



HTA

Human Tissue Authority

**Guidance on HTA
licensing of
emergency mortuaries**

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Guidance on HTA licensing of emergency mortuaries

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Overview

The Human Tissue Authority (HTA) was established under the Human Tissue Act 2004 (HT Act). The HTA licenses a number of activities in England, Wales and Northern Ireland¹, and regulates establishments carrying out these activities.

We have a system to license emergency mortuary facilities. HTA licences for emergency mortuaries are for a fixed term of 12 months. You can apply to the HTA to add or remove licensed activities on the licence, or revoke the licence, at any point.

This document provides information about HTA licensing of emergency mortuary facilities. This guidance is for teams involved in emergency planning and those working in emergency mortuary facilities.

This guide is presented in three sections:

- Part 1 – determining whether a HTA licence may be required
- Part 2 – preparing a HTA licence application
- Part 3 – applying for a HTA licence in the event of an emergency situation

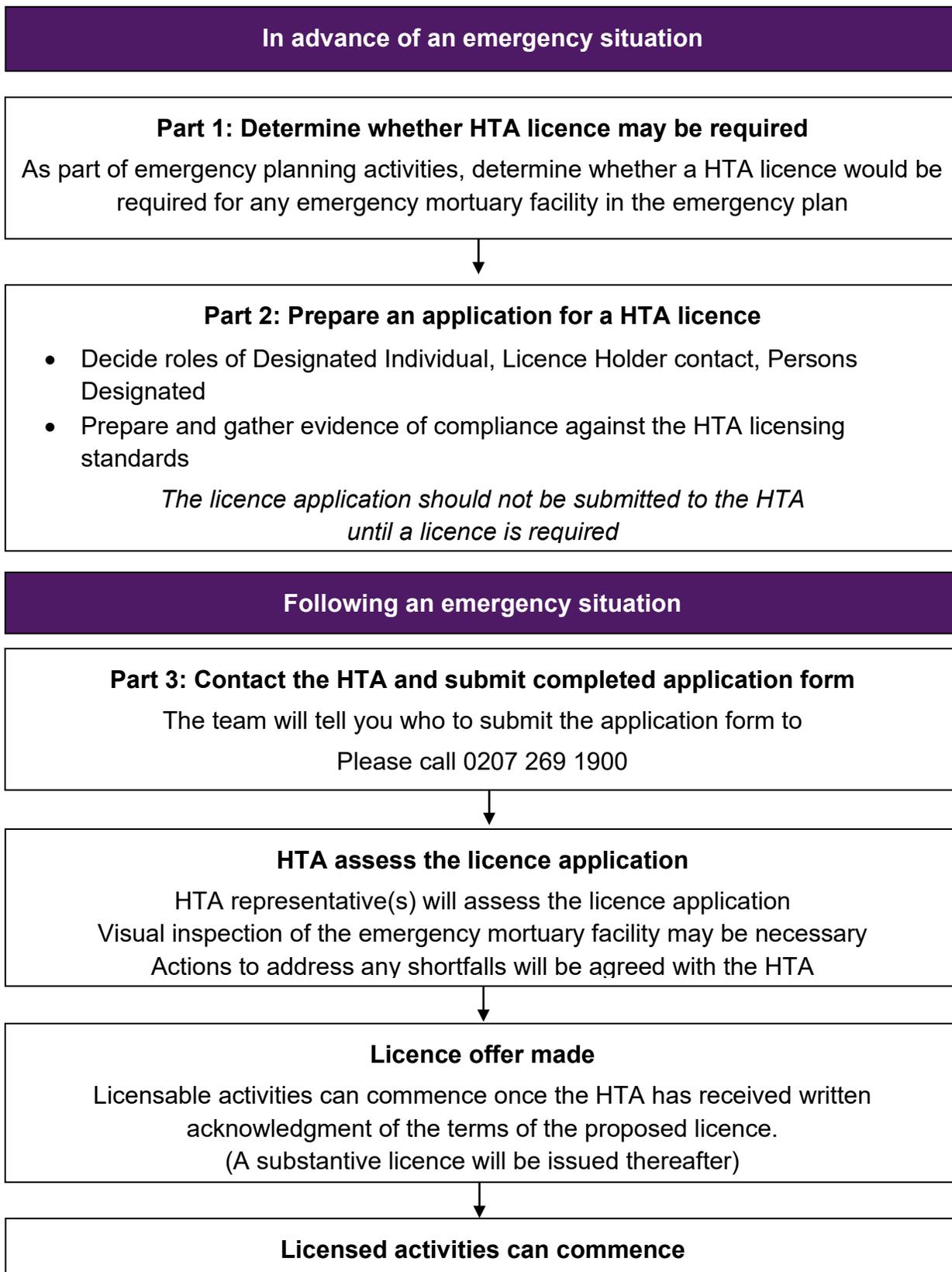
Parts 1 and 2 should be followed in advance of an emergency. The licence application form should not be submitted to the HTA until a licence is required.

