**Guidelines for the Blood Transfusion Services**

**Definitions**

http://www.transfusionguidelines.org/red-book/definitions

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**Definitions**

These definitions are taken from the Blood Safety and Quality Regulations 2005 unless stated otherwise.

**Additive solution** means a solution specifically formulated to maintain beneficial properties of cellular components during storage.

**Allogeneic donation** means blood and blood components collected from an individual and intended for transfusion to another individual, for use in medical devices or as starting material or raw material for manufacturing into medicinal products.

**Apheresis** means a method of obtaining one or more blood components by machine processing of whole blood in which the residual components of the blood are returned to the donor during or at the end of the process.

**Autologous donation** means blood and blood components collected from an individual and intended solely for subsequent autologous transfusion or other human application to that same individual.

**Autologous transfusion** means a transfusion in which the donor and the recipient are the same person and in which pre-deposited blood or blood components are used.

**Blood** means whole human blood collected from a donor and processed either for transfusion or for further manufacturing.

**Blood component** means a therapeutic constituent of human blood (red cells, white cells, platelets and plasma) that can be prepared by various methods.

Blood component release means a process which enables a blood component to be released from a quarantine status by the use of systems and procedures to ensure that the finished product meets its release specification.

**Blood Establishment** shall mean any structure or body that is responsible for any aspect of the collection and testing of human blood or blood components, whatever their intended purpose, and their processing, storage, and distribution when intended for transfusion. This does not include hospital blood banks. (EU Directive 2002/98/EC definition).


**Blood product** means any therapeutic product derived from human blood or plasma.

**Buffy coat** means a blood component prepared by centrifugation of a unit of whole blood, and which contains a considerable proportion of the leucocytes and platelets.
Commission means the European Commission.

Cryoprecipitate means a plasma component prepared from plasma, fresh-frozen, by freeze-thaw precipitation of proteins and subsequent concentration and resuspension of the precipitated proteins in a small volume of the plasma.

Cryopreservation means prolongation of the storage life of blood components by freezing.

Deferral means suspension of the eligibility of an individual to donate blood or blood components, such suspension being either permanent or temporary.

Distribution means the act of delivery of blood and blood components to other Blood Establishments, hospital blood banks and manufacturers of blood products, other than the issuing of blood or blood components for transfusion.

Doctor means a registered medical practitioner.

Donor carer means a person who has passed both the written and practical examinations of NHS Blood and Transplant, the Scottish National Blood Transfusion Service, the Northern Ireland Blood Transfusion Service or the Welsh Blood Service in the care of blood donors and who holds a current certificate of competence, awarded by that body, in the care of blood donors.

Emerging infectious disease means a newly recognised, clinically distinct infectious disease, or a known disease whose reported incidence within the past two decades is increasing in a given place or among a specific population (Health Protection Agency definition).

Facilities means hospitals, clinics, manufacturers, and biomedical research institutions to which blood or blood components may be delivered (Commission Directives on haemovigilance/traceability).

Granulocytes, apheresis means a concentrated suspension of granulocytes obtained by apheresis.

Haemovigilance means a set of organised surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients, and the epidemiological follow-up of donors.

Health service hospital has the same meaning as in section 128 of the National Health Service Act 1977.

Hospital means a health service hospital or an independent hospital.

Hospital blood bank means any unit within a hospital which stores and distributes, and may perform compatibility tests on, blood and blood components exclusively for use within hospital facilities, including hospital-based transfusion activities.

Imputability means the likelihood that a serious adverse reaction in a recipient can be attributed to the blood or blood component transfused or that a serious adverse reaction in a donor can be attributed to the donation process (Commission Directives on haemovigilance/traceability).

Independent hospital has the same meaning as in Section 2 of the Care Standards Act 2000.

Inspection means formal and objective control to identify problems in accordance with standards adopted to assess compliance with these Regulations.

Inspector means a person appointed by the Secretary of State to carry out inspections pursuant to Regulation 15(10).

Nurse means a registered nurse or registered midwife.
**Person responsible for management of a hospital blood bank** means:

(a) in the case of a hospital blood bank located in a hospital managed by a health service body, that body, and

(b) in the case of an independent hospital, the registered person.

**Plasma** means the liquid portion of the blood in which the cells are suspended. Plasma may be separated from the cellular portion of a whole blood collection for therapeutic use as fresh-frozen plasma or further processed to cryoprecipitate and cryoprecipitate-depleted plasma for transfusion. It may be used for the manufacture of medicinal products derived from human blood and human plasma or used in the preparation of pooled platelets, or pooled, leucocyte-depleted platelets. It may also be used for resuspension of red cell preparations for exchange transfusion or perinatal transfusion.

