JPAC Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee

PDF Generated
25/04/2025 17:08

Guidelines for the Blood Transfusion Services

2.3: Other standards

http://www.transfusionguidelines.org/red-book/chapter-2-quality-in-blood-and-tissue-establishments-and-hospital-blood-banks/2-3-other-standards

2.3: Other standards

There are a number of other standards that help define how a quality management system should be designed to meet the needs of a particular aspect of a Service's work. Table 2.1 provides information on some key standards inspection, licensing, accreditation and certification.

They are all applicable within England. Some apply directly to the whole of the UK (e.g. the International Standards), others to England and Wales (e.g. the NHS Litigation Authority Risk management assessment programme). Where there is not a direct cross-reference the reader should investigate further to determine how the standards might apply.

All the primary sources cited here are places where sound advice on management systems to address the various requirements of a modern Blood Service can be found. These will support the design and establishment of a system that can be confidently subjected to an external inspection process. The list is not intended to be exhaustive and by the nature of change is only current at the time of publication. It is for this reason version numbering has not been applied to the available standards; they will be constantly updated.

Table 2.1 List of some key inspection/licensing/accreditation/certification standards

Key standards	Applicable to	Responsible body	Website
Caldicott Report 1997, implementation 1998	Confidentiality of patient data	Department of Health	www.dh.gov.uk
Care Quality Commission Fundamental Standards 2014	Health and social care services in England	Care Quality Commission	www.cqc.org.uk
Health and Care Standards 2015	Healthcare in Wales	Healthcare Inspectorate Wales	www.hiw.org.uk
Health and Social Care Standards 2017	Care and treatment delivered by NHS Scotland	NHS Quality Improvement Scotland	www.nes.scot.nhs.uk

Quality standards for health and social care 2006	The availability and quality of health and social care services in Northern Ireland	The Regulation and Quality Improvement Authority, Department of Health, Northern Ireland	www.rqia.org.uk
European Foundation for Quality Management (EFQM) Self-Assessment	Measurement of the effectiveness and, over time, the improvement in a Blood Service's management system. Helping understand where they are on the path to excellence	British Quality Foundation	www.bqf.org.uk www.efqm.org
European Blood Inspection System (EuBIS)	The safety of blood transfusion in Europe	Institut für Transfusionsmedizin und Immunhämatologie	www.eubis-europe.eu
Standards for Histocompatibility & Immunogenetics Testing	Histocompatibility and Immunology (H&I) – reference and tissue typing	European Federation for Immunogenetics (EFI)	www.efiweb.eu
The Data Protection Act UK General Data Protection	Protection regarding processing of personal data of UK residents	Information Commissioner's Office	www.ico.org.uk
General Data Protection Regulation	Protection regarding processing of personal data of EU residents	EU Commission	www.eugdpr.org
Good Automated Manufacturing Practice (GAMP) Guide for Validation of Automated Systems in Pharmaceutical Manufacture	Validation of computer systems	International Society for Pharmaceutical Engineering	www.ispe.org
Good Manufacturing Practice (GMP) guidelines	Pharmaceutical environments	The European Commission publishes this online as EudraLex Volume 4	https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

HTA Directions 011/2021 – the standards required under the Human Tissue (Quality and Safety of Tissues and Cells for Human Application) Regulations 2007 HTA Codes of Practice	Quality and Safety Assurance for Human Tissue and Cells for Patient Treatment	Human Tissue Authority	www.hta.gov.uk
International standards for unrelated haematopoietic stem cell donor registries WMDA Accreditation Programme	Stem cell and donor registries	World Marrow Donor Association (WMDA)	www.worldmarrow.org
ISO 15189 Medical Laboratories - requirements for quality and competence	Medical laboratories	UKAS	www.ukas.com
ISO 17799 Information Security Management	Information security	BSI British Standards	www.bsigroup.com
ISO 9000 2000 and ISO 9001 2008 Quality management system requirements	Quality management system	BSI British Standards	www.bsigroup.com
ISO 20000 IT Service Management Standard	Service management	BSI British Standards	www.bsigroup.com
ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purposes	Management of medical devices	BSI British Standards	www.bsigroup.com
Joint Accreditation ICT Europe and EBMT (JACIE) assessment standard	Stem Cell Immunology – Human Progenitor Cells (SCI – HPC) collection, processing and storage	The Joint Accreditation Committee ISCT & EBMT (JACIE)	www.ebmt.org
NHSLA risk management assessment programme for NHS Trusts	Management of claims and litigation	National Health Service Litigation Authority	www.nhsla.com

PRINCE2	Project control	Cabinet Office	www.gov.uk/government/publications/best-management-practice-portfolio/