

B Post-mortem Examination

Standards and guidance



Version 2

Published April 2020

Post-mortem Examination Licensing Standards and Guidance

Revision history	2
About the guidance documents	3
About the standards	3
Consent (C).....	4
Governance and quality systems (GQ)	4
Traceability (T)	4
Premises, facilities and equipment (PFE)	4
HTA licensing standards	5
Classification of the level of shortfall	23
Critical shortfalls.....	23
Major shortfalls.....	23
Minor shortfalls.....	24

Revision history

Version	Date	Changes
1.0	23/01/2016	First version published
2.0	01/04/2020	Guidance updated

About the guidance documents

1. The purpose of these guidance documents is to assist licensed establishments to meet the HTA's licensing standards. The documents contain additional information and examples of how to meet certain standards.
2. These documents will be reviewed regularly to include additional guidance. In reviewing these documents, we will take into consideration enquiries, inspection findings and additional examples of good practice.
3. For further guidance on meeting the HTA's licensing standards, please contact the HTA either by:
 - a) Email: enquiries@hta.gov.uk
 - b) Telephone: 020 7269 1900
4. Refer to the [HTA website](#) for guidance on the licensing standards for emergency mortuaries.

About the standards

5. In order to obtain an HTA licence, the applicant must demonstrate that:
 - a) the premises where the activity will take place are suitable; and
 - b) the proposed Designated Individual is a suitable person to supervise the activity.
6. As part of the application process, the HTA will assess whether the establishment can meet a number of licensing standards. These were developed in consultation with representatives from the Post Mortem sector. These relate to the consent provisions of the Human Tissue Act 2004 (HT Act), governance and quality systems, traceability and premises.
7. The standards reinforce the HT Act's intention that:
 - a) consent is paramount in relation to activities involving the removal, storage and use of human tissue;
 - b) bodies of the deceased and organs and tissue removed from bodies are treated with respect; and
 - c) the dignity of the person, whether living or deceased, is maintained.
8. The HTA works with establishments through its inspection process to help them comply with these standards.
9. The standards are grouped under four headings: Consent (C); Governance and quality systems (GQ); Traceability (T); and Premises, facilities and equipment (PFE). Under each of these headings, there are overarching statements, from which the standards flow.

Consent (C)

10. Establishments meeting the consent standards will be able to demonstrate that their processes for seeking and gaining consent comply with the HT Act and the HTA's Codes of Practice. The standards also cover the documentation and information used to support the establishment's consent procedures, and ensure that staff involved in seeking consent are suitably trained and equipped for the task.

Governance and quality systems (GQ)

11. Establishments meeting these standards will be able to demonstrate that they have a suitable governance framework, underpinned by clear and controlled documentation, effective audit, staff training and organised record-keeping. In addition, they will have an effective system of risk management and suitable systems to deal with adverse events. The governance and quality systems standards govern the practices taking place on licensed premises, and ensure that they preserve the dignity of the deceased and that the deceased are treated with respect.

Traceability (T)

12. Establishments meeting these standards will be able to demonstrate full traceability for the human material for which they are responsible, from receipt to final disposal/disposition. HTA inspectors will test this through traceability audits carried out on site and the HTA expects establishments to take a proactive approach to assuring themselves of effective traceability throughout the lifetime of their licence. In addition, as the final traceability step, they will have established disposal arrangements which are in accordance with the HTA's Codes of Practice.

Premises, facilities and equipment (PFE)

13. Establishments meeting these standards will be able to demonstrate that their premises and facilities are appropriate for the licensed activities taking place, that they are safe, secure and clean and that there are effective contingency arrangements in place. In addition, establishments will have systems for ongoing monitoring to ensure all key quality specifications are maintained. These standards also cover equipment, ensuring that it is appropriate, and suitably maintained, and that it does not present an impediment to the staff using it or a risk to bodies.

HTA licensing standards

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.

Guidance

The policy should include information on who can give consent for post-mortem examination, removal of relevant material from the deceased, and the retention of tissue. References to the 'Next of Kin' should be avoided. The HTA's Codes of Practice provide information on the consent requirements of the HT Act.

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

Guidance

This should include:

- *who is able to seek consent and what training they should receive;*
- *who can give consent for post-mortem examination, removal of relevant material from the deceased and the retention of tissue (references to the 'Next of Kin' should be avoided);*
- *what information should be provided to those giving consent for post-mortem examination and the retention of tissue.*

The SOP should reference the use of scanning as an alternative or adjunct to post-mortem examination, where this is available.

HTA Code of Practice B contains guidance for establishments on seeking consent for 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 should include who can give consent for post-mortem examination, removal of relevant material from the deceased and the retention of tissue. References to the 'Next of Kin' should be avoided. The HTA's Codes of Practice provide information on the consent requirements of the HT Act.

Information on consent should be available in different languages and formats, or there should be 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.

