

ANNEX

Quality system standards and specifications

9. NON-CONFORMANCE

9.1. Deviations

Blood components deviating from required standards set out in Annex V to Directive 2004/33/EC shall be released for transfusion only in exceptional circumstances and with the recorded agreement of the prescribing physician and the blood establishment physician.

9.2. Complaints

All complaints and other information, including serious adverse reactions and serious adverse events, which may suggest that defective blood components have been issued, shall be documented, carefully investigated for causative factors of the defect and, where necessary, followed by recall and the implementation of corrective actions to prevent recurrence. Procedures shall be in place to ensure that the competent authorities are notified as appropriate of serious adverse reactions or serious adverse events in accordance with regulatory requirements.

9.3. Recall

1. There shall be personnel authorised within the blood establishment to assess the need for blood and blood component recall and to initiate and coordinate the necessary actions.
2. An effective recall procedure shall be in place, including a description of the responsibilities and actions to be taken. This shall include notification to the competent authority.
3. Actions shall be taken within pre-defined periods of time and shall include tracing all relevant blood components and, where applicable, shall include trace-back. The purpose of the investigation is to identify any donor who might have contributed to causing the transfusion reaction and to retrieve available blood components from that donor, as well as to notify consignees and recipients of components collected from the same donor in the event that they might have been put at risk.

9.4. Corrective and preventive actions

1. A system to ensure corrective and preventive actions on blood component non-conformity and quality problems shall be in place.
2. Data shall be routinely analysed to identify quality problems that may require corrective action or to identify unfavourable trends that may require preventive action.
3. All errors and accidents shall be documented and investigated in order to identify system problems for correction.