Bureau of Enforcement
Investigative Services Unit

PHARMACY INSPECTION OVERVIEW
CONTINUING EDUCATION TRAINING
November 8, 2018
Orlando, Florida

Introduction

- **Workshop Purpose**
- **Topics**
  - Program History
  - Introduction of Inspectors
  - Program Statistics
  - Environmental Monitoring
  - Hand Hygiene and Garbing

Introduction

- **Topics**
  - Certifications
  - Cleaning
  - Media Fills/ Gloved Finger testing
  - Compounding Records
  - Class III Permits

Program History

- **New England Compounding Center (NECC)**
  - 7 deaths and 25 cases of meningitis in Florida
- **Board adopted USP 797 on October 1, 2014.**

Program History

- **HB7077 (2014)**
  - Defined Compounding and Outsourcing Facilities
  - Established a Non-Resident Sterile Compounding Permit
  - Granted authority to conduct non-resident inspections

Inspectors

- **Six (6) Senior Pharmacists**
  - 156 years of licensure
  - 125 years of practice
  - 27 years of regulatory experience

Program Statistics

- **508 Sterile Compounding Inspections**
- **34 possible Non-Resident Inspections**
- **Top Deficiencies**
  - 95
  - 98
  - 68
  - 99

Program Statistics

- **Top Deficiencies**
  - 73
  - 93
  - 78
  - 89
  - 72
  - 90

Presentation Topics

- Environmental Monitoring: #’s 60, 68, 71, 72, 73, 74, 75, 89
- Hand Hygiene and Garbing: #’s 57, 86, 87, 88, 89, 90, 91, 92, 97, 98
- Certifications: #’s: 41, 42, 51, 52, 53, 54, 55, 56, 59

Presentation Topics

- Cleaning: #’62, 66, 77, 78, 79, 83, 84, 85, 97, 109, 110
- Media Fills/ Gloved Finger testing: #’s: 93, 94, 95, 99, 100
- Compounding Records: #’s: 118

Environmental Monitoring

Environmental Monitoring

- **Why is it performed?**
  - Control
  - Identify
  - Gather Data
  - Information

Environmental Monitoring

- **What it is NOT**
  - Not Highly Recoverable
  - Not Always Repeatable
  - Not Always Linked to a Direct Cause and Effect
  - Not Proof of the Absence of Contamination

Environmental Monitoring

- **Surface Sampling: Monitoring Work Practices**
  - Effectiveness of Cleaning
  - Proper Aseptic Technique
  - Personnel Practices
  - Material Movement

Environmental Monitoring

- What Media?
- How to Incubate
- General media TSA with neutralizers

Environmental Monitoring

- **Viable AIR Sampling**
  - When
  - Where
  - How Much

Environmental Monitoring

- **Importance of Environmental Sampling Plans**
  - Risk Assessment
  - Locations
  - Method of Collection
  - Frequency and Sampling Volume of Air
  - Time of Day Related to Compounding
  - Action Levels

Environmental Monitoring

- **What Do I do When Action Level Exceeded?**
  - Identification
  - Investigation
  - Remediation

Environmental Monitoring

- Gram Positive Bacteria
- Gram Negative Bacteria
- Fungi

Questions?

Hand Hygiene and Garbing

Correct Order of Donning PPE

Hand Hygiene and Garbing
Correct Process for Donning PPE

- Remove outer garments, jewelry, cosmetics, and artificial nails prior to donning PPE
- Don shoe covers, head/facial covers, and face masks
- Cleanse hands and forearms to the elbow with facility-approved soap and water for at least 30 seconds

Hand Hygiene and Garbing
Correct Process for Donning PPE

- Completely dry hands and forearms using a lint-free towel
- Don non-shedding gown

USP 39-NF-34

Hand Hygiene and Garbing
Correct Order of Donning PPE

- Apply Persistent activity hand scrub and allow for it to dry
- Don sterile gloves
- If ISOLATOR-Don sterile gloves which come in contact with the vials used in compounding inside the main chamber using the glove port

Hand Hygiene and Garbing
Correct Order of Donning PPE

- Spray or wipe gloved hands with sterile Isopropyl Alcohol, allow to dry
- Routinely disinfect gloves when reaching outside of ISO 5 to obtain products to use in compounding prior to reinitiating compounding
- May reuse gowns if maintained in ISO 8 for that shift

USP 39-NF 34

Hand Hygiene and Garbing

Donning of Impermeable Chemo Gown

https://asp.pharmacyonesource.com/images/simplifi797/ivroomflow.pdf accessed Oct 11, 2018 Best Practices for Compounding Garbing November 2016 Vol 13,#11 page 74

Hand Hygiene and Garbing

Are these compounders cleanroom ready?

