1. **Purpose**

This policy:

a) Specifies the requirements for an appropriate temperature controlled and monitored environment for the storage and transport of red blood cells.

b) Standardises the packing configuration to be used by NSW Health Pathology Laboratories when transporting red cells between laboratories and the action and acceptance criteria on receipt of the blood products.

2. **Background**

This policy has been developed to optimise the use of blood products in NSW Health Pathology in accordance with:

a) Current best and safe practice defined in the *Australian and New Zealand Society of Blood Transfusion Guidelines for Transfusion and Immunohaematology Laboratory Practice November 2016*

b) *Australian Red Cross Blood Service Shippers – Receipt and Use by External Institutions WI-00635 Version 1, 6 June 2016.*

3. **Scope**

This policy is mandatory and applies to all NSW Health Pathology staff involved in pre-transfusion laboratory practice including Laboratory Managers, Staff Specialists, Scientists and Scientific Officers.

4. **Definitions**

**Transport:** Transport is the process of shipping blood products from the supplier including:

a) Blood service to the hospital laboratory
b) Base hospital to its satellite laboratories
c) Between laboratories in a network\(^1\) including transferring blood products between NSW Health Pathology Laboratories.

**Storage:** Products issued by the laboratory to another location are considered to be storage\(^1\) including:

a) Products sent to wards
b) Products sent to theatres
c) Products sent with patients transferred from locations or facilities outside of the jurisdiction of the receiving laboratory and
d) Products accompanying emergency retrieval teams, for example, in a helicopter or an ambulance.
5. Policy Statement

5.1 Red Blood Cell Storage Temperature Range

5.1.1 Red blood cells must be stored in an appropriate temperature controlled and monitored environment.

5.1.2 Refrigerators and deep freeze cabinets used to store blood products must conform to the Australian Standard AS 3864 Medical refrigeration equipment – for the storage of blood and blood products.

5.1.3 Red blood cells must be stored between 2°C and 6°C.

5.1.4 Blood products must not be transfused, except at the discretion of the laboratory director, where:
   a) Stored at temperatures outside the specified limits
   b) Stored in nonconforming equipment or
   c) There is doubt regarding storage conditions.

5.1.5 Any deviations must be clearly documented on the Red Blood Cell Storage and Transport Temperature Deviation Form.

5.1.6 Any deviations must be quarantined until their fate is decided.

5.1.7 The laboratory director should consider a risk based approach based on publications such as the Guidelines for Blood Transfusion Services.

5.1.8 When blood packed inside a blood container is able to demonstrate logged temperature range between 2°C and 6°C, this is considered storage.

5.1.9 For remote sites without a laboratory or blood fridge, for example storage at helicopter bases, the red cells must remain in a validated sealed shipper until used and the product must be accompanied with a validated temperature monitoring device.

5.1.10 Red cells will be accepted back into inventory if the shipper is unopened and the data logger confirms the storage requirements of 2-6°C.

5.2 Red Blood Cell Transport Temperature Range

5.2.1 Red blood cells must be transported between 2°C and 10°C.

5.2.2 The upper range of 6 to 10°C is acceptable but should be limited to one occasion not exceeding 12 hours.

5.2.3 Blood products must not be transfused, except at the discretion of the laboratory director, where:
   a) Transported at temperatures outside the specified limits
   b) Transported in nonconforming equipment or
   c) There is doubt regarding transport conditions.
5.2.4 Any deviations must be clearly documented on the Red Blood Cell Storage and Transport Temperature Deviation Form.

5.2.5 Any deviations must be quarantined until their fate is decided\(^1\).

5.2.6 The laboratory director should consider a risk based approach based on publications such as the Guidelines for Blood Transfusion Services\(^2\).

5.2.7 Red blood cells which have been out of controlled storage for less than 30 minutes and not transfused can be returned to storage\(^4\).

5.2.8 If red cells are returned after 30 minutes, they must be discarded or the transfusion must be completed\(^4\).

5.2.9 Where there is any doubt regarding the conditions of storage of any products during transport, the products must not be used for transfusion\(^1\).

5.3 Transport and Receipt of Shippers

5.3.1 The Red Cross\(^5\) has validated several packing configurations see R1 to R4 in the table below.

5.3.2 These vary according to the number of components per shipper and the transport time.

5.3.3 These configurations ensure that the red cells remain within the required temperature specification during transportation.

