Operational Verification Protocol:

Verification Purpose:

To check that the process undertaken by the facility to redistribute or transfer blood components and products meets expected outcomes and requirements for shipping blood components and products outside the facility prior to implementation of the process.

Background: The Provincial Redistribution program facilitated by the Ontario Regional Blood Coordinating Network (ORBCoN) and the Factor Concentrate Redistribution Program (FCRP) and utilized by Ontario hospitals has been instrumental in reducing the overall number of components and products that outdate in Ontario hospitals each year. The process for redistributing blood components and products were evaluated by a provincial working group to standardize procedures to ensure the security and safety of the redistributed components and products are maintained during any shipment. Validated shipping containers and standardized operating procedure templates were developed for hospitals that utilize the redistribution program to ship components and products outside of their facility.
J82, E38 and Credo EMT shipping containers for the purposes of shipping components and products for redistribution or patient transfers have been validated provincially. Validation revealed that pre-conditioning of the ice-packs and gel packs as prescribed in the validation report can maintain acceptable shipping temperatures for a prescribed amount of time. The validation report is available on www.transfusionontario.org.

Verification:

Validation Requirements	Purpose	Expected Outcome	Reported Outcome
Geographical Coverage	Validation should be performed with a site where all variables affecting validation may be encountered.	<Suggest the furthest shipping site or longest transit time from the receiving site should be selected as the pilot shipping site.>	
Seasonal Coverage	Validation should identify what time of year the validation is taking place. It is recommended that Operational validation should take place when the extreme stresses can be encountered, i.e. extreme cold (winter season) and extreme heat (summer season).	<Transportation situations arise in both cold and warmer temperatures. Testing logistics in both situations gives confidence that the process can withstand temperature fluctuations.>	

Timelines	Verification Plan should include target completion dates for: - courier service agreements - operating procedures - training - Start and completion of verification.	< Timelines should be established by all participating parties, to ensure that the decided dates will be achievable.>	
Evaluators	Provides a list of people involved with the validation process, including testers, quality assurance and Medical Director. This should also include a brief description of roles and responsibilities for the validation.	▪ Testers should be the staff members that have been identified as shipping or receiving the payloads and completes the User Evaluation Form ▪ Quality Assurance individual should devise the verification plan, analyse the data and make the recommendation to implement the process. ▪ Medical Director should review the validation plan prior to executing, and then have final review and sign off of the completed validation report.	
Verification Criteria	Will establish the parameters needed for acceptance of the process for facilities and users. Methods of measuring these parameters should be identified	• All packing configurations were adhered to • All shipments were completed within allowable time limits • The shipping containers were intact after all shipments • All shipped units have acceptable visual appearance on receipt • All shipped units were maintained at acceptable shipping temperature during transit	

<table>
<tr>
<td>Verification Procedure</td>
<td>This should establish the protocol to be used for the validation (i.e. number of tests and runs). Each set of tests should be defined.</td>
<td>▪ Follow procedure as written for each set of tests
<table>
<tr><th>TEST #</th><th>RUN#</th><th>PAYLOAD</th></tr>
<tr><td>1</td><td>1</td><td>Minimum</td></tr>
<tr><td>1</td><td>2</td><td>Minimum</td></tr>
<tr><td>1</td><td>3</td><td>Minimum</td></tr>
<tr><td>2</td><td>1</td><td>Maximum</td></tr>
<tr><td>2</td><td>2</td><td>Maximum</td></tr>
<tr><td>2</td><td>3</td><td>Maximum</td></tr>
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<tr>
<td>Validation Analysis</td>
<td>All parameters defined in the validation criteria shall be checked and compared with expected results, looking for compliance or deviations whose causes have to be determined, proposing the corresponding corrective actions achieve expected result.</td>
<td>▪ Review deviation / incident Reports
▪ Evidence that container maintained acceptable temperature through the redistribution process.
▪ Results table (example #1 shown below)
▪ Evidence that all units were traceable and trackable at all times.</td>
<td></td>
</tr>
<tr>
<td>Final Operational Report</td>
<td>Accepted results and reported deviations should be summarized in a document that is made available to all that will be participating in the process to provide confidence the process has been endorsed.</td>
<td>▪ Summary of results to be documented
▪ Summary of deviations and corrective actions.
▪ Summary of user acceptance feedback and training documentation
▪ Review and approval by assigned authority (e.g. Laboratory Medical Director)</td>
<td></td>
</tr>
</table>

