


Sterility Assurance & Quality Risk Management Conference



PDA[®]
Parenteral Drug Association

Midwest Chapter



**Sterility Assurance & Quality Risk
Management Conference**

**October
25th & 26th**



USP <797> Changes and its Impact on Your Environmental Monitoring Program

Alex McDaniel

EM Program Manager, Element Materials Technology



The “Top 5” EM Related Changes

- The “Designated Person”
- New Compounded Sterile Preparation (CSP) Categories
- Minimum Sampling Frequencies
- Incubation and ID Requirements
- Aseptic Manipulation Competency & Hand Hygiene and Garbing




The “Designated Person”

- Develops facility SOPs
- Acts as a liaison with vendors
- Implements staff training program
- “Gatekeeper” of access into the cleanroom suite
- Responsible for compliant handling



New CSP Categories

USP <797> (2008)		USP <797> (2022)
Low Risk		Category 1
Medium Risk		Category 2
High Risk		Category 3

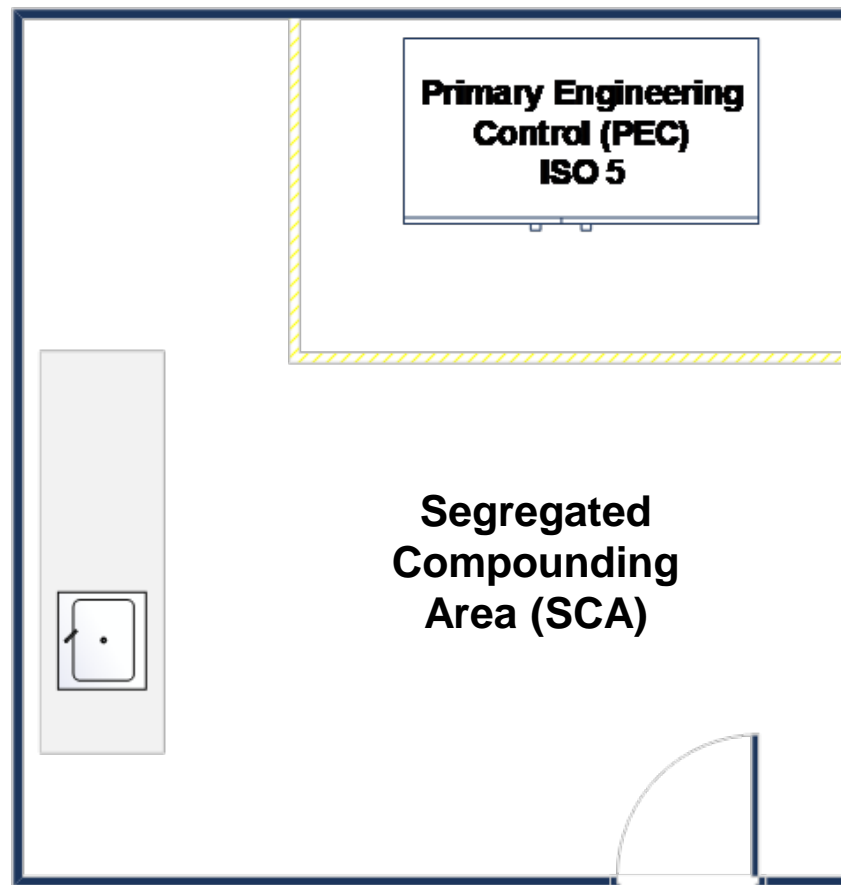


Sterility Assurance & Quality Risk Management Conference

October
25th & 26th

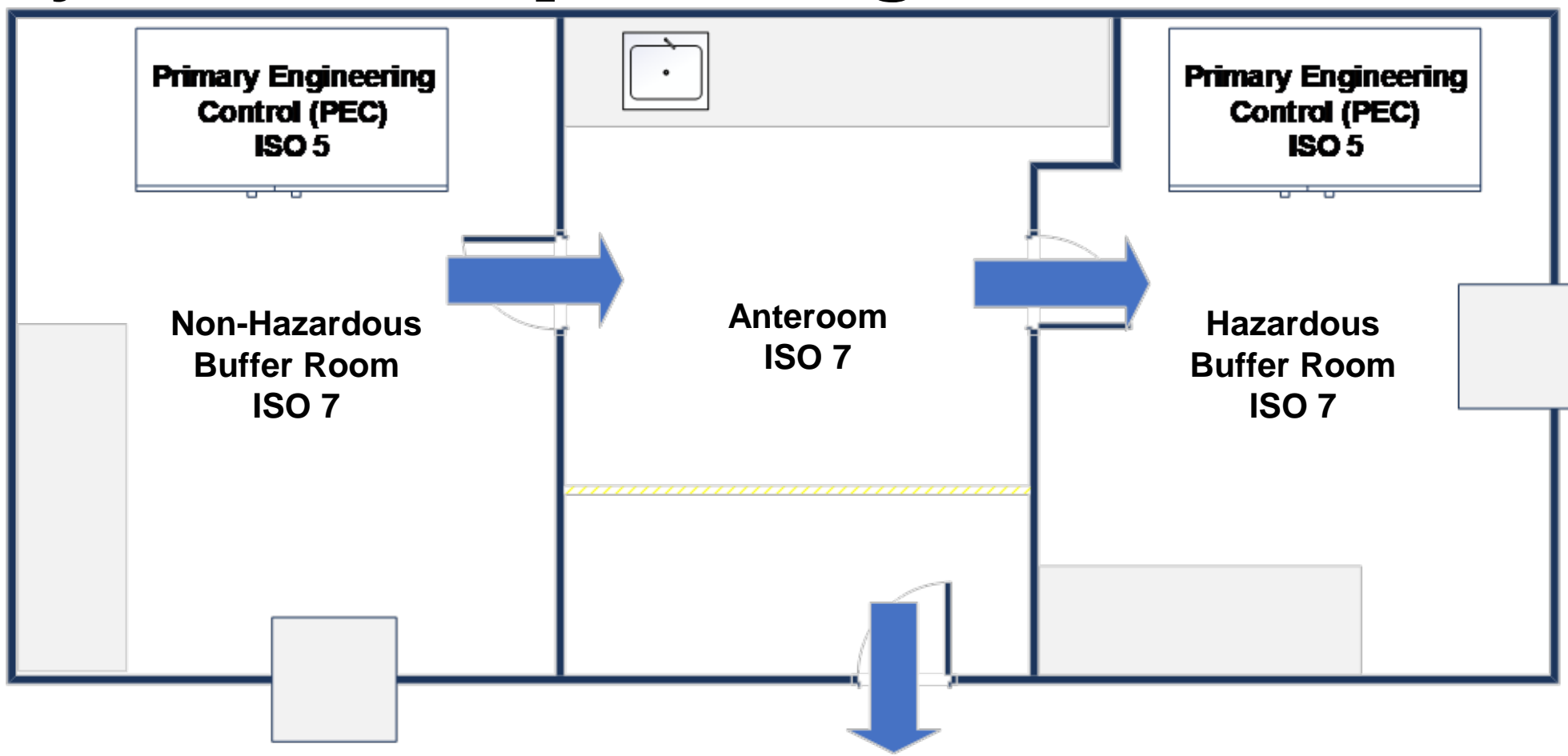


Category 1 Compounding





Category 2 & 3 Compounding





Minimum Sampling Frequencies

Category	Viable Active Air	Viable Surface	Total Particulate
1	Semi-Annual	Monthly	Semi-Annual
2	Semi-Annual	Monthly	Semi-Annual
3	Monthly	Weekly*	Semi-Annual

