during PM examination, but only one set of weighing scales; this means that samples from different cases may be on the same bench for a period. The SOP for PM examination does not provide sufficient detail of the processes in place to prevent mix-up of samples. The establishment does not record when additional slides of PM tissue are created in the Pathology Department. Although all the slides from each case are stored together to reduce the risk of loss of traceability, the establishment's records of slides are not accurate for all cases and this poses a risk of loss of traceability.	**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. ***Alexandra Hospital*** The floor in the body store is not fit for purpose and cannot be cleaned effectively. • There is a gap between the floor covering and the main fridge unit with an area of exposed porous concrete floor, an exposed wooden plinth at the base of the fridge, and a gap between the plinth and the floor. • The floor covering has not been extended into the super bariatric walk-in fridge and the floor of this unit is exposed, porous concrete. • There are several large splits in the floor covering and the surface is no longer impervious in these areas. • The skirting is coming away from the walls in several areas resulting in large gaps between the floor covering and the walls. • The tape markings on the floor are coming away from the floor and dirt is	**Critical**

	trapped in these areas. ***Alexandra Hospital*** The fridge/freezer unit in the isolation room is dirty. This unit is used to store bodies which pose a significant health and safety or environmental risk. The wall panel to the service area under the sink in the isolation room is missing. Several doors in body store are in poor condition, including a small hole in one door leading to the hospital corridor. The ceiling of the body store is in a poor condition, including: missing tiles; holes in tiles; and loose fitting tiles (including one tile suspended from only one corner). ***Worcestershire Royal Hospital*** A temporary storage unit has been erected in the PM suite for at least the past 18 months. This means that the floor in this area cannot be cleaned effectively and is dirty. Bodies are released from this storage unit when the PM suite is in use, the trolley being wheeled from a 'dirty' to 'clean' zone of the mortuary, which poses a risk of contamination of the 'clean' areas of the mortuary.	

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)	***Worcestershire Royal Hospital*** There is no access control on the door between the waiting room and the viewing room which is being used as a temporary body store. Visitors are unsupervised in the waiting room and this poses a risk of unauthorised access to the body store from the waiting room. The rear access to the body store, used by funeral services and ambulance staff when bodies are admitted to and released from the mortuary, is located in an unrestricted area which is used as a pedestrian access route and a car park for visitors to the mortuary. The access door is also directly overlooked by a nearby office building. This means that when the access door is open, part of the body store is directly visible to passers-by and those in the office building, posing a significant risk to the dignity of the deceased. There are a number of louvre windows to the mortuary building (including to the body store area, staff room and viewing room) which do not provide adequate security. This poses a risk of unauthorised access to the mortuary.	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	***Alexandra Hospital*** The fetal fridge regularly operates at temperatures from 0°C to 2°C. This temperature is too cold and could lead to freezing of bodies. The establishment's temperature records also show that the fridge was operating at minus 2°C on one occasion in the past month. Although the fetal fridge has not been used to date, the establishment has not taken action to prevent storage of bodies at inappropriate temperatures by acting on deviations in storage temperatures or ensuring that the fridge is not used. *Refer to shortfall against standard PFE2(e) and Advice, item 18.*	**Major**

b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity	***Worcestershire Royal Hospital*** The mortuary at Worcestershire Royal Hospital does not have sufficient capacity for refrigerated storage of bodies and has had to make use of two temporary storage units almost continually for at least the past 18 months. *Refer to shortfall against standard PFE2(i) and Advice, item 20.*	**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	Temperature monitoring and alarming arrangements are inadequate and present a significant risk to the integrity of bodies. ***Alexandra Hospital*** The fridge units at Alexandra Hospital (except for the isolation fridge/freezer unit), are not connected to a temperature monitoring alarm. Although staff have implemented a daily manual check of storage temperatures, the HTA observed several gaps in the temperature records for the fetal fridge over a two month period. The establishment is not aware of the parameters for the fridge/freezer unit in the isolation room at the establishment and whether the acceptable temperature range can be adjusted when the unit is switched to freezer mode. The is a risk that failure of the fridge or deviation from the acceptable storage temperatures may go unnoticed for a period of time, impacting on the integrity of bodies stored in these units. ***Worcestershire Royal Hospital*** Although the storage units at Worcestershire Royal Hospital are connected to a temperature monitoring alarm, the alarm system is not tested regularly. Mortuary staff do not all have access to the monitoring system to check and respond to alarms.	**Major**

