Site visit inspection report on compliance with HTA licensing standards

Torbay Hospital

HTA licensing number 12181

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**

24 and 25 May 2017

Summary of inspection findings

This is the first inspection of this establishment against the revised HTA licensing standards, which came into force on 3 April 2017. The previous inspection took place in October 2013. There has been a significant decline in compliance since that time, with shortfalls identified across all four groups of standards. Two critical shortfalls were found in relation to the post mortem suite facilities and nine major shortfalls were found in relation to the standards for governance and quality systems, traceability, and premises, facilities and equipment. In addition, 15 minor shortfalls were found across the range standards. In addition, the establishment was found to be storing archived PM tissue blocks and slides for use for scheduled purposes in a separate building in close proximity to the main hospital campus, but not covered by the HTA licence. This is a statutory breach of the HT Act.

The HTA found the Designated Individual (DI), who took on this responsibility around three months ago, and the Licence Holder (LH) 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.

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

Torbay Hospital (the establishment) is part of Torbay and South Devon NHS Foundation Trust. It has been licensed by the HTA since June 2007 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 establishment increased its mortuary staffing in January 2017, and the mortuary is now staffed by three Anatomical Pathology Technologists (APTs) – the mortuary manager and a locum, both of whom are experienced APTs, and a trainee (see Advice, item18).

The mortuary and PM facilities are secured by swipe card access and there is an intercom system for staff to allow entry to visitors. There is closed-circuit television (CCTV) monitoring both within the mortuary and of the building entrances. Despite these measures, the mortuary is not protected from unauthorised access because of inadequate access control arrangements (see major shortfall against standard PFE1(d)).

The mortuary has 38 fridge spaces for adult bodies, including eight spaces for bariatric bodies. There are three freezer spaces for bodies requiring long-term storage. Perinatal/ paediatric cases are stored in a separate fridge in the mortuary, which has four spaces. The establishment is currently employing a temporary refrigerated storage unit with space for 12 bodies, which was intended for use at periods of peak activity as contingency storage. However, because the mortuary does not have adequate fridge storage capacity, this temporary storage facility has been in near constant use for extended periods over at least the past 12 months (see major shortfalls against standards PFE2(b) and PFE2(i)).

Contingency arrangements for storage of bodies is provided by two local funeral services and by another HTA-licensed establishment, under an informal agreement; this includes freezer and bariatric fridge spaces (see major shortfall against standard PFE2(i)).

There is a storage temperature monitoring and alarm system for the mortuary fridges and freezers, including for the temporary refrigerated storage unit; however, this system has not been functioning for an extended period of time (see major shortfall against standard PFE2(e)). Staff check and record storage temperatures of the mortuary fridges and freezers daily, including on weekends and Bank Holidays.

There is also a facility for storage of fetuses and babies in the sluice room of the hospital's Labour Department. This room is a busy area of the department, with high-throughput of staff, and the security arrangements are not adequate (see major shortfall against standard PFE1(d)). There is no temperature monitoring alarm for this fridge and the establishment's procedure is for the temperature to be checked and recorded daily by staff during the working

week. However, the HTA observed several gaps in the temperature records over a two month period, suggesting that this daily monitoring is not always taking place. (See major shortfall against standard PFE2(e).)

The PM suite has two downdraft tables and a dedicated bench for the preparation of tissue samples. The HTA assessed the PM suite facilities and equipment as not fit for purpose (see critical shortfalls against standards PFE3(a) and PFE3(c)).

The establishment conducts approximately 500 adult PM examinations each year. The majority of PM examinations are performed under Coronial authority. High-risk, Home Office, perinatal and paediatric cases are transferred to other HTA-licensed establishments.

