Canadian Blood Services
it's in you to give

Packing Configuration – Red Blood Cells using E38 or J82 Shipping Container

VALIDATION SUMMARY REPORT
Report Number: VSR- SPR-051

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REPORT APPROVAL

This document was prepared by:

Department	Name / Title	Signature	Date
Quality System Support	Paul Birch Associate, Validation	Paul Birch	2011-01-17

VALIDATION SUMMARY ACCEPTANCE

The Canadian Blood Services representatives, by signing and dating in the spaces below, have reviewed and approved this validation summary report.

Department	Name / Title	Signature	Date
Quality System Support	Danita Leung Manager, Validation		2011-01-18
Logistics	Tom Walker Project Manager, Shipping Process Renewal		2011-01-18
Quality Assurance	Siamak Eslampanah Production Supply Chain		2011-01-18

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1.0 REVISION HISTORY

Document Version	Date Created	Author	Remarks
0.1	2011-01-04	P.Birch	• Draft release
0.2	2011-01-14	P.Birch	• Updated to current template • Incorporated review comments
1.0	2011-01-17	P.Birch	• Sent for signatures

2.0 EXECUTIVE SUMMARY

Canadian Blood Services transports red blood cell components (RBCs) in J82 shipping containers following established local practices. It was determined, through investigations by the Shipping Process Renewal project team, relying on study data collected by Medical, Scientific and Research Affairs, Quality Monitoring Program (QMP), that survival of RBC shipments could be better assured if standardized packing instructions for use with either E38 or J82 shipping containers were established.

A series of qualification activities were completed, between December 2010 and January 2011 at Head Office, to establish data to support the determination of CBS' preferred packing instructions with existing E38 or J82 shipping containers. These improve the containers' performance in maintaining an internal temperature of 1-6 °C (for RBC shipment transport time less than 24 hours). Where possible, data on how long internal temperature can be maintained at 1-10°C (for RBC shipment transport time longer than 24 hours) was also collected for information. Although QMP study data suggests that existing J82 summer packing configuration may suffice for RBC shipments during summer months and during winter if the containers are protected from the cold, the Shipping Process Renewal project team reviewed the qualification results to determine the appropriate next steps, where necessary including revision to existing Directives for RBC shipments.

Targeting the warmer seasons, the results of the qualification efforts demonstrated that E38 summer packing configurations deliver better performance than J82-based packing configurations when exposed to extreme high temperatures, i.e. 30 °C and above. However, based on QMP study data, shipment exposures to extreme high temperatures are rare occurrences. Under normal summer conditions, the results demonstrate that the E38 is an acceptable solution in maintaining 1-6°C shipment temperature but it is *not* an exceptional performer when compared to J82 shipping containers.

Targeting the colder seasons, when extreme low temperature exposures are possible, the E38 with a winter packing configuration provides acceptable performance at ambient temperatures from minus 30°C to +15°C.

A subsequent qualification was completed with the J82 container using its summer packing configuration in an effort to determine a transition point for using the J82 (summer configuration) in winter months instead of the E38 (winter configuration). The results did not provide a clear answer. CBS work instructions will, therefore, require the use of E38 containers for RBC shipments during winter months unless CBS staff are transporting the shipment or the carrier assures CBS that the container will be kept a room temperature, in which cases the J82 container may be used.

For a summary of results on the performance of E38 containers with summer and winter packing configurations, refer to Sections 5.1 and 5.3 of this report. There was one (1) non-critical deficiency identified during the execution of the Performance Qualification. The deficiency has been closed by the issuance of the instructions for selecting between the E38 and J82 containers described above.

For a summary of results on the performance of J82 shipping containers with summer packing configuration, refer to Sections 5.2 and 5.3 of this report. There were two (2) critical deficiencies identified during the execution of the Performance Qualification. The deficiencies have been addressed by the issuance of the instructions for selecting between the E38 and J82 containers described above.

Refer to Section 5.4 of this report for a detailed description of each deficiency.

3.0 BACKGROUND INFORMATION

3.1 PURPOSE

The document provides a summary of qualification evidence collected by CBS during the execution of protocols, PQ-SC-002 version 1.0 and PQ-SC-003 version 1.0.

3.2 SCOPE

The qualification of the shipping container packing configurations for RBC shipments consisted of:

- Performance Qualification: PQ-SC-002 v1.0, *Maintain 1-6°C Packing Configuration using the E38 Shipping Container*
- Performance Qualification: PQ-SC-003 v1.0, *Maintain 1-10°C Packing Configuration using the J82 Shipping Container*

The following were considered out of scope:

- Shipment distribution
- Performance qualification of J82 summer packing configuration during the summer conditions, as there are supporting data established from previous and QMP studies.

4.0 DOCUMENTATION

These documents were generated or referenced to support the qualification effort. They will be retained in the Logistics department at Head Office.

