

## Request and approval process - vertical and horizontal guides

### **Component request and allocation process – vertical 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
<b><i>Request and approval process</i></b>		
1. Change Manager	<p>Receives notification of change from Manager</p> <p>Raises Change Control record to manage actions</p> <p>Collaborates with other Blood Services to ensure awareness</p> <p>Clarifies details with requesting body and fills in request form.</p> <p>Submits request form to SACBC</p>	<p>Via requesting body e.g. SACBC, Executive, Strategic Team etc</p> <p>Managed by individual Blood Transfusion Service</p> <p>Document available from JPAC website document library</p>
2. SACBC Chair	<p>Reviews request form</p> <p>Sends request form to SACBC sub-group for review and feedback</p>	
3. SACBC sub-group	<p>Reviews request</p> <p>Seeks advice from other experts within Blood Services where required</p> <p>Feeds back outcome to Chair of SACBC</p>	
4. SACBC Chair	<p>Feeds back outcome to Change Manager</p>	
5. Change Manager	<p>If revisions/ amendments are required, updates form and re-submits to SACBC</p>	
6. SACBC Chair	<p>Upon approval of request, sends completed form back to Change Manager</p>	SACBC signs final approval
7. Change Manager	<p>Submits completed and approved request form to IT Systems Support</p>	Individual Blood Service I.T. team
8. IT Systems Support	<p>Receives notification of component code request</p> <p>Obtains any additional information that is required</p> <p>Passes request to SACIT</p>	
9. SACIT	<p>Receives request for new component code</p> <p>Allocates new component code</p> <p>Informs Blood Service(s) of new component code</p>	

<b>Component creation, qualification and final approval (actions captured in line with local change control procedures)</b>		
10. 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
11. Change Manager	Receives information from IT systems support	
12. Change Manager and individual Blood Services 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	e.g. component parameters and associated corresponding I.T. entries in computer system
13. Individual Blood Services	If there are any required changes to the label text, collaborate with colleagues from other Blood Services to determine if any standardisation is possible Once text has been finalised inform the Chair of SACBC	e.g. due to limited space on label, recent change notifications etc  may still vary by Blood Service due to local restrictions on label space
14. SACBC Chair	Receives notification of changes to label text and updates records Informs SACIT Chair of any changes	
15. SACIT Chair	Reviews changes and ensures that they do not impact on code mapping tables If there are any impacts, liaises with individual Blood Services to determine the scope for further improvements	
16. Change Manager and individual Blood Services in conjunction with IT Systems Support	On agreement of final label text, tests component codes on 'test' system On satisfactory results, IT Systems Support uploads new codes onto 'live' system	Codes to remain inactive until qualification activities commence. Individual Service change control processes will manage this.
17. Change Manager	Completes qualification activities using new component codes If outcome is satisfactory, <ul style="list-style-type: none"> <li>• Notifies SACBC, SACIT and component strategy groups of the outcome</li> <li>• Requests approval via SACBC for routine use of the component</li> </ul> If outcome is not satisfactory, <ul style="list-style-type: none"> <li>• Removes internal functionality to</li> </ul>	

	<p>manufacture the component</p> <ul style="list-style-type: none"> <li>• Notifies SACBC, SACIT and component strategy groups of outcome</li> </ul>	
18. SACBC	<p>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.</p>	<p>May also involve communications with other Service strategy groups etc</p>
19. Change Manager	<p>Receives notification of outcome from SACBC If not approved, manages further actions via internal Service change control procedures If approved,</p> <ul style="list-style-type: none"> <li>• Arranges for production of component barcodes for issue to customers</li> <li>• Provides details to relevant bodies for inclusion in Red Book, Component portfolio, controlled document library, online blood ordering systems etc</li> <li>• Informs Finance department of new component</li> </ul>	<p>Barcodes may already have been issued to limited customers during qualification period</p> <p>For consideration of potential costs associated with component</p>