Site visit inspection report on compliance with HTA licensing standards

Pinderfields Hospital

HTA licensing number 12086

Licensed under the Human Tissue Act 2004 for the

- **making of 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**

7 and 8 February 2018

Summary of inspection findings

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

Although the HTA found that Pinderfields Hospital had met the majority of the HTA's standards, seven minor shortfalls and eight major shortfalls were found against the Consent, Governance and quality systems, Traceability and Premises, facilities and equipment standards. These predominantly related to the consent process and the training for hospital PM consent seeking, standard operating procedures, risk assessments, traceability of bodies, tissue retention, cleanliness of premises and fridge temperature alarms.

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

Pinderfields Hospital (the establishment) is part of the Mid Yorkshire Hospitals NHS Trust and has been licensed by the HTA since May 2007. This report refers to the activities carried out at Pinderfields Hospital (the hub) and Dewsbury District Hospital (the satellite). The DI is the Pathology Group Manager, the Corporate Licence Holder (CLH) is Mid Yorkshire Hospitals NHS Trust and the CLH contact is the Medical Director for the Trust.

The establishment admits approximately 2900 bodies per year from the hospital and surrounding community. Approximately 440 adult post-mortem (PM) examinations are carried out annually, with the majority performed under the authority of HM Coroner for Wakefield. In addition, the establishment undertakes adult hospital consented PM examinations, with approximately five being carried out each year. The establishment has the facility to perform high-risk PM examinations (cases known or suspected to involve up to hazard group 3 biological agents). Forensic PM examinations do not take place at the establishment and all perinatal and paediatric cases are transferred to another HTA-licensed establishment.

Consent for adult hospital consented PM examinations is sought by clinical staff and is recorded on a Mid Yorkshire NHS Trust consent form that is based on the HTA's model consent form. The process of seeking consent is supported by a hospital information leaflet (see *Advice,* items 1, 2 and 3). Consent for perinatal and paediatric hospital PM examinations is sought by clinical staff, who record consent using a consent form provided by the establishment to which the cases are referred. Again, the consent seeking process is supported by an information leaflet provided by the establishment to which the cases are referred*.* Both forms used to record consent are compliant with statutory and regulatory requirements. There is a mandatory annual requirement for all clinicians at the Trust to acknowledge that they have read an on-line PowerPoint presentation on seeking consent for PM examination (see shortfall against standard C2 (a)). Competency for those seeking consent is not assessed (see shortfall against standard C2 (d)).

The mortuary at Pinderfields Hospital is located within the main hospital building. The entrances to the mortuary from the hospital and at the rear, are secured by swipe card access and there is an intercom system (with video) to verify the identity of the person requesting entry. There is closed-circuit television (CCTV) monitoring of external mortuary areas. Bodies are transferred from hospital wards to the mortuary by portering staff using a concealment trolley via a service corridor. The portering supervisors are trained by mortuary staff, who cascade the training to the wider portering team. Perinatal and paediatric cases are transferred from the Maternity Department to the mortuary by ward staff or porters. There is no refrigerated storage in the Maternity Department. Community bodies are brought to the mortuary via a service road and concealed mortuary entrance. Mortuary staff complete identification and property checks of all bodies as soon as bodies are received, or the next working day if the body was admitted out of hours. During working hours, mortuary staff are involved in organising and conducting viewings of the deceased. Mortuary staff work on-call and are contactable for help and the undertaking of community body viewings and identifications out of hours. Bodies are released from the mortuary by mortuary staff only.

The mortuary has 55 refrigerated spaces for the storage of bodies. This includes seven spaces for bariatric cases and four dedicated spaces for perinatal/paediatric bodies. There is a cold room that can accommodate a bed if necessary. There are two banks of fridges that can be converted into freezers if required; however, at the time of the inspection these units were being used as fridges.

