From Standards to Practice: Sterile Respirator Hoods

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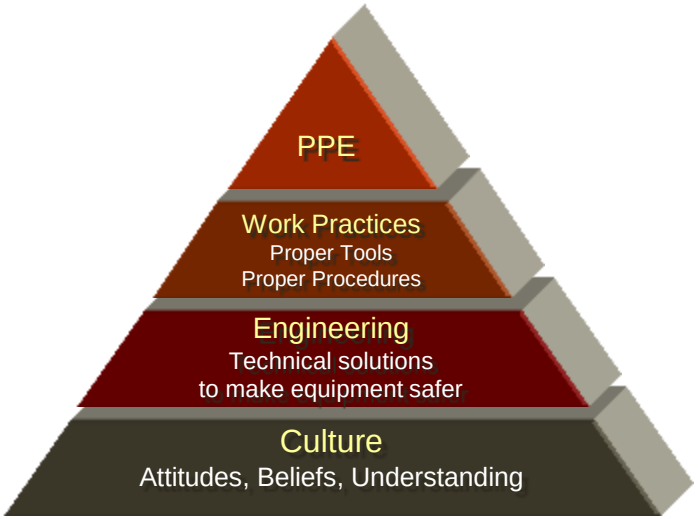
Background

Looking for an answer:

- Regulation
- Standards & Recommended Practices
- Pending & Changing Standards
- Sterile Respirators (Greg)
- Wrapping Up

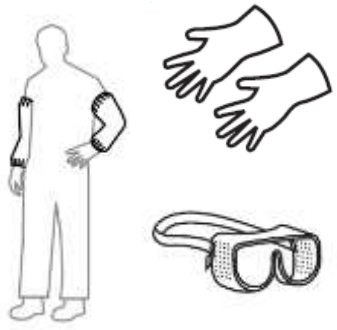


US FDA cGMP Requirements

Title 21: Food and Drugs
PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS
Subpart B—Organization and Personnel

- **§211.28 Personnel responsibilities.**
- (a) Personnel engaged in the manufacture, processing, packing, or holding of a drug product ***shall wear clean clothing appropriate for the duties they perform***. Protective apparel, such as head, face, hand, and arm coverings, shall be worn as necessary to protect drug products from contamination.

➢cGMP consideration to protect the product from contamination, however, must also consider worker protection when called for by the hazard assessment



Source: www.ecfr.gov, accessed 05/16/2018

IEST Recommended Practices

IEST-RP-CC001.5	HEPA and ULPA Filters
IEST-RP-CC002.3	Unidirectional Flow Clean-Air Devices
IEST-RP-CC003.4	**Garment System Considerations for Cleanrooms and Other Controlled Environments**
IEST-RP-CC004.3	Evaluating Wiping Materials Used in Cleanrooms and Other Controlled Environments
IEST-RP-CC005.3	Glove and Finger Cots Used in Cleanrooms and Other Controlled Environments
IEST-RP-CC006.3	Testing Cleanrooms
IEST-RP-CC007.2	Testing ULPA Filters
IEST-RP-CC012.1	Considerations in Cleanroom Design
IEST-RP-CC016.2	The Rate of Deposition of Nonvolatile Residue in Cleanrooms
IEST-RP-CC018.4	Cleanroom Housekeeping-Operating and Monitoring Procedures
IEST-RP-CC020.2	Substrates and Forms for Documentation in Cleanrooms
IEST-RP-CC021.3	Testing HEPA and ULPA Filter Media
IEST-RP-CC022.2	Electrostatic Charge in Cleanrooms and Other Controlled Environments
IEST-RP-CC023.2	**Microorganisms in Cleanrooms**
IEST-RP-CC024.1	Measuring and Reporting Vibration in Microelectronics Facilities
IEST-RP-CC026.2	**Cleanroom Operations**
IEST-RP-CC027.2	**Personnel Practices and Procedures in Cleanrooms and Controlled Environments**
IEST-RP-CC028.1	Minienvironments
IEST-RP-CC034.3	HEPA and ULPA Filter Leak Tests

Describes garment systems, generally

Sterile garments covered in CC023

Safety considerations for cleaning here

Sample gowning procedure in CC027

Note: List is non-exhaustive, see www.IEST.org

- Information on PPE assessment may be covered in multiple documents

Pending And Changing Standards –A Few Examples

- **ASTM F23 Committee**
  - ASTM F23.3 Work item WK54508 "*New Specification for Protective Clothing for Use against Liquid Chemotherapy and Other Hazardous Drugs*"
- **European Union PPE Regulation**
  - Regulation 2016/425
  - Change from directive to regulation
- **European Commission Annex 1: "Manufacture of Sterile Medicinal Products" Revision Draft**
  - Section 4 – Personnel
  - Clarifications on expectations for sterile head covers, masks, & eye coverings in grade A/B areas

