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## IMPLEMENTATION GUIDE

# Use of Product Divisions [Data Structure 032]

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# 1 Introduction

## 1.1 Purpose

The purpose of this document is to provide guidance to users and software developers in the use of the Product Divisions [Data Structure 032] for cellular therapy and regenerated tissue products.

## 1.2 Scope

This document is a guidance document to be used in conjunction with the *ISBT 128 Standard Technical Specification* (ST-001). It provides information about the format and use of the Product Divisions [Data Structure 032] when used in conjunction with the Product Code [Data Structure 003]. Additionally, it provides some guidance for software developers in creating software that utilizes this data structure.

The scope of this document is limited to the coding of product divisions using the Product Code [Data Structure 003] and Product Divisions [Data Structure 032] for cellular therapy and regenerated tissue products.

The use of the Product Divisions Data Structure in conjunction with the Processor Product Identification Code [Data Structure 034] is out of the scope of this document. It is discussed in *ISBT 128 Standard Coding and Labeling of Medical Devices Using ISBT 128* (ST-011).

## 1.3 Intended Audience

This document is intended for staff (management, laboratory, quality, validation, and information technology) of cellular therapy and regenerated tissue facilities using ISBT 128 and their software developers. While this data structure was initially intended for cellular therapy and regenerated tissue products only, there has been interest from blood bank users suggesting that the data structure might be useful for transfusion medicine. For that reason, blood bank users may also find this document of interest.

## 1.4 Normative References

*ISBT 128 Standard Technical Specification* (ST-001)

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

## 1.5 Other References

ICCBBA website ([www.iccbba.org](http://www.iccbba.org))

*Implementation Guide: Use of Data Matrix Symbols with ISBT 128* (IG-014)

*Implementation Guide: Product Coding [Data Structures 003 and 032] - Cellular Therapy (IG-022)*

## 1.6 Background

The Product Code [Data Structure 003] encodes the number of divisions of a product.

- For blood, cellular therapy, and regenerated tissue Product Description Codes, it allows up to 26 first level divisions and 26 second level divisions. This is accomplished using a two-character code in the 7<sup>th</sup> and 8<sup>th</sup> positions of the Product Code [see Section 2.1 and the *ISBT 128 Standard Technical Specification (ST-001)* for details]. Supporting 26 first and second level divisions has not been adequate for cellular therapy and regenerated tissue products. Therefore, a new mechanism for encoding more than 26 divisions at each level was needed.
- For blood, the number of divisions at each level is adequate; however, some users have indicated a third level of division would be useful. That is, these users have indicated a need to support the situation in which blood products are divided first into large aliquots, then into smaller aliquots, and finally into syringe aliquots to accommodate pediatric transfusion. While Data Structure 032 would meet this need, at this time, the Technical Advisory Groups for blood have not voted to utilize this data structure for blood components.
- For other products (tissues, ocular tissue, reproductive tissue, organs for transplant, human milk, topical products of human origin, and fecal microbiota), the Product Code Data Structure allows up to 999 divisions, which is currently adequate. Further, the use of the Product Divisions [Data Structure 032] is not possible for these products when the Product Code [Data Structure 003] is used because 99 in the last two characters of the Product Code is a valid Division Code and cannot be used to indicate a switch to Data Structure 032 for division information.
- For tissues regulated as medical devices in the US, Product Divisions [Data Structure 032] shall be used in conjunction with the Processor Product Identification Code [Data Structure 034] to indicate a serial number. See *ISBT 128 Standard Coding and Labeling of Medical Devices Using ISBT 128 (ST-011)*.

## 1.7 Implementation Time Line

Date of implementation depends on the data structure with which it will be used. That is:

**When used in conjunction with Data Structure 003:** Because this data structure becomes part of the unique identification of a product, implementation of the data structure must be coordinated so that computer systems of facilities receiving the product are able to scan and interpret the codes.

