

Guidelines for the Blood Transfusion Services

2.8: References

<http://transfusionguidelines.org/red-book/chapter-2-quality-in-blood-and-tissue-establishments-and-hospital-blood-banks/2-8-references>

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1. Statutory Instrument 2005 No. 50. The Blood Safety and Quality Regulations 2005. Available at www.legislation.gov.uk
2. Statutory Instrument 2007 No. 1523. The Human Tissue (Quality and Safety for Human Application) Regulations 2007. Available at www.legislation.gov.uk
3. Commission Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC. OJ, L 33, 08.02.2003, p. 30.
4. Commission Directive 2004/33/EC implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components. OJ, L 91, 30.03.2004, p. 25.
5. Commission Directive 2005/61/EC implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events. OJ, L 256, 01.10.05, p. 32.
6. Commission Directive 2005/62/EC implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments. OJ, L 256, 01.10.05, p. 41.
7. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices'. OJ, L 331, 07.12.1998, p. 1.
8. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. OJ, L 169, 12.7.1993, p. 1–43.
9. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 201/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. OJ, L 117, 05.05.2017, p.1-175
10. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU. OJ, L 117, 05.05.2017, p.175-332.
11. Human Tissue Act 2004. Available at www.legislation.gov.uk/ukpga/2004/30/pdfs/ukpga_20040030_en.pdf
12. Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. OJ, L 102, 07.04.2004, p. 48.
13. Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells. OJ, L 038, 09.02.2006, p. 40.
14. Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells. OJ, L 294, 25.10.2006, p. 32.

15. Commission Directive 2012/39/EU of 26 November 2012 amending Directive 2006/17/EC as regards certain technical requirements for the testing of human tissues and cells. OJ, L 327, 27.11.12, p. 24-25.
16. Human Tissue Authority, Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment. Available at www.hta.gov.uk
17. Medicines and Healthcare products Regulatory Agency (2007). Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2007. London: Pharmaceutical Press.
18. EC Guidelines to Good Manufacturing Practice. Available at http://ec.europa.eu/health/documents/eudralex/vol-4/index_en.htm
19. Commission Directive (EU) 2016/1214 of July 2016 amending Directive 2005/62/EC as regards quality system standards and specifications for blood establishments. OJ, L 199, 26.7.16, p. 14-15.
20. Council of Europe (2013). Guide to the Preparation, Use and Quality Assurance of Blood Components, 17th edition, Appendix 1.
21. NHS London (2007). Serious Untoward Incident Guidance. www.london.nhs.uk/webfiles/tools%20and%20resources/NHSL_SUI_Guidance.pdf