USP <800> and What Changes Will Mean for Oncology Practices

November 2, 2016
State Society Education Series

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Comply797 & Comply800
Learning Objectives

1. Understand USP’s purported role, scope, and authority;

2. Understand the purpose of General Chapter <800> - “Hazardous Drugs – Handling in Health Care Settings” and its implications for Oncology Practice; and

3. Understand the timeline for implementation of <800>
United States Pharmacopeial Convention (USP)

- Recognized in federal law (FDCA) as the national compendium of drugs
- Founded in Washington, D.C. in 1820 to set a system of standards for strength, quality, purity, packaging, and labeling of drugs and a national formulary
- Global reach – 140 nations around the world
- Standards (3-digit GCs) have been deemed enforceable by federal law
USP and Professional Practice

• For 195 years, USP limited its purview to substances – drugs, excipients, additives, etc.

• Early “2000s” – USP published new sets of national practice standards regarding compounded drugs (<795>, <797>)

• May-June, 2015 – revised <800> published in Pharmacopeial Forum to become officially implemented on July 1, 2018 (which gave entities > 2 years to prepare)
Purpose - <797> vs. <800>

- <800> does not replace <797>
- <797> exists to **protect patients** from receiving tainted, contaminated, or degraded sterile drugs
- <800> exists to **protect healthcare workers** from being exposed to possible health risks inherent in handling Hazardous Drugs
- Many topics of overlap between the two chapters require “harmonization.”
USP Sterile Compounding
Overlapping Abbreviations & Jargon

• CSP – “compounded sterile preparation”
• PEC – “primary engineering control”
  – LAFW – “laminar airflow workstation”
  – BSC – “biological safety cabinet”
  – CAI – “compounding aseptic isolator” (“glove box”)
  – CACI – “compounding aseptic containment isolator”
• BUD – “beyond-use date”
• SOP – “standard operating procedures”
USP Abbreviations & Jargon

ISO air quality classifications

• Both <797> and <800> have requirements for Qualified Air.

• Qualified Air – ISO classifications – log scales

ISO-5  ISO-6  ISO-7
General Chapter <797> - Scope
(Official since 2004 – Revised 2008)

• Title is, “Pharmaceutical Compounding – **Sterile** Preparations”

• “…this chapter provides minimum practice and quality standards for CSPs of drugs and nutrients…”

• Applies to, “…all persons who prepare CSPs and all places where CSPs are prepared.”

• Such persons, “…include pharmacists, nurses, pharmacy technicians, and physicians.”
General Chapter <800> - Scope
(Becomes Official on 7/1/2018)

• Title is “Hazardous Drugs – Handling in Healthcare Settings”

• “…applies to all healthcare personnel who handle HD preparations and all entities that store, prepare, transport, or administer HDs.”
  – (e.g., pharmacies, hospitals, and other healthcare institutions, patient treatment clinics, physicians’ practice facilities, or veterinarians’ offices.)
  – “…pharmacists, pharmacy technicians, nurses, physicians, PAs, home healthcare workers, veterinarians and veterinary technicians.”
USP - Should versus Shall/Must

• Even within a 3-digit Chapter, there will be both “shoulds” and “shallss”
• In USP language, “Should” is a recommendation
• A sentence that uses “Shall” or “Must” is a mandated requirement
Why <800>?

• Mustard Gas was used as a weapon in the World Wars
• Among many effects, it dropped WBC count
• Chemotherapy – Goodman & Gilman – 1946
  – Mustard Gas -> Nitrogen Mustard (stable)
  – Effectively shrank lymphoma, although the effect was short-lived
• Sydney Farber tested folate antagonists against Acute Lymphocytic Leukemia and found it effective (1948)
Why <800>?

