

ANNEX

Quality system standards and specifications

5. DOCUMENTATION

1. Documents setting out specifications, procedures and records covering each activity performed by the blood establishment shall be in place and kept up to date.
2. Records shall be legible and may be handwritten, transferred to another medium such as microfilm or documented in a computerised system.
3. All significant changes to documents shall be acted upon promptly and shall be reviewed, dated and signed by a person authorised to perform this task.