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STCL Supply Management Procedure

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STEM CELL LABORATORY SUPPLY MANAGEMENT PROCEDURE

1 PURPOSE

1.1 To describe the steps used by trained personnel to order, receive, inspect, docurrent and store supplies used in the Stem Cell Laboratory (STCL).

2 INTRODUCTION

2.1 As part of a quality program for the production of cellular products, the STCL must ensure that supplies and services used by the laboratory consistently meet specified requirements. This is accomplished by the continuous monitoring of supplies received. This procedure defines the process for assuring and monitoring the quality of supplies, from time of receipt to time of use.

2.2 STCL personnel will document receipt of supplies to provide an accurate record of the stock on hand. This record will include stock identification, lot numbers, and expiration dates for laboratory supplies.

2.3 A current manufacturer’s package insert and/or Certificate of Analysis (COA) are reviewed upon receipt and kept on file, if applicable.

3 SCOPE AND RESPONSIBILITIES

3.1 STCL laboratory personnel are responsible for:

3.1.1 evaluating inventory and ordering necessary supplies

3.1.2 accurately documenting, inspecting, and storing supplies used in the laboratory

3.1.3 alerting the laboratory manager or designee of any discrepancies discovered during this process

3.1.4 maintaining current copies of package inserts and Certificates of Analysis (C of As) when appropriate

3.1.5 retaining outdated copies of these documents and alerting the laboratory manager or designee of new versions of these documents

3.2 Laboratory manager or designated STCL staff is responsible for:

3.2.1 Resolving discrepancies that are discovered when supplies are checked in.

3.2.2 Reviewing revised package inserts, alerting personnel of any changes that affect the use of the supply, or initiating revisions to procedures and/or training staff.

3.2.3 Facilitating the receipt of required Certificates of Analysis and ensuring that certificates are on file.

3.2.4 Making sure that these certificates and product inserts are maintained.

3.3 Quality Systems Unit (QSU) / QA Designee (STCL Manager) is responsible for:
3.3.1 Reviewing and inspecting and approving or rejecting all incoming supplies/materials.
3.3.2 Reviewing all package insert review logs.

4 DEFINITIONS/ACROYMNVS
4.1 STCL Stem Cell Laboratory
4.2 COAs Certificates of Analysis
4.3 SAP Duke Electronic Supply Purchasing Program
4.4 FDA Food and Drug Administration
4.5 N/A Not Applicable
4.6 QSU Quality Systems Unit

5 MATERIALS
5.1 Supply Ordering and Receipt Notebooks
5.2 Colored Lot Dots
5.3 Box cutter (if needed)

6 EQUIPMENT
6.1 Date gun
6.2 Computer with SAP access

7 SAFETY
7.1 Use any/all appropriate personal protective equipment when working with incoming supplies that could leak (i.e., clorox, etc.) including, but not limited to, gloves, lab coats, etc.

8 PROCEDURE
8.1 ORDERING
8.1.1 Complete a Supply Ordering Log (FRM 1) to initiate the order of a required supply. Orders should be initiated when any of the following situations occur.
8.1.1.1 Inventory suggests additional supplies will be needed.
8.1.1.2 An increase in the use of a supply is anticipated.
8.1.1.3 A new product is needed for new or existing procedures.
8.1.1.4 Product available is approaching the expiration date.
8.1.2 The ordering staff will check the ordering log daily and order supplies requested.
8.1.2.1 Requests for expedited ordering should be communicated to the ordering staff through an email request, in addition to completing the order supply form.

8.1.2.2 Items in which order information is not available should be requested through email or verbally with supporting documentation concerning the item(s).

8.1.3 Orders placed in the R/3 SAP system

8.1.3.1 Request a green ticket from the Authentic Login site allowing access to SAP.

8.1.3.2 Click on the SAP icon and select the Procurement option to log on.

8.1.3.3 Click on Purchasing to begin the supply ordering process.

8.1.3.4 From the Create Requisition screen, select a requested delivery date and enter the purchasing group information in all required fields. Indicate for Goods Receipt by typing “R” in the account assignment box.

