

TEMPLATE SOP FOR LOCAL ADAPTATION

SPRAYING IN / TRAY TRANSFER

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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| 1a | 20/09/2021 |  | NCCP |
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All comments and feedback are welcome at oncologydrugs@cancercontrol.ie

# Purpose

The purpose of this procedure is to describe the transfer of products within an Aseptic Compounding Unit (ACU) in order to minimise the risk of contamination in all areas.

# Scope

The scope of this procedure outlines the process to be followed for how staff should transfer all items needed for compounding between rooms in ACU. This includes the spraying in of products as well as the transfer of trays and consumables used in the compounding process.

This procedure applies to all personnel in the ACU.

All staff should wash their hands as per ACU Handwashing SOP (Template SOP101) upon entry and exit to the ACU to minimise contamination.

# Definitions

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| **ACU** | Aseptic Compounding Unit  |
| **LAF** | Laminar Air Flow |
| **mAb** | Monoclonal Antibodies |
| **SACT** | Systemic Anti-Cancer Therapy |
| **SOP** | Standard Operating Procedure |

# 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 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

The purpose of wiping is to physically remove spores from the item as well as disinfection. Spraying allows penetration to the difficult to reach areas on surfaces.

## Transfer of items from non-sterile into the aseptic area

* Goods received from a non-sterile area into an aseptic area should be wiped down with IPA 70/30 wipes to remove any dust and bioburden. Gloves should be worn for this step.
* Storage of paper and cardboard in the preparation area should be minimised ensuring that storage requirements of products e.g. protect from light are not impacted.
* The operator should use one alcohol wipe in each hand and wipe each product in one direction only, care should only be taken with crevices or folds in packaging and place into aseptic suite hatch.
* Items are then removed from the transfer hatch and placed in appropriate storage area in the ACU.

## Procedure for transfer of items from preparation room to cleanroom

*The current practice for tray transfer is the use of 70/30 IPA and alcohol wipes as the wipe-spray disinfection technique. International evidence now recommends that a sporicidal step be introduced to this wipe-spray process. The incorporation of this step into an ACU will be dependent on local infrastructure and processes.*

* It is recommended that all operators should wear appropriate PPE while carrying out this procedure. This includes eye goggles and a FFP3 filtered safety mask. Consideration should be given to ventilation in the surrounding environment when undertaking the sporicidal step.
* All items for transfer should be gathered in the tray on the worktop at the transfer hatch.
* Once the items have been checked according to the SOP for tray preparation and checking (NCCP SOP template 104) by a trained staff member, the spraying in procedure can then proceed.
* The tray for transfer to the hatch should be cleaned with a sporicidal wipe, with a contact time of 2 minutes in the transfer hatch. The inside of the hatch should not be touched with gloved hands.
* Operators from this point on should not touch any item with a gloved hand. A fresh sporicidal wipe should be placed in each hand and the operator’s gloves should not touch any product. Using a sporicidal wipe, each product should be wiped thoroughly, taking care to wipe down all crevices or folds on product packaging. After wiping, products should sit for 2 minutes.
* Each item should be picked up by using a sporicidal wipe. Item should be sprayed thoroughly with 70/30 IPA, and care taken not to soak paper wrappers.
* After spraying, product should be placed directly into appropriate tray/hatch.
* New sporicidal wipes should be used for each tray, or earlier if needed.
* The tray should be allowed to sit for minimum of 2 minutes contact time in the hatch to allow the alcohol to evaporate.
* Once all required items have been transferred into the hatch the door should be closed to allow the cleanroom operator access to the items in hatch. Using an alcohol wipe in a gloved hand the operator should remove the tray and place onto the trolley/bench for checking in advance of compounding.

## Procedure for loading items into the isolator

* Operator should check that all items required for compounding are present on the tray. Operator should only touch the item using an alcohol wipe and should avoid touching the item with a gloved hand.
* All items should be placed on a trolley/bench and sprayed lightly with 70/30 IPA, care taken not to soak paper wrappers.
* Operator should take one alcohol wipe in each hand and wipe each product in one direction only taking care with crevices or folds in packaging and place into isolator hatch
* If there is a delay in loading the hatch door must be closed between loadings of items.
* The items should be allowed to sit in the HEPA air flow of the isolator hatch for 2 minutes before opening the inter-connecting door between the hatch and isolator cabinet. Once the outer door has closed the timer should not allow the inner hatch to open before the correct time period has elapsed.
* Once the time period has elapsed, the operator should remove the items and place inside the isolator compounding area. Items should be placed upright where possible.
* Inner hatch door should be closed.
* The operator should allow time to organised work space inside the isolator before commencing aseptic manipulations. This allows sufficient air changes to take place.

## Tray transfer procedure into LAF cabinets

* The operator should check all items required for compounding are present before commencing tray transfer procedure. The operator should not touch any item with a gloved hand.
* All items should be placed on the trolley/bench and sprayed lightly with 70/30 IPA and care taken to not soak paper wrappers.
* The operator should take one alcohol wipe in each and wipe each product, in one direction only, care taken with crevices or folds in packaging and place into LAF cabinet.
* A period of 2 minutes contact minute time should be given to allow the 70/30 IPA to evaporate before commencing aseptic manipulations.
* The operator must ensure that obstruction of the HEPA filter at the back of the cabinet is kept to a minimum. This is achieved by placing items to the right and left side of the cabinet ensuring that the area in front of the HEPA filter where the operator is working is kept clear.
* The most critical items should be placed nearer to the HEPA filter (the back), with the least critical downstream from these items.

## Validation of Tray Transfer technique

* Each staff member will be assessed for effectiveness of their Tray Transfer technique.
* This should be performed by direct observation by a trained competent member of staff. Other validation such as swabs and/or plates may be determined by local policy**.**

# References

1. Guidance for Aseptic Transfer Processes in the NHS: Addressing Sporicidal Issues 1st edition 2015. <https://www.gerpac.net/plateforme/pluginfile.php/991/mod_resource/content/1/NHS%20PQAC%20YCD%20Guidance%20for%20Aseptic%20Transfer%20-%20Sporicidal%20Disinfectants%202015%201st%20Edn%20%282%29.pdf>
2. Quality Assurance of Aseptic Preparation Services: Standards Handbook 5th Edition. Alison M. Beaney 2016
3. 3. ASHP Guidelines on Compounding Sterile Preparations. Am J Health Syst Pharm. 2014 Jan 15;71(2):145-66

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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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