Hand Hygiene and Garbing

Watch out for some gowns-Examine the COA

Hand Hygiene and Garbing

Consistency with Visual Observations VS What Inspectors See

Hand Hygiene and Garbing
Common Deficiencies Observed

- Not re-sanitizing gloved hands when returning to ISO 5 to compound
- Improper staging of items to be brought into the ISO 7 buffer room prior to compounding

Hand Hygiene and Garbing
Common Deficiencies Observed

- Leaving ISO 8 environment with shoe covers on and sometimes even entire garb, then not re-garbing upon re-entry into ISO 8 from unclassified area
- Insufficient washing of hands to the elbows
- Nail Hygiene deficiencies

Hand Hygiene and Garbing

Documented Annual Observations of Compounding Personnel vs Inspectors

- Per USP <797>, a qualified aseptic compounding expert attests to the observations of hand hygiene and garbing and documents their observations (example of the form in Appendix III of the USP <797> chapter)

Hand Hygiene and Garbing

Documented Annual Observations of Compounding Personnel vs Inspectors

- What inspectors are observing at times may not be consistent with the documented visual observations of the pharmacy
  - Example: Nail polish or artificial nails, make up, jewelry
  - Not donning beard covers if compounder has facial hair
  - Not cleaning under nails

Hand Hygiene and Garbing
Risk of Touch Contamination of Gloves

- Increased risk after improper staging
- Leaving ISO 5 (LAFW, BSC) to touch other non-sterile objects in ISO 7 or greater air then returning to ISO 5 and not re-sanitizing gloved hands

Hand Hygiene and Garbing
Risk of Touch Contamination of Gloves

- Continuous compounding or challenging media fills
- Adjusting face mask
- Reaching out of ISO 5 to use bar code device or computer screen

Hand Hygiene and Garbing

Observed Garbing Excursions and Breaches

- Glove sleeves of Isolator (CAI, CACI) rip
  - Consult the Barrier Isolator manual
- Shoe covers do not completely cover sneakers exposing ankles

Hand Hygiene and Garbing

Observed Garbing Excursions and Breaches

- Gown not completely sealed at the back
- When exiting the chemo room doffing off single gown, then exiting via the shared anteroom clean side of LOD without gown
- Hair bouffant does not fit all hair underneath the elastic circumference

Hand Hygiene and Garbing

Cleanroom Etiquette-DON'T's

- No chewing gum while compounding
- No cups or water into cleanroom
- No leaning into ISO 5 zone during compounding
- No compounding if compromised with a sunburn or rashes
- Remove jewelry-it can interfere with the effectiveness of the PPE

United States Pharmacopoeia USP 39-NF 34

Hand Hygiene and Garbing

Understanding of Persistent Activity Products

Hand Hygiene and Garbing
Persistent Activity Products Pearls

- Some features of a persistent activity agent
  - Demonstrate non-inferior antibacterial efficacy immediately after use
  - Able to demonstrate superior persistent activity after 6 hours of glove wear compared to other agents

Hand Hygiene and Garbing
Persistent Activity Products Pearls

- The agent should be bactericidal in the shortest contact time on the hand

Chojecka et al. Neutralization efficiency of alcohol based products used for rapid hand disinfection; 2017;68(4):389-394

Hand Hygiene and Garbing

Persistent Activity Products Pearls - Continued

- Some features of a persistent activity agent
  - Review the manufacturer's product sheet (COA) for efficacy

Daryl Paulson Infection Control today Persistent and Residual Antimicrobial Effects : Are they important in the Clinical Setting? Accessed October 18, 2018

