COMBINED PRIORITIES [Clustered]

1. Types of test soil being used
   - Analytical endpoints and clinical relevance. What level of soil could compromise sterilization and disinfection?
   - When we perform or write protocols, we need detail about levels of soiling. Do we need to include other parts of the device (e.g. handle of the device)? What is the best way to handle soiling?
   - Continue to use microbial markers in conjunction with other markers.
   - Ensure test soil mimics what the device will be exposed to in clinical settings (i.e. bone, cement).
   - Int'l effort within ISO for better definition of test soil. Standardization of test soil around the world.
   - Identifying the best types of tests to determine "what is clean."

2. Lack of instructions on how to tell if the device is clean.
   - Many devices don't come apart; how do we ensure that lumens and crevices are clean?
   - As patient, I want a reprocessed device to be in same condition as new. We can struggle with measuring this, but the true measure is no increased probability of adverse reaction.
   - As mfc, one of the hardest things is that the existing literature is limited re: publication of acceptance criteria for an analytical test like TOC. Who is going to provide acceptance criteria?
   - The vast number of different types of instruments causes a multitude of variables. Core question FDA is asking is, "What is clean?" Contaminants should be reduced so device is safe for subsequent patient use and won't interfere with the reprocessing.

3. Standardized, simple instructions and processes that are repeatable.
   - Instructions need to be simple, cost effective, and replicable by users with a wide variety of skills.
   - Instructions need to take into account who will be using them. Write them with input from the users and usability testing. Use symbols; keep them simple and clear; standardize when possible.
   - Clear, standardized, repeatable processes.
   - Pick a few of most common practices used or preferred and have mfc's validate to all of those practices. Validate to current reprocessing modalities.
   - Outdated instructions. Push requirements to update old device instructions. Should be updated on annual basis.
   - How many cycles before a device is obsolete? How old is old? This definition should be established. How do you track cycles?

4. Elevate reprocessing to the level we need it to be at.
   - We have to re-educate people constantly because of turnover; we need to give respect and pay to the people who are reprocessing; separate central supply and reprocessing.
   - Decontamination is often done by those with the lowest level of education and training; education and skill do not match complexity of the devices
Appropriate resources:
- required equipment in each type of facility (ambulatory surgery center, hospital, etc.)
- Adequate facilities (e.g. space)
- Adequate staffing with appropriate pay

Root cause: lack of recognition of the importance of infection control across the industry; Start with education of top-level administration that they need to spend the money and support the efforts.
- Infection prevention is everybody's business
- Getting risk management involved
- Create a business case for infection prevention.

Workflow inefficiencies from outdated facilities
Cost is a challenge.
Time constraints

5. Not able to disassemble/reassemble
- Have to disassemble instrument to clean it. Much easier to clean if you don't have to disassemble it.
- CS are going to have to disassemble devices that are not intended to be disassembled
- Need instructions for reassembly as well as disassembly.
- Something on the device that tells us it has to be disassembled.
- When should the device be disassembled--before or after sterilization?
- Devices aren't designed to be cleaned from the very beginning of the design process. Small and angled lumens; Rough surface finish of internal components
  - It's not just the marker issue, it's the design of the product. If mfc doesn't understand that you can't effectively clean it, it should go back to the design phase. We need to emphasize that the mfc is responsible for validating cleaning methods for the most difficult-to-clean location.
- Lack of data around what does/doesn't work (e.g. registry that collects info about best practices) in real clinical environment; needs to become part of feedback loop; Mfc's don't talk to each other or with those cleaning the products [Combine with 6 and 5]
  - Post-market testing of devices.
  - Communication feedback loop with the mfc.

6. Accountability of users, of employers and clarity of who is accountable
- Not knowing exactly what the FDA wants; lack of clear standards
- Communication feedback loop with the mfc.

7. Training/education; Not just certification; ensuring they remain competent
- Good training from and for the manufacturers; Ability to obtain good training from manufacturers
- Standardized excellent educational materials
- Adequately trained manufacturer's reps
- Easy to say we need to require certification of CS professionals; obstacle is at state level; it is a 3-5 year process. We need a requirement to come from FDA, CDC, Joint Commission or other regulatory agency.
  - Maybe require 2-year degree and minimum pay comparable to the competencies
Mandated certification

- Manufacturers need to put the IFU on their websites and keep them current, as well as a complaint procedure to get customer feedback.