

IMPLEMENTATION GUIDE

ISBT 128 Facility Identification Number

Version 1.3.0

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1 Introduction

1.1 Purpose

The purpose of this document is to provide guidance for the use of the Facility Identification Number (FIN) found in a number of ISBT 128 data structures.

1.2 Scope

This document is a supplement to the *ISBT 128 Standard Technical Specification* (ST-001). It describes how the FIN is assigned and maintained, the database supporting the FIN, and how the FIN is used within ISBT 128 data structures to identify an organization responsible for an action. This document also addresses some concerns for software developers.

1.3 Intended Audience

The intended audience of this document is staff (management, information technology, quality, validation, and laboratory) of facilities involved with the collection/recovery, processing, testing, distribution, and administration of medical products of human origin, as well as vendors of supplies and software utilized by these organizations.

1.4 Normative Reference

ISBT 128 Standard Technical Specification (<u>ST-001</u>)
ISBT 128 Coding and Labeling of Medical Devices Using ISBT I28 (<u>ST-011</u>)
ISBT 128 Standard Chain of Identity (Col) Identifier (<u>ST-028</u>)

1.5 Other References

ICCBBA Website (www.isbt128.org)

Implementation Guide: Use of the Processing Facility Information Code [Data Structure 033] (IG-031)

Implementation Guide: Use of the Donation Identification Number [Data Structure 001] (IG-033)

1.6 Background

ICCBBA assigns Facility Identification Numbers (FINs) to facilities that are licensed to use ISBT 128. The FIN is a five-character alphanumeric code that can be used in a variety of ways to ensure uniqueness of an identification number and thus is essential to traceability. It is currently used in the following data structures:

- Donation Identification Number [Data Structure 001]
- Donor Identification Number [Data Structure 019]
- Staff Member Identification Number [Data Structure 020]
- Product Consignment [Data Structure 028]
- Processing Facility Information Code [Data Structure 033]
- Processor Product Identification Code [Data Structure 034]
- Chain of Identity Identifier [Data Structure 040]

ICCBBA maintains a database that contains the names and locations of all ICCBBA registered facilities linking them to their assigned FINs. The full list of facilities is made available to ICCBBA-registered facilities, while a FIN lookup program that can provide the name of the facility associated with a given FIN is available to everyone on the ICCBBA Website.

Initially, ICCBBA assigned a block of FINs to each country. Over time, countries merge or separate, new countries form, and borders change, making such historical assignments impossible to maintain. Therefore, the FIN should be viewed today as simply a unique code assigned to a given facility without regard to the country.

1.7 Changes in this Version

The following table indicates the major changes between Version 1.2.0 and Version 1.3.0. Actual changes or additions to requirements of the ISBT 128 Standard are in bold print; changes to formatting or organization, or additional guidance, are in regular print. When changes were a result of a formal proposal, the number of the proposal is listed in the Rationale column.

ISBT 128 Facility Identification Number Version Control: Version 1.2.0 vs. Version 1.3.0.

	Version 1.2.0 Chapter, Section, Table, or Figure	Version 1.3.0 Chapter, Section, Table, or Figure	Change	Rationale
1.	Throughout	Throughout	Updated links and examples.	To provide up-to- date information.
2.	1.6	1.6 and 3.7	These sections were updated and added respectively to include the Chain of Identity Identifier [Data Structure 040].	To convey information on the new Data Structure 040.
3.	2	2	The references to the current and future format of the FIN were removed.	The format changes to the FIN have already been implemented.
4.	3.5	3.5	The text was amended to describe Data Structure 033 further.	For clarification and to reflect current information in ST-001.
5.	4	4	The reference table "Facility Type Codes [RT058]" was updated.	To reflect current information.
6.	5	5	The name "FIN Lookup Program" was changed to "Facility Information Lookup Tool."	To reflect the current name of the program.

