

The Q-Net™ Monthly

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What's News -

The deadline for responses to Q-Net's recent survey has been extended to August 15, 1998. Results of this survey will soon be published in this newsletter. The honesty and candor of each respondent is appreciated.

Also, access to each of Q-Net's back issues will soon be available on the Internet. Q-Net will also have its own homepage that will include links and discussions of important infection control and instrument reprocessing issues. *Comments or ideas?* Send them to Q-Net.

'ER:' Essential Reading

Deva AK, et al. "Detection of persistent vegetative bacteria and amplified viral nucleic acid from in-use testing of gastrointestinal endoscopes." *Journal of Hospital Infection* 1998 June; 39(2);149-157.

What is 'Q-Net'?

Q-Net is a technology-assessment network of questions and answers. Its newsletter is *The Q-Net™ Monthly*.

Q-Net's main goal is to encourage the infection control and endoscopy communities not only to ask good questions but also to demand succinct and well referenced responses.

Q-Net addresses the needs of both the health care provider whose goal is to provide the best care possible, and the patient who deserves affordable quality health care.

What is disinfection, sterilization?

What do *high-level disinfection* and *sterilization* really mean?

The answer may not be so obvious.

TERMS: *sterilization, disinfection, starting titer, log reduction, % of kill*

Part I: Disinfection

The labels of liquid chemical sterilants ("LCSs") used to process semi-critical and critical medical instruments typically indicate the time (and temperature) required to destroy mycobacteria and bacterial endospores.

According to the label of a commonly used 2.4% glutaraldehyde solution, an exposure time of 45 minutes at 25° C destroys 100% of *Mycobacterium tuberculosis*.¹ This product's label also indicates that an exposure time of 10 minutes at 20° C and 25° C is necessary to kill 87.9% and 99.8%, respectively, of *M. tuberculosis*.

At first glance, the meaning and significance of these percentages seem obvious, if somewhat theoretical. To be sure, claims that a process destroys 50%, 75% or 100% of a population of microorganisms would not appear to leave much room for interpretation.

To achieve high-level disinfection ("HLD") (or sterilization), several criteria must be met. For example, the instrument must be thoroughly cleaned to remove organic debris capable of shielding underlying microorganisms. Measures that prevent recontamination of the instrument after chemical exposure must also be

exercised.

Of equal importance to satisfying these criteria is understanding the significance of the total number of microorganisms exposed to the LCS - often referred to as the *starting titer*.^{1,2}

Consequently, labels of LCSs that include the percentage of microorganisms killed during a specific immersion time arguably have little meaning unless presented along with the starting titer, which is often expressed as colony forming units per milliliter, or "CFUs/ml".

Without the LCS's label displaying both the percentage of mycobacteria destroyed *and* the starting titer, it is unclear whether a label claim that, say, "45 minutes is necessary to kill 100% *M. tuberculosis*," is based on the time required to kill as few as 10 or as many as 10 million CFUs/ml of mycobacteria. Indeed, underestimating the significance of the starting titer and its impact on the outcome of a process can result in misleading data.

Several published studies have determined the exposure times (and temperatures) necessary for a LCS to destroy mycobacteria. Using a starting titer of 10⁵ to 10⁶ CFUs/ml of mycobacteria,³⁻⁷ many of these studies found that exposing cleaned instruments to 2% glutaraldehyde for 20 minutes (or "dirty" instruments for 45 minutes) reliably achieves HLD.^{1,5}

Not every study's conclusions agree, however. One recent report found that a few mycobacteria survived exposure to 2% glutaraldehyde for 45 minutes.

(Continued on page 14)

Because 100% of the mycobacteria was not destroyed, this report questioned whether HLD of endoscopes could be achieved.²

☞ *Does this study's findings void the published guidelines that universally recommend a 20 minute soak in 2% glutaraldehyde to achieve HLD of a pre-cleaned item?*⁸

The reconciliation of this study's² findings with published guidelines that recommend a 20 minute soak rests in clarifying the clinical definition of HLD. While some studies suggest that destroying 100% of mycobacteria defines HLD,^{4,6,7} the Food and Drug Administration (FDA) defines HLD as (at least) a 6 log reduction of mycobacteria.⁹ *Are these two definitions the same?* Not necessarily.

