



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

ISBT 128: The Coding System Specifically Designed for HCT/P

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ICCBBA

Agenda:

- What is ICCBBA and ISBT 128
- What makes HCT/P different from other medical devices
- Standardized product coding as an element of the Device Identifier
- The Donation Identification Number to meet the requirements of a distinct identifier in 1271.370 as element of the Production Identifier
- How to get started

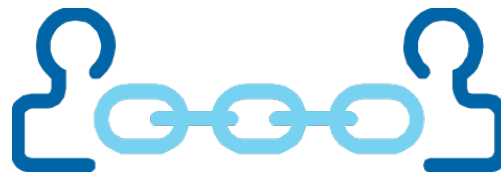
Who we are



- “International Council for Commonality in Blood Bank Automation” dba ICCBBA
- Non-profit standards setting organization that manages the ISBT 128 standard
- An issuing agency under ISO 15459
- One of the 3 issuing agencies approved for UDI by CDRH
- Non-governmental organization (NGO) in official relations with the World Health Organization
- ISO 9001:2008 certified’
- Based in the California
- Incorporated in 1995
- 10 member Board of Directors and 300+ member Technical Advisory Groups (TAGs) are volunteers from 45 countries.
- Small staff (12) that manage the technical documentation and databases, promote and support the global implementation of the standard, organize technical meetings, and administer registration and licensing.
- Operations are funded entirely from licensing fees collected from both facilities using the ISBT 128 Standard and from vendors providing equipment or software that incorporates the standard.

What is ISBT 128?

A well established terminology, coding, and labeling system specifically designed to provide traceability between donor and recipient for Medical Products of Human Origin (MPHO)