• Initially, all of the focus was on the patient
• Later, there was a realization that drugs which affect DNA and cell reproduction could be harmful to healthcare workers
• Series of studies demonstrated exposure
  – Measurable cyclophosphamide from LAFW
  – Measurable antineoplastics in the urine of healthcare workers
• Long-term effects? Still not clear.
<800> - Big Spotlight to Speed Progress

- OSHA’s Controlling Occupational Exposure to Hazardous Drugs – evolved since 1986
- ASHP’s Guidelines on Handling Hazardous Drugs - evolved since 1988
- ASCO/ONS’ Chemotherapy Administration Safety Standards Including Standards for the Safe Administration and Management of Oral Chemotherapy – evolved since 2009
<800> broader than <797>

• <800> scope is much broader than <797>’s:
  – Receipt, Handling, Storage, Disposal, Presence
  – Applies to everyone in the greater environment (nurses, receptionists, billing staff, executives, patients, waiting room, couriers, cleaning crew, etc.)
  – includes staff who receive and unpack drugs
  – Apply to non-sterile (i.e. oral, topical, etc.) drug forms
Chapter <800> Impact

• “Motherhood and Apple Pie”
• Massive cost – Uncertain benefits
• Costs will include:
  – Increased energy consumption & CO2 production
  – Increased drive to consolidate – only mega-entities can afford to construct and operate the required facilities
  – Limitation of patient access
  – Accelerated shift to automated approaches
  – Legal and Risk Management
Chapter <800> Impact

• Unfunded Mandate – <800> may bring a new area of compliance and enforcement, but with no new revenue to offset it.

• Enforcement?
  – Unpredictable

• Penalties?
  – Unpredictable

• State or Federal
Chapter <800> Impact

Impact Areas:

– Physical Facilities and Equipment (& energy)
  • requires negative-pressure PECs vented to the outside
  • negative-pressure SEC, hard walls, door, 12 or 30 ACPH
– SOPs and Quality Assurance Program
– Training - required for all staff members
– Disposable supplies – gowns, garb, gloves, etc.
– Surveillance
  • Environment
  • Medical Conditions of your Personnel (including future)
Physical Environment
Typical Current State

– Has wooden counters, drawers, shelves
– Contains paper, cardboard, carpet, drapes, etc.
– The C-PEC is a BSC resting on a counter
– Contains compressor-style refrigerator(s)
– Open to unrestricted traffic
– Walls, flooring, ceilings are of inappropriate surface and not maintained by protocol
– Compounding performed by seasoned R.N. – main focus is on clinical aspects of the drug-patient combination – NOT on sterility/stability of CSP
Impact - Physical Environment

To comply, choose between two strategies:

ISO-7 Clean Room Complex

Versus

Containment Segregated Compounding Area (C-SCA)
Impact - Physical Environment

C-SEC features:

• “...shall be void of activities and materials that are extraneous to sterile compounding.”

• Sealed – air movement controlled/monitored

• Floors/walls/ceilings/fixtures/carts smooth, impervious, easily cleaned and disinfected

• Joints coved and smooth, ceiling tiles sealed to frame(s)
Impact - Physical Environment

To make CSPs with BUDs > 12 hours:

- C-PEC must be located in an **ISO-7 Buffer Room**
  - Must have fixed walls
  - Must maintain ISO-7 under dynamic conditions
  - Must be -0.01 to -0.03 inch WC from adjacent areas
  - Must maintain $\geq 30$ ACPH
  - Must be vented to the outside

- Enter Buffer Room only via an **ISO-7 Ante Room**
  - Dynamic ISO-7, fixed walls, 30 ACPH as above
  - $\geq +0.02$ inch WC compared to *all adjacent areas*
Impact - Physical Environment

- Containment Segregated Compounding Area
  - Acceptable for CSPs with BUDs $\leq 12$ hours
  - C-SCA requires:
    - C-PEC vented to the outside
    - The air of the C-SCA must also vent to the outside
    - Solid walls and door must enclose the C-PEC
    - Negative pressure vs. adjacent spaces maintained in the range -0.01 to -0.03 inch WC
    - Minimum of 12 ACPH
    - No compounding of Medium- or High-Risk CSPs
Impact -
Physical Environment

