Guide to Completion of the Post Mortem Licence Application

Introduction

The following activities can only take place under the authority of a licence from the Human Tissue Authority:

- The making of a post-mortem examination
- The storage of the body of a deceased person or relevant material[1] which has come from a human body for use for a Scheduled Purpose[2]
- The removal from the body of a deceased person (otherwise than in the course of an anatomical examination or a post-mortem examination) of relevant material of which the body consists or which it contains, for use for a Scheduled Purpose

This document outlines the legal framework of the licensing system, explains the application process and provides guidance on how to complete the application form.

Our Code of Practice B and the Standards and Guidance provide additional guidance on the licensing requirements for the Post Mortem sector.

General

1. The Human Tissue Authority (HTA) was established under the Human Tissue Act 2004 (HT Act). The HTA licenses a number of activities and undertakes inspections of establishments carrying out these activities to ensure the requirements of the HT Act are being met.

2. We operate a continuous licensing system, with an annual licence fee although in some circumstances we can issue fixed-term licences. In the event you require an Emergency mortuary licence, please refer to our guidance on our website.

3. The HTA must receive an application before it can grant a licence. The application must specify the premises at which the licensable activities will take place. Where the establishment has multiple sites, such as a main site with remote satellite sites we can accept a single application, provided:

    - the same Designated Individual (DI) is appointed for all sites; and

[1] Go to https://www.hta.gov.uk/policies/relevant-material-under-human-tissue-act-2004 for more information on relevant material

[2] See Schedule 1 of the HT Act (Scheduled Purposes) Part 1 and Part 2

- all sites work to the same procedures and governance arrangements.

4. We issue separate licences for the hub and for each satellite site, under the same licensing number. Satellite sites are eligible for a reduced licence fee.

Completing and submitting a licence application

5. Licence applications can be downloaded from the HTA website and should be submitted by email to licensing@hta.gov.uk.

6. The application form has four sections:

   - Information about the establishment
   - Information about the DI and the Licence Holder
   - Information about how the licensing standards are being met
   - List of documents to be submitted as part of the application

7. The licensing standards section contains four sets of standards that applicants must assess and evaluate their performance against. These are:

   - Consent
   - Governance and Quality Systems
   - Traceability
   - Premises, Facilities and Equipment

8. The HTA will assess the information provided in the application form and the mandatory documents that must be submitted before the application can be assessed, taking this as evidence on which to base an informed and proportionate licensing decision.

9. Where we have considered it to be helpful, we have included guidance under individual standards to help you assess whether you meet them. You should include details of what procedures you have in place to meet each standard, or if the standard is not being fully met, what you are doing in order to achieve the standard. Key strengths or areas identified for improvement can also be given. For each applicable standard, the establishment should consider the evidence it has to demonstrate whether the standard is not met or met.

10. Where a standard is not applicable, please select 'N/A' and provide an explanation of why the standard is not applicable to your establishment.

11. We may contact applicants and undertake a site visit to obtain any additional information or evidence required. This could be at any stage in the application process.

12. Any incorrect or misleading information provided in an application could lead to the revocation of any licence granted.

13. Applicants will need to complete their application and submit all relevant information before the application can be assessed. If an application is not completed due to delays at the establishment within three months from the start of assessment, the applicant(s) will need to repay the licence application fee before their application is further assessed.

14. If an application is rejected following assessment, the applicant(s) will need to repay the licence application fee if they wish to submit a new application.

Granting a licence

15. A licence will be granted when we receive written acknowledgement of the licence offer from the proposed DI and the Licence Holder.

16. If a licence application is refused or granted with conditions and the applicant chooses to challenge this decision, the proposed Licence Holder and/or the proposed DI must give notice of their intention to make representations within 28 days from the date that notice of the proposed licensing decision was given by the HTA (i.e. the date on the Licence Offer/Notice of Proposal letter). This is a strict time limit laid down by statute.

    Notification of the intention to make representations may be given to the HTA either orally or in writing by the person entitled to make representations. If the request is given orally, it must be made to the Authority's Director of Regulation, one of the Regulation Managers or one of the Heads of Regulation only. The person receiving the oral request to make representations will record the request and confirm this in writing to the person proposing to make representations.

