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**Date Information**

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STCL-SOP-030 JA1
RECEIVING, RECONCILIATION AND DESTRUCTION OF ISBT BARCODE LABELS

1 PURPOSE

1.1 To describe the steps for receipt of ISBT 128 unique identifiers (barcodes) from the printing company for the upcoming year.

1.2 To define the steps for destruction of unused ISBT unique identifiers at the end of the year or other appropriate reason.

1.3 To describe the process for ISBT 128 barcode label reconciliation.

1.4 To describe the procedures for ISBT 128 barcode replication if/when needed.

2 INTRODUCTION

2.1 ISBT Barcodes are ordered in bulk to ensure that enough numbers are available for the entire year. Starting in 2022, a certificate of compliance, or equivalent, will be purchased when ordering the annual supply of ISBT barcodes. The certificate of compliance is an enhancement by Computype (vendor) to their production process that will reduce the expense associated with the inspection of incoming sequentially-numbered DIN label sets. The new inspection process scans and decodes every barcode symbol on every label set and automatically compares the decoded message to our facility’s master file which allows Computype to verify, at production speeds of around 75 feet per minute, that:

2.1.1 Each decoded number is within the range of numbers and is not duplicated

2.1.2 All symbols are in the correct position on the web

2.1.3 The symbols are scannable and decoded accurately

2.1.4 There is no gap in the sequence

2.2 Upon receipt of the annual supply of labels, STCL-SOP-030 FRM3 ISBT Barcode Label Receipt Log, should be completed to reflect the first and last barcode to capture the entire batch or labels received (ordered) for the year.

2.3 Any numbers not used during the order year must be destroyed in such a way (ie. shredder bin) that they cannot be inadvertently brought back into the system. Completion of STCL-SOP-030 FRM4 ISBT Barcode Label Destruction Log will capture the barcodes that are destroyed because they were not used in within one month following the year assigned (ie. 2021 label sets can be used through January 31, 2022 before they must be destroyed). This one month overlap in time allows more time to get the annual order filled and minimizes waste of labels.

2.4 When assigning a label set, attach STCL-SOP-030 FRM2 ISBT Barcode Label Reconciliation Log so that labels can be reconciled to account for all barcodes used.
3 SCOPE AND RESPONSIBILITIES
3.1 This job aid applies to all ISBT 128 Barcode Labels received, reconciled, and destroyed by STCL personnel.
3.2 The STCL Medical Director, Quality Systems Unit (QSU), STCL Manager, and STCL Processing Laboratory personnel are responsible for ensuring the requirements of this job aid are successfully met.

4 DEFINITIONS/ACRONYMS
4.1 COC Certificate of Compliance
4.2 DIN Donor Identification Number
4.3 FIN Facility Identification Number
4.4 ISBT International Society of Blood Transfusion
4.5 N/A Not Applicable
4.6 QA Quality Assurance
4.7 QSU Quality Systems Unit
4.8 STCL Stem Cell Laboratory

5 MATERIALS
5.1 ISBT 128 Barcode Labels

6 EQUIPMENT
6.1 Shred Bin or Shredder
6.2 Locked Storage Cabinet or Office
6.3 Validated Label Replicator

7 SAFETY
7.1 N/A

8 PROCEDURE
8.1 Receipt of ISBT Barcode Labels
8.1.1 When ISBT 128 Barcode Labels are received from the printing company, STCL manager or designee will review labels manually or review Certificate of Compliance (COC) to ensure label sets are accurate, legible, none missing, etc.
8.1.1.1 The FIN assigned to the STCL is W2248
8.1.1.2 Label sets are ordered using sequential numbers
8.1.2 STCL manager or designee check in the barcodes using \textit{STCL-SOP-030 FRM3 ISBT Barcode Label Receipt Log}. 
8.1.3 After the STCL manager or representative from the QSU team signs the
log releasing the lab sets, the STCL manager attach STCL-SOP-030
FRM3 ISBT Barcode Label Receipt Log with that stock of labels.