Hand Hygiene and Garbing

Persistent Activity Products Pearls - Continued

- Don’t place regular non persistent products next to persistent activity products-this confuses the compounder (ex plain Purell)
- Chlorhexidine gluconate 1% Solution and or Ethyl Alcohol 61% w/w (varying percentages)

Daryl Paulson Infection Control today Persistent and Residual Antimicrobial Effects : Are they important in the Clinical Setting? Accessed October 18, 2018

Hand Hygiene and Garbing

Examples of Agents with Persistent Activity

- Avagard
- Sterillium Rub
- Purell Waterless Surgical Scrub
  - Some cleanrooms have plain Purell which is incorrect

Centers for Disease Control and Prevention. Guideline for hand hygiene in health-care settings.MMWR.October 25, 2002; 51(RR-16):1-44

Hand Hygiene and Garbing

Examples of Agents with Persistent Activity

- When choosing a persistent activity product review the supporting documentation for persistent or extended activity
- Must be applied on hands prior to donning sterile gloves

Centers for Disease Control and Prevention. Guideline for hand hygiene in health-care settings.MMWR.October 25, 2002; 51(RR-16):1-44

Hand Hygiene and Garbing

Selection of Gloves used in compounding

- Sterile
- Powder free
- Nitrile or Neoprene vs Latex

Hand Hygiene and Garbing
Selection of Gloves used in compounding

- Use of sterile gloves
  - Single pair acceptable for Non-hazardous compounding
  - Double gloves for Hazardous compounding
- Examine product information for gloves -to suggest rated for handling hazardous drugs
  - Conformance to ASTM 6978 standards

Questions?

Certifications

Importance of reviewing Certification reports prior to an inspection

Certifications

The What, the When, and the How

Certifications
The What

A Certification is an independent evaluation of the critical environments

Certifications
The When

- Prior to operation
- Every six (6) months
- When equipment is moved, replaced or repaired

Certifications
The How

- Must be conducted by a CETA certified agent
- Equipment used by agent must be calibrated annually
- Certifier must follow garbing procedure of facility
- Dynamic Conditions

Review of a Certification Report

- **Primary Engineering Controls**
  - LAFW
  - BSC
  - CAI
  - CACI
- **Secondary Engineering Controls**
  - Ante Room
  - Buffer Room

Review of a Certification Report - Continued

Primary Engineering Controls

- ✓ Smoke Studies
- ✓ Non Viable Air
- ✓ HEPA Filter Leak Testing

Review of a Certification Report - Continued

PHOTO 1

Smoke Testing in Horizontal Laminar Flow

First air is blocked by bad technique.

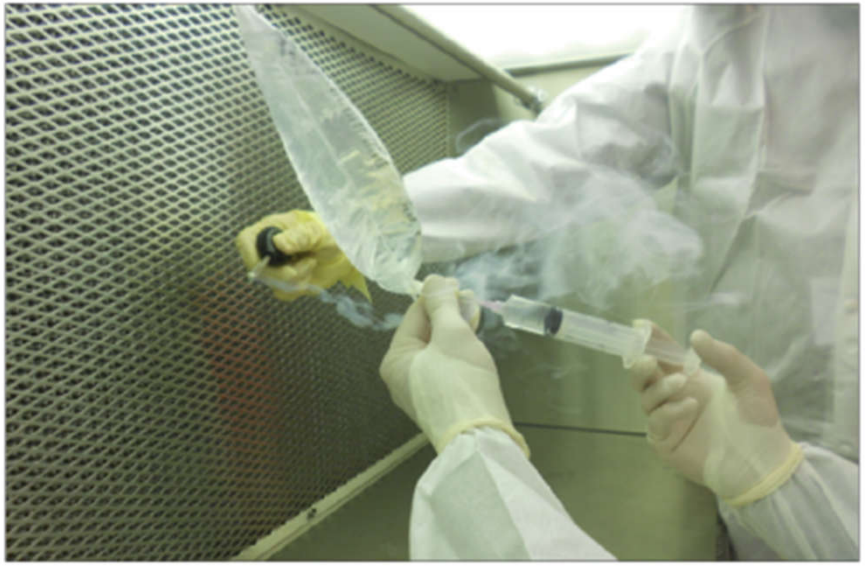


Image courtesy of Controlled Environment Consulting

Review of a Certification Report - Continued

PHOTOS 2 AND 3

Smoke Testing in Horizontal Laminar Flow

Photos 2 and 3 demonstrate good technique and effective use of first air.

Images courtesy of Controlled Environment Consulting

Review of a Certification Report - Continued

	ISO Class (Non Viable Air)	Smoke Studies	HEPA Filters	Vented to outside
LAFW	5	Yes	Yes	No
CAI	5	Yes	Ante Chamber and Main Chamber	No
CACI	5	Yes	Ante Chamber and Main Chamber	Yes
BSC *	5	Yes	Yes	Yes

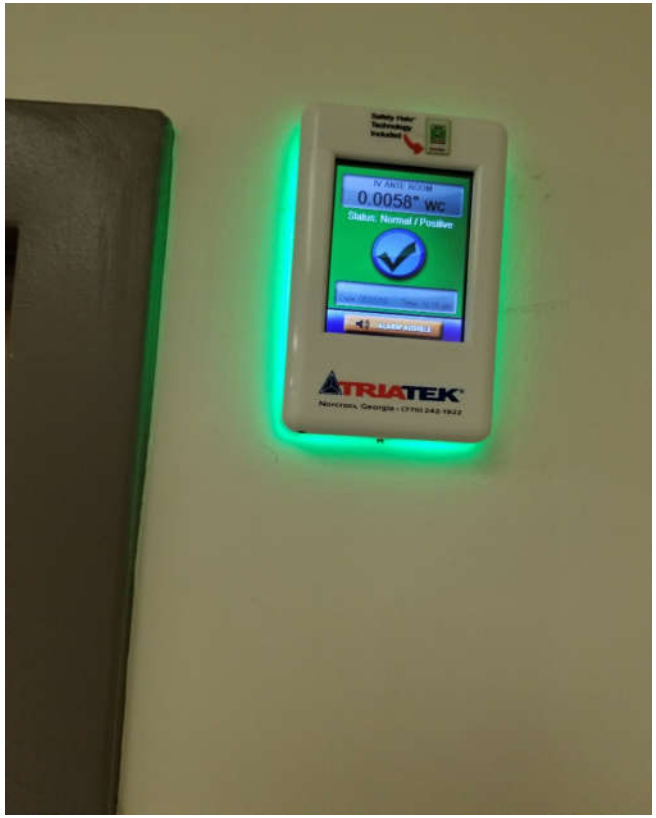
*Alarm Testing

Review of a Certification Report - Continued

Secondary Engineering Controls

- ✓ Non Viable Air
- ✓ HEPA Filter Leak Testing
- ✓ Air Changes Per Hour
- ✓ Pressure Differential – Ante Room and Buffer Room

Review of a Certification Report - Continued



Certifications

Review of a Certification Report - Continued

	ISO Class (Non Viable Air)	ACPH	Pressure Differential	HEPA Filters
Ante Room	8	20	0.02 – 0.05*	Leak Tested
Buffer Room	7	30	0.02 – 0.05*	Leak Tested
Buffer Room – Hazardous **	7	30	< -0.01*	Leak Tested

* Inch Water Column

** CACI for compounding minimum of 12 ACPH

Review of a Certification Report - Continued

What else could be part of the report?

- ✓ Viable Sampling
- ✓ Air
- ✓ Surface

Review of a Certification Report - Continued

- **Are they Actionable or Non-Actionable?**
  - Remediate immediately
- **What do we do with these results?**
  - Trend

Review of a Certification Report - Continued

ISO Class	AIR (cfu's per cubic meter) (1000 liters of air per plate)	SURFACE (cfu's Per Plate)
5	>1	>3
7	>10	>5
8	>100	>100

Review of a Certification Report - Continued

- **Identify to the genus level**
- **Actionable organisms**
  - Gram Negative Rods
  - Coagulase Positive Staph
  - Molds
  - Yeast

Review of a Certification Report - Continued

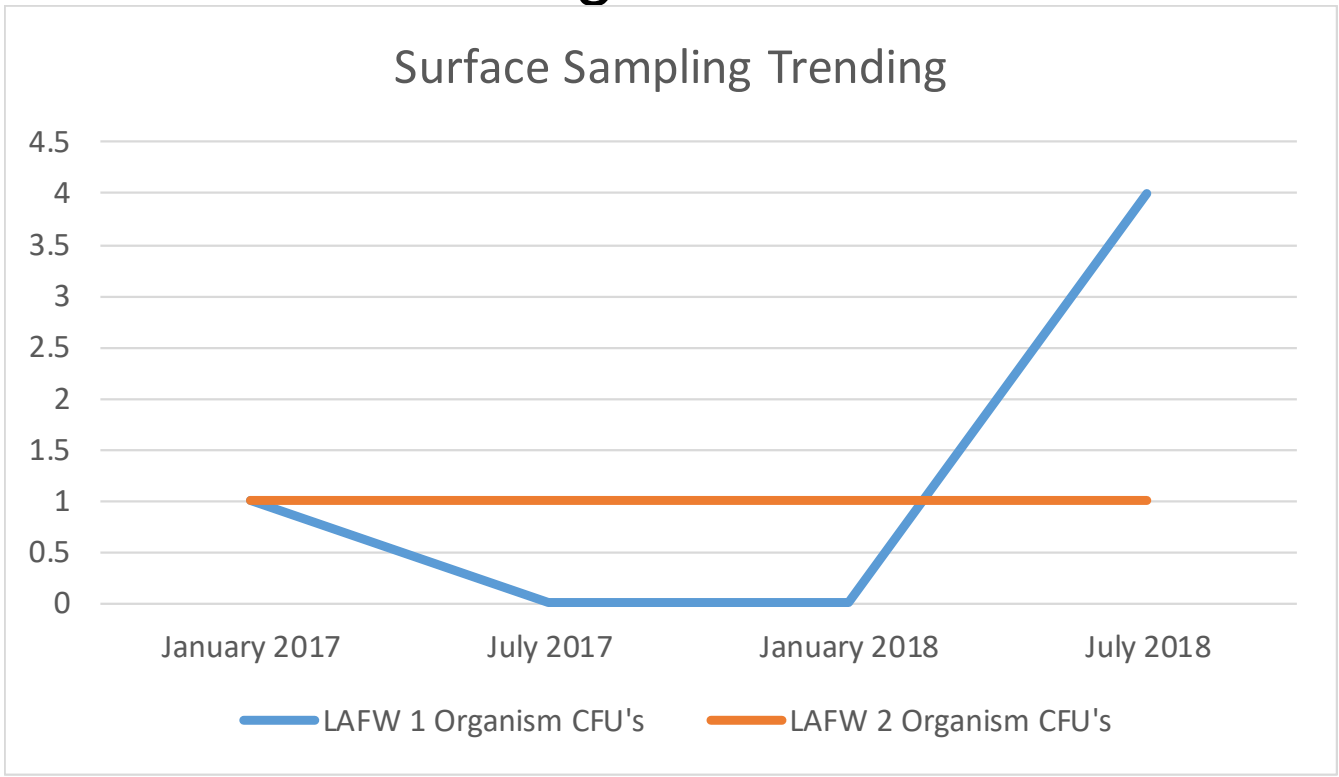
- **Remediation**
- **What is the source?**
  - Personnel work practices
  - Cleaning procedures
  - Operational procedures
  - Air filtration efficiency

Review of a Certification Report - Continued

- Remediation
- Immediate
- Documentation
- Resample

Review of a Certification Report - Continued

Trending of Bioburden



Questions?

Certifications

Dynamic Conditions

Certifications

Significance of Smoke Studies

Certifications

PEC VS SEC

Questions?

MEDIA FILLS AND GLOVE FINGER TESTS

Clear documentation of Incubator temperatures, length of incubation

MEDIA FILLS AND GLOVE FINGER TESTS

Low, Medium and High-risk Media fill testing

MEDIA FILLS AND GLOVE FINGER TESTS

Glove Fingertip Sampling

- New personnel
- Annual or Semi-Annual
- Random

MEDIA FILLS AND GLOVE FINGER TESTS

Glove Fingertip Sampling - Continued

- Media
- Technique
- Incubation
- Documentation

Questions?

CLEANING

Cleaning

- **Importance of Cleaning Documentation**
  - Accountability
  - OOS remediation
  - Training requirements
    - Initially (before compounding)
    - Annually/semi-annually (after media fill – D
  - EVS / Housekeeping records
  - Common Observations

Cleaning

- **Review of Cleaning Documentation**
  - Non pharmacy staff housekeeping/EVS
  - Who's watching?
  - EVS competencies
  - Shall be evaluated by qualified compounding expert

Cleaning

- **PEC's**
  - Most critical
  - Cleaning and disinfecting of surfaces required
  - Must allow 30 seconds for sIPA to dry
  - Documentation
  - Common Deficiencies

- **PEC's (continued)**
  - Implement DCA SOP
    - Critical factors to consider
      - Dwell times: bleach < or = 1 min bact; 5-10 min for spores *
      - Effectiveness
      - RTU vs dilution

    *5,000ppm chlorine soln against C difficile spores- Reference: *"American Journal of Infection Control"*, August 2005, pgs 320-325.

Cleaning

- **SEC's**
  - Work surfaces: daily
    - Ante room
    - Buffer rooms
    - SCA's
    - Agent must not degrade ISO 7 or 8 air quality (USP <1072>)

Cleaning

- **SEC's (continued)**
  - Floors
    - required to be done daily
    - ISO 7, ISO 8 and SCA's
    - Follow SOP
    - Consider germicidal compatibility with surfaces (USP <797> appendix II)

Cleaning

- **Factors to consider in choosing chemicals**
  - Compatibility
  - Effectiveness
  - Toxic Residues

Cleaning

USP <797> Appendix II

Appendix II. Common Disinfectants Used in Health Care for Inanimate Surfaces and Noncritical Devices, and Their Microbial Activity and Properties[1]

		Chemical Category of Disinfectant					
		Isopropyl alcohol	Accelerated hydrogen peroxide	Quaternary Ammonium (e.g., dodecyl dimethyl ammonium chloride)	Phenolics	Chlorine (e.g., sodium hypochlorite)	Iodophors (e.g., povidone-iodine)
Concentration Used		**60–95%**	**0.5%[3]**	**0.4–1.6% aq**	**0.4–1.6% aq**	**100–5000 ppm**	**30–50 ppm**
Microbial Inactivation[2]	Bacteria	+	+	+	+	+	+
	Lipophilic viruses	+	+	+	+	+	+
	Hydrophilic viruses	±	+	±	±	+	±
	M.tuberculosis	+	+	±	+	+	±
	Mycotic agents (fungi)	+	+	+	+	+	±
	Bacterial Spores	–	–	–	–	+	–
Important Chemical & Physical Properties	Shelf life >1 week	+	+	+	+	+	+
	Corrosive or deleterious effects	±	–	–	–	±	±
	Non-evaporable residue	–	–	+	+	–	+
	Inactivated by organic matter	+	±	+	±	+	+
	Skin irritant	±	–	+	+	+	±
	Eye irritant	+	–	+	+	+	+
	Respiratory irritant	–	–	–	–	+	–
	Systemic toxicity	+	–	+	+	+	+

Key to abbreviation and symbols: aq = diluted with water; ppm = parts per million; + = yes; – = no; ± = variable results.

[1] Modified from World Health Organization, Laboratory Bio Safety Manual 1983 and Rutala WA, "Antisepsis, disinfection and sterilization in the hospital and related institutions," *Manual of Clinical Microbiology*, American Society for Microbiology, Washington, DC, 1995, pages 227-245.

[2] Inactivation of the most common microorganisms (i.e., bacteria) occurs with a contact time of ≤1 minute; inactivation of spores requires longer contact times (e.g., 5-10 minutes for 5,000 ppm chlorine solution against *C. difficile spores). Reference: Perez J, Springthorpe VS, Sattar SA, "Activity of selected oxidizing microbicides against the spores of Clostridium difficile: Relevance to environmental control," American Journal of Infection Control, August 2005, pages 320-325.*

[3] *Accelerated* hydrogen peroxide is a new generation of hydrogen peroxide-based germicides in which the potency and performance of the active ingredient have been enhanced and accelerated through the use of appropriate acids and detergents.

Cleaning

- **SEC's (continued)**
  - Monthly cleaning
    - Shelving, ceilings and walls
    - Careful consideration when cleaning ceiling

Cleaning

Cleaners VS Disinfectants

Cleaner

- **Removal,** usually with **detergent** and water or enzyme **cleaner** and water, of adherent visible soil, blood, protein substances, microorganisms and other debris from the surfaces, crevices, serrations, joints, and lumens of instruments, devices, and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination

Source: www.cdc.gov/infectioncontrol/guidelines

Cleaning

Cleaners VS Disinfectants - Continued

Disinfectant

- Usually a chemical agent (but sometimes a physical agent) that destroys disease-causing pathogens or other harmful microorganisms but might not kill bacterial spores. It refers to substances applied to inanimate objects

Source: www.cdc.gov/infectioncontrol/guidelines

Cleaning
Cleaners VS Disinfectants - Continued

- Cleaning is a mechanical process
- Cleaning prepares a surface for disinfection
- Cleaning agents contain surfactants and/or detergents to remove dirt, debris and microbes
- Many cleaning agents work to disinfect but does not replace the need of sIPA!

Cleaning

Cleaners VS Disinfectants - Continued

- **EPA Registered One-Step Disinfectant Cleaners**
  - Cavicide
  - Pre-empt RTU
  - Vesophene llse
  - Sporicidin
  - Peridox RTU
  - Oxivir Five 16 concentrate
  - Spor - Klenz

Cleaning
Cleaners VS Disinfectants - Continued

sIPA and sodium hypochlorite do not contain surfactants or detergents

Cleaning
Tools and Materials

- Non-shedding wipers, mops and sponges
- Dedicated to use in buffer rooms, ante-are and SCA's
- MUST NOT be removed from these areas

Cleaning
Tools and Materials – Continued

- **Considerations**
  - EVS / Housekeeping bringing cleaners from outside
  - Are they diluting agents?
  - What is the stability of diluted agents?

Cleaning
Policy and Procedure

- **Who, What, Where, When, How**
  - **WHO** cleans what?
    - EVS vs Compounding personnel

Cleaning
Policy and Procedure - Continued

- **Who, What, Where, When, How**
  - **WHAT?**
    - Cleaning/disinfecting agents- RTU or dilution?
      - Include dilution instructions
    - Non shedding mops/ wipes
    - Mop handles

Cleaning
Policy and Procedure - Continued

- **Who, What, Where, When, How**
  - **WHERE?**
    - Ante room
    - Buffer rooms
    - PEC's
    - SCA's

Cleaning
Policy and Procedure - Continued

- **Who, What, Where, When, How**
  - **WHEN?**
    - Daily (floors and work surfaces)
    - Weekly (optional)
    - Monthly (ceilings, walls, storage bins, shelving)
    - Frequently (PEC's)

Cleaning
Policy and Procedure - Continued

- **Who, What, Where, When, How**
  - **HOW?**
    - Method of Cleaning
    - PEC's : CAI's, CACI's, LAFW's, BSC's
    - SEC's: floors, ceilings, walls, shelving, storage bins

Cleaning
Policy and Procedure - Continued

- **Do you have a <u>DCA Policy?</u>**
  - Different requirements for LAFW's, CAI's, CACI's, and BSC's
  - Include deactivating agents, disinfectants, non shedding wipes, tools (for CAI, CACI)
  - Consider changing pre-filters according to manufacturer recommendations

Questions?

Compounding Records

- **Provide a history of:**
  - How the CSP was prepared
  - Who prepared it
  - What was used to prepare it
  - When was it prepared

Compounding Records

- Communication
- Accountability
- Regulatory Requirements
- Quality Improvement

Compounding Records

Elements of a compounding record

- Name, strength, and dosage form of the medication
- Equipment needed
- Methodology
- BUD

Compounding Records

Elements of a compounding record - Continued

- Quantity
- Total theoretical yield for the CSP (# of csp's expected)
- Total actual yield of CSP'S(# of csp's prepared)

Compounding Records
Final Reconciliation

The final packaging and CSP yield information should be reviewed, reconciled, and approved

Questions?