17. The person entitled to make representations must, after any oral request, then confirm their intention to make representations in writing to the HTA. This may be by letter, email and/or fax to the Director of Regulation.

18. The following section gives specific help on completing the Application Form. Please contact us by emailing licensing@hta.gov.uk if you need further information about any part of the application form or our process for considering licence applications.

Completing and submitting a licence application

Establishment Information

19. Establishment name

    Please provide the name of the organisation on whose premises the activities will take place. Careful consideration should be given to where the licensed

activities are going to take place and whether they extend to more than one area within the premises. Include the department name if applicable.

20. Establishment address

    A licence application must specify the premises where the activities are to take place. The address of the main site should be stated in this section. Where the licensed activity will take place at more than one premises, such as a main site with satellite sites, a separate satellite licence would be needed for each site, however a single application for multiple licences may be made. Details of satellite sites should be recorded in the relevant section.

21. Names of person(s) who have consented to be designated on the licence (where the establishment is applying for a licence(s) on single premises)

    The HT Act allows the DI to designate persons on the licence, with their agreement. Persons Designated can support a DI in overseeing licensable activities. There should be an identified Person Designated in each area of the establishment where licensed activities take place, for example on maternity and in ED.

Satellite Sites

22. Address of satellite site premises and activities to be licensed

    Satellite sites are premises under the same governance arrangements as the main site (hub) and are supervised by the same DI. Each satellite site will have its own licence, under the same licensing number.

23. Names of person(s) who have consented to be designated on the licence at the satellite premises.

    There should be a primary Person Designated at each satellite site who can direct licensable activities at the site and is accountable to the DI. Please provide the name of the primary Person(s) Designated on the licence for the satellite premises and any additional persons to be designated on the licence of the satellite premises. As with the main site (hub) there should be an identified Person Designated in each area of the establishment where licensed activities take place.

Application to be Designated Individual (DI)

24. Information about the role of the DI is available on our website.

25. With regard to the organisational structure of the establishment, please indicate the lines of responsibility between the DI and any persons engaged in licensed activities.

    We must be satisfied the DI is able and willing to supervise the licensed activities. The relationship between the DI and those working under the

licence should be described here, as well as the DI's position in the overall governance structure.

26. Please explain how the DI ensures that staff, who will be working under the licence, are appropriately qualified and trained in techniques relevant to their work and continuously update their skills.

    The DI must ensure that suitable practices are carried out by those undertaking the licensed activities; staff training and competence is an important part of this. The DI's role in ensuring that staff working under a licence are suitably qualified and trained should be described here.

27. Declaration

    The DI must read and acknowledge each statement in this section.

Application to be Licence Holder/Corporate Licence Holder

28. The applicant can be a person or a corporate body and must be suitable to hold the position of Licence Holder. If the applicant is a corporate body, the application to be a Corporate Licence Holder must be completed by a person suitable to act as Licence Holder contact.

29. Declaration

    The Licence Holder or Corporate Licence Holder contact must read and acknowledge each statement in this section.

Licensing Standards

30. The licensing standards are separated into four main themes: consent; governance and quality systems; traceability and premises, facilities and equipment. Each of these four sections must be completed.

31. It is important for establishments to demonstrate how they meet HTA licensing standards.

32. Any HTA licensing standards that are not applicable to the activity undertaken should be indicated in the relevant section.

List of mandatory documents to be submitted as part of the application form

33. You will need to submit all documents in the following checklist, together with the completed application form, before your application can be assessed.

Please note that these do not need to be separate documents, they may be embedded within other governance documents (e.g. the Quality Manual). If that is the case, please provide the relevant document and indicate the page numbers or section where the mandatory document can be found in the relevant 'Further information on documentation' section of the application form.