Hospital consented PM examinations take place very occasionally, with only one undertaken in 2016. In adult cases, consent is sought by Bereavement Officers, in conjunction with clinical staff, using a consent form and information leaflet based on the HTA's model documentation (see minor shortfalls against standards C1(b), C1(f), C2(b) and C2(d)). Consent for perinatal hospital PM examinations is sought by clinical staff using the consent form and information leaflet provided by the Stillbirth and Neonatal Death (Sands) charity. Clinical staff receive training in seeking consent for PM examination as part of their clinical training and the establishment has a programme for competency assessment.

Material taken at PM examination may be transferred to the establishment's Cellular 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, including for education and training, and research.

Whole organs are stored in the mortuary. The mortuary uses paper and electronic mortuary registers to record sample details, including details of 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 Cellular Pathology Department has dedicated storage areas for tissue blocks and slides. The department uses an electronic database to record sample details, including consent for the use of samples after determining the cause of death. At the time of the inspection, the establishment was also storing archived PM tissue blocks and slides in a separate building in close proximity to the main hospital campus, but not covered by the HTA licence.

On occasion, tissue samples are removed from deceased infants in the Labour Department for genetic testing and details are recorded in the mother's patient notes. Senior clinical staff in the Labour Department oversee consent for tissue sampling and genetic testing, as well as the removal of the tissue. Samples are sent to a specialist facility for testing. Sampling of

tissues from deceased children in cases of sudden unexpected death in infancy (SUDI) is also performed in the Accident and Emergency (A&E) Department by a core team of staff, under pre-emptive Coronial authorisation.

The mortuary, Cellular Pathology, Labour and A&E Departments operate under separate departmental standard operating procedures (SOPs). The licensed activities conducted in these departments are overseen by Persons Designated (PDs) for each area, under the overall oversight of the DI.

Since the last HTA inspection of this establishment in October 2013, there was a period of around 16 months during which time there was no Designated Individual overseeing activities taking place under HTA licences. A new DI took up this responsibility in March this year. In addition, a number of mortuary staff are new to the establishment, including the Mortuary Manager, who commenced work there in January 2017.

Description of inspection activities undertaken

This report describes the third, routine site visit inspection of the establishment. The inspection team interviewed staff involved with licensable activities, reviewed documentation and conducted visual inspections of the mortuary and areas in the Labour and A&E Departments where licensed activities take place. The inspection team also conducted a visual inspection of the site where archived PM tissue blocks and slides were being stored.

A traceability audit was conducted on four adult bodies in the mortuary, including storage locations and identifiers recorded in the paper and electronic mortuary records. The storage location recorded in the paper and electronic mortuary records was incorrect for one body; this was because the body had been moved from a different fridge location and these records had not been updated (see major shortfall for standard T1(b)).

Audits of traceability were conducted for tissue blocks and slides from two PM examinations under Coronial authority and one hospital consented PM examination, including audits of the consent documentation for the retention of these samples and the consent form for the hospital PM examination. There were no discrepancies in the traceability of these samples. However, there were discrepancies in the completion of the hospital PM examination consent form (see shortfall against standard C1(f)). Disposal records were reviewed for disposal PM tissue blocks and slides. No discrepancies in disposal records were found.

At the time of the inspection, the establishment was storing one organ whilst awaiting instruction from the Coroner's Office on the family's wishes for the fate of the organ. However, the HTA's audit of the traceability and consent for storage of this organ revealed

that the family wished for the organ to be disposed of by the hospital (see minor shortfall for standard T2(a)).

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.

Compliance with HTA standards

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
b) There is a documented standard operating procedure (SOP) detailing the consent process	The establishment does not have a documented SOP detailing the process for seeking consent for adult hospital PM examinations. This is particularly important given that the establishment undertakes adult hospital PM examinations infrequently, and staff are not able to maintain awareness of the consent seeking procedure through practise.	**Minor**
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	The consent form for adult hospital PM examination includes a section to record the timeframe for withdrawal of consent; however, this section had not been completed on the consent form reviewed as part of the HTA's audit and is evidence of inconsistent practice in the consent-seeking process. *Refer to Advice, item 2.*	**Minor**

