

An update on USP <797>

USP <797> Revision Process

- USP Chapter <797> Pharmaceutical Considerations-Sterile Preparations becomes official on January 1, 2004
- USP hold five pharmacy stakeholders meeting in 2004 and 2005
- USP SCC committee (2000-2005) posts first set of proposed changes at end of 2004
 - Published in IJPC, USP website and in PF

USP <797> Revision Process

- USP SCC 2000-2005 committee term ends June 2005
- New USP SCC 2005-2010 Committee picks up
 - Number of members increased to 12 from 8
- Multiple meetings and conference calls held from July 2005 through February 2006 deliberating the 1,500 comments and questions from stakeholders and from USP public meetings.

USP 2005-2010 SCC Members

- David Newton, PhD (Chairman)
- Larry Trissel BS Pharm, (Vice-chairman)
- Sam Augustine, PharmD
- Mary Baker, PharmD, MBA
- Jim Cooper, PharmD, MS
- Don Filibeck, PharmD, MBA
- Larry Griffin, BS Pharm
- Ken Hughes, BS Pharm
- Eric S. Kastango, BS Pharm, MBA
- Keith St. John, MS
- Laura Thoma, PharmD
- Jim Wagner

USP Revision Process

- Latest proposed changes made available on website May 15, 2006
- The Proposed Revisions to General Chapter <797> were published on May 1st in the Pharmacopeial Forum (*PF*)
- Comment period from May 15, 2006- August 15, 2006
- Sought feedback from health care practitioners because of the challenges with the initial release
- 2,100 pages of comments from 360 sources were received

USP Revision Process

- USP holds a meeting for USP stakeholders in June 2006
 - ASHP, ASHE, APIC, FDA and other organizations present issues with proposed changes
 - Dr. Roger Williams, CEO of USP gives direction to USP SCC to seek additional expert advice through advisory groups
- USP SCC met on November 15-16, 2006 to discuss received comments and move towards creating a finalized