8.1.3.5 Request a delivery date (choose 1 week from order date unless expedite is required).

8.1.3.6 Choose DHSP for “Plant”, MDC for “Purchasing Group” and 420 for “Material Group”.

8.1.3.7 Press ENTER and make sure the delivery date is within 7 days from the order date.

8.1.3.8 From the Create Purchase Requisition; Item Overview screen, enter the first item number in the Material box (if an SAP number is available), or type the item description in the Short Text box when no SAP number is available.

8.1.3.9 An SAP material number search may be initiated by clicking in the Material box, clicking on the drop down menu and following instructions for search options.

8.1.3.10 Items with a number assigned on the SAP Material Master

8.1.3.10.1 Enter the SAP item number in the Material box. Enter the quantity and press ENTER.

8.1.3.10.2 Vendor material and price are automatically referenced in the system.

8.1.3.10.3 Proceed to 8.1.3.12.

8.1.3.11 Items without a number assigned on the SAP Material Master

8.1.3.11.1 Enter material name and description in the Short Text box.
8.1.3.12 Enter the quantity and unit of measure (i.e., ea, bx, cs, etc.).

8.1.3.13 A new screen will appear requesting vendor ID, price and vendor’s material number.

8.1.3.12 A new window will open requesting the account assignment for the item.

8.1.3.12.1 In the G/L account field, type 64500 (for general lab supplies) if no number is displayed.

8.1.3.12.2 In the cost center box, enter the STCL cost code.

8.1.3.12.3 Tab over to Unloading Point and type North Pavilion 2400 Pratt Street.

8.1.3.12.4 Enter Goods Recipient’s name (the name of the ordering person).

8.1.3.12.5 If additional items are to be requested, click on Repeat Acc. Ass. ON to skip this screen.

8.1.3.13 A new Delivery Address for Item screen will open.

8.1.3.13.1 At the address prompt, type 1002026076 and press ENTER.

8.1.3.13.2 The name field will display Duke University Medical Center/Stem Cell Laboratory.

8.1.3.13.3 The street address box will display 2400 Pratt Street, Durham NC, 27705.

8.1.3.14 Click on the Repeat Address ON box. Confirm that the delivery address is to be held by clicking on the green check. Click on ADOPT to accept the data.

8.1.3.15 The program returns to the Create Purchase Requisition: Item Overview screen. Additional items any vendor may be added to the request.

8.1.3.16 Upon completion of the ordering process, click on the disk icon on the upper left hand corner of the screen to generate a purchase requisition number.

8.1.3.17 Record this number on the supply ordering form or print a copy of the requisition.

8.1.3.18 Within one day from the date the purchase requisition was generated, check R/3 SAP to ensure that a purchase order number has been assigned.

8.1.3.19 If no PO# has been assigned, contact the procurement office for assistance at 681-5900.
8.1.4 Items that are not entered into the R/3 SAP system

8.1.4.1 Office supply items ordered from Staples via the Staples corporate website (www.staples.com).
  8.1.4.1.1 No requisition number of PO# is generated.
  8.1.4.1.2 Order confirmation is received via e-mail.
  8.1.4.1.3 Print this e-mail and file with the packing slip upon receipt of the order.

8.1.4.2 Items from the Duke Tissue Culture Facility
  8.1.4.2.1 Order through the website (www.cancer.duke.edu/ccf/)
  8.1.4.2.2 Send e-mail to: ccfduke@mc.duke.edu
  8.1.4.2.3 Arrangements must be made to have items picked up (no delivery)

8.1.4.3 Items from Duke Pharmacy
  8.1.4.3.1 Orders faxed on Interdepartmental Request form to the pharmacy.
  8.1.4.3.2 Arrangements must be made to have items picked up (no delivery)

8.1.4.4 Items from VWR Storeroom
  8.1.4.4.1 Orders are faxed on VWR request fax form
  8.1.4.4.2 Need to include Cost Center number on request form

8.1.4.5 Standing orders must be submitted on pink purchase requisition forms (i.e., Immucor, Sysmex, etc.) and sent to procurement so PO# can be generated.

8.1.4.6 Items from VWR website
  8.1.4.6.1 Order items directly from the VWR website, www.vwr.com
  8.1.4.6.2 Print confirmation order and file with invoice upon receipt of goods.

