

Directions given under the Human Tissue Act 2004

Directions relating to the making of a post mortem examination; the removal from the body of a deceased person (otherwise than in the course of carrying out an anatomical examination or making a post mortem) of relevant material, for use for a Scheduled Purpose other than transplantation; and 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.

Ref 002/2010

These Directions are

General Directions

Sections of the Human Tissue Act 2004 (HT Act) providing for these Directions

Sections 23 and 37

These Directions come into force

30 April 2010

These Directions remain in force

31 December 2010

1. These Directions are given in relation to licences issued to post mortem sector establishments under Sections 16(2)(b), (c) and (e) of the HT Act, and are made for the purpose of securing compliance with the requirements of the HT Act, in particular the HTA standards against which compliance with the requirements of the HT Act is evaluated.
2. HTA standards are related to consent; governance and quality systems; premises, facilities and equipment; and disposal.
3. These Directions set out two exercises which licensed post mortem sector establishments are required to undertake in relation to relevant material removed from deceased persons during post mortem examination.
4. Rationale for these exercises is provided in the accompanying letter, which must be read in conjunction with these Directions.

Inventory of whole organs and wet tissues

5. The purposes of the inventory are to identify all organs and items of wet tissue removed from the body of a deceased person since the commencement of the HT Act in September 2006 that are currently retained at licensed post mortem premises, and to identify and check documentation which verifies the reason(s) for retention.
6. Relevant material which was removed from deceased persons prior to the commencement of the HT Act in September 2006 falls outside the remit of the HTA, and is therefore not included in these Directions.
7. For the purposes of these Directions, 'whole organs' are defined as all visceral organs, brains, and whole fetuses over 24 weeks gestational age; 'wet tissue' is defined as samples of visceral organs, brains, limbs, bone and fetal tissue over 24 weeks gestational age.
8. Detailed instructions for completing the inventory, a model form for record-keeping and a results summary form for submission to the HTA are provided in a separate document which should be read in conjunction with these Directions.
<http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/htalegaldirections.cfm>
9. Records created during the inventory process must be retained and produced for review on request by the HTA.
10. Establishments must report a summary of the inventory to the HTA using the template form provided on the HTA website.
11. Establishments have until 30 September 2010 to submit the results summary to the HTA.

Audit of cases where relevant material removed from a deceased person was processed into tissue blocks and slides

12. The purpose of the audit is to review a representative sample of completed cases where organs and/or tissue were retained as part of the post mortem examination, and will include review of records and documentation which provide traceability and verify reason(s) for retention and/or disposal.
13. Detailed instructions for completing the audit of cases where relevant material removed from a deceased person, a model form for record-keeping and a results summary form for submission to the HTA are provided in a separate document.
[\[http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/htalegaldirections.cfm\]](http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/htalegaldirections.cfm)
14. Records created during the audit process must be retained and produced for review on request by the HTA.

15. Establishments have until 30 September 2010 to submit the results summary to the HTA.

16. These Directions are made by the HTA.

Dated 30 April 2010

Signed

A handwritten signature in black ink, appearing to read 'Adrian McNeil', with a small comma at the end.

Adrian McNeil
Chief Executive
Human Tissue Authority