The temperatures of the mortuary fridges are monitored and alarm locally in the event of a deviations in temperatures from their expected ranges. There is also an alarm system linked to the hospital Estates Department to notify Estates staff of a deviation in temperature. In the event of a deviation from the expected storage temperature, mortuary staff hear the alarm system and respond. If there is a deviation in temperature out of hours, hospital engineers will investigate and contact the on-call APT if necessary. The temperature is recorded manually on a daily basis and trends are reviewed monthly. There are 12 additional refrigerated spaces in a temporary refrigerated storage facility located in the PM suite and in use at the time of the inspection. The temperature is monitored and recorded daily by establishment staff, including during weekends when it is checked once each day (see *Advice,* item 20). The temporary storage unit is not connected to an alarm system to alert establishment staff to a deviation in temperature from the expected range (see shortfall against standard PFE2 (e)). The establishment's procedures require mortuary staff to conduct weekly testing of the main fridge alarm system to verify that it triggers and is responded to as expected; however, records showed that the testing is not always carried out (see shortfall against standard PFE2 (e)). All mortuary fridges and freezers are served by the hospital's emergency power supply system and are maintained under service contracts. The establishment has contingency arrangements for the refrigerated storage of bodies at the satellite site and at another HTA-licensed mortuary.

Recently, there has been a transfer of acute services from Dewsbury Hospital to Pinderfields Hospital, which has increased the number of deaths at the hub site and has affected the storage capacity there. Bodies are transferred daily from the hub to the satellite site to help assure the DI that body storage capacity is sufficient to accommodate new cases received at the mortuary.

The mortuary's main PM suite contains four downdraft PM tables. The pathologist and APTs carry out identification checks of bodies prior to external examinations and eviscerations taking place. The pathologist completes the examination of each body and the organs prior to commencing the next case. This helps to minimise the risk of a mix-up of organs and tissue samples removed during PM examinations. Tissues taken during PM examinations are recorded in a dedicated book and transferred to the establishment's Histopathology Department, at the satellite site, for histological analysis, or to other establishments for toxicological analysis and specialist tests. Pathology request forms and transfer forms are completed and accompany the removed tissue to maintain traceability of the tissues. All blocks and slides that are generated from the retained tissue are recorded using an electronic database.

Dewsbury District Hospital (the satellite site)
The body store is located within the main hospital building. Thumb and key locks secure the entrances to the body store. CCTV covers the hospital corridor entrances. The funeral

directors access door to the mortuary is not fully concealed and is overlooked by a car park (see *Advice*, item 19).

The satellite site body store has 56 refrigerated spaces for the storage of bodies. This includes six spaces for bariatric cases and three dedicated spaces for perinatal and paediatric bodies. There are two banks that can be used as either fridges or freezers. At the time of the inspection, one unit (with three spaces) was being used as a freezer and this unit was full. There is a daily log of fridge and freezer temperatures that staff monitor manually, including at weekends. Some of the fridges are alarmed, with a local audible alarm and an external alarm that alerts the Porters' Office if there are deviations from the expected temperatures. Some of the fridge (and freezer) banks are not alarmed (see shortfall against standard PFE2 (e)).

Tissues and slides are stored in the Pathology Department at Dewsbury District Hospital. The establishment uses an electronic database and paper records to record sample details, the family's wishes regarding the fate of the samples following the end of coronial authority and disposal of the samples. There are no procedures for ensuring that samples are disposed of in a timely manner following the end of the Coroner's authority (see shortfall against standard T2 (b)).

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

Description of inspection activities undertaken

This report describes the third routine site visit inspection in February 2018. The inspection team interviewed staff undertaking licensed activities, reviewed the establishment's documentation and conducted visual inspections of the mortuary including the body storage areas, PM suite, viewing rooms and the Pathology Department's storage areas.

Across the sites, traceability audits were conducted for seven adult bodies, including one from the freezer and one perinatal case. Storage locations and body identifiers were cross-checked between the paper and electronic mortuary records to those on the bodies. There were discrepancies in the traceability of two cases (see shortfall against standard T1 (c)). In once case, the date of birth in the mortuary register was different to that on the wristband of the deceased; in the other case, the storage location in the mortuary register was different to the actual location of the deceased.

With regards to the condition of the bodies, the audit also identified that one body was not fully shrouded and two bodies showed significant leaking of fluids, needing attention (see shortfall against standard GQ1 (c)).

