CLEANING, DISINFECTION, & CONTAMINATION CONTROL

STERILE COMPOUNDING

March 14, 2017

AGENDA

- Why Clean?
- USP<797> Overview
- 483's
- Best Practices – Contamination Control Principles
- Disinfectants
- FDA Expectations
- Questions

Why Clean?

1990

- Nebraska
  - Bacterial infection from non-sterile cardioplegia solution compounded in a hospital
  - 4 Patients died
- Pennsylvania
  - Pseudomonas aeruginosa infection from compounded eye drops.
  - 2 Patients lost their vision

1998

- California
  - Bloodstream infection [enterbacter cloacae] from contaminated prefilled saline syringes.
  - 11 Children became septic

2001

- Missouri
  - Bloodstream infections in pediatric patients traced to a hospital pharmacy
  - 4 Patients developed an infection, 1 case of bacterial meningitis
- California
  - Infection outbreak following injection of betamethasone compounded at a community pharmacy
  - 11 Patients developed an infection and 3 patients die

2002

- South Carolina
  - 5 Cases of fungal infection from contaminated injectable steroids manipulated by a compounding pharmacy – 1 person dies
- Michigan
  - Injectable products recalled due to contamination with penicillum mold.

2003

- Missouri
  - Bacteria contamination with Burkholderia cepacia in compounded infant solution.
  - Used by 19,000 patients with chronic lung disease.

2004

- Texas
  - Home infusion facility prefilling syringes of heparin and saline – unregistered Medical Device manufacturer
  - Pseudomonas bloodstream infections – 36 Infections in 4 states

2004

- Maryland
  - 16 Patients from 3 clinics develop Hepatitis-C infection after injection
  - Death and disease are directly associated

2005

- Texas
  - Multi-state outbreak of gram negative bacteria from contaminated intravenous compound from a compounding pharmacy
- Maryland
  - Outsourcing (pharmacy) compounding operation preparing several CSP's.
  - Discovery of gram-negative rods
  - At least 10 patient deaths from contaminated solutions
- NJ & California
  - Patients contracted Serratia marcescens infections due to contaminated magnesium sulfate prepared by a compounding pharmacy
  - 25 people effected
- Minnesota
  - Compounded trypan blue ophthalmic injection contaminated with Pseudomonas aeruginosa and Burkholderia cepacia.
  - *2 Patients were blinded*

2011

- Alabama
  - 16 Cases of gram negative bacteria from contaminated parenteral drug prepared by a compounding pharmacy
  - 9 deaths
- California
  - Severe eye infections due to contamination of Avastin during compounding.
  - 16 Patients effected - 1 with lost vision, 1 developed a brain infection.

2012

- California
  - Outbreak of fungal endophthalmitas after use of the compounded product Brilliant Blue-G [BBG] or receiving injections of triamcinolone from the same compounding pharmacy.
  - 9 Patients effected

2013

- A compounder recalled all purportedly sterile drugs within expiry and ceased sterile operations.
- 15 patients developed bacterial bloodstream infections
- 2 deaths

Investigative Findings:

- Breaks in Aseptic Technique
- Poor Employee Hygiene
- Poor Garbing Practices
- Failure to Comply with Compounding Best Practices
- Untrained Compounding Personnel
- Failure to Achieve Sterility
- Pharmacy used Non-Sterile Components in Preparations

USP <797> Overview

June 2008

- 1st Full Revision of USP<797>
  - *Pharmaceutical Compounding – Sterile Preparations*
  - Established standards to prevent harm and fatality to patients that could result from microbial contamination (non-sterility), excessive bacterial endotoxins, large content errors in the strength of correct ingredients, or incorrect ingredients in Compounding Sterile Preparations.

USP <797> Overview

1960's & 70's

- National Committee to address patient safety issues

Early 1990's

- ASHP, USP, & NABP issued practice recommendations
- ASHP Conducts 1st national survey

1992

- USP Issues 1st draft recommendation – USP<1074>

1993

- ASHP issues a Technical Assistance Bulletin [TAB]
  - *Quality Assurance for Pharmacy – Prepared Sterile Products*

1995

- Adopted finalized version - USP<1206>

USP <797> Overview

1995

- ASHP Conducted a survey – poor adherence

2002

- ASHP Conducted a similar survey

2004

- First official and enforceable chapter – USP<797>

2008

- 1st Full revision

2017 Expert Committee on Compounding – Panel Review continues

USP <797> Overview

What is USP?

