Inspection Preparation and Response

What to Expect in a Joint Commission

Inspection of a Hospital/Health-System Pharmacy

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Disclosure

I do not have any conflicts of interest to disclose related to the content of this presentation.



Objectives

 Review how USP <797> and <800> are being incorporated into Joint Commission standards

Discuss how surveyors are beginning to evaluate standards

- Develop an inspection checklist
- Review best practices for inspection preparation, engagement, and response



Good luck is when opportunity meets preparation...



Getting to know the USP Chapters

- USP<795> Nonsterile compounding
- USP<797> Sterile compounding
- USP<800> Hazardous drugs and occupational safety
- USP<825> Radiopharmaceutical preparation
- USP <71> Sterility testing

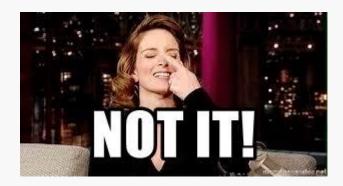


Sterile Compounding Enforcement



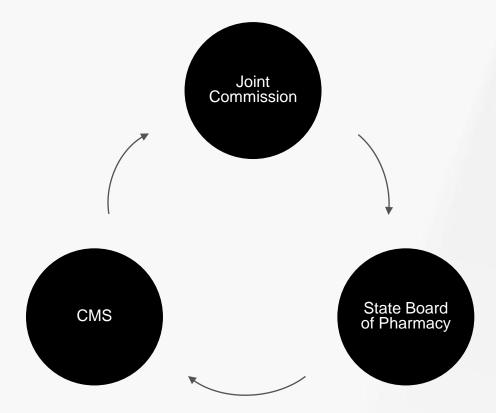
United States Pharmacopeia (USP)

- Recognized by federal Food, Drug & Cosmetic (FD&C) Act
- Enforced through FDA and state agencies
- Sterile compounding enforcement?





Enforcement of USP 797



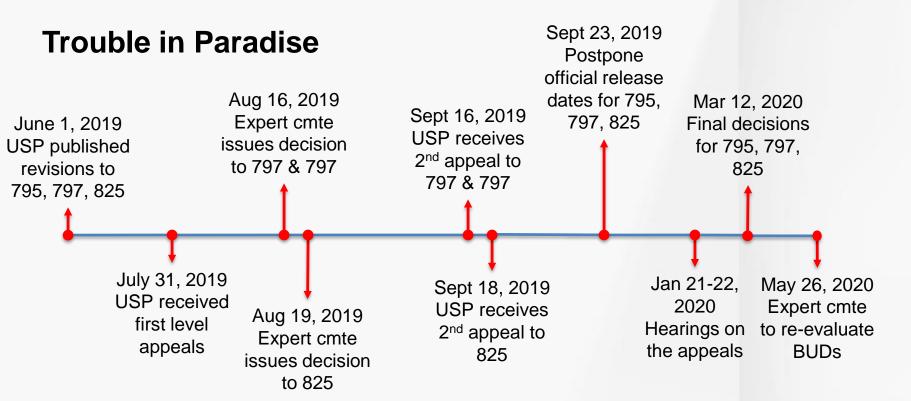


Where Does That Leave Us?

- January 1, 2018 Joint Commission
 - Medication Compounding chapter in Home Care standards
 - Enforceable in hospitals through various standards chapters







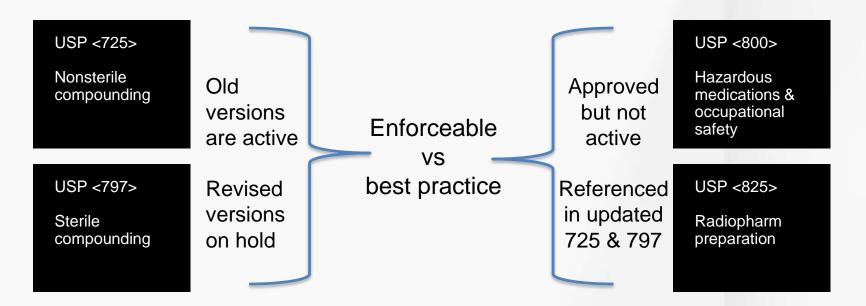


Key topics for the USP appeals

- Beyond-Use Date (BUD) provisions in <795> and <797>
- Removal of Alternative Technology provision from <797>
- Applicability of <795> and <797> to veterinary practitioners



What does this all mean?