i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods	The storage units erected in the mortuary at Worcestershire Royal Hospital have been in near continual use for at least the past 18 months. These units have now become routine storage space, instead of a temporary arrangement put in place to address an unexpected rise in the number of bodies, for example during the autumn and winter months. The use of the contingency storage units on an ongoing basis means that the establishment has had to rely on hire of an additional temporary storage unit during the winter months. The establishment does not have a documented contingency plan for storage during peak periods and has not assessed the risks of the contingency arrangements for storage of bodies.	**Major**

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	***Worcestershire Royal Hospital*** Some items of equipment in the PM suite are not fit for purpose: • two of the three oscillating saws are faulty and have exposed electrical connections. Although these saws are not in use, the establishment has not taken appropriate actions to prevent their use or taken steps to fix them; • the water hoses used for cleaning the PM suite are in poor condition (one hose is split, another has a broken spray head, and another has no spray head); and • one tool for PM examination has a wooden handle; although this tool is new and was clean at the time of the inspection, wood is porous and cannot be cleaned effectively.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(b)	The HTA identified a discrepancy in the completion of one consent form for a perinatal hospital PM examination, where the date of completion of the form was incorrect. The DI is advised to remind staff seeking consent for hospital consented 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 samples of relevant material has been given in accordance with the requirements of the HT Act. Consent forms should be audited to ensure that they are completed consistently and identify any additional training requirements for staff seeking consent.
2.	GQ1(a)	The DI is advised to ensure that references to documents in the establishment's policies and procedures are up-to-date. The DI is further advised to ensure that staff working under the licence refer to the most up-to-date versions of the HTA's Codes of Practice and licensing standards.
3.	GQ1(a)	The DI should review the establishment's policy for lone working in the mortuary at Alexandra Hospital to ensure that lone working arrangements are appropriate and protect the safety of staff. The DI is advised to ensure that the mortuary lone working policy is informed by health and safety considerations and the establishment's Occupational Health team, where required, and are in accordance with the Trust's policy on lone working.
4.	GQ1(a)	The DI is advised to review signage in the mortuary to include: • when storage units are in freezer mode or are turned off and not in use, so that staff are aware of where bodies can be placed; • the temperature monitoring and alarm arrangements and actions to be taken in the event of the temperature alarm sounding; and • the requirements and procedures for reporting incidents, including HTARIs. The DI is also advised to extend use of the 'Porter Communication' whiteboard to the mortuary at Alexandra Hospital. This whiteboard is used by porters at Worcestershire Royal Hospital when they are working out-of-hours to communicate non-urgent issues with mortuary staff, and staff report that this system works well.
5.	GQ1(d)	The DI is advised to ensure that all mortuary documents and checklists, including the storage capacity checklist, are subject to the establishment's document control procedures.
6.	GQ1(g)	As part of the corrective and preventative actions required to address the shortfall against standard GQ1(g), the DI should nominate PDs in each department where activities are carried out under the licence. This will help to ensure that all areas where activities are conducted under the licence are incorporated within the establishment's governance framework.

