IMPLEMENTATION GUIDE

Use of Flags in the Donation Identification Number for Process Control of Critical Points during Processing and Distribution

Version 1.0.3

June 2021

Tracking Number ICCBBA IG-010

Published by:
ICCBBA
PO Box 11309, San Bernardino, CA 92423-1309 USA

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1 Introduction

1.1 Purpose

This document provides an overview of one way in which flag characters of the ISBT 128 Donation Identification Number [Data Structure 001] can be used for process control.

Flag characters can be used for process control of “critical points” (during processing and distribution) to enhance the safety of medical products of human origin (MPHO).

Critical points are, for example, labeling and relabeling of blood and blood components as well as printing and attaching a record to follow specific units of blood or blood components.

1.2 Scope

This document provides an example of the use of the flag characters in the Donation Identification Number (DIN) for process control of critical points during processing and distribution of blood products. This document is intended as a supplement to the *ISBT 128 Standard Technical Specification* (ST-001).

1.3 Intended Audience

While this document uses blood products to illustrate the use/applications of flag characters, this guidance document is intended for staff (management, laboratory, quality, and information technology) of facilities using ISBT 128, software developers, and manufacturers of labels for MPHO.

1.4 Normative Reference

ISBT 128 Standard Technical Specification (ST-001)

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)

1.5 Other Reference

ICCBBA Website (www.isbt128.org)

1.6 Background

While flag characters are part of the DIN [Data Structure 001] data content string, they are intended to be used to convey specific information (e.g., process control points) and should not play a role in the unique identification of the product.

The use of flag characters shall conform to national guidelines, if such guidelines exist. It is advised for users to consult with their regulatory and accrediting agencies regarding the use of flag characters.

1.7 Changes in this Version

The following table indicates the major changes between Version 1.0.2 and Version 1.0.3. 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.

	Chapter, Section, Figure, or Table in Version 1.0.2	Chapter, Section, Figure, or Table in Version 1.0.3	Change	Rationale
1.	2.1	2.1	Update DIN purpose to include assignment of DIN to embryos	For consistency with ST-001
2.	2.1	2.1	Add reference to flag characters ff for Data Structure 001	For consistency with ST-001

2 Donation Identification Number [Data Structure 001]

2.1 Overview

Purpose: Data Structure 001 shall specify:

- a thirteen (13)-character Donation Identification Number (DIN) that is a unique identification of:
  - a donation event [collection or recovery]
  - a product pool
  - for plasma derivatives, a unique identification of an aliquot from a pooled plasma derivative product
  - a fertilized oocyte/embryo formed through ART

AND

- flag character values

The 13-character DIN shall be globally unique for a one hundred year period.

Structure: **=αppppyynnnnnnff**

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

The elements of the Donation Identification Number data structure are defined as follows:

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

shall be encoded and interpreted by reference to the ICCBBA Registered Facilities database.

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

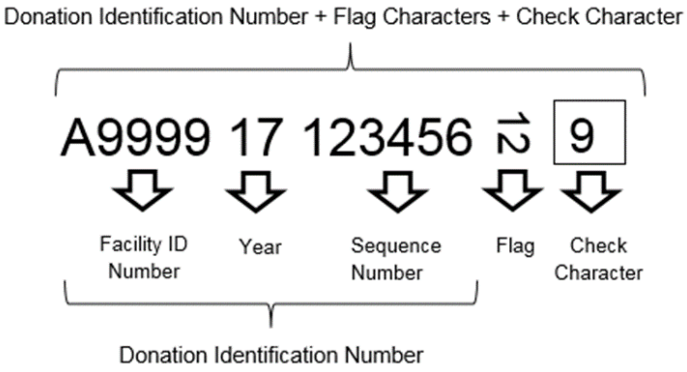
The nominal year may overlap +/- one month of the year assigned.

nnnnnn shall specify the sequence number, within the given nominal year for the FIN.

ff shall specify flag characters. Flag characters are not part of the 13-character DIN.

See Table 1 for the values and interpretations

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.
- A keyboard entry check character is also not part of the DIN, but is calculated from the DIN and printed in human-readable format (see Section 0).
- Both the flag characters and the check character are intended for process control and are not part of the unique identification of the product.