For general enquiries and advice or to apply for a HTA licence in the event of an incident:

Please call 020 7269 1900

¹ Please note that the HTA does not license mortuaries in Scotland. Information about regulation in Scotland is provided by Health Scotland.

HTA licensing flowchart for emergency mortuary facilities



Part 1 – Determine whether a HTA licence may be required

The information in this guide is to assist organisations in determining whether a HTA licence may be required and which licences may be required.

Legal framework

The HTA works within the statutory framework imposed by the HT Act. The following activities can only take place under the authority of a licence from the HTA:

- The **making of a PM examination**;
- The **storage** of the body of a deceased person or relevant material² which has come from a human body for use for a scheduled purpose³; and,
- The **removal** from the body of a deceased person (otherwise than in the course of an anatomical examination or a PM examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose.

The licensing requirements are subject to certain licensing exemptions set out in the HT Act. The licensing exemptions that may be applicable to emergency mortuaries are:

- Section 16 of the HT Act exempts the activity of **storage** from licensing where it is 'incidental to transportation'. This means storage for a matter of hours or days and no longer than a week. Storage should be for as short a period as possible, before transfer to HTA-licensed premises.
- Section 39 of the HT Act exempts the activities of **storage** and **removal** from licensing if they are undertaken for purposes related to the prevention or detection of crime or the conduct of a prosecution.

*Premises where licensable activities take place need to be licensed by the HTA.
The relevant licences must be in place before licensable activities can commence.*

² Go to www.hta.gov.uk/policies/relevant-material-under-human-tissue-act-2004 for more information on relevant material

³ See Schedule 1 of the HT Act (Scheduled Purposes): www.legislation.gov.uk/ukpga/2004/30/contents

Licensing requirements for emergency mortuary facilities

The licensing requirements for emergency mortuary facilities depend on the circumstances of the situation and the activities conducted at the facility.

This section provides general information about the licensing requirements:

- Premises on which PM examinations are conducted must be licensed by the HTA for the activity of 'making of a PM examination'. This applies to all PM examinations, including those authorised by the coroner and forensic PM examinations.
- The licensing requirements do not apply to establishments where only PM cross-sectional imaging is undertaken (i.e. PM computed tomography [PMCT] or PM magnetic resonance imaging [PMMR]). If, alongside this activity, samples are removed from the body for a scheduled purpose (for example, to determine the cause of death or obtain scientific or medical information), a licence for removal activity will be required, unless the licensing exemption under section 39 of the HT Act applies.
- Facilities where samples of relevant material are removed from the deceased for use for a scheduled purpose (for example, to determine the cause of death or obtain scientific or medical information) must be licensed, unless the exemption under section 39 of the HT Act applies. Relevant material includes samples such as nasal and buccal swabs and blood samples – further information about relevant material is available on the HTA website².
- Facilities where bodies are stored temporarily (for as short a period as possible, and for no longer than a week) before being moved to HTA-licensed premises for PM examination, do not need to be licensed for storage activity. This is because the licensing exemption under section 16 of the HT Act will apply.
- Facilities where bodies are stored only prior to being buried or cremated are not subject to the licensing requirements of the HT Act. This is because the bodies are not being stored for use for a scheduled purpose.

Information on the consent requirements of the HT Act for these activities is provided in [HTA Code of Practice B on PM examination](#)⁴.

Mass fatality incidents

In most mass fatality incidents, the licensing exemption under section 39 of the HT Act will apply, meaning that **storage** and **removal** activities will be exempt from the licensing requirements of the HT Act. In these circumstances:

- Facilities where PM examinations are not conducted do not need to be licensed.
- Emergency mortuary facilities where PM examinations are conducted need to be licensed only for the activity of 'making of a PM examination'.

