

# Standard Operating Procedure

## Title: Validation of Aseptic Gowning Procedures

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### Procedure

#### 1. Introduction

- 1.1. New personnel who will be routinely entering the sterile area will attend the Sterile Training sessions conducted by the company training department with the microbiology team. When fully competent in the entry/exit procedures for the sterile area as outlined in **MICLAB 005** the operator will be validated following the procedure outlined in this SOP.
- 1.2. Revalidation should be carried out annually within 1 months of completing the sterile retraining sessions.
- 1.3. Gowning validations assessments will be carried out in the Sterile Scrub Preparation room.
- 1.4. No more than two people can be validated in any one Sterile Scrub Preparation room at the same time.

#### 2. Method of Initial Validation

- 2.1. After the sterile training session the candidate will complete a full gowning session in the Sterile Scrub Preparation room. He/she will be observed by a fully trained and validated Microbiologist and assessed according to the Checklist for Procedure for Entry into Sterile (**Form 655**). This should occur **within 1 month** of training. It is the individual's responsibility to book their own sterile gowning validation session with the Microbiology Department.
- 2.2. If the scrub and gowning procedure requirement is met according to the checklist then the validation procedure may be conducted.
- 2.3. On completion of the full gowning procedure the candidate will perform a finger dab plate. Six (6) contact plates will be used to assess the ability of the candidate to maintain the sterility of the uniform during the sterile gowning procedure.
- 2.4. The Microbiology Lab observer will conduct the monitoring wearing sterile gloves, in order to prevent any possible contamination on the outside of the plates being transferred to the person being monitored.

## Validation Record For Sterile Gowning Procedure (Ref. MICLAB 010)

<b>Participant</b>		<b>Date</b>	
<b>Position</b>		<b>Validation Attempt</b>	
<b>Team/Work Area</b>		<b>Reason for Validation</b>	<b>Please Tick</b>
<b>Reports to</b>		New Sterile Operator	
<b>Comments</b>		Annual Re-validation	
		Three Months	
		Other (Please Specify)	

<b>GOWNING PROCEDURE CHECKLIST</b>	<b>CONFORMS (Y/N) / COMMENTS</b>	
1. "Dirty" side procedures, hands and nails free of excess dirt, fresh band aids on cuts.		
2. Undergarments and hairnets, correct use.		
3. Putting on Sterile socks while crossing barrier between "dirty" and "clean" sides.		
4. Putting on slip-on safety shoes.		
5. 1st wash - hands & forearms including area between fingers. Contact time of Biocide solution <b>at least 60 sec.</b>		
6. Nailbrush scrub with Biocide solution -Top surface of nails, under fingernails rinsing procedure.		
7. Drying with sterile wipe (picked up from the top of the pile) – forearms, hands.		
8. Putting on Hood – technique, not touching external surface, hair net coverage.		
9. Putting on Face mask – technique, position.		
10. 2nd wash - hands & forearms including area between fingers. Contact time of Biocide solution <b>at least 60 sec.</b>		
11. Drying with sterile wipe (picked up from the top of the pile) - forearms, hands		
12. Putting on Overalls – uniform not touching floor, not touching external surface, covering hood flap.		
13. Putting on Overshoes – not touching external surface, foot straps and clips.		
14. Putting on Gloves – technique, not touching external surfaces with bare hands.		
15. Pulling up Overshoes – leg straps and clips.		
<b>Validated Microbiology</b>	<b>Print</b>	<b>Sign</b>