2 Format

The structure of the FIN is apppp where:

Element	Length	Туре
α	1	Alphanumeric {A–N; P–Z; 1–9}
pppp	4	First two characters alphanumeric {A–N; P–Z; 0–9}; second two characters numeric {0–9}. Current usage is numeric for all four characters. Alpha characters may be introduced into positions 1 and 2 in the future (e.g., if α = A and pppp = BC12, the α pppp will be ABC12).

3 Usage

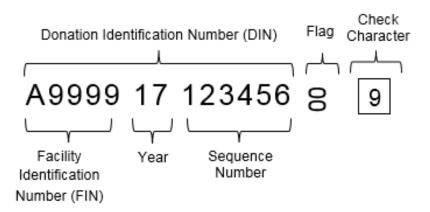
The FIN is currently used in seven data structures. The *ISBT 128 Standard Technical Specification* (ST-001) provides more information on each data structure.

3.1 Donation Identification Number [Data Structure 001]

The FIN comprises the first 5 characters of the 13-character Donation Identification Number (DIN). It identifies the facility that assigned the DIN. See Figure 1.

More information on this data structure can be found in the *Implementation Guide: Use of the Donation Identification Number [Data Structure 001]* (IG-033).

Figure 1 Donation Numbering

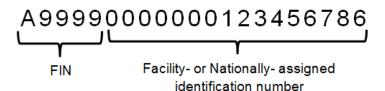


3.2 Donor Identification Number [Data Structure 019]

The FIN comprises the first 5 characters of the 21-character Donor Identification Number. It identifies the facility that assigned the donor number. See Figure 2. Alternatively, if the Donor Identification Number is nationally assigned using this data structure, a dedicated FIN can be assigned by ICCBBA to distinguish nationally from facility assigned numbers. To exercise this option, a national authority should contact the ICCBBA office (support@isbt128.org).

Note: There is an alternative nationally defined data structure that may be used for a donor identification number [see the ISBT Standard Technical Specification (ST-001)].

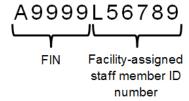
Figure 2 Donor Identification Number



3.3 Staff Member Identification Number [Data Structure 020]

The FIN comprises the first 5 characters of the 11-character Staff Member Identification Number. It identifies the organization that assigned the Staff Member Identification code. See Figure 3.

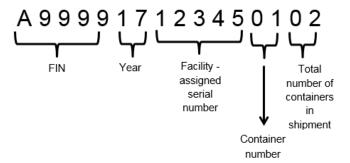
Figure 3 Staff Member Identification Number



3.4 Product Consignment [Data Structure 028]

The FIN comprises the first 5 characters of the 16-character Product Consignment number. It identifies the facility that prepared the consignment. See Figure 4.

Figure 4 Product Consignment



3.5 Processing Facility Information Code [Data Structure 033]

The FIN comprises the first 5 characters of the 11-character Processing Facility Information Code. Data Structure 033 shall convey information about the facility that assigned the Product Code, and may include a Facility-defined Product Code (FPC) assigned by the processing or labeling facility. See Figure 5. When the FIN identifies the processing facility, it is called a FIN(P).

More information on this data structure can be found in *Implementation Guide: Use of the Processing Facility Information Code [Data Structure 033]* (IG-031).

Facility
Identification
Number of the
Facility
Assigning the
Product Codes
or

FacilityDefined
Product Code
or
FPC

Figure 5 Processing Facility Information Code

3.6 Processor Product Identification Code [Data Structure 034]

FIN(P)

The FIN comprises the first 5 characters of the 16-character Processor Product Identification Code. It identifies the facility that assigned the Facility-defined Product Code (FPC) and the standardized ICCBBA Product Description Code (PDC). See Figure 6. When the FIN identifies the processing facility, it is called a FIN(P).

More information on this data structure can be found in the *ISBT 128 Standard*, *Coding and Labeling of Medical Devices Using ISBT 128* (ST-011).

