ISBT 128

ICCBBA is a nongovernmental organization in official relations with the World Health Organization

An Introduction to ISBT 128

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1 Preface

A great deal of important information is presented on the label of medical products of human origin (MPHO) such as blood, cells, tissues, and organs. The information varies from country to country according to licensing regulations, language differences, and local practice but, in all cases, it is essential that the information is recorded accurately, transferred correctly, and that critical items are clearly understood by medical personnel administering/transplanting the product. In addition, robust audit trails must be in place to allow tracing between donor and recipient.

This need for accurate transfer of information goes beyond national borders. In today's world of multinational relief programs and military operations, the need to closely match donors and recipients for some products, and growing international collaboration in meeting the clinical needs of transplant recipients, MPHO collected in one country may be used in another. This creates a need for international agreement on product descriptions and a means of ensuring a unique identification of the donation throughout the world to support traceability requirements.

Information transfer involves text on labels, but it also involves information transfer among computer systems. Increasingly, facilities involved in MPHO operate sophisticated computer systems to enhance safety and efficiency. Transfer of information between such facilities by electronic means ensures accuracy, but can only be effectively achieved in a global context by use of internationally agreed standards to define the information environment.

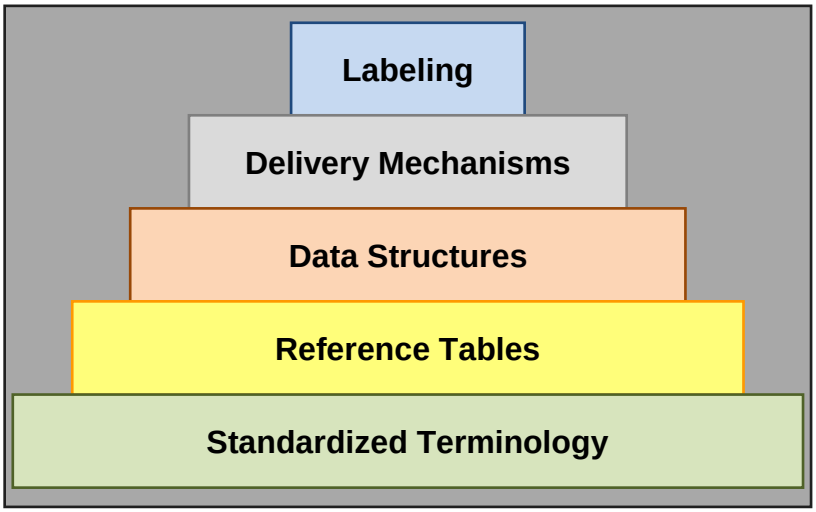
Recognizing that the safety of MPHO is enhanced by effective systems of traceability, transparency, vigilance and surveillance, the World Health Organization has established an organization-wide initiate for MPHO. This initiative identifies three states for global governance of MPHO, one of which is the "global use of ISBT 128 for all medical products of human origin to ensure unique identification, optimal traceability and interoperability between countries, and across all medical products of human origin, for both routine and emergency use".
WHO and ICCBBA have had a joint work program since 2011 and the

status of NGO in official relations with WHO was conferred on ICCBBA at the WHO Executive Board Meeting on 25 Jan 2014.

If you would like more information on any of the topics in this document, go to www.iccbba.org or email iccbba@iccbba.org

2 What is the Information Environment?

The information environment comprises a number of layers each of which needs to be in place to ensure that standardization can be achieved.



Standardized Terminology

At the base lies the standardized terminology (ST-002 *ISBT 128 Standard Terminology for Medical Products of Human Origin*) that will ensure common understanding of terms. Without clarity at this level any further attempt at standardization is lost. However, obtaining agreement on standardized terminology at the necessary level of detail involves careful analysis and robust consensus. Simple examples serve to illustrate this.

- For blood, the term “leukodepleted” is widely understood as meaning the removal of leukocytes from a blood component. However there are different ways of carrying out such a removal and differing amounts of residual leukocytes that are used to define “leukodepleted.”
- For cells, DMSO is used during cryopreservation of a cellular therapy product. However, different concentrations may be used and hydroxyethyl starch may be added.

- For tissues, glycerol may be used at different concentrations for different purposes.

In order to accommodate these variations a range of standardized terminology and associated values are required. Extreme care is needed in order to ensure that internationally agreed standardized terminology is defined at the required level of granularity. This provides confidence in the consistency of both the information being transferred and the quality of the product described. The standardized terminology needs to be accessible to all users of the standard.