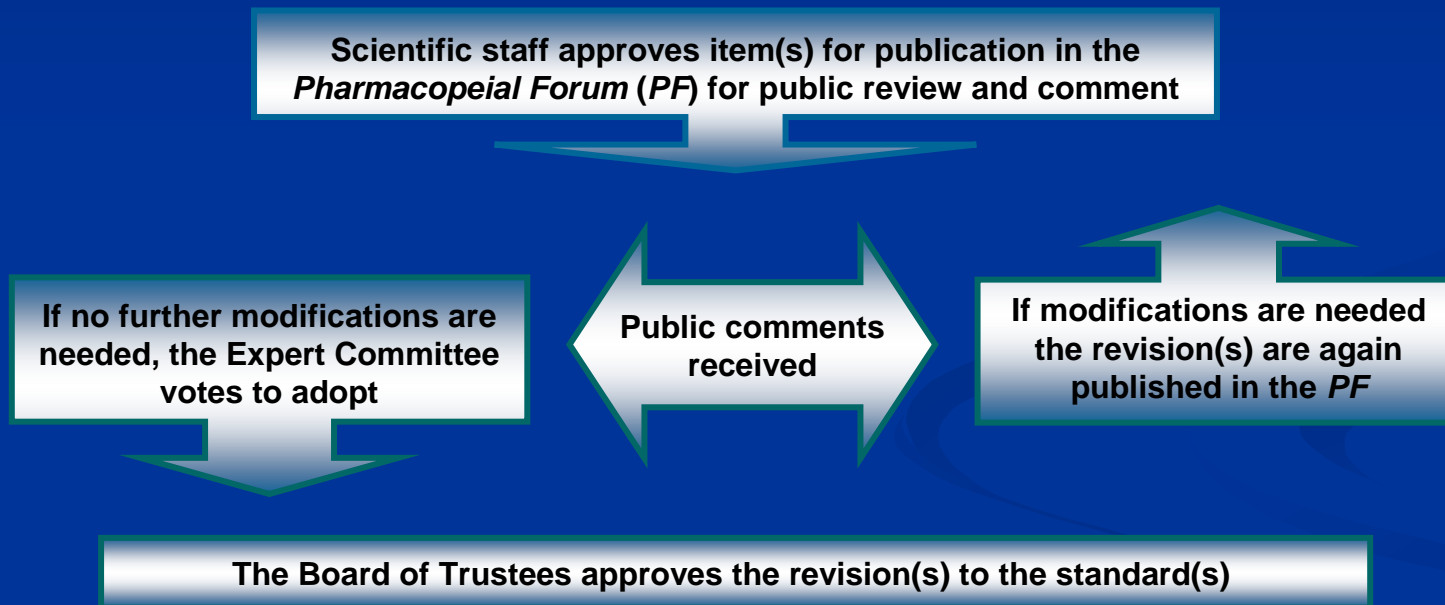
USP Revision Process

- Primary objective of USP SCC to get a finalized chapter published as soon as reasonable
 - Lock down critical chapter elements ASAP
 - Immediate-Use CSPs
 - Single-Dose and Multiple-Dose Containers
 - Facility Design and Environmental Controls
 - Personnel Cleansing and Garbing
 - Environmental Monitoring
 - Hazardous Drugs as CSPs
 - Radiopharmaceuticals as CSPs

Important to reiterate!


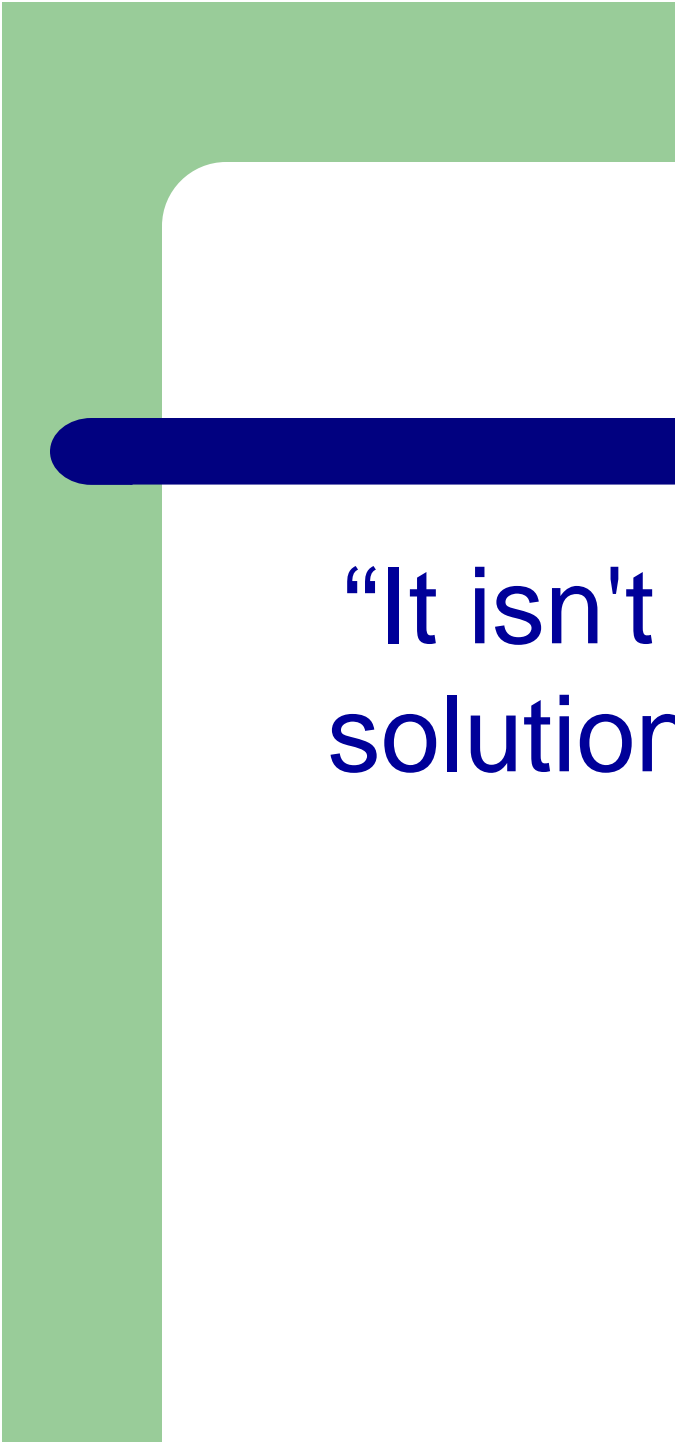
- The proposed changes are exactly that—
PROPOSED
- They were made public for the purpose of review and comment
- The proposed changes have not been adopted or made final at this time
- The proposed revisions may be—and in all likelihood will be—changed in some aspects after the Expert Committee has reviewed and considered comments from healthcare professionals

Revision of Official Standards



Using Air, Surface, and Personnel Sampling Data as a Cost-Effective Quality Metric

Eric S. Kastango, MBA, RPh, FASHP
ASHP MCM 2006



“It isn't that they can't see the solution. It is that they can't see the problem.”

