CLEAN ROOM GARMENT MONITORING

1st Edition

February 2006

Clean Room Garment Monitoring

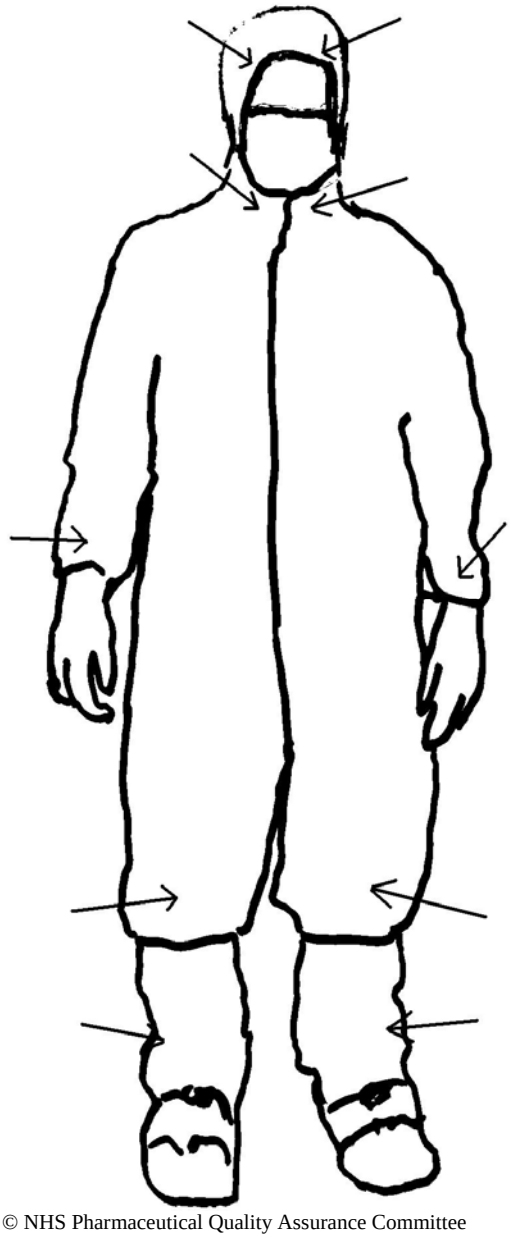
Introduction

In hospital aseptic preparation of pharmaceutical products the operator is an essential part of the production process. To minimise the risk of contaminating products with microbes and particles originating from the operators it is necessary to wear clean room garments tailored from special fabrics. In a grade B clean room with open fronted cabinets this comprises of a full sterile coverall, over boots, hood, mask and gloves.

It is not possible to validate the wearing of the garments as every change and preparation process is a unique operation with a range of variables. It is, however, possible to monitor the wearing of the garments and compare results with set limits.

Garments should be monitored using contact plates or wetted swabs and tested as indicated in appendix 1 of the 'Quality Assurance of Aseptic Preparation Services' 4th edition 2006, Editor A M Beaney.

It is not considered appropriate to monitor clean room clothing in Isolator Suites where the rooms are of a minimum Grade D standard.



Monitoring of donning process

This procedure may be used as part of staff training for entry into the Grade B room. Poor technique can result in the outside of garments becoming contaminated during the donning procedure. A laminated SOP should be available in the change detailing the change procedure. A useful guideline is given in Chapter 17 Entry and Exit of Personnel, Clean Room Technology, Fundamentals of Design, Testing and Operation W Whyte, 2001 John Wiley ISBN 0-471-86842-6. The tests are usually conducted in the white change area as soon as the operator has completed the full change procedure. Immediately after monitoring the operator exits the suite. The test areas on the clean room clothing are wiped with 70% IMS to remove residual media transferred from the contact plate. The garment is then sent to the laundry in the usual manner. Proposed action levels are 5 cfu/plate for any individual result. Ideally the outside of clean room clothing should remain sterile following donning. Test positions on the fabric are illustrated in the diagram.

Action Level

If the action level is reached an investigation should be carried out by checking the donning process and retest. If this shows no improvement the clean room garment may be checked to ensure that the contamination occurred during the donning process. Identification tests on the micro-organisms will assist in locating the source of contamination.

Test positions on donned clean room garments

Tests to be carried out on the right hand side and left hand side. Front hood, collar cuff, wrist, leg and boot

Monitoring of worn garments

The outside of clean room garments can become contaminated whilst working in the clean room. It is important that levels of microbial contamination remain very low, ideally zero, in order that manipulation of products within the laminar flow cabinet is not compromised.