Reference Tables

Once the standardized terminology is in place, these can be combined to give the required items of information. Reference tables are built to map each item to a suitable coding. Such tables can be large and complex and it is essential that they are managed to ensure that they can be modified to meet the changing needs of clinical practice in a manner which maintains their integrity and avoids ambiguity or redundancy.

Product reference tables in particular need to combine a tightly defined structure with the flexibility to accommodate expansion and change in ways which cannot be anticipated.

Successful management of standardized terminology and reference tables requires input from both clinical experts in the field and information specialists. The tables themselves need to be published in a manner that allows all users of the standard to access the most up-to-date versions in a timely manner.

Data Structures

Having built reference tables which convert the clearly defined information into codes suitable for electronic transmission, it is necessary to define data structures in which to embed the data. Data structures define the technical characteristics necessary for the interpretation of the information. They specify the context and structure and provide the links to the appropriate reference tables for conversion of codes to meaningful information.

Data structures need to be clear and unambiguous and must take into account any constraints imposed by the anticipated delivery mechanisms. For example, data structures that will be used in linear bar codes are limited in the number of characters they can contain.

Delivery Mechanism

The delivery mechanism is the means of delivering the electronic information. Probably the most well-known delivery mechanism is the linear bar code that has been used in blood transfusion practice for many years. There are in fact several types of linear bar codes, including Code 128, a bar code standard widely used in coding standards such as GS1 and ISBT 128.

Higher capacity delivery systems are available using 2-dimensional or reduced space symbology bar codes. These codes can carry much more information in each symbol. Data Matrix has been chosen as the 2-D symbology used with ISBT 128 in labeling applications.

More recently the use of Radio frequency identification (RFID) chips that can carry encoded information is being developed for medical products of human origin.

It is important to recognize that a range of delivery systems can sit at this level of the hierarchy. The standardized terminology, reference tables, and data structures of the information standard can be delivered as easily in a linear bar code as they can in an RFID tag. The standards themselves need to be adaptable in order to make best use of new delivery mechanisms as they are developed.

Labeling

The final element in the information environment is the associated labeling. Although there will be other labeling requirements that fall outside the information environment described in this document, an effective system needs to consider the physical association between the information and the product. Whether incorporated into a bar code or an electronic tag, there needs to be a mechanism that will ensure correct physical assignment of information to the product, and confidence in the association between electronically stored information and eye-readable printed information. This latter requirement must not be overlooked in the enthusiasm to embrace remotely re-writable tags.

The Information Environment

Together these elements form the information environment. For such a system to be, and to remain effective, it must be carefully designed and managed. There must be an on-going dialogue between clinical users, information specialists, and equipment and software vendors to ensure that the standard continues to support rapidly developing clinical practice.

3 The ISBT 128 Standard

The ISBT 128 standard provides the specification for many of the elements of the information environment required in transfusion and transplantation. It defines the lower three levels of the model, the standardized terminology, reference tables, and data structures. Minimum requirements are also defined for delivery mechanisms and labeling. By complying with ISBT 128, collection and processing facilities can provide electronically readable information that can be read by any other compliant system.

ISBT 128 specifies:

- a donation numbering system that ensures globally unique identification;
- the information to be transferred, using internationally agreed reference tables;
- an international product reference database;
- the data structures in which this information is placed;
- a bar coding system for transfer of the information on the product label;
- a standard layout for the product labels of some subject areas;
- a standard reference for use in electronic messaging.

The standard, originally accepted by the ISBT Council in 1994, has gained widespread acceptance. It has been extended beyond blood transfusion to include all medical products of human origin. By the end of 2017, more than 5,000 facilities in 87 countries across six continents were registered to use ISBT 128, and this number continues to grow.

More than 40 million blood, cell, and tissue products are labeled with ISBT 128 each year.

