Guide to Completion of the Post Mortem Licence Application

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 Post-mortem examination licensing 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 licensing fee, although in some circumstances we can issue fixed-term licences.
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 where bodies, body parts or tissue samples are stored, we can accept a single application, provided:
    - the same Designated Individual (DI) is appointed for all sites; and
    - 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.

[1] Go to http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/definitionofrelevantmaterial.cfm for more information on relevant material
[2] See Schedule 1 of the HT Act (Scheduled Purposes) Part 1 and Part 2

Completing and submitting a licence application

5. Licence applications can be downloaded from the HTA website and should be submitted by email to licensing.enquiries@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 HTA licensing standards are 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. Where applications are complete and demonstrate a satisfactory level of compliance with standards we will aim to issue a licence offer within 20 working days of receipt of the application.
13. Any incorrect or misleading information provided in an application could lead to the revocation of any licence granted.
14. 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.

15. 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

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

17. 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.

18. 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.
    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.

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

How to complete the application form

Establishment Information

20. 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.

21. 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.

22. 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.

Satellite Sites

23. 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.

24. 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.

Application to be Designated Individual (DI)

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

26. 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.

27. 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 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.

28. Declaration

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

Application to be Licence Holder/Corporate Licence Holder

29. 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.

30. Declaration

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

Licensing Standards

31. 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.

32. It is important for establishments to demonstrate how they meet HTA quality standards.

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.

34. 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 CQC

Consent

☐ Post mortem consent SOP and consent form

Governance and Quality Systems

☐ Organisational chart relevant to the mortuary and all other departments where activities take place under the licence (e.g. maternity, A&E, pathology departments)

☐ Quality manual

☐ List of SOPs of licensable activities (please note that these must be developed in line with guidance provided for standard GQ1)

☐ A copy of the SOP for storage of bodies including long-term storage and bodies moved into frozen storage

☐ A copy of the SOP for post mortem examination, evisceration and reconstruction

☐ SOP for receipt and release of bodies

☐ HTARI SOP

☐ A copy of all risk assessments relevant to licensable activities (please note that these must be developed in line with the guidance provided in relation to standard GQ6)

Traceability

☐ A copy of the SOP for labelling and identification of bodies (if separate from the release SOP)

☐ A copy of the SOP for traceability of samples removed for other purposes e.g. pathology, toxicology analysis

☐ A copy of the disposal SOP (if applicable)

Premises, Facilities and Equipment

☐ Risk assessment of premises

☐ Site plan, indicating where storage of relevant material will take place

☐ Contingency plan for power failure in storage area, body overflow

☐ A copy of the SOPs for monitoring and testing of storage conditions

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. b) There is a documented standard operating procedure (SOP) detailing the consent process. *Guidance* *This should include who is able to seek consent, what training they should receive, and what information should be provided to those giving consent for post-mortem examination. It should make reference to the use of scanning as an alternative or adjunct to post-mortem examination.* c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice. *Guidance* *Information on consent should be available in different languages and formats, or there is access to interpreters/translators. Family members should be given the opportunity to ask questions.* d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives. e) Where consent is sought for tissue to be retained for future use, information is provided about the potential uses to ensure that informed consent is obtained. f) The deceased's family are given an opportunity to change their minds and it is made clear who should be contacted in this event and the timeframe in which they are able to change their minds. g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided. *Guidance* *This may be based on the HTA's model consent form for adult post-mortem examinations*

available on the HTA website, or in relation to infants, the resources pack developed by the Stillbirth and neonatal death charity, Sands.

The consent forms should record the consent given for the post-mortem examination and for the retention and future use of tissue samples.

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

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

Guidance

Refresher training should be available (for example annually).

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

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

d) Competency is assessed and maintained.

Governance and quality 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

SOPs should reflect guidance contained in the HSE's document: Managing the risks of infection in the mortuary, post mortem room, funeral premises and exhumation. Individual SOPs for each activity are not required. Some SOPs will cover more than one activity.