If the section 39 exemption **does not apply**, a licence for storage and removal may be required. *Refer to the previous section for the licensing requirements for these activities.*

Disease outbreak situations

In situations of disease outbreak, it is unlikely that the licensing exemption under section 39 of the HT Act will apply. In these circumstances:

- Facilities will need to be licensed for storage and removal activities, if these activities are conducted at the facility. *Refer to the previous section for the licensing requirements for these activities.*
- Emergency mortuary facilities where PM examinations are conducted need to be licensed for the activity of 'making of a PM examination'.

Please contact the HTA for advice if you are uncertain about whether your planned emergency mortuary arrangements would require premises to be licensed.

⁴ HTA Code of Practice B on PM examination: www.hta.gov.uk/hta-codes-practice-and-standards-0

Information about HTA licences

HTA licences are premises specific. Premises must be licensed before licensable activities commence. Emergency mortuary licences are for a fixed term of 12 months. You can apply to the HTA to add or remove licensed activities on the licence, or revoke the licence, at any point.

If an emergency mortuary is planned on premises already licensed by the HTA, this should be agreed with the Designated Individual. The HTA should be notified of this.

If the planned emergency mortuary requires an HTA licence, emergency planning teams should prepare a HTA licence application, to submit to the HTA in an emergency. Please contact the HTA for information on licensing fees for emergency mortuaries.

Part 2 – Prepare an application for a HTA licence

Complete as much of the emergency mortuary licence application form as possible **in advance of the requirement for a licence**. The information on the application form should be reviewed regularly and, or when major changes to emergency plans are made.

Emergency plans should identify whose responsibility it is to contact the HTA in the event of an emergency and within what timeframe.

Teams will need to decide which individuals will take on the roles of Designated Individual (DI), Licence Holder (LH) contact, and Persons Designated (PD). Guidance is provided below, and further information is available on the [HTA website](#)⁵.

It is important that the licence application is completed and kept under regular review as part of the emergency plan. This will assist the prompt assessment of the licence application by the HTA in event of an emergency.

⁵ Information for DIs and named contacts: www.hta.gov.uk/useful-information-dis-and-named-contacts-0

HTA licence application form

The emergency mortuary licence application form is available to download from the HTA website: www.hta.gov.uk/policies/emergency-mortuaries.

The licence application form has five sections:

- Section 1 – Establishment information
- Section 2 – Satellite site application (where applicable)
- Section 3 – Application to be Designated Individual
- Section 4 – Application to be Licence Holder (individual or corporate)
- Section 5 – Compliance with HTA licensing standards

Completing the HTA licence application form

The information provided in the application form will help to inform the HTA's licensing decision. It is important to provide as much information as possible on the form.

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

Section 1 – Establishment information

HTA licences are premises specific. The licence application must specify the premises where the activities are to take place.

Where licensable activities are undertaken at different locations, one location may be the hub premises and the additional location(s) may be the satellite site(s). In this case, the satellite site section of the application form should also be completed – section 2.

Parent organisation

Provide the name of the parent organisation; for example, this may be the Local Authority or the Local Resilience Forum.

Activities to be licensed

Select the licensed activities to be conducted at the facility.

Proposed Persons Designated (PDs)

The HT Act allows the DI to designate persons on their licence, with their agreement. PDs can support the DI in overseeing licensable activities.

Organisations may wish to consider the following individuals to be PDs on the licence:

- DVI Senior Identification Manager
- Mortuary Operations Manager (Police)
- Mortuary Documentation Manager
- Mortuary Facilities Manager
- Senior Anatomical Pathology Technologist

Synopsis information

Provide a detailed synopsis of the arrangements for the emergency mortuary facility. This should include the following information:

- The activities that will take place at the licensed premises;
- The coroner and police force authorising the activities (where applicable);
- Local Resilience Forum the facility is linked to (where applicable);
- Type of structure and equipment to be used;
- Storage arrangements and capacity (if applying for storage activity);
- Who is providing the structure and facilities, for example are they owned by the Corporate Licence Holder or supplied under contract by a third party;
- An estimate of how long the facility will be required; and,
- How the facility relates to, or interacts with, other establishments, for example links with other establishments for specialist examination.

Section 2 – Satellite sites

Where licensable activities are at different locations, a licence application can be made for a hub and satellite(s) site. Hub and satellite licence arrangements may be used for large or complex emergency mortuary arrangements. Licensable activities at the satellite site should be under the same governance arrangements as the hub site and supervised by the same DI.

If a satellite site is required, complete the satellite site section of the application form and submit this as part of the licence application. The satellite application section of the form must be completed by the DI or the LH.

Persons Designated at the satellite site

There must be a primary PD at each satellite site, who can direct licensable activities at the site and who is accountable to the DI.