As previously mentioned, this publication will deal with the use of the flag characters for process control. For further information about the other elements of the DIN, see the *ISBT 128 Standard Technical Specification* (ST-001).

2.2 Donation Identification Number Flag Characters

Use of flag characters “ff” shall conform to national guidelines, if such guidelines exist. As shown in Table 1, there are three general types of usage:

- **Type 1**: Two-character code used for process control and defined by ICCBBA within the ISBT 128 Standard.

- **Type 2**: Two-character code used for process control, but “locally” defined. 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.

- **Type 3**: A two-character code used to convey a weighted ISO/IEC 7064 modulo 37-2 check character that is calculated on the thirteen-character DIN within the bar code. [The use of the flag characters for this purpose will not be discussed further in this document.]

In all cases, the following two rules shall be observed when using flag characters:

- When not used or not specified, the value of “ff” shall be set to “00”.
- When used, the selected values of “ff” must conform to Table 1.

When Type 1 or Type 2 process control flag characters are used (which means the encoded value of “ff” is in the range 01-59) they must be represented in a nationally specified eye-readable format. This format may either be a numeric, text, or other symbol as noted below.

2.2.1 Numeric Format

When printed as a two-digit number the digits should be rotated 90° clockwise to make them visually different from the other data characters in the Donation Identification Number. An example is shown in **Figure 2.**

Figure 2 Numeric Presentation

2.2.2 Non-numeric Format

Text or a symbol representing “ff” may be preferable. For example:

- Where “ff” is “03", printing the phrase “Container 3” on the label may be more useful to the person handling the unit.
- Where “ff” is “07”, printing an icon showing a small test tube may be preferable. An example is shown in Figure 3.

Figure 3 Non-numeric Presentation

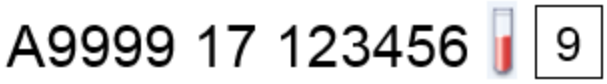


Table 1 Data Structure 001: Donation Identification Number Flag Digits, ff [RT004]

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

3 Scandinavian Use of Flag Characters for Process Control

3.1 Overview

This section discusses the Scandinavian use of the flag characters for process control. This system uses a combination of the flag characters allocated by ICCBBA and flag characters defined in Scandinavia (see Table).

The process control is partly dependent on an amendment to the international label. At the bottom of the main label there is a smaller label (100 mm x 25 mm [4" x 1"]) with the Donation Identification Number and the Product Code data structures (see Figure 4). These two data structure codes uniquely identify the product worldwide. The label can be torn off and placed in the patient's records. Although the Donation Identification Number on this smaller label is identical to the Donation Identification Number in the upper left quadrant, the flag characters are different and therefore it is possible to discriminate between the two identical Donation Identification Numbers.

The flags characters are used to discriminate between identical donations numbers that are in different places and thereby control critical points during processing.

Examples of critical points that can be controlled by this system are:

- labeling at collection
- labeling after separation
- labeling after change of product code
  - same container (e.g., irradiation, thawing)
  - new container (e.g., filtration, washing)
- pooling
- dividing and splitting
- distribution or issuing of component

Table 2 Scandinavian Specified Values for Donation Identification Number Flag Characters, "ff"

Location	Flag characters	Container
Donor documentation	08	
Upper left quadrant	01 and 31	Container 1
	02 and 32	Container 2
	03 and 33	Container 3
	04 and 34	Container 4
	etc.	
Label for the patient's records	41 and 51	Container 1
	42 and 52	Container 2
	43 and 53	Container 3
	44 and 54	Container 4
	etc.	
Record following the unit	46	

Figure 4 Scandinavian Blood Label

Hyperlinks given below will access images from www.iccbba.org web site when this document is viewed on-line

3.1.1 Process Control of Labeling at Collection [images]

The base label of an ISBT 128-labeled blood container has two ISBT 128 bar codes: The Container Manufacturer and Catalog Number [Data Structure 017] and the Container Lot Number [Data Structure 018].

