Appendix 2: Example Validation Plan

1. Purpose / Scope

This document describes the validation of:

- Shipper [enter shipper name] for the use in the inter-hospital/laboratory transport of [Enter components as required].

Responsibilities

Position	Responsibility
Senior Scientist	Design validation; analyse results; prepare the report; perform the validation; compile results
Quality Manager	Authorise validation and approve for implementation

2. References

A reference you may like to review is the Council of Europe's "Guide to the Preparation, Use and Quality Assurance of Blood Components", 16th edition.

[List references you outline in this document]

3. Materiel (add/delete below as required)

3.1. 3x Shipper [enter shipper name].
3.2. Room temperature coolant packs (conditioned at +20 to +24°C for 24hrs prior to use).
3.3. Chilled coolant packs (conditioned at +2 to +6°C for 24hrs prior to use).
3.4. Frozen coolant packs (conditioned at approximately -19°C for 24hrs prior to use).
3.5. Tamper evident labels.
3.6. Cardboard dividers.
3.7. Expired red cells with defaced label "Research Only" or empty dummy packs filled with 275ml saline.

4. Equipment

Temperature Data Loggers (TDL): [Enter Company Name], [Enter Model No].

Temperature Data Logger	Serial Number	Asset Number
TDL1		
TDL2		
TDL3		

Note: Performance Qualifications for the data loggers have been included in Attachment [X].

Cool Room [Enter name e.g. CR001]

Incubator [Enter name e.g. I001]

Note: Records for Cool Room [CR001] and Incubator [I001] are located in [Enter location e.g. Engineering Department]

5. Acceptance criteria

5.1. Temperature maximum does not exceed 10^{O} C.

5.2. Temperature minimum does not fall below 2^{O} C.

5.3. There should not be a temperature range difference of $\pm 1^{O}$ C between the lowest and highest values for the maximum temperature recorded for each of the data loggers and each of the replications when determining maximum transport time.

5.4. There should not be a temperature range difference of $\pm 1^{O}$ C between the lowest and highest values for the minimum temperature recorded for each of the data loggers and each of the replications when determining minimum transport time.

6. Procedure (add/delete below as required)

6.1. Description / Background Information

6.1.1. This laboratory will be validating/revalidating the [enter shipper name] for the transport of red blood cells [or other component] between the following health providers [insert names].

6.1.2. Routine transfer of blood components is undertaken by [enter name]

6.1.3. A review of Bureau of Meteorology for local climatic conditions indicates that minimum environment temperatures do not drop below [enter minimum temperature e.g. 10˚C].

6.1.4. Validation time was set at [x] hours as a review of transport arrangements and non-compliance reports indicate that this would be the worst case scenario the laboratory would experience in the transfer of components.

6.2. Key Variables (add/delete below as required)

6.2.1. Staff will be accessing cool room during low temperature qualification period.

6.2.2. Building air conditioning is switched off from [enter time e.g.10pm] to [enter time e.g. 6am] during ambient temperature qualification period.

6.3. Samples (add/delete below as required, set temperature levels to represent your requirements)

6.3.1. Data logging sample rate set at [x] minute intervals.

6.3.2. Sampling was undertaken over [x] hours for [10 ˚C - 14˚C] low temperature qualification period.

6.3.3. Sampling was undertaken over [x] hours for [20 ˚C - 24 ˚C] ambient temperature qualification period.

6.3.4. Sampling was undertaken over [x] hours for [32 ˚C - 42 ˚C] high temperature qualification period.

6.4. Data logger Parameter Settings

6.4.1. Data logger delay setting set to 15 minutes to allow equilibration.

6.4.2. Data logging sample rate set at [x] minute intervals.

6.4.3. Data logger sample points set at [number of readings to reach 30 hours].

6.5. Participating centres & personnel

[Enter Health Provider/Laboratory Name/s], [Enter Location], Senior Scientist, Quality Manager

6.6. Packing Configuration

Packing configuration as outlined in **Figure 1** below. For each configuration you will need to determine the minimum and maximum number of packs allowed for each configuration to be validated.