- The *User Requirements Specification* shipping containers, Document Number SPR-014, v5.0, approved on 2010-03-08.
- Protocol PQ-SC-002-135-2010-31, *Maintain 1-6°C Packing Configuration using the E38 Shipping Container*, Approved 2010-12-23.
- Protocol PQ-SC-003-135-2011-01, *Maintain 1-10°C Packing Configuration using the J82 Shipping Container*, Approved 2011-01-17.
- Directive D30050 revision 2,*Packing Configurations and Shipping Guidelines for CPD Platelets,Pooled, LR and Platelets, Apheresis.*

5.0 RESULTS

5.1 PERFORMANCE QUALIFICATION - MAINTAIN 1-6°C PACKING CONFIGURATION USING E38 SHIPPING CONTAINERS, PQ-SC-002-135-2010-31

Acceptance Criteria	Acceptance Criteria met (Yes or No)
All test equipment used during the execution of the protocol must be identified and in a calibrated state.	Yes
E38 shipping containers with appropriate packing configurations will maintain an internal temperature of 1-6 °C for not less than the specified length of time.	Yes (refer to DRF-001)

5.2 PERFORMANCE QUALIFICATION - MAINTAIN 1-10°C PACKING CONFIGURATION USING J82 SHIPPING CONTAINERS, PQ-SC-003-135-2011-01

Acceptance Criteria	Acceptance Criteria met (Yes or No)
All test equipment used during the execution of the protocol must be identified and in a calibrated state.	Yes
J82 shipping containers with winter packing configuration will maintain an internal temperature of 1-10 °C for not less than the specified length of time.	No (refer to DRF-001, DRF-002)

5.3 SUMMARY OF RESULTS

Only worst case scenarios were tested. Survival time is rounded down to the nearest 15 minutes. Only the most stringent result from triplicate runs is reported. Refer to the executed protocols for the entire dataset, as required.

5.3.1 RBC IN E38 SHIPPING CONTAINERS – WINTER PACKING CONFIGURATION (W1)

Pack-out	Ambient temperature (°C)	Survival time 1-6°C	Survival time 1-10°C (info. only)	Acceptance Criteria	Pass/Fail
W1	30	2 hr 15 min	9 hrs 15 min	≥30 hrs	Fail
	-30	10 hrs 15 min	Not Relevant*	≥10 hrs	Pass
	15	4 hrs 45 min	26 hrs	Not specified	Not applicable
	16	Not available	22hr 45 min		
	40	2 hrs 30 min	7 hrs 45 min	Not specified	Not applicable
	0	> 48 hrs	Not Relevant*	Not specified	Not applicable

W1 = 1 unit, 0 ice pack, 2 gel packs
*Same as 1-6°C range, container failed to maintain temperature above 1 °C

5.3.2 RBC IN E38 SHIPPING CONTAINERS – SUMMER PACKING CONFIGURATION (S1)

Pack-out	Ambient temperature (°C)	Survival time 1-6°C	Survival time 1-10°C (info. only)	Acceptance Criteria	Pass/Fail
S1	30	46 hrs	Not available	≥30 hrs	Pass
	-30	2 hrs		≥10 hrs	Fail
	15	> 48 hrs		Not specified	Not applicable
	16	Not available			
	40	16 hrs 45 min		Not specified	Not applicable
	0	11 hrs		Not specified	Not applicable

S1 = 5 units, 2 ice packs, 0 gel pack

5.3.3 RBC IN E38 SHIPPING CONTAINERS – SUMMER PACKING CONFIGURATION (S2)

Pack-out	Ambient temperature (°C)	Survival time 1-6°C	Survival time 1-10°C (info. only)	Acceptance Criteria	Pass/Fail
S2	30	45 hrs 30 min	Not available	≥30 hrs	Pass
	-30	2 hrs		≥10 hrs	Fail
	15	> 48 hrs		Not specified	Not applicable
	16	Not available			
	40	17 hrs 45 min		Not specified	Not applicable
	0	10 hrs		Not specified	Not applicable

S2 = 1 unit, 2 ice packs, 1 gel pack

5.3.4 RBC IN J82 SHIPPING CONTAINERS – SUMMER PACKING CONFIGURATION (S)

Pack-out	Ambient temperature (°C)	Component Placement Orientation	Survival time 1-10°C	Acceptance Criteria	Pass/Fail
S	-30	Vertical	2 hrs 30 min	≥3 hrs	Fail
		Horizontal	45 min		

S = 1 unit, 2 ice packs, 1 gel pack

5.4 DEFICIENCY REPORTS

DEFICIENCY REPORT NUMBER AND CRITICALITY	DESCRIPTION AND IMPACT	ROOT CAUSE ANALYSIS	CORRECTIVE ACTION/RESOLUTION	STATUS
Performance Qualification: PQ-SC-002-135-2010-31, Maintain 1-6 °C Packing Configuration using E38 Shipping Containers				
DRF-001 Non-critical	Section 10.0 – Table 10-2, 7,and 11 E38 with two different summer packing configurations at extreme cold conditions and one winter packing configuration at warm ambient condition did not maintain the required internal temperature for the specified length of time.	The packing configurations were not designed for the temperature exposures in which the shipping containers failed.	Directive D30220 version 1.0 will be revised to provide instructions for choosing between E38 and J82 shipping containers during winter months	Closed
Performance Qualification: PQ-SC-003-135-2011-01, Maintain 1-10 °C Packing Configuration using J82 Shipping Containers				
DRF-001 Critical	Section 10.0 – Table 10-1 J82 did not maintain the required internal shipment temperature for the specified length of time at cold conditions, when RBC is packed vertically following the winter packing configuration.	The packing configuration is not designed to meet the performance requirement.	Directive D30220 version 1.0 will be revised to provide instructions for choosing between E38 and J82 shipping containers during winter months	Closed
DRF-002 Critical	Section 10.0 – Table 10-2 J82 did not maintain the required internal shipment temperature for the specified length of time at cold conditions, when RBC is packed horizontally following the winter packing configuration.	The packing configuration is not designed to meet the performance requirement. When component is packed horizontally, it is open to air without gel pack to buffer ambient temperature.	Directive D30220 version 1.0 will be revised to provide instructions for choosing between E38 and J82 shipping containers during winter months	Closed

6.0 CONCLUSION

The combination of a J82 summer packing configuration and an E38 winter packing configuration is capable of maintaining the internal temperature of Red Blood Cell shipments within required limits. The results have been accepted by Logistics and Quality Assurance.