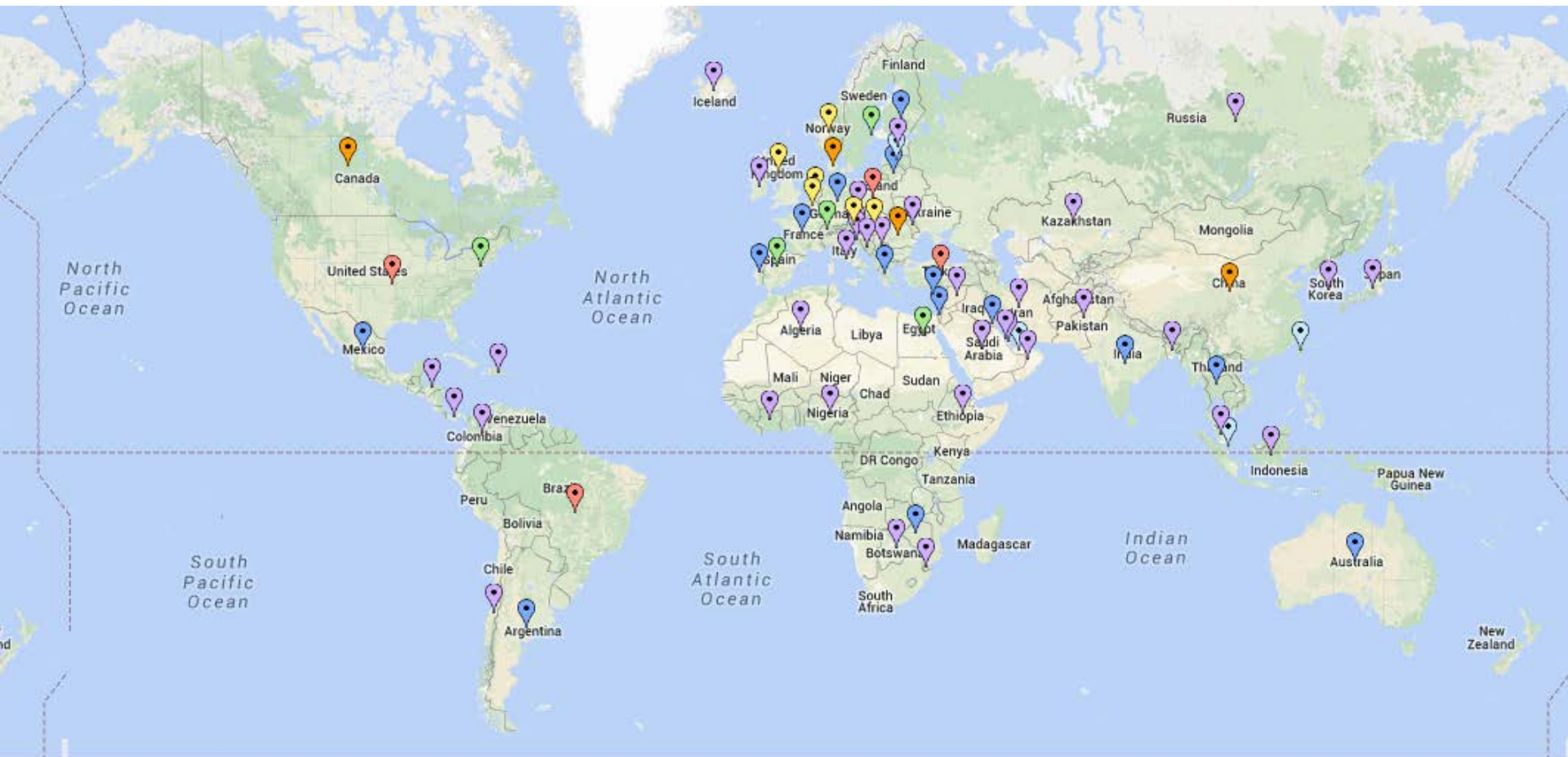


(MPHO: includes organs, tissues, blood, cells, tissue engineering/regenerative medicine products, milk—includes HCT/P)

ISBT 128

- Recognized by WHO on its website as the sole global standard for the identification and coding of MPHO (including HCT/P)
- Endorsed by 21 international professional societies and accreditation bodies
