

**Frederick National Laboratory
for Cancer Research**

sponsored by the National Cancer Institute

Vaccine, Immunity and Cancer Directorate
Standard Operating Procedure

SOP Title: Use and Maintenance of -20°C Freezer

Document ID: 26013

Version

3.0

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Supersedes

2.0

Effective Date: 11Aug21

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1. PURPOSE

- 1.1. The purpose of this procedure is to describe the proper use and handling of the -20°C freezer.

2. SCOPE

- 2.1. This procedure applies to all -20°C freezer.

3. REFERENCES

- 3.1. Thermo Fisher -20°C Freezer User Manual
3.2. Thermo Scientific TSX Series High-Performance -20°C Manual Defrost Freezer Manual
3.3. 10007-01: Non-Routine Equipment Maintenance Form
3.4. HSL_GL_001: Waste Disposal at the Advanced Technology Research Facility

4. RESPONSIBILITIES

- 4.1. The Research Associate, hereafter referred to as Analyst, is responsible for reviewing and following this procedure, and documenting performance of equipment maintenance.
4.2. The Scientific Manager or designee is responsible for training personnel in this procedure and reviewing associated documentation.
4.3. The Quality Assurance Specialist is responsible for quality oversight and approval of this procedure.
4.4. Trained personnel perform equipment maintenance record review per "10009: General Record Review."

5. DEFINITIONS

- 5.1. °C – Degree Centigrade
5.2. As Needed Maintenance – maintenance that is performed outside of routine maintenance but is not performed in response to equipment malfunction.
5.3. Non-routine Maintenance – maintenance that is performed in response to equipment malfunction or failure.

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- 5.4. Routine Maintenance – maintenance that is performed at planned intervals to identify and prevent problems before they result in equipment failure.

6. REAGENTS, MATERIALS, AND EQUIPMENT

- 6.1. Absorbent Pads (FNLCR Warehouse, Cat # 66401352 or equivalent)
- 6.2. Primary Disinfectant (Cavicide, FNLCR Warehouse, Cat # 79300360 or equivalent)
- 6.3. -20°C Freezer (Thermo Fisher, Model # 3752 or equivalent)
- 6.4. Wipe, Low-Lint, Wypalls (FNLCR Warehouse, Cat # 79300335 or equivalent)
- 6.5. Thermometer, National Institute of Standards and Technology (NIST) certified, Freezer (VWR, Cat # 89495-970 or equivalent)

7. HEALTH AND SAFETY CONSIDERATIONS

- 7.1. Proper safety precautions should be taken while working in a laboratory setting. This includes, but is not limited to, proper protective equipment such as lab coats, safety glasses, closed-toe shoes, and non-latex gloves.
- 7.2. Refer to the respective Safety Data Sheet (SDS) when working with any chemicals.
- 7.3. Refer to “HSL_GL_001: Waste Disposal at the Advanced Technology Research Facility” regarding waste disposal processes at the Advanced Technology Research Facility (ATRF).

8. PROCEDURE PRINCIPLES

- 8.1. Undercounter units are monitored using a NIST certified thermometer, while upright freezers are monitored by REES alarm monitor system.
- 8.2. Do not leave door open for extended periods of time.
- 8.3. When undercounter units are turned on for the first time (or after defrosting), set the control to its maximum position, and leave it for at least two hours before introducing the material to be stored. Confirm temperature has been reached via a calibrated NIST thermometer.
- 8.4. After 24 to 48 hours, adjust the temperature control, so the temperature is in range.
- 8.5. Do not use a sharp instrument, blade, or scraper to remove ice and frost from cooling surfaces due to potential damage to cooling coil.

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- 8.6. When frost accumulates to ¼ inch or greater, the operating efficiency of the freezer will be decreased. If this occurs, see 9.1 for performing Biennial Maintenance.
- 8.7. Daily temperature is recorded on business days on "26013-02: -20°C Freezer Temperature Monitor Log Form." Reset digital thermometer prior to periods when a daily temperature log is not achievable (holidays, weekends) and record temperature min and max for the missed days. Add an asterisk to the "Actual Temp" cell during holidays and weekends when the actual temperature is not recorded on the same day.

9. MAINTENANCE

9.1. Biennial Cleaning Maintenance

- 9.1.1. Empty freezer.
- 9.1.2. Turn freezer off and disconnect power cord from its outlet.
- 9.1.3. Set the temperature control to OFF position.
- 9.1.4. Line the bottom of freezer and floor immediately in front of freezer door with absorbent pads. Leave door ajar and allow the unit to thaw for at least 12 hours before starting step 9.1.5.
- 9.1.5. Spray the internal unit with Cavicide, wait at least 3 minutes and wipe with a clean low-lint wipe.
- 9.1.6. Close freezer door, reconnect power cord, and turn unit on.
- 9.1.7. Set the temperature control to its maximum position and allow freezer to equilibrate for a minimum of 2 hours.
- 9.1.8. Confirm temperature range has been achieved via NIST certified thermometer before placing material inside freezer.
- 9.1.9. Document maintenance on "26013-01: -20°C Freezer Maintenance Form."