For starting titers of mycobacteria equal to 10^5 to 10^6 CFUs/ml,^{3,7} these two definitions are virtually identical, as achieving a 6 log reduction is essentially the same as destroying 100% of the mycobacteria. (Refer to this newsletter's January 1997 issue for the definition of a 'log reduction.') But for starting titers that exceed 10^6 CFUs/ml, differences between these two definitions can be significant.

For example, if a starting titer of 10^8 CFUs/ml of mycobacteria were exposed to a process that destroyed all but 100 CFUs/ml (i.e., a 6 log reduction), would HLD have been achieved? Yes, according to the FDA's rigorous 6-log-reduction definition, despite the survival of some mycobacteria.² Per the definition of HLD that requires destroying 100% of the mycobacteria, however, HLD was not achieved. To destroy 100% of this starting titer, the process would have had to achieve an 8 log reduction, which is quite different from, and two orders of magnitude greater than, a 6 log reduction. In short, whether a process satisfies the FDA's definition of HLD depends on the starting titer and does not necessarily require destroying 100% of mycobacteria.

☞ *The FDA's definition of HLD requires (at least) a 6 log reduction of mycobacteria. Therefore, for a starting titer of 10^8 CFUs/ml, HLD is achieved even if as many as 100 CFUs/ml survive the process.*^{2,9}

To eliminate confusion, both clarifying the clinical definition of HLD and standardizing the starting titer of mycobacteria used to challenge the process is recommended. Otherwise, claims that a 45 minute soak in 2% glutaraldehyde may be insufficient to achieve HLD will likely persist.²

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Part 2: Sterilization

The same logic would apply to *sterilization*. To satisfy the FDA's requirements, a process must typically achieve a 12 log reduction of very resistant spore-forming bacteria to claim sterilization. Demonstration that the process destroys 10^6 bacterial endospores during a *half* cycle satisfies this requirement and defines a sterility assurance level, or SAL, of 10^{-6} . (That is, if the process's cycle lasts 12 minutes, 10^6 bacterial endospores must be destroyed within 6 minutes to claim sterilization. Note that destroying 10^6 bacterial spores during the sterilizer's *full* cycle defines a SAL of 10^{-3} .)

☞ *What if an item were contaminated with a starting titer of 10^{14} bacterial spores? Would 100% of these spores have to be destroyed to claim sterility? Or would only a 12 log reduction be required?*

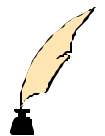
For a starting titer of 10^{14} bacterial endospores, as many as 100 would presumably be permitted to survive the process without violating the universally accepted definition of sterilization that specifies a 12 log reduction. And so it would appear that, for starting titers greater than 10^{12} , a process does not necessarily have to destroy 100% of the bacterial endospores to claim sterilization.

References

- 1 Rutala W, Weber D. Infect Control Hosp Epidemiol 16(4):231-235.
- 2 Urayama S, et al. Gastrointest Endosc 1996;43:451-456.
- 3 Collins FM. Appl Environ Microbiol 1987 Apr;53(4):737-739.
- 4 Ascenzi J, et al. Appl Environ Microbiol 1987 Sept;53(9):2189-2192.
- 5 Procide's "510(k) summary of safety and efficacy." Cottrell Ltd.
- 6 Bruckner NI. 1986 Mar;Johnson & Johnson Medical, Inc.
- 7 Ascenzi JM, et al. 1984 Oct;Johnson and Johnson Medical, Inc.
- 8 Muscarella L.F. Am J Infect Control 1998 Apr;26(2):153-155.
- 9 The FDA's "Guidance on the content and format of premarket 510(k) submissions for liquid chemical germicides," 1995,1997.

Thank you for your interest in this newsletter. *I have addressed each issue to the best of my ability. Respectfully, the Publisher: Lawrence F. Muscarella, PhD. Please mail all correspondence to:*

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