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## IMPLEMENTATION GUIDE

# Use of Flexible Date and Time [Data Structure 031]

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# 1 Introduction

## 1.1 Purpose

The purpose of this document is to provide guidance in the use of the Flexible Date and Time [Data Structure 031].

## 1.2 Scope

This document is a supplement to the *ISBT 128 Standard Technical Specification* (ST-001). It

- provides specific guidance for cellular therapy, ocular tissue, regenerated tissues, and organ transplantation in the use of the Flexible Date and Time [Data Structure 031];
- provides guidance on printing bar codes and text for dates on labels; and
- addresses some concerns for software developers.

## 1.3 Intended Audience

The intended audience of this document is cellular therapy, ocular tissue, regenerated tissues, and organ transplantation facility staff (collection/recovery, processing, and transplantation centers), software developers, and label vendors.

At the present time, this data structure is not intended for use with other medical products of human origin. However, it may become used for these products in the future if users request it.

## 1.4 Normative References

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

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

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

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

ISO 8601:2004(E) Data elements and interchange formats — Information interchange — Representation of dates and times (<https://www.iso.org/store.html>)

AABB Standards for Cellular Therapy Services (available from AABB at <http://www.aabb.org>)

FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing and Administration (<http://www.factwebsite.org/Standards/>)

## 1.5 Other References

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

World Clock website (<http://www.timeanddate.com/worldclock/>)

## 1.6 Background

### Time Zones:

AABB, FACT, and JACIE Standards require that the time zone be included for collection and expiration dates on the labels of cellular products that will be shipped across time zones. Additionally, the *ISBT 128 Standard Technical Specification (ST-001)* requires that date and time information appear in Coordinated Universal Time (UTC) on these products. Because of these requirements, a mechanism is needed to incorporate time zones into an ISBT 128 date and time data structure.

Calculating the local time of expiration of a product based on an expiration date applied in a different time zone can be complicated. Daylight saving/summer time occurs at different times in the Southern and Northern hemispheres. Even among countries in the same part of the world, start and end times for daylight saving/summer time can vary. Further, time zones in different parts of the world may have the same abbreviation. Therefore, encoding the time zone with only a local time abbreviation may lead to misinterpretation.

UTC does not change in winter and summer. Local time will relate variably to UTC if the facility is within a country that observes daylight saving/summer time; however, each facility will be well aware of when it goes on, and comes off, daylight saving/summer time. It can therefore utilize facility software to accurately calculate the UTC based on the local time and label its products accordingly. The receiving facility may then calculate the expiration date in local time based on the UTC, rather than another local time zone. Software may be used, or if software is not available, the World Clock converter function found at <http://www.timeanddate.com/worldclock/converter.html> may be used.

*Note: The use of the World Clock website (or any of the software or other services therein) does not imply any warranty that it currently, or always will, work correctly.*

### Types of Time:

As ISBT 128 expands into new areas, new types of time are needed. For example, in organ transplant, a cross-clamp time is needed.

To accommodate new types of time that need to be encoded, the Flexible Date and Time [Data Structure 031] can be used to convey any type of time that is defined on its reference table. Further, additional types of time can be added to the table as needed.

Some facilities may want to use the same date and time data structure for all types of date and time information. This data structure allows for this practice.

### Format of Date:

The format of the date in this data structure is different from most ISBT 128 date (or date and time) data structures in that an ordinal number of the calendar year is not used. The

ordinal number of the calendar year had been selected for other date (and time) data structures because it uses fewer characters and thus results in a shorter linear bar code, which was desirable at the time these data structures were introduced. As 2-D symbols are used more commonly, the length of the data structure will not be a concern.

It should be noted that a linear bar code with the Flexible Date and Time Data Structure will be significantly longer than bar codes for other date (and time) data structures, but should still fit within a 50 mm wide quadrant.

## **1.7 Implementation Time Line**

For cellular therapy, regenerated tissue, ocular tissue, and organs, this data structure is available for use immediately. For other categories of product, this data structure is not an option yet to allow software developers to create, and users to validate, software capable of reading and interpreting the data structure. When it becomes available to these facilities, this document will be updated.

## 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 Flexible Date and Time [Data Structure 031] 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 reference titles and website links.	To correct minor errors and reflect current information.
2.	Throughout	Throughout	Updated figures and examples.	To reflect current dates and ISBT 128 Standard requirements.
3.	1.7	1.7	Updated section text.	To reflect current wording in ST-001, Section 2.4.31, v5.10.0.
4.	4.1	4.1	Removed references to bar code text and data content text.	Terminology is no longer used in the ISBT 128 Standard.
5.	4.1	4.1	Clarified that the use of the UTC is not required, but when used, it shall follow specific requirements.	To reflect requirements in Section 7.4.4.2 of ST-001, v5.10.0.
6.	6.2	6.2	Changed “time” to “date” in reference to the date format.	Sentence is referencing the date, not the time, format (YYYYMMDD).

