Guidelines for the Blood Transfusion Services in the UK; Component request and allocation process – process map.

Note; This process map provides information on the operational steps taken by Blood Services in conjunction with the relevant oversight and approval groups when new, but not novel, components are required.

For requests relating to novel components, refer to Red Book chapter 8.

Step / Responsibility	Actions	Information
Request and approval process		
1. Change Manager	Receives notification of change from Manager Raises Change Control record to manage actions Clarifies details with requesting body and fills in request form. Submits request form to SACBC	Via requesting body e.g. SACBC, Executive, Strategic Team etc Managed by individual Blood Transfusion Service Document available from JPAC website document library
2. SACBC	Reviews request form If request is rejected, informs Change Manager and requesting body If revisions/ amendments are required, feeds back to Change Manager	
3. Change Manager	If revisions/ amendments are required, updates form and re-submits to SACBC	
4. SACBC	Upon approval of request, sends completed from back to Change Manager	SACBC signs final approval
5. Change Manager	Submits completed and approved request form to IT Systems Support	Individual Blood Service I.T. team
6. I.T. Systems Support	Receives notification of component code request Obtains any additional information that is required Passes request to SACIT	
7. SACIT	Receives request for new component code Allocates new component code Informs Blood Service of new component code	

Component creation, qualification and final approval (actions captured in line with local change control procedures)

8. IT Systems Support	Receives notification of new component code from SACIT Sends information to Change Manager Awaits further information from Change Manager	e.g. next steps, timescales for work plan etc
9. Change Manager	Receives information from IT systems support	
10. Change Manager in conjunction with IT Systems Support	Completes internal Blood Service documentation relating to new component code Sets up new component barcodes and labels on IT 'test' system If there are any required changes to labelling, Change Manager informs SACBC and obtains approval before proceeding Tests component codes on 'test' system On satisfactory results, IT Systems Support uploads new codes onto 'live' system	e.g component parameters and associated corresponding I.T. entries in computer system e.g. due to limited space on label, recent change notifications etc Codes to remain inactive until qualification activities commence. Individual Service change control processes will manage this.
11. Change Manager	Completes qualification activities using new component codes If outcome is satisfactory, • Notifies SACBC, SACIT and component strategy groups of the outcome • Requests approval via SACBC for routine use of the component If outcome is not satisfactory, • Removes internal functionality to	Degree of validation depends upon how 'novel' the component is

	manufacture the component • Notifies SACBC, SACIT and component strategy groups of outcome	
12. SACBC	Receives notification of outcome of qualification activities Reviews data and considers approval for routine use of components and inclusion in Red Book Liaises with JPAC regarding recommended way forward Informs Change Manager of the outcome.	May also involve communications with other Service strategy groups etc
13. Change Manager	Receives notification of outcome from SACBC If not approved, manages further actions via internal Service change control procedures If approved, • Arranges for production of component barcodes for issue to customers • Provides details to relevant bodies for inclusion in Red Book, Component portfolio, controlled document library, online blood ordering systems etc • Informs Finance department of new component	Barcodes may already have been issued to limited customers during qualification period For consideration of potential costs associated with component