Guidelines for the Blood Transfusion Services

7.1.3: Other component specifications

http://transfusionguidelines.org/red-book/chapter-7/7-1/7-1-3

7.1.3: Other component specifications

Other component and process monitoring specifications are detailed later in this chapter. As far as possible, all parameters tested should be derived from a single component. Because of biological variability, it is acceptable if a minimum of 75% of the results from component and process monitoring tests (other than leucocyte depletion specifications, or others where specified) achieve the specifications.

Allowing for losses due to material retained in the associated tubing, yield specifications (e.g. platelet yield /unit, total haemoglobin/unit) for components produced by splitting primary components should be the indicated specification for the primary component divided by the number of split components produced.

Haemolysis measurements on red cell components are performed at the end of the component shelf life. Due to intermittent availability of outdated red cell components, each primary process should be validated to give haemolysis of <0.8% of the red cell mass at the end of component shelf life in >75% of components with a minimum of 20 components tested. Revalidation of the red cell preparation processes for red cell haemolysis must be performed at least annually and after any alteration to the production method.

For mandatory microbiology screening and blood grouping tests, all components must conform to the requirements specified in Chapter 9. Concessionary procedures for release of components that do not conform to these requirements are given in section 6.10.