The data structure may be used for cellular therapy or regenerated tissue products if:

- A product will remain within the facility that labeled it with this data structure

- There is an agreement between supplier and receiver of a product to utilize this data structure sooner

**When used in conjunction with Data Structure 034:** This data structure may be used at any time.

*Note: At the present time, use of the Product Divisions Data Structure with Data Structure 003 is restricted to cellular therapy and regenerated tissue Product Codes (where  $\alpha$  is S and P, respectively) and for products identified using Data Structure 034. However, in the future, the use of the Product Divisions Data Structure may be extended to blood products (where  $\alpha$  is E or F).*

## 1.8 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 Product Divisions [Data Structure 032] 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	Figures and examples were updated.	To accurately reflect information in ST-001 and use current dates.
2.	1.1	1.1	Updated Purpose to include guidance for users in the use of the Product Divisions Data Structure.	Per ST-001, this data structure may now be used for cellular therapy and regenerated tissue products.
3.	1.6	1.6	Updated types of other products that cannot use Data Structure 032.	To accurately reflect the products in this section.
4.	1.7	1.7	Updated entire section.	To accurately reflect current information in ST-001.
5.	2.1	2.1	Removed references to local codes.	Data Structure 032 is not defined for use with local codes in the ISBT 128 Standard.
6.	2.1	2.1	Added comment to see note in text box for divisions.	To reflect current information for Data Structure 003 in ST-001.
7.	<b>2.1</b>	<b>2.1</b>	<b>Added additional condition for when the ds portion of the Product Code shall be set to 00.</b>	<b>Proposal 17-002</b>
8.	<b>2.1</b>	<b>2.1</b>	<b>Updated allowable characters in Data Structure 003.</b>	<b>Proposal 16-005</b>



	Version 1.1.0 Chapter, Section, Table, or Figure	Version 1.2.0 Chapter, Section, Table, or Figure	Change	Rationale
9.	Figure 1	Figure 1	This figure was moved from Section 2.2 to Section 2.1.	The Product Code section is the more appropriate placement for this figure.
10.	2.2	2.2	<b>Expanded the purpose of the Product Divisions Data Structure and updated the section.</b>	<b>Proposal 17-002 and to reflect current information in ST-001.</b>
11.	Figure 2	Figure 2	<b>Added the text “Undivided Product” for the product with the Product Divisions Code 000000.</b>	<b>Per Proposal 17-002, division code 000000 can now be used for undivided products.</b>
12.	Figure 2	Figure 2	Changed “Division Code” to “Product Divisions Code” for label examples on bags.	To accurately reflect terminology in Section 2.2 and terminology used in other label examples.
13.	Figure 2	Figure 2	Changed text boxes to read “...characters in the Product Divisions code” for all three levels of division.	To accurately reflect the terminology used in Section 3.1.2.
14.	3.1.2	3.1.2	Changed wording for additional first level divisions to “...position changes to C through Z.”	To correspond to the wording in the previous examples.
15.	3.1.2	3.1.2	Replaced “six-character field” with “six-character code.”	To be consistent with terminology throughout the section.
16.	3.2.2	3.2.2	Removed “Code” from the section header.	This section is referring to the uniqueness of a product, not the Product Code.
17.	3.3, Figure 5, and Figure 6	3.3, Figure 5, and Figure 6	Removed bar code text and data content text references.	The ISBT 128 Standard no longer uses this terminology.
18.	4.1	4.1	Replaced “2-D data structure” with “2-D symbol.”	There is no 2-D data structure.

## 2 Data Structures

For cellular therapy and regenerated tissue products, the Product Divisions [Data Structure 032] must be used in conjunction with the Product Code [Data Structure 003]. Therefore, information about both of these data structures is included in this section.

### 2.1 Product Code [Data Structure 003]

- Purpose: Data Structure 003 shall:
- identify a product intended for human use
  - optionally encode information about the type of collection
  - encode whether or not the product has been divided

Structure: =<αoooo tds

Element	Length	Type
=	1	data identifier, first character
<	1	data identifier, second character
α	1	alphabetic {A–Z}
oooo	4	alphanumeric {A–Z; 0–9}
t	1	alphanumeric {A–Z; a–z; 0–9} (depends on value of α, see below)
d	1	alphanumeric {A–Z; 0–9}, (depends on value of α, see below)
s	1	alphanumeric {a–z; 0–9} (depends on value of α, see below)

The eight (8)-character data content string, **αoooo tds**, shall be encoded and interpreted as follows:

**αoooo** shall specify the Product Description Code (PDC) and shall be encoded and interpreted by reference to the Product Description Code database table published and maintained by ICCBBA in the password-protected area of the ICCBBA website.

**α** shall specify the category of products. The full list of **α** values is found in the *ISBT 128 Standard Technical Specification (ST-001)*. Because the use of the Product Divisions Data Structure is currently restricted to cellular therapy and regenerated tissue products, this document describes coding pertaining only to these products:

- S – Cellular Therapy Products
- P – Regenerated Tissue Products

**oooo** shall be interpreted through reference to the ISBT 128 Product Description Code Database.

**tds**

The encoding and interpretation of **tds** shall depend upon the value of  $\alpha$ .

