IMPLEMENTATION GUIDE

Use of the Donation Identification Number [Data Structure 001]

Version 1.2.0

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1 Introduction

1.1 Purpose

The purpose of this document is to provide guidance for the use of the Donation Identification Number [Data Structure 001].

1.2 Scope

This document is a supplement to the *ISBT 128 Standard Technical Specification* (ST-001). It provides specific guidance for facilities managing medical products of human origin (MPHO) in the use of the Donation Identification Number [Data Structure 001]. This document also addresses some concerns for software developers.

1.3 Intended Audience

The intended audience of this document is the staff (management, information technology, quality, validation, and laboratory) of facilities involved with MPHO, software developers, and label/software vendors.

1.4 Normative References

ISBT 128 Standard Technical Specification (ST-001)

ISBT 128 Standard Terminology for Medical Products of Human Origin (ST-002)

ISBT 128 Standard Labeling of Human Tissues (ST-003)

ISBT 128 Standard Labeling of Cellular Therapy Products (ST-004)

ISBT 128 Standard Labeling of Blood Components (ST-005)

ISBT 128 Standard Labeling of Ocular Tissue (ST-009)

ISBT 128 Standard Coding and Labeling of Medical Devices Using ISBT 128 (ST-011)

ISBT 128 Standard Labeling of Human Milk Banking Products (ST-013)

1.5 Other References

ICCBBA Website (www.iccbba.org)

Implementation Guide: Use of Flags in the Donation Identification Number for Process Control of Critical Points during Processing and Distribution (IG-010)

Implementation Guide: Use of Product Divisions [Data Structure 032] (IG-023)

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

Implementation Guide: ISBT 128 Facility Identification Number (IG-034)

1.6 Background

The Donation Identification Number (DIN) is a key element of traceability for medical products of human origin. It provides globally unique identification of products from: (1) a donation event [collection or recovery]; (2) a product pool; (3) for plasma derivatives, a unique identification of an aliquot from a pooled plasma derivative product; or (4) a fertilized oocyte/embryo formed through assisted reproductive technology (ART). For full traceability of most MPHO, it must be used in conjunction with a data structure that uniquely identifies individual products from a donation. The data structure, or combinations of data structures, that may uniquely identify products from a donation include:

- The Product Code [Data Structure 003]
- The Product Code [Data Structure 003] and Product Divisions (Data Structure 032]
- The Product Code [Data Structure 003] and the Processing Facility Information Code [Data Structure 033]

See the *ISBT 128 Standard Technical Specification* (ST-001) and *Implementation Guide: Use of the Processing Facility Information Code [Data Structure 033]* (IG-031).

In some countries, certain MPHO are regulated as medical devices. For these products, the Processor Product Identification Code [Data Structure 034] must be used in conjunction with the DIN for traceability. See the *ISBT 128 Standard Coding and Labeling of Medical Devices Using ISBT 128* (ST-011).

While the DIN applies to all categories of MPHO, specifics of use vary among categories of products.

1.7 Changes in this Version

The following table summarizes the major changes between Version 1.1.0 and Version 1.2.0 of this document. 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.

Implementation Guide: Use of the Donation Identification Number [Data Structure 001]
Version 1.1.0 vs. Version 1.2.0

	Version 1.1.0 Chapter, Section, Table, or Figure	**Version 1.2.0 Chapter, Section, Table, or Figure**	**Change**	**Rationale**
1.	Throughout	Throughout	Updated references to ISO/IEC 7064	To be consistent throughout document
2.	Throughout	Throughout	Updated references titles	To reflect changes in current references titles
3.	**1.6**	**1.6**	**Added reference to information for fertilized oocyte/embryo**	**New addition to the Standard**
4.	**2.1**	**2.1**	**Added information for fertilized oocyte/embryo**	**New addition to the Standard**
5.	2.1	2.1	Changed the word “Section” to “Chapter” for type 3 flag entry	This is a reference to the entire chapter, not just a section of it
6.	Figure 1	Figure 1	Changed “Flag” to “Flag Characters”	Updated to reflect correct terminology
7.	3.3	3.3	Expanded “Step 6” and added “Step 7”	Clarification for following calculation steps
8.	4.2	4.2	Changed DIN to FIN in reference to text appearance	Text appears beneath the DIN
9.	4.4	4.4	Added that the check character is required	Missing on previous version
10.	Figure 4	Figure 4	Corrected dates in label example	Dates were incorrect
11.	Figure 5	Figure 5	Deleted reference to Check Character	Figure is referring to Flag Characters
12.	5.2.2	5.2.2	Changed the word “donation” to “product”	The DIN is affixed to a product
13.	2.2 and 6.5	2.2 and 6.5	Corrected the name for solvent detergent-treated plasma	Corrected to reflect current terminology
14.	N/A	**6.6**	**Added a section for ART products**	**New addition to the Standard**

2 Donation Identification Number [Data Structure 001]

2.1 Structure

Note: This is the only data structure in which the second character of the data identifier shall be part of the data content.

Purpose: Data Structure 001 shall specify a Donation Identification Number (DIN) that is a unique identification of: (1) a donation event [collection or recovery]; (2) a product pool; (3) for plasma derivatives, a unique identification of an aliquot from a pooled plasma derivative product; or (4) a fertilized oocyte/embryo formed through assisted reproductive technology (ART).

These identifiers are globally unique for a one hundred year period.

Structure: =αppppyynnnnnnff

Element	Length	Type
=	1	data identifier, first character
α	1	data identifier, second character 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 αpppp will be ABC12)
yy	2	numeric {0–9}
nnnnnn	6	numeric {0–9}
ff	2	alphanumeric {0–9}, {A-H, J-N, P, R-Y}

The fifteen (15)-character data content string, **αppppyynnnnnnff**, shall be encoded and interpreted as follows:

αpppp shall specify the Facility Identification Number (FIN) of the organization that assigned the DIN and shall be encoded and interpreted by reference to the ICCBBA Registered Facilities database published and maintained by ICCBBA in the password-protected area of the ICCBBA Website.

yy shall specify the last two digits of the year in which the DIN was assigned.

nnnnnn shall specify a sequence number indicating the donation event (collection or recovery), product pool, plasma derivative product, or a fertilized

oocyte/embryo formed through ART, within the given year for the facility identified by the FIN.