Provide details of the primary PD and any additional PDs for the satellite site.

Further information

Provide information of how the satellite site links to governance of the hub site, how the satellite site facility will be used, and relevant further information.

Section 3 – Application to be Designated Individual

The DI has a key role to play in implementing the requirements of the HT Act. They are the person under whose supervision the licensed activity is authorised to be carried out. They have the primary legal responsibility under section 18 of the HT Act to secure:

- That suitable practices are used in undertaking the licensed activity;
- That other persons working under the licence are suitable; and,
- That the conditions of the licence are complied with.

The HT Act is not prescriptive about who should act as the DI. Consider the following points when nominating a suitable person. They should:

- Have some supervisory responsibility over other persons working under the licence;
- Be in a senior enough position to be able to instigate change; and,
- Not be too far removed from the operational aspects of the licensable activities for which they are responsible, thus ensuring that suitable practices are taking place under that licence.

Organisations may wish to consider one of the following individuals to be the DI:

- Mortuary Operations Manager (Police)
- Lead Pathologist
- Mortuary Manager
- DVI Senior Identification Manager

The DI application must be completed by the DI.

If the person is already a DI for another HTA licence, it is not necessary for information to be provided on this application form about education and/or professional qualifications, membership of relevant professional bodies and details of experience.

With regard to the organisational structure of the establishment, indicate the lines of responsibility between the DI and any persons working under the licence

Describe the relationship between the DI, PDs and those working under the licence, as well as the DI's position in the overall governance structure.

The HTA must be satisfied that the DI is able and willing to supervise the licensed activities. The DI should have some supervisory responsibility over other persons working under the licence and be in a position to be able to instigate change.

Involvement in ensuring that staff who will work under the licence are appropriately qualified and training in techniques relevant to their work and that they are continuously updating their skills

The DI must ensure suitable practices are carried out by those undertaking licensed activities; staff training is an important part of this.

Describe the DI's role in ensuring that staff working under the authority of a licence are suitably qualified and trained.

Involvement in governance and quality management activities within the establishment

The DI should not be too far removed from the operational aspects of the licensable activities for which they are responsible, thus ensuring that suitable practices are taking place under that licence.

Describe details of how the DI will be involved in and ensure appropriate activities are taking place, including those that they may not have direct oversight of.

Please explain why you think you are suitable for the role of DI

Provide any further supporting information of suitability for the role of DI.

Declaration

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

Section 4 – Application to be Licence Holder or Corporate Licence Holder

The role of LH does not impose the duties that are expected of the DI; however, it is important to note that they have the right to apply to the HTA to vary the licence. This enables them to substitute another person as the DI when the DI is unable to oversee the licensable activity.

The HTA prefers the LH to be a corporate body, where possible.

Either the 'Application to be Individual Licence Holder' or 'Application to be Corporate Licence Holder' sections of the form should be completed. Establishments applying as a corporate body should provide the contact name of an individual who will act as a representative for the corporate body – the Licence Holder contact. This individual should be more senior than the DI, in order to substitute the DI where necessary.

Declaration

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

Section 5 – HTA licensing standards

As part of the licence application process, the HTA will assess whether the establishment can meet the HTA licensing standards.

Emergency planning teams should liaise with teams that will be involved in managing and running the emergency mortuary, to ensure that the licensing standards will be met.

Guidance on how the licensing standards may be met is provided in Appendix 1. There is additional advice and guidance in [HTA Code of Practice B on PM examination](#)⁶.

Assess compliance with the HTA licensing standards by indicating for each standard:

- N/A – Not applicable
- Standard not met

⁶ HTA Code of Practice B on PM examination: www.hta.gov.uk/hta-codes-practice-and-standards-0

- Standard met

Describe how each standard will be met. If a standard is not met, describe what will be done to rectify this and the timeframe for completing these actions. Where a standard is not applicable, describe why the standard is not applicable to your establishment.

List any supporting documents and who is responsible for them. We do not usually require documented evidence of procedures to be supplied with the application, but we may request these to be submitted at a later date.

Seek advice from the HTA if you require further information or guidance about the licence application form or the HTA licensing standards.

Part 3 – Applying for a HTA licence in an emergency

The relevant licences must be in place before licensable activities commence.

Emergency facilities can be built and body recovery and storage initiated immediately following the emergency. However, it is unlawful to carry out any licensable activities until the relevant HTA licence is granted.

