

Guidelines for the Blood Transfusion Services

19.1: Regulatory environment in the UK

<http://www.transfusionsguidelines.org/red-book/chapter-19-tissue-banking-general-principles/19-1-regulatory-environment-in-the-uk>

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The whole process of tissue banking is now covered by legislation. The EU Directive on Tissues and Cells and its associated Commission Directives were transposed into UK law as the Human Tissue (Quality and Safety for Human Application) Regulations 2007, (as amended), referred to as the Quality & Safety Regulations.¹ These regulations lay down standards of quality and safety for all aspects of banking of human tissues and cells intended for human applications. The UK retained the same quality and safety standards after 1 January 2021.

In addition, the Human Tissue Act 2004² applies throughout the UK with the exception of Scotland, where the Human Tissue (Scotland) Act 2006³ applies, and the Human Transplantation Act (Wales) 2013⁴ applies in Wales.

All Tissue Establishments need to be licensed by the 'Competent Authority', which in the case of the UK is the Human Tissue Authority (HTA). Under the Human Tissue Act the HTA issues its expected standards in the form of 'Directions'⁵ and 'Codes of Practice'⁶ to Tissue Establishments. HTA expected standards are contained in the Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment⁵ which is implemented via Directions and is periodically updated.

Every Tissue Establishment must designate a responsible person (termed the Designated Individual) who shall be responsible for ensuring that all activities relating to human tissues and cells intended for human application are in accordance with the laws in force in the UK. It is therefore the responsibility of the Designated Individual to ensure that all the requirements of the HTA are met in a timely and comprehensive manner. The Designated Individual may if necessary, delegate some of these responsibilities to appropriately trained and qualified individuals (Persons Designate), for example if the Tissue Establishment is located on multiple sites.