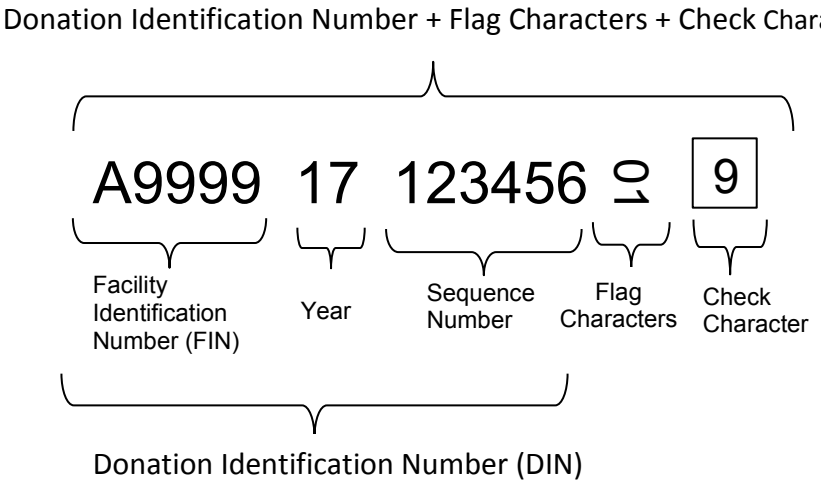
ff are "flag characters." Use of flag characters "ff" shall conform to national guidelines, if such guidelines exist. There are three general types of usage:

- Type 1: Two-character code used for process control and defined by ICCBBA,
- Type 2: Two-character code used for process control, but locally defined, and
- Type 3: A weighted ISO/IEC 7064 modulo 37-2 check character on the entire thirteen character DIN (see Chapter 3 for method of calculation). The check character acts on the DIN as a secondary check within the bar code itself.

When not used, the value of the flags shall be 00.

Type 2 flag characters shall only be interpreted by the facility that has defined them or within the group of facilities that have agreed on a common definition.

Figure 1 Donation Numbering



As shown in Figure 1, the combination, αppppyynnnnnn, forms the DIN. Flag characters, while part of the Donation Identification Number data structure, are not a part of the DIN itself. The keyboard entry check character is also not part of the DIN, but is calculated from the DIN and printed in human-readable format (see Chapter 3). Both the flag characters and the check character are intended for process control and are not part of the unique identification of the product.

2.2 Facility Identification Number

ICCBBA assigns Facility Identification Numbers (FINs) to facilities licensed to use ISBT 128 to ensure uniqueness of the number. See *Implementation Guide: ISBT 128 Facility Identification Number* (IG-034).

The FIN contained within the DIN identifies the facility that assigned the DIN. Often, this will be the collection or recovery facility, but this is not always the case. For example:

Cord Blood Facilities: In the situation of cord blood facilities, a processing lab may be administratively responsible for collections and assignment of DINs. In this situation, the DIN that appears on the product may be that of the processing facility. Ideally, the DIN would be affixed at the time of collection. If the DIN is not affixed until the donation reaches the processing laboratory, it is essential that suitable mechanisms be in place to ensure the accurate identification and traceability of the product prior to the application of the DIN.

Tissue Facilities: As ISBT 128 is adopted by organizations involved in tissue banking, it is possible that tissue processing facilities will adopt the Standard prior to recovery organizations. In this transitional situation, the tissue processor may assign the DIN to the product. It is essential that suitable mechanisms be in place to ensure the accurate identification and traceability of the product prior to the application of the DIN.

Plasma Derivatives: ISBT 128 is used to label those plasma derivatives for which the ABO group is relevant. At the present time, only solvent detergent-treated plasma products have been labeled with ISBT 128. These products comprise a large pool of plasma products that are processed and subsequently divided by a plasma fractionator. The plasma fractionator (manufacturer) assigns the DIN to the product.

Any Products: A facility using ISBT 128 receives a product that is not labeled with an ISBT 128 DIN. Because the donation identifier on the product may not be unique, the receiving facility may decide to assign a DIN. In this situation, the DIN would have the FIN of the receiving facility. See Chapter 5.

2.3 Year Code

In practice, this is the “nominal” year. To cut down on wastage, DIN labels may be used for up to one month in the year before, and one month in the year after, the year shown on the label. For example, labels bearing the year “17” may be used from December 1, 2016 through January 31, 2018. The collection facility must have an accurate record of the actual date of collection, and must ensure that the combination of year code and sequence number remains unique. This code does not in any way replace the expiration date (or collection date, as appropriate) on the label. The rationale behind allowing the 14-month tolerance in the collection year appearing in the DIN is that this year notation is present only to ensure uniqueness of the DIN every 100 years.

Facilities (and their auditors) should be reasonable in their approach to management of preprinted DIN sets in unusual situations. DINs should be unique for a 100-year period, and beyond that, reason should prevail. For example:

Use of year code beyond January 31: Occasionally facilities report to ICCBBA that staff have inadvertently used a DIN with the prior year's code during the first few days or weeks after January 31. As long as the DIN is unique, this should not be a problem. Potential errors in re-labeling far outweigh the minor problem of having used the wrong year code. Facilities may handle this as they would any error and follow their error management policies.

Use of year code prior to December 1: Facilities are expected to manage preprinted DIN sets to minimize wastage. In doing so, should an unexpected high rate of usage (e.g., a disaster that results in a high turnout of donors) occur near the end of a calendar year, it is possible to run out of DINs with the appropriate year code before December 1. If the facility has already received its DINs for the following year, it is permissible under such unusual circumstances to use the next year's DINs prior to December 1.

2.4 Sequence Number

Facilities assign the sequence number. While some facilities choose to start with 000001 at the time they change the year code and assign numbers sequentially thereafter, this is by no means required. As long as the sequence number is unique for the FIN and year, the facility has complete freedom to use the sequence number in a way that is most beneficial to its operations.

Assignment of blocks: Facilities may choose to assign blocks of sequence numbers to various activities. For example, a facility has multiple locations using a single FIN (i.e., satellite centers of a large regional blood center). They assign blocks of numbers to their four facilities:

Location 1: 000001 - 009999
Location 2: 010000 - 019999
Location 3: 020000 - 029999
Location 4: 030000 - 039999

This same system of assignment of blocks might also be used with a transfusion service that shares FINs with a cellular therapy facility within the same organization.

2.5 Flag Characters

Flag characters provide (1) a process control by indicating the item on which a DIN appears or (2) a data transmission check character. For convenience, the flag character reference table is shown in Table 1; however, the *ISBT 128 Standard Technical Specification* (ST-001) should be consulted for the latest version of the table.

