Guidelines for the Blood Transfusion Services in the UK.
Component request and allocation process – user guide (updated post EWG meeting).

Introduction.

This document provides reference material that defines the roles and responsibilities required to ensure a smooth chronological order to the process for approval, registering and validating new components with the aim of providing support for stakeholders who are unfamiliar with the process.

Scope.

This process applies to components that are not considered as novel, as identified in chapter 8 of the Red Book. Such components may require a lower degree of validation than that identified in the Red Book.

Note that the process for requesting and approving novel components is managed separately in chapter 8 of the Red Book and although there is some crossover with chapter 8, this document provides more operational guidance relating to non-novel components.

The process applies to the allocation of codes in CODABAR format only.

Purpose.

To provide users with more detailed instructions on actions to be taken when requesting new component codes for non-novel components that have been pre-approved for clinical use.

Key stakeholders

Change Manager; raises request, works with I.T. to set up new component codes in internal supply chain, manages manufacture and validation of the new component under routine conditions, feeds back to SAC's, arranges for inclusion of component into required published materials.

Standing Advisory Committee on Blood Components (SACBC); reviews request and communicates outcome to Change Manager, reviews outcome of validation activities and considers next steps.

IT systems support (individual Blood Service); refers application to SACIT, works with Change Manager to set up new component codes in internal supply chain.

Standing Advisory Committee on Information Technology (SACIT); allocates new component codes, communicates details of new codes across UK Blood Services (via membership of SACIT), receives information on outcomes.

Additional activities will be managed in more detail via the application of approved and validated procedures under the corresponding areas of responsibility in the relevant Blood Transfusion Service.

It is important to note that, although the change manager starts the process by requesting new component(s), the creation of new components may already have been pre-approved as a result of strategic direction of the Blood Service. However, the process remains the same and a formal request must still be made so that there is a documented auditable trail of the actions taken.

The process map includes details of request, creation, validation, outcome reporting and inclusion into published materials for new components. It does not manage activities going forward (e.g. routine implementation, operational requirements, component monitoring, event reporting etc.), which are managed via systems appropriate to individual Blood Services.

A summary of the steps is provided below;

Summary of process;

- Request for new component code
- Review and approval by SACBC
- Further review by IT systems support and SACIT
- Allocation of component code by SACIT
- Assimilation of component code into the I.T. system (e.g. label text, required parameters)
- Validation of new component
- Final review and approval

More details are available in the accompanying document suite.

This includes;

- both vertical and horizontal process maps to guide the user through the process
- the form to be used when requesting new components.

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.