Joint Commission's Opinion





USP 797: 2008 → 2019 crosswalk highlights

- Risk levels High Medium Low Category 1 Category 2
- Immediate use: 1 hr → 4 hrs
- Competencies: 12 months → 6 months
- BUDs: various changes
- Surface sampling: every 6 months → monthly
- Record keeping: Master formulation now required





Joint Commission Surveys



Surveyor Expectations



- Person
- Product
- Environment



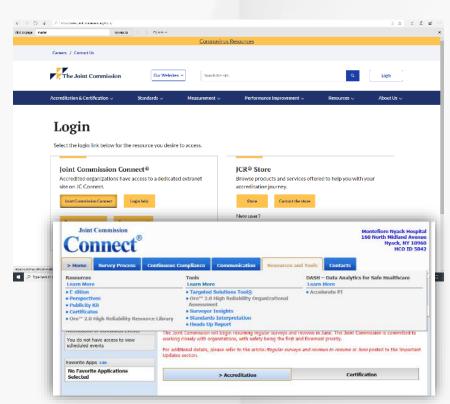




Surveyor checklist tool

- Joint Commission Connect®
 - "Resources and Tools"
 - "Tools-Learn More"
- Survey to the principles of the USP chapter → entire chapter contents may not be reflected in the tool

https://www.jointcommission.org/resources/news-and-multimedia/blogs/leading-hospital-improvement/2020/01/29/sterile-medication-compounding-update-for-hospital-accreditation-program/ Accessed 7/21/2020.







Inspector Checklist

Certification/Testing report evaluation

Assessment Item	2008 USP 797 Chapter	Revised USP 797/800 Chapters	JC Standard	CMS CoP x- walk
PEC – ISO level	Must be ISO 5 or less	For non-ha MM.05.01 Must be loo of ress For hazardous (USP800) Must be externally vented C-PEC must operate continuously	.07 EP	
Assessment Item	2008 USP 797 Chapter	Revised USP 797/800 Chapters	JC Standard	CMS CoP x- valk
PEC – Air Exchanges per Hour	30/hr, hood can contribute up to 15	For non-ha: ISO7: 30 ACPH (15 can come from PEC but room & PEC reported separately) ISO8: 20 ACPH	UTEP	.42

Montefiore





Evaluating a certification report

Not just whether it is a passing or failing evaluation



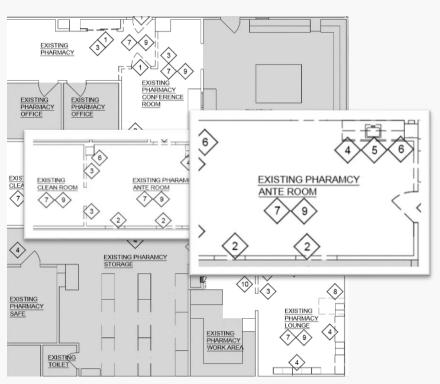
Certification Reports

	Anteroom	Buffer room	Hood			
Nonviable particles	< 3.5M (ISO 8)	< 352,00 (ISO 7)	< 3,520 (ISO 5)			
Viable particles	<100 CFU	<10 CFU	<1 CFU			
Air exchanges	20+ ACPH	30+ ACPH	30+ ACPH			

Nonviable particles can attract and carry variable particles



Tour of the Sterile Preparation Area



Physical structure:

- Ducts/vents
- Wall to floor
- Sink
 - Garbing area
 - Computer/printer
 - Fridge

Particle generators

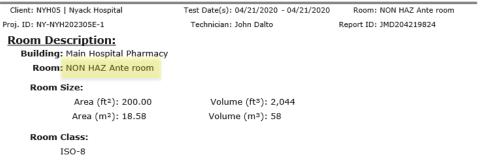


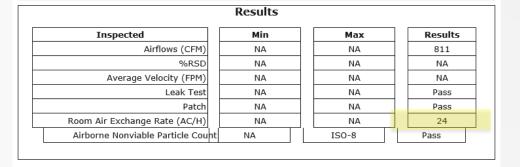


Proj. ID: NY-NYH202305E-1				l echnic	an: Joh	n Dalto	Report !	Report ID: JMD204219824			
	Airborne Nonviable Particle Count Test Report										
Clean	Clean Zone: Ante Room			Status:	Operati	onal/Dyr	namic	Cust ID: NA	Duration: 1.0 Min(s).		
Report Date: 4/21/2020 9:08:30 AM				Class:	ISO-8			Area: 200.00 ft ²	Flow Rate: 50.0 LPM		
Retest	Date: 10/2	1/2020	0	ccupants:	2			Tot	Total Sample Vol.: 50.0 L		
			Tes	ting is pe	rforme	d to sat	isfy IS	D 14644-1:2015			
						Pas	S				
	P	PCM (um)	≥ 0.5								
Loc	Count 1	Count 2	Count 3	Average	Result	T. C°	% rH				
1)	33040	NA	NA	33040	Pass	21.0	44				
2)	55040	NA	NA	55040	Pass	21.0	44				
3)	25160	NA	NA	25160	Pass	21.0	44				
4)	14300	NA	NA	14300	Pass	21.0	44				
5)	8080	NA	NA	8080	Pass	21.0	44				
6)	6220	NA	NA	6220	Pass	21.0	44				
	Class Limit: 3,520,000 21.0 44										
	Sample Volume Test: Pass										
	Class Limit Location Test: Pass										