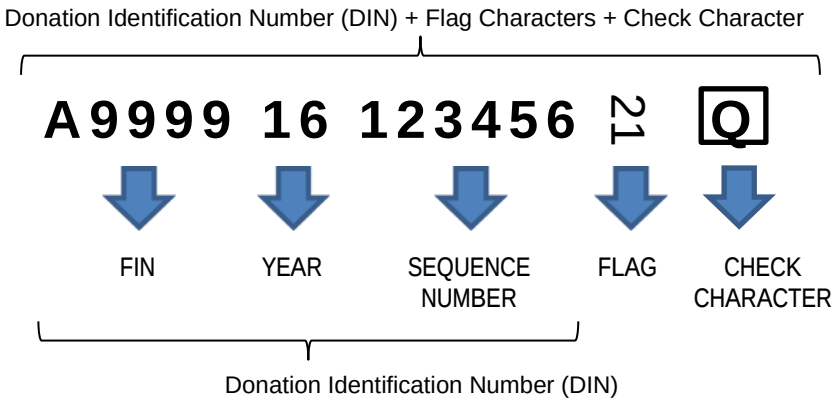
Following meetings between FACT, JACIE, and ICCBBA, an agreement was reached to support the use of ISBT 128 for coding and labeling CT products, and this decision has been endorsed by the Boards of major cellular therapy professional organizations.

A plan for full implementation of ISBT 128 is also required by AABB.

The most current version of the standard terminology is maintained on the ICCBBA website at www.iccbba.org.

4 Unique Donation Identification

ISBT 128 provides for unique identification of any donation worldwide. It does this by using a 13-character identifier built up from three elements, the first identifying the facility that assigned the number, the second the year, and the third a sequence number for the donation. For example:



where:

A9999 is the **F**acility **I**dentification **N**umber (FIN) of the facility that assigned the DIN;

16 identifies the year in which the DIN was assigned;

123456 is the 6 digit sequence number controlled and maintained by the facility assigning the DIN.

These first 13 characters comprise the **D**onation **I**dentification **N**umber (DIN).

The two digits printed vertically (the “flag” characters) allow individual bar codes in a number set to be discretely identified hence providing an option to add process control into the collection process.

An additional character is enclosed in a box at the end of the identifier. This is a checksum character used when a number is entered into a computer system through the keyboard to verify the accuracy of the keyboard entry.

More information about the DIN can be found in the *ISBT 128 Standard Technical Specification*.

FINs are assigned by ICCBBA who maintain a database of all registered facilities on their website (www.iccbba.org). A lookup program allows lookup of individual facility codes. ICCBBA licensed facilities and vendors are able to download a full listing of all licensed facilities.

5 Product Descriptions

ISBT 128 provides a comprehensive and highly flexible system for describing products and assigning product codes. The foundation of this system is a standard terminology which is constructed by international consensus to ensure global consistency in use and understanding. The standard terminology is maintained on the ICCBBA website and is publicly available. Terminology for each MPHO field is managed by Technical Advisory Groups of ICCBBA that are composed of experts in appropriate fields.

New products are defined by combining pieces of information from the standardized terminology in a way that unambiguously describes the product. This process is made easier by the use of the concepts of Class, Modifier, and Attributes. (Note: Modifiers are not used in all product types.)

This unique product description is assigned a code that becomes incorporated into the ISBT 128 Product Description Code Database, ensuring that the product will be accurately identified in any facility in the world that is using ISBT 128.

New entries into the Product Description Code Database can be readily accommodated allowing the system to expand to meet a growing range of products without losing the overall structure of the coding system.

The following examples are taken from the database table:

Component Class:	RED BLOOD CELLS
Modifier:	None
Core Conditions:	Anticoagulant CPDA-1; Original volume 450 mL; Storage conditions refrigerated
Attribute:	Irradiated

Is assigned product description code E0206

Component Class:	HPC, CORD BLOOD
Core Conditions:	Anticoagulant not specified; Volume not specified; Storage conditions: <=-150C
Attributes:	10% DMSO Other Additives:Yes Cryopreserved

Is assigned product description code S1150

Component Class:	TENDON, TIBIALIS, POSTERIOR
Attribute:	Left

Is assigned product description code T0246

While the description of a product in the database is standardized, the text that appears on the actual label of a product is under national control. This allows for differences in languages and regulatory requirements.

6 Other Data Structures

In addition to the donation identifier and product identifier, many other pieces of important information need to be provided with a product. These vary by the type of product being labeled, as well as by national requirements. The ISBT 128 standard provides over thirty data structures that can be used to code product information such as:

- ABO and RhD Blood Groups;
- Type of Donation (Volunteer, Directed, Autologous, etc.);
- Expiration Date and Time;
- Collection Date and Time;
- Red Cell Phenotyping Information;
- CMV and other test results;
- Collection Container Catalog and Lot Number;
- Patient Date of Birth.