## 2 Flexible Date and Time [Data Structure 031]

**Purpose:** Data Structure 031 shall convey information about date and time, including the type of time (collection, recovery, production, cross clamp, etc.) and the time zone (local or UTC).

**Structure:** =(ZUTTYYYYMMDDhhmm

Element	Length	Type
=	1	data identifier, first character
(	1	data identifier, second character
Z	1	numeric {0-9}
U	1	numeric {0-9}
TT	2	numeric {0-9}
YYYY	4	numeric {0-9}
MM	2	numeric {0-9}
DD	2	numeric {0-9}
hh	2	numeric {0-9}
mm	2	numeric {0-9}

The sixteen (16)-character data content string, **ZUTTYYYYMMDDhhmm**, shall be encoded and interpreted as follows:

<b>Z</b>	Shall specify local or UTC time interpreted from Table 1
<b>U</b>	Shall be reserved for future use. The value shall be set to 0.
<b>TT</b>	Shall specify the type of time interpreted from Table 2
<b>YYYY</b>	Shall specify the year
<b>MM</b>	Shall specify the month (01-12)
<b>DD</b>	Shall specify the day (01-31)
<b>hh</b>	Shall specify the hour (00-23)
<b>mm</b>	Shall specify the minute (00-59)

This data structure would be an alternative to existing date and time data structures (Data Structures 005, 007, and 009) for cellular therapy, regenerated tissues, ocular tissue, or organ products. Facilities could select the data structure that best meets their needs.

**Table 1 Data Structure 031: Time Zone [RT045]**

<b>Value</b>	<b>Meaning</b>
1	Local time zone of facility assigning the date
2	Coordinated Universal Time (abbreviated UTC)

**Table 2 Data Structure 031: Type of Time [RT046]**

<b>Value</b>	<b>Meaning</b>
01	Expiration date and time
02	Collection date and time
03	Production date and time
04	Cross Clamp date and time
05	Time of preservation
06	Time of death of donor

## 3 Usage

This data structure should be used when:

- The time zone needs to be encoded on the product label.
- The type of time needed is not covered by other data structures.
- Optionally, whenever it is preferred. That is, the Flexible Date and Time Data Structure may be used in place of other date and time data structures for cellular therapy, regenerated tissues, ocular tissue, or organ product labels. (This may be expanded to other product categories if a Technical Advisory Group should decide this is appropriate.)

## 4 Labeling Facilities

When time zones are needed, the bar code on the label should be the Flexible Date and Time Data Structure and it should encode UTC. Both local time and UTC should appear in text.

In addition to the time being different, the date may also be different between UTC and local time. For example, a product is collected on 14 April at 07:00 Australian Eastern Standard Time (AEST) in Sydney, Australia. AEST is UTC+10 hours, so the collection date and time of this product is 13 April at 21:00 UTC.

### 4.1 Label Text

Text corresponding to the data content shall correspond to the UTC date and time since this is the information in the bar code.

Text associated with the electronically readable information in the bar code should first provide the local date and time with the time zone abbreviation. The UTC is not required; however, if included on the label, UTC date and time shall appear beneath the local time with “UTC” following it and shall be printed within parentheses to distinguish it from the local date and time, and it may be printed in italics to further differentiate it. See Figure 1.

**Figure 1 Text**



Dates shall be printed in compliance with ISO 8601-2004 extended format (YYYY-MM-DD) or in the format day — month — year. In the latter case, the day shall be numerical and the month alphabetical using a three-letter abbreviation. The year shall be a four-digit numerical representation.

*Note: Other standards-setting organizations may restrict the format in which text for time may appear. Facilities accredited by these organizations must comply with both standards.*

Times shall be printed based on a twenty-four hour clock with a colon placed between the hours and minutes.

Expiration Date and Time:

2018-03-17 11:30  
OR  
17 MAR 2018 11:30

*Note: Abbreviations for month shall comply with relevant national standards where applicable.*

## 4.2 Label Examples

The sections below discuss how information related to date and time should appear on labels. Detailed information about other elements of the label may be found in the ISBT 128 Standard Labeling documents that are listed in Section 1.4.

### 4.2.1 100 mm x 100 mm Label

On a 100 mm x 100 mm label, collection and expiration date and time bar codes shall appear in the standard quadrants (collection date and time in the upper left quadrant and expiration date and time in the lower right quadrant) regardless of which data structure is used. See Figure 2.