➢ **Regulations & standards are changing all the time, is a review of hazard assessments or PPE selection needed?**

ISO 14644-- Cleanrooms and associated controlled environments

- Part 1 Classification of air cleanliness by particle concentration
- Part 2 Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
- Part 3 Test methods
- Part 4 Design, construction, start-up
- Part 5 Operations
- Part 7 Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)
- Part 8 Classification of air cleanliness by chemical concentration
- Part 9 Classification of surface cleanliness by particle concentration
- Part 10 Classification of surface cleanliness by chemical concentration
- Part 12 (FDIS) Specifications for monitoring air cleanliness by nanoscale particle concentration
- Part 13 Cleaning surfaces to achieve defined levels of cleanliness in terms of particle and chemical classifications
- Part 14 Assessment of suitability for use of equipment by airborne particle concentration
- Part 15 Assessment of suitability for use of equipment and materials by airborne chemical concentration

ISO 14644 Series

Part 1 Classification of air cleanliness by particle concentration

Part 2 Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration

- Significant revision to Parts 1 & 2 in 2015
  - Sampling locations numbers and positioning
  - Statistical acceptance criteria
  - Addition of risk assessment into monitoring
- Referenced by both European Commission GMP Annex 1 (current and draft) and FDA guidance "*Sterile Drug Products Produced by Aseptic Processing*"

➢ **Understand which standards are referenced in other regulatory documents.**

➢ **When are they slated for update?**

ISO 14644 Series

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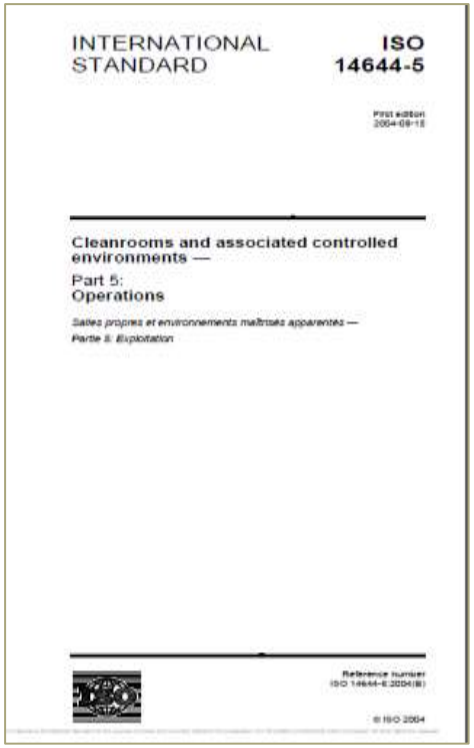
Information on garments and PPE suitability here

ISO 14644-5


INTERNATIONAL STANDARD

ISO 14644-5

Cleanrooms and associated controlled environments —

Part 5: Operations

- **B8. Facemasks and other Headgear (informative)**
- "*Headgear is available that provides an active barrier to contamination from the mouth and head. A helmet with hood and clear face-shield encloses the head and is provided with a filtered exhaust system that prevents contamination from escaping into the cleanroom.*"

ISO 14644-5, Annex C (informative)

C.7.2 Emergency situations may arise and emergency response personnel, trained in all aspects of potential emergencies, can minimize the effects of mishaps that may occur. All employees should be trained for an orderly evacuation. If an evacuation is necessary, provisions should be made for the orderly return to the cleanroom once the situation is cleared. An emergency procedure for supplying fresh cleanroom clothing should be implemented.

A Brief Aside….

- **Cleanroom evacuations and safety drills—a few considerations**
  - Plan for fully gowned personnel
    - Is consideration of decontamination of the evacuation route/gathering point needed?
  - Plan for PPE or garments that were being worn
  - Plan to assess the health/recovery of the cleanroom
    - After a drill
    - After an emergency event

Sterile hood offerings

Important notes

- Sterile assemblies include hood and pre-attached breathing tube
- Tychem® 2000 material construction
- Double bagged
- Gamma irradiated, FDA validated to 10^{-6} sterility assurance.
- Blower unit can be wiped down with 70%IPA or Clorox wipes.
- Assigned Protection Factor up to 1000 with independent third party testing protocols
- Primary current applications are for formulations and cleaning

Wrapping Up

- There are a myriad of standards out there
  - Most standards bodies have information on the status/timing of relevant documents and changes
- Relevant information may be contained in one or more documents
- Understand which regulations reference which standards
  - Revision schedule?
  - What's up for major changes?

➢ **Opportunity for input and influence -- many of the consensus bodies are always looking for experts to provide input**

Thank You, and Any Questions?

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www.fda.gov
www.ec.europa.eu/health/documents/eudralex/vol-4_en
www.astm.org/COMMITTEE/F23.htm
www.ec.europa.eu/growth/sectors/mechanical-engineering/personal-protective-equipment_en