



POLICY AND PROCEDURE

Title: Temperature Monitoring and Control	
Policy Number: 7.1	Version Date: 02/01/2023

TEMPERATURE MONITORING

For temperature monitoring and control, IDS utilizes VIZZIA, an electronic, continual monitoring system. VIZZIA sensors are placed in all IDS refrigerators, freezers and ambient drug storage locations. Temperature settings for each monitored storage area are indicated below. Alarms are set within the normal ranges so that IDS personnel are notified before a storage area actually goes out of range.

Storage Area/Unit	Normal Range	Alarm Settings
Ambient	15 to 25 degrees C	14 and 24 degrees C
Refrigerators	2 to 8 degrees C	3.0 and 6.5 degrees C
-20 Freezers	-15 to -25 degrees C	-16 and -23.5 degrees C
-80 Freezers	-70 to -90 degrees C	-69 and -87.5 degrees C

IDS completes a calibration process of each VIZZIA probe every year. Calibration records for each probe are maintained in Vestigo with temperature logs and are available to sponsors for review.

All refrigerators and freezers in IDS are connected to emergency power in Emory Clinic Building A, Emory University Hospital and the Hope Clinic. If a power outage occurs in one of the buildings, generators are activated and produce emergency backup power. Emory Facilities Management maintains the generators and conducts a routine system check on a monthly basis to ensure the generators are working properly.

TEMPERATURE MONITORING REPORTS

IDS maintains temperature logs in Vestigo for monitors to review during monitor visits. Logs are generated at the end of each month from the VIZZIA system, and are uploaded to Vestigo for each drug storage location. At the end of each year, a cumulative log for the year is uploaded to Vestigo, and the monthly reports are deleted.

DAILY TEMPERATURE CHECK and MANUAL BACKUP SYSTEM

IDS personnel conduct daily temperature checks in VIZZIA and also maintain a backup system using manual min/max thermometers. Each Monday morning for the previous weekend and each



Tuesday - Friday morning for the previous 24 hour period, an IDS technician reviews the digital thermometer in all refrigerators, -20 freezer and ambient drug storage areas. The technician records temperatures in Simplifi to include the current temperature and the min/max temperatures since the last check. For the -80 freezer, the technician checks the digital display on the front of each freezer and documents the readings in Simplifi. On-demand reports for the backup system can be generated from Simplifi and provided to sponsors for review if requested.

MANAGING TEMPERATURE EXCURSIONS

If an out-of-range temperature occurs, IDS personnel receive notification via email and cellphone. Once notified, IDS personnel check the unit and move investigational product to a backup refrigerator, -20 or -80 freezer, if needed, and quarantine the IP in Vestigo. Temperatures of all backup units are continually monitored. If an excursion occurs during off hours, the pharmacist on call receives a text to his/her cellphone and pager. The pharmacist will go in to assess the unit and move Investigational Product to a back-up unit if the unit is failing.

IDS personnel notify sponsors immediately if the excursion occurs during a weekday and on the next business day if the excursion occurs during evening, weekend and holiday hours. IDS also quarantines study product that is affected by the excursion in Vestigo and by separating and labeling the inventory as "Do not use." IDS awaits notification from the sponsor on whether or not the product is acceptable for use. For brief incidents where the temperature goes out of range by ≤ 1 degree C for ≤ 15 minutes, IDS will round to the nearest whole number, and the incident is not considered reportable to the sponsor.

DOCUMENTING TEMPERATURE EXCURSIONS

If the sponsor determines that the IP is acceptable for use, IDS personnel file notification from the sponsor in the protocol file and remove the IP from quarantine. If the sponsor determines that the inventory is not acceptable for use, the IP remains in quarantine and IDS personnel request replacement IP from the sponsor. Damaged IP is destroyed locally or returned to the sponsor per the sponsor's request. In addition, all correspondence between the sponsor and IDS is maintained electronically in Vestigo.

EQUIPMENT MAINTENANCE

IDS contracts with a local company, Southeast Scientific, to provide service and preventive maintenance of all refrigerators and freezers. All units are serviced and evaluated every six months.



EXCURSION PREVENTION

IDS maintains the alarm set points for each storage area within the normal ranges. If a unit is going out of range, IDS personnel will be notified before the out of range temperature occurs, so IDS personnel have time to move IP to a backup storage unit. If this occurs, and IP is moved before an out of range temperature occurs, it is not reportable as an excursion. A note to file describing the incident is uploaded to Vestigo in the Temperature Documents section.

HOPE CLINIC/ECC

Specifically for VTEU studies of the Hope Clinic, IDS notifies the principal investigator if an excursion occurs, at the time of the event. The investigator then notifies the Clinical Project Manager and Project Officer.

References:

Georgia Board of Pharmacy Rules 480-33-.05

Prior Versions: 2/24/2014, 3/24/2017, 1/30/2020, 3/02/2020, 1/30/2021, 2/1/2022