The scope of this document is limited to cellular therapy and regenerated tissue products, where  $\alpha$  is S and P, respectively. For information about other values of  $\alpha$ , see the *ISBT 128 Standard Technical Specification* (ST-001).

If  $\alpha$  is S or P, then:

- t** shall specify the type of collection and shall be encoded and interpreted by reference to Table RT008 in the *ISBT 128 Standard Technical Specification* (ST-001).
- ds** shall specify information as to whether the unit has been divided.
  - If the unit has not been divided, and the Product Divisions [Data Structure 032] is not being used, **ds** shall be set to the default value of 00 (zero, zero).
  - If the Product Divisions [Data Structure 032] is used, **ds** shall be set to 99. Software shall require that when a 99 appears in positions 7 and 8 of the Product Code [Data Structure 003], the Product Divisions Data Structure shall be scanned and recorded.
  - If divisions are encoded in the Product Code:
    - d** may encode the first division. First level divisions (up to 26) of the primary collection shall be encoded using capital letters (but see note in the text box below).
    - s** may encode the second division. Second level subdivisions (up to 26) shall be encoded using lowercase letters (but see note in the text box below).

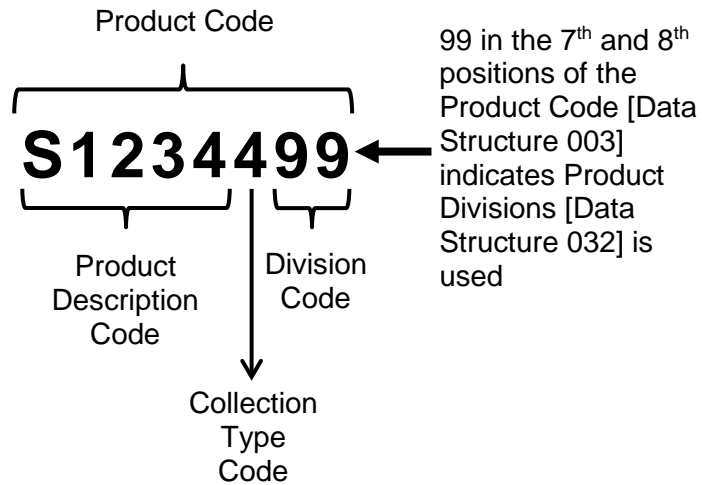
*Divisions need not be equal and this nomenclature does not require this.*

*Note: If  $\alpha$  is S or P, until the Product Divisions [Data Structure 032] is implemented, **d** and **s** may be used to uniquely identify divisions without regard to hierarchical level. Facilities utilizing this option shall ensure that each product is uniquely identified (i.e., multiple products with the same DIN and Product Description Code shall have a unique Division Code).*

More information about encoding divisions within Data Structure 003 may be found in the *ISBT 128 Standard Technical Specification* (ST-001).

The Product Code Data Structure supports up to 26 first level divisions and 26 second level subdivisions. If more than 26 divisions are needed, **ds** shall be encoded as 99, indicating division information is encoded in the Product Divisions [Data Structure 032].

**Figure 1 Division Code in Product Code when Data Structure 032 is Used**



## 2.2 Product Divisions [Data Structure 032]

Purpose: Data Structure 032 shall convey information about

- aliquots or
- one or more individual collections from the donor within the same donation event.

The division code may represent

- one of the subunits from a single container that has been divided. This can also be referred to as an aliquot or a split.
- one of the containers from a collection where the volume of product collected required the use of more than one container.
- a single collection into one container.

**Date of implementation depends on the data structure with which it will be used. That is:**

**When used in conjunction with Data Structure 003:** Because this data structure becomes part of the unique identification of a product, implementation of the data structure must be coordinated so that computer systems of facilities receiving the product are able to scan and interpret the codes.

The data structure may be used for cellular therapy or regenerated tissue products if:

- A product will remain within the facility that labeled it with this data structure
- There is an agreement between supplier and receiver of a product to utilize this data structure sooner

**When used in conjunction with Data Structure 034:** This data structure may be used at any time.

*Note: At the present time, use of the Product Divisions Data Structure with Data Structure 003 is restricted to cellular therapy and regenerated tissue Product Codes (where  $\alpha$  is S and P, respectively) and for products identified using Data Structure 034. However, in the future, the use of the Product Divisions Data Structure may be extended to blood products (where  $\alpha$  is E or F).*

Structure: =,dddddd

Element	Length	Type
=	1	data identifier, first character
,	1	data identifier, second character
dddddd	6	alphanumeric {A–Z, 0–9}

The six (6)-character data content string, **dddddd**, shall be encoded and interpreted as follows:

**dddddd** shall specify the Division Code.

The Division Code allows for a high level of flexibility.