Verification Team Performance Qualification Approval:

Results:

Test 1: Minimum payload
(Circle appropriate choice)

	Run 1	Run 2	Run 3
Date			
Origin			
Destination			
Ambient Temp			
Transit time			
Condition of shipping container on receipt OK	Yes No	Yes No	Yes No
Visual inspection of RBCs on receipt OK	Yes No	Yes No	Yes No
Temperature of RBCs on receipt			
Temperature X-XºC throughout shipment	Yes No	Yes No	Yes No
Documentation complete and accurate	Yes No	Yes No	Yes No
Protocol deviations (attach deviation report):	Yes No	Yes No	Yes No

Test 2: Maximum payload
(Circle appropriate choice)

	Run 1	Run 2	Run 3
Date			
Origin			
Destination			
Ambient Temp			
Transit time			
Condition of shipping container on receipt OK	Yes No	Yes No	Yes No
Visual inspection of RBCs on receipt OK	Yes No	Yes No	Yes No
Temperature of RBCs on receipt			
Temperature X-XXºC throughout shipment	Yes No	Yes No	Yes No
Documentation complete and accurate	Yes No	Yes No	Yes No
Protocol deviations (attach deviation report):	Yes No	Yes No	Yes No

User Evaluation Form for Shipping Blood Component/Products For Redistribution Procedure / Process*

Test #: _____
Run #: _____

Ambient Temp: _____
Time of packing: _____
Shipping Time: _____
Receiving Time: _____

Title of Standard Operating Procedure to be used during test:

Date of User Acceptance test:

User's Name:

Facilities involved in testing:

Courier service used:

Analysis:

SOP:

Is the procedure easy to understand and does it have a consistent flow to the steps required for shipping components/products for redistribution?

☐ Yes ☐ No Comments:

Are the objectives of the procedure listed and were the objectives met after the completion of all required steps ?

☐ Yes ☐ No Comments:

Are all required equipment and materials listed in the procedure in order to complete the redistribution of components/product?

☐ Yes ☐ No Comments:

PACKING:

When assembling the shipping container's packing configuration stated in the procedures, were the materials easy to work with?

☐ Yes ☐ No Comments:

Temperature recording / monitoring devices: are they easy to apply to the product or package, to ensure constant temperature monitoring can be achieved? (Answer if applicable to your facility)

☐ Yes ☐ No Comments:

Can the shipping container be easily secured with a tamper evident seal?

☐ Yes ☐ No Comments:

Were the ice packs and gel packs preconditioned for the required time?
☐ Yes ☐ No Comments:

Was the time required to remove the products from storage to the time of packing into the shipping container exceed 30 minutes when using the procedures?
☐ Yes ☐ No Comments:

SHIPPING:

Was completion of the Inter-hospital redistribution form easy to complete and did it capture all required information for shipping products to another transfusion medicine facility?
☐ Yes ☐ No Comments:

Was the shipping label easy to attach to the container, and does it clearly state the shipping facility and the intended receiving facility and its address?
☐ Yes ☐ No Comments:

RECEIVING:

Was the shipping container received in good condition, with no dents or breaches into the container?
☐ Yes ☐ No Comments:

Were products visually inspected to ensure there was no breakage or leakage during transit?
☐ Yes ☐ No Comments:

Was the packing configuration used a known validated packing configuration?
☐ Yes ☐ No Comments:

Was the time in transit within the allowable limit for the validated container?
☐ Yes ☐ No Comments:

Overall Impression:
Are the shipping containers, procedure for shipping blood components and products, and the forms ready to be put into operation at your facility?
☐ Yes ☐ No Comments:

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*Each participant in the validation should complete this form to aid in the overall evaluation of this process.

Final Results Reviewed by: Date:

Deficiencies Report:

To be used to document any deviations from procedure, incidents or errors and any corrective action taken and final outcome.

Copy this page as required to list deficiencies. Complete all requirements. Forward for sign off for both minor and major deficiencies prior to continuing tests. Attach all documents

Deficiency Title and Number:
Deficiency Classification: □ Minor □ Major Details of Deficiency
Reported by:
Corrective Action:
Reported by: _____ Signature/Date Approved by: _____ Signature/Date
Comments: