


Ante Room & Clean Room: General Procedures

TXCH Global HOPE




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Objectives

By the end of this presentation, the participant should be able to:


- Identify where and when medications should be unpacked/unboxed
- Explain proper technique for cleaning the biologic safety cabinet
- Describe the concept of laminar airflow and techniques for ensuring appropriate airflow



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General Ante & Clean Room Concepts


- All recommendations are designed to safeguard the integrity and sterility of the final product for patient administration
- Recommendations and guidance aim to:
 - Maintain a clean, sterile environment, with minimal particulate matter and minimal risk of fungal or bacterial growth
 - Ensure adequate airflow in the ante room, clean room, or biologic safety cabinet (BSC)
 - Protect the product from aberrant storage conditions



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Receipt of Medications


- All medication shipments should be delivered to the pharmacy immediately upon receipt to ensure proper storage conditions (e.g., temperature)
- Remove all medications and supplies from cardboard boxes in the pharmacy workroom
 - Particulate matter, dust, and infectious particles (e.g., fungi, bacteria) may be present on delivery boxes or vial boxes
 - Boxes and vials may be contaminated with hazardous chemicals; follow guidance for the use of personal protective equipment (PPE), such as gloves, during unboxing
 - Cardboard/paper boxes should never be in the ante room or clean room; dispose of empty boxes in the pharmacy workroom
 - Excess particulate matter can put strain on the HEPA filter



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Medication Storage

- All products (vials, equipment) must be swabbed with 70% isopropyl alcohol in the ante room before entering clean room
 - Introduce via pass-through window, if available
- Medication Safety Considerations
 - **Hazardous medications** should be stored separately from non-hazardous medications
 - **High alert medications** require special storage considerations (e.g., red bins, alert stickers)
 - **Look-alike-sound-alike medications** should be stored apart from each other with special storage considerations (e.g., colored bins, alert stickers)
 - *Refer to Medication Safety Module for additional details*




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Clean Room Entry


Sticky Mats


- Can be placed in ante room at the entrance to the clean room to attract additional dirt
- Change mats as needed



Shoe Covers

- Put on before entering clean room as part of Donning procedure
- Step on sticky mat with shoe covers before entering/leaving clean room
- Always remove covers just before leaving ante room





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Inspect All Products for Integrity

1. Inspect all products and supplies in detail

- Inspect all items for dust, debris, contamination, or damage
- Inspect bottles, IV bags, vials, and ampules for particulate matter, discoloration, and other abnormalities (e.g., vial breakage)
 - When selecting, prior to preparation, and after preparation before dispensing

2. IV bag specifics

- Wipe all vials and equipment with isopropyl alcohol prior to stocking in ante room **and also** upon intent to use in clean room
- Remove outer wrapping from IV bags and wipe with isopropyl alcohol before placing in hood for compounding
- Squeeze IV bags to detect leaks

3. Check manufacturer expiration dates prior to use

4. Do not use if the quality or integrity is questionable



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Particles Matter

- Microorganisms need particles to travel; by reducing or eliminating them, the risk of contamination is reduced
- **Personnel** are the biggest source of airborne particles
 - Skin, hair, cosmetics, clothing fibers, sweat, etc.
- Particulate matter can be reduced by using or improving the use of personal protective equipment (PPE), biologic safety cabinets, and cleaner air (e.g., HEPA filtered, negative pressure airflow, with frequent air exchanges)



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Ante and Clean Room Restrictions

ALWAYS	NEVER
Wear personal protective equipment (PPE)	Wear make-up, false eyelashes, nail polish, or fake fingernails
Focus on patient safety!	Bring cardboard or vial boxes in the ante or clean room, and limit all paper products
Adhere to correct donning, doffing, and scrubbing procedures	Chew gum or bring food or drinks in the pharmacy
Follow procedures for aseptic technique, safe handling, and equipment maintenance	Allow excess traffic or non-pharmacy staff in the ante or clean room



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Biologic Safety Cabinets (BSCs)

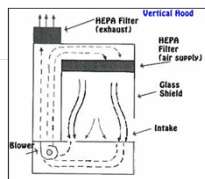
- A BSC is designed to protect the sterility of products in the cabinet
- BSCs may have horizontal or vertical laminar airflow
 - Horizontal airflow is used for non-hazardous drugs (air blows from the back of the hood toward the preparer's face)
 - Vertical airflow **must** be used for hazardous drugs, as this prevents hazardous contamination of the external environment
- Airflow in the room should be controlled to prevent drafts
- The BSC should be left on to provide an optimal work environment
 - If the BSC is turned off, it must run for **30 minutes** before cleaning and resuming use



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What is Laminar Airflow?

- Air which moves particles in a uniform direction, from cleanest area under the hood (by the filter) to the exit (sash opening or vents at the back or bottom of hood)
- Air moving in the **same direction**, at the **same speed**, with **no or minimal cross-over** of air streams ("lamina")
 - Turbulent flow creates swirls and eddies which can deposit particles/contamination on surfaces
 - Turbulence is created by movement in the path of air flow
 - Good aseptic technique can prevent excess turbulence and therefore product contamination



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Maintaining Laminar Airflow

- Place **only objects for immediate use** in the hood
- Work at least **16 centimeters inside** the hood and **8 centimeters from the sides** of the hood
- **Minimize disruption** of laminar flow by avoiding use of large objects (e.g., solution bottles)
- Do not place anything between the **HEPA filter** and objects on work surface, including the compounding's hands



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BSC Cleaning

- Clean the BSC, or "hood" with 70% isopropyl alcohol...
 1. At the beginning of every shift
 2. After spills or other incidents during compounding
 3. Before major projects involving sterile preparation
 4. At least every 30 minutes during continuous prep
 5. Clean any equipment inside the hood (e.g., automatic compounding pumps) as part of this procedure
- The area around the BSC should be kept as clean as possible to prevent introduction of contaminants into the BSC
- Document date and time the hood was cleaned on the maintenance sheet in the Global HOPE SOP



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What's Next?

- Complete practice questions
- Review answer file



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