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
b) Records demonstrate up-to-date staff training	The establishment was not able to provide records of up-to-date staff training in consent seeking for the Bereavement Officers seeking consent for adult hospital PM examinations. 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.	**Minor**
d) Competency is assessed and maintained	The establishment was not able to provide records that the competency of Bereavement Officers in seeking consent for adult hospital PM examinations has been assessed.	**Minor**

GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath.	The establishment does not have SOPs covering all mortuary procedures. There are no SOPs governing: • the movement of bodies between fridge locations in the mortuary; • PM examination, including the procedure for identification of the deceased prior to PM examination; • lone working in the mortuary; • access to the mortuary by non-mortuary staff; and • access to Trust equipment for the management of bariatric bodies. Many of the SOPS currently in place do not accurately reflect current practices and do not contain sufficient details for staff on the procedures that must be followed, for examples SOPs describing the process for identifying the deceased. The inadequacy of SOPs, and the general approach to them, means that mortuary staff do not follow many of them.	**Major**

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	The establishment's SOP for evisceration states that the APT may undertake evisceration prior to the Pathologist having conducted the external examination of the body. Staff informed the HTA that a new procedure has recently been introduced, whereby the Pathologist completes the external examination of the body prior to evisceration by the APT and places a wristband on the body confirming this has been done, thereby instructing the APT to proceed. However, this procedure has not been documented in the establishment's SOPs.	**Minor**
e) There is a system for recording that staff have read and understood the latest versions of these documents	There is no system to ensure that all staff undertaking activities in the mortuary have access to and have read and understood the SOPs relevant to the activities they perform. This includes Pathologists, porters and staff from other departments who undertake work in the mortuary (for example, the Bereavement Officer). This poses the risk that staff are not aware of the SOPs governing mortuary procedures, including updates to procedures, and may not carry out their duties in accordance with the requirements. *Refer to Advice, item 6.*	**Minor**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Although the establishment introduced governance meetings for the HTA licence in the period during which the inspection was being planned, the establishment had not conducted governance meetings before this. This is particularly important given that there have been a number of changes to the staff working under the licence, the Medical Director has recently taken on the role of DI after a significant period during which there was no DI and activities are taking place in several different areas.	**Minor**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Although the establishment has undertaken audits of the mortuary premises, facilities and equipment, regular audits have not been undertaken of compliance with mortuary procedures, traceability and consent documentation for hospital PM examinations. (Immediately prior to the inspection, the establishment undertook a vertical audit of mortuary procedures for one body, which found that some mortuary SOPs were incomplete and inaccurate and training had not been completed.) *Refer to Advice, item 7.*	**Minor**
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	Although the findings from mortuary audits have been documented, a number of required actions have not been completed within the required timeframes and there is no evidence that these actions have been followed up appropriately. The establishment had been aware of a number of significant issues relating to the PM suite prior to the inspection, but had not implemented effective corrective and preventative actions to address these issues.	**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	Although the establishment has a documented training and induction programme for mortuary staff, this was not in use until immediately prior to this inspection. Porters undertaking activities in the mortuary have not all been trained in mortuary procedures. There is no system to ensure that porters who have not completed mortuary training are supervised by trained staff when undertaking activities in the mortuary. The establishment's training programme and system of supervision does not include all staff who undertake activities in the mortuary, in particular: • the Bereavement Officer who works in the mortuary on an on-call basis, unsupervised; • Senior Nursing Managers who facilitate viewings of the deceased out of hours.	**Major**
