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Standard Operating Procedure **NHX/SOP-163-001**

Title: Refrigerators and Freezers

Source: Research Triangle Institute

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TITLE: STANDARD OPERATING PROCEDURE FOR REFRIGERATORS AND FREEZERS

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Standard Operating Procedure for
Refrigerators and Freezers

NHX/SOP-163-001

1.0 INTRODUCTION

Refrigerators and freezers are used as temperature-controlled repositories for reagents and analytical samples. Temperature maintenance is critical for preserving the integrity of materials stored in these units. The proper functioning of cold storage units is thus important for the prevention of factors that might adversely affect data quality when those reagents or analytical samples are used. Calibration and maintenance activities are the responsibility of a refrigerator custodian; the name of the custodian is on record with the unit QA Officer.

2.0 INSTRUMENTATION

This SOP refers to commercially available, cabinet-style refrigerators and freezers used only for the storage of laboratory samples, reagents or specimens. Working temperatures for refrigerators cover a range of approximately 0-5°C, and for freezers a range of about -25 to -15°C. All units are explosion-proof. Temperatures are monitored either by thermometers kept in the units, or by digital thermometers using a thermocouple probe.

3.0 THERMOMETER CALIBRATION

Given the purpose of refrigerators/freezers, it is only necessary to establish the accuracy of thermometers in the -25 to +5°C range. For the precision needs of these units, calibration of thermometers can be conducted by measuring, with the refrigerator/freezer thermometer, the freezing point of water. The thermometers should be calibrated by immersing each to the immersion mark in a beaker of ice/water. The ice/water bath should

consist of at least 250 mL of a roughly equal volume of ice and water that has been allowed to equilibrate for at least 5 minutes. After standing in the bath until a constant reading is obtained, the temperature is noted and recorded. The thermometer is considered sufficiently accurate for refrigerator/freezer use if it reads 0° ± 3°C. Each refrigerator/freezer thermometer is to be calibrated in this manner at least once per year, or each time a new thermometer is designated for use with a refrigerator/freezer.

NOTE: Each refrigerator/freezer thermometer is to be affixed with an identifying tag for reference purposes.

4.0 ROUTINE TEMPERATURE CHECKS

In order to insure that the refrigerator/freezer is maintaining a constant temperature, periodic checks are to be made of thermometer readings. Such checks are to be made no less than every week. In the event that recorded temperatures are outside the acceptable range, the temperature will be verified with a different thermometer (also calibrated). If the second value confirms the first reading, all sample/reagent/specimen custodians will be notified of the problem. The staff member previously designated as responsible for the unit will restore the unit to working specifications.

5.0 ROUTINE MAINTENANCE

To maintain the refrigerators/freezers in a manner appropriate for cold storage of chemicals, reagents, or specimens, regulator inspections will be conducted at least monthly by the refrigerator custodian. Improperly stored or unlabeled items, spills, and items no longer in use will be noted and action taken to rectify any problems. Each unit is to be defrosted whenever ice accumulation in any part of the unit is excessive.

6.0 NONROUTINE MAINTENANCE

In the event of refrigerator/freezer failure or malfunction, the unit custodian is responsible for effecting appropriate repairs in order to return the unit to working specifications. The custodian will also ensure that the unit is not used until it is returned to an acceptable working state. Following any repairs, it must be demonstrated (and documented) that the unit operates at its normal temperature range. This is accomplished by monitoring refrigerator/freezer temperature twice a day for a period of at least three days.

7.0 DOCUMENTATION

A hard-bound book must be maintained for refrigerator/freezer records. All calibration activities (date of calibration, name of person performing the calibration, results of the calibration) must be recorded. For routine temperature checks, the temperature, date, and name of recorder must be entered in the logbook. Inspection and maintenance activities (date, name of maintainer, description of maintenance operations) also are to be noted in the instrument logbook. The logbook shall be kept in close proximity to the refrigerator/freezer.