Air Conditioning:

– The air delivered to the C-SEC (Buffer room or C-SCA) needs to be chilled to about 65°F to offset heat from C-PECs and body heat from workers
– C-PEC and C-SEC must both vent to the outside
– Depending on the C-SEC modality chosen:
  • ISO 7 C-SEC must achieve ≥ 30 ACPH while maintaining -0.01 to -0.03 inch WC
  • C-SCA must achieve ≥ 12 ACPH and -0.01 to -0.03 inch WC
– Thousands of dollars in energy costs per year
Impact - SOPs and Quality Program

• If you have written SOPs, you’re miles ahead
• Even if you have not formally written them down, you do have SOPs
• Whether written or not, <800> compliance will drastically alter the way you do business
• “Quality Assurance Program” = “a mechanism for monitoring, evaluating, correcting, and improving the activities and processes described” in the Chapters
Impact - SOPs

The SOPs for handling of HDs should include:
- Hazard communication program
- Occupational safety program
- Designation of HD areas
- Receipt
- Storage
- Compounding
- Use and maintenance of proper engineering controls (e.g., C-PECs, C-SECs, and CSTDs)
- Hand hygiene and use of PPE based on activity (e.g., receipt, transport, compounding, administration, spill, and disposal)
- Deactivation, decontamination, cleaning, and disinfection
- Dispensing
- Transport
- Administering
- Environmental monitoring (e.g., wipe sampling)
- Disposal
- Spill control
- Medical surveillance

Develop or Adopt SOPs, thoughtfully and one at a time, ranked by (1) impact and (2) difficulty – “Low hanging fruit”
Impact - SOPs

• “Hazard Communication” Requirement
  • Mandated since 1994 (29 CFR 1910.1200) (OSHA)
  • Pharmacies and physicians exempt from labeling aspects
  • **Requires** employers to transmit hazard information to employees
  • Entity must collect and store retrievable **proof** that employees were warned (signatures)
  • SDS (formerly MSDS) (Material Safety Data Sheets) must be “**easily accessible**” for each and every hazardous agent
Impact - SOPs

• Occupational Safety Program
  – Entity’s list of HDs (to include NIOSH List - 2016)
  – Facility and Engineering Controls
  – Safe Work Practices
  – Proper use of PPE
  – Policies for HD waste segregation and disposal
Impact - SOPs

• Receipt/Unpacking/Storage of HD
  • Unpacking **cannot** be performed:
    – in positive pressure area(s)
    – In sterile compounding area(s)
  • HDs must be stored to prevent breakage if container falls
  • HDs cannot be stored on the floor
  • Antineoplastic HDs must be **stored** in externally vented, negative pressure room with \( \geq 12 \) ACPH
  • Refrigerated HDs must be stored in a **dedicated** refrigerator located in a negative-pressure room, \( \geq 12 \) ACPH
Impact - SOPs

• Compounding
  • All requirements of <797> must also be followed
  • C-PEC must operate **continuously**
  • Loss of power = immediate suspension of all C-PEC activities
  • Power returned – must decontaminate, clean, & disinfect
  • Handwashing sink must be available
  • Eyewash station must be readily available
  • Water sources and drains must not degrade ISO qualification
  • Water sources and drains located ≥ 1 meter from C-PEC
  • Neither LAFW nor CAI are acceptable for HD compounding
Impact - SOPs

• Hand hygiene and PPE
  • Disposable PPE must not be reused
  • Gowns, head, hair, shoe covers and two pairs of chemotherapy gloves to compound HDs
  • Two pairs of chemotherapy gloves required to administer antineoplastic HDs
  • Gowns must have demonstrated permeability resistance
  • Chemotherapy Gloves
    – Must meet ASTM Standard D6978 (or successor) [read the box]
    – Must be powder-free
Impact - SOPs