The HTA should be notified in the event that a licence is required for an emergency mortuary facility. To apply for a HTA licence:

Please call 020 7269 1900

The team will give you details of who to submit the form to. We may request additional information and conduct a visual inspection of the facility. Where we assess that not all of the applicable standards are met, actions to address shortfalls should be agreed.

The following requirements need to be met before a licence can be issued:

- We must have received a licence application form
- We must be satisfied that the proposed DI is a suitable person
- We must be satisfied that the proposed LH is a suitable person/entity
- We must be satisfied that the premises are suitable
- The licence and conditions must be acknowledged in writing by the DI and LH

There is a statutory 28 day period to acknowledge the licence. Licensable activities can commence once the HTA confirms receipt of the written acknowledgments from the DI and LH. A substantive licence will then be issued.

Representations

The applicant has the right to ask the HTA to reconsider a licensing decision, provided they give written notice within 28 days of being notified of the original decision.

This is in the form of representations. Further information is provided on the [HTA website](#)⁷.

Further information

The following links to the HTA website are referenced in this guidance document:

- Emergency mortuary licence application form:
www.hta.gov.uk/policies/emergency-mortuaries.
- HTA Code of Practice B on PM examination:
www.hta.gov.uk/hta-codes-practice-and-standards-0
- Information on HTA Reportable Incidents:
www.hta.gov.uk/policies/post-mortem-hta-reportable-incidents
- Information on relevant material:
www.hta.gov.uk/policies/relevant-material-under-human-tissue-act-2004
- Information for DIs and named contacts:
www.hta.gov.uk/useful-information-dis-and-named-contacts-0
- Representations process:
www.hta.gov.uk/policies/how-challenge-hta-licensing-decision

Please refer to the glossary in Appendix 2 for the definition of commonly used terms.

⁷ Representations process: www.hta.gov.uk/policies/how-challenge-hta-licensing-decision

Appendix 1 – HTA licensing standards and guidance

The licensing standards are detailed below, as they apply to emergency mortuaries undertaking each licensed activity. Licensing standards that are not applicable to emergency mortuaries are not included in this document.

The making of a PM examination	PM
The storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose	S
The removal from the body of a deceased person (otherwise than in the course of an anatomical examination or a PM examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose.	R

Seek advice from the HTA if you require further information or guidance about the licensing standards.

Consent The HTA standards for consent apply to PM examination and removal activities, unless the activity is conducted under coronial or police authority.	
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	
<p>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.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>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 samples. 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.</i></p>	<p>PM, R</p>
<p>b) There is a documented standard operating procedure (SOP) detailing the consent process.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>This should include:</i></p> <ul style="list-style-type: none"> • <i>who is able to seek consent and what training they should receive;</i> • <i>who can give consent for post-mortem examination, removal of relevant material from the deceased and the retention of samples (references to the 'Next of Kin' should be avoided);</i> • <i>what information should be provided to those giving consent for post-mortem examination, removal of relevant material from the deceased and the retention of samples.</i> <p><i>The SOP should reference the use of scanning as an alternative or adjunct to post-mortem examination, where this is available.</i></p> <p><i>HTA Code of Practice B contains guidance for establishments on seeking consent for post-mortem examination.</i></p>	<p>PM, R</p>
<p><i>HTA Code of Practice B contains guidance for establishments on seeking consent for post-mortem examination.</i></p>	<p>PM, R</p>

<p>c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's Codes of Practice.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>Information should include who can give consent for post-mortem examination, removal of relevant material from the deceased and the retention of samples. 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.</i></p> <p><i>Information on consent should be available in different languages and formats, or there should be access to interpreters/translators. Family members should be given the opportunity to ask questions.</i></p> <p>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.</p> <p>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.</p> <p>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.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>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.</i></p> <p><i>There may be specific occasions where a shorter timeframe is agreed with the family. This should be discussed with the family and documented.</i></p> <p>g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided.</p> <p><i>Guidance for emergency mortuaries</i></p>	<p>PM, R</p> <p>PM, R</p> <p>PM, R</p> <p>PM, R</p>
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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. 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	
<p>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.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>Anyone seeking consent for post-mortem examination and tissue retention should have relevant experience and a good understanding of the consent procedure.</i></p>	PM, R
<p>b) Records demonstrate up-to-date staff training.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>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).</i></p>	PM, R
<p>c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual.</p>	PM, R
<p>d) Competency is assessed and maintained.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>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).</i></p>	PM, R