**Figure 2 100 mm x 100 mm Label**

 A9999 18 123456 ♂  Collection Center City, State, Postal Code	 4700  RhD Positive
 2002201803311015 Collection Date/Time 2018-03-31 12:15 CEST (2018-03-31 10:15 UTC) <i>Do Not Irradiate</i> <i>Do Not Use Leukoreduction Filter</i>	For Use by Intended Recipient Only  Related Donor: 1st or 2nd degree JOHNSON, MICHAEL A Donor ID: 987654321 Date of Birth: 1990-03-04
 S1697400  <b>HPC, MARROW</b> 3rd Party Blood Component Present Other Additives Present Mononuclear Cells Enriched See Attached Documentation  Total Volume ____ mL containing approx ____ mL Heparin (____ U/mL) Store at room temperature	 2001201804021015 Expiration Date/Time 2018-04-02 12:15 CEST (2018-04-02 10:15 UTC)  Intended Recipient: JOHNSON, JOHN Q. Recipient ID: 1234566789 Date of Birth: 1996-01-03  Processing Laboratory Name 2nd Line of Name City, State, Postal Code

## 4.2.2 Smaller Labels

On smaller labels, 2-D symbols may be needed for encoding the Flexible Date and Time Data Structure because of inadequate space for a linear bar code. In the 2-D bar code shown in Figure 3, the collection date is encoded using Data Structure 006 because time is not needed. The expiration date and time are encoded using the Flexible Date and Time Data Structure.

**Figure 3 Small Label**



## 5 Receiving Facilities

### 5.1 Time Conversion

Using the facility software, or a tool such as the World Clock (<http://www.timeanddate.com/worldclock/converter.html>), the receiving facility should calculate the critical dates and times (e.g., expiration date and time) into local time based on the UTC time.

*Note: The use of the World Clock website (or any of the APIs or other services therein) does not imply any warranty that it currently, or always will, work correctly.*

### 5.2 Over-Labeling

There may be a number of reasons a facility might want to over-label a product it receives from another facility. These include:

- modification of the product requiring a new product code label,
- receipt of a product labeled in a foreign language, or
- receipt of a product labeled with the expiration date expressed in a different local time zone.

Products will be received labeled with the UTC and local time of the collecting or processing center. If the product was shipped through a registry, the location of the shipping facility (if it was also the collecting facility) may not be on the label. Further, confusion could arise because time zone abbreviations do not always have the same meaning. For example, CST can be China Standard Time (UTC+08 hours) or Central Standard Time in North America (UTC-06 hours). Because of the potential for confusion, facilities may want to over-label with the correct local time. It should be noted that the bar code itself would be the UTC time and would not necessarily need to be changed.

Over-labeling could involve anything from the full label to only a portion of the label. Should a facility decide to over-label, it should be done with stringent controls (e.g., handling only one product at a time and manual and/or automated confirmation of the final label).

If a 2-D bar code has been used, over-labeling the bar code would require over-labeling key electronic traceability information—the DIN and Product Code. Regulations and other standards should be consulted to determine if this is allowed by pertinent authorities.

## 6 Software Developers

The bar code for this data structure is longer than those of other date and time data structures. Therefore, some adjustment of text on the label may be needed.

### 6.1 Coordinated Universal Time

Use of this data structure requires that software have the functionality to calculate UTC date and time based on local date and time and to calculate local date and time based on UTC date and time.

Software controls should be created if the application provides the functionality to over-label with the local time zone. Options should be discussed with users, including whether only text will be over-labeled or both the text and bar code(s) will be over-labeled. If bar codes are over-labeled, scanning the bar codes before and after over-labeling to confirm accuracy is recommended. With linear bar codes, it is possible to over-label only the date and time bar code(s), allowing software to confirm the new date and time against the DIN and Product Code. With 2-D bar codes, this will not be possible and procedural controls will be required.

### 6.2 Types of Time

This data structure allows different types of time (collection, expiration, production, cross clamp, etc.) to be encoded using the same time format. Unlike many ISBT 128 data structures, the date is encoded in a year, month, and day (YYYYMMDD) format. It is expected that Table 2 (Type of Time) will be expanded as users become familiar with this data structure.

Where other appropriate ISBT 128 date and time data structures exist, users have the option of using either those data structures or the Flexible Date and Time [Data Structure 031]. Software should be developed to accommodate any of the date and time data structures. All future requests to encode different types of date and time will likely be accommodated with the Flexible Date and Time Data Structure.