



NCCP TEMPLATE SOP FOR LOCAL ADAPTATION

 TEMPERATURE MONITORING

This template SOP has been developed and approved by the NCCP, considering the input of the parenteral SACT Resilience Group. The template is developed considering best practice and supported by evidence, as referenced, where available and appropriate.

Please note that these template SOPS are the minimum requirements to be used in ACU processes which should be adopted and adapted as appropriate to the local processes and documentation templates. If these minimum requirements cannot be met, the reason for this should be clearly documented locally.

|  |  |  |  |
| --- | --- | --- | --- |
| **Version** | **Date** | **Amendment** | **Approved By** |
| V1 | 30/11/2021 |  | NCCP |
| V1a | 18/10/2023 | Update to footer | NCCP  |

All comments and feedback are welcome at oncologydrugs@cancercontrol.ie

# Purpose

The purpose of this SOP is to describe the process of temperature monitoring in an aseptic compounding unit and of all systemic anticancer therapy (SACT) drugs kept in the pharmacy. Where these drugs are not stored in the ACU or pharmacy they may be included in the local hospital temperature monitoring SOP.

# Scope

The scope of this SOP describes the process that should be followed for the temperature monitoring in an ACU, including for SACT as appropriate to the storage of SACT locally.

# Definitions

|  |  |
| --- | --- |
| **ACU** | Aseptic Compounding Unit |
| **OOS**  | Out of Specification  |
| **SACT** | Systemic Anti-Cancer Therapy |

# Responsibilities

It is the responsibility of the ACU/Pharmacy manager to ensure all staff are trained in and adhere to this procedure.

It is the responsibility of all staff to comply with this procedure

It is the responsibility of all staff to notify the ACU manager/Pharmacy manager of any temperature excursions in the ACU.

# Procedure

All pharmacy fridges and ambient temperature areas should be routinely monitored to ensure that they are maintained within the specified temperature limits. Temperatures should be using a validated temperature monitoring system. All fridges and air conditioning units should be serviced and maintained as per local hospital policy.

SACT drugs requiring storage at 2-8 degrees centigrade should only be stored in a pharmaceutical fridge. Other items such as food or drink should not be stored in a fridge containing medication.

Refrigerators should not be situated near any heat source that could affect their functioning and should be appropriately ventilated. Sufficient space should be allowed in the refrigerator so that air can circulate freely. Over-packed refrigerators lead to poor air flow, potential freezing and poor stock rotation.

Thermometers/probe/loggers used to record fridge temperatures should be positioned in the middle of the fridge amongst the medicines. The probe should not rest on, or be near, the refrigerator light, the back of the fridge or placed near the door.

Thermometers/probes/loggers used to record ambient temperatures should be placed in designated locations of an ACU and not situated near any heat source.

To evaluate the correct location of thermometers/probes/loggers temperature mapping maybe considered (3).

**Applicable Temperature ranges**

Ambient/Room Temperature ACU

The accepted temperature storage range within the ACU is 15°C to 25°C

Fridge Temperature

* The accepted temperature storage range within pharmacy fridges is 2°C to 8°C

SACT Drugs

SACT drugs should be stored according to the conditions described on the label or as according to the SmPC.

The impact of temperatures outside the specified range is dependent on the temperature the medicine has been stored at and the length of time the temperature has been out of range.

**Temperature monitoring systems**

A variety of temperature monitoring systems are used in hospitals which are either paper based or automated electronic systems and record ambient or fridge temperatures via:

* Manual digital maximum/minimum thermometer
* Data Logger – an electronic device set to record temperatures at regular intervals over a period. This is then connected to a USB port on a computer and the data downloaded e.g Comark data logger
* Continuous electronic temperature monitoring system e.g. Rees, IceSpy

All temperature monitoring systems/devices should be calibrated and validated regularly as per local policy.

##  Temperature Monitoring and Record Keeping in ambient areas and ACU fridges:

* Temperature monitoring should be continuous and recorded at the start of each working day as part of the quality management system of the ACU. Please see appendix 1 for a sample temperature monitoring log.
* Temperature monitoring devices/systems should be used in accordance to their product instructions.
* A summary temperature reading report should be generated, reviewed and signed off by the ACU Manager or delegated staff member on a weekly basis. Weekly temperature reports should be filed as per local policy.

## Managing Temperature Excursions: Alarm Alerts and Action to be taken

* A temperature excursion is deemed to have occurred if the recorded temperature for a given storage location falls outside its pre-defined limits over a defined period of time as per local policy.
* It is essential that action is taken if temperatures fall outside the pre-defined limits to identify and resolve the cause prior to a temperature excursion.
* In the event of a temperature excursion, the pharmacy fridge or temperature monitoring system should issue an audible alarm and identify the affected fridge/storage area.

**Fridges**

* Establish that there is a functioning power supply and that the fridge door is closed fully.
* Consider if the excursion could have been due to stock transfer into or out of the fridge where the door may have been open in excess of the accepted time limit e.g. 60 seconds.
* Ensure the fridge is not overloaded; an overloaded fridge can obstruct the air circulation and cause a fridge to work less efficiently.
* If the points above are not the reason for the alarm alert, local technical services should be contacted immediately.

**ACU ambient areas**

* Establish that there is a functioning power supply to the air con unit
* Check if the monitoring probe is plugged in
* If the points above are not the reason for the alarm alert local technical services.
* A full temperature report should be generated to determine the extent of the temperature excursion, e.g. temperature reached, the duration of time the temperature was out of specification (OOS).
* The report should be printed and reviewed by the ACU manager or delegated member of staff to determine the extent of the temperature excursion.
* If a temperature deviation is due to a malfunctioning fridge or air conditioning unit, the fridge/storage area should be taken out of use, clearly labelled with a “NOT IN USE” sign. All stock should be removed and transferred to a functioning fridge/storage area.
* Any SACT drugs affected by the temperature excursion should be quarantined and assessed for use by contacting the manufacturer and / or utilising the local medicines information department where available.
* Once the affected fridge/ambient storage area has been repaired and brought back into use, SACT stock may be transferred back.

## 5.3 Managing Temperature Excursions out of hours:

* A local out of hours policy for temperature excursions should be in place to manage temperature excursions that occur out of hours.

**5.4 Report and Documentation:**

* A temperature excursion should be recorded as a medicine safety incident within the hospital.
* For each excursion/deviation, a root cause analysis report documenting the nature of the excursion, possible explanations and corrective action taken should be generated and filed as per local policy.

# References

1. RPS Quality Assurance of Aseptic Preparation Services: Standards Handbook, 5th Edition 2016, Parts A and B.
2. WHO Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products. Annex 9 <https://www.who.int/medicines/areas/quality_safety/quality_assurance/ModelGuidanceForStorageTransportTRS961Annex9.pdf?ua=1>
3. HPRA Guide to Control and Monitoring of Storage and Transportation Temperature Conditions for Medicinal Products and Active Substances

<https://www.hpra.ie/docs/default-source/publications-forms/guidance-documents/ia-g0011-guide-to-control-and-monitoring-of-storage-and-transportation-conditions-v2.pdf>

**Appendix 1** Sample Temperature Monitoring Log

|  |
| --- |
| **Temperature Monitoring Log** |
| Temperature area: \_\_\_\_\_\_\_\_\_\_\_\_\_ | Temperature Range:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Date  | Minimum Temperature  | Maximum Temperature  | Initials  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| Reviewed & approved by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date reviewed and approved \_\_/\_\_/\_\_\_\_\_\_  |