

Sterile Compounding: Findings and Lessons Learned

Maddison Mickle & Ruth Aminu

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Speakers

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Maddison Mickle, MPH, CIC, LSSGB

- She is a Senior Infection Preventionist at JPS Health Network in Fort Worth, Texas. Education includes earning a Bachelor of Science in Microbiology from Texas State University in San Marcos, Texas, and a Masters of Public Health degree from Texas Tech University Health Sciences Center in Lubbock, Texas. Maddison has spent the last 3 years working as an infection preventionist, with a focus on pharmacy, as it relates to antimicrobial stewardship and USP standards. Her additional interests include CAUTI and CLABSI Prevention, collaboration with behavioral health and correctional health, prevention of surgical site infections, and construction projects and renovation.



Speakers

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Ruth Aminu, PharmD, MBA, LSSYB

- Ruth Aminu, PharmD, MBA, LSSYB is a Medication Safety Officer at JPS Health Network in Fort Worth, Texas. Upon completion of her PharmD degree at Ohio Northern University, she completed a residency in Health System Administration at Parkland Health and Hospital System. She works closely with pharmacy leadership to ensure medication management practices result in safe and efficient care for JPS patients. She also works with nursing leadership, infection prevention, other ancillary services, the quality department, and executive leadership to ensure a multidisciplinary approach is employed in fulfilling her role.



Relevant Financial Disclosures

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- None of the faculty or planners for this activity have relevant financial relationship(s) to disclose with ineligible companies whose primary business is producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients



Learning Objectives

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1. Understand the importance of evaluating current USP standards to ensure a sterile environment is maintained.
2. Describe the implementation of a collaborative multidisciplinary approach through the development of education, training, competency, and compliance monitoring.
3. Develop a systematic way of ensuring environmental quality standards are met.



*FY 2022

Revenue



- Patient Revenue | 37%
- Property Taxes | 37%
- Federal & State Programs | 17%
- Retail Pharmacy | 6%
- Others | 3%



Patient Encounters

| | |
|--|--------------------------------------|
| 578,710 Community Health Visits | 18,617 Psych Emergency Visits |
| 176,243 Hospital Patient Days | 14,417 Total Surgeries |
| 125,812 Total Emergency Visits | 4,093 Babies Born |
| 39,973 Urgent Care Visits | 206 Languages Translated |
| 26,188 Geriatric Patients | |



A hospital licensed for **582 beds** and **25+ clinics** across Tarrant County



A **Level I Trauma Center** and **psychiatry emergency center**



19 residencies and fellowships with the largest **hospital-based family medicine residency program** in the nation



A **Level III Neonatal** and **Level IV Maternal** Facility for exceptional women and infants services



Designated by ANCC as a **Pathway to Excellence®** organization



Certified in **stroke, heart attack, sepsis, and delirium care**



115 volunteers served 9,000+ patients (4,600+ hours total)



JPS Health Network
Fort Worth, Texas

Introduction

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What is sterile compounding?

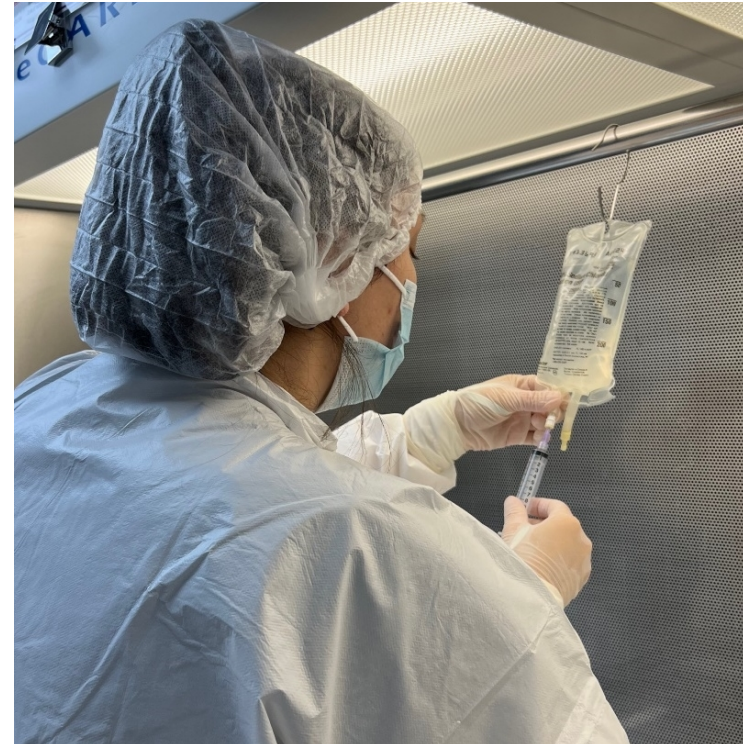
- Definition: The preparation of medication, in an environment free from potentially infectious microorganisms

What is the importance?

