### DOCUMENT NUMBER: STCL-EQUIP-016 JA1

### DOCUMENT TITLE:
LN2 Distribution System Preventive Maintenance JA1

### DOCUMENT NOTES:

<table>
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**Previous Number:** STCL-EQUIP-016 JA1 Rev 01  **Change Number:** STCL-CCR-349
STCL-EQUIP-016 JA1
LIQUID NITROGEN DISTRIBUTION SYSTEM
PREVENTIVE MAINTENANCE

1 PURPOSE

1.1 This document describes the procedure for the maintenance of the Liquid Nitrogen (LN2) Distribution System in the Stem Cell Laboratory (STCL), located on the plaza level of the North Pavilion Building at 2400 Pratt Street, Durham, North Carolina. The output from the LN2 system automatically supplies LN2 freezers used to store frozen HPC-A, HPC-M, and HPC-C products.

1.2 The LN2 Distribution System supplies LN2 from a bulk tank located in the loading dock area on the ground floor level to LN2 freezers located on the Terrace level (also known as the Lower Level or ground floor) and the Pavilion level (1st floor) of the building.

1.3 Each LN2 freezer is monitored continuously by the Rees Environmental monitoring system, which is programmed to contact laboratory personnel in the event of an alarm condition, low level of liquid nitrogen, or temperature above or below acceptable range. In addition to the automated monitoring of the units, the Thermogenesis BioArchive freezer’s LN2 level is manually monitored Monday-Friday to check the volume of LN2 in the freezer; the laboratory is not staffed on weekends and/or holidays so LN2 levels are not manually captured on those days. The Rees system measures voltage of the Thermogenesis freezer which will acknowledge an alarm condition should one occur.

1.4 An oxygen sensor is present in each room where LN2 freezers are located; STCL personnel are alerted in the event of low oxygen levels.

1.5 The level of LN2 at the bulk tank at 2400 Pratt Street (North Pavilion) is continuously monitored by the Rees system. If the LN2 level drops below the minimal level in inches, the Rees system will trigger an alarm. The level of LN2 at the bulk tank located at 2309B Pratt Street is monitored manually at least once per week.

1.6 The report of a single LN2 freezer with a low level of liquid nitrogen or an out-of-range temperature is, by itself, not necessarily an indication of a problem with the distribution system, but the possibility must be considered when investigating the individual unit.

1.7 A leak or other problem in the distribution system may manifest itself before there is any degradation of conditions within the cryogenic storage units themselves.

1.8 The LN2 distribution system is manually inspected every six months for leaks as a preventive measure. Additionally, the system will be inspected when reports are received of leaks, or when the system experiences an unexplained pressure variation, or problems with units filling as expected.
1.9 To inspect the system and make repairs as needed, the STCL contracts with Barlow Scientific, who works in collaboration with the STCL, Duke E & O Refrigeration Department (if appropriate), and Air Gas National Welders.

2 INTRODUCTION

2.1 Preventative maintenance of the LN2 Distribution System is performed in an effort to assure the reliable distribution of liquid nitrogen to LN2 freezers and to make sure that all accessible portions of the distribution system are intact and functional. For portions of the distribution system that are not accessible, inspection of areas adjacent to the piping system will be inspected for indirect signs of leakage, such as moisture damaged ceiling tiles or walls. Additionally, the system will be automatically monitored for unexplained pressure variation. In addition, inspections will be conducted upon receiving reports from users of the system or occupants of the workspaces reporting suspected leaks. Procedures for these inspections are given below.

3 SCOPE

3.1 This document applies to the procedures for the maintenance of the Liquid Nitrogen (LN2) distribution system within the Stem Cell Laboratory (STCL).

3.2 The STCL Medical Director and Laboratory Management are responsible for ensuring that the requirements of this procedure are successfully met.

4 DEFINITIONS/ACRONYMS

4.1 STCL Stem Cell Laboratory
4.2 LN2 Liquid Nitrogen
4.3 HPC-A Hematopoietic Progenitor Cells, Apheresis
4.4 HCP-M Hematopoietic Progenitor Cells, Marrow
4.5 HPC-C Hematopoietic Progenitor Cells, Cord
4.6 E&O Engineering and Operations

5 MATERIALS

5.1 REAGENTS, SPECIAL SUPPLIES

5.1.1 (None needed)

6 EQUIPMENT

6.1 Ladders
6.2 Flashlights

7 SAFETY

7.1 Protective gear (as needed) to include, by not limited to goggles, gloves, cryogenic gloves, cryogenic aprons, face shields, etc.
7.2 Hazards exist with the use of cryogenic liquids. One of the main hazards arises from overpressures that may occur if the liquid evaporates to gas. The volume ratio between the gas at room temperature and the cryogenic liquid is about 1000. As a result, unless preventive measures are taken, substantial pressures will occur with cryogenic fluids confined to small, fixed, unvented volumes. Overpressures are also possible if a blockage occurs in one of the tubes that exhaust the nitrogen. Blockages can occur in tubes at low temperature if condensates such as water vapor enter the system.

7.3 Nitrogen gas from LN2 contains no oxygen and can cause asphyxiation by diluting the air. If the oxygen concentration is below 8%, unconsciousness occurs in less than a minute. Depending on the room volume, modest quantities of cryogenic liquid can create an oxygen deficiency hazard if vaporized. Cold N2 is especially dangerous because it can settle near floor level.

7.4 Cryogenic liquids create hazards because of their low temperatures. Contact with the liquids, their vapors, and anything cooled to cryogenic temperatures can freeze living tissue; eyes are particularly vulnerable. Freezing can also cause breakage and loss of strength of materials which are not suited for cryogenic use such as most plastic or rubber.

7.5 If air condenses on a cold surface, the resulting liquid will contain a high percentage of oxygen, since it condenses at a slightly higher temperature than does nitrogen. Such liquid should be treated as liquid oxygen and not be allowed to contact combustible materials.

7.6 Cold surfaces will freeze water from the air, and over time build up ice. Ice can interfere with the operation of nearby mechanical devices (valves, relief devices, etc.) or cause shorting of electrical connections.

7.7 If other gases, particularly air, are allowed to leak into spaces containing LN2, they can condense and solidify, leading to plugged vent lines (possibly causing dangerously high pressure), plugs in other piping, interference with valve operation, erosion of valve seats and moving parts, and contamination of the LN2. Such contaminants will build up over time until they are removed by warming the system to temperatures above their boiling point.

8 PROCEDURE

8.1 For accessible areas, conduct an inspection every six months. Accessible areas are those defined as not requiring the demolition of fixed walls, floors, or ceilings, or the opening of spaces that would put at risk patients or sterile processing. An example of a non-accessible area would be a patient waiting or examination area.

8.1.1 A contractor, Barlow Scientific, will perform and document, using their controlled forms, the preventative maintenance of the LN2 piping system. Using the LN2 System Piping Diagram and starting at the bulk LN2 tank. The bulk tank, all valves, vents, and connecting piping will be visually inspected for any defects or improper operation, checking for loose fittings, signs of corrosion or damage. All valves shall be stroked and verified to operate normally.
8.1.2 Continuing with the checklist form and piping diagram, follow the system piping in the same general sequence as the flow of the system. Adjust sequence as needed for efficient use time, but all sections are to be inspected. All accessible valves, vents, and connecting piping will be visually inspected for any defects or improper operation, checking for loose fittings, signs of corrosion or damage. All valves shall be stroked and verified to operate normally.

8.1.3 For sections of the distribution system that are not accessible, check for signs of leakage, such as moisture or discoloration of adjacent building elements (floors, walls, ceilings.)

8.1.4 Note any sections or items needing repair in the work-order tracking system and notify STCL Management.

8.1.5 Any needed repairs are to be completed by qualified service personnel and documented in the work-order tracking system. In addition, notify the STCL Management as to the status of repairs.

8.1.6 Forward completed checklist to the STCL.

9 RELATED DOCUMENTS/FORMS

9.1 STCL-EQUIP-016 FRM 1 LN2 Preventative Maintenance Checklist
9.2 STCL-EQUIP-016 FRM2 LN2 Distribution Bi-Annual Checklist
9.3 STCL-EQUIP-016 JA2 LN2 System Piping Diagram for North Pavilion
9.4 STCL-EQUIP-016 Liquid Nitrogen Storage System
9.5 Thermogenesis BioArchive Freezers Daily, Bi-Weekly, Monthly Maintenance and QC Schedule.

10 REFERENCES

10.1 NA

11 REVISION HISTORY

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<td>02</td>
<td>B. Waters-Pick</td>
<td>• Updated Section 1.5 to include locations of both LN2 bulk tanks.</td>
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<td>• Updated Section 1.9 to include Duke E &amp; O Refrigeration Department <em>(if appropriate)</em>, Air Gas National Welders.</td>
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<td>• Updated Section 7.1 to include “cryogenic gloves, cryogenic aprons, face shields, etc”</td>
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### STCL-EQUIP-016 JA1 LN2 Distribution System Preventive Maintenance

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#### Manager

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<td>(MULLI026)</td>
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