• Hand hygiene and PPE
  – Gloves must be physically inspected for defects
  – Gloves must have no pin holes or weak spots
  – If sterile compounding, gloves must be sterile
  – Gloves must be changed ≤ 30 minutes
  – Gowns must close at back and not be cloth
  – Gowns must not have HD-permeable seams
  – Potentially contaminated clothing is never taken home
<800> Impact - SOPs

• Hand hygiene and PPE
  – Gowns worn in areas of HD handling must never be worn into other areas
  – Head/hair/beard/moustache covers required
  – Second pair of shoe covers required when entering C-SEC and removed upon exiting
  – Eye and face covers required when risk of HD spills/splashes (e.g., administration in O.R., hanging HD CSPs above eye level, spill cleaning)
Impact - SOPs

- Hand hygiene and PPE
  - Full-facepiece respirator protects eyes/face
  - Goggles required when eye protection needed
  - Face shields alone do not protect eyes from splash
  - Face shields + goggles = full eye/face protection
  - Unpacking HD requires elastomeric half-mask with a multi-gas cartridge and P100 filter until ascertained that there was no leakage/spill
  - Surgical masks = inadequate respiratory protection
Impact - SOPs

• Hand hygiene and PPE
  – Surgical N95 respirator provides N95 respiratory protection + barrier to splashes or sprays
  – Fit-tested N95 respirators protect against airborne particles, but no protection for gasses/vapors and little protection against liquid splashes
  – Full facepiece or PAPR when at risk, including:
    • Attending to an HD spill
    • Deactivating, decontaminating and cleaning below C-PEC
    • Known or suspected airborne powders or vapors
Impact - SOPs

• Deactivation/Decontamination/Cleaning
  – All areas where HD are handled and any reusable equipment they touch must be deactivated, decontaminated, and cleaned
  – Sterile compounding areas and devices must also be disinfected
  – The procedures and the agents used, dilutions, frequency and documentation requirements
  – Procedures include eye, face and respiratory protection as required
Impact - SOPs

• Drug Administration
  – HDs must be administered using protective devices and techniques (needle-less, closed systems)
  – Appropriate PPE must be worn when administering HDs
  – Used PPE must be disposed of in a waste container approved for trace-contaminated HD
  – Equipment and packaging materials disposed likewise
  – CSTDs must be used to administer antineoplastic HDs whenever the dosage form allows
Impact - SOPs

• Personnel Training
  – Personnel who handle HD must be trained based on their job functions
  – Training must occur before employee independently handles HDs
  – Effectiveness of training must be demonstrated for each employee
  – Competency reassessed every 12 months
  – Each employee trained for all new HD and every new or altered SOP
Impact - Personnel Training/Competency

• Not enough to train your staff, you must demonstrate that you did
• Must demonstrate that training was effective
• Not enough to train initially,
• You must demonstrate that you’ve reiterated training regularly and that staff know what they need to know to protect themselves and others from HD exposure
Impact – Disposable supplies

- PPE (as noted) (gloves, gowns, booties, etc.)
- Cleanroom supplies and ancillaries
  - Tacky mats
  - Sterile, non-shedding wipes
  - Sterile alcohol (liquid and waterless foamers)
  - Steel or plastic shelving and carts
  - Deactivating/Decontaminating/Disinfection liquids
  - Dedicated disposable mops/buckets/scrubbers
Impact - Surveillance - Environment

- Surface wipe sampling should include:
  - Interior of the C-PEC and equipment contained in it
  - Pass-through chambers
  - Surfaces in staging or work areas near the C-PEC
  - Areas adjacent to C-PECs (e.g., floors directly under C-PEC, staging, and dispensing area)
  - Areas immediately outside the HD buffer room or the C-SCA
  - Patient administration areas
<800> Impact - Surveillance - Environment

• Surface wipe sampling:
  – Example = cyclophosphamid
  – Not many vendors
  – Expensive
  – Paying for the test is step 1.
  – Cost to try to eliminate HD is step 2.
  – Paying to demonstrate elimination was effective is step 3.
Impact - Surveillance - Medical

- Healthcare workers who handle HDs as a regular part of their job assignment *should* be enrolled in a medical surveillance program.