Guidance

The time relatives have to reflect on their decision and the point up to which they may withdraw consent should be clearly stated and should not be less than 12 hours. The HTA recommends 24 hours.

There may be specific occasions where a shorter timeframe is agreed with the family. This should be discussed with the family and documented.

- 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. In Northern Ireland, standardised consent forms agreed with the Department of Health Northern Ireland should be used.

The consent forms should record the consent given for the post-mortem examination and for the retention and future use of tissue samples. Separate consent should be obtained for the removal and future storage and use of organs and tissue (including blocks and slides) for scheduled purposes.

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

Anyone seeking consent for post-mortem examination and tissue retention should have relevant experience and a good understanding of the consent procedure.

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

Guidance

Refresher training should be available (for example annually). There should be a system to ensure that only staff who have up-to-date training seek consent (unless they are accompanied by a trained individual).

- c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual.
- d) Competency is assessed and maintained.

Guidance

There should be a system to ensure that only staff who have been competency assessed seek consent (unless they are accompanied by a trained individual).

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

Documented policies and procedures should reflect the requirements of the HT Act and the HTA's Codes of Practice. They should also reflect other relevant legislation and guidance. This includes the Health and Safety Executive's document: 'Managing infection risks when handling the deceased' (HSG283, published 2018).

Individual policies and SOPs for each activity are not required. Some policies and 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

Practices such as 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 or 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 forensic 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.

Guidance

This should include all staff who undertake licensed activities, including for example, portering staff, site managers and funeral directors who carry out mortuary activities out of hours.

- 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 departments where storage of fetuses and stillborn babies takes place, areas where material is stored for research, Accident and Emergency Departments where removal of samples may take place in cases of sudden unexpected death in infancy. There should be an identified Person Designated in each area of the establishment where licensed activities take place.

The Designated Individual has a duty to ensure that suitable practices are carried out by those working under the licence, that the other persons to whom the licence applies are suitable persons to participate in the carrying on of those activities and that the conditions of the licence are complied with.

- 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 of bodies and tissue.

- 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 should include all staff who undertake mortuary activities, for example, portering staff, site managers and funeral directors who may carry out mortuary activities out of hours. APTs should be trained in reconstruction techniques to ensure that the appearance of the deceased is as natural as possible.

Staff should be encouraged to obtain vocational and educational qualifications relevant to their work.

- b) There are clear reporting lines and accountability.
c) Staff are assessed as competent for the tasks they perform.

Guidance

This should include for all staff who undertake mortuary activities, for example, portering staff, site managers and funeral directors who may carry out mortuary activities out of hours.

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 SOPs 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 (whistleblowing).

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 (HTARIs) and near-miss HTARIs must be reported within five working days of the incident occurring or being discovered.

Establishments must not wait until any internal review or investigation is complete before notifying the HTA of the HTARI. Person Designated should register for a HTA Portal account, to ensure that HTARIs can be reported to the HTA within the required timescale in the absence of the Designated Individual.

The HTARI reporting requirements and process for reporting incidents should be documented in a standard operating procedure.

All staff involved in licensable activities should be aware of the HTARI reporting requirements and procedure. This includes staff working in those areas outside of the mortuary, such as pathology, Maternity and Accident and Emergency departments.

Incidents that do not fall within the HTARI reporting requirements should be reported and investigated internally.

- 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 HTARI 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. Relevant staff should be involved in the risk assessment process and should be aware of the risks associated with the activities they undertake.

- 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.

Guidance

This includes to the relevant Trust, Health Board or Local Authority, and should include appropriate risk mitigation measures.

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 should always be checked and their identity confirmed. Identification labels should be attached to the body. Body bags and shrouds should not be labelled in place of labels attached to 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 and 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

This licensing standard aims to ensure that identification procedures are robust. Any deviation from documented procedures should be considered on a case-by-case basis, escalated internally (for example, to the mortuary manager) and documented.

Bodies should be identified using a minimum of three identifiers attached to the body that can be used to check the identification of the deceased. Age is not considered to be robust as an identifier; date of birth should be used wherever possible.

Where there are fewer than three identifiers on a body, enquiries should be made to obtain a minimum of three identifiers, wherever possible. In cases where the identity of the deceased is unknown, information such as mortuary register number, date of admission to the mortuary and place of death may be used, whilst enquiries are ongoing. It is good practice to obtain this information in writing and keep it with the deceased's mortuary record. The additional

identifiers should be added to existing or additional identification bands on the body.

If the mortuary register number has been written on the identification band of the body, it may be used to locate a third identifier for the deceased recorded in the mortuary register or other mortuary documentation.

Identification for post-mortem examination or removal of relevant material from the deceased: A minimum of three identifiers of the deceased on the body should be checked against post-mortem examination consent or authority documentation prior to evisceration of the body. Any discrepancies in the identifiers should be thoroughly investigated before the proceeding with the post-mortem examination or removal of relevant material from the body.