Audits were conducted of the mortuary processes for admission and release of bodies. The HTA observed mortuary staff fail to check identification bands on a body prior to release. The inspectors halted the procedure to ensure that the appropriate identification check was performed in accordance with the required standards (see shortfall against standard T1 (c)).

Audits of traceability were conducted for nine tissue samples that had been retained following PM examinations under the Coroner's authority. In addition, tissue samples that had been retained following hospital consented PM examinations were also reviewed. Consent documentation relating to the retention of samples, consent forms for the hospital PM examinations and disposal records were reviewed. A number of discrepancies were identified. Errors were found in the completion of the hospital PM examination consent forms in three out of five cases. The staff seeking consent had ticked multiple boxes indicating the consent giver's wishes with regards to the fate of the tissue. Examples include instances where the form indicated that the consent giver had requested to dispose as well as to retain tissues. Furthermore, the establishment is storing tissue samples from a number of PM cases for which it is not known whether Coroner's authority for retention has ended. There are no procedures for following up and auditing these samples, to enable timely disposal where consent has not been given for continued retention.

Inspection findings

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

Compliance with HTA standards

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
b) There is a documented SOP detailing the consent process (including who is able to take consent, what training they must receive, and what information must be provided to those giving consent for post mortem examination).	The Trust's consent policy does not detail the consent seeking process for hospital consented PM examinations. This is particularly important given that the establishment only rarely undertakes hospital PM examinations meaning that staff may not be able to maintain awareness of the correct consent-seeking procedure. Some of the establishment's SOPs do not accurately reflect the consent requirements of the HT Act. • The SOP for 'The Post Mortem Examination' (SOP-MORT-004) describes that the Pathologist may test bodies for the presence of infectious agents without appropriate qualifying consent. Staff informed the HTA that this procedure has not been undertaken. This should be removed from the SOP. • The SOP for 'Confidentiality and consent' (SOP-PATH-038) and the SOP for the 'Retention and disposal of tissues and organs' (SOP-MORT-008) states that consent for retention of tissue should be sought from the next of kin rather than an appropriate person as defined by the HT Act. The HTA did not find evidence that the establishment has removed or used relevant material without consent from a person who is not an appropriate person under the HT Act; however, these procedures, if followed, have the potential to result in a breach of the HT Act.	**Major**

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
a) There is training for those responsible for seeking consent for post mortem and tissue retention, which addresses the requirements of the HT Act and the HTA's Codes of Practice.	The presentation used for training clinicians responsible for seeking PM consent for adults (GUID-HIST-001) does not reflect the requirements of the HT Act and the HTA's codes of practice. A number of areas are incorrect and need updating. Examples include, but are not limited to: • The presentation states that it is 'best practice' to seek consent and that consent 'is usually' sought from a person in a qualifying relationship. Seeking consent from an appropriate person is a legal requirement under the HT Act. • The presentation does not reference the most appropriate person to give consent: the deceased themselves in life; their nominated representative; or, in the absence of these, a person who ranked the highest in a 'qualifying relationship' to the deceased immediately prior to their death. • The presentation refers to 'next of kin' rather than a person who ranked the highest in a 'qualifying relationship' to the deceased immediately prior to their death. • The presentation does not refer to or include any guidance on the completion of the PM consent forms or detail the use of information sheets currently in use by the establishment.	**Major**
d) Competency is assessed and maintained.	There are no competency assessments for any staff who seek PM examination consent.	**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 the guidance from the RCPath.	Some of the SOPs covering key mortuary procedures do not contain sufficient detail of the procedures that staff must follow. For example: • SOPs describing the process for identifying bodies do not state the minimum number of identifiers to be used and how the identification check should be performed; • the SOP for viewing of bodies does not reflect practice. Although details are checked, the SOP does not describe what information is required from the family before staff perform the identification check. • the contingency plan for the mortuary overflow does not address the temporary storage facility.	**Minor**
c) Procedures on body storage prevent practices that disregard the dignity of the deceased.	The establishment does not check the condition of bodies regularly. At the time of the inspection, two bodies had leaked significantly and excess fluid was pooling on the fridge tray. In addition, some bodies were not fully shrouded, preventing the dignity of the bodies being maintained.	**Major**

