

STEM CELL LABORATORY (STCL)



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Cleaning and Decontamination of STCL by External Vendor

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STCL-SOP-054

CLEANING AND DECONTAMINATION OF STCL BY EXTERNAL VENDORS

1 PURPOSE

- 1.1 The purpose of this procedure is to describe the cleaning and decontamination of the Stem Cell Laboratory (STCL) facility, instruments, and equipment, to reduce the potential for exposure to contaminants for both products and personnel.

2 INTRODUCTION

- 2.1 To minimize the risk of contamination to those products processed in the Stem Cell Laboratory; processing will be performed in a clean, semi-sterile environment which is achieved by using aseptic technique for all product processing. To assist in obtaining the cleanest, most sanitary environment possible, daily, weekly, and monthly cleaning and decontamination procedures are performed.

3 SCOPE AND RESPONSIBILITIES

- 3.1 The STCL Medical Director, Laboratory Manager, STCL Personnel, and the Quality Systems Unit (QSU) are responsible for ensuring that the requirements of this procedure are successfully met by the cleaning company employees who are contracted to perform the high level cleaning in the Stem Cell Laboratory once per month.

4 DEFINITIONS/ACRONYMS

- 4.1 STCL: Stem Cell Laboratory
- 4.2 Clean: To rid of impurities or extraneous matter.
- 4.3 Contaminated: The presence of blood or other potentially infectious materials found on an item or surfaces.
- 4.4 Decontamination: The use of physical or chemical means to remove, inactivate or destroy blood borne pathogens on a surface or item so that they are no longer capable of transmitting infectious particles, and in order to render the surface safe for handling, use or disposal.
- 4.5 Disinfectant: A chemical that destroys vegetative (living) forms of harmful microorganisms but does not ordinarily destroy bacterial endospores (dormant bacterial spores). Generally, a disinfectant is used on an inanimate surface (e.g. work surface, floor, and instruments) and is not used on skin.
- 4.6 Other Potentially Infectious Materials (OPIM):
 - 4.6.1 Blood and body fluids
 - 4.6.2 Any unfixed tissue or organ, other than intact skin, from a human (living or dead)

5 MATERIALS

- 5.1 70% Isopropyl/Ethyl Alcohol wipes or spray (IPA)
- 5.2 Activate Bleach
- 5.3 Quaternary Detergent/Disinfectant
- 5.4 Germicidal wipes
- 5.5 Glove
- 5.6 Goggles or face shield
- 5.7 Spray bottle
- 5.8 Mop buckets (at least two)
- 5.9 Mop bucket liners
- 5.10 Clean wipes or towels (non-linting)
- 5.11 Deionized water
- 5.12 Vesphene sterile disinfectant cleaner
- 5.13 LpH sterile disinfectant cleaner
- 5.14 Simple Green cleaner
- 5.15 Mop (non-wooden) with non-linting, polyester mop head for mopping floors
- 5.16 Mop (non-wooden) with flat head for cleaning vinyl curtains
- 5.17 Isolator tool with handle
- 5.18 Synthetic (polyester or polyimide) mop covers
- 5.19 2 plastic buckets (appropriate for cleanroom use)
- 5.20 Irradiated bucket liners
- 5.21 Broom (as needed)
- 5.22 Biohazard Material Container
- 5.23 Biohazard Plastic Bags for lining the Biohazard Material Container

6 EQUIPMENT

- 6.1 HEPA Vacuum

7 SAFETY

- 7.1 Use a minimal amount of solution to avoid electrical shocks and do not allow solutions to run into electrical outlets, light switches, lab equipment, or other sensitive devices (microscopes, pressure sensors, temperature/humidity sensors, fire sprinklers, fire alarms, etc.)
- 7.2 Take care not to splash solution into the filters on the ceiling.
- 7.3 Use extreme care when cleaning around fire sprinklers and REES/BAS Monitoring System probes.

- 7.4 Be careful not to accidentally flip any electrical switches on equipment or unplug while moving, which might interrupt operations.
- 7.5 Do not clean or disrupt the inside of any incubators, refrigerators, or freezers that are in use.
- 7.6 Wear appropriate attire and personal protective equipment (e.g., gloves, goggles) as required.
- 7.7 Wear appropriate eye protection such as face shields or goggles when cleaning overhead surfaces, such as ceilings, etc.

