



NCCP TEMPLATE SOP

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

# 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. |
| **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

External visitors should be instructed in the ACU gowning procedure and the gowning process should be demonstrated to them.

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 not adequate protection is possible, the person should not be allowed to be involved in preparation or compounding activities.

# Procedure

General gowning rules should be followed prior to entering the change rooms, preparation rooms and clean rooms.

* Wrist watches, make-up and jewellery and other personal items such as mobile phones should not be allowed in clean areas
* No eating or drinking is allowed in the preparation room or clean rooms
* All street clothing and external shoed in the changing area should be removed before entering the controlled environment. Clean area scrubs consisting of clean room top and trousers and internal shoes should be donned.
* Bare feet in clogs are not permitted, socks that cover the ankles should be worn at all times (tights are acceptable)
* Gowning should follow the sequence of ‘dirtiest’ to ‘cleanest’ items
* The minimum clothing requirements for each controlled environment is described in table 1 below. These are in line with EU GMP requirements:

**Table 1: Minimum clothing requirements (EU GMP)**

|  |  |
| --- | --- |
| **Controlled Environment** | **Minimum clothing Requirements** |
| Grade B (ISO 5) | * Headgear should totally enclose hair and, where relevant, beard and moustache; it should be tucked into the neck of the suit.
* A face-mask should be worn to prevent the shedding of droplets.
* Appropriate sterilised, non-powdered rubber or plastic gloves and sterilised or disinfected footwear should be worn.
* Trouser-bottoms should be tucked inside the footwear and garment sleeves into the gloves.
* The protective clothing should shed virtually no fibres or particulate matter and retain particles shed by the body.
 |
| Grade C (ISO 7)Clean rooms | * Hair, arms, beards and moustaches should be covered.
* A single or two piece trouser suit gathered at the wrists and with a high neck
* Appropriately dedicated disinfected or sterilized shoes or overshoes should be worn. They should virtually shed virtually no fibres or particulate matter.
 |
| Grade D (ISO 8)Preparation rooms | * Hair, arms, beards and moustaches should be covered. A general protective suit and appropriately disinfected shoes or overshoes should be worn.
* Appropriate measures should be taken to avoid any contamination coming from outside the clean area.
 |

* 1. **Entering the preparation rooms (grade D, IS0 8 area)**

### The second change between prep room (grade D) and Grade B/C room should be entered and touching the door with hands should be avoided.

### There is a ‘clean’ side and ‘dirty’ side of grade D change rooms. Enter preparation room change area on ‘dirty’ side

### Wrist watches, make-up and jewellery should be removed

### A hair cover should be donned (beard cover as appropriate) ensuring that all hair is covered

### Hands should be washed as per ACU Handwashing SOP (template SOP101) and a pair of sterile or non-sterile nitrile gloves (as per local recommendation) should be put on using good gloving technique and then sprayed with alcohol before entering the change room

### Step across/over to the ‘clean’ side of preparation room change area

### The gown should be removed from the packaging, held from the inside and should be examined for any holes, tears, or other defects before donning. Do not allow item to touch the floor.

### Appropriately sized gloves should be selected ensuring that a tight, comfortable fit, should cover the cuffs of the gown with no skin visible

### The gloves should be examined for no defects, holes or tears

### Gloved hand should be sanitised with IPA 70/30 solution

### Entrance to the preparation room is now possible. The entrance to the preparation room door should be opened without using gloved hands

* 1. **Entering Clean room from Preparation room (Grade D, IS0 8 to grade C, ISO 7 and or grade B ISO 5)**

### The second change between prep room (grade D) and Grade B/C room should be entered and touching the door with hands should be avoided

### The preparation room gown should be removed and hung on the area provided in the preparation room side of the change room.

### All relevant gowning items should be selected as per local policy (e.g. gown, mobcap, mask, hood, gloves, and footwear) for entry into grade B/C room.

### The gown should be removed from the packaging, held from the inside and should be examined for any holes, tears, or other defects before donning. Do not allow item to touch the floor.

### A hair covering/mobcap should be applied over the preparation room cap ensuring all hair and ears are covered.

### A face mask should be put on ensuring the correct side is facing out. The wire at the top of the mask should be clasped to fit snugly over the bridge of nose. The upper ties of the mask should be high on the head and above the ears. The bottom set of ties should be tied at the back of the head or neck. The mask should be tied securely so the mask does not slip off.

### Appropriately sized booties/footwear should be worn and all openings closed where applicable.

### Gloves should be removed and discarded. IPA 70/30 alcohol spray should be applied to hands and a new pair of sterile gloves put on. The gloves should be examined for defects, holes, or tears. IPA 70/30 alcohol spray should be applied to the gloves and then a second pair of sterile gloves put on. The cuffs of the gloves should cover the wrists/cuffs of the suit so that no skin is exposed. The gloves should be sprayed with IPA 70/30 solution.

### The clean room may now be entered – avoid touching the door with hands.

* 1. **Exiting the cleanrooms**

### All gloves and gowns used in the preparation of aseptically prepared should be discarded in the yellow hazardous waste bin in the clean room before exiting the clean room.

### In the grade B/C change room, the gloves should be removed by slipping a finger from one hand underneath the cuff of the glove on the opposite hand.

### The outer glove should be pulled off by turning inside out as it is removed and placed in waste bin. Repeat for the other hand.

### The face mask should be removed (if wearing one) by untying ties and then placed in the waste bin.

### The cleanroom mobcap should be removed ensuring the cap underneath is not affected.

### One arm should be removed from the sleeve of the gown toward the front of the body. The other arm should be removed from the gown ensuring the front of the gown does not come in contact with hands or clothing. The gown should be placed on a designated hanger in the area provided at clean side of the grade B/C change room if to be reused. Otherwise the gown should be discarded in the waste bin provided.

### The clean room gown must be replaced at the start of each workday or more frequently if necessary e.g. tear or spill.

### The clean room shoes or shoe covers should be removed one at a time by sitting on the bench without touching the floor, and then the preparation room clogs/shoes should be put on.

### The preparation room gown may now be donned.

###  IPA 70/30 spray should be applied to the gloves and a fresh pair of gloves put on. Gloved hands should be sprayed with IPA 70/30 solution.

### The change room may now be exited into the preparation room is grade D change room.

* 1. **Exiting the preparation room/ grade D change room :**

### Upon exiting the preparation room or exiting the clean room into grade D change room the preparation room gown should be removed on the ‘clean’ side.

### Upon exiting, gloves, mask/beard cover, hair cover, and shoe covers/preparation room shoes should be removed and discarded.

### All staff must wash hands as per ‘Handwashing procedure SOP101’

# References

1. RPS Quality Assurance of Aseptic Preparation Services: Standards Handbook, 5th Edition, 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

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