

Directions given under the Human Tissue Act 2004 implementing the Human Tissue (Quality and Safety for Human Application) Regulations 2007

Directions relating to licences granted under the Human Tissue (Quality and Safety for Human application) Regulations 2007

Ref 003/2010

These Directions are

General Directions

Sections of the Human Tissue Act 2004 providing for these Directions

Sections 23 and Schedule 3 paragraph 2 (5)

Regulations under the Human Tissue (Quality and Safety for Human Application) Regulations 2007

Regulation 16

These Directions come into force

12 November 2010

These Directions remain in force

Until revoked or superseded

1. These Directions are given in relation to Human Tissue Authority (HTA) licences issued to establishments storing tissues and/or cells for human application under Regulation 7(1) of the Human Tissue (Quality and Safety for Human Application) Regulations) 2007 and licences and / or third party agreements authorising the carrying out of procurement, testing, processing, distribution , import or export of tissues and/ or cells for human application under Regulation 7(2) of the Regulations.
2. The Directions are made for the purpose of securing adherence to the standards required under the European Tissues and Cells Directive (2004/23/EC) and the technical Directives 2006/17/EC and 2006/86/EC.

Implementation of the Guide for Quality and Safety Assurance for Human Tissues and Cells for Patient Treatments

3. These Directions implement the HTA consolidated requirements for human application licences and third party agreements. The requirements are set

out in the “Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment” which forms the Annex to these Directions. The Guide will be the primary reference for establishments and will be subject to periodic updates.

Revocation of HTA Directions 001/2006, 002/2007 and 004/2007

4. The Guide represents the consolidated, clarified and updated guidance given previously in HTA Directions for the sector. Directions 001/2006, 002/2007 and 004/2007 are therefore no longer required and are revoked.

Dated 12 November 2010

Signed



Liz McAnulty
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