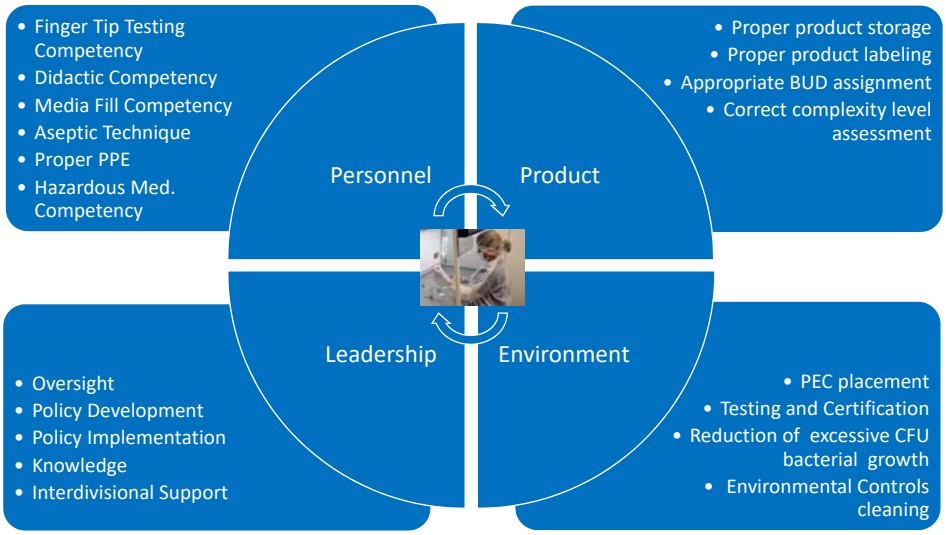
Medication Management Update

Medication Compounding

USP Delay

- USP 795 and 797 appeal process
- USP 800 is informational only until revisions are finalized and go into effect
- Timeline is uncertain
- The Joint Commission will continue to evaluate compliance with the current chapter 797

Medication Compounding



Medication Compounding

Environment

Compounding: Environment

Jan 1 2018 – December 31, 2018

LIKELIHOOD TO HARM PATIENT/STAFF/VISITOR	LIMITED	PATTERN	WIDESPREAD	
Immediate Threat to Life 0.51%				
HIGH	2.43%	4.54%	5.56%	12.53%
MODERATE	26.21%	21.23%	7.99%	55.43%
LOW	20.40%	9.08%	2.05%	31.52%
	49.04%	34.85%	15.60%	

SCOPE

Jan 1 2019 – June 30, 2019

	LIMITED	PATTERN	WIDESPREAD	
Immediate Threat to Life 0.26%				
HIGH	3.22%	5.41%	5.93%	14.56
MODERATE	26.42%	19.85%	10.05%	56.31%
LOW	18.17%	8.25%	2.45%	28.87%
	47.81%	33.51%	18.43%	

SCOPE

Segregated Compounding Area (SCA)

- Must have designated perimeter
- Must be located away from
  - Unsealed windows
  - Doors that connect to the outdoors
  - Traffic flow
  - Must not be located adjacent to
    - Restrooms
    - Food preparation areas
    - Warehouses
  - Restricted to Category 1 Products

Compounding Suite

- Free standing dehumidifiers, heaters, coolers are prohibited
- Must have fixed walls and doors
- HEPA filters must be installed in the ceiling of the suite
- Must have a pressure differential monitoring device installed
  - Daily documentation is required when compounding is occurring
- Category 2 Products

Testing and Certification of Controlled Areas and PEC

- **Airflow testing:** Airflow testing is performed to determine acceptability of the air velocity and volume, the air exchange rate, and the room pressure differential in doorways between adjacent rooms to ensure consistent airflow and that the appropriate quality of air is maintained under dynamic conditions.
- **HEPA filter integrity testing:** HEPA filters must be leak tested at the factory and then leak tested again after installation and as part of recertification.
- **Total particle count testing**: ISO Level
- **Dynamic airflow smoke pattern test**: to demonstrate unidirectional airflow

Viable Sampling

- The microbiological air and surface monitoring program must be clearly described in the facility's SOPs, which must include:
  - a diagram of the sampling locations
  - procedures for collecting samples
  - frequency of sampling
  - size of samples
  - time of day of sampling in relation to activities in the compounding area
  - action levels that will trigger corrective action.

Viable Sampling

- Air Sampling
  - Completed every 6 months
  - Must be conducted during dynamic conditions
- Surface Sampling
  - Completed monthly
  - Must occur at the end of compounding activities
  - Prior to the cleaning of the area
- Actional planning to results

Agents

Type of agent	Description
Cleaning	An agent used for the removal of residues (e.g., dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
Disinfectant	A chemical or physical agent used on inanimate surfaces and objects to destroy fungi, viruses, and bacteria.
Sporicidal	A chemical or physical agent that destroys bacterial and fungal spores when used at a sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms.