<table>
<thead>
<tr>
<th>Packing Configuration</th>
<th>Max Number of Components per Shipper</th>
<th>Validated Transport Time*</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1</td>
<td>1-8 red cell units</td>
<td>2hr:40 min</td>
</tr>
<tr>
<td>R2</td>
<td>1-12 red cell units</td>
<td>2hr:45 min</td>
</tr>
<tr>
<td>R3</td>
<td>1-14 red cell units</td>
<td>4hr:55 min</td>
</tr>
<tr>
<td>R4</td>
<td>1-10 red cell units</td>
<td>7hr:26 min</td>
</tr>
</tbody>
</table>

*If anticipated transport time exceeds the maximum transport time, a data logger must be placed in the shipper between the components.

5.3.4 NSW Health Pathology must use the approved Red Cross Blood Shippers for transport between our laboratories.

5.3.5 Red cells will be accepted into inventory if:

a) Packed by our staff using any of the above configurations

b) There is a sheet on the outside of the box indicating the packing date and time and packing configuration and

c) The laboratory of origin is identified.

5.3.6 If the shipper has been opened during transport then the red cells cannot be accepted into inventory.
5.3.7 The use of a routine validated temperature monitoring device is not required to accept red cells into inventory as long as the shipper meets other requirements as per this policy.

5.3.8 If a validated temperature monitoring device is able to verify that storage temperature is not out of range, blood can be accepted beyond the validated transport times.

5.3.9 Blood products must not be transfused, except at the discretion of the laboratory director, where:
   a) Transported at temperatures outside the specified limits
   b) Transported in nonconforming equipment or
   c) There is doubt regarding the transport condition.

5.3.10 Any deviations must be clearly documented on the Red Blood Cell Storage and Transport Temperature Deviation Form.

5.3.11 Any deviations must be quarantined until their fate is decided.

6. Roles and Responsibilities

   6.1 This policy applies to all NSW Health Pathology staff involved in pretransfusion laboratory practice including Laboratory Managers, Staff Specialists, Scientists and Technical Officers and laboratory staff.

7. Legal and Policy Framework

   1 ANZSBT Guidelines for Transfusion and Immunohaematology Laboratory Practice, Nov 2016
   2 Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee Guidelines for Blood Transfusion Services
   3 Australian Standard AS 3864-2 Medical refrigeration equipment – for the storage of blood and blood products
   4 ANZSBT Guidelines for Administration of Blood Products, 2011
   5 Australian Red Cross Blood Service Shippers – Receipt and Use by External Institutions WI-00635 Version 1 6 June 2016

8. Review

   This policy will be reviewed by 11/09/2019.

9. Risk

   | Risk Statement | The policy ensures the safety of blood products for transfusion by providing clear direction on the appropriate temperature controlled and monitored environment for storage and transport of red blood cells. |
   | Risk Category  | Clinical Care and Patient Safety |

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10. Further Information
For further information, please contact:

<table>
<thead>
<tr>
<th>Policy Contact Officer</th>
<th>Position:</th>
<th>Chair, Transfusion Clinical Stream</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Name:</td>
<td>Professor Mark Dean</td>
</tr>
<tr>
<td></td>
<td>Telephone:</td>
<td>(02) 4320 3894</td>
</tr>
<tr>
<td></td>
<td>Email:</td>
<td><a href="mailto:Mark.Dean@health.nsw.gov.au">Mark.Dean@health.nsw.gov.au</a></td>
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11. Version History
The approval and amendment history for this document must be listed in the following table.

<table>
<thead>
<tr>
<th>Version No</th>
<th>Effective Date</th>
<th>Approved By</th>
<th>Approval Date</th>
<th>Policy Author</th>
<th>Risk Rating</th>
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<tr>
<td>1.0</td>
<td>25/08/17</td>
<td>ELT</td>
<td>25/08/17</td>
<td>Transfusion Clinical Stream Lead</td>
<td>High</td>
<td>- New Policy.</td>
</tr>
</tbody>
</table>
| 2.0        | 13/09/17       | Clinical Governance and Quality Committee | 11/09/17 | Transfusion Clinical Stream Lead  | High        | - Changed transport acceptance ranges in accordance with the ANZSBT Guideline.  
- Removed reference to the Council of Europe Guide.  
- Transportation between labs has been incorporated.