c) Staff are assessed as competent for the tasks they perform	Although the establishment has a procedure for assessing the competency of mortuary staff undertaking activities in the mortuary, this programme was not in use until immediately prior to this inspection. The establishment's competency assessment programme does not include all staff who undertake activities in the mortuary, including: • the Bereavement Officer who works in the mortuary on an on-call basis, unsupervised; and • Senior Nursing Managers who facilitate viewings of the deceased out of hours.	**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 does not have a documented policy or SOP for the management of mortuary records. The Cellular Pathology Department records management policy covers records in the histology department only.	**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	A number of staff undertaking licensed activities demonstrated a lack of awareness of the reporting requirements for HTA Reportable Incidents (HTARIs) and the establishment's procedures for reporting HTARIs to the HTA. The establishment's SOP for HTARIs does not reflect accurately the establishment's procedures for reporting HTARIs to the HTA. In addition, this SOP refers to an HTA licence at a different establishment, references a previous version of the HTA's 'Guidance for Reporting HTARIs' and does not include a complete list of the HTARI categories. *Refer to Advice, item 8.*	**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 does not have documented risk assessments of all procedures related to licensed activities. In particular, the following activities have not been risk assessed: • removal of relevant material from the deceased and storage of foetuses and babies in the Labour Department; • removal of relevant material from the deceased in the A&E Department; • seeking consent for hospital PM examinations; • contingency storage arrangements, including movement of multiple bodies from the mortuary to other premises; • viewings of the deceased; • mortuary security arrangements and access to the mortuary; and • disposal of tissue. Where risk assessments have been documented, many of the assessments of risks and current control measures do not accurately reflect procedures and practices. The residual risk ratings do not therefore provide an accurate representation of the risks involved with undertaking licensed activities.	**Major**
c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register	The establishment could not evidence that significant risks related to licensed activities are included on the Trust's organisational risk register and escalated for action appropriately. The establishment has not addressed significant risks relating to the suitability of the PM suite facilities and mortuary storage capacity, in spite of having been aware of these risks for some considerable time.	**Minor**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records)	Mortuary staff do not update the storage location recorded in the paper and electronic mortuary records when bodies are moved between fridges in the mortuary. This means that, although the storage location recorded on the mortuary whiteboard is updated, the location of the deceased recorded in the paper and electronic mortuary records is incorrect for bodies which have been moved to a different fridge. As the establishment uses the fridge location recorded in the mortuary register as part of the procedure to locate the deceased for viewings, PM examination and release from the mortuary, this presents a significant risk of misidentification of the deceased.	**Major**
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 procedure for identification of deceased who have died outside of the hospital relies on only two identifiers (name and date of birth). This includes for the identification checks performed prior to PM examination, viewing and release from the mortuary. This poses a significant risk of misidentification of the deceased.	**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's procedure for managing retained organs is inadequate. At the time of the inspection, the establishment was storing one organ whilst awaiting instruction from the Coroner's Office on the family's wishes for the fate of the organ. However, the HTA's audit of the traceability and consent for storage of this organ revealed that the family wished for the organ to be disposed of by the hospital.	**Minor**