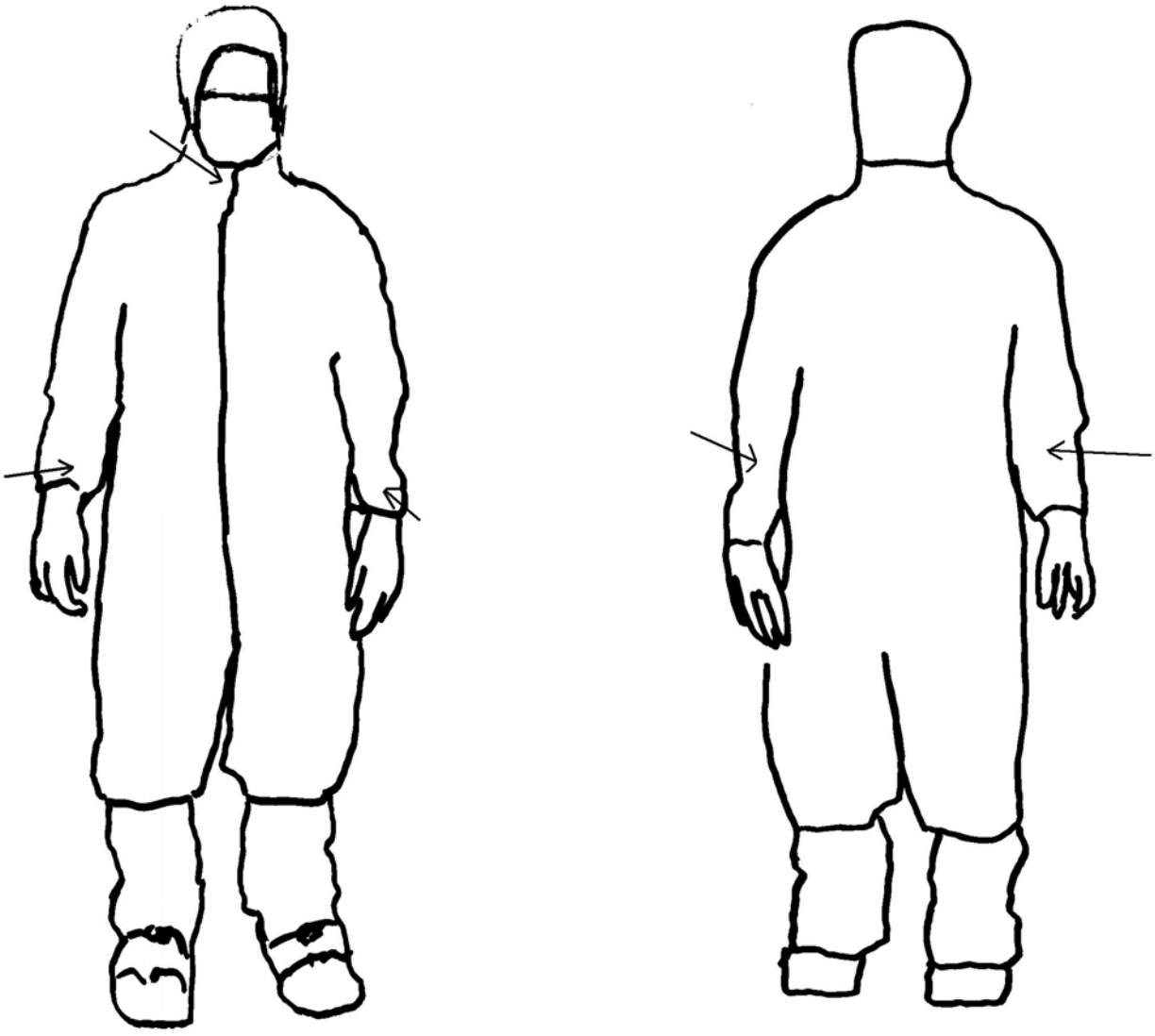
Guidance on good practice is given in Chapter 16 Clean room Disciplines, Clean Room Technology, Fundamentals of Design, Testing and Operation. W Whyte, 2001 John Wiley ISBN 0-471-86842-6. The tests are usually conducted in the white change room on the way out and the operator exits the suite immediately afterwards. The test areas on the clothing are wiped with 70% IMS before the garment is sent to the laundry. Proposed action levels are 10 cfu/plate for any individual result and a warning level of 5 cfu/plate for any individual result.

Action Level

If the action level is reached the donning process and clean room discipline should be investigated.

Test positions on exiting the clean room

Front neck, right and left cuff . Rear right and left arm



Frequency of testing

Different members of staff should be tested on a rota. Each Grade B clean room within the aseptic suite should be tested every 6 months.

Prepared by John Rhodes for the Microbiology Protocols Group, a working group of the NHS Pharmaceutical Quality Assurance Committee.
October 2005

Members of the Microbiological Protocols Group.
Trevor Munton
Phil Hunt
John Rhodes
Alison Webber