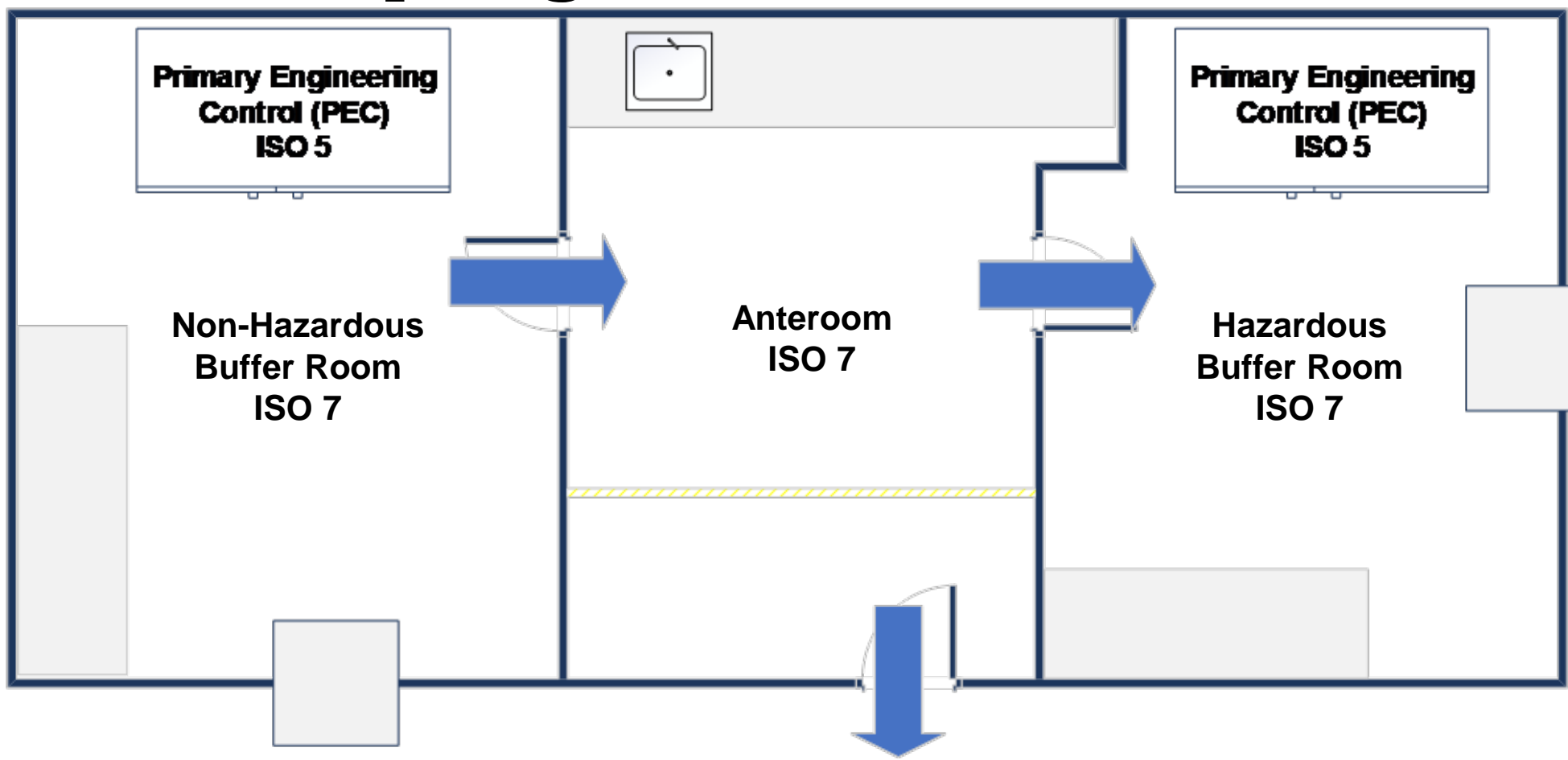


Revised Viable Action Levels

ISO Class	Viable Active Air	Viable Surface
5	> 1 CFU/m ³	> 3 CFU/plate
7	> 10 CFU/m ³	> 5 CFU/plate
8	> 100 CFU/m ³	> 50 CFU/plate

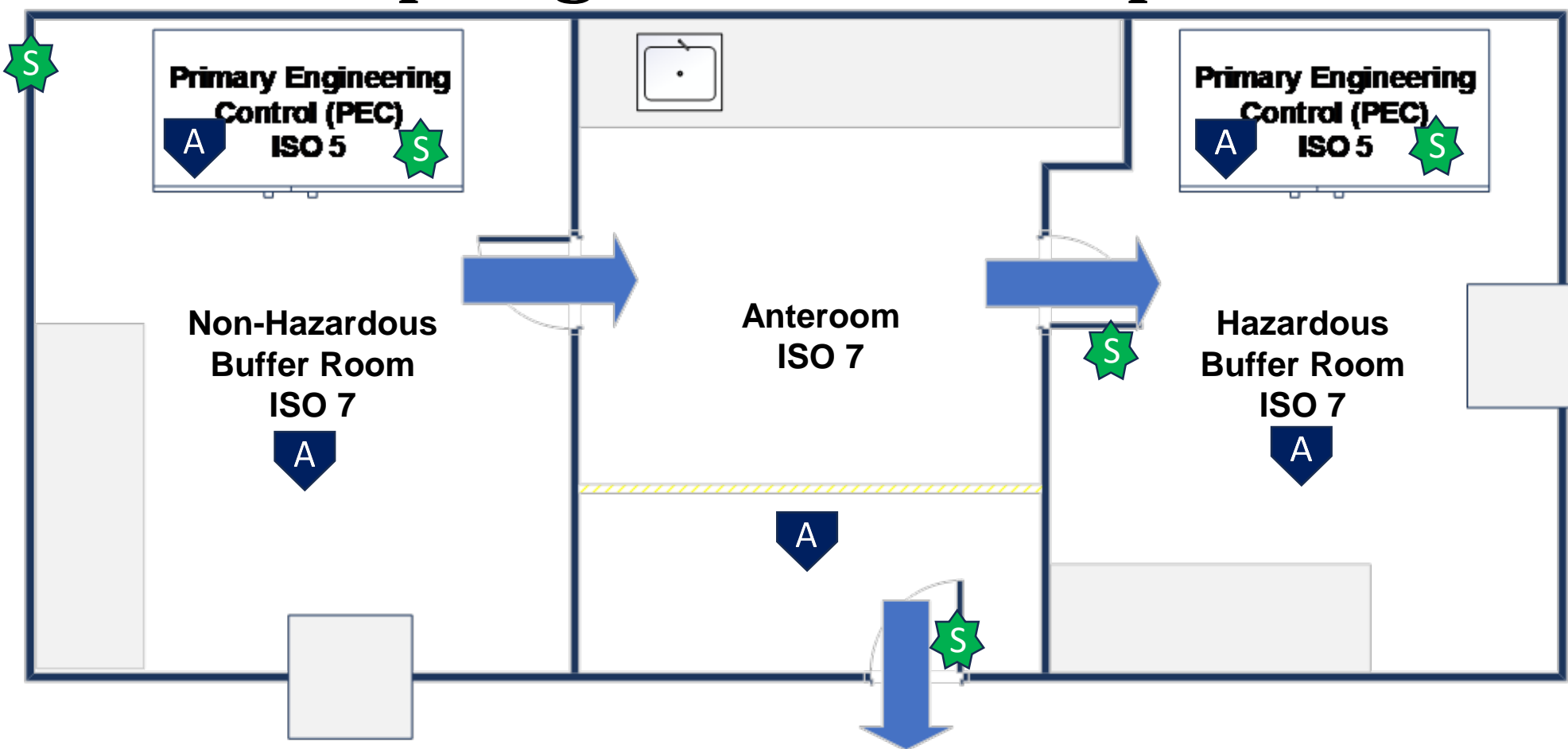


Risk-Based Sampling Locations?