- Terminology is incorporated into the Single European Coding System for cells and tissues
- Recommended by Advisory Committee for Blood and Tissue Safety and Availability (ACBTSA) for all MPHO in the United States

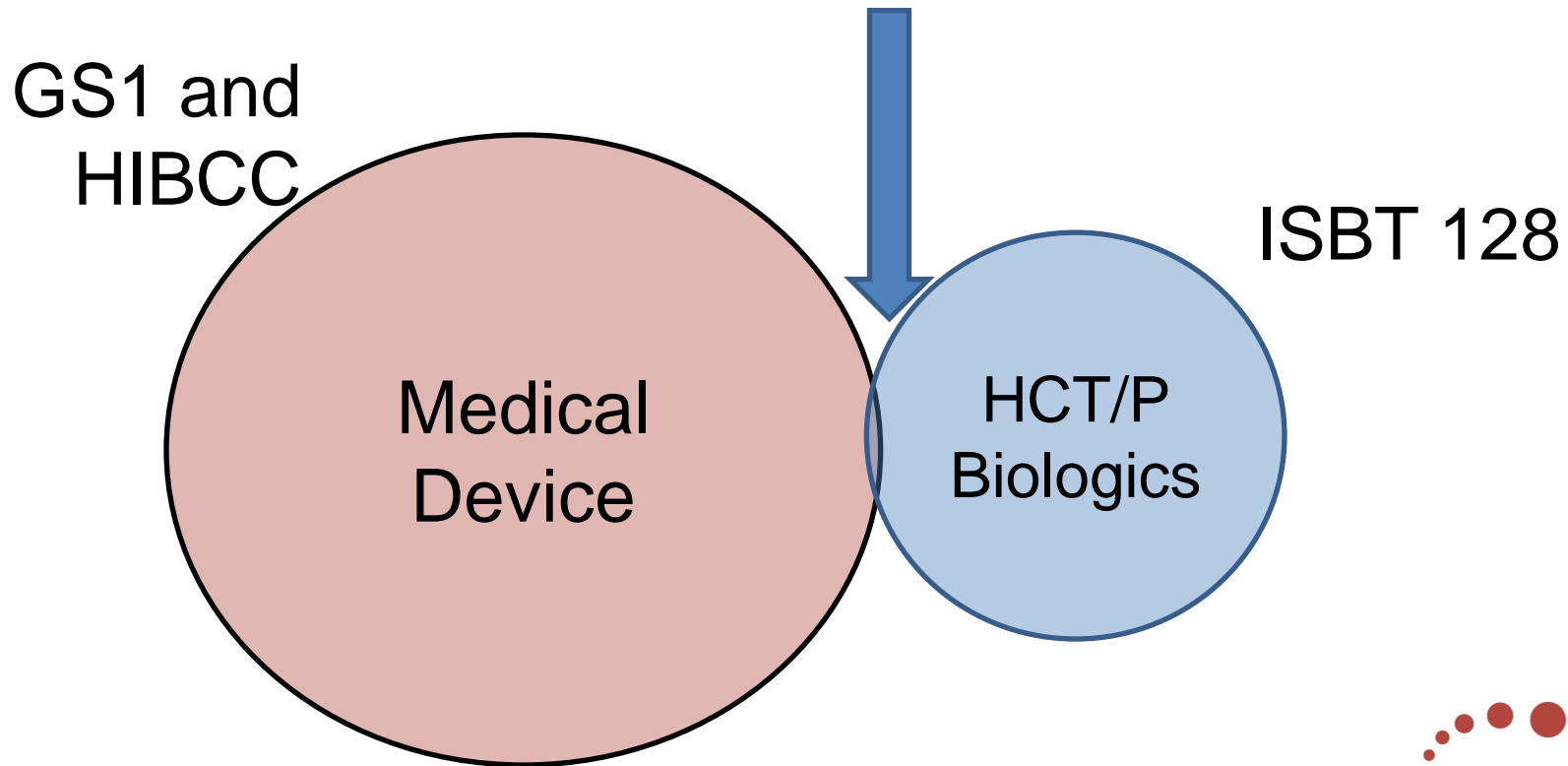
77 Countries with Facilities Registered to Use ISBT 128