A 9 9 9 7 A B 3 4 5 6 T 0 1 2 3 Standardized Facility Facility-Product Identification Defined Description Number of the **Product Code** Code Facility or Assigning the or **Product Codes** FPC PDC or

Figure 6 Processor Product Identification Code

FIN(P)

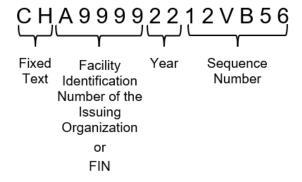
3.7 Chain of Identity Identifier [Data Structure 040]

The FIN comprises the 5 characters in positions three to seven of the 15-character Chain of Identity Identifier. In this context, the FIN identifies the organization that issued the Chain of Identity (CoI) Identifier. See Figure 7 Chain of Identity Identifier.

The FIN in the Col Identifier is present as a means of ensuring global uniqueness across multiple organizations. However, it is not intended to be parsed as a data item in its own right to identify the organization with which the product is associated. Where it is necessary to transmit the identity of this organization, the FIN should be used in a data field specifically designed for the purpose.

More information on this data structure can be found in the *ISBT 128 Standard Chain of Identity (CoI) Identifier* (ST-028).

Figure 7 Chain of Identity Identifier



4 Facility Identification Number (FIN) Database

This Microsoft Excel® spreadsheet contains the names and locations of all ICCBBA registered facilities. It is published in the password-protected area of the ICCBBA Website and is called:

Registered Facilities [RT065]

It is also available on the website as a tab delimited text file (Registered Facilities – Text File). It contains the fields shown in Table 1.

The FIN information held in the ICCBBA database is provided by the facility at the time of registration and it is the responsibility of the facility to ensure that it remains accurate by notifying ICCBBA of any changes.

Table 1 Registered Facilities [RT030]

Field Name	Field Size	Field Description
FIN	5	Facility Identification Number*
Firm Name	100	Legal name of facility
City	60	Mailing address details of facility
State/Province	20	Mailing address details of facility
Country	20	Mailing address details of facility
Postal Code	10	Mailing address details of facility
Website	100	Website of the facility
Alternative Name	1 100 1	
Country ISO	Country ISO 2 Code for country as as 3166-1*	
Facility Type	80	Indicates category or categories of products the facility manages

^{*10} FINs have been set aside for validation purposes. These are A9990-A9999. ICCBBA has used the user-defined country code of XA (as allowed by ISO 3166-1) for these FINs.

Table 2 is used to identify the Facility Type that is encoded in the Registered Facilities Database.

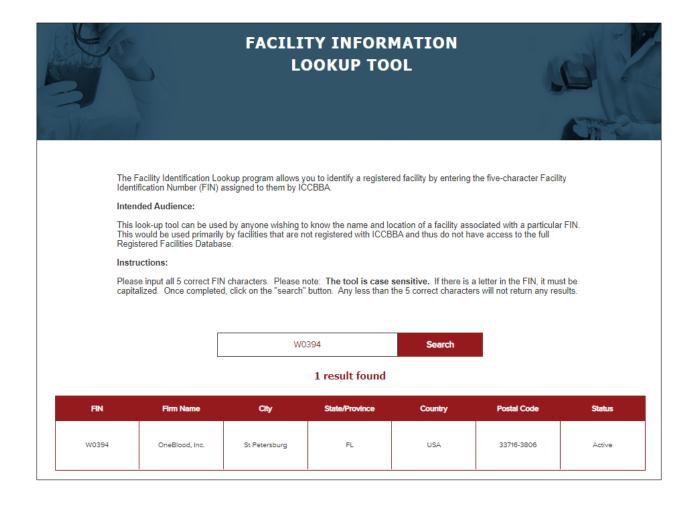
Table 2 Facility Type Codes [RT058]

Code	Definition	Retired Date
ART	Assisted Reproductive Technology Facility	
BCF	Blood Collection Facility	
BTS	Blood Transfusion Service	
CLN	Clinical Trials Facility	02 AUG 2021
CTF	Cellular Therapy Facility	
FMB	Fecal Microbiota Facility	
HMB	Human Milk Banking Facility	
OTF	Ocular Tissue Facility	
ОТО	Organ Transplant Organization	
PFR	Plasma Fractionator	
PTF	Proficiency Testing Facility	
RMF	Regenerative Medicine Facility	
SED	Serum Eye Drops Facility	
TBF	Tissue Banking Facility	
UDI	Medical Device Manufacturer	

5 Facility Information Lookup Tool

The ICCBBA Website has a lookup tool that can be used to identify the facility encoded in the FIN. See Figure 8. To utilize the program, type the FIN into the search field, click on the "Search" button, and the identity of the facility will appear in the Search Results field.