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
c) There are documented cleaning and decontamination procedures and a schedule of cleaning	There are no records of cleaning of the PM suite and body store areas of the mortuary.	**Minor**

d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access)	<u>Mortuary</u> The mortuary does not have adequate access control arrangements: • There is no system to review who has electronic swipe card access to the mortuary and the establishment was not able to evidence that access to the mortuary is limited to only those who require it (at the time of the inspection there were around 180 staff freely able to access the mortuary). There is a risk that individuals have access to the mortuary who do not legitimately require this and have not received training in undertaking mortuary procedures. • The establishment does not have a documented policy or procedure covering which doors within the mortuary should be kept shut/locked and at what times. • There is no access control on the door between the viewing room and the body store area. This poses a risk of unauthorised access by visitors to the mortuary from the viewing room into the body store area. • The door to the PM suite viewing room is not always locked during working hours. There is no covering at the window in the PM suite viewing room, which looks into the PM suite. This arrangement poses the risk of inadvertent and unauthorised viewing of PM examinations. <u>Labour Department</u> The Labour Department does not have adequate access control arrangements for the fridge used for storage of deceased foetuses and babies. The fridge is not locked and is located in an unsecured sluice room within the department. This room is a busy area of the department with high throughput of staff.	**Major**

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 mortuary does not have sufficient storage capacity for refrigerated storage of bodies and has had to make use of the temporary contingency storage unit almost continually for at least the past 12 months. *Refer to shortfall against standard PFE2(i).*	**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. <u>Mortuary</u> The temperature alarm for the mortuary fridges and freezer is not functioning correctly and does not call out to the switchboard. Although mortuary staff have implemented a daily manual check of storage temperatures, there remains a risk that failure of the fridge and freezer may go unnoticed for a period of time. <u>Labour Department</u> The fridge in the Labour Department for storage of foetuses and babies is not alarmed. The establishment's procedure is for the fridge temperature to be checked and recorded by staff daily during the working week. However, the HTA observed several gaps in the temperature records for this fridge over a two month period.	**Major**
i) There are documented contingency plans in place should there by a power failure or insufficient numbers of refrigerated storage spaces during peak periods.	The storage unit erected in the mortuary has been in near continual use and has 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 unit on an ongoing basis means that the establishment does not now have sufficient contingency arrangements for refrigerated storage of bodies. An informal arrangement with another HTA-licensed establishment, for access to freezer storage and storage of bariatric bodies, is informal and the terms are not specified. *Refer to Advice, item 16.*	**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	Key items of equipment in the PM suite are not fit for purpose: • the downdraft ventilation systems on the PM tables are not functional; • the drainage system on one PM table does not function correctly, leading to pooling of body fluids on the table during PM examination and cleaning; • the bases of the PM tables are not sealed with the floor, leading to difficulties cleaning these areas effectively and rusting of the bases of the PM tables; • hydraulic trolleys in the PM suite are rusty, meaning that they cannot be cleaned effectively; • the housing unit for the oscillating saw in the PM suite shows extensive rusting, and cannot be cleaned effectively; and • the dissection board in the PM suite is in poor condition and the surface is no longer impervious. The poor condition of these key items of equipment poses significant risks to the dignity of the deceased and health and safety of staff working in this environment.	**Critical**
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	The ventilation system in the PM suite is not functioning correctly and does not produce a negative pressure gradient from the mortuary to surrounding areas. The establishment's Critical Care Ventilation System Annual Verification report from March 2016 states that compliance with minimum ventilation standards is poor and the pressure regime is incorrect. The establishment was not able to evidence that these issues with the ventilation system have been addressed. The incorrect functioning of the ventilation system in the PM suite poses significant risks to the health and safety of staff working in this environment and staff and visitors in the surrounding areas.	**Critical**

Advice

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

No.	Standard	Advice
1.	C1(g)	The DI is advised to strengthen the procedure for storage and access to completed consent forms for hospital PM examinations to ensure that they can be accessed readily by appropriate staff in the mortuary and Cellular Pathology Departments. 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.
2.	C1(f)	The DI is advised to remind all staff seeking consent for hospital consented PM examinations of the importance of completing consent forms in a consistent manner. The DI is advised to audit consent forms to ensure that these are completed consistently and identify any additional training requirements for staff seeking consent.
3.	GQ1(a)	The DI is advised to review the establishment's policy for lone working in the mortuary to ensure that lone working arrangements are appropriate and protect the safety of staff. In particular, the DI is advised to review the suitability of APTs undertaking evisceration of bodies when lone working in the mortuary in the morning out of hours (prior to arrival of the Pathologist).
4.	GQ1(a)	The DI is advised to review the SOP for removal of relevant material in SUDI cases and incorporate the written amendments made to the controlled copy of this SOP in the A&E Department. The DI is also advised to ensure that there is a documented process to review the contents of the SUDI sampling kits, including ensuring that all consumables are within their expiry dates.
5.	GQ1(a)	The DI is advised to review signage in the mortuary to include details of: • the locations of the fridge banks and the establishment's procedure for allocating fridge spaces to bodies received from the hospital and community; • the temperature monitoring and alarm arrangements and actions to be taken in the event of the temperature alarm sounding; • the requirements and procedures for reporting incidents, including HTARIs. This will help to raise awareness of, and ensure compliance with, the establishment's procedures for undertaking activities in the mortuary.
6.	GQ1(e)	In addition to the corrective and preventative actions required to address the shortfall against standard GQ1(e), the DI is advised to provide controlled paper copies of key mortuary SOPs in the mortuary so that relevant staff can refer to these without requiring computer access. This is particularly important given that a number of non-mortuary staff undertake activities in the mortuary and may not have computer access in this department readily.