Count 3058 - 101 99 - 45 44 - 27 25 - 18 15 - 8 7 - 4 3 - 1

ISBT 128

Human Cells, Tissues, and Cell or Tissue Based Products (HCT/P) regulated as devices

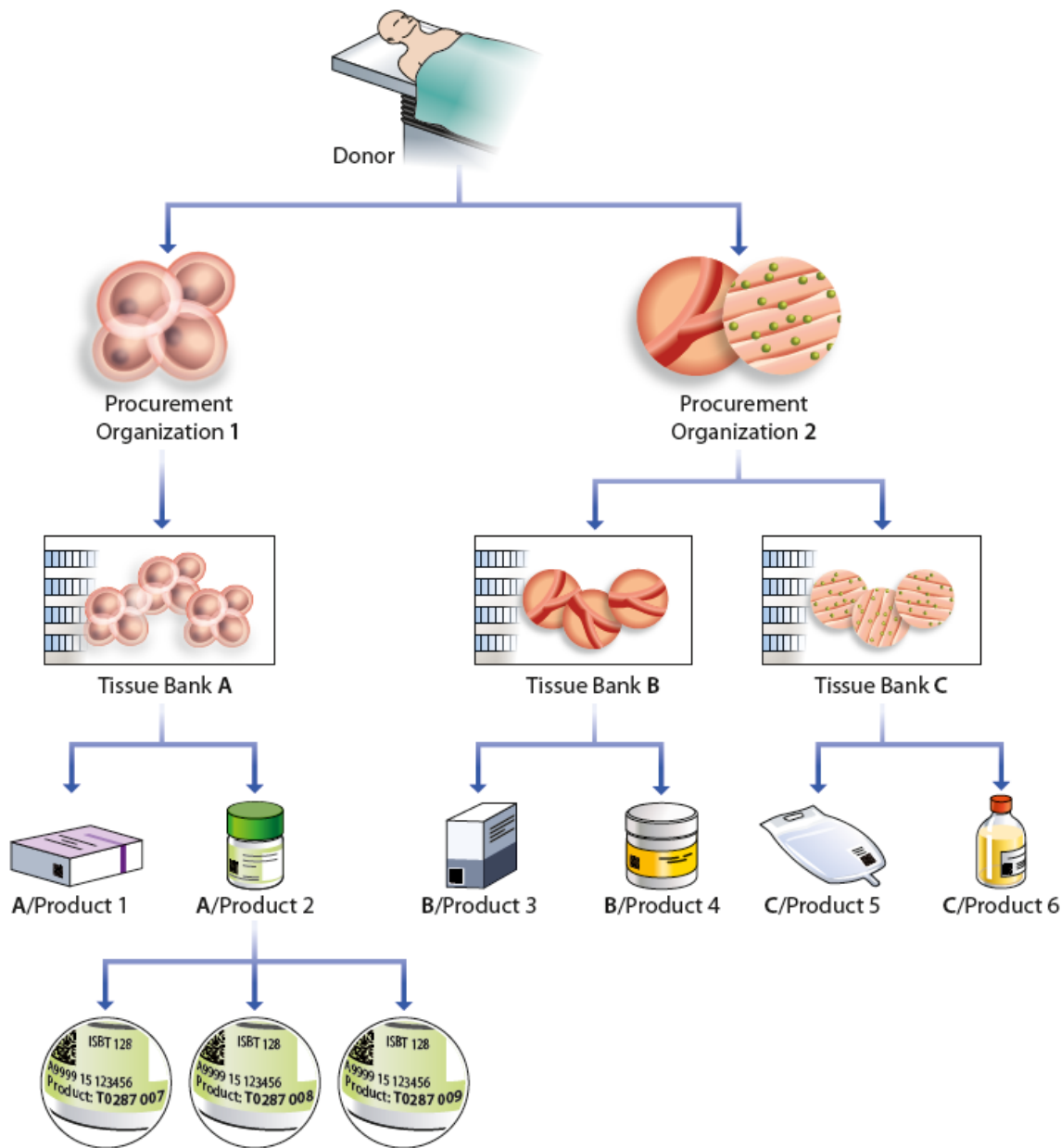


HCT/P Regulated as Devices

- **DEVICES COMPOSED OF HUMAN TISSUES** regulated under the FD&C Act and device regulations
 - ❑ CORNEAL LENTICULES
 - ❑ PRESERVED UMBILICAL CORD VEIN GRAFTS
 - ❑ HUMAN COLLAGEN
 - ❑ FEMORAL VEINS INTENDED AS A-V SHUNTS
- **COMBINATION PRODUCTS** regulated as Devices
 - ❑ DEMINERALIZED BONE combined with HANDLING AGENTS (glycerol, sodium hyaluronate, calcium sulfate, gelatin, collagen)
 - ❑ BONE-SUTURE-TENDON ALLOGRAFTS
 - ❑ CULTURED CELLS (fibroblasts/keratinocytes/nerve/ligament/bone marrow) on SYNTHETIC MEMBRANES or combined with COLLAGEN may be regulated as DEVICES or BIOLOGICAL PRODUCTS (these products are currently under review and may be regulated by CBER under either the device authorities or under section 351 of the PHS Act)

HCT/P are different

- From a human source
 - Inherent risks of infectious diseases
 - Precious resource—not a commodity with an almost limitless supply
- Must be handled with respect for the donor and the donor's family
- Additional regulations apply
- Complicated supply chain—and as substitutes (regenerated tissues) are developed, it will only get more complicated



Added complexity:

- Some products are devices and some are biologics.
- Distributors/re-labelers

Criteria for traceability of MPHO

- Single system of traceability, irrespective of how products are regulated (biologic vs device)
- System should allow recall based on issues related to:
 - ❑ Donor (Donation Identification Number)
 - ❑ Manufacturing process (lot number, expiration or manufacturing date)
 - ❑ Individual device (serial number)
- Meet requirements for both device and biologics traceability

ISBT 128 is unique in enhancing safety and traceability of MPHO by providing:

- A standardized product code that supports vigilance and surveillance (emerging infectious diseases)
- A donation identification number that identifies all products recovered from a given donor (important if recall due to a donor-related issue is initiated)

Device Identifier (DI)

- Device Identifier has three elements:
 - 5-character code identifying manufacturer
 - A 6-character code assigned by the facility
 - A 5-character internationally defined high level code