7 Delivery Mechanisms

The delivery mechanism is the means by which the information is represented in a machine readable manner. The most common such mechanism is the linear bar code. ISBT 128 has traditionally been based on the linear bar code using the Code 128 symbology and this is still required on blood donations. However, an additional two-dimensional Data Matrix symbol can be added to a blood product label. A single Data Matrix symbol can carry the same information as encoded in multiple linear bar codes. This allows much more rapid scanning of products at the point of issue and receipt. In the Cellular Therapy and Tissue Banking fields the need to use very small containers means that label size is severely restricted. In these situations the use of a Data Matrix symbol may replace linear codes and be the sole bar code on the label.

Figure 1 Comparative size of Code 128 and Data Matrix Symbols

The Data Matrix symbol on the left contains all of the information held in the five Code 128 symbols on the right.

To use Data Matrix, or other high efficiency delivery mechanisms, ISBT 128 data structures must be strung together in a standardized way into a single message called a Compound Message. More information on Compound Messages may be found in the *ISBT 128 Standard Technical Specification* (http://www.iccbba.org/tech-library/iccbba-documents/standards-documents).

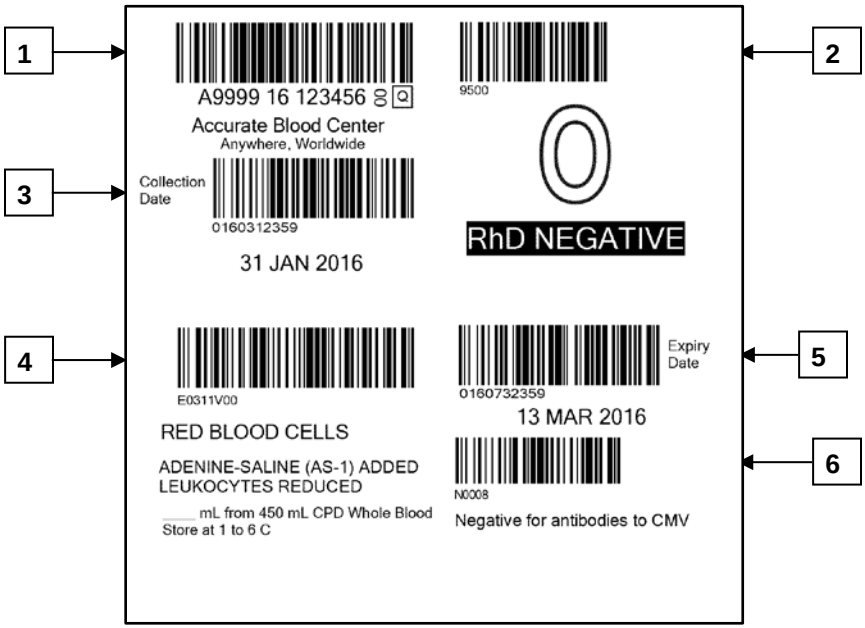
There is much interest in the use of RFID tags. This technology is still developing, but may provide significant benefits in some situations. ISBT 128 Compound Messages are compatible with RFID.

8 Product Labeling

In addition to specifying the requirements for the electronic coding of information, ISBT 128 provides a standard labeling format that ensures a consistent layout of the bar codes on product labels. Critical eye-readable information such as blood groups (when pertinent), product description, and expiration date also appear in fixed positions on the label. This reduces the risk of confusion when products from multiple sources are being used. Labels are designed to meet requirements of other standard setting organizations.

ISBT 128-specified labels are illustrated below.

Figure 2 Blood Label



1 Donation Identification Number
2 ABO/RhD Blood Groups
3 Collection Date (optional)
4 Product Code
5 Expiration Date (and Time)
6 Special Testing (optional)

In addition to linear bar codes, a 2-D symbol, comprising all the information in the linear bar codes, may be placed on the label. Scanning a single symbol improves efficiency, but requires an imaging scanner.