Table 1 Data Structure 001: Donation Identification Number Flag Digits, ff [RT004]

Value of ff	Meaning When Used in the Donation Identification Number
00	Flag not used; null value
01	Container 1 of a set
02	Container 2 of a set
03	Container 3 of a set
04	Container 4 of a set
05	Second (or repeated) “demand-printed” label
06	Pilot tube label
07	Test tube label
08	Donor record label
09	Sample tube for NAT testing
10	Samples for bacterial testing
11	Match with Unit label
12	Affixed partial label
13	Attached label (intended to be used with affixed partial label)
14	Reserved for future assignment
15	Container 5 of a set
16	Container 6 of a set
17	Container 7 of a set
18	Container 8 of a set
19	Container 9 of a set
20-59	Reserved for assignment and use by each local facility. Therefore, the meaning and interpretation of flag values 20–59 may differ with each FIN and should not be interpreted at any other site.
60–96	ISO/IEC 7064 modulo 37-2 check character on the preceding thirteen (13) data characters, **αppppyynnnnnn,** including the FIN, year, and the unit sequence number — value is assigned as 60 plus the modulo 37-2 checksum
97–99	Reserved for future assignment
Alphanumeric using numbers in the range 0-9 and alphas in the range A-N, P, R-Y.	Reserved for future assignment

The eye-readable flag characters are printed rotated 90^{o} clockwise so that they are easily differentiated from the DIN.

Flag characters are used to identify the location (blood container, donor record, test tube, etc.) of a scanned DIN. For example, using values from Table 1, flag characters in the DINs in **Table 2** can be interpreted as shown.

Table 2 Example DIN Flag Character Interpretation

DIN with Flag Characters	Location of DIN
A9999 17 123456 01 9	Container 1 of a set
A9999 17 123456 07 9	Test tube label
A9999 17 123456 08 9	Donor Record Label

As seen in Table 1, the values 20-59 are reserved for local assignment, meaning each facility can use these flag characters to meet their internal operational needs. Flag characters in this range should not be interpreted outside of the facility assigning them. Flag characters are not intended to convey divisions of products and should not be used for this purpose. Coding of divisions is handled within the Product Code [Data Structure 003] or through the Product Divisions [Data Structure 032].

2.5.1 Examples of Use of Flag Characters

Example 1: Cord Blood

One unique use of locally defined flag characters in cellular therapy facilities has been to differentiate between mother and infant samples for a cord blood collection. For example, both mother and infant samples have the same DIN (e.g., A9999 17 123456), but the flag characters will vary depending on the source of the sample. In the example below, the value 21 is used to identify the mother's sample and the value 22 is used to identify the infant's sample.

Samples from the mother may be labeled:

Samples from the infant may be labeled:

Note: In the situation of multiple births, the facility would need to create a means to link the mother's sample to more than one Cord Blood DIN.

Example 2: Partial Labels

Another potential use of flag characters is to link information from partial labels to full label information. There are two standardized flag characters for this purpose: the value 12 is defined as “Affixed Partial Label” and 13 is defined as “Attached label (intended to be used with affixed partial label).”

In practice, 12 would be assigned as the value for the partial label and 13 as the value for the full label. If the DIN is A9990 17 123457, the partial label would have:

And the attached full label would have:

Manual and computerized systems could be set up to ensure that the affixed label matches the attached label (except for the flag characters). If software is used, it could require that the processing facility scan the affixed label of the product. If the value 12 is present, software could require a scan of the second label (the attached, full label) with a value of 13.

Alternatively, if the attached, full label is scanned first, software could be designed to recognize the value 13 and require a scan of a DIN with value of 12 (an affixed label). Software could then confirm the two DINs and Product Codes agree.

A similar system could be used in the receiving facility to ensure the labels matched.

Thus a full label would be securely associated with the product electronically as well as being physically attached in some way to the product.

Example 3: Verifying correct application of labels on modified products

For a description of one way in which flags can be used within a processing laboratory, see: *Implementation Guide: Use of Flags in the Donation Identification Number for Process Control of Critical Points during Processing and Distribution* (IG-010) available on the ICCBBA Website.

3 Check Character

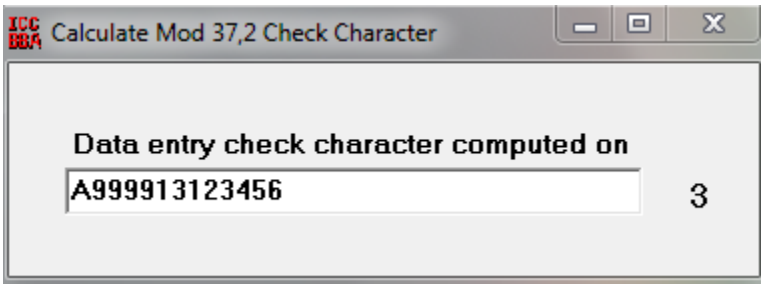
While keyboard entry is not recommended, it is sometimes essential. The check character is used for process control to verify accurate keyboard entry of the DIN. It is not a part of the data content of the DIN data structure and so is not included in the bar code. This is because it is not intended for use when the DIN is scanned electronically.

The check character is calculated on the 13-character DIN; the first character of the data identifier (=) and the flag characters are not included in the calculation.

3.1 Lookup Tool

A lookup tool for calculating a check character that is useful for validations is available on the ICCBBA Website. It is found by going to the home page, selecting the Lookup Tools tab, then the Quick K Calculator, and then downloading the program onto a computer. The program is used by entering a DIN into the search field with no spaces. See Figure 2.

Figure 2 Check Character Lookup Tool



3.2 Calculation of Check Character

ISBT 128 DINs utilize checksum characters based on the ISO/IEC 7064 Mod 37-2 algorithm. The example below shows how to calculate the checksum character for any given DIN. The calculation is based on the DIN thirteen (13)-character string (*i.e.*, excluding the leading **=** symbol and the flag characters).

The steps in the process are as follows:

1. For each character in the string, determine its check value as required by ISO/IEC 7064 from Table 3;
2. For each character in the string, determine its weighted check value by multiplying the check value from Table 3 by the nth power of 2, where n is the position of the character from the right hand end of the string;
3. Sum the weighted check values from step 2;
4. Find the modulus 37 value of the sum from step 3 (the value **remaining** when the weighted sum is divided by 37);
5. Subtract the value obtained in step 4 from 38;
6. Find the modulus 37 value of the result of step 5 (the value **remaining** when divided by 37), this is the ISO/IEC modulus 37-2 checksum;

7. Using the value in Step 6, determine the check character by again referring to Table 3 (this time read the character from the value) — this is the modulo 37-2 checksum character (referred to as K throughout this guidance document).

