Guidelines for the Blood Transfusion Services

2.5: Application of a quality management system

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2.5: Application of a quality management system

2.5.1: Blood Establishments

Blood Establishments are required under Directive 2005/62/EC[7] to implement EC standards and specifications relating to a quality system for Blood Establishments, taking fully into account the principles of GMP. Commission Directive (EU) 2016/1214 of 25 July 2016 amended Directive 2005/62/EC as regards quality system standards and specifications for blood establishments.[19] This replaced article 2 with the requirement that systems should be developed taking into account the Good Practice Guidelines jointly developed by the Commission and the European Directorate for the Quality of Medicines and Healthcare of the Council of Europe and published by the Council of Europe.[20]

The approach we have taken in this chapter is to outline the requirements of a quality management system in the context of the collection, processing, testing, storage and distribution of blood and blood components and tissues.

In addition, Blood Establishments should ensure they are compliant with the specific standards identified within the Blood Safety and Quality Regulations 2005[1] and other relevant standards and guidelines. These elements of the quality management system can be adapted to support other activities that a Blood Establishment may undertake, such as diagnostic testing and reagent production.

Blood Establishments are required to obtain a Blood Establishment Authorisation from MHRA before operating and to ensure that it is maintained through inspections scheduled every 2 years.

2.5.2: Hospital blood banks

Hospital blood banks are required to comply with the elements of the quality system outlined below relevant to their activities (see section 2.6). In addition, they must:

- Maintain donor to recipient traceability. Specifically BSQR (SI 2005 No.50) Regulation 9 (1)(e) requires hospital transfusion laboratories to ‘maintain, for not less than 30 years, the data needed to ensure full traceability of blood and blood components, from the point of receipt of the blood or blood component by the hospital blood bank’.

- Undertake mandatory reporting of serious adverse events and serious adverse reactions related to transfusion to the Competent Authority. Specifically BSQR (SI 2005 No. 50) Regulation (1)(f) and Regulation 12B, Directive 2005/62 Annex, section 9.2 requires that ‘there are procedures in place for quality assurance within the transfusion laboratory – Reporting Serious Adverse Events (SAE) and Serious Adverse Reactions (SAR)’.

- Complete an annual form, the Blood Compliance Report, developed by the MHRA, in which the laboratory indicates its compliance with the regulations. The form is reviewed by the Inspectorate division of the MHRA and those laboratories where there is deemed non-compliance are inspected as ‘for cause’ inspections. There may also be some control inspections undertaken to verify the use of the Blood Compliance Report and its completion.

- Establish their bona fides with the supplying Blood Establishment and sign a service level agreement between both parties to outline how compliance will be achieved. This must be done before a hospital blood bank can operate.

2.5.3: Tissue and cell establishments

These establishments should also operate a quality system that reflects the requirements below (section 2.6). The Tissues and Cells Directives are not as explicit on the requirements of a quality management system as the Blood Safety and Quality Directives and a quality system in the context of the Tissues and Cells Directives consists of the following elements: the organisational structure, defined responsibilities, procedures, processes, and resources for implementing quality management, and includes all activities which contribute to quality, directly or indirectly. Experience has shown that the elements below are effective in maintaining quality and safety in the procurement and supply of tissues and cells.