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1 Introduction

1.1 Purpose

The purpose of this document is to provide standards for the coding of the Medical Products of Human Origin (MPHO) Unique Identifier.

1.2 Scope

This document is a supplement to the ISBT 128 Standard Technical Specification. It provides the rules for the construction of the MPHO Unique Identifier, a single data item providing globally unique instance identification and designed to optimize the electronic capture of critical MPHO traceability information.

1.3 Intended Audience

The intended audience of this document is electronic health record (EHR) developers, electronic message developers, software developers, regulators, and staff working in facilities collecting, processing, and utilizing MPHO.

1.4 Normative Reference

ISBT 128 Standard Technical Specification (ST-001)

1.5 Other Reference

ICCBBA Website (www.isbt128.org)

Reference Table RT042 – ISBT 128 Data References for use in Electronic Messages

1.6 Background

The ISBT 128 Standard requires that every MPHO labeled with ISBT 128 is identified in a globally unique manner in order to facilitate traceability. The Donation Identification Number (DIN), in conjunction with the Product Description Code (PDC), Division Identifier (DIV), and, in some specific circumstances, the Processing Facility Code [FIN(P)] are the essential data elements to uniquely identify an MPHO and provide the information necessary for traceability.

However, the unique identification of an MPHO product has previously required combining multiple identifiers to provide unique identification. For electronic messaging and electronic health record applications a single unique identifier for an instance is often required. The MPHO Unique Identifier was developed to provide a single identifier built from these critical traceability elements for use in both electronic messaging and electronic health records. The MPHO Unique identifier provides a standardized
mechanism to transmit or store traceability information about any MPHO, regardless of product type, and maintains the integrity of the unique identification by ensuring a direct mapping to the bar coded information on the label.

1.7 Changes in this Version

The following table indicates changes between Version 1.0.0 and Version 1.0.1. Bold print indicates a change to the ISBT 128 Standard; regular print indicates a clarification or additional guidance. When changes were a result of a formal proposal, the number of the proposal is listed in the Rationale column.

<table>
<thead>
<tr>
<th>Version 1.0.0 vs. Version 1.0.1</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Version 1.0.0</strong></td>
</tr>
<tr>
<td>Chapter, Section, Table, or Figure</td>
</tr>
<tr>
<td>1. 1.4 &amp; 1.5</td>
</tr>
</tbody>
</table>
2 MPHO Unique Identifier

The MPHO Unique Identifier is constructed from elements critical to the unique identification of an MPHO. The twenty-nine-character code is a combination of the Processing Facility Code (5 characters), Product Description Code (5 characters), Donation Identification Number (13 characters), and Division Identifier (6 characters). The data identifiers for each contributing element are not included in the MPHO Unique Identifier.

Figure 1  MPHO Unique Identifier Example

W9999E1234W000018123456Ab0000

Processing Facility Identification Number [FIN(P)]

Product Description Code (PDC)

Donation Identification Number (DIN)

Division Identifier (DIV)

2.1 Data elements included in the MPHO Unique Identifier:

The information held in the MPHO Unique Identifier shall match the information held in corresponding data structures on the product label. For the Division Identifier portion, leading or trailing zeroes may need to be added; see section 2.1.4 for details.

The MPHO Unique Identifier shall be constructed by combining data elements as described below.

Table 1  Source of MPHO data elements

<table>
<thead>
<tr>
<th>MPHO Unique Identifier Element</th>
<th>Length</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Processing Facility Identification Number [FIN(P)]</td>
<td>5</td>
<td>Data Structure 033 OR Data Structure 034</td>
</tr>
<tr>
<td>Product Description Code (PDC)</td>
<td>5</td>
<td>Data Structure 003 OR Data Structure 034</td>
</tr>
<tr>
<td>Donation Identification Number (DIN)</td>
<td>13</td>
<td>Data Structure 001</td>
</tr>
<tr>
<td>Division Identifier (DIV)</td>
<td>6</td>
<td>Data Structure 003 OR Data Structure 032</td>
</tr>
</tbody>
</table>
2.1.1 Processing Facility Code [FIN(P)]

FIN(P) shall be the Facility Identification Number of the facility that assigned the Product Description Code (PDC).

Characters 1-5 of the MPHO Unique Identifier shall be the Processing Facility Code (FIN(P)) if this information is encoded on the product label.

FIN(P) in the MPHO Unique Identifier shall be identical to the FIN(P) in either the Processing Facility Information Code (Data Structure 033) or the Processor Product Identification Code (Data Structure 034) on the product label.

When neither the Processing Facility Information Code nor the Processor Product Identification Code is present on the label then characters 1 to 5 of the MPHO Unique Identifier shall be set to all zeros.

See *ISBT 128 Standard Technical Specification* (ST-001) for complete details on Data Structure 033 and Data Structure 034.

2.1.2 Product Description Code (PDC)

Characters 6 through 10 of the MPHO Unique Identifier shall be the Product Description Code.

The PDC in the MPHO Unique Identifier shall be identical to the PDC held in either the Product Code (Data Structure 003) or the Processor Product Identification Code (Data Structure 034) on the product label.

See *ISBT 128 Standard Technical Specification* (ST-001) for complete details on Data Structure 003 and Data Structure 034.

2.1.3 Donation Identification Number (DIN)

Characters 11-23 of the MPHO Unique Identifier shall be the Donation Identification Number.

The MPHO Unique Identifier DIN shall be identical to the DIN element of Data Structure 001 on the product label.

See *ISBT 128 Standard Technical Specification* (ST-001) for complete details on Data Structure 001.

2.1.4 Division Identifier (DIV)

Characters 24-29 of the MPHO Unique Identifier shall be the Division Identifier.
Divisions are encoded in different ways, with different formats and lengths, across the MPHO range of products. The following rules ensure a consistent mapping between the Division Identifier in the MPHO Unique Identifier and the divisions indicated on the product label.

DIV shall be derived from either the Product Code (Data Structure 003) or the Product Divisions (Data Structure 032).

For products labeled using Data Structure 003 on the label and the two-character division information in positions ds of this data structure, DIV shall be the two characters (ds) of the Division Identifier from Data Structure 003, left justified and followed by 4 trailing zeros.

For products labeled using Data Structure 003 on the label and the three-digit division information in positions tds of this data structure, DIV shall be the three digits (tds) of the Division Identifier from Data Structure 003, right justified and preceded by 3 leading zeros.

For products labeled using Data Structure 032 on the label, DIV shall be identical to the six-character data string of this data structure.

See ISBT 128 Standard Technical Specification (ST-001) for complete details on Data Structure 003 and Data Structure 032.
END OF PUBLICATION