- Digits shall be used where a single level of divisions is required (allowing up to 999,999 divisions).
- If it is desirable to show levels of divisions (to allow for divisions of divisions), alpha characters shall be used. In this situation, the six-character field may be split into three pairs, each allowing AA through ZZ. This provides up to three levels of division.

When the Product Divisions Data Structure is used in conjunction with the Product Code [Data Structure 003], 99 shall appear in the 7<sup>th</sup> and 8<sup>th</sup> positions of the Product Code. See Section 2.1. The Product Divisions Data Structure, when used, is essential for traceability. Software shall require that when a 99 appears in positions 7 and 8 of the Product Code [Data Structure 003], the Product Divisions Data Structure shall be scanned and recorded. If manual records are maintained, the Divisions Code shall be recorded along with the Donation Identification Number (DIN) and the Product Code for all records needed for traceability.

Each Product Divisions code shall be unique for a given Product Code [Data Structure 003] and DIN.

## 3 Usage

### 3.1 Coding Divisions

The Product Divisions Data Structure allows for a high level of flexibility in the coding of divisions.

#### 3.1.1 Single Level of Divisions

Digits are used where a simple single level of divisions is required; 000001 to 999999 may be used.

#### 3.1.2 Hierarchical Levels of Divisions

To support hierarchical levels of divisions (to allow for divisions of divisions), alpha characters should be used. The six-character code may be split into three pairs, each allowing AA through ZZ.

The first level divisions are identified by changing the first two characters of the six-character code from 00 to letters (AA to ZZ). First, the first position changes to an A, with the second position changing from A through Z.

AA0000  
AB0000  
AC0000  
Through AZ0000

Then, if more than 26 first level divisions are needed, the first position changes to B, with the second position changing from A through Z.

BA0000  
BB0000  
BC0000  
Through BZ0000

If additional first level divisions are needed, the first position changes to C through Z. The last group of first level division codes, if all possibilities are used, is:

ZX0000  
ZY0000  
ZZ0000

Each of these divisions may be divided again (second level divisions) by changing the second pair of characters to letters in the same way (AA to ZZ). For example, AA0000 may be divided up to 676 times:

AAAA00  
AAAB00  
AAAC00  
Through AAAZ00

Then,  
AABA00  
AABB00  
AABC00  
Through AABZ00

Up to  
AAZX00  
AAZY00  
AAZZ00

Finally, each of the second level divisions can be divided again up to 676 times (third level divisions) by changing the third pair of characters to letters (AA to ZZ). For example, the division labeled AAAA00 may be divided again:

AAAAAA  
AAAAAB  
AAAAAC  
Through AAAAAZ

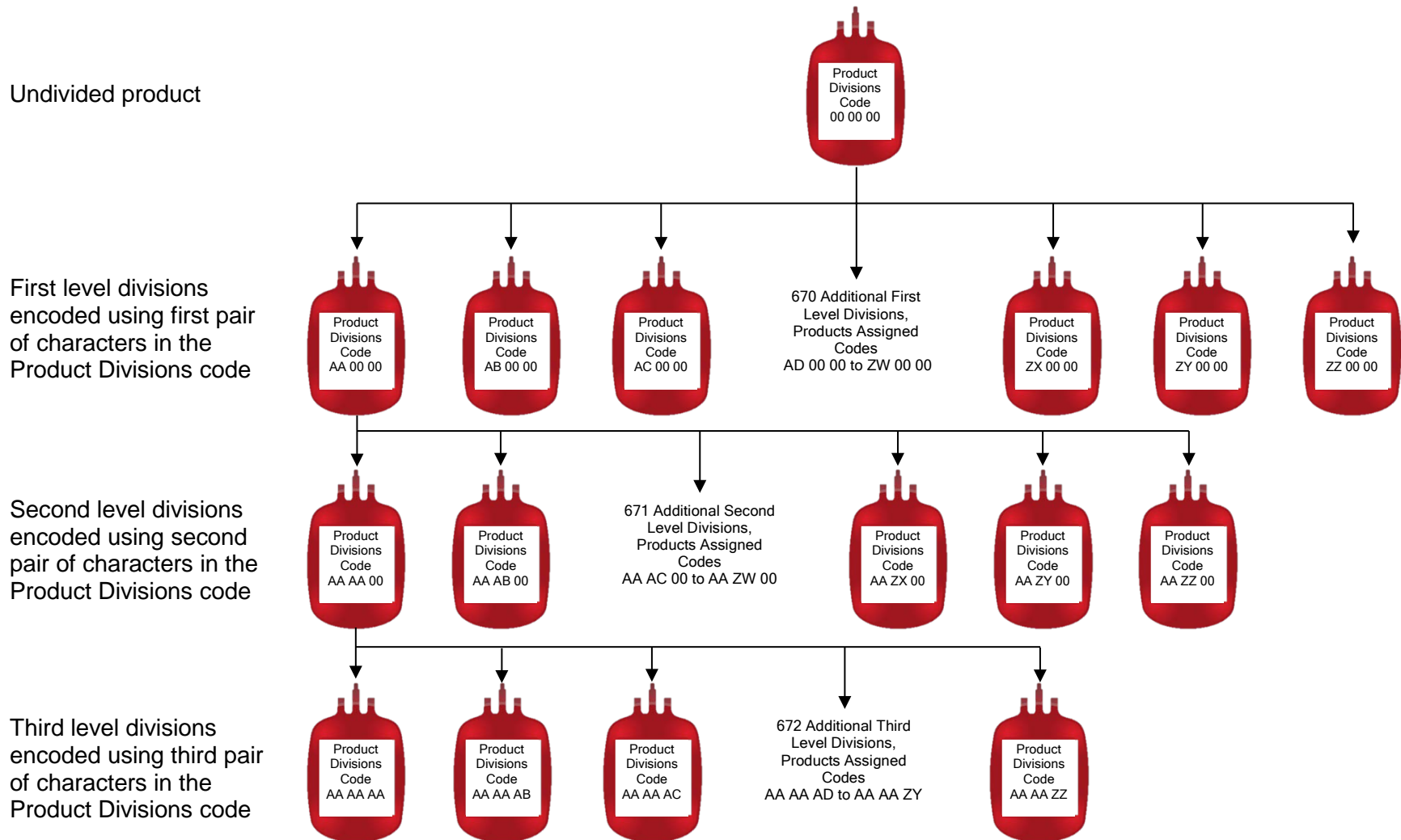
Then,  
AAAABA  
AAAABB  
AAAABC  
Through AAAABZ

Up to  
AAAAZX  
AAAAZY  
AAAAZZ

This data structure supports >300 million unique Product Division codes.



**Figure 2 Illustration of Division Codes Used with Product Divisions Data Structure**



## 3.2 Uniqueness and Traceability

### 3.2.1 Data Structures Required for Product Uniqueness

The Product Divisions Data Structure, Donation Identification Number, and Product Code together create the unique identification of the product. These identifiers are therefore required for traceability and must be recorded in all records (manual or automated) needed for traceability.

### 3.2.2 Uniqueness for a Given Product

The Product Divisions code must be unique for any given DIN and Product Description Code. That is, for the DIN A9995 18 123456 and the Product Description Code S1122 (HPC, MARROW|NS/XX/<=-150C|10% DMSO|Cryopreserved), only one Division Code AA0000 can be assigned. Systems (manual or automated) shall be designed to support this requirement for uniqueness.

### 3.2.3 Subsequent Processing of Products that Carry a Division Code

When a product labeled with a Product Divisions code is further modified, the division code must carry through to the modified product, as illustrated in Figure 3. For example:

Starting Product:

DIN: A9999 18 123789

Product Code: S1561499 (HPC, MARROW|Citrate/XX/rt|Plasma reduced, from a designated donor, with the code indicating the Product Divisions Data Structure is used)

Product Divisions code: AA0000

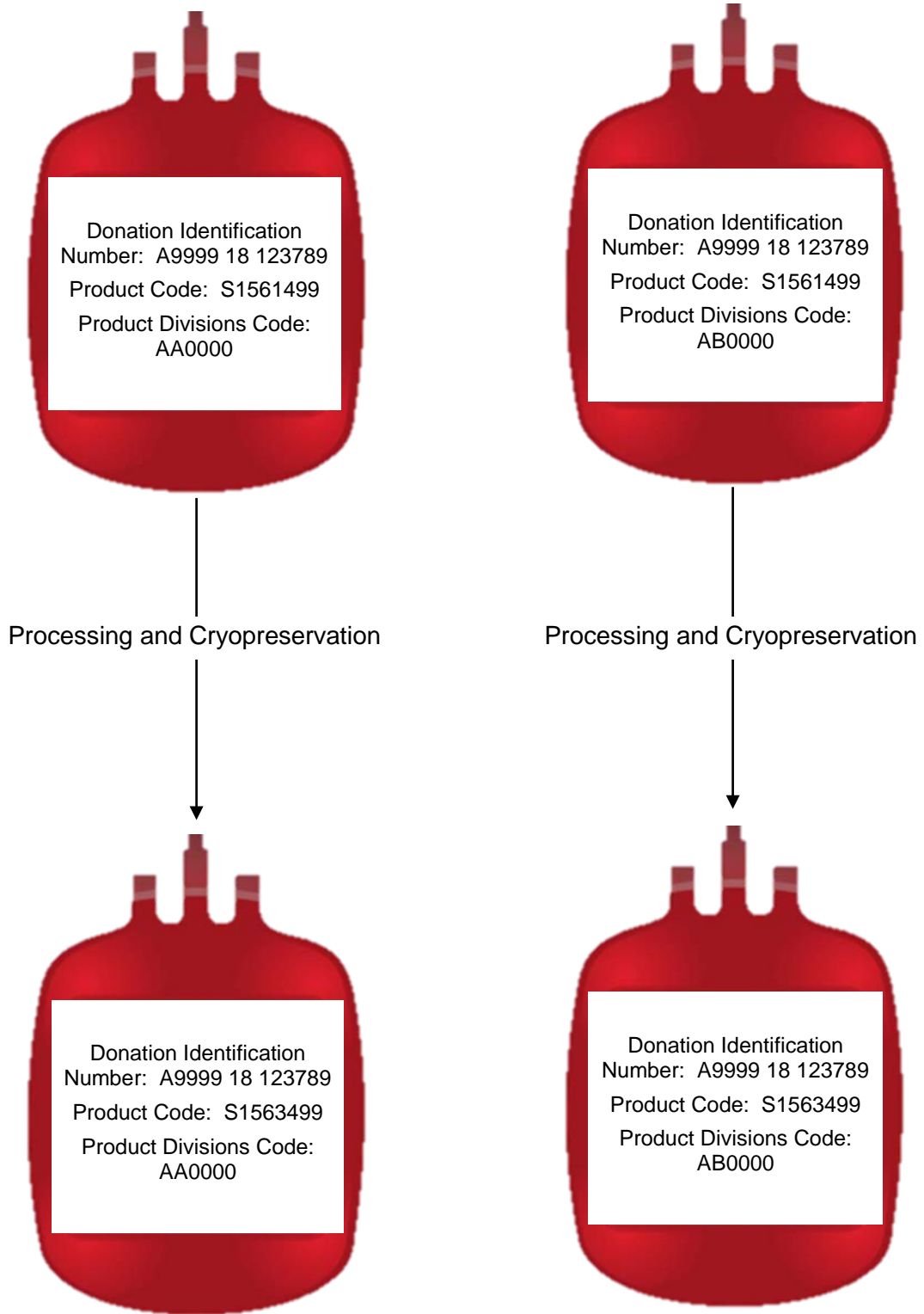
This product is subsequently modified by adding a product from a third party donor and other additives. It is then cryopreserved using 5% DMSO. The new information for the modified product would be:

DIN: A9999 18 123789

Product Code: S1563499 (HPC, MARROW|Citrate/XX/<=-150C|5% DMSO|3rd Party Comp:Yes|Other Additives:Yes|Cryopreserved)