Governance and quality systems	
GQ1 All aspects of the establishment's work are governed by documented policies and procedures	
<p>a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant</p>	PM, S, R

<p>Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPATH. These include:</p> <ol style="list-style-type: none">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. <p><i>Guidance for emergency mortuaries</i></p> <p><i>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 July 2018). Individual</i></p>	
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<p><i>SOPs for each activity are not required. Some SOPs will cover more than one activity.</i></p> <p>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.</p> <p>c) Procedures on body storage prevent practices that disregard the dignity of the deceased.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>Practices such as placing more than one body on a tray, placing bodies unshrouded on trays, or storing bodies in unrefrigerated storage should not take place.</i></p> <p><i>The family's permission should be obtained for any 'cosmetic' adjustments or other invasive procedures prior to release of bodies. 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.</i></p> <p><i>If identification of the body is to take place before a post-mortem examination, if available, a Police Family Liaison or Coroner's Officer should have a discussion with the family about the injuries and let them know that reconstruction may be required.</i></p> <p><i>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.</i></p> <p>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.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>Emergency plans may need to be reviewed regularly and changed accordingly. Policies and procedures that govern the activity in the mortuary should also be reviewed regularly.</i></p> <p>e) There is a system for recording that staff have read and understood the latest versions of these documents.</p>	<p>PM</p> <p>S</p> <p>PM, S, R</p> <p>PM, S, R</p>
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<p><i>Guidance for emergency mortuaries</i></p> <p><i>This includes all staff who undertake licensed activities, including portering staff, site managers and funeral directors who carry out mortuary activities.</i></p> <p>f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity.</p> <p>g) All areas where activities are carried out under an HTA licence are incorporated within the establishment’s governance framework.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>There should be an identified Person Designated in each area of the establishment where licensed activities take place.</i></p> <p><i>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.</i></p> <p>h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>The DI should have regular debriefs with the emergency mortuary team.</i></p>	<p>PM, S, R</p> <p>PM, S, R</p> <p>PM, S, R</p>
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GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks	
<p>a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>This includes staff who have responsibility for bringing bodies into the mortuary and who may not be aware of the potential risks to the deceased during transfer into refrigerated storage.</i></p>	PM, S, R
<p>b) There are clear reporting lines and accountability.</p> <p>c) Staff are assessed as competent for the tasks they perform.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>This includes all staff who undertake mortuary activities, including portering staff, site managers and funeral directors who may carry out mortuary activities.</i></p> <p><i>Assessment of competence should include the standard of APTs' reconstruction work.</i></p>	PM, S, R PM, S, R
<p>f) There is a documented induction and training programme for new mortuary staff.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>This will be specific to each facility and staff should be familiar with processes before starting work.</i></p>	PM, S, R
<p>g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>The qualifications of staff should be checked prior to them commencing work in the mortuary and their competency to undertake each task should be assessed.</i></p> <p><i>Contractors, visiting and temporary staff and funeral service staff bringing bodies out of hours should be required to read relevant SOPs and sign to confirm their understanding.</i></p>	PM, S, R

<p>GQ4 There is a systematic and planned approach to the management of records</p>	
<p>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.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>Records include mortuary registers, PM examination records, tissue retention forms and records of transfer and return of organs/tissue sent elsewhere for examination.</i></p>	<p>PM, S, R</p>
<p>b) There are documented SOPs for record management which include how errors in written records should be corrected.</p>	<p>PM, S, R</p>
<p>c) Systems ensure data protection, confidentiality and public disclosure (whistleblowing).</p>	<p>PM, S, R</p>
<p>GQ5 There are systems to ensure that all untoward incidents are investigated promptly</p>	
<p>a) Staff know how to identify and report incidents, including those that must be reported to the HTA.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>HTA reportable incidents (HTARIs) and near-miss HTARIs must be reported within five working days of the incident occurring or being discovered. Establishments must not wait until any internal review or investigation is complete before notifying the HTA of the HTARI. Person Designated should register for a HTA Portal account, to ensure that HTARIs can be reported to the HTA within the required timescale in the absence of the Designated Individual.</i></p> <p><i>The HTARI reporting requirements and process for reporting incidents should be documented in a standard operating procedure.</i></p>	<p>PM, S, R</p>

