

# Statement of the International Society of Blood Transfusion position on the labelling, coding and identification of blood, blood components, tissues, cells and organs



## Recognizing

- the importance of a globally unique and generally accepted standard for labelling, coding and identification of blood and blood components as a prerequisite for ensuring safety and effectiveness of international and regional relief operations in major disaster and emergencies<sup>1</sup> ;
- that the World Health Assembly in Resolution WHA63.22 encourages the implementation of globally consistent coding systems for human cells, tissues and organs as such in order to facilitate national and international traceability of materials of human origin for transplantation<sup>2</sup> ;
- the European Union requirement for a unique identification code for each donation of blood, tissues and cells as specified in the European Directives 2002/98/EC and 2004/23/EC<sup>3,4</sup> ;
- the importance of a consistent approach to coding and labelling of substances of human origin to ensure effective traceability and vigilance of all donated human material;
- the need for a standard that is stable, flexible, and effectively managed to meet the rapidly changing needs of the transfusion and transplantation communities;
- the widespread successful adoption of the ISBT 128 information standard in many countries throughout the world<sup>5</sup> ;
- the international support for the use of ISBT 128 coding and labelling for cellular therapy products<sup>6,7,8</sup> ;
- the ongoing effectiveness of ICCBBA in maintaining and developing the ISBT 128 Standard to the satisfaction of the professional user community;

The International Society of Blood Transfusion supports the principle of universal use of ISBT 128 for labelling, coding and identification of blood, blood components, tissues, cells and organs. Its use should be progressively implemented as appropriate to the individual service situation.

## References

1. Proceedings of the Blood Safety and Availability Committee, Center for Biologics and Evaluation 1997. <http://www.fda.gov/ohrms/dockets/ac/97/transcpt/3304t2.rtf>. Accessed 20 Apr 2010.
2. World Health Assembly Resolution 63.22 Human Tissue and Organ Transplantation. May 2010 [http://apps.who.int/gb/ebwha/pdf\\_files/WHA63/A63\\_R22-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_R22-en.pdf). Accessed 20 Nov 2011
3. Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components. OJEU L33/30 (2003)
4. Directive 2004/23/EC of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. OJEU L102/48 (2004)
5. Ashford P, Fearon M, Bedford R. Report on the joint IBEPAG/ICCBBA survey on import/export and blood component labeling. Vox Sang 2010;98:85-6
6. Ashford P et al. Standards for Terminology and Labeling of Cellular Therapy Products. Transfusion 2007;47:1319-27
7. Second Consensus Statement on Terminology, Coding and Labeling of Cellular Therapy Products. March 2011. <http://www.iccbba.org/docs/tag/ctclag-joint-statement.pdf>. Accessed 20 Nov 2011
8. World Marrow Donor Association Position Paper: Introduction and Importance of a Globally Unique Identity and Labeling Format (ISBT 128) April 2011. [http://www.worldmarrow.org/fileadmin/WorkingGroups\\_Subcommittees/RLAC/20110401-RLAC-INFO-LABEL.pdf](http://www.worldmarrow.org/fileadmin/WorkingGroups_Subcommittees/RLAC/20110401-RLAC-INFO-LABEL.pdf). Accessed 20 Nov 2011