Guidelines for the Blood Transfusion Services

6.10: Release of components which do not conform to specified requirements

http://transfusionguidelines.org/red-book/chapter-6/6-10

6.10: Release of components which do not conform to specified requirements

Blood and/or blood components may be issued for research, for reagent and, in exceptional cases, for therapeutic use when they do not conform to specified requirements. Each Blood Establishment must have written instructions detailing the circumstances under which such concessionary issues can be made and the procedures to be followed.

For major non-conformances in components intended for therapeutic use (e.g. an HLA-matched platelet that is significantly below specified cell counts, extension of shelf life for an autologous donation or, in extreme circumstances, a donor sample not tested for mandatory microbiological marker etc.) the instructions should, as a minimum, include the following:

- that such component issues are authorised by a Blood Establishment consultant to the relevant registered medical practitioner
- that the reason for the issue is fully documented
- that a verbal and written warning indicating an increased level of risk is given by a Blood Establishment consultant to the receiving registered medical practitioner who should sign a statement indicating that he/she is willing to accept these risks
- that the name of the recipient is entered on the issue documentation
- that the component is clearly identified with a label indicating that it does not conform to specification, the details of the non-conformance, the name of the recipient and that it must not be used for any other patient.

Issues of non-conforming components should be subjected to a formal review process.

Minor non-conformances in components intended for therapeutic use (e.g. non-critical blood pack faults, minor label issues) should be referred for assessment by the quality manager.