- *United States Pharmacopeia*
- Scientific non-profit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements.
- Not an enforcement body

Recognized in Federal Law

- Federal Food, Drug, and Cosmetic Act

USP <797> Overview

- Enforcement ?
- By whom ?

USP <797> Overview

- Enforcement? ..... <1000 = A Requirement
  Subject to Inspection by FDA
  ≥1000-1999 = General information chapters
  Guidelines not enforceable by FDA
- By whom?
  - Boards of Pharmacy (limited to licensed 503A pharmacies)*
    - Some states have changed their practice standards in response to the national publicity of pharmacy compounding errors.
      - Adopted more stringent standards than USP<797>
  - FDA (discretionary enforcement – patient well-being and affect to public health is suspect)
    - Greater emphasis on 503B's

  Surveyable by accreditation organizations
  - JACHO - Joint Commission on Accreditation of Healthcare Organizations
  - ACHC – Accreditation Commission for Health Care, Inc.
  - CHAP – Community Health Accreditation Program

* January 1 2017 – CA Outsourcing facilities must register with CA BofP

USP <797> Overview

- Non-Compliance
  - Violation of law
    - Monetary penalties
    - Healthcare professional (HCP) licensure at risk

USP <797> Overview

- Pharmaceutical Compounding Personnel are now held accountable for the cleanliness and sound aseptic technique principles of their sterile compounding areas.

USP <797> Overview

Applies to compounded:

- Biologics
- Diagnostics
- Drugs
- Nutrients
- Radiopharmaceuticals

USP <797> Overview

Applies to practitioners in:

- Hospitals
- Patient treatment clinics
- Retail pharmacies
- Physician's practice facilities
- Other facilities in which CSP's are prepared, stored, and dispensed

2012

NECC

- 751 Cases of fungal meningitis - 64 deaths
- 20 States
  - Untrained compounding personnel
  - Failure to achieve sterility – improper use of filter

In this Thursday, Oct. 4, 2012, file photo, a sign requesting "No Soliciting" hangs on the door of the New England Compounding Center. (AP Photo/Stephan Savoia, File)

(NEWSER) – Staffers at a pharmacy linked to the deadly meningitis outbreak documented dozens of cases of mold and bacteria growing in rooms that were supposed to be sterile, according to federal health inspectors. In a preliminary report on conditions at the pharmacy, the US Food and Drug Administration said today that even when the contamination at New England Compounding Center exceeded the company's own safety levels, there is no evidence that staffers investigated or corrected the problem. The FDA uncovered some four dozen reports of potential contamination in company records, stretching back to January this year.

Compounding outsourcing facilities - 503B

Compounding Quality Act - November 2013

"Outsourcing facilities will be inspected by FDA and must comply with other provisions of the FD&C Act, such as current good manufacturing practice (cGMP) requirements."

→ *Key requirements will apply equally to drugs that are compounded and those that are manufactured.*

21 CFR 210 & 211

CITED 483's

- Environmental Monitoring [80%]
  - Air
  - Surfaces
  - Personnel
- Gowning [73%]
  - Poor employee hand hygiene and garbing practices
- Cleaning & Disinfection [60%]
  - Poor cleaning
  - Insufficient written protocols
  - Insufficient execution of written protocols
  - Untrained personnel
  - Failure to achieve sterility

RECENT 483 OBSERVATIONS

- The ISO 5 hood is located in an area that is not a classified area.
- The operator's movements were not slow and deliberate within the ISO 5 hood.
- The operator initially sprayed the ISO 5 hood surface with IPA and using an ungloved hand wiped the front inside working surface of the ISO 5 hood.
- While an operator was gowning in the anteroom, we observed that the sleeve of the operator made contact with the floor of the anteroom. Following contact of the garb with the floor, no corrective action was initiated. This operator then entered the ISO 5 cleanroom.
- The cleaning procedures do not include the use of sporicidal agents and did not specify to use sterile 70% IPA. Currently, no sporicidal cleaning agent is used.
- The type of wipes to use in the hood are not specified, regular household paper towels were observed to currently be in use.
- The gowning of operators prior to entering the aseptic processing areas is done using non-sterile gowning materials including the outer gown, gloves, hairnet, and shoe covers.
- The operator did not wash his hands prior to gowning and donning gloves.
- Specifically, sterile wipes used to sanitize surfaces including those within the ISO 5 classified area and LAF (Laminar Airflow Hood) are opened in respective ISO 7 buffer rooms stored in a manner that does not guarantee they remain before use.

Source: www.fda.gov

RECENT 483 OBSERVATIONS

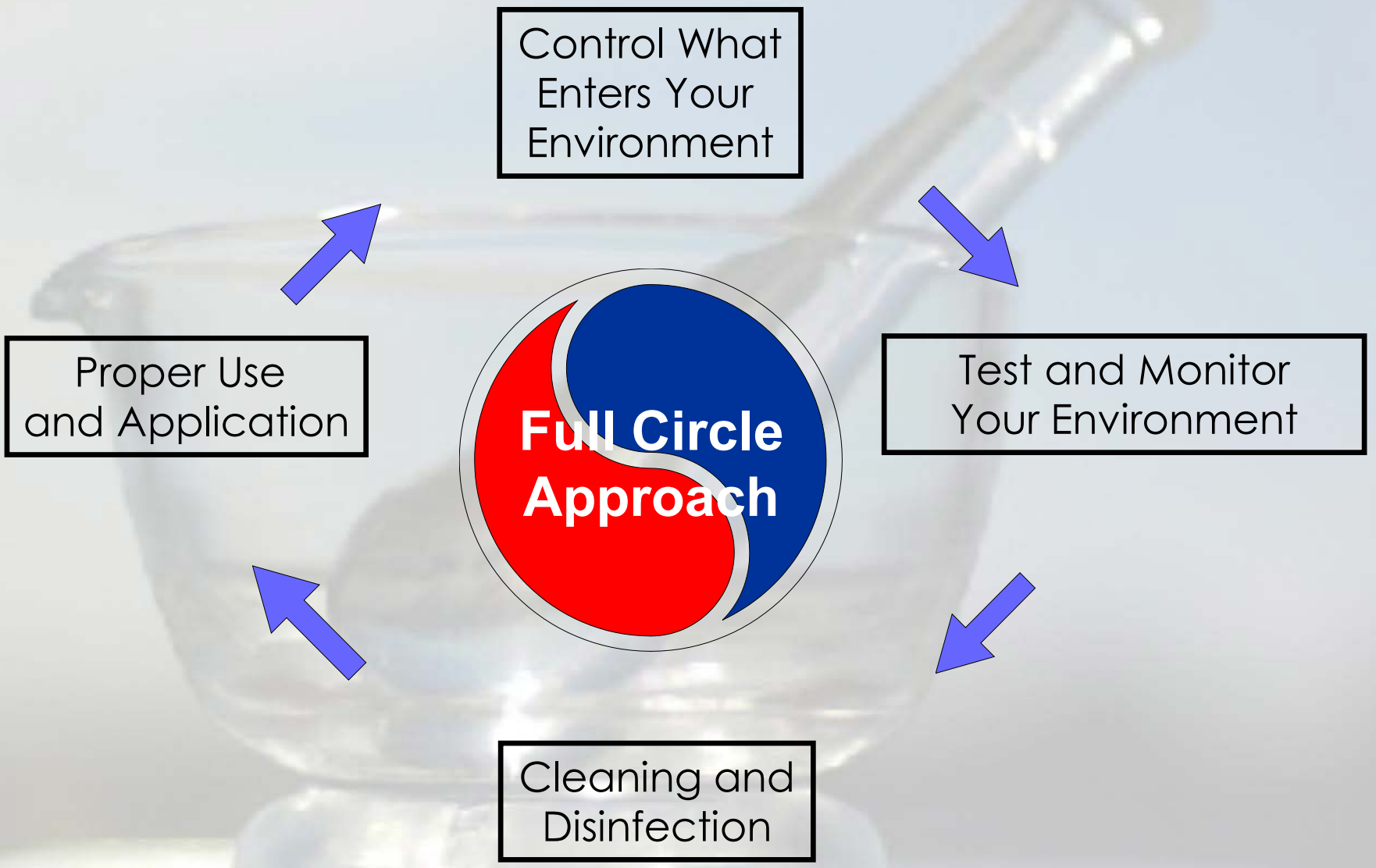
- Your pharmacist uses non-sterile disinfectants to clean the laminar flow hood where sterile drug products are prepared.
- Although sterilized IPA is used to sanitize surfaces of the ISO 5 LAFWs, the wipes used in unison with the IPA to sanitize ISO 5 LAFWs are not sterile.
- ... I observed a pharmacist passed gloved hands over open drug product containers, closures, and components while they produced the sterile drug product…
- You have failed to document cleaning of your "Clean Room", including the cleaning of your IV hoods where you produce sterile drug products.
- Specifically, the firm's cleaning procedure lacks the use of a sporicidal agent.
- We observed what appeared to be various colors of dried material beneath the metal surfaces where the pharmacist reconstitutes sterile drug product, within the ISO 5 hood at approximately face-level to the operator.
- Non-sterile wipes are used to disinfect the ISO 5 hoods' sterile processing surfaces and they are composed of particle shedding material.
- Materials including IV bags and packaged syringes used in manufacturing were observed to be transferred from ISO 7 to ISO 5 areas without sanitizing.
- The cleaning procedure provides minimal detail regarding the technique for cleaning the ISO 5 LAF hood where aseptic filling occurs.