8.2 RECEIPT OF SUPPLIES

NOTE: It is imperative that STCL personnel accepting delivery of packages promptly evaluate the shipment to determine if refrigeration or freezing is required. If required, these products should be handled immediately.

8.2.1 Compare the supplies received with both the order placed in the ordering notebook and the packing slip for correctness and completion of order. Initial and date the packing slip to be filed.

8.2.2 Visual Inspection

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Durham, NC
8.2.2.1 Inspect the boxes/cartons/bottles for damage, contamination or leakage, abnormal color and/or cloudiness that may compromise the contents. Ensure that all labels are intact.

8.2.2.2 If no obvious damage or contamination is seen, proceed to step 8.5.5.

8.2.2.3 If damage is apparent, notify the staff in charge of ordering or the STCL manager. Initiate an Unacceptable Supply/Product Recall Corrective Action Log.

8.2.2.4 Store the item in the quarantine supply cart in the STCL until the vendor is contacted and the problem is resolved (i.e., product replaced, credit issued, etc.).

8.2.3 Once the packing slip and items have been reconciled, the supplies should be placed in the Quarantine Cage until QSU has signed off approving usage.

8.2.3.1 Complete STCL-GEN-002 FRM2 STCL Supply Receipt Log

8.2.3.1.1 If a correct product is received, but the quantity is incomplete (i.e., part of the order is on backorder), note this in the comment section of the form.

8.2.3.1.2 Verify that the expiration date (if applicable) has not been exceeded or it is not considered too short. If NO expiration date is assigned to a product, the STCL will assign an internal expiration date that is “two (2) years from the date of receipt” of that item.

8.2.3.1.3 If the order is incorrect and resolution cannot be accomplished, refer the issue to the laboratory manager or QA designee.

8.2.3.2 If there are no problems with the order, QSU will come to the STCL at 11:00 and 15:00 each day, Monday-Friday. If items are temperature sensitive, the QSU staff will come off schedule.

8.2.3.2.1 Supplies that have NOT been released by QSU must remain in the quarantine cage and can NOT be used.

8.2.3.2.2 Once QSU has signed off and released the supplies, the items will be placed on the supply cart so they can be distributed and used throughout the laboratory.

8.2.4 Verify receipt of a package insert and/or COA (if applicable).
8.2.4.1 Package inserts will be obtained on all FDA licensed reagents. Check for the package insert.

8.2.4.2 COA will be obtained from the manufacturer on products incorporated into the final unit or on non-licensed reagents. Consult the COA List (JA1) to know if a COA should be located for the received item.

8.2.4.3 Document the received date on the certificates and/or package inserts.

8.2.4.4 Record receipt of the package insert on the Package Insert Review Log.

8.2.4.4.1 If there is no insert on file, write the date received on the insert.

8.2.4.4.2 Place a copy of it, attached to page 2 of the STCL-GEN-002 FRM4 Package Insert Review Log, in the laboratory manager’s mailbox.

8.2.4.4.3 If there is an insert on file, verify that the revision date of the new package insert is the same as the package insert on file in the logbook. If so, discard the new insert.

8.2.4.4.4 If the new insert is a new revision, write the date received on the insert and place a copy of it, attached to page 2 of the STCL-GEN-002 FRM4 Package Insert Review Log, in the laboratory manager’s mailbox.

8.2.4.4.5 When indicated, the lab manager or QSU will review the insert and initiate any appropriate procedural revisions.

8.2.4.5 Certificate of Analysis review

8.2.4.5.1 If a COA is included, check the certificate to ensure it is appropriate for the lot number of the supply being used.

8.2.4.5.2 If no COA is included and one is required, obtain the COA. Consult the COA list (JA1) for instructions to obtain the certificate.

8.2.4.5.3 Certificates will be maintained in the designated COA book.

8.2.5 Labeling chemical materials

8.2.5.1 All chemical materials must be labeled appropriately. Affixing the appropriate label to these materials will be the responsibility of the STCL Safety Deputy. (NOTE: Clorox is assigned a “one year” expiration date from the Julian date reflected on the container).
8.2.5.2 Biological materials should be handled with universal precautions.