Figure 3 Blood Label with example 2-D Symbol

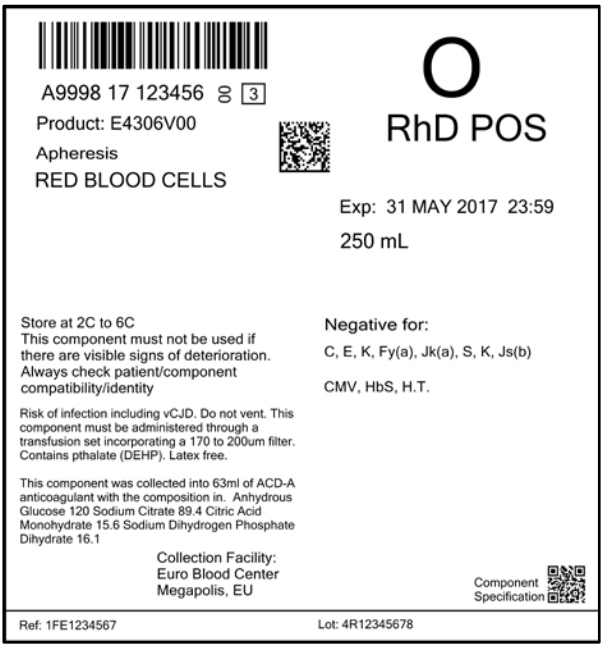
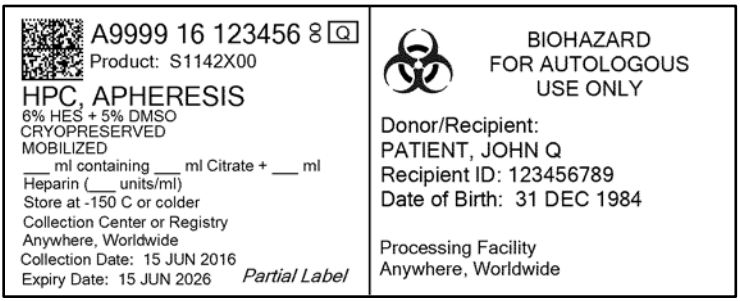


Figure 4 Cellular Therapy 100 mm x 100 mm Label

1 Donation Identification Number
2 ABO/RhD Blood Groups
3 Collection Date/Time
4 Product Code
5 Expiration Date/Time

Figure 5 Fold-over Cellular Therapy Label

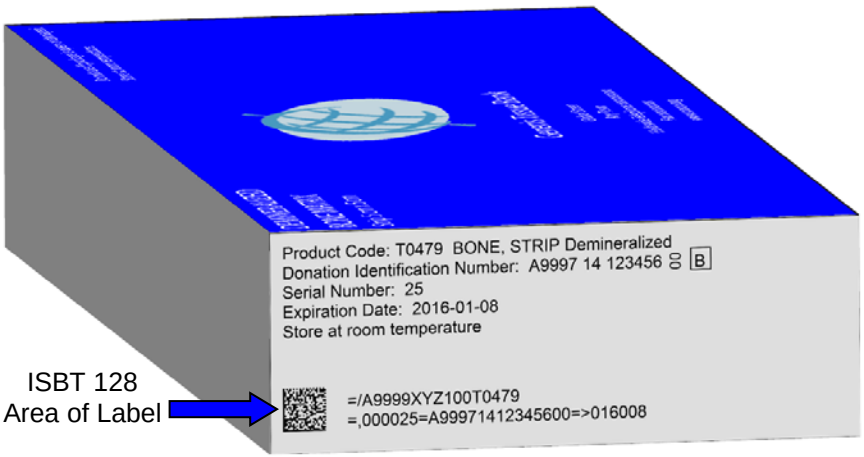


Single 2-D symbol contains electronic information for the Donation Identification Number, Product Code, Expiration Date/Time, Collection Date, Patient Hospital Identification Number, and Patient Date of Birth.

Figure 6 Tissue Label - 2-D Symbol

Single 2-D symbol contains electronic information for Donation Identification Number, Product Code, and Expiration Date/Time.

Figure 7 Use of Small Label on 360 mm by 100 mm Container



9 The Role of Technical Advisory Groups

ICCBBA involves international volunteer experts in several areas of MPHO in the development and maintenance of the standard. These experts are organized into Technical Advisory Groups (TAGs) that meet regularly (both face-to-face and through conference calls) to further develop and expand the standard ensuring it continues to meet the needs of its users. The vital role of these groups cannot be overemphasized. It is only through the involvement of such expert panels that ICCBBA can be assured it has the knowledge base to anticipate the needs of its users in fields where change is constant. More than 250 experts participate in the ICCBBA TAGs.

