Commission Directive 2005/62/EC of 30 September 2005 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 (Text with EEA relevance)

Article 1

Definitions

For the purposes of this Directive, the following definitions shall apply:

(a) 'standard' means the requirements that serve as the basis for comparison;

(b) 'specification' means a description of the criteria that must be fulfilled in order to achieve the required quality standard;

(c) 'quality system' means the organisational structure, responsibilities, procedures, processes, and resources for implementing quality management;

(d) 'quality management' means the co-ordinated activities to direct and control an organisation with regard to quality at all levels within the blood establishment;

(e) 'quality control' means part of a quality system focussed on fulfilling quality requirements;

(f) 'quality assurance' means all the activities from blood collection to distribution made with the object of ensuring that blood and blood components are of the quality required for their intended use;

(g) 'trace-back' means the process of investigating a report of a suspected transfusion-associated adverse reaction in a recipient in order to identify a potentially implicated donor;

(h) 'written procedures' means controlled documents that describe how specified operations are to be carried out;

(i) 'mobile site' means a temporary or movable place used for the collection of blood and blood components which is in a location outside of but under the control of the blood establishment;

(j) 'processing' means any step in the preparation of a blood component that is carried out between the collection of blood and the issuing of a blood component;

(k) 'good practice' means all elements in established practice that collectively will lead to final blood or blood components that consistently meet predefined specifications and compliance with defined regulations;

(l) 'quarantine' means the physical isolation of blood components or incoming materials/reagents over a variable period of time while awaiting acceptance, issuance or rejection of the blood components or incoming materials/reagents;

(m) 'validation' means the establishment of documented and objective evidence that the pre-defined requirements for a specific procedure or process can be consistently fulfilled;

(n) ‘qualification’, as part of validation, means the action of verifying that any personnel, premises, equipment or material works correctly and delivers the expected results;

(o) ‘computerised system’ means a system including the input of data, electronic processing and the output of information to be used either for reporting, automatic control or documentation.