

Directions given under the Human Tissue Act 2004

Ref: 004/2023

Legislation providing for these Directions: Sections 23 and 37 Human Tissue Act 2004

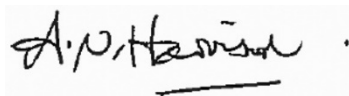
These Directions take effect from: 10 November 2023

These Directions remain in force: Until further notice by the Human Tissue Authority

1. These directions are given in relation to Human Tissue Act (HTA) licences issued to establishments undertaking storage of the body of a deceased person for use for the scheduled purpose of determining the cause of death.
2. The Directions are made for the purpose of securing compliance with the following standards from HTA Code B Post-mortem Examination Standards and guidance version 3: GQ1(a) (xiv); GQ1(c); GQ6(a); PFE2(a), (b), (c), (h), and (i).

The HTA DIRECTS that all Designated Individuals undertake the following as soon as possible and by no later than 24 November 2023:

1. Review your documented contingency plan in place for body storage and ensure all staff undertaking licensable activities are fully aware of contingency arrangements and procedures.
2. Review all documented policies, SOPs, SLAs and MOUs relating to contingency storage arrangements.
3. Update your risk assessments in respect of:
 - (i) the suitability, location and security of stand-alone temporary storage units
 - (ii) the suitability, location and security of external contingency storage arrangements
 - (iii) internal storage arrangements and capacity
4. Escalate concerns, relating to the sufficiency of storage space as well as capacity to meet both current requirements and anticipated peaks in activity over the winter period, to Senior Leadership Teams.
5. Review your documented processes for the expediting of the release of the deceased.
6. Review your documented procedures for the management of long-stay deceased to include condition checking and confirmation of timing for transfer to frozen storage.
7. Ensure fridges and freezers are up to date with service and maintenance requirements, escalating any concerns to Senior Leadership Teams in relation to suitability and efficiency.
8. Ensure any temporary units are appropriately temperature controlled and alarmed.



Nicolette Harrison
Director of Regulation

10 November 2023