

## 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 001/2010**

**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**

Until revoked

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 the requirement for licensed post mortem sector establishments to submit an annual report relating to current compliance with HTA standards.
4. Rationale for these exercises is provided in the accompanying letter, which must be read in conjunction with these Directions.

## Compliance self-assessment report

5. The purposes of the compliance self-assessment exercise are
  - a. to obtain up to date information regarding establishment compliance with HTA standards;
  - b. to ensure Designated Individuals understand how to evaluate whether their establishment is compliant with HTA standards. For this reason, establishments which have recently been inspected by the HTA are still required to complete this exercise.
6. Detailed instructions for completing a self-assessment report which ranks compliance against HTA standards, including examples of evidence of compliance and an evidence summary form, are provided in a separate document.  
<http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/htalegaldirections.cfm>
7. A completed compliance report and a summary of the evidence on which the compliance ratings are based must be submitted to the HTA.
8. Establishments have until 30 June 2010 to submit the first compliance report and evidence summary form to the HTA. Establishments are subsequently required to submit annual compliance reports and evidence summaries to the HTA no later than 30 June each year.
9. These Directions are made by the HTA.

Dated 30 April 2010

Signed



**Adrian McNeil**  
Chief Executive  
Human Tissue Authority