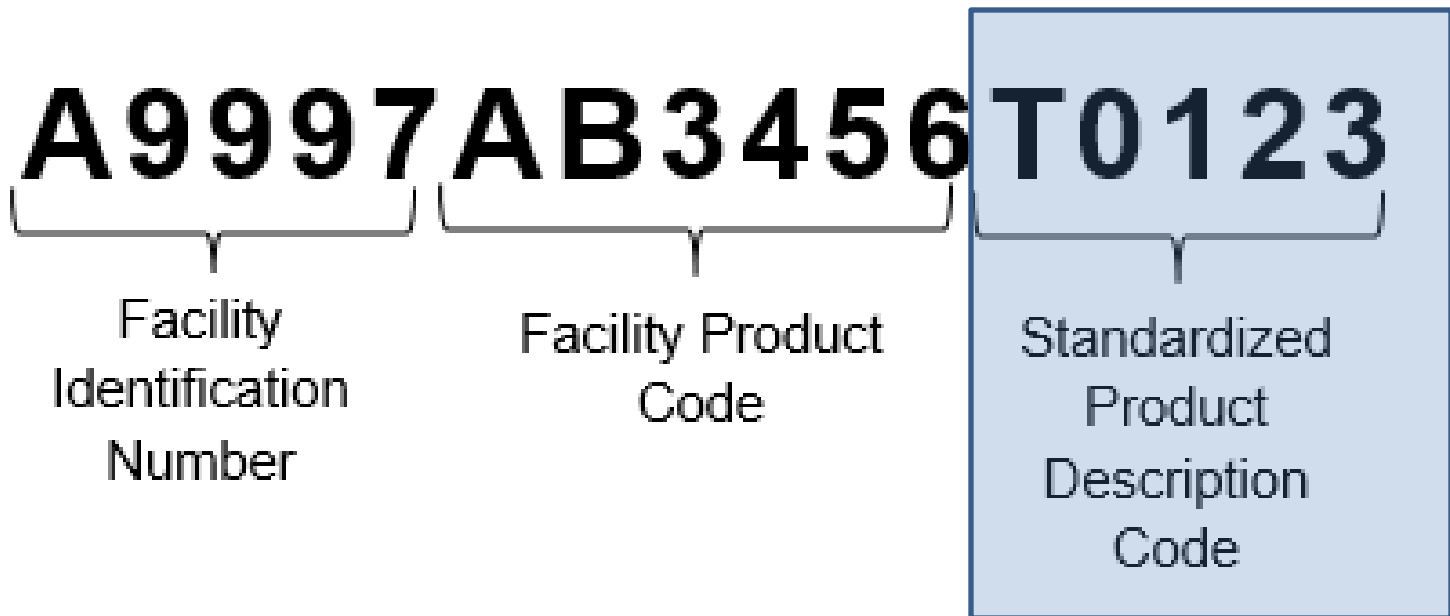
ISBT 128 Device Identifier (DI)



First two elements:

- Facility identifier
 - ❑ Assigned by ICCBBA to ensure global uniqueness
 - ❑ In the US always begins with “W” plus 4 digits
- Facility-defined product code
 - ❑ Catalog number or any other number the facility wants to use to identify its product
 - ❑ Supports a facility-controlled description and product name

ISBT 128 Device Identifier (DI)



Standardized Product Description Codes

- Required within the DI for ISBT 128 coding
- Select from a list maintained by ICCBBA or request a new code
- Flexibility in selection of standardized product code
 - Varying amount of detail (e.g., may select a code that includes an additive like albumin or may encode just the class of the product)
 - Can select a code with just need enough information for vigilance efforts and inventory management

Possible codes

- CANCELLOUS BONE CUBES
- CANCELLOUS BONE CUBES|Freeze dried|Radiation sterilization|Demineralized:Yes

Why a standardized product code?

- Internationally standardized product coding and nomenclature allows pooling of data from multiple organizations and globally to detect emerging infectious diseases supporting biovigilance
- Product identity is maintained across disparate computer systems (length, characters, and meaning for a code is standardized)

Biovigilance

- Monitoring designed to prevent the risks associated with the use of organs, tissues, and cells of the human body
- Allows recognition of emerging problems at an early stage
- Usually done by a individual organizations and by a national authority (e.g., CDC)

Facility Assigned vs. Standardized Product Codes

Facility	Standardized
Intended to manage inventory and convey information to customer	Support biovigilance and end-user data management
Description under facility control	Internationally defined
Definition can be highly detailed	Less detailed
Drives product proprietary name	Drives generic description
Optional (can use 000000)	Required for traceability with ISBT 128