Figure 8 Facility Information Lookup Tool



6 FIN Assignment and Maintenance

ICCBBA routinely assigns one FIN to each organization that registers with it. Facilities must use the assigned FIN when using the data structures described in Section 3 in order to achieve global uniqueness for identifiers essential in tracing and tracking products.

6.1 Requesting a FIN

To obtain a FIN, organizations must register with ICCBBA and pay the one-time registration and annual licensing fees. The form that must be completed is found on the ICCBBA Website https://www.isbt128.org/how-to-register.

6.1.1 Multiple FINs Assigned to One Organization

Facilities may request more than one FIN if having multiple FINs is beneficial to their operation. Examples of when more than one FIN might be useful include:

- A blood center has multiple locations and wants to identify blood collected at each site through its FIN.
- A medical center collects both blood and cellular therapy products.
 While both activities are within the same organization, they are under separate management and are located in different areas of the building. Each activity area wants to manage its own FINs.
- An organization has both cellular therapy and tissue operations. It is beneficial from an operations standpoint to have different FINs for cells and tissues.
- An eye bank has multiple processing sites in different cities.
- A facility collects 1,000,000 or more products a year.

Multiple FINs can be linked to a single registration or each part of the facility may register separately. Facilities can choose the method that works best for their operations.

6.1.2 One FIN Assigned to Multiple Locations of an Organization

Facilities at different locations but under the same ownership (e.g., hospitals within a hospital corporation or different recovery centers for an eye bank) may register as a single entity and be assigned a single FIN. If hospitals are not assigning FINs to products (that is, they are not collecting blood or cellular therapy products and are not pooling products), this may work well. However, if FINs are used to label products, these facilities may find it easier to register as a single entity but request additional FINs for those hospitals labeling products.

There may be national restrictions on the use of a single FIN for multiple locations. Users should review national guidelines for any restrictions.

6.2 Requesting Additional FINs

Additional FINs can be requested either at the time of the original application or later. If the request is made at the time of the original application, one copy of Part B of the Facilities Registration Form (https://www.isbt128.org/how-to-register) must be completed for each FIN requested.

If the request for additional FINs is made after the original registration form is completed, Part A must be completed again in order to connect the new FIN with the past registration for the organization.

There is a one-time fee for additional FINs. See the ICCBBA Website for details.

6.3 Inactivating a FIN

If a FIN is no longer needed (e.g., the hospital closes or no longer modifies products), the FIN may be inactivated. This means that the facility will no longer pay licensing fees and users will not have access to password-protected areas of the ICCBBA Website and may not request Product Description Codes. However, the inactivated FIN will still be included in the FIN database and in the Facility Information Lookup Tool. This is to ensure traceability for products which have been labeled with this FIN.

Facilities wishing to inactivate their FIN should contact the ICCBBA office (support@isbt128.org). They will be asked to complete a FIN Inactivation Request form prior to ICCBBA inactivating the FIN.

6.4 Reactivating a FIN

If the activities of a facility that has inactivated a FIN change such that they again need to register with ICCBBA, they may request their previous FIN. If criteria for traceability are met, ICCBBA can reactivate the FIN. The facility must again pay registration and licensing fees at the time the FIN is reactivated. Contact the ICCBBA office (support@isbt128.org) for more information.

