

# Standard Operating Procedure

## Title: Validation of Aseptic Gowning Procedures

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### 3. Areas of the gown to be monitored at validation

- Gloves (without the addition of Hexifoam).
- Gown sleeves (at cuff)
- Gown chest (at zipper top)
- Hood (near forehead)
- Hood (side or back)
- Gown (at top of overshoes at knee)
- Overshoes (at top of foot)

3.1. At the time of the Validation session, the Microbiology Laboratory observer will label all plates with the candidate's name, area monitored and the date.

3.2. The plates will then be brought to the Microbiology Laboratory together with Form 655 for incubation at 32°C for 48 hours. The plates will be then transferred into the 25°C for 72 hours. After the incubation the results will be read and recorded in the registrar book. The form is to be signed by the Microbiology Laboratory observer and photocopied and the copy sent to Training Dept. for filing in the Operator's Training File. The original document will be kept in the Microbiology Laboratory Validated Sterile Operators folder.

The individual should not enter the sterile area until a gowning validation has been successfully completed.

3.3. Individuals will be notified with their results and copied to their Process Manager. Successful trainee should be grant access to the sterile areas.

### 4. Method of Re-Validation

4.1. Annual re-validation is required for all validated personnel and will consist of the sterile re-training sessions followed by the aseptic gowning procedure validation. For personnel being retrained a Re-validation needs to be completed within 1 month.

4.2. The re-validation procedure is the same as the procedure outlined in Section 3

### 5. Acceptance Criteria

5.1. The acceptance criteria are less than or equal to 1 cfu per plate for finger dabs and no more than a total of 3 cfus / set of 6 contact plates or per single contact plate.

5.2. If the acceptance criteria are not met then a second validation is permitted. In this event notification will be sent to the Process Manager and the individual concerned.

### 6. Actions in the Event of a Failure

6.1. In the event of a failure the Microbiology Laboratory will inform the relevant individual concerned and their Process Manager to ensure follow up steps are appropriate. This may include counselling or re-training if deemed necessary.

6.2. The objective of the counselling session is to:

6.2.1. Highlight the results to the operator.

6.2.2. Discuss potential causes; provide advice to help prevent recurrence.

6.2.3. Outline the remedial action, which will be taken.

### 7. Remedial Actions Initial Validation (After Full Sterile Training)

7.1. In the event of a failure of the initial validation a re-validation is permitted.