<p><i>All staff involved in licensable activities should be aware of the HTARI reporting requirements and procedure.</i></p> <p><i>Incidents that do not fall within the HTARI reporting requirements should be reported and investigated internally.</i></p> <p>b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents.</p> <p>c) The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.</p> <p>d) Information about incidents is shared with all staff to avoid repeat errors.</p> <p>e) e) The establishment adopts a policy of candour when dealing with serious incidents.</p>	<p>PM, S, R</p> <p>PM, S, R</p> <p>PM, S, R</p> <p>PM, S, R</p>
<p>GQ6 Risk assessments of the establishment’s practices and processes are completed regularly, recorded and monitored</p>	
<p>a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>Risk assessments should be reviewed once the mortuary is set up and at regular intervals thereafter and when circumstances change. Staff should be involved in the risk assessment process and should be aware of the risks associated with the activities they undertake.</i></p> <p><i>Risks to the dignity and integrity of bodies and stored tissue should be covered. This should include risks to the security of the facility. The HTARI categories provide a good basis for risk assessments.</i></p> <p>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.</p> <p><i>Guidance for emergency mortuaries</i></p>	<p>PM, S, R</p> <p>PM, S, R</p>

<p><i>and which are subsequently returned before release to funeral service staff.</i></p> <p>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.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>This licensing standard aims to ensure that identification procedures are robust.</i></p> <p><u><i>Any deviation from documented procedures should be considered on a case-by-case basis, escalated internally (for example, to the mortuary manager) and documented.</i></u></p> <p><i>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. This may be done in accordance with the disaster victim recovery process. Age is not considered to be robust as an identifier; date of birth should be used wherever possible.</i></p> <p><i>Where there are fewer than three identifiers on a body, enquiries should be made to obtain a minimum of three identifiers, wherever possible. In cases where the identity of the deceased is unknown, information such as mortuary register number, date of admission to the mortuary and place of death may be used whilst enquiries are ongoing. It is good practice to obtain this information in writing and keep it with the deceased's mortuary record. The additional identifiers should be added to existing or additional identification bands on the body.</i></p> <p><i>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.</i></p> <p><u><i>Identification for post-mortem examination or removal of relevant material from the deceased:</i></u> <i>A minimum of three identifiers of the deceased on the body should be checked against post-mortem</i></p>	<p>PM, S, R</p>
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<p><i>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.</i></p> <p><i><u>Identification for viewings:</u> 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.</i></p> <p><i><u>Identification for release from the mortuary:</u> 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 mortuary release form).</i></p>	<p>PM, S, R</p>
<p>d) There is system for flagging up same or similar names of the deceased.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>This should consider the sound and spelling of forenames and surnames. 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.</i></p>	<p>PM, S, R</p>
<p>e) Identity checks take place each time a body is moved whether inside the mortuary or from the mortuary to other premises.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>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.</i></p>	<p>PM, R</p>

<p><i>Fridge/freezer failures that require bodies to be moved temporarily whilst repairs take place present a risk to traceability. Full identification checks should be made when bodies are placed back into normal storage.</i></p> <p><i>Checks should be made to ensure that identification bands on bodies are accessible when bodies are transferred into freezer storage.</i></p> <p>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:</p> <ul style="list-style-type: none">i. material sent for analysis on or off-site, including confirmation of arrivalii. receipt upon return to the laboratory or mortuaryiii. the number of blocks and slides madeiv. repatriation with the bodyv. return for burial or cremationvi. disposal or retention for future use. <p><i>Guidance for emergency mortuaries</i></p> <p><i>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.</i></p> <p>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.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>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.</i></p>	S
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Premises, facilities and equipment	
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue	
<p>a) The premises are clean and well maintained.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>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.</i></p> <p>b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors.</p> <p>c) There are documented cleaning and decontamination procedures and a schedule of cleaning.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>There should be records of cleaning and decontamination.</i></p> <p>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).</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>Security arrangements should consider the risk of media intrusion.</i></p> <p><i>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.</i></p> <p>e) Security arrangements protect against unauthorised access and ensure oversight of visitors and contractors who have a legitimate right of access.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>Consideration should be given as part of the planning process in order to ensure dignity of the deceased and reduce the risk of media intrusion.</i></p>	<p>PM, S, R</p> <p>PM, S, R</p> <p>PM, S, R</p> <p>PM, S, R</p> <p>PM, S, R</p>

<p><i>Swipe card access lists should be reviewed regularly.</i></p> <p><i>Staff and authorised visitors and contractors should be aware of the establishment's security arrangements.</i></p>	
<p>PFE2 There are appropriate facilities for the storage of bodies and human tissue</p>	
<p>a) Storage arrangements ensure the dignity of the deceased.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>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.</i></p> <p><i>The Health and Safety Executive's document: 'Managing infection risks when handling the deceased' (HSG283, published July 2018) includes guidance on storage of bodies.</i></p> <p>b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>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.</i></p> <p>c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>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</i></p>	<p>S</p> <p>S, R</p> <p>S</p>