The following outlines the structure of Data Structure 017:

Structure: =)bqqwwwwwww

Element	Length	Type
=	1	data identifier, first character
)	1	data identifier, second character
b	1	alphanumeric {A–Z; a-z, 0–9}
qq	2	alphanumeric {A–Z; 0–9}
wwwwwww	7	alphanumeric {A–Z; a–z; 0–9}

b shall specify the container identification character in a container or transfer set.

qq shall specify the identity of the container set manufacturer and is encoded and interpreted from Table W1, Manufacturer Identifier Codes.

wwwwwww shall specify the manufacturer's catalog number.

For further information about the elements of the Container Manufacturer and Catalog Number [Data Structure 017], see the *ISBT 128 Standard Technical Specification* (ST-001).

When Donation Identification Numbers for the different containers have different flag characters, it is possible after collection and labeling to read on each container first the bar code Donation Identification Number [Data Structure 001] and then the bar code of the Container Manufacturer and Catalog Number [Data Structure 017]. The computer can then compare the flag characters of the Donation Identification Number bar code and the container number in the Container Manufacturer and Catalog Number bar code, and recognize if the two bar codes are discordant. The correct placement of the Donation Identification Numbers is pivotal for process control further down the production line as described below.

When this registration takes place after the collection, it is also possible to make certain that an identical Donation Identification Number is on the donation record, any pilot tubes, the tube for bacterial testing, and the tube

for NAT testing. Newer mixers provided by several companies are able to collect this data during the collection procedure. Therefore, the process control described above can take place just beside the donor. This saves time and may even make control checks by a second staff person unnecessary.

3.1.2 Process Control of Labeling after Separation and Testing [images]

After a whole blood collection has been separated and tested, the flag characters make it possible to control the critical final labeling of the resulting blood component(s):

- The computer system has information on the manufactured product.
- The computer system has information on the results of the testing and blood group control procedures.
- Any missing items for the final ISBT 128 label is printed on-line (on-demand).
- A second identical Donation Identification Number with different flag characters is printed on an attached label for the patient's records.

In practice, this can be done by the following series of events:

- Donation Identification Number read in upper left quadrant (for example, flag characters 02).
- On-line (on-demand) label printed automatically.
- Label placed on container.
- Donation Identification Number read again in upper left quadrant.
- Donation Identification Number read on label for patient's records (for example, flag characters 42).
- If the Donation Identification Number or flag characters are incorrect (e.g., if the Donation Identification Number is read from the same place twice) the computer alarms.
- Product Code read (to make certain that the computer's information regarding the product is identical to that on the label).

3.1.3 Process Control for Change of Product Code (component stays in same container) [images]

After the final label has been attached to the component it may be necessary to change the Product Code even though the component stays in the same container, for example, after irradiation or thawing.

In practice, this can be done by the following series of events:

1. Donation Identification Number read on label for patient's records (for example, flag characters 42).
2. Product Code read on label for patient's records (these two steps can be done in a single scan [read] if concatenation is used).
3. New Product Code chosen.
4. On-line (on-demand) label printed automatically.
5. Label placed on container.
6. Donation Identification Number read in upper left quadrant again (flag characters 02).
7. Donation Identification Number read on label for patient's records again (flag characters 52).
8. If the Donation Identification Number or flag characters are incorrect (e.g., if the Donation Identification Number is read from same place twice or if the flag characters are unchanged) the computer alarms.
9. Product Code read (to make certain that the computer's information about the product is identical to that on the label).

3.1.4 Process Control for Change of Product Code (component moved to a new container) [images]

After the final label has been attached to the component, it may be necessary to change the Product Code during the production of the component in a new container—for example, for leukodepletion or washing.

In practice this can be done by the following series of events:

1. Donation Identification Number read on label for patient's records (for example, flag characters 42).
2. Product Code read on label for patient's records (these two steps can be done in a single scan [read] if concatenation is used).
3. New Product Code chosen.
4. On-line (on-demand) label (whole label and label for patient's records) printed automatically.
5. Label placed on new container.
6. Donation Identification Number read on label for patient's records on original container (flag characters 42).
7. Product Code read on label for patient's records on original container (these two steps can be done in a single scan [read] if concatenation is used).
8. Donation Identification Number read on label for patient's records on new container (flag characters 42).
9. Product Code read on label for patient's records on new container (to make certain that the computer's information on the Product Code is identical to that on the label) (these two steps can be done in a single scan [read] if concatenation is used).
10. If the Donation Identification Number or flag characters are incorrect (e.g., if the Donation Identification Number is read from the same place twice or if the flag characters are unchanged) the computer alarms.