Identification for viewings: A minimum of three identifiers of the deceased on the body should be checked against details of the deceased provided by family members when they attend the mortuary for viewings. If family members cannot provide a minimum of three identifiers of the deceased, other information (such as place of death) may assist the establishment in assuring itself that the correct body is prepared for the viewing.

Identification for release from the mortuary: A minimum of three identifiers on the body should be checked against documentation brought by the funeral directors. The mortuary register number can be used as a unique identifier while a body is in the care of the mortuary but should not be used as an identifier for release of a body to a funeral director, unless it has been specifically provided by the establishment beforehand (for example, on a hospital release form).

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

Guidance

This should consider the sound and spelling of forenames and surnames. The system should include bodies that are moved off site for contingency storage, where they may be returned to the establishment.

- 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 bodies are placed back into normal storage.

Checks should be made to ensure that identification bands on bodies are accessible when bodies are transferred into freezer 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

When material is sent for analysis on or off-site, records should clearly indicate the type and quantity of the samples (including swabs, blood samples, tissue blocks and slides). There should be a system to highlight and follow up if samples have not arrived at the destination within a specified timeframe. 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.

Guidance

The communication flowchart in Code of Practice B (Annex B) provides information on communication for Coroner's post-mortem examinations.

- 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 clean, 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.

Guidance

There should be records of cleaning and decontamination.

- 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

This includes body storage units in areas outside of the mortuary, for example, temporary storage units and storage facilities in maternity departments.

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.

Guidance

Swipe card access lists should be reviewed regularly.

Staff and authorised visitors and contractors should be aware of the establishment's security arrangements.

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

- a) Storage arrangements ensure the dignity of the deceased.

Guidance

Storage temperatures should be appropriate to ensure that the condition of bodies is preserved. Refrigeration of bodies should be at a temperature of approximately 4 degrees Celsius. The optimal operating temperature for freezer storage is around -20 degrees Celsius.

The Health and Safety Executive's document: 'Managing infection risks when handling the deceased' (HSG283, published 2018) includes guidance on storage of bodies.

- 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 regularly or for extended periods. Where storage capacity is identified as an ongoing issue, this should be escalated to the relevant Trust, Health Board or Local Authority.

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

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. Where storage capacity is identified as an ongoing issue, this should be escalated to the relevant Trust, Health Board or Local Authority.

- 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.

Guidance

This includes storage units in which bodies or tissues are stored under the HTA licence in other areas, for example in maternity departments.

The HTA advises that storage units in areas that are not permanently staffed should have a remote alarm system to alert staff to temperature deviations out of hours.

Temperature alarm trigger points should be set to ensure that alarms will trigger in the event that the storage temperature deviates from an acceptable range to ensure that the condition of bodies and tissue is appropriately preserved. Staff should be aware of the acceptable temperature ranges and temperature alarm trigger points.

Alarm tests should include call out procedures and should be recorded.

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

Guidance

This includes storage units in which bodies or tissues are stored under the HTA licence in other areas, for example maternity departments.

Temperature monitoring should enable the establishment to identify trends and the extent of any variations in storage temperatures.

- 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.

Practices such as placing more than one body on a tray or storing bodies in unrefrigerated storage should not take place.

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, nonrusting, non-decaying and non-staining.

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

Guidance

The 'safe working load' of mortuary equipment should not be exceeded.

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

Guidance

The minimum recommended air supply rate to a post mortem room is ten air changes an hour (AC/h); the recommended extract rate from a post mortem room is 12 AC/h. The ventilation system should achieve not less than 75% of the design air change rate given in Appendix 2 of Health Technical Memorandum (HTM) 03-01: Specialised ventilation for healthcare premises (Part A).

Control of Substances Hazardous to Health (COSHH) regulations require a thorough examination of the ventilation system at 14-month intervals, and sets out what the examination should cover.

Relevant staff should be notified of servicing and have access to service records.

- d) Staff have access to necessary PPE.

Guidance

Where face masks should be worn, they should be face-fitted and the highest-efficiency filter (FFP3). Where face-fitted face masks cannot be used, alternative PPE should be provided (for example, fully ventilated hoods).

The Health and Safety Executive's document: 'Managing infection risks when handling the deceased' (HSG283, published 2018) includes guidance on PPE. Establishments should also refer to guidance from Public Health England.

- 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 departments where fetuses or stillborn babies are stored prior to examination.

Relevant staff should be notified of servicing and have access to service records.

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.

Critical shortfalls

A critical shortfall is:

- a shortfall which poses a significant risk to human safety and/or dignity or is a breach of the HT Act or associated Directions
- 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:

- a notice of proposal being issued to revoke the licence
- 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
- a notice of suspension of licensable activities
- additional conditions being proposed
- directions being issued requiring specific action to be taken straightaway.

Major shortfalls

A major shortfall is a non-critical shortfall that:

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

- is 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.

Minor shortfalls

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.