8 PROCEDURE

8.1 General considerations

- 8.1.1 Proper gowning required for entry into the manufacturing facility.
- 8.1.2 It is unacceptable to use non-approved cleaning equipment in the manufacturing facility. Approved long handled mops are recommended for floors. Non-linting wipers should be used for soft walls, ceilings, and hard to reach surfaces. A specially designed mop may be used for vinyl curtains.
- 8.1.3 Approved materials for cleaning and sanitization of the manufacturing facility include:
 - 8.1.3.1 Sterile Wipe HS II Cleanroom wiper
 - 8.1.3.2 PolySat CleanPaks Presaturated 70% Isopropanol wipers
 - 8.1.3.3 70% Isopropyl/Ethyl Alcohol (IPA) (Refer to Table I)
 - 8.1.3.4 Activate Bleach (Refer to Table I)
 - 8.1.3.5 Lint free wipes
 - 8.1.3.6 Germicidal wipes
 - 8.1.3.7 Deionized water
 - 8.1.3.8 Vesphene II sterile disinfectant cleaner
 - 8.1.3.9 LpH sterile disinfectant cleaner
 - 8.1.3.10 Simple Green cleaner
 - 8.1.3.11 Mop (non-wooden) with non-linting polyester mop head for mopping floors
 - 8.1.3.12 Mop (non-wooded) with flat head for cleaning vinyl curtains
 - 8.1.3.13 Isolator tool with handle
 - 8.1.3.14 Synthetic (polyester or polyamide) mop covers
 - 8.1.3.15 Plastic buckets (appropriate for cleanroom use)
 - 8.1.3.16 Irradiated bucket liners
 - 8.1.3.17 Lint free cloth towels

Table I

Disinfectant	Minimum Contact Time
Activate Bleach	10 minutes
70% isopropyl alcohol wipes or 70% ethyl alcohol	10 minutes – without evaporation
Any disinfectant product, used according to the manufacturer's directions, that contains all three of the following requirements:	
1) The Environment Protection Agency (EPA) registration number	
2) The words "hospital" and "disinfectant" or "disinfect"	
3) Specific claims of the effectiveness against <i>Mycobacterium tuberculosis</i>	

8.2 The flow of cleaning must be:

8.2.1 Cleanest to dirtiest area (walls before floors and starting with nearest equipment and moving away)

8.2.2 Top to bottom (ceiling first, then walls, then equipment, floors last)

8.3 Environmental Services personnel (Duke University Medical Center) will perform the following Stem Cell Laboratory (STCL) cleaning:

8.3.1 Empty and/or remove the large biohazardous and non-biohazardous trash daily. All biohazardous materials are discarded by Environmental Services staff per Duke University Medical Center's policy "Medical and Hazardous Medical Waste Disposal".

8.3.2 Sweep and mop all the floors at least weekly or as needed with approved disinfectants.

8.3.3 Vacuum carpeted areas at least weekly.

8.4 An approved contractor will perform and document the following STCL cleaning on a monthly basis or as needed:

8.4.1 The following will be wiped down or cleaned with an approved disinfectant:

8.4.1.1 Walls (6' and down), wall mounted accessories, windows, window frames and ledges

8.4.1.2 Doors and door jams

8.4.1.3 Counters, counter tops, cabinets, casework, shelving and exterior of hoods

8.4.1.4 Panels and piping

8.4.1.5 Tables, benches, chairs and carts

8.4.1.6 Sink areas and eye wash station.

8.4.2 At least monthly the floors will be HEPA vacuumed and mopped.

8.4.3 Disinfectants will be alternated between Lph and Vesphene each cleaning.

8.4.4 All cleaning will be documented on *FRM1 STCL Laboratory Contracted Services Cleaning Checklist*.

8.4.5 Steps for cleaning STCL by contracted services (non-Duke personnel),
EXTERNAL VENDORS:

- 8.4.5.1 Prepare disinfectant. LpH and Vesphene come in sterile, pre-measured unit dose pouches. Each pouch makes 2 gallons of diluted disinfectant. Three pouches are packaged in a bag.
 - 8.4.5.1.1 Place bucket liner in bucket.
 - 8.4.5.1.2 Place mop bucket in sink.
 - 8.4.5.1.3 Remove 59.1 ml pouch of disinfectant from outer bag.
 - 8.4.5.1.4 Cut open disinfectant pouch at notch.
 - 8.4.5.1.5 Pour entire contents of pouch into mop bucket.
 - 8.4.5.1.6 Fill mop bucket with water up to 2 gallon mark.
 - 8.4.5.1.7 Gently rock the bucket, as it is filling, to mix the disinfectant.
 - 8.4.5.1.8 Repeat steps to prepare disinfectant for second bucket of disinfectant.
 - 8.4.5.1.9 Discard disinfectant pouch in waste basket.
- 8.4.5.2 Start in the cleanest areas of the lab as outlined in Diagram I.
- 8.4.5.3 Cleaning should begin in the Processing area (1), then to sections (2) Flow Cytometry Area, (3) HPC Plating, (4) File Room, (5) Microscopy Area, (6) Receiving Room, and finally (7) Freezer Room.