Preventing Contamination

Intrinsic

Extrinsic



United States Pharmacopeia (USP) 797

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General Overview

Definition: USP 797 is utilized to describe conditions and practices that prevent harm to patients that could result from contamination.

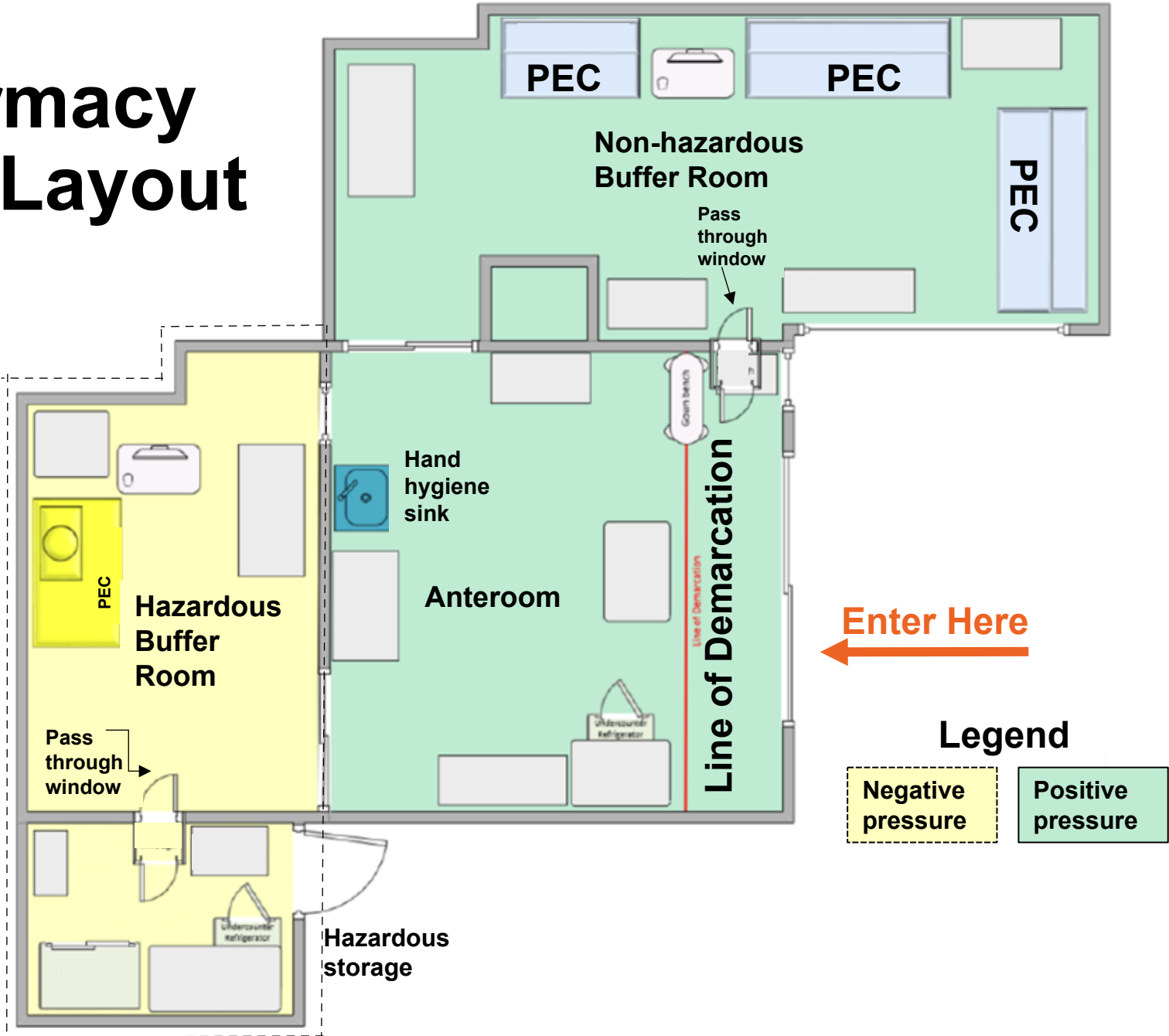


USP – United States Pharmacopeia
FDA – Food and Drug Administration
BOP – Board of Pharmacy



JPS Pharmacy IV Room Layout

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*PEC – Primary Engineering Control