9.2. Non-Routine Maintenance

- 9.2.1. In the case that the equipment is not operating correctly, transition processes being performed to another unit (when applicable), post a sign stating the equipment is out of service and initiate non-routine maintenance documentation per "10007: Non-Routine Equipment Maintenance."

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9.2.2. Document the nature of any failures or malfunctions, how and when it was discovered, and the personnel involved on "10007-01: Non-Routine Equipment Maintenance Form."

9.2.3. Initiate a service request and complete the non-routine maintenance process following 10007.

10. SETTINGS

10.1. Temperature Range: -10°C to -30°C

10.2. Out of Range Events

10.2.1. If the instrument maintains a temperature out of range for more than 2 hours, then transfer biological contents to another unit. Initiate non-routine maintenance per section 9.2.

10.3. REES monitoring

10.3.1. If REES temperature monitoring system used, the system will monitor freezer temperature range of -30°C to -10°C.

10.3.2. Temperature range will be monitored at: -30 °C to -10 °C.

10.3.3. Out of Range Events

10.3.3.1. If REES system or freezer unit goes into alarm, acknowledge alarm by emailing the laboratory personnel and log-in to the REES system to inhibit freezer for no more than 2 hours.

10.3.3.1.1. If freezer maintains temperature out of range for more than 2 hours, then transfer biological contents to another freezer.

10.3.3.1.1.1. Initiate non-routine maintenance per section 9.2.

11. ATTACHMENTS

11.1. Attachment 1: 26013-01: -20°C Freezer Maintenance Form

11.2. Attachment 2: 26013-02: -20°C Freezer Temperature Monitor Log Form

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12. REVISION HISTORY

Version	Change	Reason
1.0	New SOP for use and maintenance of -20°C Freezer	Currently no SOP
2.0	Remove Date column from Form .02.	Redundant
3.0	<ol style="list-style-type: none"> Moved procedure and forms to new template; forms now separate. Reformatted form HSL_EQ_016.01: <ul style="list-style-type: none"> Removed "Use and" from title Removed all columns and replaced with Equipment ID column, Biennial Maintenance section with due date, recorded by/date, Cavicide lot and expiration date, performed by/date and reviewed by/date. Added section at bottom for unscheduled maintenance (date, QE number, activity performed, recorded by/date, reviewed by/date). Reformatted form HSL_EQ_016.02: <ul style="list-style-type: none"> Added comment "thermometer reset" in comments column Minor reformatting of column width and font size Removed procedures HSL_GL_002, HSL_GL_003, HSL_GL_007, HSL_GL_008, HSL_GL_009, HSL_GL_010. Removed Definitions section. 	<ol style="list-style-type: none"> Consistency between procedures. Documenting use of freezer not required per quality requirements; maintenance documentation only. Ease of use Not referenced in body of procedure. Acronyms captured in body of procedure, or not used in procedure.

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Attachment 1: 26013-01: -20°C Freezer Maintenance Form

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Form Title: -20°C Freezer Maintenance Form			
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Equipment ID:	
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Biennial Maintenance:

Date Maintenance Due:		Cavicide Lot Number:	
		Cavicide Expiration Date:	
		Performed by/date:	
		Reviewed by/date:	

As Needed Maintenance: ☐ N/A

Date	Activity Performed	Performed by/date	Reviewed by/date
<input type="checkbox"/> N/A			
<input type="checkbox"/> N/A			

QA Reviewed by/date: _____

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Attachment 2: 26013-02: -20°C Freezer Temperature Monitor Log Form

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Form Title: -20°C Freezer Temperature Monitor Log Form			
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Month / Year		Equipment ID:			
Thermometer Serial #:		Temperature Range		-30°C to -10°C	
Day	Actual Temp (°C)	Min Temp (°C)	Max Temp (°C)	Analyst Initials	Comments
<input type="checkbox"/> N/A 1					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 2					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 3					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 4					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 5					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 6					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 7					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 8					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 9					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 10					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 11					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 12					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 13					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 14					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 15					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 16					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 17					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 18					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 19					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 20					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 21					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 22					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 23					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 24					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 25					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 26					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 27					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 28					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 29					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 30					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset
<input type="checkbox"/> N/A 31					<input type="checkbox"/> N/A <input type="checkbox"/> Thermometer reset

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Note: Add asterisk "*" to Actual Temperature cell if recording Min and Max temperature over the weekend or holiday. The asterisk indicates the actual temperature was not recorded during the indicated days, but the min and max temperature values were recorded by the thermometer during the days that the actual temperature was not recorded. Typically, this occurs during weekends and holidays.

Reviewed by/date: _____

QA Reviewed by/date: _____

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