Class III Permits

Class III Permits
Overview

- Beginning on October 19, 2018, the Board of Pharmacy began issuing permits for Class III Institutional Pharmacies.

- **Rule Reference: 64B16-28.750, Florida Administrative Code**

Class III Permits
Overview

- Class III institutional pharmacy permits were created for hospital-affiliated institutional pharmacies, including central distribution facilities that provide the same services authorized by a Class II permit.

- **Rule Reference: 64B16-28.750, Florida Administrative Code**

Class III Permits
Overview - Continued

- **Class III Institutional permitees may:**
  - Dispense, distribute, compound, and fill prescriptions for medicinal drugs;

Class III Permits
Overview - Continued

- **Class III Institutional permitees may:**

  - Prepare prepackaged drug products;
  - Conduct other pharmaceutical services for the affiliated hospital and for entities under common control that are each permitted under Chapter 465, F.S., to possess medicinal drugs; and

Class III Permits
Overview - Continued

- **Class III Institutional permitees may:**
  - Provide the aforementioned services to an entity under common control that holds an active health care clinic establishment permit as required under Chapter 499, F.S.

Class III Permits
Overview - Continued

- A Class III Institutional Permit may be issued to existing Class II or Modified Class II Institutional Pharmacy Permittees or as an initial permit to new pharmacy facilities meeting the statute's requirements or Central Distribution Facilities under common control with a hospital.

Class III Permits
Overview - Continued

- The term **“common control”** is defined as the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or otherwise.

Class III Permits
Overview - Continued

- **<u>Change of Association for Existing Permittees</u>**. Institutional Pharmacies affiliated with a hospital currently holding Class II or Modified Class II Institutional Pharmacy Permits may request the facility be associated as a Class III Institutional Pharmacy Permit by completing an application (Form DH5033).

Class III Permits
Overview - Continued

- Because pharmacy permits are non-transferrable, this option is not available if there is any change in the ownership or identity of the business entity holding the existing Class II or Modified Class II Institutional Pharmacy Permit.

Class III Permits
Overview - Continued

- Upon approval of the request, the existing Class II or Modified Class II permit will be re-associated as a Class III Institutional Pharmacy Permit, with no change of permit number.

Class III Permits
Overview - Continued

- **New Class III Permits.** Applicants for a new Class III Institutional Pharmacy permit must complete an application (Form DH5032).

- Applicants for an Institutional Pharmacy Permit must designate a consultant pharmacist of record as required by Section 465.019, F.S. and Rule 64B16-28.501, F.A.C.

Class III Permits
Overview - Continued

- A copy of the permittee's policy and procedure manual as provided herein shall accompany the permit application.

Class III Permits
Overview - Continued

- As required by paragraph 64B16-28.100(1)(c), F.A.C., prior to issuance of a Class III Institutional Pharmacy Permit, the applicant must pass an on-site inspection.

Class III Permits
Overview - Continued

- For applicants who currently hold Institutional Class II or Modified Class II permits, the on-site inspection required for issuance of the Class III permit shall be coordinated, to the extent practicable, with any other inspections required or recently conducted, and in no event, shall reset or disrupt the permittee's existing inspection schedule.

Class III Permits
Overview - Continued

- Each applicant must comply with the fingerprinting requirements of section 465.022, F.S., unless the applicant qualifies for the statutory exception for corporations having more than $100 million of business taxable assets in Florida

Class III Permits

- Please visit the Board of Pharmacy Resources page to download the application form for the Class III Pharmacy and Change of Permit Association for the Class III Pharmacy.

Class III Permits

- Staff Processors for Class III Pharmacies: Shekinah Dawkins or Ahjia Ponders.
- Board of Pharmacy Telephone: (850)245-4292
- E-mail address: MQA.Pharmacy@flhealth.gov

Questions?

REFERENCES*

- Centers for Disease Control (CDC)
- USP <797>
- Critical Point LLC.
- PDA
- FDA Guidance

*If not indicated on slide

Medical Quality Assurance
Bureau of Enforcement/
Investigative Services Unit
850-245-4478