GQ2 There is a documented system of audit		
c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why to enable timely disposal of tissue where consent has not been given for continued retention.	Regular audits are not conducted on tissue blocks and slides retained at PM however there is a centralised spreadsheet that is reviewed which lists all tissue held and the families wishes for the fate of the tissue (if the forms have been returned). *See Advice, item 9.*	**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	Although there is a SOP for HTA reportable incidents a review of the incident log and mortuary meeting minutes highlighted three incidents that should have been reported to the HTA. *See Advice, item 11.*	**Minor**

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

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.	There are risk assessments relating to health and safety matters, and some in relation to licensed activities and the potential risks to the deceased and tissue. Some control measures do not reflect the risks identified. Current control measures do not reference specific SOPs. *See Advice, item 12.*	**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 during release is not always sufficiently adhered to: • Bodies may be released from the mortuary using one, two or three identifiers. • Funeral directors do not always bring paperwork, verbally stating only a name on collection of a body. • During the inspection, the mortuary staff attempted to release a body without physically checking the identification on the body. In addition, the identification of the body was not checked against any external documentation brought by the funeral directors. These issues present a significant risk of misidentification of the deceased. The SOPs describing procedures for identification of bodies do not include details of the minimum number of identifiers, what those identifiers should be, how the identification checks should be performed and the procedures to follow in the event of discrepancies being identified. *See Advice, items 6 and 15.*	**Major**
f) There are procedures for releasing a body that has been in long-term storage and is therefore not in the current register.	There are no procedures in place for identifying bodies that have been in long-term storage. This has led to discrepancies in the mortuary register. Two cases were identified where details of the deceased had been added to the mortuary register twice as the first record could not be found on release of these bodies. This presents a risk of misidentification of the deceased.	**Minor**

T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's Codes of Practice

a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete	The establishment's tissue retention form (FORM-MORT-22) completed by pathologists following Coroner's PM examinations, states that 'tissues will be retained until investigations are complete and then permanently as slides and blocks unless advised otherwise'. This procedure, if followed, has the potential to result in a statutory breach of the HT Act. Appropriate consent is required for the continued retention of tissue for use for scheduled purposes under the HT Act 2004, following the end of the Coroner's authority.	**Major**
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary	There is no procedure for following up with the Coroner to determine when Coroner's authority has ended. This means that the establishment cannot assure themselves that tissue is not kept for longer than necessary.	**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.	The mortuary premises are not cleaned and maintained to a sufficiently good standard: • The PM suite floor is not clean and is contaminated with debris, blood and other organic material. • There is a significant build-up of hair in the drains of the PM suite. • An instrument trolley, the weighing scales and PM tables are contaminated with blood and organic material and require deep cleaning. • The paintwork on the windowsills of the PM suite is peeling and exposing areas of porous material. Inadequate cleaning and disinfection routines can present a significant health and safety risk to staff and other service users	**Major**

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

e) Fridge and freezer units are alarmed and tested regularly to ensure that they trigger when temperatures go out of upper and lower set range.	There is no alarm system on a number of fridges and freezer units at Dewsbury District Hospital to alert staff to deviations in temperatures from their expected ranges. There is no external alarm system on the temporary fridge unit at Pinderfields Hospital to alert staff to a deviation in temperature from the expected range. The SOP details that mortuary staff conduct testing of the main fridge alarm system weekly to verify that it triggers and is responded to as expected; however, records showed that the testing is not always carried out. There was no weekly alarm testing in January 2018.	**Major**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored.		
b) Equipment is appropriate for the management of bariatric bodies.	The concealment trolley used at Dewsbury District Hospital is not suitable for the transport of bariatric bodies as the base and cover are too narrow.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(d)	The wording of the adult hospital PM information sheet 'Post Mortem Examination' does not clearly state that consent is required for blocks and slides to be retained for use for scheduled purposes. The DI is advised to rephrase this section to help provide assurance that those giving consent are fully informed. In addition, the form does not give an indication of how long retained samples will be kept for if they are not used for the scheduled purpose(s) for which they were retained. The DI is advised to add wording to reflect the time period for which samples retained following PM examination with appropriate consent will be retained.
2.	C1(f)	When the consent forms for adult hospital PM examinations are next reviewed, the DI is advised to include a section on the form to record the time and date that the relatives have until to withdraw consent if they wish.
3.	C1(g)	In addressing the shortfalls against standard C1(b) and C2(a), the DI is advised to include information for the completion of the adult hospital PM consent forms in the PM consent training for clinicians. This will highlight the importance of completing PM consent forms in a correct and consistent manner. In addition, this may help the establishment to evidence that appropriate consent for hospital PM examinations and storage of PM samples has been given in accordance with the requirements of the HT Act. Consent forms should be audited to ensure that they are completed in a correct and consistent manner.

