Operational Verification Protocol:

**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 was 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 are available for hospitals that participate in the redistribution program to ship components and products outside of their facility.

Purpose of performing an Operational Verification:

The purpose of performing an operational verification of the process to redistribute or transfer blood components and products is to confirm that it meets expected outcomes and requirements for shipping blood outside the facility prior to implementation. This can be considered similar to the accreditation requirement to validate a new process or new equipment, a change in a process or repair of equipment (IQMH Medical Laboratory Accreditation Requirements v9).

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](http://www.transfusionontario.org).

The table below describes how to set up an operational verification protocol to measure how the process functions using your own laboratory processes, personnel and transportation.

**Operational Verification Protocol:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Verification Requirements** | **Purpose** | **Expected Outcome** | **Reported Outcome** |
| Geographical Coverage | Perform runs with a site where all variables affecting verification 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 | Identify what time of year the verification 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 | The 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 | Provide a list of people involved with the verification process, including testers, quality assurance and Transfusion Medicine Laboratory Medical Director. This should also include a brief description of roles and responsibilities for these individuals. | * Testers should be the staff members that have been identified as shipping or receiving the payloads and completing the User Evaluation Form * Quality Assurance individual should devise the verification plan, analyse the data and make the recommendation to implement the process. * TM Lab Medical Director should review the verification plan prior to executing, and then have final review and sign off of the completed verification report. |  |
| Criteria | 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 |  |
| Procedure | Establish the protocol to be used for the verification (i.e. number of tests and runs). Each set of tests should be defined. The process should be tested with both a minimum payload and maximum payload. | |  |  |  | | --- | --- | --- | | TEST # | RUN# | PAYLOAD | | 1 | 1 | Minimum | | 1 | 2 | Minimum | | 1 | 3 | Minimum | | 2 | 1 | Maximum | | 2 | 2 | Maximum | | 2 | 3 | Maximum |  * Follow procedure as written for each set of tests |  |
| Verification Analysis | All parameters defined in the verification criteria shall be checked and compared with expected results, looking for compliance or deviations whose causes must be determined, proposing the corresponding corrective actions achieve expected result. | * 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. |  |
| Final Report | 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. | * 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. TM Laboratory Medical Director) |  |

**Results:**

*Test 1: Minimum payload*  *Test 2: Maximum payload*

(Circle appropriate choice) (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\***

|  |  |
| --- | --- |
| Title of Standard Operating Procedure to be used during Verification: |  |
| Date of User Acceptance of Run: |  |
| User’s Name: |  |
| Facilities involved in Verification: |  |
| 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:

Did 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 in 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:

\*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: Approved by:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature/Date Signature/Date |
| Comments: |