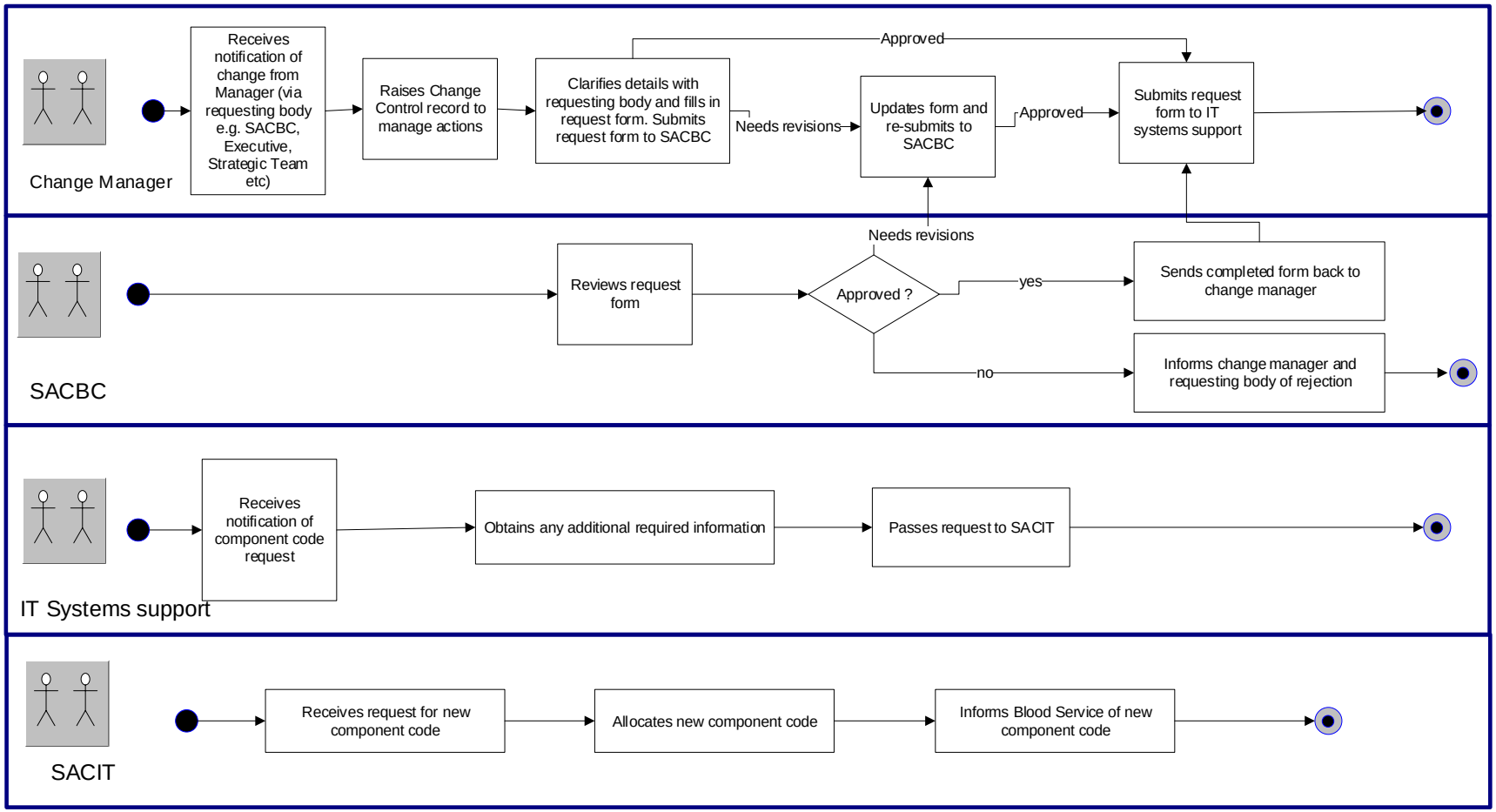
For requests relating to novel components, refer to Red Book chapter 8.

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	

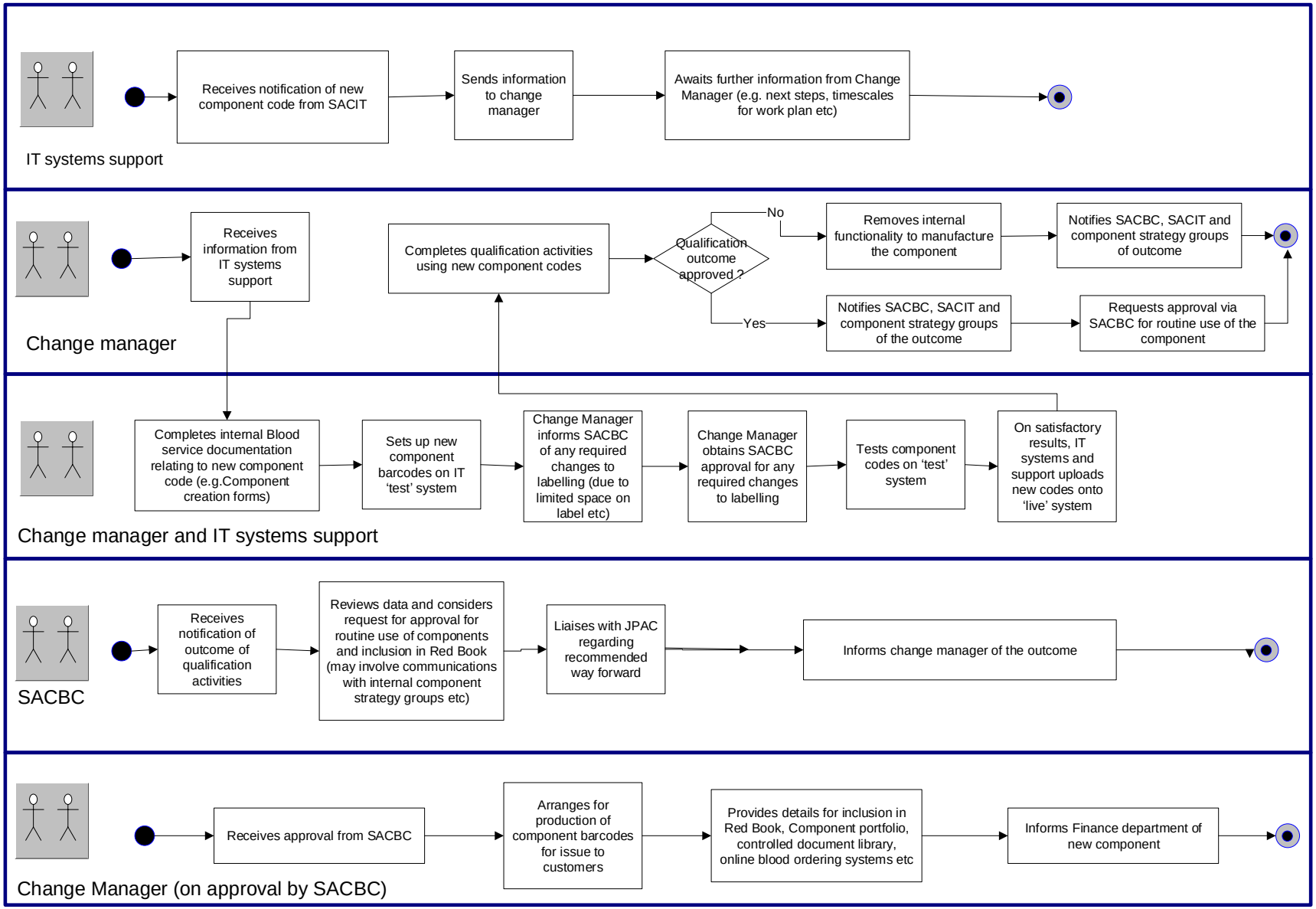
Component creation, qualification and final approval (actions captured in line with local change control procedures)		
8. IT Systems Support	Receives notification of new component code from SACIT Sends information to Change Manager Awaits further information from Change Manager	 e.g. next steps, timescales 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 manufacture the component • Notifies SACBC, SACIT and component	Degree of validation depends upon how 'novel' the component is

	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

Request and approval process



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



UK Blood Services

Component Code (CODABAR) Request Form (to be used in conjunction with processes defined in Red Book)

Section 1; Details of request – To be completed by Requestor / Change Manager

Requestor Name:		Email address:	
Organisation:		Change control:	(insert CC reference number)

Component Description (including method of manufacture)	Reason for request

Shelf Life	
Anticoagulant Volume	
Additive Volume	
Storage Temperature	
Volume of component	
Other parameters (e.g. Haematocrit)	
Proposed Label Text (Max Chars)	
Component Description line 1	
Component Description line 2	

Please send this form to SACBC for review

Section 2; Outcome of request – To be completed by SACBC

Approved/ Not approved (Delete as necessary)

Signed on behalf of SACBC		Date:	

Please send this form to I.T. Systems Support within your Blood Service for review			
Section 3; To be completed by I.T. Systems Support			
Further information required? Yes / No (delete as applicable)			
Enter details of further information;			
Signed on behalf of I.T. Systems Support		Date:	
Please send this form to SACIT for review			
Section 4; To be completed by SACIT			
Component code(s) allocated;			
Signed on behalf of SACIT;		Date:	
Please return this form to I.T. Systems Support			