G. K. Chesterton

What is Quality?

- **Qual-i-ty** (n): peculiar and essential character, degree of excellence or fitness for use
- Who defines quality?
 - Client or customer
- Who requires quality?
 - Client or customer
 - Regulatory authorities

ISO 9001:2000

- One of the most popular quality accreditation standard
 - Applies to all types of organizations.
- ISO 9001:2000 is primarily concerned with:
 - Quality management and fulfilling customer needs;
 - Regulatory requirements through continuous improvement of the quality system.

ISO Standard Clause 4.2

- Document your quality system: Requirements include:
 - Approve documents before distribution;
 - Provide correct version of documents at points of use;
 - Use your records to prove that requirements have been met;
 - Develop a procedure to control your records.

Why is documentation so important?

- Communicates information to staff
- Facilitates continuity of performance
- Aids in audit and peer review activities
- Improves likelihood that proper procedures are followed
- Provides data for benchmarking
- Provides opportunities to acknowledge staff
- Documents regulatory compliance
- Provides data valuable in cost evaluations
- Acts as the **best** witness in a court of law

Good Documentation in a nutshell

1. If it isn't written down, it didn't happen.
2. If it isn't written down *correctly*, it still didn't happen.
3. Don't forget rules 1 and 2.



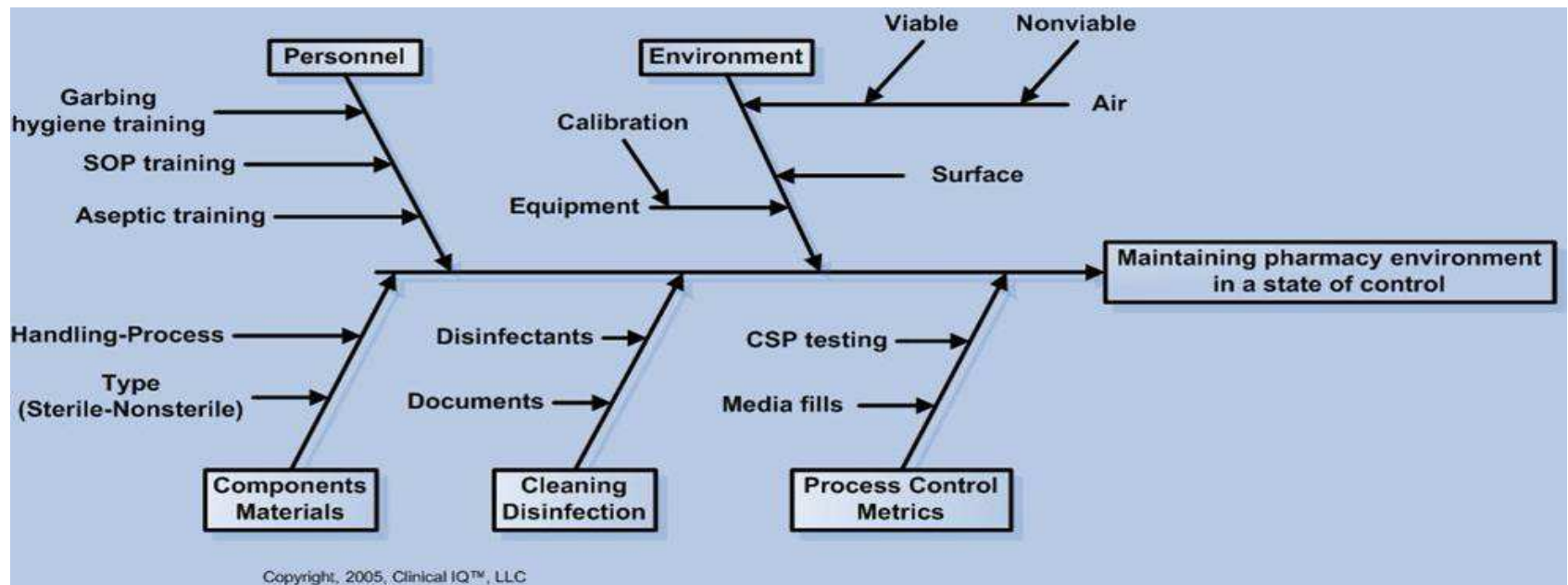
5 rules to live by...