<p><i>should be checked regularly; this should include confirmation of their identity and the reason for their continued storage.</i></p> <p><i>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.</i></p> <p>d) Fridge and freezer units are in good working condition and well maintained.</p> <p>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.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>The HTA recognises that emergency mortuary facilities may not have temperature alarm systems. In these cases, a risk-based approach should be taken to ensure temperatures of fridges and freezers are monitored on a regular basis. Staff should be aware of the acceptable temperature ranges and what do if the temperature deviates from the accepted range.</i></p> <p>f) Temperatures of fridges and freezers are monitored on a regular basis.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>Temperature monitoring should enable the establishment to identify trends and may mitigate the risk of a possible fridge failure.</i></p> <p>g) Bodies are shrouded or in body bags whilst in storage.</p> <p>h) There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.</p> <p>i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods.</p> <p><i>Guidance for emergency mortuaries</i></p>	<p>S</p> <p>S</p> <p>S</p> <p>S</p> <p>S</p> <p>S</p> <p>PM, S</p>
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<p><i>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).</i></p> <p><i>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.</i></p> <p><i>Relevant staff should be notified of servicing and have access to service records.</i></p> <p>d) Staff have access to necessary PPE.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>Refer to guidance from Public Health England for PPE requirements.</i></p> <p>e) Where chemicals are used for preservation of tissue samples, there is adequate ventilation.</p> <p>f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept.</p> <p><i>Guidance for emergency mortuaries</i></p> <p><i>Relevant staff should be notified of servicing and have access to service records.</i></p>	<p>PM, S, R</p> <p>PM</p> <p>PM, S, R</p>
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Appendix 2 – Glossary

Term	HTA definition
Code of Practice	<p>The HTA Codes of Practice aim to provide anyone undertaking licensable activities with a reference source which gives practical advice on the minimum steps necessary to comply with the relevant legislation and HTA licensing standards.</p> <p>The Codes of Practice are available on the HTA website.</p>
Coroner	<p>Coroners are independent judicial office holders, appointed by a local council. They investigate deaths that have been reported to them if it appears that the death was violent or unnatural, the cause of death is unknown or the person died in prison, police custody, or another type of state detention. In these cases, coroners must investigate to find out, for the benefit of bereaved people and for official records, who has died and how, when, and where they died. As part of their duties, coroners authorise post-mortem examinations and conduct inquests.</p>
Designated Individual (DI)	<p>The person named on 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.</p>
HTA Reportable Incident (HTARI)	<p>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 can be found on the HTA website.</p>
Licence Holder (LH)	<p>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.</p>
Licensed premises	<p>Where the licensed activity takes place.</p>

Term	HTA definition
Licensing	<p>A number of activities can only be carried out when an establishment is licensed under the HT Act by the HTA. Organisations whose activities involve the removal, storage or use of relevant material may need to work under a HTA licence. All establishments working under a HTA licence must work to specified licensing standards set by the HTA.</p>
Person designated (PD)	<p>A person working under an HTA licence acting under the direction of the Designated Individual.</p>
Post-mortem cross-sectional imaging (PMCSI)	<p>Post-mortem computed tomography (PMCT) or post-mortem magnetic resonance (PMMR), which may be used instead of, or as an adjunct to post-mortem examination, to determine the cause of death. It provides a three-dimensional image of the patient's internal organs and structure, particularly of the soft tissues.</p>
Post-mortem (PM) examination	<p>Dissection and examination of a body after death, principally in order to determine the cause of death or the presence of disease processes.</p> <p>A hospital post-mortem examination is carried out with appropriate consent from relatives to gain a fuller understanding of the deceased person's illness or the cause of death, and to enhance future medical care.</p> <p>Coroners' post-mortem examinations are carried out under the authority of the coroner, without consent being required from the relatives, to assist coroners in carrying out their functions.</p>
Relevant material	<p>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.</p>

Term	HTA definition
Scheduled purpose	Under the HT Act, consent must be obtained to remove, store and use bodies or relevant material for scheduled purposes. The licensing requirements of the HT Act also refer to the scheduled purposes.
Service Level Agreement (SLA)	A formal agreement that sets out the roles and responsibilities of two parties.
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.