Application Checklist – Mandatory documents	
General	
☐	Inspection report from other regulators such as CQC and UKAS if appropriate
Consent	
☐	Post-mortem examination consent standard operating procedure (SOP), consent form and information leaflet (or similar)
☐	Plans for staff training and competency assessments
Governance and Quality Systems	
☐	Organisational chart relevant to the mortuary and all other departments where activities will take place under the licence (e.g. maternity, A&E, pathology departments)
☐	List of SOPs of licensable activities (please note that these should be developed in line with guidance provided for standard GQ1)
☐	SOP for storage of bodies including long-term storage, bariatric bodies and bodies moved into frozen storage
☐	SOP for post-mortem examination, evisceration and reconstruction of bodies
☐	SOP for HTA Reportable Incidents (HTARIs) including near miss incidents
☐	All risk assessments relevant to licensable activities (please note that these should be developed in line with the guidance provided in relation to standard GQ6)
Traceability	
☐	SOP(s) for labelling and identification of bodies, including identifying bodies for: • post-mortem examination; • viewings; and, • release of bodies from the mortuary • Internal and external transfer eg for CTPM scanning and PMs
☐	SOP for traceability of samples removed for other purposes e.g. pathology, toxicology analysis
☐	SOP for disposal of organs and tissue (if applicable)
Premises, Facilities and Equipment	
☐	Risk assessment of premises
☐	Site plan, indicating where storage of bodies or relevant material will take place and location of security equipment including CCTV and panic alarms

- ☐ Contingency plan for power failure in storage area, capacity management
- ☐ SOPs for monitoring and testing of storage conditions
- ☐ SOPs detailing security arrangements in place to protect against unauthorised access and ensure oversight of visitors and contractors to all areas of the establishment carrying out licensed activity.

HTA Licensing Standards

Consent standards
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 postmortem 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 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.

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 system standards

GQ1 All aspects of the establishments 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) which can be found at: https://www.hse.gov.uk/pubns/priced/hsg283.pdf

Individual policies and SOPs for each activity are not required. Some policies and SOPs will cover more than one activity. Procedures should be detailed enough to ensure uniformity between staff in the performance of a specific function and should be followed to the letter by all staff who have been appropriately trained. People undertaking the processes should be involved in developing the SOPs to ensure that the written procedures accurately reflect practices. A standard operating procedure (SOP) should be a clear and accurate representation of an existing procedure or process, preferably set out in the format of a stepwise guide (e.g process chart). SOPs should be understandable to enable new staff to follow a procedure from beginning to end. Procedures should take account of both standard and out-of-hours arrangements. Lone working has the potential for greater risks to staff and the dignity of the deceased and requires careful management and oversight. Establishments may be assisted by the HSE guidance on Lone Working which can be found at: https://www.hse.gov.uk/pubns/indg73.pdf

Access to the mortuary should be strictly controlled with clear policies and procedures which protect bodies from harm and breaches of confidentiality.

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.

Guidance:

Bodies should not be held in unrefrigerated conditions for prolonged periods of time prior to the arrival of the pathologist to undertake the external examination.

This is to ensure the dignity and safety of the deceased and to preserve the body and any evidence of the cause of death.

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.

Guidance:

Regular review of SOPs will help to prevent incremental departure from written processes with passing time and allow establishments to identify improvements.

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 wards where storage of foetuses and still born babies takes place, areas where material is stored for research, the 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 involved in licensed activities.

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 as outlined in standard GQ1a, the completion of records and traceability of bodies and tissue. Audits should include checking of CCTV as well as records of mortuary access.

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. Processes should be in place to ensure that feedback of audit findings to all staff takes place in a timely and appropriate manner to ensure up to date procedures are embedded and being followed.

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.

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 records of access to the mortuary (by whom and for what purpose), mortuary registers, electronic management systems, 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 of 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 security, dignity and integrity of bodies and stored tissue should be covered. The HTARI categories provide a good basis for risk assessments.

Establishments may also be assisted by the Health and Safety Executive's guidance on the steps needed to managing risk which can be found at: https://www.hse.gov.uk/simple-health-safety/risk/index.htm

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 standards

T1 A coding and records system facilitates the 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 recorded, 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 or the electronic database, 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-bycase 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.

Upon admission, where there are fewer than three identifiers on a body, enquiries should be made as soon as possible 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 they are placed back into normal storage.

Checks should be made to ensure that identification bands on bodies are accessible and legible 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 standards

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:

Security arrangements should be robust, with effective mechanisms to strictly control access. This includes body storage units in areas outside of the mortuary such as temporary storage units and storage facilities in maternity departments.

