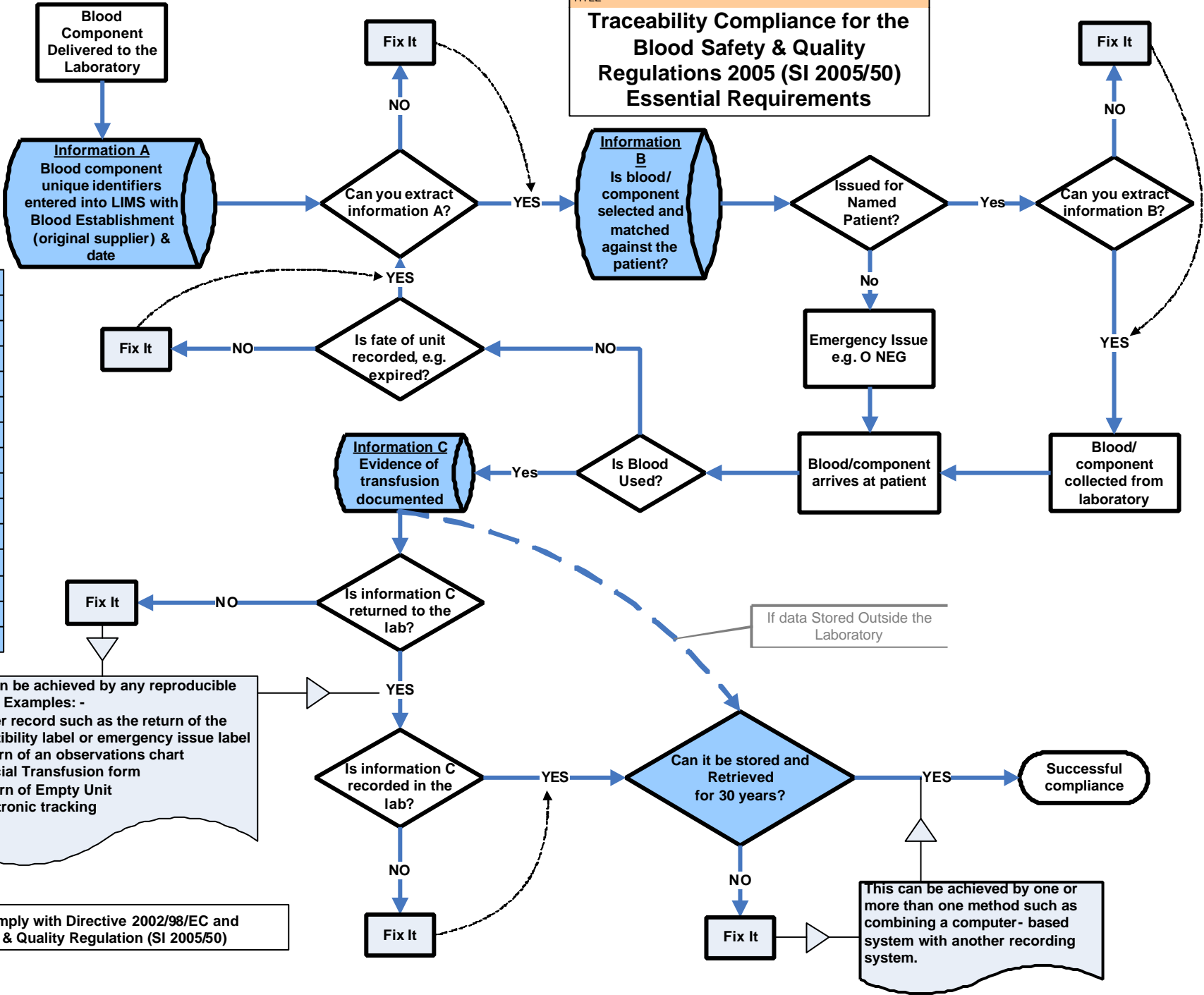


Version 2.5 10/03/2005

Traceability Compliance for the Blood Safety & Quality Regulations 2005 (SI 2005/50) Essential Requirements

Information Required for Compliance
Information A
1. Donation Number
2. Component Type
3. Blood Establishment Provider
4. Date provided
Information B
5. Identification of patient
Information C
6. Identity of patient who received component or final fate if not transfused.
Information retrievable for 30 years



Fix It = Failure to comply with Directive 2002/98/EC and Blood Safety & Quality Regulation (SI 2005/50)

This can be achieved by any reproducible means. Examples: -
 1) Paper record such as the return of the compatibility label or emergency issue label
 2) Return of an observations chart
 3) Special Transfusion form
 4) Return of Empty Unit
 5) Electronic tracking

This can be achieved by one or more than one method such as combining a computer-based system with another recording system.