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 to review the forms used for recording mortuary audits to ensure that they cover all activities undertaken in the mortuary and, where relevant, reference the most up-to-date HTA standards.
8.	GQ5(a)	In addition to the corrective and preventative actions required to address the shortfall against standard GQ5(a), the DI is advised to add a section to the mortuary incident form about HTARI reporting requirements and the details of HTARI reference number assigned to the incident by the HTA, where applicable. This will help to raise staff awareness of the HTARI requirements and also ensure that all HTARIs are reported to the HTA, in line with Standard Condition 4 (Annex B) of the establishment's HTA licence. 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.
9.	T1(b)	The DI is advised to review the use of whiteboards in the mortuary for recording the storage locations of bodies, to strengthen the establishment's procedures for identification and traceability of the deceased. In particular: • The use of magnetic and some non-magnetic whiteboards results in differences in mortuary procedures involving use of magnetic signs on the whiteboards to flag deceased with same/similar names, high risk of infection, implanted medical device and awaiting repatriation of tissue. Variation in mortuary procedures can lead to increased risks of incidents occurring. • The establishment's procedures use different colour pens to record details of the deceased on whiteboards to indicate: when the deceased is admitted to the mortuary by porters; when mortuary staff have checked the deceased's identity and completed the paper and electronic mortuary registers; and when the deceased died in the community. To strengthen this process, the DI is advised to include signage in the mortuary to outline the colour-coding system. The DI is also advised to ensure that the correct colour pens are readily available to staff.
10.	T1(b)	The DI is advised to consider introducing use of wristbands to indicate bodies where tissues are required to be repatriated prior to release of the body from the mortuary, in addition to the fridge and whiteboard labels which are currently in use. This will provide an additional visual trigger for staff when managing these bodies to ensure that bodies are not released from the mortuary prior to repatriation of tissues, where this is required.
11.	T1(e)	The DI is advised to review procedures for checking the identity of the deceased to ensure that the checks are performed by two members of staff and recorded. This will help to reduce the risks of misidentification of bodies and incidents resulting from this.
12.	T1(g)	The DI is advised to review the establishment's procedure for the dissection of organs and tissues during PM examination. The PM suite has only one bench for dissection of organs and the establishment's procedure is to only undertake dissection of samples from one body at a time. The DI is advised to strengthen this procedure, for example by using colour-coded bowls for each PM table.