Key Components

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Requirements for Personnel and Environment

Required for Personnel

- Audio/video and professional training
- Didactic test
- Gloved fingertip
- Media fill



Environmental sampling requirements

| ISO Class | Air Sample (cfu/m ³) | |
|-----------|----------------------------------|----------------------------|
| 5 | > 1 | |
| 7 | > 10 | |
| 8 | > 100 | |
| ISO Class | Fingertip Sample | Surface Sample (cfu/plate) |
| 5 | > 3 | > 3 |
| 7 | NA | > 5 |
| 8 | NA | > 50 |

Key Components

PPE and Cleaning Requirements

- Required PPE
- Cleaning requirements

| Site | Minimum Frequency |
|--|-------------------|
| Counter and easily cleanable work surfaces | Daily |
| Floors | Daily |
| Walls | Monthly |
| Ceilings | Monthly |
| Storage shelving | Monthly |



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Garbing process Non-Hazardous Buffer Room

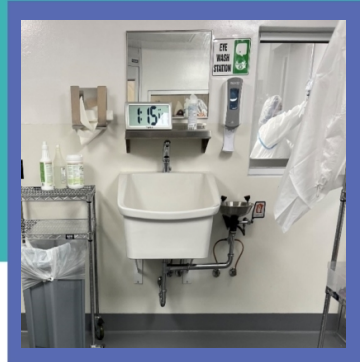
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1



- A. Personal outer garments
- B. Cosmetics and jewelry
- C. Nails
- D. Shoe covers, head and facial hair covers, and face masks/eye protection

2



- E. Hand hygiene
- F. Nail cleaner
- G. Lint free disposable towel

3



- H. Non-shedding gown

4



- I. Alcohol-based hand rub
- J. Sterile gloves

Mock Survey Findings 2020

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Infection Prevention

| | Finding |
|---|---|
| 1 | Items failed to be disinfected . |
| 2 | A pharmacist stayed behind the line of demarcation and opened the door of the buffer area ungloved to send medication labels into the room. |
| 3 | The team member donned shoe covers on the "dirty" side of the anteroom. |
| 4 | One sample was cultured over 72 hours and on another record, a different sample was cultured over 4 days. The team was not certain, at what temperature the surface sample is cultured in the laboratory department. |



Mock Survey Findings 2020

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Infection Control

| | Finding |
|---|---|
| 5 | The viable sample was listed as "unquantifiable" and reported as "spready bacillus." It was stated that there were potential contaminants in the testing process . The negative controls demonstrated "no growth." |
| 6 | Staff unable to speak to Contact time was for disinfectants and sporicidal agents. |
| 7 | Single-use sterile alcohol wipe across multiple ports/vial tops . |
| 8 | Dust and debris was found on the floors. Staff could not speak to daily floor cleaning and disinfection . |



Mock Survey Findings 2020

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Medication Management

| | Finding |
|---|---|
| 1 | In the sterile preparation area, medications were stored on the ledge adjacent to the wall of the buffer room. |
| 2 | In the negative pressure buffer room the temperature of the space was 19.7 C . A review of the medication stored demonstrated that Abraxane should be store 20-25C . |
| 3 | In the primary engineering control, a large volume bag of sterile water , used for medication reconstitution, was found with a 24-hour expiration date. |
| 4 | A review of the Master Formulation Record for "NICU Hydrocortisone 1 mg/mL IV Syringe" demonstrated an assigned beyond use date of 7 days at room temperature. |



Mock Survey Findings 2020

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Medication Management

| | Finding |
|---|---|
| 5 | Team member preparing the medication did not disinfect the ports prior to entry. |
| 6 | Team member placed hands in a manner that blocks first air to critical points in the vertical biologic safety cabinets. |
| 7 | Team member did not know the distance within the primary engineering control items must be placed. |
| 8 | The team member did not know how to assess compounding risk associated with sterile compounding: low, medium, and high. |



Audience Question

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Type in the chat box or Discuss with your neighbor:

Based on the listed mock survey findings, what would be your first step to decrease the risk of an accreditation citing?