Table 3 Mapping from Characters to ISO/IEC 7064 Check Values and Calculated Values to the Checksum Character [RT035]

Character	0	1	2	3	4	5	6	7	8	9	A	B	C
Value	0	1	2	3	4	5	6	7	8	9	10	11	12
Character	D	E	F	G	H	I	J	K	L	M	N	O	P
Value	13	14	15	16	17	18	19	20	21	22	23	24	25
Character	Q	R	S	T	U	V	W	X	Y	Z	*		
Value	26	27	28	29	30	31	32	33	34	35	36		

3.3 Example of Calculation

Donation number G1234 17 654321

Position from right (n)	2^n (a)	Character	ISO/IEC 7064 value (step 1) (b)	Weighted value (step 2) (a x b)
13	8192	G	16	131072
12	4096	1	1	4096
11	2048	2	2	4096
10	1024	3	3	3072
9	512	4	4	2048
8	256	1	1	256
7	128	7	7	896
6	64	6	6	384
5	32	5	5	160
4	16	4	4	64
3	8	3	3	24
2	4	2	2	8
1	2	1	1	2
Step 3	sum of weighted values			146178
Step 4	modulo 37 (first MOD)			28
Step 5	subtract from 38			10
Step 6	modulo 37 (second MOD)			10
	ISO/IEC 37-2 checksum			10
Step 7	ISBT 128 check character (K)			A

4 Text Associated with the DIN

4.1 DIN

The DIN text shall be printed in a font that clearly differentiates between similar characters (e.g., O and 0; I and 1).

A national authority should determine how it should be displayed, for example:

A999917654321

V0043 17 499999

7004 217 123 456

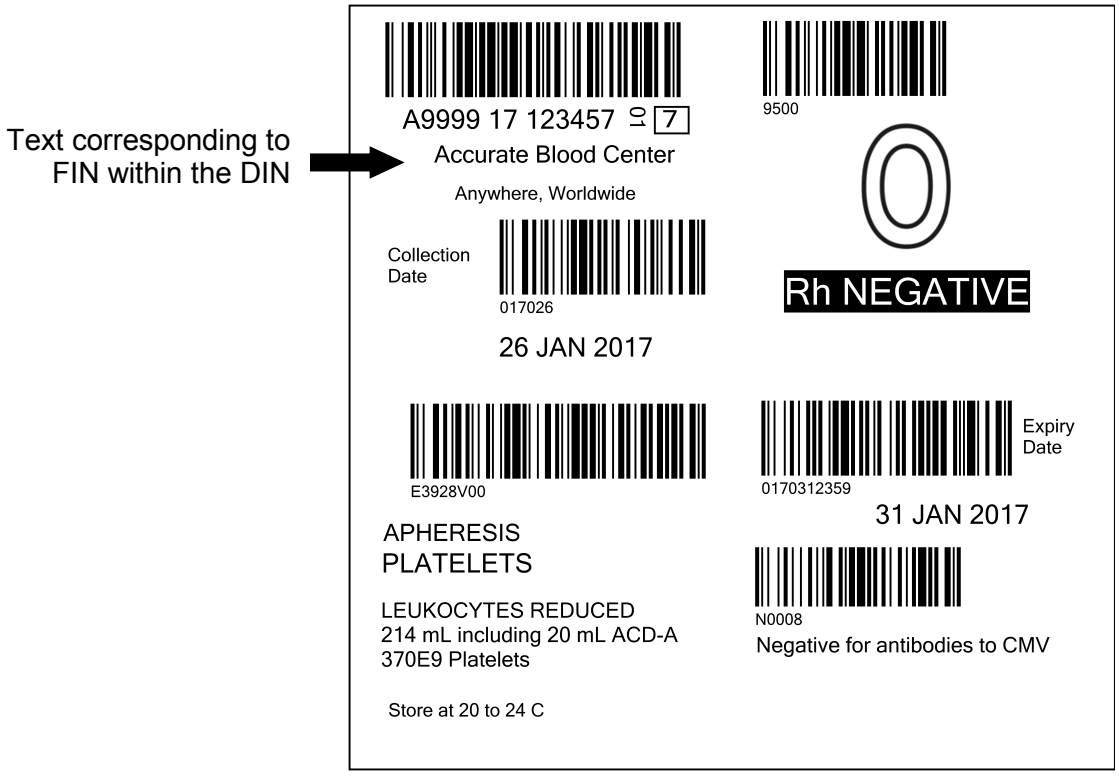
All data characters shall be printed (in this data structure only, the second data identifier character is also a data character).

In some countries, emphasizing any part of the DIN (e.g., making the sequence number larger or in a different color) is not allowed. Refer to national guidelines for more information.

4.2 FIN

Text pertaining to the Facility Identification Number (FIN) printed beneath the DIN should correspond to the FIN within the DIN. That is, if the FIN is for “Accurate Blood Center,” text appearing beneath the DIN should also indicate “Accurate Blood Center” (see Figure 3).

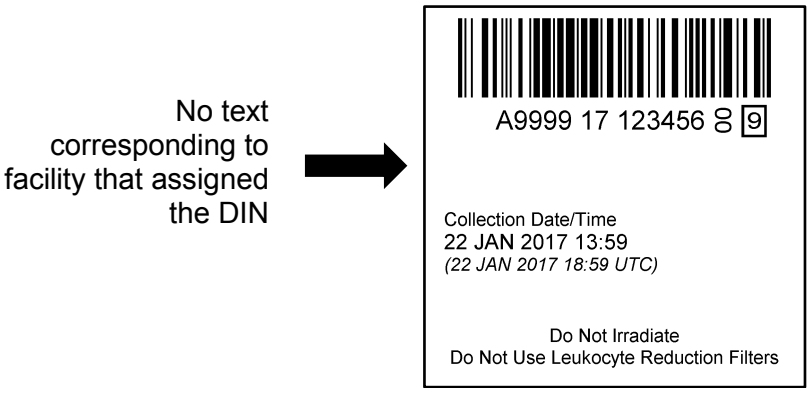
Figure 3 Text Related to Facility Identification Number



Text corresponding to the FIN is not required by the ISBT 128 Standard and there may be times when it is not desired. For example:

Facility Confidentiality with Matched Unrelated Donor Products: In general, eye-readable facility identifying information that corresponds to the FIN embedded in the DIN appears in the upper left quadrant beneath the DIN. However, if the product is from a Matched Unrelated Donor, it may be acceptable to omit the eye-readable facility information (see Figure 4). This may be required when shipping product into some countries.

Figure 4 Upper Left Quadrant for Matched Unrelated Donor Product



While the name of the facility corresponding to the FIN does not appear in an eye-readable form, the facility may be identified from the FIN and the name should also be documented in the receiving facility's records.

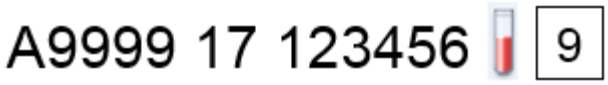
Tissue (including Ocular) Processing Facilities: Tissue processing facilities that receive recovered products from a different organization may not want to routinely include the text name of the recovery organization on their product labels. While the DIN itself is essential for rapid recall of products from a particular donor, the text name of the recovery organization may not be needed.

4.3 Flag Characters

Flag characters should be printed rotated 90º clockwise from the DIN (see Figure 5) or appear as an icon (see Figure 6).

