



NCCP TEMPLATE SOP

HANDWASHING 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.

|  |  |  |  |
| --- | --- | --- | --- |
| **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 handwashing process to be followed for all staff entering and exiting the controlled environment in an aseptic compounding unit (ACU).

# Scope

The scope of this SOP includes the handwashing process to be followed by staff upon entry/ exit of any area where aseptic compounding or clean procedures related to aseptic compounding may occur. This may include the change rooms, the preparation rooms and the clean rooms in an aseptic compounding unit (ACU). This may also apply to other areas used to prepare products e.g. bench top preparation work of monoclonal antibodies (mAbs).

This procedure applies to all personnel entering/exiting these areas including contract cleaners, maintenance staff, external contractors and visitors.

All staff must wash their hands on entry and on exit to minimise contamination.

# Definitions

|  |  |
| --- | --- |
| **ACU** | Aseptic Compounding Unit |
| **Controlled Environment** | Clean rooms and preparation rooms that maintain grade B, C or D environmental conditions as per EU GMP. Controlled areas are supplied with HEPA filtered air to maintain environmental cleanliness to specified limits for viable and non-viable particles. |
| **GMP** | Good Manufacturing Practice |
| **mAb** | Monoclonal Antibodies |
| **SACT** | Systemic Anti-Cancer Therapy |
| **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

The aims of hand washing are to remove all transient microorganisms and to substantially reduce resident microorganisms.

* Hands must be washed well and frequently.
* An appropriate time must be spent on the task (40-60 seconds).
* An alcoholic anti-bacterial hand wash such as chlorhexidine or povidone iodine must be used.
* A no touch technique must be used including measures to protect against accidental contamination e.g. use of elbows to turn off tap.

## Preparation:

* All wristwatches should be removed, along with jewellery and cosmetics (incl. nail varnish, tinted foundation, lashes). Please note that false, gel or acrylic nails are not suitable in ACU. Natural nails must be kept short and neat.

## Washing

### Wet hands under running water.

### Apply one pump of antimicrobial hand wash into the hands.

### Rub hands together to form a lather.

### Wash hands thoroughly in the following sequence repeating each movement a minimum of 5 times:

* Rub palm to palm
* Right palm over left back of the hand and left palm over right back of the hand
* Palm to palm fingers interlaced
* Backs of the fingers to opposing palms with fingers interlocked
* Rotational rubbing of right thumb clasped in left palm.
* Rotational rubbing of the left thumb clasped in the right palm.
* Rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm.
* Rotational rubbing, backwards and forwards with clasped fingers of left hand in right palm.
* Encircle the right wrist with the left hand and rotate the left hand, clean up to the elbow.
* Encircle the left wrist with the right hand and rotate the right hand, clean up to the elbow.
* Rinse hands with water.
* Turn off the tap with your elbow.

## Drying

* Dry hands thoroughly with non-sterile minimal/non shedding paper towels and discard the paper towels in the pedal bin using foot to open.
* Ensure washed hands do not come in contact with any surface or material before being gloved.
* Optional, depending on local recommendations; Sanitise hands using an alcohol-based (IPA 70/30) solution and allow to dry prior to donning gloves.
* Put on a pair of non-sterile nitrile gloves using good gloving technique and spray with alcohol after.

## Validation of Handwashing

* Each staff member will be assessed for effectiveness of handwashing technique
* This will be performed by direct observation by trained competent member of staff. Other validation may be determined by local policy
* Cleaning validation – please refer to local Finger Dab SOP

# 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. <https://www.who.int/gpsc/5may/Hand_Hygiene_Why_How_and_When_Brochure.pdf>
4. ASHP Guidelines on Compounding Sterile Preparations. Am J Health Syst Pharm. 2014 Jan 15;71(2):145-66

|  |  |  |  |
| --- | --- | --- | --- |
| **Version** | **Date** | **Amendment** | **Approved By** |
| 1 | 10/11/2020 |  | NCCP and SACT Resilience group |
| 1a | 20/09/2021 | Amended standard wording on page 1 of template  | NCCP |
| 1b | 18/10/2023 | Updated footnote |  |
|  |  |  |  |