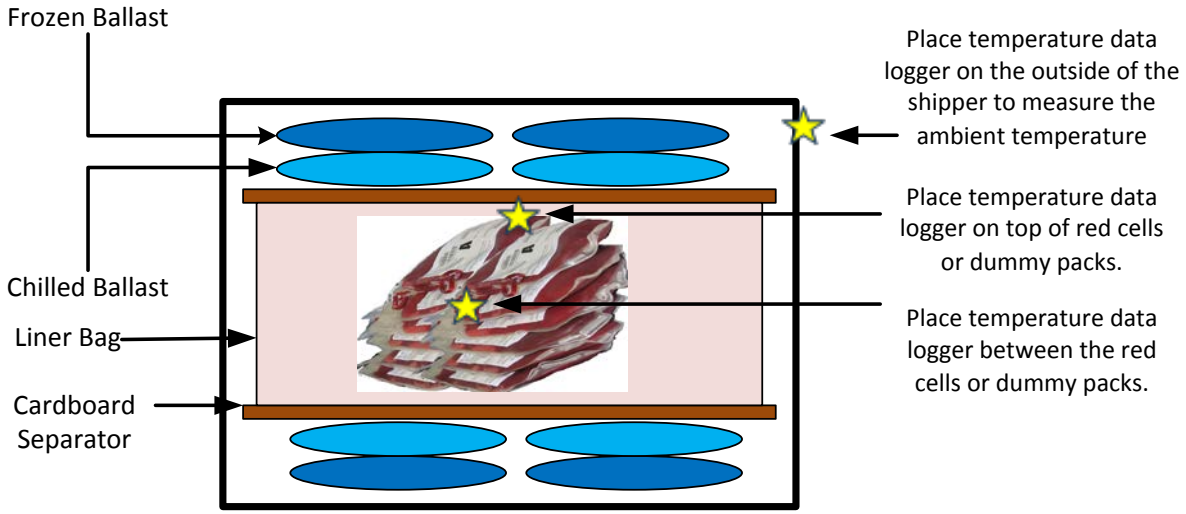

*Figure 1 adapted from the Australian Red Cross Blood Service *Receipt and Use of Blood Service Shippers by External Institutions to Transport Blood and Blood Products* Red Cell Configuration R1.

6.7. Temperature Data Loggers and Placement

6.7.1. Data loggers equilibrated to required temperature e.g.10 ^{O}C - 14^{O}C, 20 ^{O}C - 24^{O} C, 32^{O}C and 52 ^{O}C.

6.7.2. Place one logger in-between the red cells or dummy packs.

6.7.3. Place one logger above the red cells or dummy packs.

6.7.4. Attach one logger to the outside of the shipper to measure the environment temperature.

6.7.5. Refer to **Figure 1** above.

6.8. Temperature Validations

6.8.1. Shipper packed in accordance with Figure 1 was placed in Cool Room CR001 for [as per 6.1.4] for minimum temperature validation. This was repeated on three separate occasions.

6.8.2. Shipper packed in accordance with Figure 1 was placed in Blood Bank Laboratory for [as per 6.1.4] for ambient temperature validation. This was repeated on three separate occasions.

6.8.3. Shipper packed in accordance with Figure 1 was placed in Incubator I001 set at 32 ^{O} C for [as per 6.1.4] and then at and at 42^{O} C for maximum temperature validations. This was repeated on three separate occasions.

7. Results

7.1. Data logger Performance Qualification

Performance testing was undertaken and completed by [Enter detail e.g. Engineering Department] on [Enter date]. Results of performance testing against a reference thermometer are outlined in the **Table 1** below.

Table 1 Reference thermometer performance testing

Temperature Data Logger	Recorded Temp ^{O} C	Ref Thermometer Recorded Temp ^{O} C	Difference ^{O} C
TLD1	23.6	23.5	- 0.1
TLD2	23.6	23.6	0.0
TLD3	23.6	23.5	- 0.1

Note: Reference Thermometer [Enter Serial No] records can be obtained from [Enter Engineering Department]

7.2. Minimum Temperature Validation

7.2.1.Raw data of data logger download is included in Attachment 1.

7.2.2.Summary of results of data logger mapping is in **Table 2** below:

Table 2: Data logger mapping results

Position	Date	Data Logger	Minimum	Maximum
Position 1	[Enter date]	TDL1	[4.9] ˚C	[6.8] ˚C
Position 1	[Enter date]	TDL1	[5.7] ˚C	[7.9] ˚C
Position 1	[Enter date]	TDL1	[5.2] ˚C	[7. 2] ˚C

[Enter other tables as required]

8. Discussion and recommendations

The performance testing of the four data loggers was undertaken and completed by [Enter name e.g. Engineering Department], an ISO9000 accredited facility, on [enter date]. The results against a reference thermometer showed that no data logger had a variance greater than ± [enter variation e.g. 0.1] ^{O} C.

The minimum temperature validation occurred on three separate occasions over a 7 day period from [enter date] to [enter date]. Cool room CR001 decommissioned for maintenance was recommissioned and set to 10 ^{O}C - 14^{O}C for this validation study. The packing configuration and data logger placement is outlined in Figure 1.

The results show that the shipper stored at 10 ^{O}C - 14^{O}C for [x] hours did not drop below [x] ^{O}C for the validation period. The variation of minimum temperature across the three validations for each of the

data loggers is [0.8] ^{O}C within the allowable ±1^{O}C acceptance criteria. The results show that the shipper stored at 10 ^{O}C - 14^{O}C for [x] hours did not exceed 10^{O} C until [x] hours. The maximum temperature variation across the three validations for each of the data loggers is [enter variation e.g. 1.1] ^{O}C and is within the allowable ±1^{O}C acceptance criteria.

[Discuss ambient temperature validation]

[Discuss maximum temperature validation]

It is recommended that Shipper [Enter name] is suitable for the transport of red cells as inter-hospital/laboratory for up to [x]hours. If the transport is expected to exceed [x] hours or if non-contracted transport such as a taxi is required then consignments should include a data logger as part of the packing configuration, to be positioned next to the red cell packs.

9. Appendices

Attachment [1]: Raw data download of [data logger] for minimum temperature validations.

Attachment [2]: Cool Room Temperature Map

Attachment [3]: [other documents as required]

10. Approvals

	Name	Signature	Date
Report prepared by:			
Quality Manager Approval			

End of document

Repeat the process below for ***each*** configuration, product and possible temperature exposure range, for example: 0˚C to 4˚C, 4˚C to 24˚C, 24˚C to 40˚C, 40˚C to 52˚C