Figure 5 Rotation of Flag Characters

Figure 6 Icon Printed in Place of Flag Characters

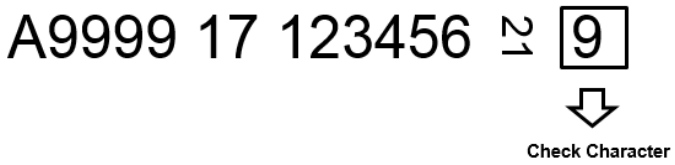


If the default flag characters (00) are used, requirements vary. In some countries, the default characters must be printed in text; in other countries, they may be omitted from the text. Refer to national guidelines for more information.

4.4 Check Character

The check character is required and shall be printed along with the 13 character DIN. It should be printed within a box as shown in Figure 7.

Figure 7 Printing of Check Character



5 Re-labeling of Products

5.1 Products Labeled with ISBT 128

Products labeled with ISBT 128 should not be re-labeled using another labeling system. ISBT 128 provides globally unique identifiers so there is no need to re-label products and there is a risk of losing traceability if they are re-labeled.

5.2 Products Labeled with Other Systems

Ideally, ISBT 128 would be used throughout the entire chain from donor to recipient. This would ensure the most effective traceability trail and help to minimize tracking and recall times.

However, as organizations around the world transition to ISBT 128, facilities already utilizing ISBT 128 may receive products that are not labeled with ISBT 128. When this happens, identifiers on these products may not be unique. Since lack of uniqueness could result in duplication and loss of traceability, such products should be re-labeled. This section provides guidance on re-labeling of products using ISBT 128.

Re-labeling should only be performed if the incoming unit is identified using a system that ensures all products from a donation event carry a single donation number that provides traceability back to the donor.

Local regulation and other standards should be reviewed to ensure compliance with all pertinent requirements.

5.2.1 Defining a mapping process to ISBT 128 Donation Identification Number

It is essential to ensure that there is no loss of traceability due to duplication of identifiers, or ambiguity in product codes, in the re-labeling of product received from other facilities. To ensure this, products should be re-labeled with ISBT 128 identification upon receipt and records maintained to ensure traceability.
The original identifier may not be over-labeled, obscured, or removed. If space does not permit affixing the new Donation Identification Number to the label without obscuring required information, it should be attached to the container with a tie-tag.

Each product must be assigned an ISBT 128 DIN using the ISBT 128 Facility Identification Number (FIN) of the re-labeling facility.

The facility must maintain traceability records linking the ISBT 128 DIN to the original donation number. This may be accomplished utilizing a register (or log) or computer record. Information retained for each product shall include enough information to uniquely identify that product. The required information to record includes:

- original identifier
- name of facility that assigned the original identifier
- ISBT 128 DIN

One or more of the following data elements might also be essential for unique identification:

- location of the facility that collected the product
- name/location of the facility that shipped the product if different from the facility that assigned the original identifier
- collection/recovery date
- expiration date
- date of shipment
- date of receipt

5.2.2 Assigning the ISBT 128 Identification

The mapping from the existing donation number to the ISBT 128 DIN should be achieved electronically when possible. If the collection facility bar codes its donation number, this should be scanned. The ISBT 128 DIN may be assigned by allocating a pre-printed number set or by the computer generating a number set using on-demand printing. In either case, the assigned DIN should be scanned immediately after it is affixed to the product.

When manual recording of identifiers is required, procedures should be designed to minimize the risk of transcription errors (e.g., by requiring duplicate entry).

When products undergo further processing, the product type will change and appropriate ISBT 128 Product Codes should be assigned. If a collected product is to be distributed without further processing, then an ISBT 128 Product Code that corresponds to the product code from the procurement organization should be used. A list of appropriate product code mappings should be maintained to ensure a consistent approach.

If the product (e.g., a cellular therapy product) is distributed to the patient care room still cryopreserved, the ISBT 128 DIN and Product Code should be affixed to a secured outer wrapper/container.

5.2.3 Maintaining Traceability Records

Records of the mapping between the collection facility donation numbers and the ISBT 128 DINs must be maintained in a way that supports rapid bi-directional tracking for recall purposes and meets regulatory requirements.

6 Traceability Issues

Unique identification of a product with ISBT 128 requires both the DIN and identifiers that identify a specific product from a collection/recovery. Generally, this is the full Product Code (Product Description Code and Divisions Code; and for blood, cellular therapy, and regenerated tissue/seeded scaffolds, a donation type). Other data structures that may be required for traceability include:

- Product Divisions [Data Structure 032], if present, for cellular therapy or regenerated tissue products
- Processing Facility Identification Code [Data Structure 033], if present, for tissues or ocular tissues
- A combination of Product Divisions [Data Structure 032] and Processor Product Identification Code [Data Structure 034], if present, for tissues

The entire 13-character DIN must be recorded in all records to ensure uniqueness. Traceability requires the retention of these unique identifiers at all steps in the transfusion or transplantation pathway, together with local records of interventions and appropriate mapping of identifiers between starting and final products.

6.1 Blood

6.1.1 Collection

Whole blood and apheresis products are generally assigned a DIN at the time of collection. This DIN remains with the product through final disposition, which supports a need for recall. However, this may not always be the case. For example, during transition periods within a country, there may be times when a facility using ISBT 128 receives a product that is not labeled with an ISBT 128 DIN. Because the donation identifier on the product may not be unique, the receiving facility may decide to assign a DIN. In this situation, the DIN would contain the FIN of the receiving facility.

6.1.2 Product Pools

Pooled blood components should be given a unique DIN. The DIN would be assigned by the pooling facility, which may be different from the facility(ies) that collected the products within the pool. The DIN should contain the FIN of the facility that pools the products, assigns the DIN, and retains the records of the products contained in the pool.

6.2 Cellular Therapy

6.2.1 Collection

Cellular therapy products are generally assigned a DIN at the time of collection. This DIN remains with the product through final disposition, which supports a need for recall. However, this may not always be the case. For example, as cellular therapy facilities around the globe implement ISBT 128,

there may be times when a facility using ISBT 128 receives a product that is not labeled with an ISBT 128 DIN. Because the donation identification number on the product may not be unique, the receiving facility may decide to assign a DIN. In this situation, the DIN would contain the FIN of the receiving facility.

Regulations in some countries may require that any information that could allow identifying the collection facility for a matched unrelated donor be removed from the product label. While there are a number of ways to approach this, a processing facility may need to assign a new DIN with its own FIN to meet requirements.

6.2.2 Product Pools

While pools of products from more than one donor are generally not allowed in the field of cellular therapy, multiple products from the same donor may be pooled.