7.	GQ2(a)	To address the shortfall against standard GQ2(a), the DI should ensure that, as a minimum, the audit schedule should include a range of vertical and horizontal audits checking compliance with documented procedures, the completion of records and traceability. The DI is advised that audits should be undertaken on a regular basis and following material changes to procedures. Audits can help to ensure that procedures are performed in-line with SOPs and identify areas where additional training may be required or where a process needs to be amended.
8.	GQ3(f)	The DI is advised to ensure that there are documented training plans for staff returning to work after an extended period of absence. This will help to ensure that staff are trained and competency assessed in up-to-date mortuary procedures. Where staff have not been trained and assessed as competent in mortuary procedures, they should be supervised by appropriately trained staff.
9.	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/posst-mortem-hta-reportable-incidents.
10.	GQ6(a)	The DI is advised to consider the HTARI categories when reviewing the establishment's risk assessments to ensure they identify where there is the potential for a serious incident to occur. The DI is also advised that the HTA's 'Regulation of the Post Mortem Sector 2014 – 16: What we have learned' review may also be useful to help identify further risks and actions to mitigate these risks: www.hta.gov.uk/policies/regulation-post-mortem-sector-2014-16-what-we-have-learned.
11.	T1(b)	The DI is advised to ensure that where bodies or PM samples are sent from the mortuary to other establishments, confirmation of receipt at the establishment is received and that there are systems to follow up where confirmation of receipt is not received. This will provide the establishment with assurance that the chain of custody is complete and provide records of this for auditing.
12.	T1(b)	The DI is advised to review the form for recording retrieval of organs and tissue for transplantation or research to include the date and the deceased's unique mortuary number. This will facilitate audits of these records.
13.	T1(d)	The DI is advised to adopt a consistent procedure at both sites for highlighting where there are bodies with same or similar names in the mortuary. This will help to minimise the risk of procedural errors, given that some staff work at both mortuaries.
14.	T2(b)	The DI is advised to consider reviewing the system for communication with the Coroner's Office. The establishment's current system relies on the Pathology Department relaying information from the Coroner's Office to the mortuary, and this can cause delays in the mortuary receiving information of when Coronial authority for storage of samples has ended and of the family's wishes for the fate of samples.
15.	PFE1(c)	The fridge and freezer units are no longer on a deep-clean cleaning schedule. In addition to the corrective and preventative actions required to address the shortfall against standard PFE1(a) relating to cleanliness of the isolation fridge at Alexandra Hospital, the DI should review the mortuary cleaning schedules for both mortuaries to ensure that the cleaning regimes are appropriate and are kept under regular review.

16.	PFE1(d)	The DI is advised to review the security of the door used by porters to access the mortuary at Alexandra Hospital. This door is secured by key only and does not lock automatically when shut. This poses the risk that the door may be left unsecured inadvertently, which could result in unauthorised access to the mortuary. The DI is also advised to review use of the side door to the body store at Worcestershire Royal Hospital. This door is secured by key lock only and enters directly into the body store. Although the door is used by a small number of staff only, the location of the door means that when it is in use, visitors to the mortuary in the garden area may be able to see into the body store. The DI is also advised to review the CCTV coverage of the mortuaries at both sites to ensure that the key areas of the mortuaries are covered.
17.	PFE1(d)	The DI is advised to ensure that electrical sockets used for key equipment are protected from being unplugged or switched off inadvertently. This includes the sockets used for the temperature monitoring alarm at Worcestershire Royal Hospital and the fetal fridge at Alexandra Hospital. The DI is also advised to review the siting of electrical cables to ensure that they do not pose hazards of tripping or electrocution. In particular, the DI is advised to review the siting of the computer power cable in the PM suite at Worcestershire Royal Hospital, which is trailing near to the floor.
18.	PFE2(a)	The DI is advised to introduce periodic analysis of storage temperatures for the fridges and freezers. This will help to identify any trends in temperatures which may indicate the need for preventative maintenance of storage units. The HTA advises that optimal fridge temperature is 4°C. In addition to the corrective and preventative actions required to address the shortfall against standard PFE2(a) relating to the fetal fridge at Alexandra Hospital, the DI is advised to review the storage temperatures of the super bariatric and main fridge units at this site, which are operating at temperatures of 5°C to 6°C.
19.	PFE2(a)	The DI is advised to conduct more frequent checks on the condition of bodies and consider the introduction of a documented checklist to record checks performed. This will provide assurance that that the establishment's storage arrangements ensure the dignity of the deceased is maintained. The DI is also advised to review the procedure for transferring bodies to frozen storage, to initiate the follow-up and authorisation processes earlier so that appropriate actions can be implemented in good time. The HTA advises that bodies should be moved into frozen storage after 30 days in refrigerated storage if there is no indication that they are soon to be released or further examined, or before, depending on the condition of the body.
20.	PFE2(b)	The DI is advised that transfer of bodies to other premises for storage increases the risk of loss of traceability of bodies and should not be relied upon as a permanent solution to inadequate storage capacity at Worcestershire Royal Hospital. The DI is advised that setting up the fetal fridge in the mortuary at Worcestershire Royal Hospital will make five spaces in the main fridge unit (currently used for storage of fetuses and perinatal cases) available for storage of adult bodies. This will provide much needed additional capacity for refrigerated storage of adult bodies in this mortuary.