Source: www.fda.gov

Contamination Control Principles

- Hand hygiene
- Garbing
- Cleaning and disinfecting the work areas
- Competency and personnel monitoring
- Environmental monitoring

FULL CIRCLE APPROACH



Control What Enters Your Environment

- If you don't let the contamination in, you don't have to contend with it
- Lack of control for the cleanliness and sterility of components entering the cleanroom can compromise the environmental conditions during compounding
- Once the disinfectant dries, our killing power is complete and the level of control as to what enters is our security blanket for satisfactory environmental conditions

Control What Enters Your Environment

- Activities that generate particles, including removing supplies from corrugated boxes, should be performed outside of the critical areas.
- Items should be unpacked outside the ante area.
- Supplies and equipment should be sprayed and wiped with a suitable disinfecting agent.
- Allow disinfectant to dry before placing in bins.

What to Control that Enters your Environment

- Start with items transferred into the cleanroom
  - Personnel (#1 Source)
  - Syringes
  - Needles
  - Bags
  - Disinfectants
  - Water
  - Etc.
- Have proper procedures in place for entry into the cleanroom

Material Handling Procedure for Introducing Supplies into the Compounding Environment

All cartoned supplies must be removed from shipping cartons in the warehouse or other area outside of the controlled environment.

Apply sterile 70% IPA directly onto the supplies and wipe down using a sterile, non-linting wiper. This should be performed in the dirty side of the anteroom or outside of the segregated compounding area.

Place supplies and equipment onto a clean cart on the clean side of the controlled environment. (The segregated compounding area, ante area, or buffer room depending on facility design.) Storage of supplies in the anteroom should be limited to those required for compounding.

Transfer only the supplies required into the buffer area or segregated compounding area by transporting on a clean, disinfected cart.

Are You Letting Contamination In?

Table 1: Sample testing of items routinely used in isolators		
Item	**% Contaminated**	**% Bacillus (spores)**
Syringe package	60	40
Swab package	66.7	16.6
Needle package	60	20
Sharps bin	57.1	42.9

Source: M. G. Cockcroft, D. Hepworth, J. C. Rhodes, P. Addison, A. M. Beaney. "Validation of Liquid Transfer Disinfection Techniques for Transfer of Components Into Hospital Pharmacy Cleanrooms," Hospital Pharmacist (September, 2001).

How to Clean & Disinfect Incoming Components?

Table 2: Validation of liquid disinfection techniques			
Reduction of organisms	Spray (with Alcohol)	Wipe (with Alcohol)	Spray & Wipe (with Alcohol)
S.aureus	99.8%	99.6%	100%
B.subtilis	27.6%	80.6%	93.9%

Source: M. G. Cockcroft, D. Hepworth, J. C. Rhodes, P. Addison, A. M. Beaney. "Validation of Liquid Transfer Disinfection Techniques for Transfer of Components Into Hospital Pharmacy Cleanrooms," Hospital Pharmacist (September, 2001).

PEOPLE

Outer layer of human skin can host up to 1 million microorganisms per cm^2

Activity	Number of particles generated (0.5 micron and larger/minute)
Sitting or standing still	100,000
Sitting, small movement of arms or head	500,000
Sitting, moving arms, legs or head	1,000,000
Standing Up	2,500,000
Walking slowly	5,000,000
Walking normally	7,500,000
Walking ~ 5.5 MPH	10,000,000
Performing a workout	15,000,000 - 30,000,000

Source: Introduction to Contamination Control & Cleanroom Technology, Matts Ramstorp

Minimize Personnel Contamination

- Good Hygiene
  - Shower Daily
  - Wear Clean Clothes
- Proper Gowning
- Skin Conditions
- Illness
- No Cosmetics
- No Jewelry
- Aseptic Technique
- Wash Hands
- Smoking

GARBING/GOWNING

Similar Interpretations

- USP<797> Chapter 3
- CA State Board of Pharmacy Section 1751.5
- FDA 21 CFR 211.28

GARBING/GOWNING

- Non-shedding material
  - Shoe Covers
  - Hair Cover
  - Face Mask
  - Garment
  - Sleeves
  - Gloves
- Appropriate for the duties the personnel performs

GARBING AND HAND HYGIENE

Remove outer garments, i.e. coats, jackets, hats, scarves, sweaters, etc., and place in a designated area.

Don shoe covers, one at a time, placing the covered shoe on the clean side of a line of demarcation

Don head cover. Don facial hair cover if applicable

GARBING AND HAND HYGIENE

Don facemask.
Don eye shield if applicable.

Perform hand hygiene [wash] procedure.

Don a non-shedding gown with closed neck and elastic cuffs.

Apply waterless hand scrub.
Don sterile gloves.

(Optional)
Don protective sterile sleeves over lab coat sleeves.

GLOVING PROCEDURE

Clean fingernails under warm running water with a nail pick, then wet hands and forearms and wash with [*unscented*] soap and water for at least 30 seconds. Dry thoroughly using lint-free wipes.

Don a non-shedding gown with sleeves that fit snugly around wrists and neck.

USP<797>
"Before entering the buffer area, apply a suitable alcohol based handrub with sustained antimicrobial activity".

CA State Board of Pharmacy
"Hand cleansing with a persistently active alcohol-based product followed by donning of sterile gloves…"

Gloves are to be routinely disinfected with sterile 70% IPA.

- Every 30 minutes for continuous sterile compounding
- Between interventions

ASEPTIC TECHNIQUES BASICS

- Do not touch sterile product contact parts (needle, septum, etc.)
- Slow and deliberate movements in classified areas
- Minimize talking – No yelling
- Minimize interventions
- Sanitize gloves between interventions
- If an item falls on the floor, leave it there
- Maintain first air
  - Unidirectional HEPA filtered air free of particulate

DISINFECTING ISO 5 HOOD

- Spray and wipe surfaces in the following order (avoiding filter media):
  - Ceiling
  - Back Wall
  - Side Walls, IV bar and hooks
  - Equipment
  - Counter/Work Surface
- Wipe from top to bottom and back to front, include all sides and work surface
- Use overlapping strokes
- Change wipers when soiled

DISINFECTING ISO 5 CAI/PEC

- Spray and wipe surfaces of main chamber in the following order (avoiding filter media):
  - Ceiling
  - Back Wall
  - Side Walls, IV bar and hooks
  - Equipment
  - Counter/Work Surface
- Clean and disinfect antechamber in the same order.
- Wipe from top to bottom and back to front, include all sides and work surface
- Use overlapping strokes
- Change wipers when soiled

USING THE 2 BUCKET MOP SYSTEM

Small amount of active solution in the back bucket (enough to cover mop)

Active solution in the front bucket

USING THE 2 BUCKET MOP SYSTEM

- Dip the mop into the back bucket
- Wring the mop
- Dip the mop to the front bucket (active)
- Wring the mop
- Apply to appropriate surface [based on SOP] starting from top to bottom, back to front, (do not contact filters).
- Repeat
- Next stroke should overlap the first by approximately 2 inches
- Change mop if it contacts the floor when cleaning the wall.
- Keep surface wet for a minimum of 10 minutes