Pooled products should be assigned a unique identification number in the same format as the DIN. This number should be assigned by the pooling facility and reflect its FIN. The name and location beneath the DIN bar code should be that of the pooling facility. Facility records should reflect the identification numbers of the various units within the pooled product.

Pooling often involves multiple products of the same Class, from the same donor, collected on different days (e.g., multiple units of HPC, Apheresis from the same donor collected on different days).

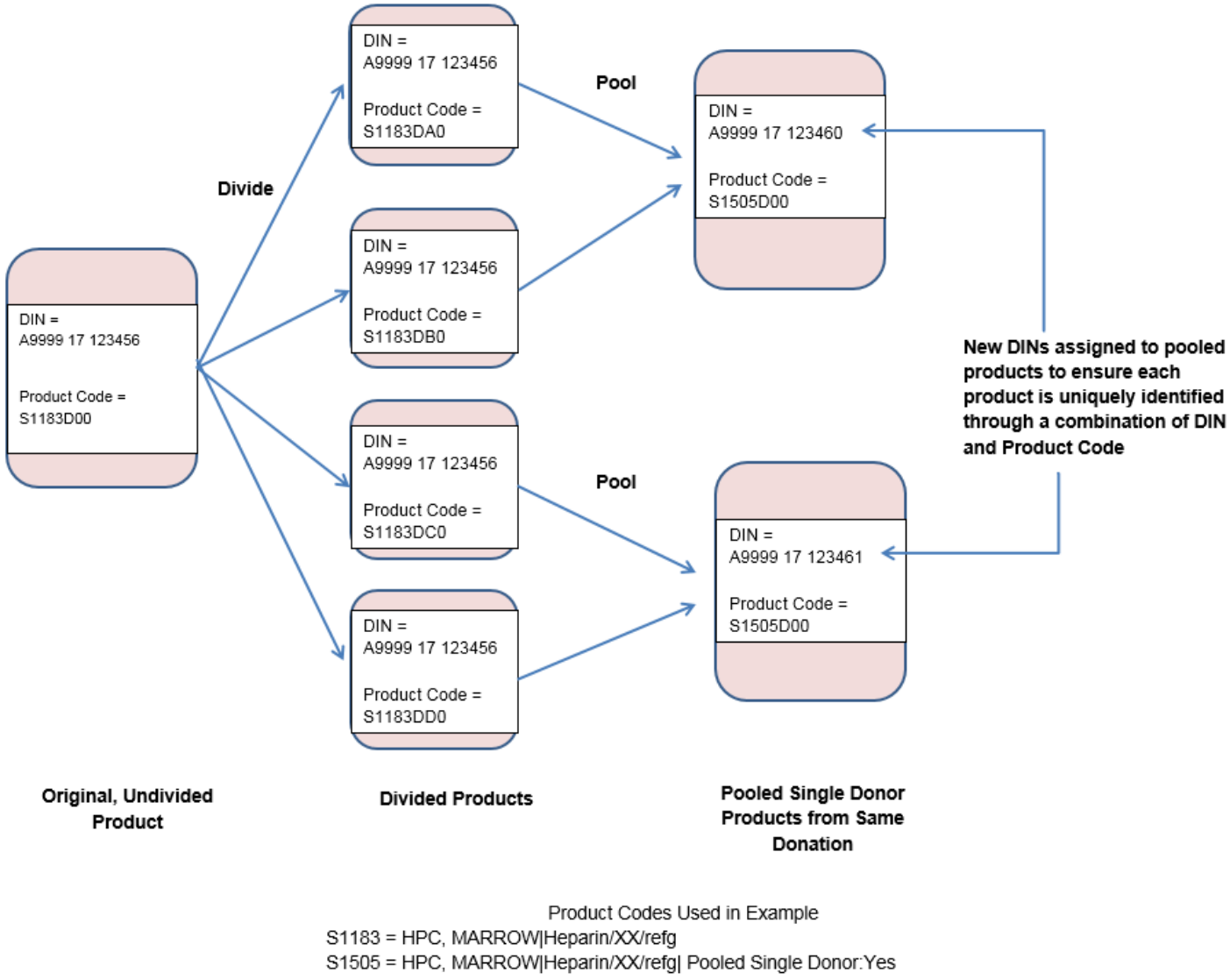
Recombining aliquots from the same donation is also called pooling by some facilities. When this occurs, a potential problem for uniquely identifying each pool may arise if the DIN from the original product is retained for the pooled products and more than one pooled product is prepared. In this situation, two pooled products could share both a DIN and a Product Description Code. To prevent the problem, one of two methods may be used:

1. A new DIN may be assigned to the product pool (see Figure 8)
2. A Division Code may be used within the Product Code (see Figure 9)

Users should refer to national guidelines, as some countries have determined which of these solutions is preferred.