1. Correct form
2. Correct information on form
3. Form is complete
4. Information is legible
5. Demonstrates conformity: ZERO GAP between actual performance and established policy

Some helpful hints....

- ...assume “others” will read
- ...maintain records for as long as possible and make them readily retrievable
- ...develop list of accepted abbreviations and use only those abbreviations
- ...signatures/initials must correspond to signature log
- ...provide mechanism for management overview daily
- ...involve staff in development of documentation

A Compounding Quality System



Environmental Monitoring – Why Is It Important?

- Can allow for **early detection** of contamination and its possible sources.
 - Sources may include:
 - Personnel
 - Supplies
 - Equipment
 - Failure of engineering controls
 - Surrounding environment

Environmental Monitoring – Why Is It Important?

- Assessment and verification of the adequacy of the aseptic compounding environment is essential.

(USP <797>)

Elements of an EM Program

- Getting started
- **Accumulating data**
- Establishing alert and action levels
- **Responding to excursions**

Accumulating Data

- Important aspect of a successful sampling session
 - Ties results to a specific location in the pharmacy per sampling plan
- Ascertains specific analytical methods and samples used
 - Allows for reproducibility
- Establish baseline data
 - Use actual data from pharmacy to establish levels
- Creates data trends that can be measured and managed

Responding To Excursions

- Responding to excursions
 - Review of data with OOL (out-of-limits) conditions identified
- Allows for corrective actions
 - Goal to prevent re-occurrence

EM Costs

<u>Company</u>	<u>Product</u>	<u>Price Each</u>	<u>List price</u>	<u>Product ID#</u>	<u>Website</u>
Remel	100mm Settling Plate	\$2.53	y	111570	http://www.remel.com/
Remel	RODAC	\$4.38	y	111101	
MG Scientific	100mm Settling plate	\$4.79	y	22205	http://www.mgscientific.com
MG Scientific	RODAC	\$2.45	y	21288	
Voigt	100mm Settling Plate	\$4.94	y	222205	http://www.vgdusa.com
Voigt	RODAC	\$7.14	y		
Fisher Scientific	RODAC	\$6.85	y	B292481	https://www1.fishersci.com/
Fisher Scientific	100mm Settling Plate	\$2.63	y	B4392396	
VWR	RODAC	\$4.83	y	BB4321238	http://www.vwrsp.com/
VWR	100mm Settling Plate	\$3.18	y	29446-044	
PML Microbiologicals	RODAC	\$1.52	y	P3500IC	http://www.pmlmicro.co
PML Microbiologicals	100mm Settling Plate	\$1.78	y	P8798	
BioMerieux	RODAC	\$1.11	n	C6045	http://industry.biomerieux-usa.com
BioMerieux	100mm Settling Plate	\$0.84	n	M1040	
BD-BBL	Rodac	\$4.83	y	221238	http://www.bd.com/Industrial/products/environmental
BD	Settling	\$4.81	y	222205	
QI Medical	Paddle	\$3.80	n	ET1000	http://www.qimedical.com

*All rodacs asked for with trypticase soy, lecithin, and polysorbate-80

Sampling Devices

Biotest USA	RCS Plus	\$3,350.00	y		http://www.biotestusa.com/rcsst.html
EMD Chemical	MAS 100 air sampler	\$6,334.50	y		http://www.emdchemicals.com/analytics/literature/
Bioscience International	SAS 180	\$4,850.00	y		http://www.biosci-intl.com/products/sas100.htm
EMT Technologies	RS2				http://www.bd.com/Industrial/products/environmental
New Brunswick Scientific	STA-203	\$4,560.00	y		http://www.nbcs.com/

Summary

- Understand your process
- Build controls to identify and minimize and/or eliminate risks
- Respond to excursions or OOL conditions
- Communicate quality through documentation