Cleaning engineering controls (including SCA)

Location	Cleaning	Disinfecting	Sporicidal Agent
PEC and interior	Daily and when contaminated Under work tray monthly	Daily and when contaminated Under work tray monthly	Monthly Under work tray monthly
• Pass through • Work surface outside PEC • Floors	Daily	Daily	Monthly
• Walls • Doors (inc frames) • Ceilings • Shelving	Monthly	Monthly	monthly

Medication Compounding

Personnel

Compounding: Personnel

Jan 1 2018 – December 31, 2018

LIKELIHOOD TO HARM PATIENT/STAFF/VISITOR	LIMITED	PATTERN	WIDESPREAD	
	Immediate Threat to Life 1.68%			
HIGH	2.68%	2.97%	4.06%	9.71%
MODERATE	17.24%	15.36%	6.74%	39.35%
LOW	34.19%	13.28%	1.78%	49.26%
	54.11%	31.62%	12.59%	

SCOPE

Jan 1 2019 – June 30, 2019

	LIMITED	PATTERN	WIDESPREAD	
	Immediate Threat to Life 1.55%			
HIGH	1.77%	4.42%	4.86%	11.04%
MODERATE	22.08%	13.69%	5.96%	41.72%
LOW	33.33%	9.27%	3.09	45.70%
	57.17%	27.37%	13.91%	

SCOPE

Competency Changes

- Competency must be demonstrated every 12 months in at least the following:
  - Hand hygiene
  - Garbing
  - Cleaning and disinfection
  - Calculations, measuring, and mixing
  - Aseptic technique
  - Achieving and/or maintaining sterility and apyrogenicity
  - Use of equipment
  - Documentation of the compounding process (e.g., master formulation and compounding records)
  - Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 area
  - Proper use of primary engineering controls (PECs)
  - Principles of movement of materials and personnel within the compounding area

Revalidation Processes

- Shall be completed every 6 months
  - Media Fill Test
  - Gloved fingertip testing
  - Validation of hand hygiene processes
  - Validation of garbing processes

Medication Compounding

Products

Compounding: Products

Jan 1 2018 – December 31, 2018

LIKELIHOOD TO HARM PATIENT/STAFF/VISITOR	LIMITED	PATTERN	WIDESPREAD	
	Immediate Threat to Life 0.54%			
HIGH	0.81%	1.63%	0.54%	2.98%
MODERATE	20.87%	22.22%	3.52%	46.61%
LOW	33.88%	12.20%	3.79	49.86%
	55.56%	36.04%	7.86%	

SCOPE

Jan 1 2019 – June 30, 2019

	LIMITED	PATTERN	WIDESPREAD	
	Immediate Threat to Life 0%			
HIGH	0%	1.52%	2.27%	3.79%
MODERATE	21.97%	18.18%	5.3%	45.45%
LOW	28.03%	18.18%	4.55%	50.76%
	50%	37.88%	12.12%	

SCOPE

Category Modification

- Current
  - **Low Risk Compounding**
    - Based on number of containers/products
  - **Medium Risk Compounding**
    - Based on number of containers/products
  - **High Risk Compounding**
    - Product/utensils are non-sterile
- Future
  - **Category 1**
    - Conducted in a segregated compounding area
  - **Category 2**
    - Conducted in a compounding suite
    - Non sterile product

Assigning Beyond Use Dates

Category 1 Compounded Sterile Products	
Stored at Room Temperature	≤ 12 hours
Stored in Refrigeration	24 hours

Assigning Beyond Use Dates

Starting with Sterile Products

Compounding Method	Sterility Testing	Controlled Room Temperature	Refrigeration	Frozen
Aseptically Processed	No	4 days	10 days	45 days
	Yes	30 days	45 days	60 days
Terminally Sterilized	No	14 days	28 days	45 days
	Yes	45 days	60 days	90 days

Medication Compounding

Leadership

Leadership Implementation

- Must establish a designated person who shall:
  - Develop and oversee competencies
  - Review testing and certification
  - Develop policies and procedures
  - Oversee documentation

USP 800: Hazardous Medication Handling

Where to start

- Organizations should completed a risk assessment to determine
  - The NIOSH category medications utilized
  - The degree of manipulation performed on products
- Don't forget a process for monitoring variation if processes/products based on medication shortages

Hazardous product designation

- Must utilize the NIOSH listing
- Local list must be evaluated every 12 months
- As new medications are added to formulary must be evaluated

NIOSH Categories

- NIOSH Group 1
  - Antineoplastic agents
- Cannot risk assess out of requirements listed in USP Chapter for receiving, compounding and storage.
- NIOSH Group 2
  - Non-antineoplastic hazardous drugs
- NIOSH Group 3
  - Drug with reproductive effects
- Level of implementation determined by organizations risk assessment

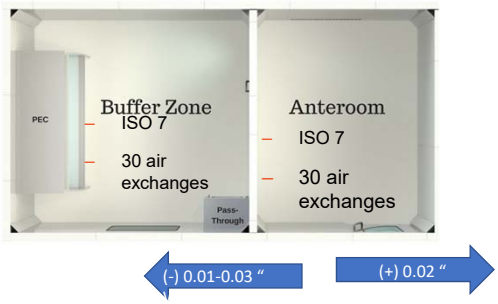
Environment

- Sterile and Non-Sterile preparations must be prepared in a physically separate space with fixed walls and doors
  - Including C-SCA
- Must have negative pressure 0.01-0.03 " water column
  - Including C-SCA
- PEC and SEC must be externally vented
  - Including C-SCA
- Must have adequate air exchanges
  - Classified = 30 ACPH
  - C-SCA= 12 ACPH

Contained Segregated Compounding Area (C-SCA)

- must have fixed walls and doors
- Must have negative pressure continuously monitored
  - -0.01 to -0.03 " water column
  - 12 ACPH
  - Vented externally

Compounding Suite



- Free standing dehumidifiers, heaters, coolers are prohibited
- Must have fixed walls and doors
- HEPA filters must be installed in the ceiling of the suite
- Must have a pressure differential monitoring device installed

PPE Requirements

- Gloves
  - must be ASTM D6978
- Gowns
  - must close in back and long sleeved with cuffed wrists
  - must be changed based on instruction for use
- Shoe covers
  - must be doubled when entering the C-SEC and external pair removed upon leaving the C-SEC

Key Takeaways

- Competency assessments are now specific and detailed with enhanced documentation requirements
- Construction may or may not be necessary in non hazardous compounding
- Organizations should start with a risk assessment of hazardous medications prior to making construction changes or process changes

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