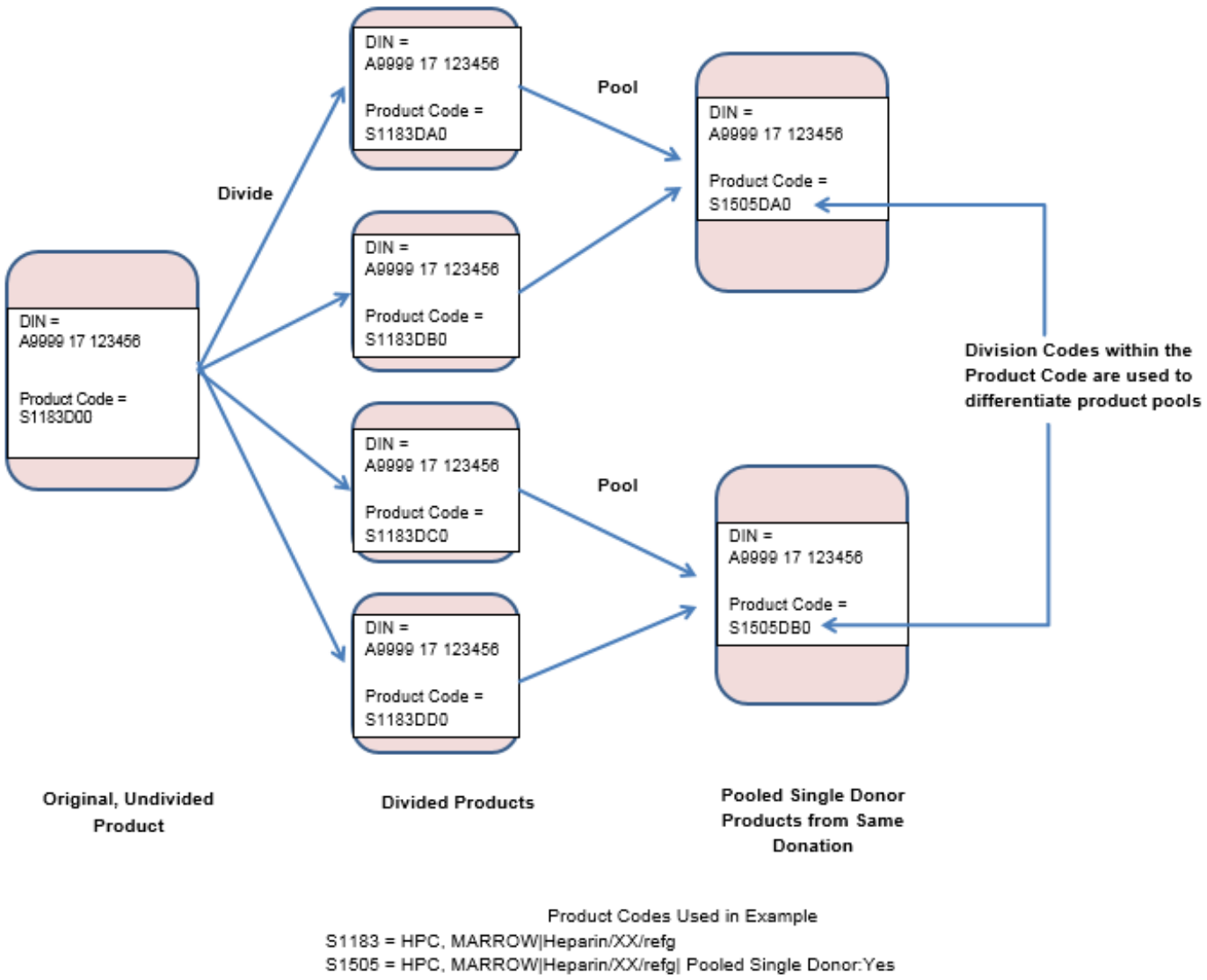
Note that in the situation when, as part of initial processing, a portion of the product is removed and added back, the product is not considered to be pooled. For example, a portion of the original product is set aside before processing; T/B-cell depletion is performed on the remainder of the product; and at the end, based on the final T-cell dose required, the non-depleted part is added back to the final depleted product. This is not considered "pooling" and the product is not assigned a new DIN.

Figure 8 Assigning a New DIN to Recombined Aliquots from Same Donation



Product Codes Used in Example
S1183 = HPC, MARROW|Heparin/XX/refg
S1505 = HPC, MARROW|Heparin/XX/refg| Pooled Single Donor:Yes

Figure 9 Assigning a Division Code to Recombined Aliquots from Same Donation



6.2.3 Product Divisions [Data Structure 032]

If the Product Divisions [Data Structure 032] is used, it is required for traceability and must be recorded, along with the DIN and Product Description Code, in all records (manual and electronic).

6.3 Tissues (Including Ocular) and Organs

Tissue banking and organ transplant provide new challenges in that tissue and organs from a single donation may be sent to more than one facility for processing. For example, in some countries, ocular tissue may be sent to an eye bank facility, cardio-vascular tissue to a specialist cardiovascular processing facility, and musculoskeletal tissue to a third tissue facility. Each of these facilities may identify the tissue or organs using their own identification numbers, resulting in tissue and organs from a single donor carrying more than one donation identification number.

However, traceability and biovigilance will be best served by using a single DIN issued at the time of recovery/procurement to identify all organs and/or tissue grafts derived from one donor. This model is used in some countries (for example, the Italian system of a nationally assigned identifier) and should be encouraged on a global basis.

ICCBBA strongly supports the adoption of this approach and has developed the ISBT 128 Standard to be compatible with the required changes to the traceability model through the introduction of the Facility Identification Number and Processing Facility Information Code [Data Structure 033].

Use of a single DIN assigned at the point of recovery will require tissue banks to be able to carry the assigned DIN throughout their process to final product labeling. It will mean that the facility identified in the DIN may not be the facility responsible for processing and labeling the final graft; and that grafts from different tissue processors may carry the same DIN. For this reason, it becomes necessary to electronically identify the organization responsible for assigning the Product Code to the finished graft with Data Structure 033. This information will become an essential element for the traceability of key data.

Certain tissues may be regulated as medical devices in some countries. These products are identified through a Unique Device Identifier (UDI) as described in *ISBT 128 Standard Coding and Labeling of Medical Devices Using ISBT 128* (ST-011).