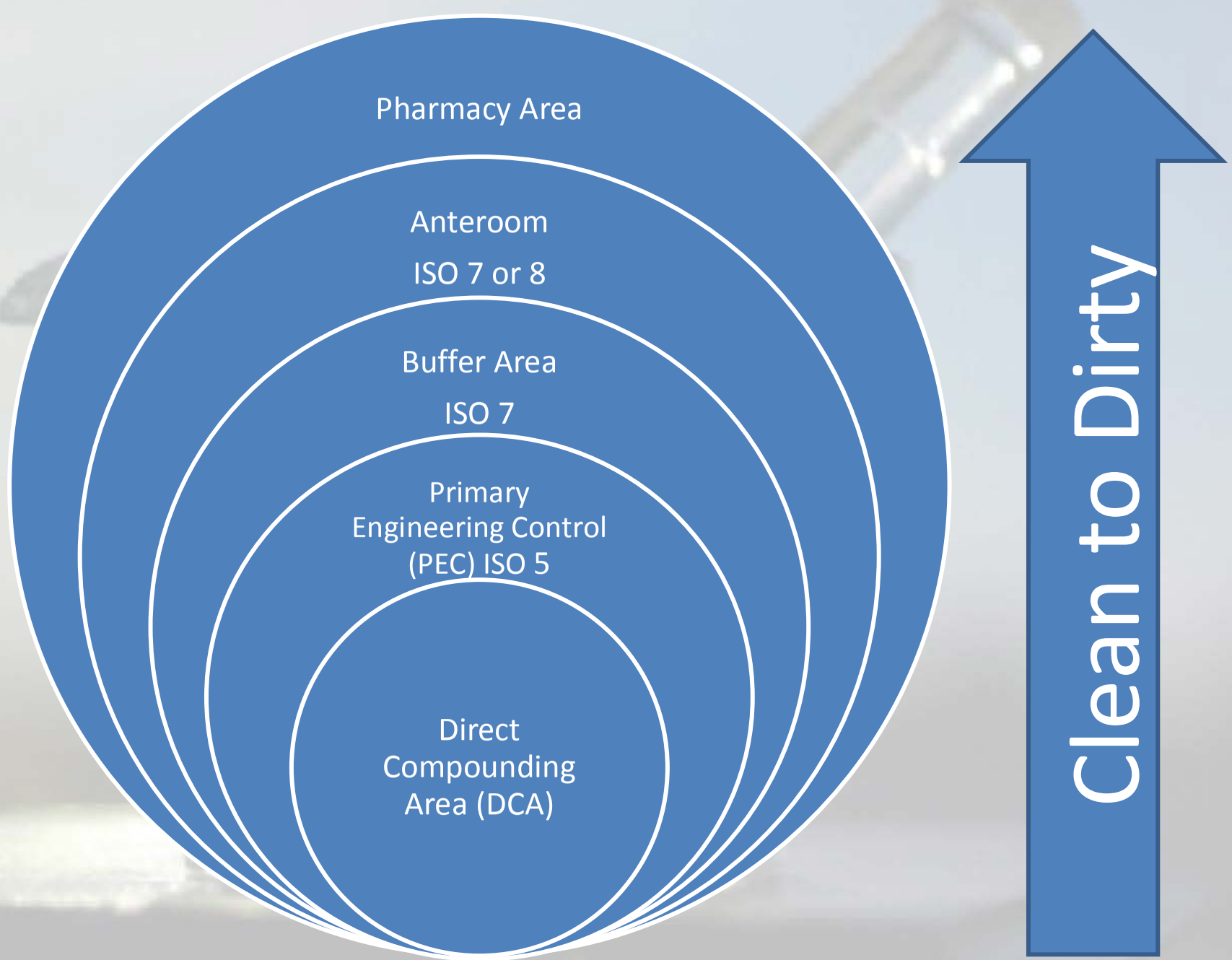
General Order of Disinfection

Start with "cleaner" areas and work your way to "dirtier" areas

- Disinfect Equipment (PEC's)
- Disinfect Ceilings
- Disinfect Walls
- Disinfect Floors
- Allow to Air Dry

All cleaning MUST be documented in the area cleaning log.

General Order of Disinfection



CLEANING VS DECONTAMINATION

"You can clean without decontaminating, however, you **can not** decontaminate without cleaning".