4.	GQ1(a)	The DI is advised to keep the establishment's arrangements for lone working at both Pinderfields and Dewsbury Hospital mortuaries under review, to ensure that they are appropriate and protect the safety of staff. Whilst there is a single, wall-mounted panic alarm in the viewing room at Pinderfields Hospital, the use of individual lone working alarms, that alert hospital security teams, may help to manage further the risks of lone working in the mortuary. This is particularly important where staff undertake work during out-of-hours periods.
5.	GQ1(a)	The DI is advised to amend references to the HTA's Codes of Practice in the establishment's documents are up-to-date. For example, the Quality Manual (POL-PATH-033) does not reference the current Codes of Practice, which came into force in April 2017.
6.	GQ1 (a)	The DI is advised to consider implementing a release form that is completed by the deceased's relatives, given to the appointed funeral directors and brought to the mortuary by the funeral directors when collecting a body. This form should contain the required minimum of three identifiers (one being unique) that the mortuary staff can use to identify the body, independent of any other documentation given to the funeral directors by the mortuary staff; for example, cremation forms. The release form could be used in addition to any other documentation available to the funeral director; for example, the green disposal order. Documentation is not legally required to release a body but may help in mitigating the risk of releasing a wrong body.
7.	GQ1(a)	The DI is advised to liaise with the Coroner's Office to revise the Coroners release form that currently uses only the name to identify the deceased so that it includes three identifiers.
8.	GQ1(h)	The DI is advised to ensure that minutes of meetings relating to licensed activities include sufficient details of the matters discussed, the outcomes of discussions and actions agreed. The DI is also advised to include incidents and non-conformances as a standing item on the agenda for departmental meetings covering licensed activities. This may help to assure the DI that staff are aware of the types of incidents that must be reported to the HTA and encourage learning from incidents and non-conformances.
9.	GQ2(a)	Although there is a schedule of audits, the DI is advised to strengthen audits of mortuary activities by ensuring that they cover all mortuary procedures in sufficient detail and are regularly conducted throughout the year. 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 may need to be amended. The most recent audit of October 2017 references the HTA's previous Codes of Practice. The DI is advised to audit against the new Codes of Practice that came into force on April 2017.
10.	GQ4(b)	The DI is advised to remind staff that amendments of written records should be made by striking through the original text with a single line so that it is still readable. The HTA found examples of minor written amendments of records for traceability of bodies and PM samples, which had not been completed in accordance with the establishment's procedure.
11.	GQ5(a)	In addressing the shortfall identified against GQ5(a), the DI is advised to improve awareness of the HTARI reporting requirements and the establishment's procedures for reporting incidents. The DI may wish to include

