Date of publication: 15 August 2016	**Implementation:** To be determined by each Service

Change Notification UK National Blood Services No. 33 - 2016

Removal of red cells from a controlled temperature environment

Applies to the Guidelines for the Blood Transfusion Services in the United Kingdom – 8th Edition 2013

Following a review of data from UKBTS and published studies, a number of changes are being made in relation to red cells as follows:

Guidance relating to re-issue of blood components that have been removed from controlled storage is currently given in the BCSH Guidelines on the Administration of Blood Components (2009) but not the Red Book. Following a review of data relating to the quality and safety of red cells removed from controlled storage, we are making a number of changes to the storage and transport sections of the specifications of red cell components in the Red Book. This includes giving guidance relating to removal from 2-6oC controlled storage within hospitals which will also be detailed in the revised BCSH guidelines (due for release 2016). A paper describing the rationale for these changes can be found in the Document Library, General Documents section, on the JPAC website http://www.transfusionguidelines.org.uk/document-library/general-documents

These changes apply to the following components:

- 7.5:Red Cells, Leucocyte Depleted
- 7.6:Red Cells in Additive Solution, Leucocyte Depleted
- 7.22: Red Cells for Intrauterine Transfusion (IUT), Leucocyte Depleted
- 7.24:Red Cells for Exchange Transfusion, Leucocyte Depleted
- 7.25:Red Cells for Neonates and Infants, Leucocyte Depleted
- 7.26:Red Cells in Additive Solution for Neonates and Infants, Leucocyte Depleted

These changes **DO NOT** apply to the following components

- 7.7:Red Cells, Washed, Leucocyte Depleted
- 7.8:Red Cells, Thawed and Washed, Leucocyte Depleted

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The storage and transport sections of these specifications are changed as follows:

Storage

For general guidelines, see section 6.7.

- Variation from the core temperature of 4 ±2℃ of th e finished component must be kept to a minimum during storage at all stages of the blood supply chain and restricted to any short period necessary for examining, labelling or issuing the component.

- Exceptionally, i.e. due to equipment failure at a Blood Centre or hospital, for temperature excursions where the core temperature has not exceeded 10℃ or fa llen below 1℃, components may be released for transfusion provided that:
  - the component has been exposed to such a temperature change on one occasion only
  - the duration of the temperature excursion has not exceeded 5 hours
  - a documented system is available in each Blood Centre or hospital to cover such eventualities
  - adequate records of the incident are compiled and retained.

Transportation

For general guidelines, see section 6.11.

For red cell components, transit containers and packing materials and procedures should have been validated to ensure the component surface temperature can be maintained between 2℃ and 6℃ during transportation. Additionally:

- the validation exercise should be repeated periodically

- if melting ice is used, it should not come into direct contact with the components

- dead air space in packaging containers should be minimised

- as far as is practicable, transit containers should be equilibrated to their storage temperature prior to filling with components

- for transportation between blood supplier and hospital an upper limit of 10°C surface temperature is acceptable but should be limited to one occasion, not exceeding 12 hours.

In some instances it is necessary to issue red cell components from the blood supplier to hospitals that have not been cooled to their storage temperature prior to placing in the transit container. The transport temperature specified above is not applicable for such consignments.

Removal from and return to 2-6°C controlled storage within hospitals [Entirely new section]

For occasions when red cells are removed from 2-6°C controlled storage (eg when issued to a clinical area immediately prior to transfusion) and returned then:

- If possible, time out of a controlled temperature environment should be restricted to under 30 minutes

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- if 30 minutes is exceeded the unit should not be returned to the issue location in the refrigerator, but returned to the transfusion laboratory or quarantined remotely using electronic blood tracking

- up to 60 minutes out of controlled temperature is acceptable, provided the unit is then quarantined by placing in a secure refrigerator for at least 6 hours prior to reissue, to allow the unit to return to 2-6^{o}C

- Hospitals will need to identify such units so that they are not subject to being out of controlled temperature storage for between 30 and 60 minutes on more than three occasions.

Transfusion should be completed within 4 hours of issue out of a controlled temperature environment.

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