Although CCTV is an important security measure, it should not be used in a way that compromises the dignity of the deceased. Systems should prevent the inappropriate access or use of images.

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

Guidance:

The Designated Individual, or persons acting under their authority, should use a controlled-access system to monitor entry into the mortuary or body storage facility, either during the day or outside working hours (e.g. by hospital porters, undertakers and tissue retrieval staff). There should be documented procedures for access as well as a system for recording who has been in the mortuary or body store, the nature of their business and when they arrived and left.

Levels of oversight, particularly surrounding mortuary access and mortuary activities undertaken, should be clearly defined and take into account risks to the dignity of the deceased.

Staff should be encouraged to raise concerns regarding any behavior within the mortuary which could compromise the dignity of the deceased. 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.

Lone working arrangements should also be overseen and authorised by the Designated Individual.

Swipe card access lists should be reviewed and updated regularly. Records of access (electronic and paper-based) and CCTV footage should be regularly audited to ensure adherence to relevant policies and procedures. Anyone entering the mortuary should have a legitimate right of access and audits should scrutinise the purpose, frequency and duration of access and be particularly alert to unusual patterns, times of entry or other unexplained or suspicious activity which must be investigated immediately.

Staff and authorised visitors and contractors should be aware of the establishment's security arrangements. Authorised visitors and contractors should also be supervised while in the mortuary.

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: https://www.hse.gov.uk/pubns/priced/hsg283.pdf

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.

Guidance:

Shrouding practices should preserve the dignity of the deceased, including during release and transportation. Shrouds should be clean and appropriate for use and checked regularly.

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 into 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.

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): Health Technical Memorandum 03-01 Part A (england.nhs.uk)

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. This can be found here:

https://www.hse.gov.uk/pubns/priced/hsg283.pdf

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 foetuses or still born babies are stored prior to examination and fridges used for storage of tissue samples.

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

Glossary

Anatomical examination	Macroscopic examination by dissection for the purposes of teaching or studying or, or researching into, the gross structure of the human body.
Code of practice	The HTA codes of practice provide guidance and lay down expected standards for each of the sectors we regulate. There are nine codes available via the HTA website.
Designated Individual (DI)	The person named a licence issued by the HTA, under whose supervision licensed activities are carried out. The DI has a statutory responsibility to ensure that those carrying out licensed activities, and their practices, are suitable, and that the conditions of the licence are met. Further guidance is provided on the HTA website.
Existing holdings	The body of a deceased person, or any relevant material which has come from the human body, held immediately prior to 1 September 2006.
HTA Reportable Incident (HTARI)	A serious incident in the post mortem sector which falls within the classifications defined by the HTA and about which the HTA must be notified. Further information is available on the HTA website.
Licensed premises	Where the licensed activity takes place.
Licence Holder (LH)	The person who holds a licence and is responsible for the payment of any fees charged by the HTA. The LH can be a corporate body. Where the applicant is not the proposed DI, the HTA must be satisfied that the applicant is a suitable person to be the holder of the licence.
Person designated (PD)	A person, or persons, nominated by the DI (in writing to the HTA) who has the ability to 'direct' others in relation to the conduct of activities licensed under the Human Tissue Act 2004. There must be a Person Designated at each satellite site who can direct activities that are licensed there and who is accountable to the DI at the main hub site.

Post-mortem examination (PME)	Dissection and examination of a body after death, principally to determine the cause of death or the presence of disease processes. A hospital post-mortem examination is carried out with appropriate consent to gain a fuller understanding of the deceased person's illness or the cause of death, and to enhance future medical care. Coroners' post-mortem examinations are carried out under the authority of the coroner, without consent being required from relatives, to assist coroners in carrying out their functions.
Relevant material	Defined by the HT Act as material other than gametes, which consists of, or includes, human cells. In the HT Act, references to relevant material from a human body do not include: (a) embryos outside the human body, or (b) hair and nail from the body of a living person. See policy guidance on how to apply this definition on the HTA website.
Service Level Agreement (SLA)	A formal agreement between two parties to provide a service.
Standard operating procedure (SOP)	A document that sets out the established process to be followed to complete a task.
Tissue	Any and all constituent part/s of the human body formed by cells.