CLEANING VS DECONTAMINATION

VS

CLEANING VS DECONTAMINATION

CLEANING

- Removal of all foreign matter

DECONTAMINATION

- Involves the use of physical or chemical means to remove, inactivate, and destroy [pathogenic] microorganisms

What are Sanitizers, Disinfectants, & Sporicides?

Sanitizers

- Reduce some level of microbial contamination; least effective agents
- 10^3 reduction in vegetative cells
- Examples: Isopropyl Alcohol (70% IPA) and Denatured Ethyl Alcohol (70% EtOH)

Disinfectants

- Reduce higher levels of vegetative microorganisms than sanitizers depending on the strength and contact time
- 10^6 reduction in vegetative cells
- Examples: Phenolics, Quaternary Ammoniums

Sporicides

- Effective against all microorganisms provided the wetted contact time is achieved
- 10^6 reduction vegetative cells and spores - *General Sporicidal/Sterilant*
- Examples: Appropriate Concentrations of Sodium Hypochlorite, POAA, and Hydrogen Peroxide

OVERKILL?

Classified Area	Normal Action Level in cfu's
Grade A: Equipment/Filling Machines:	0-1
Grade A: Walls	1 to 3
Grade A: Floors	1 to 5
Grade A: Air	0-1
Grade B: Equipment	5 to 10
Grade B: Walls	10
Grade B: Floors	10 to 15
Grade B: Air	0-10
Grade C: Walls	25
Grade C: Floors	50
Grade D: Air	25 to 50

EPA Registration requires 60/60 carriers with no failures at 10x6

1,000,000 = 6 log

PEC CLEANING & DISINFECTING

Room Type/Surface	Minimum Frequency*	Method	Application	Product **
ISO 5 Primary Engineering Controls				
LAFW BSC CAI CACI	· Beginning of each shift	Spray & Wipe	Cleaning (Disinfecting) Disinfecting*	Germicidal Detergent Sterile 70% IPA
	· Before each batch · Every 30 minutes during compounding · When spills occur · When surface contamination is known/suspected	Spray & Wipe	Disinfecting*	Sterile 70% IPA
	Monthly or based in response to EM micro monitoring results	Spray & Wipe	Sporicidal	General Sporicide Or *C.Diff Spore ??* *** ***(not an EPA test organism for sporicidal claim)
	During use as required	Spray & Wipe		Sterile 70% IPA

* Always refer to site specific SOP's for cleaning and disinfection instructions.

** All cleaners, disinfectants, sporicidal products and wipes must be sterile in the ISO 5 Classified area.

ISO 7 & 8 CLEANING & DISINFECTING

Room Type/Surface	Minimum Frequency*	Method	Application	Product
ISO 7 & 8 - Buffer Area & Anteroom				
Counters, Work surfaces, door plates, handles, gowning benches	Daily	Wipe	Cleaning (Disinfect)	Germicidal detergent
Floors	Daily	Mop	Cleaning (Disinfect)	Germicidal detergent
	Monthly or quarterly based in response to EM micro monitoring results	Mop	Sporicidal	General Sporicidal Agent
Walls & Ceilings	Monthly	Mop	Cleaning (Disinfect)	Germicidal detergent
	Quarterly or yearly based in response to EM micro monitoring results	Mop	Sporicidal	General Sporicidal Agent
Storage Shelving	Monthly	Wipe	Cleaning (Disinfect)	Germicidal detergent
In-coming Supplies	As needed	Spray & Wipe	Disinfecting	Sterile 70%IPA *Or* other appropriate sterile product

* Always refer to site specific SOP's for cleaning and disinfection instructions.