Methods to Address Findings

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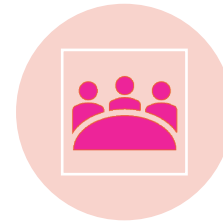
6 key components



EXTERNAL
CONSULTANTS



MULTIDISCIPLINARY
TEAMS



ESTABLISHED
WORKGROUP



ELECTRONIC FILES



NEW CERTIFICATION
COMPANY



TRACER
DEVELOPMENT



Methods to Address Findings

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External Consultants



Fresh set of eyes



Check list of high priority areas



Accountability



Shared priority with executive leaders



Methods to Address Findings

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Multidisciplinary team

Pharmacy
Leadership

C-Suite

Infection
Prevention

Facilities

Environmental
Services



Methods to Address Findings

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Established Workgroup

- Twice weekly meetings
- Action Plans
 - Personnel Training & Evaluation
 - Engineering Controls
 - Hazardous Drugs
 - Environmental Quality & Control
- Tech leads
- Construction Team

| DESCRIPTION | RECOMMENDATION | SUGGESTED RESOURCES | ITEM DESCRIPTION | PRICE PER UNIT QUOTE | RESPONSIBLE PARTY | DISTRIBUTION |
|---|---|--|---|----------------------|-------------------------------|--|
| The LAFW diffuser screen of the Naikite LAFW is excessively scratched by the IV bar baskets holding IV bag seals which may release metal shavings (of the diffuser screen) into the ISO Class 5 environment and may be considered an insitary condition by the FDA. | Replace the Naikite diffuser screen and remove IV bar baskets from the ISO-5 environment. | Need no longer rec. by FDA due to formica. Will replace with a baker egi232 which comes with diffuser panel. | Baker Edgardard EG5232 (6 foot batching hood) | \$ 3,838.55 | Drug Chung - capital purchase | Failed HEPA filter. Beyond its usable age. Contains particle board which is no longer recommended by the FDA |
| The older Baker 8-foot model LAFW present in the buffer room is known to have turbulent airflow at the work surface of the unit due to a lip at the back of the work surface caused by the older style diffuser. Baker Company has a retro fitted diffuser screen designed to remedy the issue available for purchase. The retro fitted new diffuser screen is appropriately installed in the Baker 8-foot model located next to the 8-Foot LAFW. | Install a baker pharmacy-style diffuser screen on the Baker 804232 to supply "First Air" on the work surface. | Baker company diffuser screen. Moving forward with purchasing. | | \$ | TRB 00 Amber marlee | Completed 3/7/21 |
| Main Total | | | | \$ 988.55 | | |

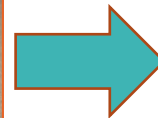
| DESCRIPTION | RECOMMENDATION | SUGGESTED RESOURCES | ITEM DESCRIPTION | PRICE PER UNIT QUOTE | RESPONSIBLE PARTY | DISTRIBUTION |
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| The LAFW diffuser screen of the Naikite LAFW is excessively scratched by the IV bar baskets holding IV bag seals which may release metal shavings (of the diffuser screen) into the ISO Class 5 environment and may be considered an insitary condition by the FDA. | Replace the Naikite diffuser screen and remove IV bar baskets from the ISO-5 environment. | Need no longer rec. by FDA due to formica. Will replace with a baker egi232 which comes with diffuser panel. | Baker Edgardard EG5232 (6 ft batching hood) Quote#-41828A | \$ 9,816.55 | Drug Chung - capital purchase | Failed HEPA filter. Beyond its usable age. Contains particle board which is no longer recommended by the FDA |
| The Baker ED-4232 LAFW surfaces display the presence of rust that may be considered an insitary condition. | If possible, repair all surface deterioration and evaluate the presence of rust and delots of the LAFW. If rust cannot be adequately removed without further damage to the LAFW, replace LAFW with similar model. | | Edgardard ED-4232 (4 ft home health hood) Quote#-41879 | \$ 8,309.53 | Drug Chung - capital purchase | There is rust on the equipment used it is aged. Contains particle board which is no longer recommended by the FDA |
| The nonoperational BSC has a custom exhaust connection fashioned on top of the unit used to integrate the exhaust duct work together. The facility had challenges with installation of the duct work to the original manufacturers BSC connection aligning and customized this connection. | WCO recommends the removal of Class B Type A2 BSCs for energy use savings and ease of integration into the facility. See "Alternative BSC Considerations" section at the end of the report for more detailed information. | Procure new Baker A2 BSC hood. Amber Hardee to get quote for 6 foot replacement | Sterigard 48483 (18 ft A2 BSC) Quote#-41877 | \$ 12,048.48 | Drug Chung - capital purchase | Existing hoods require individual exhaust stack. Cost for second exhaust stack is \$80,000. A2 hoods consume considerably less energy and can both utilize the same exhausting exhaust stack. This will net a \$65,000 cost avoidance. |
| The nonoperational BSC has a custom exhaust connection fashioned on top of the unit used to integrate the exhaust duct work together. The facility had challenges with installation of the duct work to the original manufacturers BSC connection aligning and customized this connection. | WCO recommends the removal of Class B Type A2 BSCs for energy use savings and ease of integration into the facility. See "Alternative BSC Considerations" section at the end of the report for more detailed information. | Procure new Baker A2 BSC hood. Amber Hardee to get quote for 6 foot replacement | Sterigard 094E3 (18 ft A2 BSC) Quote#-41879 | \$ 13,861.65 | Drug Chung - capital purchase | Existing hoods require individual exhaust stack. Cost for second exhaust stack is \$80,000. A2 hoods consume considerably less energy and can both utilize the same exhausting exhaust stack. This will net a \$65,000 cost avoidance. |
| Main Total | | | | \$ 13,861.65 | | |