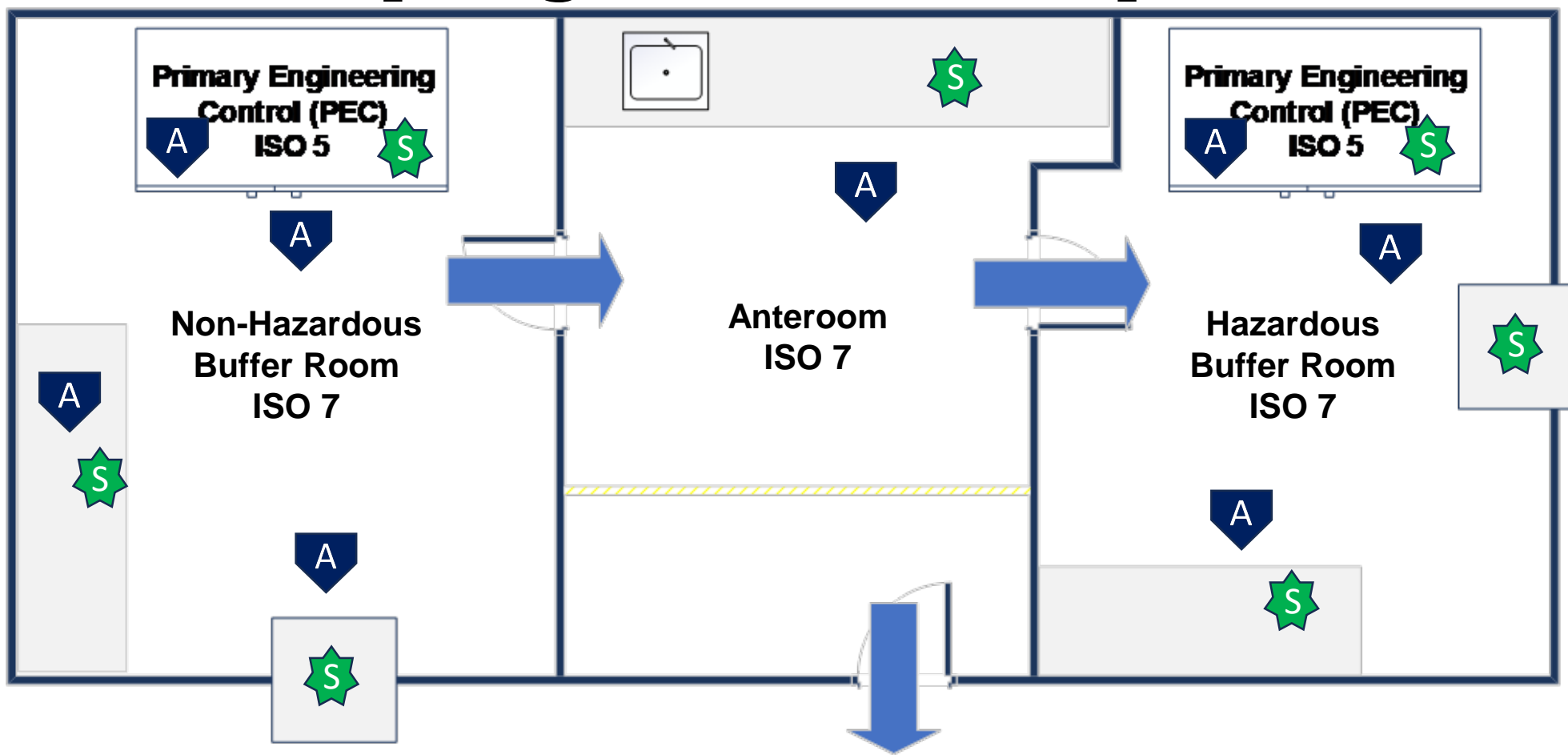


Risk-Based Sampling Locations? Option A





Risk-Based Sampling Locations? Option B





Routine Sampling vs. Cleaning “Spot Check”

- Based on the previous slides, which one provides the most useful information? Is one more risk-based than the other?
 - Option B, but it depends!
 - How to identify trends?
- May need to have different sampling plans for different situations
 - Leads to adoption of better work practices!
- Important to review and revise the plan over time...



Incubation and ID Requirements

- SDA media and TSA dual incubation “back half” = 20° C to 25° C
 - Fungal media requirement has been removed from the 2022 version
- Organism ID requirement is still to genus level
 - Now only if action level is exceeded
- “Highly pathogenic” focus organisms removed
- How to handle ISO 5 recoveries?



Aseptic Manipulation Competency

- Initial frequencies remain unchanged, however:
 - Post-fill surface sample of the PEC has been added
- Ongoing training for Category 1 and 2 = Semi-annual
- Requalification for Category 3 = Quarterly
- Media-fill TSB = two temperatures
 - 20° C to 25° C for 7 days, then 30° C to 35° C for 7 days

Testing Scope

TSB Media-fill

Post-fill DCA surface sample

Post-fill GFT samples



The Direct Compounding Area (DCA)





Aseptic Manipulation Competency Action Levels

Test	Action Level
TSB Media-fill	Any growth
Post-fill DCA surface sample	> 3 CFU/plate
Post-fill GFT samples	> 3 CFU (total both hands)



Hand Hygiene and Garbing

- Initial frequencies remain unchanged
 - Requires three separate and complete garbing and GFT samples
- Ongoing Training for Category 1 and 2 facilities = Semi-annual
- Ongoing Training for Category 3 = Quarterly
- Gloved Fingertip and Thumb Sampling (GFT) = dual temperature incubation
 - Previously only 30° C to 35° C for 48 to 72 hours



Hand Hygiene and Garbing Action Levels

Test	Action Level
Initial GFT (3 trials)	Any growth
Ongoing GFT (1 trial)	Any growth



Sterility Assurance & Quality Risk Management Conference

October
25th & 26th



Contact Information

Alex McDaniel

Environmental Monitoring Program Manager

Element Materials Technology

alex.mcdaniel@element.com