Production Identifiers (PI)

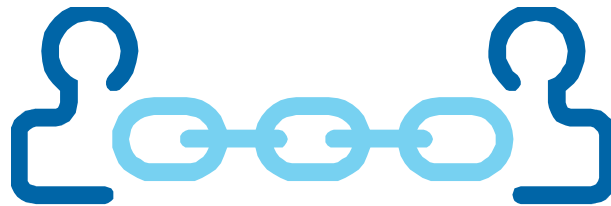
- Donation Identification Number [distinct identification code required by 1271.290(c)]
- Lot Number
- Serial Number (“Product Divisions” in ISBT 128 terminology)
- Expiration Date
- Manufacturing Date

Required PI

- Donation Identification Number [distinct identification code required by 1271.290(c)]
- Serial Number (“Product Divisions” in ISBT 128 terminology)

ISBT 128 Traceability

- ISBT 128 supports donor to patient traceability through a globally unique Donation Identification Number (DIN) that links HCT/P from a single donor



Sec. 1271.370 Labeling (excerpt)

The following information must appear on the HCT/P label:

- Distinct identification code affixed to the HCT/P container and assigned in accordance with 1271.290(c)
- Description of the type of HCT/P
- Expiration date, if any
- Name and address of the establishment that determines that the HCT/P meets release criteria and makes the HCT/P available for distribution
- Storage temperature

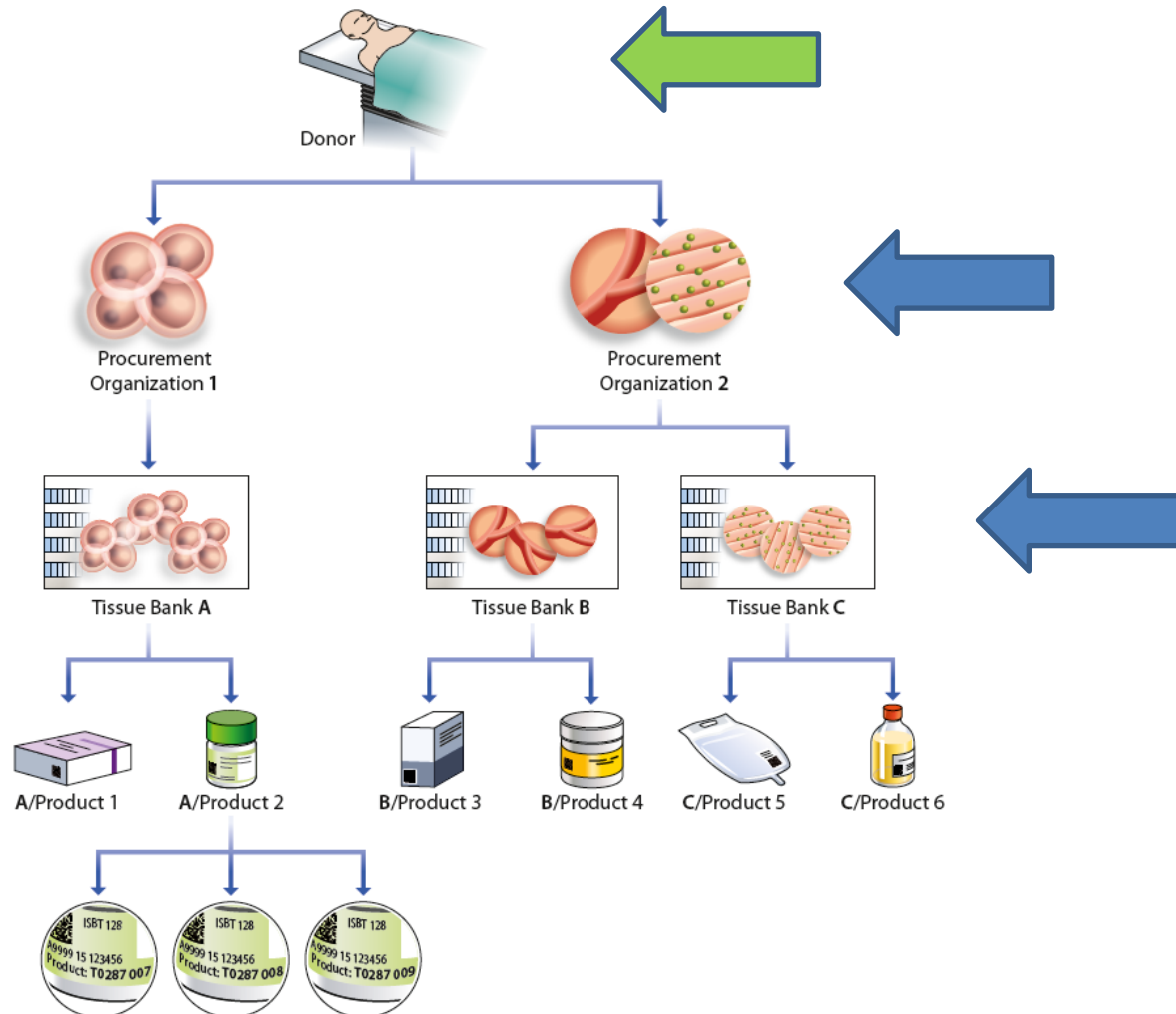
Distinct identification code 1271.290 (c)

