



STEM CELL LABORATORY (STCL)



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DOCUMENT TITLE:

Receiving, Reconciliation, and Destruction of ISBT Barcode Labels JA1

DOCUMENT NOTES:

Per STCL-CCR-529, this IC was RECALLED to change the Vault location from STCL-General to STCL-Processing so the entire series of STCL-SOP-030 documents would align in the same Vault. The original effective date of this document for Rev 01 was 31Mar2021. bj42 07Jan2022.

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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 to 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 *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 tix 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: HHH HHH* 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 (*ie. 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

Revision No.	Author	Description of Change(s)
01	Barbara Waters-Pick	NEW document to comply with 21 CFR PART 1271.250 Labeling Controls and new FACT standard regarding label reconciliation

Signature Manifest**Document Number:** STCL-SOP-030 JA1**Revision:** 01**Title:** Receiving, Reconciliation, and Destruction of ISBT Barcode Labels JA1**Effective Date:** 07 Jan 2022

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