Guidelines for the Blood Transfusion Services

6.1: Scope of the guidelines

http://aws-lon-jpac.targetservers.uk/red-book/chapter-6/6-1

6.1: Scope of the guidelines

These guidelines provide a framework on which Blood Establishments should assemble standard operating procedures (SOPs) for the manufacture of blood components.

These guidelines apply to single-donor and small-pool components (up to and including 12 donors) prepared from units of whole blood or by apheresis. Should a proposal be made to change the specifications for a pooled blood component by increasing the pool size this should follow the usual procedures as set out in Chapter 8, including risk assessment and validation.

Blood Establishments should ensure that the hospital blood banks that they supply are informed of these component production guidelines, and should consult with them on proposed changes to existing component processing and on the adoption of new components.

Technologies for pathogen inactivation of blood components are now being used in Europe. Within the UK, the medicinal product solvent detergent treated pooled plasma is in use. Treatment of plasma and of platelets with amotosalen ultraviolet (UV) treatment or riboflavin UV treatment is CE marked and may be used in the UK in the future. Specifications for these and similar products will be considered as and when they are adopted. At present no CEmarked technology exists for pathogen inactivation of red cells, although some companies are working on suitable approaches.

Occasionally processes may require deviation from a supplier’s Instructions for Use (IFU), in which case the deviation must comply with the Medical Device Regulation (EU 2017/745) article 5 sub-section 5, and the associated component must be fully validated. Additional guidance can be found in Chapter 8 (section 8.1).