Methods to Address Findings

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Electronic Files

- 15 FT/3PT/2PRN tech positions
- Difficult to keep up-to-date
- Shared folder with standard formatting
- Certifications
- Initial Competencies
- 3 years



| Name |
|------------------------------|
| 1. Current Job Description |
| 2. Confidentiality Agreement |
| 3. Certifications |
| 4. Competencies - 3 years |
| 5. Department Checklist |
| 6. Initial Competencies |
| 7. Education Documentation |



Methods to Address Findings

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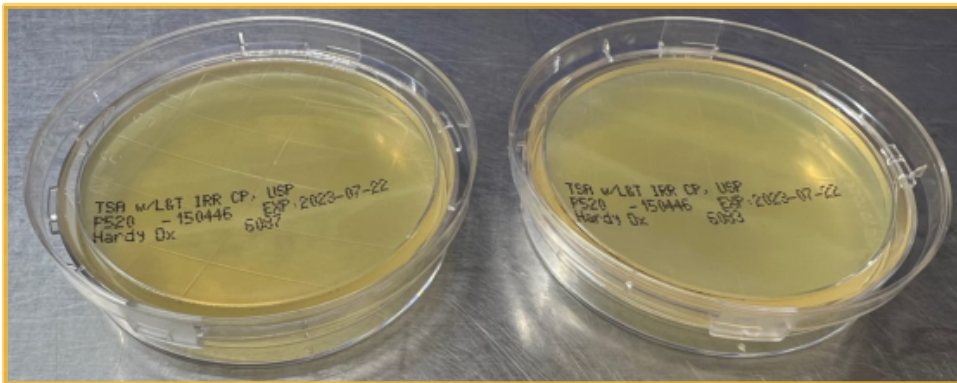
Certification Company

Old Company

- Gaps in reports
- Difficult to navigate
- Lack of urgency

New Company

- Appropriately trained staff (NSF/ANSI 49 N-5 Field Certification)
- Surface Sampling kits
- Comprehensive reporting
- Dedicated field technician and customer service rep



Methods to Address Findings

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Tracer implementation



| Questions (* = Required) | |
|--|------------------------------|
| Competencies | |
| 1. Did compounding staff complete the three (3) initial glove fingertip tests? | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |
| 2. Do compounding staff have media fill tests completed? | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |
| 3. Has the pharmacy established a passing level of the didactic test? | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |
| 4. Has the compounding staff demonstrated appropriate donning of Personal Protective Equipment (PPE)? | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |
| 5. Has the staff demonstrated hand washing competency? | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |
| 6. Do compounding staff have semi-annual surface sampling test? | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |
| Evaluation of Environment | |
| 7. Walls smooth without cracks? Absence of ledge where flooring meets walls? | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |
| 8. Floor covering solid with coved corners to prevent 90-degree angles where floor meets wall (check for dust)? No rips, tears, cracks, holes? | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |
| 9. PEC placed in an area with ISO 7 or less? If not, then only 12-hour beyond use date (BUD) | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |
| 10. Are all walls and ceilings cleaned at least monthly within the compounding environment? | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |
| 11. Single dose vials are discarded after 6 hours or less if stated by the manufacturer from initial puncture if kept in the ISO 5 environment, and one hour if it is removed from the compounding room? | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |
| 12. Do sterile water bags used for compounding have an appropriate expiration date on the bag? | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |
| 13. No high dust is present and air vents are free of dust. Storage bins and drawers are free from dust and debris. | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |

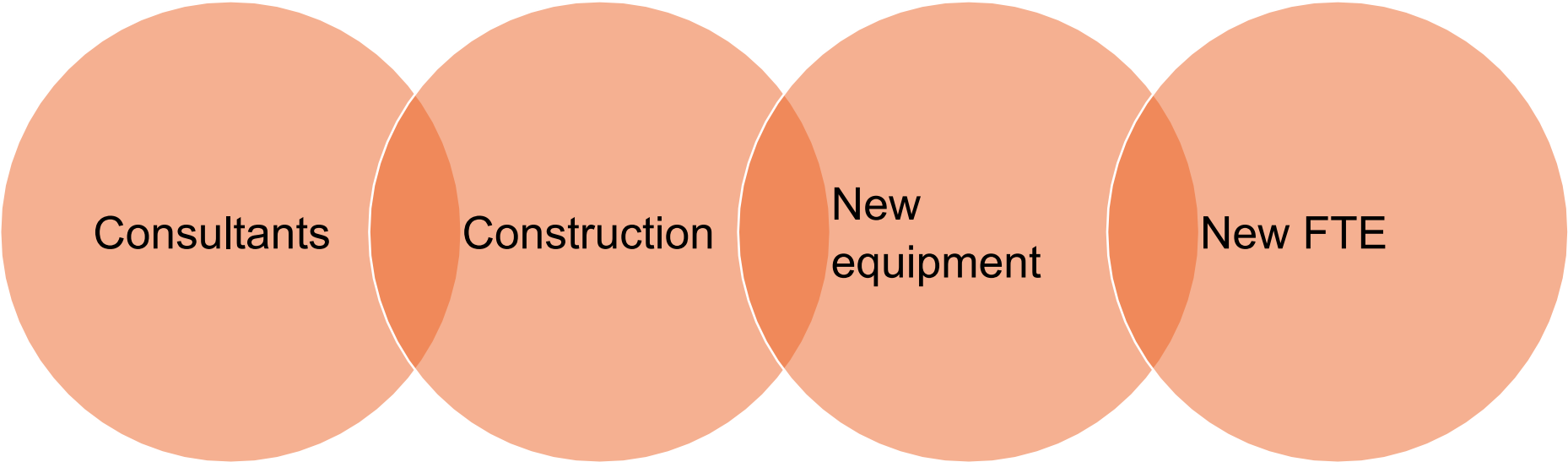


| | |
|--|------------------------------|
| 14. Floors, countertops, cabinets, walls and ceiling are clean, free of dust and free of damage. Walls, doors and patient care equipment is free of tape/paper signs? | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |
| 15. Disinfectant products are present, used appropriately, not expired and staff can speak to wet times. | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |
| 16. No expired items are present. Supplies are rotated on a first-in first-out basis. | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |
| Sterile Compounding Direct Observation | |
| 17. Has the staff demonstrated proper hand hygiene? | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |
| 18. The compounding staff demonstrated appropriate donning procedure of Personal Protective Equipment (PPE) | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |
| 19. Staff with upper respiratory infections or skin conditions that cause sloughing of skin (such as sunburn, dandruff, eczema) do not work in the IV room. | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |
| 20. Are the staff performing compounding not wearing any make-up, jewelry, ear buds, artificial nails etc.? | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |
| 21. Syringes, needles and tubing remain in their individual packaging and only opened in ISO Class 5 work area? | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |
| 22. Components/vials disinfected with sterile alcohol as they enter compounding hood? | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |
| 23. Items placed 6 inches from all sides of the hood, including the front? | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |
| 24. The following critical sites are never touched: any part of the needle; septum of the vial, sides of the plunger of syringe? | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |
| 25. Disinfects stoppers, injection ports, and ampule necks by wiping the sterile alcohol and allows sufficient time to dry? | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |
| 26. Compounder glove cleaning with sterile alcohol performed any time hands leave ISO 5? | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |
| 27. Can staff appropriately speak to how to disinfectant the hood? | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |
| Hazardous Compounding | |
| 28. What is the required PPE for hazardous compounding? | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |
| Beyond Use Dating (BUD) | |
| 29. Does the pharmacy correctly use Beyond Use Date (BUD) defined as the date or time after which a compounded sterile preparation shall not be stored or transported? | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |
| Miscellaneous | |
| 30. Select N/A for this question. In the notes section please list any other findings not captured from the above questions. | <input type="checkbox"/> N/A |
| Compliant? <input type="radio"/> Yes <input type="radio"/> No | Num: _____ Den: _____ |