		signs in the mortuary to remind staff of the reporting requirements and procedures for reporting incidents, including near-miss incidents.
12.	GQ6(b)	In addressing the shortfall identified against GQ6(b), the DI is advised to risk assess the activities outlined in GQ1 using the HTA reportable incident categories as a template. In particular, risks to the dignity and integrity of bodies and stored tissue should be included. In addition, it is important that risk assessments contain sufficient and relevant information. Risk assessments should be reviewed regularly and after any changes to procedures. The DI is advised to ensure that staff have access to risk assessments and that familiarity with them is incorporated into the staff training programme. The DI may wish to review the 'Regulation of the Post Mortem Sector 2014-16' document on the HTA website, In particular, 'What we have learned' (page 20) provides helpful information in relation to risk assessments.
13.	T1(a)	The DI is advised to develop a procedure through which all perinatal bodies are placed in an appropriate container to maintain the dignity of these bodies and ensure that they are easily identified when in storage. In addition, these containers could be numbered and the number recorded on the fridge door and associated paperwork, which may assist with traceability.
14.	T1(a)	Identification details of bodies within the freezer are written on the outside of the body bag. Although the bodies themselves are also labelled, there is a potential risk that the identification details on the bag are used to release a body, rather than physically checking the identification on the body. The DI is advised to cease the practice of labelling the outside of the body bags.
15.	T1(c)	In addressing the shortfall against standard T1(c), the DI is advised to amend SOPs to help give assurance that a minimum of three identifiers, including at least one unique identifier, are used to identify bodies. SOPs describing the procedures for checking the identification of bodies should describe, as a minimum: • The minimum number of identifiers that must be used and what these identifiers are expected to be; • What records or documented information are required for the identification check and who this is provided by; • How the identification check should be performed; • The actions to take in the event of any discrepancies in the identifiers. The DI should ensure that the procedure for viewings includes details of what information the family are required to provide to mortuary staff so that the identification check of the deceased is conducted in line with the required standards. The DI may wish to consider introducing a form to gather this information from the family in a way that is sensitive and ensures that the required standard is met for the identification check of the deceased.
16.	T1(d)	The DI is advised to consider strengthening the procedure for management of bodies with same or similar names by introducing robust visual prompts in the mortuary register, on the body, on the fridge door and on any associated documentation. This could include coloured identification tags to be placed on the body and/or a visual flag/ stamp on the records and mortuary register.

		The DI is also advised to develop a procedure through which establishment staff check and identify bodies with same or similar names as part of the establishment's daily mortuary checks.
17.	T1(e)	The DI is advised to develop a procedure for transferring bodies to frozen storage. It is advised that bodies are positioned appropriately to allow easy removal when required to help prevent potential damage. In addition, the identification tag on the body should be positioned so that it can be easily read. This will help to facilitate periodic identity checks on frozen bodies ensuring storage and identity checks upon the body's release.
18.	PFE1(a)	In addressing the shortfall against standard PFE1(a), the DI should ensure that the PM room and equipment is sufficiently rinsed and cleaned prior to any disinfection taking place to help prevent blood and other organic material being missed.
19.	PFE1(d)	The external door to the body store at Dewsbury District Hospital is partially transparent. The DI is advised to consider fully frosting the glass to restrict people looking through into the corridor between two body store areas. The entrance to the body store at Dewsbury District Hospital is overlooked by a car park at one side. Although the mortuary staff informed the HTA that funeral directors usually park in a way that restricts the view of the entrance, the DI is advised to put procedures in place to assure themselves that this always happens before bodies are admitted or released. The external door at the entrance of Dewsbury District body store was left open whist bodies were prepared for release. This may lead to unauthorized or unintentional access and the DI is advised to implement a procedure to assure themselves that this door remains closed and secured when not in use.
20.	PFE2(f)	Fridge temperatures are monitored once per day during weekends. For the un-alarmed temporary storage units, this is not sufficient and there is a potential for failures to go unnoticed for long periods, compromising the dignity of the deceased. The DI is advised to implement more frequent checks during out of hours periods until an alarm system is fitted. In addition, the DI is advised to revise the temperature monitoring procedure so that fridge temperatures are recorded prior to the opening of the fridge doors. This will help obtain more consistent monitoring data.
21.	PFE3(a)	Although fully ventilated hoods are available, mortuary staff are not 'face-fitted' for the disposable masks available for use in the PM room. The DI is advised to face fit all staff working in the PM Suite. During the inspection, the APTs working in the PM room were not wearing eye protection to help prevent contamination from splashing fluids. The DI is advised to remind all staff to wear appropriate PPE.
22.	N/A	The DI is advised to suggest to all staff working under the licence to subscribe to the HTA monthly newsletter, via the HTA website, to keep abreast of relevant information for the areas they work in.