- Medical surveillance programs involve assessment and documentation of symptom complaints, physical findings, and laboratory values (such as a blood count) to determine whether there is deviation from the expected norms.

- Tracking personnel through medical surveillance allows the comparison of health variables over time in individual workers, which may facilitate early detection of a change in a laboratory value or health condition.
Impact - Surveillance - Medical

- Medical surveillance programs also look for trends in populations of workers.
- Examining grouped data compared with data from unexposed workers may reveal a small alteration or increase in the frequency of a health effect that would be obscured if individual workers' results alone were considered.
- Medical surveillance evaluates the protection afforded by engineering controls, other administrative controls, safe work processes, PPE, and worker education about the hazards of the materials they work with in the course of their duties.
• Why did USP prescribe such a costly, ineffective, inefficient, and disastrous process as “Medical Surveillance?”

• Because we had the data at our fingertips, but we never did the study...
  – We knew who handled and who were exposed to these drugs
  – The simplest case-control epidemiological study ever
  – Contrast rates of malignancy and specific “candidate” diseases between cohorts of orthopedic surgical workers vs. E.D. workers vs. El-Ed teachers vs. us + our staff and determine Relative Risk
  – No increase in risk obviates any need for “Medical Surveillance”
Who wrote <800>

- Expert Committee on Compounding formed an Expert Panel
- There were 9 members:
  - Chair – a pharmacist/executive from Cardinal Health
  - Pharmacists (2) – neither still practicing
  - Air flow/HVAC expert/Cleanroom Consultant (1)
  - Nursing Professor (1)
  - NIOSH Ph.D.s (2)
  - Physician (1) – a workplace epidemiologist
Who were conspicuously absent from writing <800>?

- Practicing Oncologists
- Practicing Pharmacists
- Hospital Administrators
- Oncology Professional Associations
- Business Owners (persons making a payroll)
- State Board authorities
- Payers of any type
How to Implement?

• Stratify actions – Rank for impact and difficulty
• Start with actions that (1) have the biggest impact and (2) are easiest to implement
• Change minds:
  – Change your own mind first – inform yourself
  – Live and breathe the new priorities
  – Change the minds of your personnel
<797> and <800>

How to Push Back?

• Articulate a sane position
• Deploy that sane position to all oncologists
• United front to deploy the oncology message
• Educate/Inform/Persuade – Beat the drum
• Pile consequences on the other side:
  – FDA
  – PhRMA
  – Monolithic Vendors (Cardinal, McKesson, etc.)
Dialogue

• Questions?
• Comments?
Willis C Triplett, Pharm.D.

- Best e-mail: willis.triplett@comply797.com
- Cellular telephone: 317-626-6973
- Please do not hesitate to reach out!
Background Reading

- Purchase USP Compounding Compendium
- USP FAQs on <800>
- NIOSH List - 2016
- Controlling Occupational Exposure to Hazardous Drugs-OSHA
- ASCO/ONS Safety Standards-2013
- ASHP Guidelines on Handling Hazardous Drugs
- New Jersey Assembly Bill No. 837 – 2016 Session
- FDA Guidance on Process Validation
- Sterile Drug Process Inspections-FDA
Off-Label Use Disclosure(s)

I do not intend to discuss any off-label use of any drug product during this activity.
I currently have or have had the following relevant financial relationships to disclose:

– I do not have financial, consulting, and advisory relationships with any pharmaceutical companies other than “former consultant.”

– I do have business relationships with several companies that provide products or services in the sterile product compounding arena, including clean room builders, consulting companies, accreditation bodies, software providers, professional organizations, cGMP validation firms, certification companies, and commercial laboratories. I do not intend to mention any of those by name during this presentation.
Loyd Allen’s Editorial

Authority for Establishing Professional Practice Standards

The IJSP does not appear to have been granted the authority for establishing "OFFICIAL" professional practice standards for pharmacy, medicine, nursing, etc. The actual authority for establishing professional practice standards generally resides with the individual states, especially the state boards of pharmacy, medicine, nursing, etc. The individual Boards can either prepare the standards, use model standards from other sources (e.g., NABP in the case of pharmacy), or some other entity, etc. In summary, to view the USP professional practice standards published as "official" and "enforceable" does not seem to be appropriate and seems to be without foundation.