21.	PFE2(d)	The DI is advised to review the suitability of personal protective equipment for staff during PM examinations for known or suspected high-risk cases (up to hazard group 3 biological agents).
22.	PFE2(d)	The DI is advised to monitor the condition of the fridge/freezer unit in isolation room at Alexandra Hospital. This storage unit may be nearing the end of its working life and staff have experienced problems when switching it from fridge to freezer mode. Although the storage unit has been repaired recently and is serviced regularly, the use of this unit should be kept under review.
23.	N/A	Although staffing levels in the mortuary had increased in the months preceding this inspection by employing locum staff, prior to this the mortuary had been significantly understaffed at times. The establishment has plans to return the staffing level to six APTs in the coming months. This would likely result in the mortuary at Worcestershire Royal Hospital being understaffed. Staff have to travel from the hub site outside of normal working hours to assist the lone working staff member at the satellite site with tasks that require two staff members. A number of staff work additional hours regularly and work on the on-call rota for extended periods. The Mortuary Manager does not have sufficient time in working hours to undertake all of the tasks required to ensure effective management of the mortuaries. The DI is advised to keep staffing levels of the mortuary under regular review to ensure that they are sufficient to provide safe and effective services.

Concluding comments

This reports describes the third, HTA site visit inspection of each of Worcestershire Royal Hospital and Alexandra Hospital. A number of changes to mortuary procedures have taken place over the past twelve months since the pathology services at the two sites merged.

The HTA observed some areas of strength. The establishment has undertaken a thorough review of the traceability of PM samples and has strengthened procedures; the HTA has given the DI advice on how to strengthen these further. A ‘Porter Communication’ whiteboard has been introduced at Worcestershire Royal Hospital for porters who are working out-of-hours to communicate non-urgent issues with mortuary staff, and staff report that this has improved communication between porters and mortuary staff. The mortuary has good communication with the A&E Department at Alexandra Hospital and the Labour Department.

Staff involved in the inspection demonstrated a sensitive approach to their work and dedication to providing a good service. Staff also demonstrated a willingness for continual improvement and compliance with the regulatory requirements, and were open to the advice given by the HTA. Mortuary staff involved in the inspection also demonstrated that they work hard under significant workload pressures to deliver a good service, often working additional hours and travelling outside of working hours to assist the lone working staff member at the satellite site with tasks that require two staff members. 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 governance and quality systems, traceability, and premises, facilities and equipment standards, with one shortfall assessed as critical and eight as major (see Appendix 2 for information about the HTA's classifications of shortfalls).

The HTA has written to the Chief Executive of the Trust and the Designated Individual 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 corrective and preventative actions plans (CAPAs).

The HTA requires the Designated Individual to submit a completed CAPA plan setting out how the minor 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: 6 July 2017

Report returned from DI: 19 July 2017

Final report issued: 26 July 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: 08 March 2019

Appendix 1: HTA licensing standards

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

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

b) 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.

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

d) 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.

e) Staff have access to necessary PPE.

Guidance

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

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

g) 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.