6.5 Changing the Name Associated with a FIN

If the legal status of an organization changes (e.g., a facility is acquired by a larger organization), the issue of reassignment of existing FINs may arise. For example, a hospital is purchased by a large hospital corporation and it results in changing the name of the hospital. This hospital pools products and uses its FIN to assign DINs to the product pools. Because the name of the hospital has changed, the name corresponding to the FIN in the ICCBBA database needs to change or a new FIN needs to be assigned to the new entity.

This example of an acquisition is just one type of change that could require reassignment of a FIN. Other examples include mergers, splits, reorganizations, and simple name changes. Organizations wishing to change the name associated with a FIN should contact the ICCBBA office (support@isbt128.org).

Whether the name of the facility corresponding to the current FIN is changed or a new FIN is assigned depends on traceability issues. Of major concern will be which facility retains records pertaining to products previously labeled with the FIN. For example, a new FIN would be assigned to the hospital if records pertaining to products labeled with the previous FIN will not be retained by them. On the other hand, the name associated with the FIN may be changed if the organization will retain such records, although other factors such as legal relationships are also considered.

When asked to change the name associated with the FIN, ICCBBA will ask the requester to complete and submit a form entitled "Request to Change Name of Facility Associated with FIN(s)" that documents information related to traceability of units. Based on the information obtained, ICCBBA will determine an appropriate course of action. If there are any concerns about traceability, a new FIN will be assigned.

6.6 Reserved FINs

6.6.1 FINs Reserved for Validation Purposes

A range of FINs has been reserved for purposes of validation testing. This range is A9990 through A9999. Facilities should use FINs within this range when performing validation testing. This range may also be used for example labels when the use of an actual FIN is not recommended (e.g., a cellular therapy facility wanting to show an example label on a website).

6.6.2 FINs Reserved for Proficiency Testing Organizations

A range of FINs has been reserved for assignment to Proficiency Testing Organizations for use on their samples. This range is A9900 through A9989. Specimens with these FINs may be identified as proficiency testing samples.

7 Software Developers

7.1 Facility Identification Number (FIN) Database

The FIN database is in two formats: A Microsoft Excel® spreadsheet and a tab delimited text file. It is updated with new facilities and changes to existing facility information once a month. A version control sheet updated at the time the database is posted identifies changes that have been made. The database (in both formats) and the version control sheet are posted in the password-protected area of the ICCBBA Website.

7.2 Traceability

The FIN plays a key role in traceability since it ensures global uniqueness of an identification number provided the facility-assigned portion is also unique for that FIN.

While the FIN within the DIN identifies the facility that assigned the DIN, it should not be used by software to identify the supplier of the product. Products may pass through multiple organizations and a complete supply chain record must exist. That is, facility records must reflect the actual supplier of the product, as well as the facility to which a product was shipped.

The FIN(P) portion of the Processing Facility Information Code [Data Structure 033] may be required for traceability of some tissue products. This situation would occur when:

- The organization that assigns the Product Code is not the same as the organization that assigns the DIN **and**
- More than one processing facility receives the same type of tissue from the same recovery organization and
- The processing facilities make the same products from the tissue

See Implementation Guide: Use of the Processing Facility Information Code [Data Structure 033]) (IG-031) for more information. This should be taken into consideration as software is developed or modified. This data structure is currently used in the fields of cellular therapy and tissue, but this could expand.

7.3 Global Requirements

Medical products of human origin may have global distribution. Even when global distribution is uncommon (e.g., blood components), such distribution may occur during a disaster or military operation. Therefore, it is essential that software be written to accept products labeled in compliance with the Standard. For example, software should not be written to accept only the α character (in $\alpha pppp$) used within the country utilizing the software.

END OF PUBLICATION

FOR ICCBBA USE ONLY

These links are for internal document control and cannot be used externally:

ST-001 ISBT 128 Standard Technical Specification

ST-011 ISBT 128 Standard Coding and Labeling of Medical Devices using ISBT 128

ST-028 ISBT 128 Standard Chain of Identity Identifier

IG-031 Use of the Processing Facility Information Code [Data Structure 033]

IG-033 Use of the Donation Identification Number [Data Structure 001]