8.1.4 Barcodes are placed stored in a designated file cabinet in the STCL
manager’s office that is locked at all times when not occupied.

8.2 Reconciliation of ISBT Barcode Labels

8.2.1 In an effort to reconcile all of the ISBT128 Label (barcodes) that are
used, please record the # of barcodes used on STCL-SOP-030 FRM2
ISBT Barcode Label Reconciliation Log.

8.2.2 Since it is not known ahead of time how many labels will be used for
various steps in the process, use tick marks to capture the # of barcodes
used at each phase in the process (ie. if 10 barcodes were used to label
processing paperwork, reflect it as follows: 111 111 in the designated
spot on the form).

8.2.3 There are two sections on the form: Processing and Thawing

8.2.4 Each label set (sheet of labels) will remain attached to the STCL-SOP-
030 FRM2 ISBT Barcode Label Reconciliation Log until the product
has been thawed for infusion (if applicable). The form along with any
remaining labels will remain in the designated lab file.

8.2.5 If there are multiple thaws, more than one STCL-SOP-030 FRM2 ISBT
Barcode Label Reconciliation Log can be initiated as long as all of the
forms are kept together and all labels are accounted for.

8.3 ISBT Barcode Label Replication

8.3.1 Validated label replicators are maintained in a secure, limited access
location (in the Receiving Room where STCL access is limited to
authorized personnel only).

8.3.2 Only designated STCL processing personnel are granted access to these
areas (printers).

8.3.3 Labels are replicated only as needed, using a verified source barcode from
the label set or primary container.

8.3.4 Only designated and authorized personnel may replicate an ISBT
barcode label to apply to associated documentation on an as needed
basis.

8.3.5 Unused replicated ISBT Barcode Labels are destroyed promptly by
shredding.

8.4 Destruction of Original ISBT Barcode Labels

8.4.1 Bulk Destruction of Previous Year’s ISBT 128 Barcode Labels

8.4.1.1 STCL manager or designated processing staff will destroy
unused ISBT Barcode Labels via shredding as reflected on
STCL-SOP-030 FRM4 ISBT Barcode Label Destruction
Log.
8.4.1.2 The STCL’s shredder bin is located in the Receiving Room with limited access to only those who have the key to open the shredder bin (i.e. STCL manager or designated STCL personnel).

8.4.2 Individual Destruction of ISBT 128 Barcode Labels

8.4.2.1 If not doing bulk destruction of labels, enter initials and date at the bottom of STCL-SOP-030 FRM2 ISBT Barcode Label Reconciliation Log for each label set.

9 RELATED DOCUMENTS/FORMS

9.1 STCL-SOP-030 Label Release

9.2 STCL-SOP-030 FRM1 ISBT Barcode Label Release Log

9.3 STCL-SOP-030 FRM2 ISBT Barcode Label Reconciliation Log

9.4 STCL-SOP-030 FRM3 ISBT Barcode Label Receipt Log

9.5 STCL-SOP-030 FRM4 ISBT Barcode Label Destruction Log

9.6 STCL-GEN-015 JA3 Disposition of Labels, Barcodes, and Ribbons

10 REFERENCES

10.1 21 CFR 211.125d, Labeling Issuance

10.2 21 CFR 1271.250, Labeling Controls

11 REVISION HISTORY

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<th>Description of Change(s)</th>
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<td>Barbara Waters-Pick</td>
<td>NEW document to comply with 21 CFR PART 1271.250 Labeling Controls and new FACT standard regarding label reconciliation</td>
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# Signature Manifest

**Document Number:** STCL-SOP-030 JA1  
**Title:** Receiving, Reconciliation, and Destruction of ISBT Barcode Labels JA1  
**Effective Date:** 31 Mar 2021  

All dates and times are in Eastern Time.

## STCL-SOP-030 JA1 Receiving, Reconciliation, and Destruction of ISBT Barcode Labels JA1

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