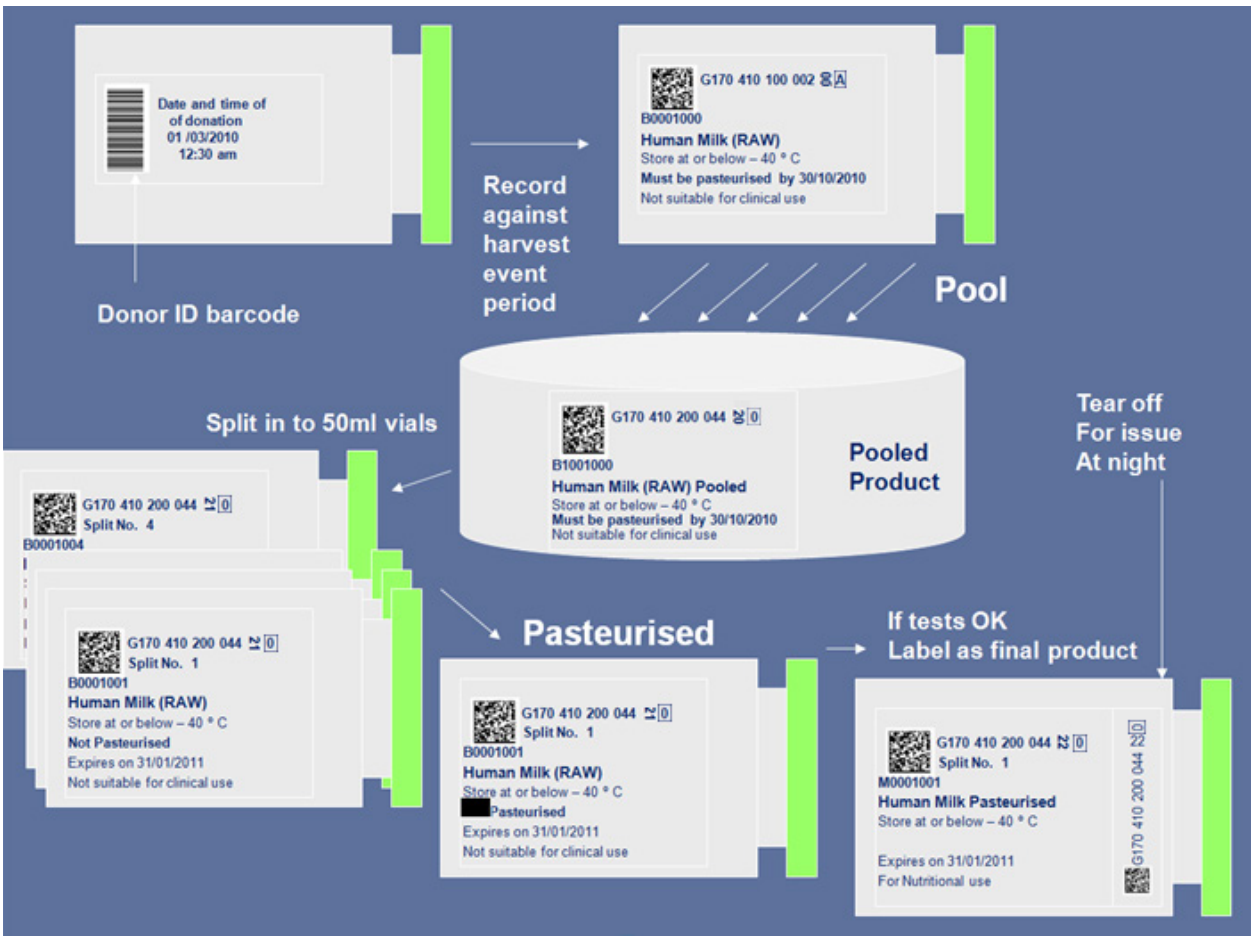
6.4 Milk

Labeling of human milk follows the format described in *ISBT 128 Standard Labeling of Human Milk Banking Products* (ST-013). As with other products, a DIN is assigned to a collection. If milk from more than one collection is pooled, a new DIN is assigned to the pool.

Figure 10 outlines the process used in a pilot study by the NHS Greater Glasgow and Clyde (GGC) Milk Bank in the United Kingdom. In this process, the product is assigned a DIN at the time of harvest/expression. Milk from the same donor is subsequently pooled

and pasteurized and the product pool is assigned a new DIN. The pooled product is subsequently divided and each aliquot retains the DIN of the pool and is assigned a Division Code within the Product Code to ensure each product is labeled uniquely.

Figure 10 NHS Greater Glasgow and Clyde (GGC) Milk Bank Process for Human Milk



6.5 Derivatives

As discussed in Section 2.2, ISBT 128 is used to label those plasma derivatives for which the ABO group is relevant. At the present time, only solvent detergent-treated plasma products have been labeled with ISBT 128. These products comprise a large pool of plasma units that are processed and subsequently divided by a plasma fractionator.

Each individual product is given a unique DIN. This means that products from the same pool, having the same batch number, will have different DINs providing unique identification for each product.

6.6 Assisted Reproductive Technology (ART)

In assisted reproductive technology, it is recommended that the embryo be assigned a unique Donation Identification Number (DIN). The organization responsible for assigning the DIN to the embryo is responsible for retaining traceability records back to the identifiers of the gametes.

7 Software Developers

7.1 Global Issues

Because medical products of human origin have global distribution, software should be written to comply with variations allowed by the ISBT 128 Standard. That is, software should be able to interpret DINs from any country, with both default and standardized flag characters.

7.2 Check Characters

7.2.1 Recognition of Keyboard Entry of DIN

Software should be written to recognize when a DIN is entered via a keyboard (no data identifiers) and require the entry of the check character. Code examples for calculating the DIN check character are provided below.

7.2.2 Code Examples for Calculating the DIN Check Character Using ISO/IEC 7064

This is an *informative* section designed to assist programmers by giving two representative methods for the calculation of the DIN ISO/IEC 7064 modulo 37-2 check character. Both use the "*Pure system recursive method*" for calculation of the check character as documented in section 7.1 of the ISO/IEC 7064 specification: "Information technology—Security techniques—Check character systems."

Programmers must validate that their programs and algorithms comply with the *normative* ISO/IEC 7064:2003 specification and good programming practice. Prior to performing the check digit calculation, software should verify that the input string meets all the format requirements for the data structure expected.

The following PASCAL language function **ISOmod37_2** calculates and/or validates the ISO/IEC 7064 Mod 37-2 pure check character:

```
function ISOmod37_2(DonationInfo:string; K:integer) : char;
(Calculate or validate ISO mode 37-2 pure check character}
function ISOvalue(InputString:string; I:integer) : integer;
begin {Convert ASCII character value to ISO 7064 value in range 0...36}
case InputString[I] of
'0' .. '9': ISOValue := (ord(InputString[I]) - 48);
'A' .. 'Z': ISOValue := (ord(InputString[I]) - 55);
'*': ISOValue := 36;
end;
end {function ISOvalue};
var
J,Sum,CharValue,CheckValue : integer;
```



```
const
ISOCharTable : string[37] = '0123456789ABCDEFGHIJKLMNOPQRSTUVWXYZ*';
begin
Sum := 0;
for J:= 1 to K do
begin
CharValue := ISOvalue(DonationInfo,J);
Sum := ((Sum + CharValue)*2) mod 37;
end;
{Check character value is defined to be congruent to 1 mod 37}
CheckValue := (38 - Sum) mod 37;
ISOmod37_2 := ISOCharTable[CheckValue + 1];
end {function ISOmod 37_2};
```

The following 'C' language function **CalculateMod37_2** also implements the *"Pure system recursive method"* documented in section 7.1 of the ISO/IEC 7064: specification:

```
int CalculateISO7064Mod37_2(char *inputString)
{
int ch, sum, charValue, isDigit, isUpperAlpha;
static char iso7064ValueToCharTable[] =
"0123456789ABCDEFGHIJKLMNOPQRSTUVWXYZ*";
// Read the characters from left to right.
for (sum = 0; ch = *inputString; inputString++)
{
// Ignore invalid characters as per ISO 7064.
isDigit = ((ch >= '0') && (ch <= '9'));
isUpperAlpha = ((ch >= 'A') && (ch <= 'Z'));
if (isDigit || isUpperAlpha)
{
// Convert the character to its ISO 7064 value.
if (isDigit)
charValue = ch - '0';
else
charValue = ch - 'A' + 10;
// Add the character value to the accumulating sum,
// multiply by two, and do an intermediate modulus to
// prevent integer overflow.
sum = ((sum + charValue) * 2) % 37;
}
}
// Find the value, that when added to the result of the above
// calculation, would result in a number who's modulus 37
// result is equal to 1.
charValue = (38 - sum) % 37;
// Convert the value to a character and return it.
return (iso7064ValueToCharTable[charValue]);
}
```

ICCBBA thanks Dr. Clive Hohberger, for providing the PASCAL function ISOmod37_2, and Mr. Harold Boe, for providing the C-language function CalculateISO7064Mod37_2.