**Plasma, cryoprecipitate depleted for transfusion** means a plasma component prepared from a unit of plasma, fresh-frozen. It comprises the residual portion after the cryoprecipitate has been removed.

**Plasma, fresh-frozen** means the supernatant plasma separated from a whole blood donation or plasma collected by apheresis, frozen and stored.

**Platelets, apheresis** means a concentrated suspension of blood platelets obtained by apheresis.

**Platelets, apheresis, leucocyte depleted** means a concentrated suspension of blood platelets, obtained by apheresis, and from which leucocytes are removed.

**Platelets, recovered, pooled** means a concentrated suspension of blood platelets, obtained by processing of whole blood units and pooling the platelets from the units during or after separation.

**Platelets, recovered, pooled, leucocyte depleted** means a concentrated suspension of blood platelets, obtained by processing of whole blood units and pooling the platelets from the units during or after separation, and from which leucocytes are removed.

**Platelets, recovered, single unit** means a concentrated suspension of blood platelets, obtained by processing of a single unit of whole blood.

**Platelets, recovered, single unit, leucocyte depleted** means a concentrated suspension of blood platelets, obtained by processing of a single whole blood unit from which leucocytes are removed.

**Qualified health professional** means:

(a) a doctor

(b) a nurse or

(c) a donor carer.

**Quality assurance** means all the activities from blood collection to distribution made with the object of ensuring that blood and blood components are of the quality required for their intended use (Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003).

**Red cells** means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed.

**Red cells, apheresis** means the red cells from an apheresis red cell donation.
Red cells, buffy coat removed means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed. The buffy coat, containing a large proportion of the platelets and leucocytes in the donated unit, is removed.

Red cells, buffy coat removed, in additive solution means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed. The buffy coat, containing a large proportion of the platelets and leucocytes in the donated unit, is removed. A nutrient or preservative solution is added.

Red cells in additive solution means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed. A nutrient or preservative solution is added.

Red cells, leucocyte depleted means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed, and from which leucocytes are removed.

Red cells, leucocyte depleted, in additive solution means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed, and from which leucocytes are removed. A nutrient or preservative solution is added.

Reporting establishment means the Blood Establishment, the hospital blood bank or facilities where the transfusion takes place that reports serious adverse reactions and/or serious adverse events to the Competent Authority (Commission Directives on haemovigilance/traceability).

Reporting year means the period of 12 months ending on 31 March.

Responsible person in relation to a Blood Establishment means the person who has been designated pursuant to Regulation 6 as the responsible person for that Blood Establishment.

Serious adverse event means any untoward occurrence associated with the collection, testing, processing, storage and distribution, of blood or blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.

Serious adverse reaction means an unintended response in a donor or in a patient associated with the collection or transfusion of blood or blood components that is fatal, life-threatening, disabling, or which results in, or prolongs, hospitalisation or morbidity.

Site means any premises at which a Blood Establishment carries out any of the activities listed in Regulation 3(2), but shall not include any premises not owned or managed by the Blood Establishment at which blood is collected, or any mobile blood collection unit.

Statistical process control means a method of quality control of a product or a process that relies on a system of analysis of an adequate sample size without the need to measure every product of the process.

Tissue Establishment means a tissue bank or a unit of a hospital or another body where activities of processing, preservation, storage or distribution of human tissues and cells are undertaken. It may also be responsible for procurement or testing of tissues and cells (Directive 2004/23/EC).

Traceability means the ability to trace each individual unit of blood or blood component derived thereof from the donor to its final destination, whether this is a recipient, a manufacturer of medicinal products or disposal, and vice versa (Commission Directives on haemovigilance/traceability).

Validation means the establishment of documented and objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.
Washed means a process of removing plasma or storage medium from cellular products by centrifugation, decanting of the supernatant liquid from the cells and addition of an isotonic suspension fluid, which in turn is generally removed and replaced following further centrifugation of the suspension. The centrifugation, decanting, replacing process may be repeated several times.

Whole blood means a single blood donation.

Explanation of terms used in the eighth edition

The terms ‘Blood Service’/‘Blood Transfusion Service’/‘Transfusion Service’ refer to Blood Establishments. The terms ‘Blood Centre’/‘Blood Transfusion Centre’/‘Transfusion Centre’ refer to the sites from which the services of the Blood Establishments are delivered.

The reason for such diversity is that in 2012 the four Blood Establishments in the UK use slightly different titles.