***Important*: steps 5 to 9 must be performed before the two containers are disconnected.**

3.1.5 Process Control in Pooling [images]

Pooling may be performed in the original container of one of the components or in a new container. A new Donation Identification (batch) Number may be required by national legislation; in some countries one of the original Donation Identification Numbers may be used for the pool. In both cases, traceability of all included components and correct labeling are of paramount importance.

In practice the control of this process can be done as follows:

1. Registration of new component's Donation Identification (batch) Number and Product Code.
2. Registration of old component's Donation Identification Numbers (for example, flag characters 01).
3. On-line (in-demand) label (whole label and label for patient's records) printed automatically.
4. Donation Identification Number (for example, flag characters 41) and Product Code read from label for the patient's records on the new label. Can be done in a single scan (read) if concatenation is used.
5. Donation Identification Numbers (and Product Codes, if available) read from old containers.
6. If Donation Identification Number or flag characters are incorrect (e.g., if the Donation Identification Number is read from the same place twice or if the flag characters are unchanged) the computer alarms.

***Important*: steps 4 to 6 must be performed before the containers are disconnected.**

3.1.6 Process Control for Dividing and Splitting Units [images]

Dividing and splitting of a product necessitates a change in the 7th and/or the 8th character of the ISBT 128 Product Code. Traceability of all divisions and splits and correct labeling are important.

In practice the control of the division/split process can be done as follows:

1. Registration of component to be divided or split: Donation Identification Number (for example, flag characters 52) and Product Code read on the label for the patient's records.
2. Number of wanted division or splits is entered into the computer, which automatically creates the needed new Product Codes.
3. On-line labels (whole label and label for patient's records, one for each division or split, each with a different Product Code) printed automatically
4. Donation Identification Number (for example, flag characters 52) and Product Code read from label for the patient's records on the original container. This can be done in a single scan if the concatenation is used.
5. Donation Identification Number (for example, flag characters 42) and Product Code read from the divided or split container(s). This can be done in a single scan if the concatenation is used.

6. If Donation Identification Number or flag characters are incorrect (for example, if the Donation Identification Number is read from the same place twice or if the flag characters are unchanged) the computer alarms.

***Important*: steps 4 to 6 must be performed before the containers are disconnected.**

3.1.7 Process Control in Shipping

When shipping, the Donation Identification Number and the Product Code on the label for the patient's records can be read in a single scan and used to create a delivery note. This feature can also be used for billing and inventory control.

3.1.8 Process Control in Issuing [images]

Control of issuing of blood components from the hospital's transfusions service to the wards is critical. The practice used in connection with an electronic cross match is described, but the process control can also be adjusted to a system using serological cross matching.

Control of this critical point can be achieved as follows:

1. The necessary requirements for an electronic cross match are fulfilled.
2. The patient's identification number is scanned.
3. Unit(s) is (are) ordered in the computer system.
4. The computer chooses appropriate unit(s).
5. A transfusion record for each unit is printed.
6. Unit(s) obtained from stock.
7. Donation Identification Number (flag characters 46) and Product Code scanned from transfusion record.
8. Donation Identification Number (flag characters different from 46) and Product Code scanned from label for patient's record.
9. If Donation Identification Number or flag characters incorrect (for example if the Donation Identification Numbers or Product Codes are different or the Donation Identification Number is read from the same place twice) the computer alarms.

3.2 Does it work?

The described system for process control has now been implemented in several facilities in Scandinavia beginning in 2000. In practice, process control of labeling does not result in a substantial increase in work load. Staff has welcomed the concept. Mislabeling has been a much rarer event. Most importantly, documentation of all labeling events, including registration of staff and time, has become possible.