Concluding comments

There are a number of areas of practice that require improvement, including eight major shortfalls and seven minor shortfalls.

The HTA requires the Designated Individual to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 08 March 2018

Report returned from DI: 19 March 2018

Final report issued: 22 March 2018

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 05 November 2018

Appendix 1: HTA licensing standards

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

Consent

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

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

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

Guidance

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

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

Guidance

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

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

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

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

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

Guidance

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

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

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

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

Guidance

Refresher training should be available (for example annually).

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

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

d) Competency is assessed and maintained.

Governance and quality systems

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

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

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

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

iii. practices relating to evisceration and reconstruction of bodies;

iv. systems of traceability of bodies and tissue samples;

v. record keeping;

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

vii. lone working in the mortuary;

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

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

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

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

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

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

xiv. contingency storage arrangements.

Guidance

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

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

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

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

Guidance

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

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

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

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

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

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

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

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

Guidance

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

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

Guidance

Meeting minutes should be recorded and made available to staff.

GQ2 There is a documented system of audit

a) There is a documented schedule of audits.

Guidance

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

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

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

Guidance

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

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

Guidance

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

applicable.

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

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

Guidance

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

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

b) There are clear reporting lines and accountability.

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

Guidance

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

d) Staff have annual appraisals and personal development plans.

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

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

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

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

Guidance

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

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

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

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

Guidance

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

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

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

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

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

Guidance

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

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

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

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

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

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

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

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

Guidance

Risks to the dignity and integrity of bodies and stored tissue should be covered. The HTA's reportable incident categories provide a good basis for risk assessments. Risk assessments should be reviewed at regular intervals, for example every 1-3 years or when circumstances change. Staff should be involved in the risk assessment process.

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

Guidance

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

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

Traceability

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

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

Guidance

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

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

Guidance

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

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

Guidance

Identification details should not be written on bodies. Where bodies are moved off site for contingency storage the DI should ensure that suitable systems are in place to identify same or similar names.

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

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

Guidance

Mortuary white boards containing the names of the deceased give potential for error if wiped

clean (such as when visitors attend for reasons of confidentiality), and should not be relied upon as the sole source of information about the locations of bodies.

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

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

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

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

ii. receipt upon return to the laboratory or mortuary

iii. the number of blocks and slides made

iv. repatriation with the body

v. return for burial or cremation

vi. disposal or retention for future use.

Guidance

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

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

Guidance

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

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

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

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

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

Guidance

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

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

d) The method and date of disposal are recorded.

Premises, facilities and equipment

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

a) The premises are clean and well maintained.

Guidance

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

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

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

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

Guidance

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

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

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

a) Storage arrangements ensure the dignity of the deceased.

Guidance

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

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

Guidance

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

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

Guidance

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

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

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

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

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

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

Guidance

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

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

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

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

Guidance

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

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

The hire of temporary storage units should not be the sole contingency arrangement for an establishment. Establishments should put in place other formally agreed arrangements for contingency storage. Where the hire of temporary storage facilities

forms part of establishments' contingency arrangements, consideration should be given well in advance and steps taken to ensure availability of funds, and of units for hire.

Establishments should consider entering in to Mutual Aid Agreements

with neighbouring organisations in order that they can provide and obtain support during periods of capacity shortages.

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

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

   i. fridges / freezers

   ii. hydraulic trolleys

   iii. post mortem tables

   iv. hoists

   v. saws (manual and/or oscillating)

Guidance

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

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

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

Guidance

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

d) Staff have access to necessary PPE.

Guidance

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

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

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

Guidance

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

Appendix 2: Classification of the level of shortfall

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

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

1. Critical shortfall:

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

or

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

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

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

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

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

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

2. Major shortfall:

A non-critical shortfall that:

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

or

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

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

3. Minor shortfall:

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

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

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

Follow up actions

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

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

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

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