13.	PFE1(c)	The body store and bariatric body store are not on the establishment's deep-clean cleaning schedule. Although these areas are cleaned by mortuary staff, the DI is advised to review the mortuary cleaning schedule to ensure that the cleaning regimes are appropriate and are kept under regular review.
14.	PFE1(d)	The DI is advised to review the rear access to the mortuary, used by funeral services and ambulance staff when bodies are admitted to and released from the mortuary, to ensure that it affords appropriate privacy to protect the dignity of the deceased. Although the rear access to the mortuary is not directly overlooked by patient areas of the hospital, the area where attending vehicles wait and load and unload bodies can be overlooked by patient areas of the hospital and a hospital service building.
15.	PFE1(e)	The DI is advised to review the procedures for out of hours access to the mortuary to ensure that any out of hours access is recorded. This will provide a record that can be audited, of all staff undertaking activities in the mortuary out of hours. This will also enable the DI to ensure that only those staff who have received appropriate training and have been assessed as competent to undertake these activities have access out of hours.
16.	PFE2(i)	The DI should review the establishment's contingency storage arrangements to ensure that they provide sufficient contingency storage capacity, protect the dignity of the deceased, and mitigate the risks of incidents resulting from changes to normal working practices. In addition, the DI should review arrangements with the two local funeral services for provision of contingency storage and determine whether they also provide arrangements for contingency storage of bodies for other establishments, which may impact on their ability to assist during peak periods, for example, over the winter months. The DI should also assure himself of the suitability of the premises, storage conditions and procedures at these funeral services. To strengthen arrangements for contingency storage capacity, the DI is advised to consider entering into a Mutual Aid Agreement with relevant organisations, including other Trusts, NHS commissioners and local authorities. Mutual Aid Agreements set out the arrangements that may be invoked when one or more of the organisations experiences an emergency or business continuity event that they are not able to deal with on their own. The HTA has seen this model adopted by other establishments and it works well.
17.	PFE3(b)	The DI is advised to review the suitability and availability of equipment in the mortuary for management of bariatric bodies. • The hoist in the bariatric body store area is suitable for moving bodies weighing up to 250 kg. The establishment also has access to a hoist for moving bodies weighing up to 320 kg, through the Trust's arrangements for provision of shared equipment. This hoist was on site at the time of this inspection; however, the establishment may have to send the hoist to a different site within the Trust at short notice. The procedures for arranging loan of this hoist should be documented and the suitability of this loan arrangement reviewed regularly. • The establishment does not have a concealment cover suitable for use with hospital beds. This is necessary if a body cannot be transferred from a hospital ward to the mortuary using the concealment trolley due to the weight restriction for operation of this trolley.

18.	N/A	The DI is advised to keep staffing levels of the mortuary and Cellular Pathology Department under regular review to ensure that they are sufficient to provide safe and effective services. Although staffing levels in the mortuary had increased in the months preceding this inspection, prior to this the mortuary had been significantly understaffed, with at times, only one trainee APT staffing the mortuary.

Concluding comments

Although the HTA found that the establishment had met some of the HTA's standards, significant shortfalls were found against all four groups of standards, with two shortfalls assessed as critical and nine as major (see Appendix 2 for information about HTA's classifications of shortfall).

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, and in relation to the statutory licensing breach.

All shortfalls will be managed through the HTA's process for agreeing and overseeing corrective and preventative action plans (CAPAs).

The HTA requires the Designated Individual to submit a completed corrective and preventative action (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: 09 June 2017

Report returned from DI: 22 June 2017

Final report issued: 06 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: 21 June 2018

Appendix 1: HTA licensing standards

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

Consent

C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice

a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice.

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

Guidance

This should include who is able to seek consent, what training they should receive, and what information should be provided to those giving consent for post-mortem examination. It should make reference to the use of scanning as an alternative or adjunct to post-mortem examination.

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

Guidance

Information on consent should be available in different languages and formats, or there is access to interpreters/translators. Family members should be given the opportunity to ask questions.

d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives.

e) Where consent is sought for tissue to be retained for future use, information is provided about the potential uses to ensure that informed consent is obtained.

f) The deceased's family are given an opportunity to change their minds and it is made clear who should be contacted in this event and the timeframe in which they are able to change their minds.

g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided.

Guidance

This may be based on the HTA's model consent form for adult post-mortem examinations

available on the HTA website, or in relation to infants, the resources pack developed by the Stillbirth and neonatal death charity, Sands. The consent forms should record the consent given for the post-mortem examination and for the retention and future use of tissue samples.

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

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

Guidance

Refresher training should be available (for example annually).

b) Records demonstrate up-to-date staff training.

c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual.

d) Competency is assessed and maintained.