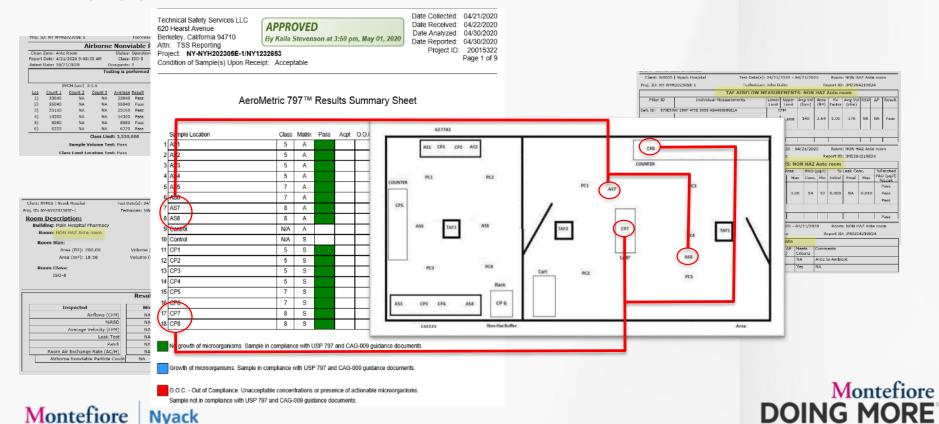




	Client: NYH05	Hospital	Test Date(s): 04/21/					/21/2020 - 04/21/2020 Room: NON					HAZ Ante room		
PYO, ID: NY-NYMZUZSUSE-1 Technician: John Datio	Proj. ID: NY-NYH	5E-1 Technician:					n: John Dalto				Report ID: JMD204219824				
Airborne Nonviable Particle Count To	TAF AIRFLOW MEASUREMENTS: NON HAZ Ante room														
Clean Zone: Ante Room Status: Operational/Dynamic Cust ID: Report Date: 4/21/2020 9:08:30 AM Class: ISO-8 Refere Lides: 10/27/2020 Groupeets: 2	Filter ID Individual Measurements							Upper Limit	Avg Vel (fpm)	Area (ft²)	Kv Factor	Avg Vo	RSD	ΔΡ	Result
Testing is performed to satisfy ISO 14644-1 Pass	Cert, ID: 879E996	0.2500	4F0F-00EE-4D4400	00E4 A			Limit	FM	(IpIII)	(11-)	ractor	(cilli)	+		\vdash
PPCM (um) ≥ 0.5	Cert. ID: 6/9E990	٠	LIM												
LOS SCHRELL SCHILZ SCHILZ AVERSER BEZUR TLC: 5s rfl 1) 33040 PMA NA	TAF-01 (CFM) 370							1,000	140	2.64	1.00	370	NA	NA	Pass
5) 8080 NA NA 8080 Pass 21.0 44 6) 6220 NA NA 6220 Pass 21.0 44	comments: N/A														
Class Limit: 3,520,000 21.0 44 Sample Volume Test: Pass	Cert. ID: E0987F9	94-9975-	4CD3-B096-ABA400	D88E28	3		CFM								
Class Limit Location Test: Pass	Client: NYH05	Client: NYH05 Nyack Hospital Test Date(s): 04/21/2020 - 04/21/2020 Room: NON HAZ Ante room										m			
	Proj. ID: NY-NYH202305E-1 Technician: John Dalto Report ID: JMD204219824														
	TAF INSTALLATION LEAK TEST RESULTS: NON HAZ Ante room														
Client: NYHOS Nyack Hospital Test Date(s): 04/21/2020 04/21/2020			Leakage Diagram (Magnitude, Location, and Dimension)		% Patched Area				(1-3, 7)		Leak Conc.			atched (µg/l)	
Room Description:		١ '	ocadon, and Dim	CHSION	′ I	Initial	Fina	al Ma	x Cond	. Min	Initial	Final	Max		Leak
Building: Main Hospital Pharmacy Room: NON HAZ Anta room															Pass
Room Size:	TAF-01		No Diagram			0.00	0.00	3.00	00 54	10	0.000	NA	0.010		Pass
Area (ft²): 200.00 Volume (ft²): 2,044	TAF-01		No Diagran	ı		0.00	0.0	3.0	0 34	10	0.000	INA	0.010		
Area (m²): 18.58 Volume (m²): 58							. J	l		_		J		1!	Pass
Room Class: ISO-8	comments: N/A														
							1			1	Ι			Τ.	
Results	= = recrimen an	ety aervi	DEW LLG		I		ı	- 1	ı	1	I	I			Pass
Inspected Min Max	Client: NYH05	l Nyack	Hospital		Test Da	ate(s):	04/21/	2020 -	04/21/20	20	Room	: NON H	AZ Ant	e roo	m
Airflows (CFM) NA NA NA NA			•									111000	40400		
Average Velocity (FPM) NA NA	Proj. ID: NY-NYH	202305	E-1		recnr	nician:	John D	aito		K	eport IL): JMD20	42198.	24	
Leak Test NA NA Patch NA NA					Pre	ssuriz	zation	Data							
Room Air Exchange Rate (AC/H) NA NA	Zone (+)		Zone (-)	Actual Min			n ΔP Max ΔP Meets		Meets	Comments					
Airborne Nonviable Particle Count NA ISO-8	ΔP ("wc) ("w				("wc	'wc) ("wc) Criteria									
	NON HAZ Ante re	oom	Ambient Room		0.111	NΑ	N.	A	NA	Ante t	nte to Ambient				
	NON Hazardous	NON HAZ Ante ro	000	0.145	0.02	O N	^	Yes	NΔ						







Tour of the Sterile Preparation Area





Room Description:

Building: Main Hospital Pharmacy

Room: NON-Hazardous Sterile Buffer room

Room Size:

Area (ft²): 119.00 Area (m²): 11.06 Volume (ft³): 968 Volume (m³): 27

Room Class:

ISO-7

Results

Inspected
Airflows (CFM)
%RSD
Average Velocity (FPM)
Leak Test
Patch
Room Air Exchange Rate (AC/H)
Room Air Exchange Rate + PEC (AC/H)
Airborne Nonviable Particle Count

Inspected

Min
NA
15
30
NA

	nli
Max	Results
NA	411
NA	NA
NA	NA
NA	Pass
NA	Pass
NA	25
NA	133
ISO-7	Pass



Tour of the Sterile Preparation Area

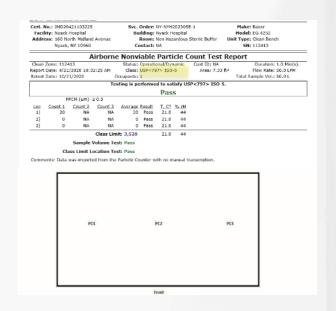
IV Compounding Hood





Unidirectional Flow Device Certification Report Cert.: JMD20421101040 Facility: Nyack Hospital ID: 627742 Cust ID: NA SO: NY-NYH202305E-1 Addr: 160 North Midland Avenue Make: Baker Contact: Daryl Schiller Nyack, NY 10960 Model: EG 4252 Phone: (845) 348-2604 Bld: Nvack Hospital SN: 112413 Email: schillerd@Montefiorenyack.org Rm: Non Hazardous Sterile Buffer Class: NA Type: Clean Bench Test Standard(s): MANUFACTURER, IEST-RP-CC002.4 Results Min Max Measured Results 90 110 99 Pass NA 15 Pass At-Rest Unidirectional Airflow Visualization Test NA NA. Pass Operational/Dynamic Unidirectional Airflow NA NA. Pass Pass Supply Delta Pressure ("W.C.) NA Duct Pressure ("W.C.] NΑ NA. FIO Backstreaming Test NA NA. NA NA Fluorescent Lighting (FC) NA NA NA. MA Ultraviolet Lighting (µW/cm²) NA NA NA NΔ NA. NΑ NA Noise Level NΔ Vibration NA NA NA Electrical Current Leakage NA NA. NA NA NA Electrical Ground Resistance MΔ NA NΑ NA Electrical Polarity NA NA NA Electrical GCFI NΔ NA NA Max Results HEPA As Found Max Point Leak (%) 0.000 0.010 Pass HEPA As Left Max Point Leak (%) 0.010 NA 0.000 Patch (%) Pre:0.00/New:0.00/Tot:0.00 Pass Aerosol Concentration (ug/l) Comments:

**** Unit Certified ****







What is the appropriate particle count for the buffer room?

- A. ISO 8 (less than 3.5 million)
- B. ISO 7 (less than 352,000)
- C. ISO 5 (less than 3,520)



Checklist Topics – compounding evaluation

- Room structure Floor/ceiling/walls
- Handwashing/PPE garbing
 - Handwashing time
 - Restricted items, ie. cosmetics, etc
 - Order of PPE donning
- Sterile compounding observation
 - Item placement in PEC
 - Dating of single dose vials, large volume bags
- PEC/SEC cleaning/disinfecting frequency, products used



Checklist Topics – other paperwork

- Leadership policy requirements
- Compounding staff competency evaluation
 - Didactic
 - Media fill, glove fingertip (initial AND ongoing)
 - Observation/aseptic technique





Checklist Topics – USP 800

- Hazardous specific compounding additional items USP 800
 - Annual evaluation of HDs, assessment of risk
 - HD receipt
 - HD storage
 - HD PPE

Montefiore Nyack Hospital Hazardous Drug Assessment of Risk (AoR) Template							
Drug Name: Abacavir Date AoR Initially Performed: _12	Date AoR Initially Performed: _12/26/19 Date AoR 🗌 Reviewed or 🗍 Revised:						
HD Drug Category: ☐ Antineoplastic ☒ Non-antineoplastic ☐ Reproductive Risk Only							
Dosage form (select one): 🗆 Sterile dosage form manufactured or compounded by an approved vendor and not requiring additional manipulation							
Dosage form of conventionally manufactured antineoplastic product that requires only packaging or counting							
Obsage form of conventionally manufactured non-antineoplastic or reproductive hazard product that requires only packaging or counting							
Other (explain):							
Describe Packaging: _bulk bottle from purchaser, unit-dosed from SafeCor							
Rationale for not requiring all <800> containment strategies	Specific Alternative Administrative, Engineering and Work Practice Control Strategies						
Minimal exposure risk – preference for unit-dosed product from SafeCor	The following strategies are documented in SOPs attached to HD policy						
PPE required per policy	Training in the following strategies was provided and documented						
Higher risk of contamination by storing with Table 1 medications than under general storage conditions							
general acorage conditions	Document specific alternative strategies below or \(\subseteq N/A (see below) \)						
	Preference for unit-dosed product						
	Do not use prepacking machine to prepack if unit-dosed unavailable						
	Decontaminate prepacking area with PeridoxRTU after prepacking						
	PPE for administration and prepacking						
	Nursing to decontaminate prep area after administration						
	No product manipulation allowed for administration						
	Dispense product with HD sticker						
	If product in ADC – dispense message alert						