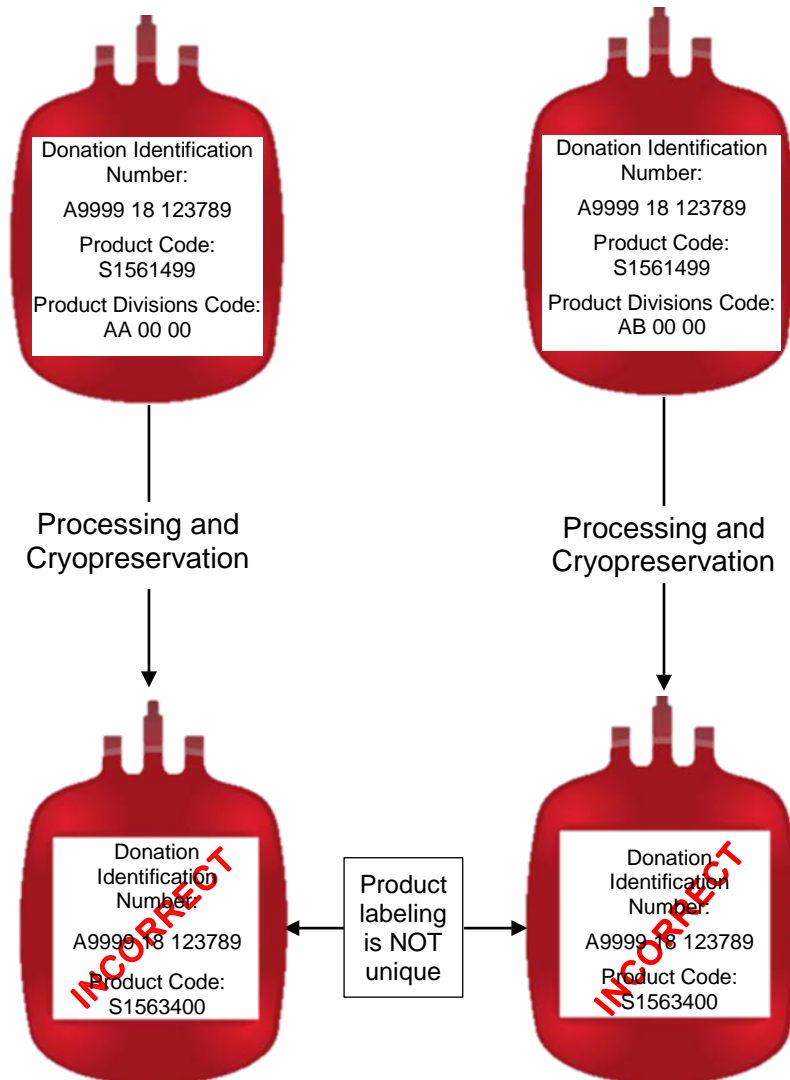
Product Divisions code: AA0000

**Figure 3 Correct Labeling of Modified Products**



If the Product Divisions code is not associated with the new, modified product (S1563), then a product from another aliquot (e.g., AC0000) could be assigned the same DIN and Product Description Code. This can be seen in Figure 4 where the products resulting from modifying aliquots AA0000 and AB0000 have the same DIN and Product Code.

**Figure 4 Incorrect Labeling of Modified Products**



### 3.3 Labels

It is recommended that this data structure be used in conjunction with a 2-D bar code to ensure that the information is encoded and scanned by the receiving facility. Information about the use of the 2-D bar code, and how data is encoded within it, may be found in the document *Implementation Guide: Use of Data Matrix Symbols with ISBT 128* (IG-014).

100 mm x 100 mm label: If linear bar codes are used, the new linear bar code would go beneath the current Product Code bar code to encourage scanning of both codes when 99 appears in Data Structure 003 (see Figure 5). Bar code height will likely need to be reduced, but should be at least 15% of the length of the bar code.

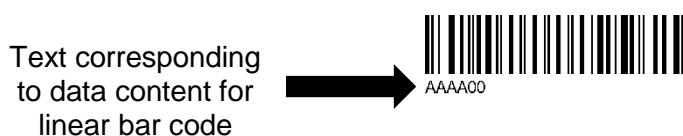
It is expected that the text on the product label (see last line of text in the lower left quadrant in Figure 5) would include only the significant characters of the Product Divisions code. That is, the label text for 00002 would be 2. Similarly, label text for the Product Divisions code ACAA00 would be ACAA. Should the division information need to be entered via a keyboard, this information can be found in small print just beneath the Product Divisions bar code (see Figure 6).

**Figure 5 100 mm x 100 mm Label**

Figure 5 illustrates a 100 mm x 100 mm label template. The label contains the following information:

- Top Left:** A large barcode with the alphanumeric string `A9999 18 123456` and a small square icon containing the letter `T`.
- Top Right:** A smaller barcode with the number `5300` below it, and a circle icon containing the text `RhD Positive`.
- Middle Left:** A barcode with the number `0180360915` below it.
- Middle Right:** The text `For Autologous Use Only`.
- Below Middle Left:** The text `Collection Date/Time` followed by `2018-02-05 09:15`.
- Below Middle Left:** The text `Do Not Irradiate` and `Do Not Use Leukoreduction Filter`.
- Bottom Left:** A barcode with the number `S1142199` below it, and another barcode with the text `AAAA00` below it. A callout arrow points to this barcode with the text `Bar Code for Product Divisions Data Structure`. Below the `AAAA00` text, a callout arrow points to it with the text `Text for Product Divisions with significant characters only (exact location on label may vary). The text may be printed with or without spaces (e.g., AA AA or AAAA).`
- Bottom Left (Text):** `HPC, APHERESIS`, `6% HES + 5% DMSO`, `Cryopreserved, Mobilized`, `Total Volume _____ mL containing approx _____ mL Citrate and _____ mL Heparin (_____ U/mL)`, `Store at -150 C or colder`, and `Division AAAA`.
- Bottom Right:** `Expiration Date/Time` followed by `2028-02-05 23:59`, `Donor/Recipient:` `LAWSON, JOHN Q.`, `Recipient ID: 1234566789`, `Date of Birth: 1990-01-03`, `Processing Laboratory Name`, `2nd Line of Name`, and `City, State, Postal Code`.

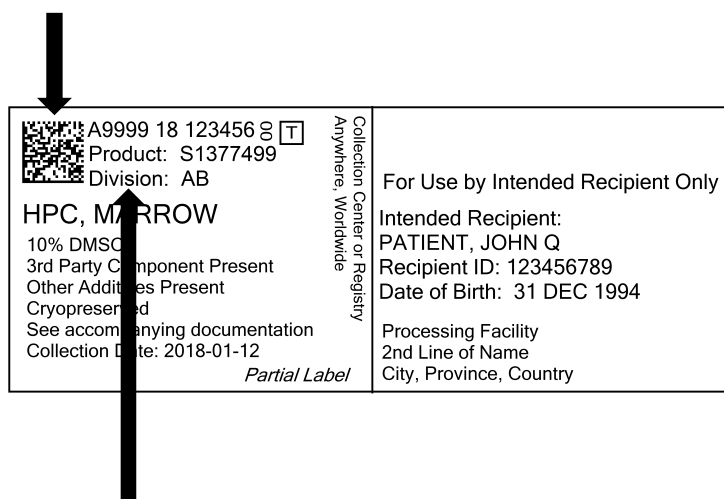
**Figure 6 Text Beneath a Linear Bar Code**



Small labels: It is likely that a 2-D bar code would be used, and thus a different label design is not needed. The information from the Product Divisions Data Structure must appear in text, along with the DIN and Product Code, because it is required for traceability.

**Figure 7 Small Product Label with 2-D Bar Code**

Product Divisions code is encoded in the 2-D bar code



Text for Product Divisions code is included with information required for traceability

In Figure 7, the text for the Product Divisions code includes only the significant characters. If the bar code cannot be scanned for some reason, then the information from Data Structure 032 may be entered using a keyboard, and zeroes will have to be entered for non-significant figures if required by the software.

## 4 Software Developers

### 4.1 Traceability

When used with Data Structure 003 for cellular therapy or regenerated tissue products, **ds** shall be set to 99 to indicate that division values are carried in Data Structure 032. Previously, the only numerical values allowed in **ds** were 00. When **ds** is set to 99, three data structures (DIN, Product Code, and Product Divisions) are required to uniquely identify the product.

While it is recommended that a 2-D symbol be used whenever the Product Divisions Data Structure is used to ensure all three data structures encoded are read, linear bar codes may be used. If linear bar codes are used, then software must be designed to require printing/reading/recording of the information in the Product Divisions [Data Structure 032] if 99 appears in **ds** within the Product Code [Data Structure 003].

Software should prevent the same Product Divisions code from being assigned to more than one product with the same DIN and Product Code. See Section 3.2.2.

If a product with a Product Divisions code is further modified, software should support assigning the Product Divisions code to the resulting products even though they may have a different Product Code. See Section 3.2.3. If the product with a Product Divisions code is further divided, new Product Divisions codes should be assigned.

### 4.2 Blood Products

At present, ICCBBA advisory committees have not approved the use of this data structure for blood because existing software does not support it. However, it would be prudent to design future software for blood products to support this data structure because a need for third level divisions has been identified. That is, users have indicated a need to support the situation in which blood products are divided first into large aliquots, then into smaller aliquots, and finally into syringe aliquots to accommodate pediatric transfusion.

### 4.3 Other Categories of Products

Because values for **tds** within the Product Code of most categories of products (tissues, ocular tissue, reproductive tissue, organs, human milk, and fecal microbiota) are numerical, 99 is a valid value, meaning the product is the 99<sup>th</sup> division. Because of this, the Product Divisions Data Structure may not be used with these categories of products.