Guidelines for the Blood Transfusion Services

5.11: Adverse events

http://aws-lon-jpac.targetservers.uk/red-book/chapter-5-collection-of-a-blood-or-component-donation/5-11-adverse-events

5.11: Adverse events

All adverse events must be documented and reported according to standard protocols.

All bag/harness defects (e.g. pinhole leaks) must be recorded and all defects should be reported to the Quality Assurance Manager. If the defect appears to be batch-related, all packs and blood collected in them must be set aside for further investigation.

Any safety-related defects in equipment, including single-use items, must be reported and escalated as per local procedures, in accordance with the requirements of the Competent Authority, currently the Medicines and Healthcare products Regulatory Agency (MHRA).

Serious adverse events must be reported to the Competent Authority according to the Blood Establishment protocol.