I recall back when we wrote the first practice standards at the request of the CEO of USP, Dr. Roger Williams; he explained that he wanted to establish a series of professional practice standards for the USP, including those for nonsterile compounding, sterile compounding, hazardous drugs compounding, etc. After the Pharmacy Compounding Expert Committee wrote USP <795>, the question of 'Where do we put it in the USP?' was asked. The chapters didn't really "fit" anywhere, but it was decided by USP personnel to insert them in the Physical Tests section of the General Chapters. This was followed by USP <797>, etc.

At the time, the expert committee was given a task by the USP CEO and didn't really consider the question of the authority to do this task. There was a lot of pressure from the FDA, and it was discussed at that time that these chapters may aid in keeping the FDA at bay... but we know that has not been the case. In summary, it does not seem that there was ever any "legal authority" provided to the IJSP to establish "official" professional practice was simply done. If this is the case, they are not "official" and should be removed from the LISP, and the responsibility for development of professional practice standards be placed on the state boards of pharmacy.

Loyd V Allen, Jr., PhD, RPh
Editor-in-Chief
International Journal of Pharmaceutical Compounding
Remington- The Science and Practice of Pharmacy Twenty-second edition
History of <797> Enforcement
History of <797> Enforcement in “Pharmacy World”

• USP <797> - 2004 – Apprehension and Near Panic in Pharmacy – but no enforcement
• Updated in 2008 – Anxiety, but “wait-and-see” approach – again, no enforcement
• Fungal Meningitis Outbreak in 2012
• Drug Quality and Security Act of 2013
• Marked shift in enforcement by state and federal authorities ➔ massive enforcement
History of Enforcement

• State Pharmacy Boards should have enforced acceptable sterile compounding practices forever, but lacked the requisite competencies

• FDA couldn’t legally enter pharmacies until unleashed by DQSA

• 503A “Traditional pharmacies” vs. 503B ROFs

• “Compounding in Advance”; “Office-Use”

• FDA-citations issued to 215 503A pharmacies
USP and FDA
Borrow a cup of sugar?
Enforcement in Medicine

• Has been non-existent in private practices
• Most Pharmacy Boards have inspectors, but most Boards of Medicine do not
• Where will “inspection” come from, if and when it comes?
  – Research Consortia (MSK example)
  – Accreditation Bodies (JCAHO, FACT, etc.)
  – State Government (Professional Boards)
  – Federal Government (FDA, OSHA)
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• Firm Press Release: Wellness Pharmacy, Inc. Issues Voluntary Recall of Six Medications Due to Concerns of Sterility Assurance at Testing Vendor (08/26/2013)

Wells Pharmacy Network, LLC, Ocala, FL

• Warning Letter (11/10/2014)
• 483 Issued 06/19/2014 (PDF - 1MB)
• 483 Issued 03/07/2014 (PDF - 1.2MB)
• 483 Issued 07/26/2013 (PDF - 1.1MB)

Wiley Chemists, Inc., Santa Fe, NM

• 483 Issued 10/02/2013 (PDF - 221KB)
• 483 Issued 07/08/2016 (PDF - 485KB)

M.D. P. C., New York, NY

• 483 Issued 07/08/2016 (PDF - 485KB)

Wingate’s Pharmacy and Compounding (see Anderson Holdings Inc.), Nashua, NH

Wingate’s Pharmacy and Compounding (see Algunas, Inc.), Woodland Hills, CA

Woodland Hills Compounding Pharmacy, (see Algunas, Inc.), Woodland Hills, CA

Wood’s Pharmacy, Inc., (dba The Medicine Shoppe), Boones Mill, VA

• 483 Issued 01/15/2015 (PDF 2.4MB)