DISINFECTANT CHOICES

Alcohols

No Residue	Poor Detergency
Broad Spectrum	Not Sporicidal
Evaporates Quickly	Limited Contact Time
EPA Registered (Some)	VOC Emissions
	Not all 70% IPA's are EPA registered

Phenolics

Broad Spectrum

Moderate Detergency

EPA Registered

Not Sporicidal

Heavy Residues

Slippery When Wet

Restricted Ingredients

Quaternary Ammonium (Quats)

Broad Spectrum

Good Detergency

Low Residue

EPA Registered

Not Sporicidal

Hydrogen Peroxide (H_2O_2)

Broad Spectrum	Poor Detergency
Sporicidal Activity	Not EPA Registered
No Residue	Exposure Limits [PEL]
Evaporates to H_20 and O_2	(depending on air exchanges)

Sodium Hypochlorite (Bleach)

Broad Spectrum

Sporicidal (0.52% and greater via efficacy testing)

Moderate Detergency

EPA Registered (Some)

$NaCl_2$ Salt Residue

Corrosivity Concerns

Unpleasant Odor

Hydrogen Peroxide/Peracetic Acid

Broad Spectrum	Poor Detergency
General Sporicide	Soft metal compatibility
Very low residue	Pungent Odor
EPA Registered	Exposure limits [PEL] (depending on air exchanges)

PERFECT DISINFECTANT

- Full spectrum of activity
- Rapid kill
- Easily prepared and soluble in water
- Stable
- Sterile
- Hard water and soil tolerant
- Environmental compatibility
- Non-corrosive
- No residues
- Economical
- Safe to use

PERFECT DISINFECTANT

- Full spectrum of activity
- Rapid kill
- Easily prepared and soluble in water
- Stable
- Sterile
- Hard water and soil tolerant
- Environmental compatibility
- Non-corrosive
- No residue
- Economical
- Safe to use

Does Not Exist

WHY USE A STERILE DISINFECTANT?

- Disinfectants do not kill all organisms
- May transfer organisms through disinfectants to the aseptic compounding areas
- Disinfectants are spread on ceilings, walls, and floors
- The concern is mainly for spores in the solution
- Packaging is a potential source of contamination.

IN-USE EXPIRATION

- Many variables are at play including:
  - Storage
  - Handling
  - Air traffic/movement
  - People traffic/movement

  → Sterility and efficacy

ROTATION OF DISINFECTANTS AND RESISTANCE

- Rotation is an applicable method and term used to address possible contamination that is not killed by the first disinfecting agent
- **Resistance does not mean (in disinfection):**
  - Developing an immunity to a disinfectant
- **Resistance means (in disinfection):**
  - An organism that was never destroyed by a chemical agent in the population tested
- Frequency of rotation from a Disinfectant to Sporicide should be based on your Environmental Monitoring Program Data

CA CR

Potential issues:

- Sterile water but no sterile germicidal detergent?
  - 503A's vs 503B's - Is there really a difference in CSP's?
- Which sporicide is being used?
  - C.Diff spore *disinfectant* in rotation is inappropriate
  - <10 minute dwell time at room temperature?
- Non-sterile wipes for use inside the PEC's
  - For obvious reasons

throughout the assigned expiry period. Investigators collected a sample of unused wipes, intended for use in disinfecting the aseptic processing areas, from within your cleanroom for testing. Testing results of the sample identified microbial contamination, including spore-forming bacteria.

https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm544740.htm

FDA EXPECTATIONS

What about 503A exemptions relative to cGMP?

"Compounded drugs that meet the conditions of section 503A are still subject to the other public health protections in the FD&C Act, such as the prohibition on insanitary conditions."*

* US FOOD & DRUG ADMINISTRATION
FDA's Human Drug Compounding Progress Report:
Three Years After Enactment of the Drug Quality and Security Act
January 2017
www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding.ucm536549.pdf

FDA EXPECTATIONS

Insanitary Conditions at Compounding Facilities

Guidance for Industry

August 2016

- Examples of Insanitary Conditions
  - Insanitary Conditions Applicable to the Production of Sterile and/or Non Sterile Drugs.
  - Insanitary Conditions in a Sterile Operation
    - Aseptic Practices
    - Equipment / Facilities
    - Sterilization
    - Cleaning and Disinfecting
- Identifying Insanitary Conditions
- Corrective Actions
- Regulatory Action

www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

FDA EXPECTATIONS

Insanitary Conditions at Compounding Facilities

Guidance for Industry

August 2016

Cleaning and Disinfecting

- Use of sterile disinfecting agents, wipes, and pads in the aseptic processing areas.
- Proper & frequent use of a sporicidal agent in the facilities cleanrooms and ISO 5 area.
- Disinfection of equipment & supplies entering each of the classified areas.
- Sufficient disinfectant contact time.

QUESTIONS?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