Governance and quality systems

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

a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath. These include:

   i. post-mortem examination, including the responsibilities of Anatomical Pathology Technologists (APTs) and Pathologists and the management of cases where there is increased risk;

   ii. practices relating to the storage of bodies, including long term storage and when bodies should be moved into frozen storage;

   iii. practices relating to evisceration and reconstruction of bodies;

   iv. systems of traceability of bodies and tissue samples;

   v. record keeping;

   vi. receipt and release of bodies, which reflect out of hours arrangements;

vii. lone working in the mortuary;

viii. viewing of bodies, including those in long-term storage, by family members and others such as the police;

ix. transfer of bodies internally, for example, for MRI scanning;

x. transfer of bodies and tissue (including blocks and slides) off site or to other establishments;

xi. movement of multiple bodies from the mortuary to other premises, for example, in the event that capacity is reached;

xii. disposal of tissue (including blocks and slides), which ensures disposal in line with the wishes of the deceased person's family;

xiii. access to the mortuary by non-mortuary staff, contractors and visitors;

xiv. contingency storage arrangements.

Guidance

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

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

b) Procedures on evisceration ensure that this is not undertaken by an APT unless the body has first been examined by the pathologist who has instructed the APT to proceed.

c) Procedures on body storage prevent practices that disregard the dignity of the deceased.

Guidance

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

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

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

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

d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use.

e) There is a system for recording that staff have read and understood the latest versions of these documents.

f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity.

g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework.

Guidance

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

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

Guidance

Meeting minutes should be recorded and made available to staff.

GQ2 There is a documented system of audit

a) There is a documented schedule of audits.

Guidance

As a minimum, the schedule should include a range of vertical and horizontal audits

checking compliance with documented procedures, the completion of records and traceability.

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

Guidance

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

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

Guidance

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

applicable.

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

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

Guidance

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

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

b) There are clear reporting lines and accountability.

c) Staff are assessed as competent for the tasks they perform.

Guidance

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

d) Staff have annual appraisals and personal development plans.

e) Staff are given opportunities to attend training courses, either internally or externally.

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

f) There is a documented induction and training programme for new mortuary staff.

g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures.

Guidance

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

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

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

a) There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.

Guidance

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

b) There are documented SOPs for record management which include how errors in written records should be corrected.

c) Systems ensure data protection, confidentiality and public disclosure (whistle-blowing).

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

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

Guidance

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

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

b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents.

c) The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.

d) Information about incidents is shared with all staff to avoid repeat errors.

e) The establishment adopts a policy of candour when dealing with serious incidents.

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

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

Guidance

Risks to the dignity and integrity of bodies and stored tissue should be covered. The HTA's

reportable incident categories provide a good basis for risk assessments. Risk assessments should be reviewed at regular intervals, for example every 1-3 years or when circumstances change. Staff should be involved in the risk assessment process.

b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.

Guidance

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

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

Traceability

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

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

Guidance

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

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

Guidance

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

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

Guidance

Identification details should not be written on bodies. Where bodies are moved off site for

contingency storage the DI should ensure that suitable systems are in place to identify same or similar names.

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

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

Guidance

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

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

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

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

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

ii. receipt upon return to the laboratory or mortuary

iii. the number of blocks and slides made

iv. repatriation with the body

v. return for burial or cremation

vi. disposal or retention for future use.

Guidance

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

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

Guidance

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

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

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

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

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

Guidance

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

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

d) The method and date of disposal are recorded.

Premises, facilities and equipment

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

a) The premises are clean and well maintained.

Guidance

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

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

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

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

Guidance

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

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

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

a) Storage arrangements ensure the dignity of the deceased.

Guidance

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

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

Guidance

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

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

Guidance

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

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

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

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

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

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

Guidance

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

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

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

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

Guidance

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

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

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

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

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

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

i. fridges / freezers

ii. hydraulic trolleys

iii. post mortem tables

iv. hoists

v. saws (manual and/or oscillating)

Guidance

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

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

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

Guidance

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

d) Staff have access to necessary PPE.

Guidance

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

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

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

Guidance

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

Appendix 2: Classification of the level of shortfall

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

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

1. **Critical shortfall:**

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

   or

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

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

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

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

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

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

2. **Major shortfall:**

   A non-critical shortfall that:

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

   or

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

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

3. **Minor shortfall:**

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

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

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

Follow up actions

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

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

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

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