Yeung Business Solutions, LLC, (dba Reliant Pharmacy), Southbury, CT

• Referral Letter to the Connecticut Commission of Pharmacy Issued 03/25/2015 (PDF - 68KB)
DR. [REDACTED] IS A DISGRACE... FORCED CHEMO ON MY MOM KNOWING SHE HAD FISTULAS DEVELOP FROM CT SCAN CAUSING HER FURTHER DAMAGE. LET HER BE RELEASED WITHOUT TREATMENT AND CONCEALED KNOWLEDGE OF LEAKS WHICH GOT WORSE DUE TO HIS NEGLECT ABUSE... HE CURSED HER TO MY FACE IN HIS OFFICE AND SHE CONTRACTED DANGEROUS BLACK MOLD VIRUS FROM HIS OFFICE FROM OLD CHEMO MEDS NEGLIGENCE... HE THEN Continued TO HARASS HER WHEN TOLD NOT TO CONTACT HER ANYMORE CAME TO HER ROOM 3X ALTHOUGH HE WAS TOLD NOT TO. HE BELongs IN JAIL AND HIS LICENSE REVOKED. HE IS BY FAR THE WORST DOCTOR I HAVE EVER MET OR HEARD OF DO NOT TRUST HIM HE IS VERY BAD MAN.

- The above appeared on the web on Wed, June 22
- FDA appeared at the physician’s practice on Tues, June 28
- FDA said to have a team of web search experts working M-F.
What does <797> prescribe?

- Responsibilities of Compounding Personnel
- CSP “Risk Levels” – Low, Medium, or High
- Personnel Training and Evaluation
- Special conditions for compounding HD, Radiopharmaceuticals, & Allergen Extracts
- Verification - Compounding Accuracy/Sterility
- Environmental Quality and Control
- Suggested SOPs
What does <797> prescribe?

- Finished Preparation Release Checks/Tests
- Storage and Beyond Use Dating
- Sterility, Purity, and Stability of Dispensed CSP
- Patient and Caregiver Training
- Patient Monitoring and A.E. reporting
- Quality Assurance (QA) Program
- Many other technical aspects
Compliance in Medicine

• Compliance in oncology practices is lacking
• Gaining compliance will require massive, sustained effort; *A Process not an Event*
• Costs and Benefits of current state = unknown
• Medical Oncology practices typically:
  – Lack standard operating procedures for sterile compounding (SOPs);
  – Lack formal, standardized training/tracking process for new hires and existing staff
<797> Compliance in Medicine

– Lack <797>-compliant environments;
– Lack compliant release checking;
– Lack storage compliance and BUD labeling;
– Do not Verify Compounding Accuracy and Sterility
– Lack compliance with “Hazardous Drugs as CSPs”
– Lack Adverse Drug Events reporting process
– Lack an effective and functional Continuous Quality Improvement process (CQI)
Motivations for <797> Compliance

• Governmental enforcement? What’s the penalty?

• Publicity and media?

• Expulsion from research network(s)?

• Moral/Ethical motivation? (right thing to do)
Hurdles to Adoption

- Arcane nomenclature/jargon/terminology
- Lack of experience in traditional “clean” space
- Excess attention to qualified air environment, insufficient attention to DCA, “First Air,” “Critical Site,” and touch contamination
- Inertia among staff – Organizational culture:
  - “We’ve always done it this way…”
  - “If it ain’t broke, don’t fix it…”
  - Unlearning bad habits is very difficult
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Compliance Roadmap

- Research deeply and plan carefully
- Begin by reading and comprehending <797>
- Perform a painstaking “Gap Analysis”
- Develop or Adopt SOPs, one at a time
  - Training and education = biggest bang for buck
  - ISO-7 environmental compliance = large $$$
    - Restrict traffic, eliminate particles, improve gowning, garbing, gloving, and cleaning/disinfection
    - Plan to move from BSC to CACI as soon as feasible