- For Blood Banking, the advisory groups are the Asia Pacific Technical Advisory Group (APTAG), the Europe, Middle East and Africa Technical Advisory Group (EMATAG), and the Americas Technical Advisory Group (ATAG). The groups comprise participants from blood collection facilities, testing laboratories, transfusion services, professional organizations, regulatory agencies, and vendors from around the world.
- For Cellular Therapy, the advisory group is the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). The group comprises representatives from the following professional organizations: AABB, Asia Pacific Blood and Marrow Transplant (APBMT), American Society for Blood and Marrow Transplantation (ASBMT), American Society for Apheresis (ASFA), European Group for Blood and Marrow Transplantation (EBMT), Foundation for the Accreditation of Cellular Therapy (FACT), ICCBBA, International Society of Blood Transfusion (ISBT), International Society for Cellular Therapy (ISCT), Joint Accreditation Committee of ISCT and EBMT (JACIE), National Marrow Donor Program (NMDP), and the World Marrow Donor Association (WMDA). In addition to these representatives, technical experts and regulatory liaisons also serve on the committee.
- For tissues, there are four advisory groups: the North American Tissue Technical Advisory Group (NATTAG), the European Tissue Technical Advisory Group (ETTAG), the International Tissue

Technical Advisory Group (ITTAG), and the international Eye Bank Technical Advisory Group (EBTAG). EBTAG comprises representatives from the following professional organizations: Asia Cornea Society (ACS), Eye Bank Association of Australia and New Zealand (EBAANZ), Eye Bank Association of India (EBAI), European Eye Bank Association (EEBA), Eye Bank Association of America (EBAA), and the Pan American Association of Eye Banks. Experts in recovery and processing of tissues, surgeons (transplant, corneal tissue, and retinal), regulators, representatives from standard-setting organizations, and vendors participate in these groups.

- In the field of organ terminology, the World Health Organization (WHO) and ICCBBA have collaborated to harmonize nomenclature through the Standardization of Organ Nomenclature Globally (SONG) project.
- For tissue engineered products, the advisory group is the Regenerative Medicine Technical Advisory Group (RMTAG). RMTAG comprises a core membership of other ICCBBA TAG chairs and experts, along with ICCBBA staff members. Technical experts in a given area are called upon to provide their knowledge and expertise when needed.
- For assisted reproductive technology products, the advisory group is the Assisted Reproductive Technology Technical Advisory Group (ARTTAG). The membership comprises technical experts in ART and representatives appointed by organizations with an interest in assisted reproductive technology.
- For milk banking, the advisory group is the Milk Banking Technical Advisory Group (MBTAG). The group comprises representatives from the European Milk Bank Association, the Human Milk Banking Association of North America, and international experts in the field of milk banking.

10 The Role of ICCBBA

ICCBBA is the not-for-profit, nongovernmental standards body responsible for the management, development and distribution of the ISBT 128 Standard. It maintains a permanent office to manage the registration of facilities, update reference tables and databases, and develop additional functionality. It supports the Technical Advisory Groups comprising experts from the transfusion/transplantation communities and relevant manufacturers.

Fees collected by ICCBBA from registered facilities are used to support these functions.

Through its activities, ICCBBA provides the management support essential to sustain standard coding in the complex environment of medical products of human origin. In particular it delivers:

1) stability – users can be confident in the stability of the standard to satisfy the long time periods over which information has to be retained (e.g. EC requirements for data to be stored and traceable for 30 years);
2) user focus – the user community are the experts in their field and ICCBBA, through its Technical Advisory Groups, ensures that the information standard meets, rather than dictates, user needs;
3) flexibility – as clinical and scientific knowledge grows there is rapid development with changing information needs. ICCBBA ensures that the standard is flexible enough to accommodate these needs;
4) responsiveness – in these rapidly developing medical fields ICCBBA ensures that the standard is able to respond to user needs in a timely manner;
5) globalization – ISBT 128 is a truly international standard with endorsement worldwide;
6) compatibility – standards do not work in isolation but need to interface with equipment, software, and other standards. ICCBBA works with industry and other standards bodies to maximize compatibility.

Blood, cellular therapy, tissue, organ, and banked human milk collection

facilities, and manufacturers of equipment or software that uses ISBT 128, are required to register with ICCBBA and pay a registration and an annual license fee. Registered organizations obtain access to all ICCBBA documents and databases.

For further information on ISBT 128, visit the ICCBBA Website at www.iccbba.org.