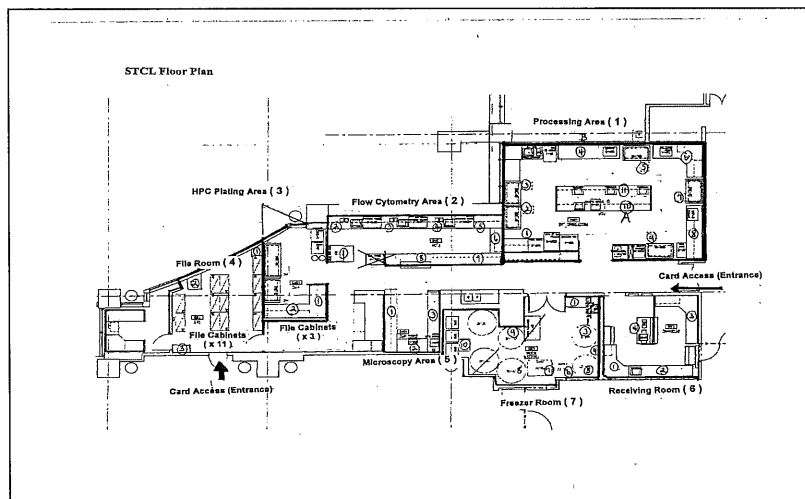


Diagram I

- 8.4.5.4 Checklist should be strictly adhered to for each section, listing dates, times and cleaning agents for each.
- 8.4.5.5 Checklist must be signed by cleaning personnel and is retained by the Stem Cell Laboratory Manager following completion.
- 8.4.5.6 Walls and doors - Clean the walls using non-linting wipers or the special flat mop. The walls may be cleaned with disinfectant solution or IPA. Cleaning will proceed from top to bottom.
- 8.4.5.7 If using non-lint wipes, inspect and refold after each pass to make sure that the wipe is not soiled and a fresh surface of the wipe is always used on a new cleaning pass.
- 8.4.5.8 The cleaning chemical should never be sprayed onto the surface that is being cleaned, rather sprayed on the wipe.
- 8.4.5.9 Wipe from top to bottom. Wiping in a circular motion will contaminate areas which have already been cleaned.
NOTE: Extra care must be taken when cleaning electrical equipment and outlets. Cleaning supplies must be very lightly dampened for cleaning. Sprayers or excess liquids must not be used on or near electrical equipment and outlets.
- 8.4.5.10 Windows - Clean the windows using non-lint wipes or the special flat mop. The walls may be cleaned with IPA or disinfectant solution followed by IPA.
- 8.4.5.11 Wipe down exteriors of the hoods with approved disinfectant then followed by 70% IPA to remove any disinfectant residue.
- 8.4.5.12 For items not covered by a particular SOP (for example, chairs, waste receptacles, etc.) wipe the entire surface with a pre-saturated IPA wiper or a non-lint wipe and disinfectant solution. Check first to insure that the material is compatible with IPA or the cleaning solution.
- 8.4.5.13 Inspect and refold wipers after each pass to make sure that the wipe is not soiled and a fresh surface of the wipe is always used on a new cleaning pass.
- 8.4.5.14 The cleaning chemical should never be sprayed onto the surface that is being cleaned, rather sprayed on the wipe.
- 8.4.5.15 Wipe from left to right or from right to left. Wiping in a circular motion will contaminate surfaces which have already been cleaned.

8.4.5.16 Mop floor with disinfectant.

8.4.5.16.1 Note: Mopping done in a clean room is very different than mopping performed by a typical janitorial service.

8.4.5.16.2 A two bucket system is used in which disinfectant solution is in both buckets. This assures that a newly cleaned area will not be re-mopped with dirty or contaminated disinfectant.

8.4.5.16.3 Start at the farthest point in the room and work towards door.

8.4.5.16.4 Wet mop in "clean" bucket and wring out excess liquid.

8.4.5.16.5 Mopping should be done using the pull and lift method. The mop is placed no more than three feet in front of the body and is pulled straight toward the body. The mop is then lifted and replaced slightly to the side, three feet in front of the body again. The strokes should overlap by at least four inches. This method, similar to the wiping technique, prevents the dirty mop surface from touching an area that has already been cleaned.

8.4.5.16.6 Rinse mop in "dirty" bucket, wring out excess liquid, then wet mop in "clean" bucket and wring out excess liquid. Repeat steps until complete.

8.4.5.16.7 The wet disinfecting solution should remain in contact with the floor for a minimum of ten minutes.

8.4.5.17 Remove all trash generated during the disinfection process, including soiled cleaning supplies after the cleaning is complete.

8.4.5.18 Document the cleaning of each section on FRM1 STCL Contracted Cleaning Services Checklist.

8.5 Allow the areas to air dry before use. All forms documenting general cleaning/disinfection will be maintained per procedure Records Management.

9 RELATED DOCUMENTS/FORMS

9.1 FRM1 STCL Contracted Cleaning Services Checklist

9.2 Records Management

10 REFERENCES

- 10.1 Duke University Medical Center Bloodborne Infectious Diseases Exposure Control Plan
- 10.2 FDA regulations: 21 CFR 1271, Human Cellular and Tissue – Based Products

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
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