Challenges

Resources



Successes

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Results of methods

Zero accreditation survey findings 2021

Education and training

- More frequent training and testing
- Annual to semi-annual testing

FTE – Sterile Compounding Coordinator

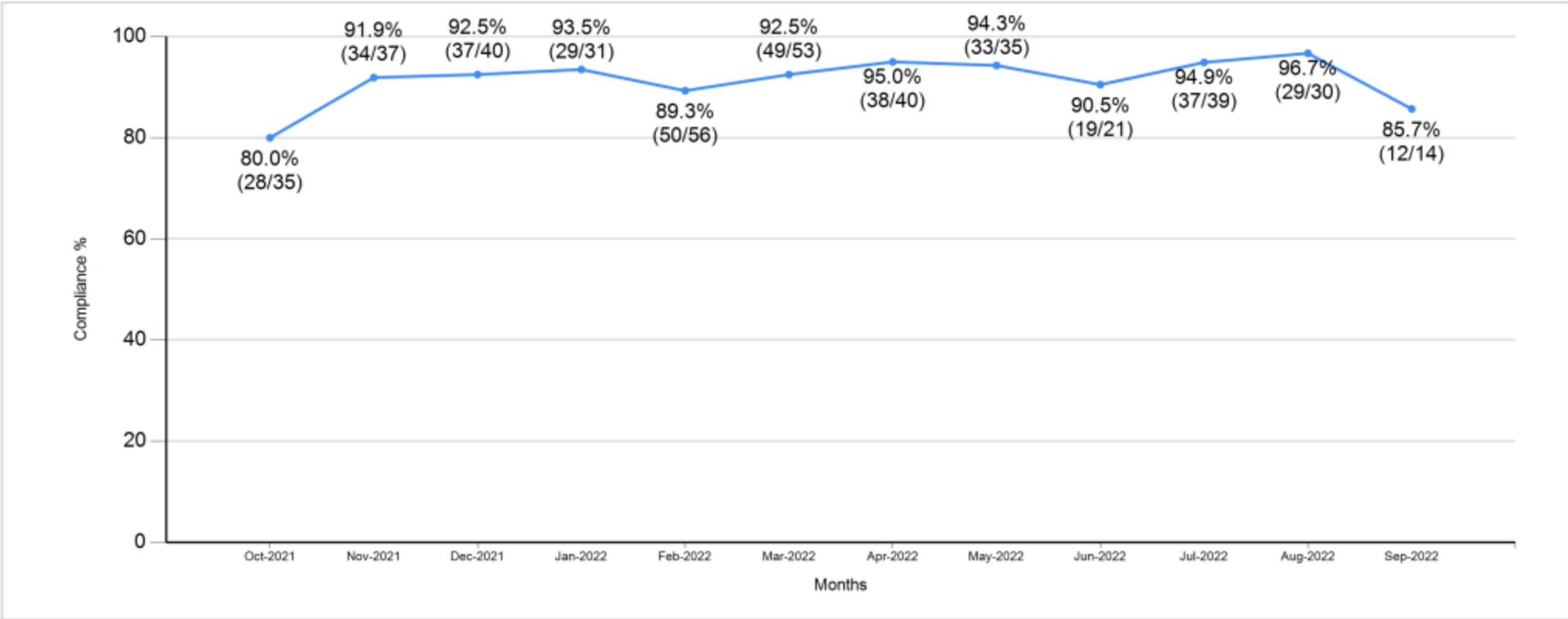
- Organizational Structure

Sustainability

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Infection Prevention Compliance Monitoring









Total Compliance: 91.6%



Sustainability

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Infection Prevention Compliance Monitoring

| Question | Total Num | Total Den | Overall Comp % | |
|---|-----------|-----------|----------------|---|
| Floors, countertops, cabinets, walls and ceiling are clean, free of dust and free of damage. Walls, doors and patient care equipment is free of tape/paper signs? | 3 | 10 | 30% |  |
| No high dust is present and air vents are free of dust. Storage bins and drawers are free from dust and debris. | 7 | 11 | 64% |  |
| Compounder glove cleaning with sterile alcohol performed any time hands leave ISO 5? | 7 | 9 | 78% |  |
| Disinfectant products are present, used appropriately, not expired and staff can speak to wet times. | 9 | 11 | 82% |  |
| Walls smooth without cracks? Absence of ledge where flooring meets walls? | 9 | 11 | 82% |  |
| Has the pharmacy established a passing level of the didactic test? | 7 | 8 | 88% |  |
| Has the staff demonstrated proper hand hygiene? Note: Handwashing must occur to elbows for a minimum of 30 seconds | 7 | 8 | 88% |  |
| Are the staff performing compounding not wearing any make-up, jewelry, ear buds, artificial nails etc.? | 10 | 11 | 91% |  |



Sustainability

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Compounding 360



QC Templates Locations Shifts QC Schedules QC Alerts Views

Reference Materials

Daily Floor Cleaning - Hazardous Buffer Room

Description: Floors cleaned according to policy

Assessment Steps:

Information Resource:

Author Notes:

Form Type: Log

Tags: Cleaning

Links:

Review

Review Criteria Detail

Answer (Yes or No)

Hazardous Buffer Room Mop/Mop handles are cleaned and disinfected prior to use and after use with Peridox-RTU

No Yes

Hazardous Buffer Room Floors are cleaned at a time when no aseptic operations are in progress

No Yes

Hazardous Buffer Room cleaned with Peridox-RTU (with a 3 minute contact time)

No Yes

Hazardous Buffer Room Floors are checked for any stickers or sticky residue

No Yes



Next Steps

Remain up-to-date with USP

- USP 797 2022 Gap Analysis
- ASHP Resource Center
- New changes take into effect in November 2023

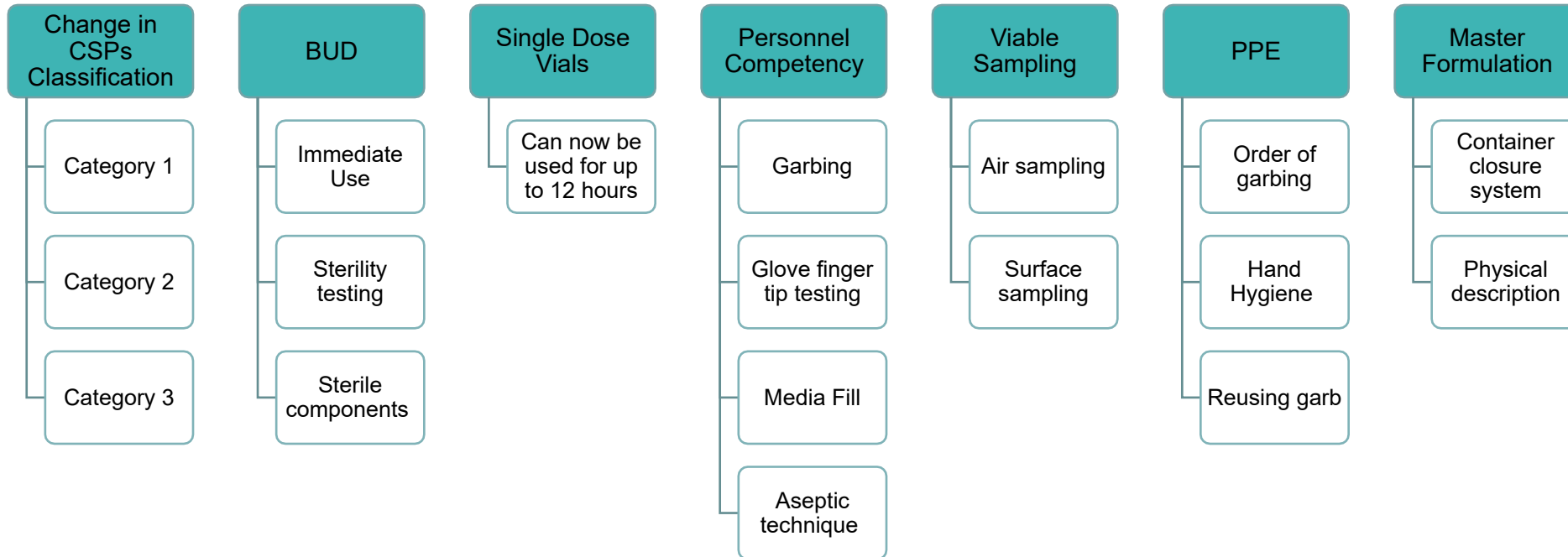
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Next Steps

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Changes within USP



Key Takeaways

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USP
Standards

Stay up-to-date with USP standards

Collaborative
approach

Ensure that all key stakeholders are present.

Environmental
standards

Implement a standard process to ensure all environmental quality standards are met

Acknowledgements



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References



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- Pharmaceutical Compounding – Sterile Preparations | USP. (n.d.-b). <https://www.usp.org/compounding/general-chapter-797>
- Recognition of USP Compounding Standards | USP. (n.d.). <https://www.usp.org/compounding/legal-considerations>
- U.S. Food And Drug Administration. <https://www.fda.gov/drugs/drug-safety-and-availability/questions-and-answers-fda-requests-label-changes-and-single-use-packaging-some-over-counter-topical>
- USP 797 Key Changes | ASHP. (n.d.). <https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/compounding/docs/USP-797-Key-Changes.pdf>

Contact Us

For additional questions:

Maddison Mickle

Email: mmickle@jpshealth.org

Phone: (817) 702 – 5753

Ruth Aminu

Email: RAminu@jpshealth.org

Phone: (817) 702 – 6859

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Questions?