As part of your tracking system, you must ensure: That each HCT/P that you manufacture is assigned and labeled with a distinct identification code, e.g., alphanumeric, that relates the HCT/P to the donor and to all records pertaining to the HCT/P

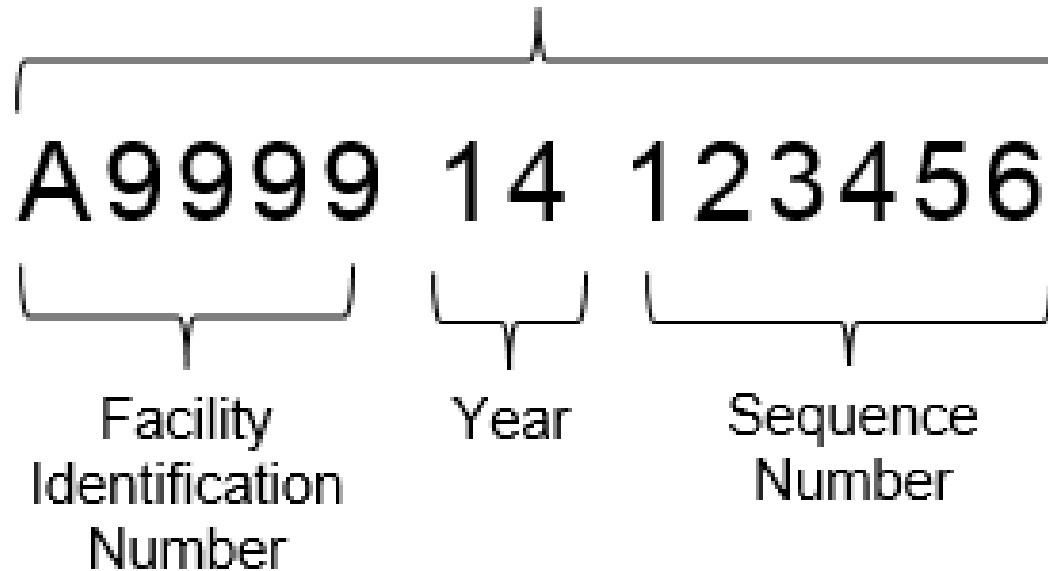
Donation Identification Number (DIN)

- Assigned to a donation event and appears on all products from that donation event
 - Initially all tissues from a donor for a given processor
 - Long term, the hope is that it will relate to all organs and tissues from the donation event

When can DIN be assigned?



Donation Identification Number



When speed of a recall is critical for patient safety

Recall by DIN

- A9999 14 123456

Recall by serial number:

- XY1234567
- XY1234568
- XY1234569
- XY1234510
- XY1234511
- XY1234512
- XY1234513
- XY1234514
- XY1234515
- XY1234516
- XY1234517
- XY1234518
- XY1234521
- XY1234522
- XY1234523
- XY1234524
- XY1234525
- XY1234526
- XY1234527
- XY1234528
- XY1234529
- XY1234530
- XY1234531
- XY1234532
- XY1234533
- etc.