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

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

Guidance

For example, placing more than one body on a tray, placing bodies unshrouded on trays, or storing bodies in unrefrigerated storage should not take place. The family's permission should be obtained for any 'cosmetic' adjustments or other invasive procedures prior to release of bodies, for example, sewing the deceased's mouth to close it or the removal of a pacemaker. It is also good practice to discuss with the family any condition that may cause them distress, for example when viewing or preparing the body for burial, such as oedema, skin slippage of signs of decomposition.

If identification of the body is to take place before a post-mortem examination, if available, a Police Family Liaison or Coroner's Officer should have a discussion with the family about the injures and let them know that reconstruction may be required. However, the Pathologist should see the body without any changes being made, so if there is a need to reconstruct or clean a body before the post-mortem examination, it should be with the

agreement of both the Pathologist and the Coroner. In Home Office cases, a viewing cannot normally take place until after the post-mortem examination.

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

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

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

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

Guidance

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

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

Guidance

Meeting minutes should be recorded and made available to staff.

GQ2 There is a documented system of audit

a) There is a documented schedule of audits.

Guidance

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

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

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

Guidance

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

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

for continued retention.

Guidance

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

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

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

Guidance

This includes portering staff, who have responsibility for bringing bodies to the mortuary out of hours and who may not be aware of the potential risks to the deceased during transfer into refrigerated storage, and unqualified mortuary 'assistant' staff. APTs should be trained in reconstruction techniques to ensure that the appearance of the deceased is as natural as possible. APTs should be encouraged to work towards the achievement of the RSPH Level 3 Diploma in Anatomical Pathology Technology.

b) There are clear reporting lines and accountability.

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

Guidance

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

d) Staff have annual appraisals and personal development plans.

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

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

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

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

Guidance

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

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

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

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

Guidance

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

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

c) Systems ensure data protection, confidentiality and public disclosure (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 must be reported within five days of the date of the incident or date of discovery.

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

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

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

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

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

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

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

Guidance

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

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

Guidance

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

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

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

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

Guidance

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

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

Guidance

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

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

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

Guidance

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

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

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

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

i. material sent for analysis on or off-site, including confirmation of arrival
ii. receipt upon return to the laboratory or mortuary
iii. the number of blocks and slides made
iv. repatriation with the body
v. return for burial or cremation
vi. disposal or retention for future use.

Guidance

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

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

Guidance

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

forthese cases.

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

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

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

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

Guidance

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

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

d) The method and date of disposal are recorded.

Premises, facilities and equipment 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.

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

Guidance

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

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

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

a) Storage arrangements ensure the dignity of the deceased.

Guidance

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

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

Guidance

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

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

Guidance

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

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

Where new fridges are installed, these should measure 24"-26" in width and consideration

should be given to the proportion that should be larger to accommodate bariatric bodies.

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

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

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

Guidance

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

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

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

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

Guidance

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

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

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

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

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

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

i. fridges / freezers

ii. hydraulic trolleys

iii. post mortem tables

iv. hoists

v. saws (manual and/or oscillating)

Guidance

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

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

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

Guidance

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

d) Staff have access to necessary PPE.

Guidance

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

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

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

Guidance

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

Glossary

Anatomical examination	Examination by dissection for the purpose of teaching, studying or conducting research into the 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 individual designated on the licence to supervise the licensable activities being carried out. DIs are trained by the HTA to carry out this important role and they have statutory responsibilities they must fulfil. 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.
Licensed premises	Where the licensed activity takes place. If the licensed activity will take place at more than one place, a separate licence will be issued for each place. Premises in different streets or with different postal codes are considered as being in different places. In contrast, different buildings on a hospital site could be regarded as the same 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 in order 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 and without consent 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.
Serious Untoward Incident (SUI)	An incident that occurs in post mortem sector establishments which are categorised by the HTA and must be reported accordingly. Further information is available on the HTA website.
Service Level Agreement (SLA)	A formal agreement between two parties to provide a service
Standard operating procedure (SOP)	A document which provides detailed, written instructions to achieve uniformity of the performance of a specific operation, function or task. An SOP must be written with sufficient detail so that someone with limited experience or knowledge of the procedure can successfully reproduce it without supervision.
Tissue	Any and all constituent part/s of the human body formed by cells.