8.2.6 Preparation for Storage
8.2.6.1 Use the date gun to label all received supplies and reagents with the received date.
8.2.6.2 For supplies monitored with colored lot dots, affix the appropriately colored lot dot to each supply or reagent.
8.2.6.3 Notify the ordering area that the ordered item(s) are ready for storage.

8.2.7 Storage
8.2.7.1 When storing reagents (and dated disposables), be sure to rotate the stock. Always use the earliest outdated supplies first; first IN, first OUT (referred to as FIFO). Follow the colored lot dot sequence of Red, Orange, Yellow, Green and Blue (ROYGB).
8.2.7.2 Store reagents as indicated by the manufacturer’s instructions, maintaining receive date and colored lot dot designation on all items.
8.2.7.3 Pay special attention to ensure that supplies that need to be refrigerated or frozen are stored as quickly as possible upon receipt.
8.2.7.4 Appropriately dispose of all outdated supplies. (NOTE: Notify the lab manager if there is a high volume of supplies being discarded due to expiration dates; since it is the responsibility of all staff to minimize waste, discarding supplies should not occur frequently).

8.3 RECALLS
8.3.1 If there is notification of a recalled item, check the supply management documentation to see if the affected items, lot #s, etc., have been ordered and/or used in the STCL.
8.3.2 Notify the lab manager (or designee), QSU, and applicable lab staff so an investigation can be initiated. A deviation will need to be submitted in MasterControl if it is determined that there is any negative impact on cellular products that may have come in direct contact with patients.
8.3.3 Complete STCL-GEN-002 FRM3 Unacceptable Supply/Product Recall Corrective Action Log.
8.3.4 Since recall notifications are generated through the hospital system as well, it may be necessary to communicate accordingly through the hospital system as per the institutional policies and procedures regarding recall of supplies, equipment, etc. See DUH Recall Procedure and/or DUH Medical Recall Policy.

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Durham, NC
8.4 QUALIFICATION of SUPPLIES

8.4.1 If critical supplies coming in contact with cellular therapy products during processing, storage, and/or administration are not the appropriate grade for intended use those supplies must undergo further qualification for the intended use.

8.4.1.1 Each new lot of the current StemSol DMSO product that is used to cryopreserve cellular therapy products is currently being sent to an outside agency (i.e., BioTools, Inc. or equivalent) for qualitative ID for DMSO and quantitative determination of the concentration of DMSO before the new lot can be implemented for use in the STCL. Sterility (14 days) of each new lot of DMSO is tested in the STCL before it is released for use.

8.4.1.2 Although culture bottles are sterile upon receipt, we internally qualify new lot #s in the STCL by testing sterility of a set of culture bottles for 14 days before we start using the new lot #.

8.4.1.3 If other critical supplies are identified in the future and not found to be of the appropriate grade, qualification testing will have to be performed.

9 RELATED FORMS/DOCUMENTS

9.1 STCL-GEN-002 FRM1 Supply Ordering Log
9.2 STCL-GEN-002 FRM2 STCL Supply Receipt Log
9.3 STCL-GEN-002 FRM3 Unacceptable Supply/Product Recall Corrective Action Log
9.4 STCL-GEN-002 FRM4 Package Insert Review Log
9.5 STCL-GEN-002 JA1 Certificates of Analysis
9.6 Purchase Requisition Form, Form DA-29A

10 REFERENCES

10.2 FDA: Code of Federal Regulations, Title 21
10.3 FACT Standards for Hematopoietic Progenitor Cell Collection, Processing and Transplantation.
10.4 SAP R/3 Procedure
## Revision History

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<tr>
<th>Revision No.</th>
<th>Author</th>
<th>Description of Change(s)</th>
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| 07           | Barbara Waters-Pick   | - Removed from Section 5.2 “Do NOT Use” labels  
- Removed from Section 5.3 “Ready for Use labels  
- Section 8.2.2.3 Removed reference of “Do NOT Use” labels.  
- Section 8.2.2.4 Removed “Store the item *in a designated quarantine area*” and replaced with “Store the item *in the quarantine supply cart in the STCL*” |


# STCL-GEN-002 STCL Supply Management Procedure

## Author

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## Manager

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