

NCCP TEMPLATE SOP FOR LOCAL ADAPTATION

TRAY ASSEMBLY/PREPARATION AND CHECKING PROCEDURE

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.

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| **Version** | **Date** | **Amendment** | **Approved By** |
| 1a | 20/09/2021 |  | NCCP |
| 1b | 18/10/2023 | Update to footer | NCCP  |

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

# Purpose

The purpose of this standard operating procedure (SOP) is to describe the steps involved in the assembly and preparation of a tray for compounding items in the Pharmacy Aseptic Compounding Unit (ACU).

# Scope

The scope of this SOP relates to the assembly and preparation of trays for all items to be compounded in the ACU.

# Definitions

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| **ACU** | Aseptic Compounding Unit |
| **Disinfection**  | The process of reducing the number of vegetative microorganism in or on an inanimate object by the action of an agent on their structure or metabolism to a level judged to be appropriate for a specified defined purpose. |
| **Sanitisation** | Sanitisation is the process of achieving pharmaceutically clean objects and surfaces by cleaning and disinfection processes |
| **SOP** | Standard Operating Procedure |

# Responsibilities

It is the responsibility of the relevant person in the hospital pharmacy department/ACU 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 infectious diseases or open lesions on the exposed surface of the body. The ACU manager/Pharmacy manager will decide on the fitness of the staff member to carry out activities in the preparation area or clean room and the specific protective measures that should be taken to avoid contamination of the product. If adequate protection is not possible, the person should not be allowed to be involved in preparation or compounding activities.

# Procedure

A worksheet is generated containing all the relevant information required for the product to be prepared e.g. drug name, drug dose, drug volume, reconstitution instructions, infusion solution, infusion volume. This worksheet may be paper based or form part of an electronic workflow process. There may be some additional consumables that are required for the compounding process which may not be detailed on the worksheet.

Products and materials should be protected against microbial and other contamination at preparation steps.

## Tray set up in preparation room

The corresponding generated worksheet should be placed in a sanitised tray for set up. A pre-process documentation check of the worksheet against the prescription should have been completed prior to tray assembly.

* The worksheet should be assessed for drug and consumables required for set up.
* The relevant drug required should be retrieved and placed on the tray
* Refrigerated items should only be removed from the fridge immediately prior to product preparation.
* The brand, batch number(s) and expiry date(s) of drug vials should be documented on the worksheet
* Diluents, infusion solutions, if required, should be placed on the tray with batch number(s) and expiry date(s) documented
* Consumables required for compounding should also be placed in the tray – this includes closed system transfer devices, needles, syringes, filters, caps etc.
* The worksheet should be signed and dated (may be electronic or handwritten signature) by the person setting up the tray and left to one side for a second check before it can be transferred into the cleanroom for compounding.

## Tray check

* Tray has been set up for checking in advance of compounding
* The items in the tray should be checked against the corresponding worksheet to ensure all items required have been gathered above
* This should include:
	+ Correct drug label for attachment to bag post compounding for identification
	+ Number of vials to correspond to dose and volume required
	+ Correct infusion fluid and volume e.g. NaCl 0.9% 500ml bag
	+ Correct number of diluents if applicable e.g. 10ml Water for Injection
	+ Correct number and size of consumables e.g. vial adaptors, syringes, needles, devices, bag spike, syringe caps
* The batch number and expiry of each drug, infusion bag and diluent should correspond with what has been recorded on the worksheet
* Once satisfied that the tray is complete and ready for compounding the worksheet should be signed and dated by the checker (may be electronic or handwritten signature).
* Refer to SOP103 ‘Spraying In/Tray Transfer Procedure’ for the next steps of transferring a tray into the cleanroom transfer hatch for compounding

# References

1. RPS Quality Assurance of Aseptic Preparation Services: Standards Handbook, 5th Edition 2016, Parts A and B.
2. EudraLex Volume 4. The Rules Governing Medicinal Products in the European Union EU Guidelines to Good Manufacturing Practice. Chapter 2 Personnel.
3. ASHP Guidelines on Compounding Sterile Preparations. Am J Health Syst Pharm. 2014 Jan 15;71(2):145-66
4. PIC/S PE-010-4 Guide to Good Practices for the preparation of medicinal products in Healthcare Establishments. Available at <https://picscheme.org/en/publications>

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| 1 | 10/11/2020 |  | NCCP and SACT resilence group |
| 1a | 20/09/2021 | Amended standard wording on page 1 of template  | NCCP |
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