

Implementing ISBT 128: Guidance on Handling non-ISBT 128 Labeled Collections

The following guidance has been developed by ICCBBA and approved by the international Cellular Therapy Coding and Labeling Advisory Group (CTCLAG).

Introduction and Scope

Cell therapy accreditation bodies require that accredited facilities have in place an ISBT 128 implementation plan that will lead to the ISBT 128 labeling of all products distributed by the facility. In an ideal situation such a plan would be based on the use of ISBT 128 throughout the entire chain from donor to recipient. This will ensure the most effective traceability trail and help to minimize tracking and recall times.

However it is recognized that cellular therapy processors may be receiving some donations that are not identified using ISBT 128. Possible reasons for this are:

- a) The donation was collected under contract/formal agreement by another organization that may not currently be utilizing ISBT 128.
- b) The donation was collected and frozen before ISBT 128 labeling was required.

This guidance bulletin provides advice on implementation of ISBT 128 in such situations. An ISBT 128 implementation plan developed around the approach outlined, and taking into account local regulation, should satisfy accreditation requirements.

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 labeling of product received by the processing facility.

To ensure this, products should be re-labeled with ISBT 128 identification on receipt and records maintained to ensure traceability.

Note: 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 donation must be assigned an ISBT 128 Donation Identification Number (DIN). The processing facility must assign a DIN using its own ISBT 128 Facility Identification Number. The processor must ensure traceability records link the ISBT 128 DIN to: the original donation number used by the collection facility; the identification of that facility; and, the collection date.

The processing facility must maintain a register that maps old identifier to ISBT 128 DIN. The register must record each mapping individually and should be maintained electronically.

The table below illustrates the mapping process. Additional information (e.g., a product code or description) may also be needed for traceability.

Example traceability register

Collection facility	Collection Date	Original Donation Number	ISBT 128 DIN
XX Blood Service	2013-05-12	1272354	A9999 13 100123
YY Hospital	2013-06-16	59921	A9999 13 100124
YY Hospital	2013-06-21	59927	A9999 13 100125
XX Blood Service	2013-07-19	1272391	A9999 13 100126

Assigning the ISBT 128 identification

The mapping from the existing identification to ISBT 128 should be achieved electronically as far as 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 donation.

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

Where donations received 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 has been received frozen and will not be thawed prior to distribution, the ISBT 128 DIN and product code should be affixed to a secured outer wrapper.

Maintaining traceability records

Records of the mapping between procurement organization identifiers and ISBT 128 must be maintained at all times in a way that supports rapid bi-directional tracking for recall purposes and meets regulatory requirements.

Version Control Sheet

Version	Date Issued	Change(s)	Rationale
1.0.0	29 Aug 2013	New document	
1.1.0	17 Mar 2014	Added note stating original identifier may not be obscured.	Required by FACT/JACIE and AABB Standards