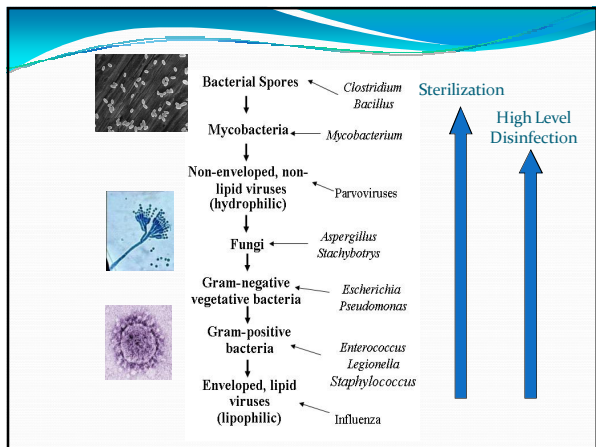


What is Liquid Chemical Sterilization?

Part II

The difference between LCS and High Level Disinfection (HLD)

- Hierarchy of organism resistance
- Validation data required to support LCS versus HLD claim



FDA definition of HLD and LCS

High Level Disinfectant
 A germicide that inactivates all microbial pathogens, except large numbers of bacterial endospores.

HLD cannot make sporicidal claims

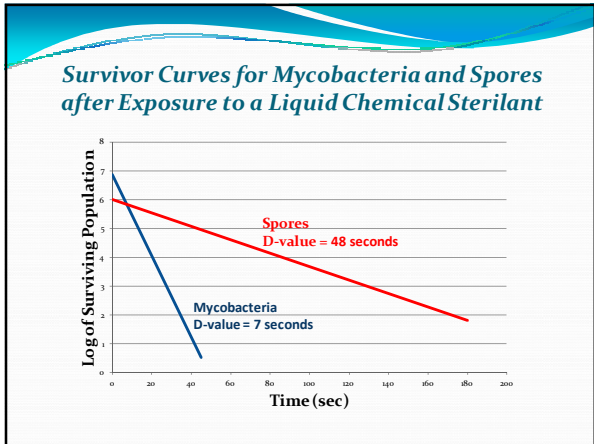
Sterilant
 An agent that destroys all forms of microbial life

Differences in Validation Methodology

Test	High Level Disinfection	Liquid Chemical Sterilization
Potency	Sporicidal Test > labeled contact time	Sporicidal test at labeled contact time
Simulated Use	Challenge Organism Mycobacterium	Challenge Organism Most Resistant Organism
In Use	No difference	

HLD Time Required to pass AOAC Sporocidal Test and Labeled Contact Time

High Level Disinfectant	Passed AOAC Sporocidal Test	Labeled Contact Time
EndoSpore Plus	3 Hours	15 Minutes
Reset XL	6 Hours	8 Minutes
Aldahol III	10 Hours	10 Minutes
Sporicidin	12 Hours	20 Minutes
Cidex OPA Concentrate	32 Hours	5 Minutes



Summary of Learning

- Part II: The difference between LCS and High Level Disinfection (HLD)
 - LCS is different from HLD in that LCS is effective against bacterial endoscopes while HLD are not
 - Validation testing for LCS differs from HLD in that the AOAC Sporidical Potency Test for LCS is conducted at the labeled contact time. For HLD the test is conducted for a much longer time as compared to the labeled contact time
 - Simulated use for LCS uses the most resistant organism (typically a bacterial endospore). HLD uses mycobacteria, which is much less resistant.