ACBTSA (one finding from April 2015 meeting):

- Regulatory and standards setting organizations have made significant advancements in tissue tracking and tracing; however, gaps in tissue tracking and tracing remain including:
 - Absence of a universally standardized unique donation identifier that would link each tissue product and other MPHOs to the donation event

ACBTSA (one recommendation)

- In consideration of its findings, the Committee recommends that the Secretary take action in a stepwise risk-based approach to
 - Establish use of ISBT 128 code in electronically readable format as a universal standard for mandatory implementation of unique donation identifiers for all human tissue products

Problems with using a serial number or lot number:

- If distinct identifier could be lot number or serial number, receiving computer systems have no way to know which to enter into a distinct identifier field
- Makes it very difficult to search on the distinct identifier

Bone, Strip Demineralized

Donation Identification Number: A9997 14 123456 8 B

Product Code: T7049

Pack (Serial) Number: 25

Expiration Date: 2016-01-08

Store at room temperature



=/A9999XYZ100T7049

=,000025=A99971412345600=>016008

Within the computer system of the end user, it is intended that the DIN be parsed and present in a separate field for easy searching.

**DEMINERALIZED
BONE MATRIX**
Strip 5 cm x 5 cm




Generis Tissue Bank

Global Street
Any Town
Worldwide
Telephone: xxxxxxxx
Fax: xxxxxxxx
www.xxxxxx.org

Do not use if package is open or damaged.
Store at room temperature.

Bone, Filler, Strip
Demineralized

Donation Identification Number: A9997 14 123456 ☐☐
Product Code: T7049
Pack (Serial) Number: 25
Expiration Date: 2016-01-08
Store at room temperature

 =/A9999XYZ100T7049
=.000025=A99971412345600=>016008



ISBT 128 and UDI

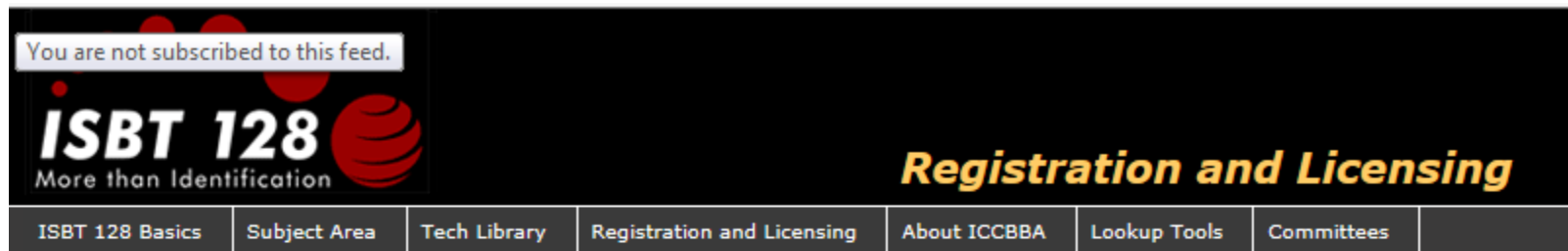
- Each product has a standardized product code to support international vigilance and surveillance
- Each product has a unique identifier for the donation that provides a direct link to the donor
- Accommodates traceability requirements for both devices and biologics

Recommendation from GS1 and ICCBBA:

- GS1 labeling: for the general supply chain
- ICCBBA labeling: for medical products of human origin (“tissue devices” and “tissue tissues”)

Where to begin:

- Register with ICCBBA via website:
www.iccbba.org



[Home](#) > [Registration and Licensing](#) > [How to Register](#) > [Facility Registration](#)

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Registration and Licensing

in Following 132

How to Register

Facility Registration

Vendor Registration

What are the Fees?

Definitions of Use

License Holder Agreement

Request Password

Facility Registration Form

- [Facility Registration Form](#) - PDF

[Click here](#) to view ICCBBA's License Agreement.

Following Registration

- Facility Identification Number will be assigned
- Selection of the appropriate standardized product codes
 - From existing list
 - Request new codes
- Work with ICCBBA help desk (iccbba@iccbba.org)