Based on Assessment of Risk will proceed as follow: 🖾 Follow alternative strategies documented above 🔲 Follow all USP <800> requirements





AND NOW THIS...

A stockbroker was filling out a job application when he came to the question: "Have you ever been arrested?"

He answered no to the question.

The next question, intended for those who answered the preceding question with a yes, was "Why?"

Nevertheless, the stockbroker answered it "Never got caught."





Real Life Experience



No Brown M&Ms



Attention to details

Multidisciplinary involvement



Our Path to a Successful IV Room













April 2018

Fail
Positive
fungal
cultures

Clean, reduce inventory, reduce BUDs

June 2018

Fail
Positive
fungal
cultures

Clean, educate staff, contact architect

Sept 2018

Fail High CFUs, Hood issues

Clean, redesign garbing process, replace HEPA filter

Oct 2018

Construction

Install door between ante & buffer rooms

Nov 2018

Fail
High CFUs
anteroom
only

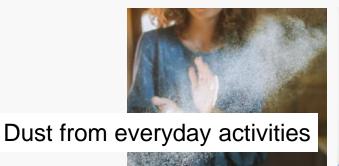
Clean, update ceiling ductwork and vent filters

Jan 2019

Pass



What Do These Have In Common?













Lessons Learned

- Understand the results of a failed certification
 - Personnel- vs environmentallyintroduced particles
 - Non-viable particles
 - Gram-positive/negative/fungal organisms
 - Role of air exchanges
- Enlist the right people to help
 - Infection Prevention
 - Facilities
 - Environmental Services











When does an IV room become a segregated compounding area?



- Define beyond use dating for products
 - Immediate use vs low-SCA vs low risk, etc



Experience with 12-hour BUDs

- Eliminate batch preparations
- Coordinate with anesthesiologists
 - Epidurals during the day
 - IV push narcotics at night
- Increase 503B oursourcing



Joint Commission Experience

- Direct observation
 - Depth of observations vary by surveyor
 - Garbing procedure received most attention
 - Random Q&A with staff
- Review of competencies
 - Written competency needs to define passing score
 - Reviewed during unscheduled session and during HR session
- Review of certification reports and corrective action plans



Corrective Action Plans

- Primary interest of JC surveyor
 - Separate, private session to review CAP, others
 - Provide executive summary with the data
- Identify source of failure → Viable vs nonviable particles
 - Nonviable particles → Environmental modifications
 - Viable particles → Gram-positive vs –negative vs fungi
- Beyond Use Dating → 12 hour expiration
- Re-educate
- RETEST



How to Prepare

- Paperwork
 - Completed competencies
 - Up to date room and hood certifications
 - Corrective action plans and retesting results if necessary
- People
 - Garbing procedure
 - Knowledge of policies
- Products
 - Expired products
 - Proper BUDs



Sterile Compounding Certification

- 2 year certification
- Does not need to be a JC-certified organization
- Based on Medication Compounding chapter from Home Care manual



"Joint Commission certification is a hallmark of excellence. We found that preparing for certification unified our entire staff. They rallied as a team to work toward the goal of meeting the certification requirements. Our hospital wanted to be a center of excellence and certification helped us achieve this goal."

Shannon M. Jackson, M.S.W., L.I.S.W. - Director, Continuum of Services Carolinas Medical Center



What should be done after failing a certification inspection?

- A. Shut the IV room and outsource all compounded medications
- B. Require nurses to make all parenteral medications
- C. Hire a consultant
- D. Understand the cause of the failure and work with the corresponding department in the hospital to fix it



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