SDRN: Scottish Diabetes Research Network

Monitoring and Recording Refrigerator & Freezer Temperatures

Clinical SOP No. 31

Version 1.0

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1.0	New SOP	Louise Greig	29 June 2015

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1 Introduction

All refrigerators and freezers used for the storage of Investigational Medicinal Products (IMPs) must be temperature controlled, and continuously monitored and maintained within the appropriate ranges as defined by the protocol. ICH GCP Principle 2.13 states "Systems with procedures that assure the quality of every aspect of the trial should be implemented."

2 Objective

This SOP describes the procedures that should be followed by research staff when monitoring and recording the temperatures of products requiring cold storage, and specifies actions to be taken in the event of a temperature deviation. (Temperature monitoring ensures that products are fit for use and that the quality of the product has not been compromised.)

3 Background

It is an essential part of good practice to monitor refrigerator and freezer temperatures to ensure that each piece of equipment is functioning within its specified range. All areas used for the storage of IMPs at ambient temperature similarly require temperature monitoring with limits, usually between 15°C and 25°C or higher depending on the drug stability data.

GCP dictates that all clinical trial materials must be stored at the correct temperature. In addition, temperature monitoring of refrigerators and freezers is required in accordance with local NHS policies and national guidelines.

4 Responsibility

All research staff are responsible for making sure that refrigerated items are stored appropriately, and that each piece of equipment is working within its specified range. The research staff are accountable for verifying that refrigerator and freezer temperatures are recorded, wherever possible, on a daily basis ensuring that they are within the approved limits.

5 Procedure

- Current maximum/minimum thermometers must be monitored as a minimum at least once on a daily basis on all working days, and recorded legibly on the temperature monitoring log.
- The digital maximum/minimum thermometer -
  - Should be read from the outside of the refrigerator without opening the door.
  - Have an accuracy of at least +/- 1°C.
  - Be able to record temperatures to one decimal place.
  - Be supplied with a calibration certificate.
  - Have the calibration check on an annual basis.
- Temperature logs should be kept close to the refrigerator/freezer (but not inside) to which they relate for ease of reference, and should be clearly identified as relating to that appliance.
- A separate temperature record must be kept for each fridge/freezer. (The use of whiteboards as a method of logging results is not acceptable.)
- It is good practice to record the temperature at a similar time each day e.g., first thing in the morning before the refrigerator door is opened for the first time. This will allow review of trends in results recorded; help highlight any changes in temperatures recorded and deviation in refrigerator performance.

- Record any activity which may affect the temperatures recorded e.g., tidying, re-stocking, cleaning, defrosting at the time it takes place.
- The maximum/minimum thermometer must be reset after each reading.
- To ensure the reset has been carried out correctly, the maximum, minimum and current temperatures should be checked again and if the thermometer has been correctly reset these should all show the same (current) temperature.
- Reset the thermometer at the end of a clinic if the refrigerator door has been opened on several occasions, re-stocked, cleaned or defrosted.
- Resetting should be carried out once the current temperature reading has returned to within the recommended range.
    - The acceptable range for refrigerators is +2 to 8^{o}C.
    - The acceptable range for freezers is -15 to -23^{o}C.
- The person checking the readings should sign and date the temperature log.
- Temperatures out with the recommended range should be recorded along with any action taken to resolve the issue. (For example if defrosting has taken place this must be recorded in the comments column.)
- Temperatures noted to be out with the recommended range should be reported to the appropriate member of staff and the equipment adjusted accordingly. The equipment should then be monitored and adjusted as necessary until the temperature settles to within the stated range, or an engineer contacted.
- If readings are out of the accepted limits for an unknown reason then advice must be obtained from pharmacy regarding the stability of the medication stored within the device.
- **Do not** administer any medication stored within the device until advice has been provided.

6 Equipment

- Temperature monitoring must be carried out using a calibrated maximum/minimum digital thermometer that will allow the recording of the highest and lowest temperature over a period of time.
- For new refrigerators a calibrated digital thermometer will be provided in the form of an integral probe connected to a liquid crystal display (LCD).
- For older refrigerators without an integral thermometer connected to a LCD display, a calibrated independent maximum/minimum digital thermometer should be used. If using this type of device the probe should be positioned in the middle of the refrigerator among the investigational medicinal products (IMPs). The probe should not rest on, or be near, the refrigerator light and should not be near the door. Analogue devices are not acceptable.

Appendix 1 – Example of a Fridge/Freezer Temperature Log

Fridge/Freezer Temperature Log

Name of facility:
Year:
Month:

Day/Date	Actual temp (°C)	Min temp (°C)	Max temp (°C)	Memory clear	Comments	Initials
Mon						
Tues						
Wed						
Thurs						
Fri						
Mon						
Tues						
Wed						
Thurs						
Fri						
Mon						
Tues						
Wed						
Thurs						
Fri						
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