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What's New

The FDA is soliciting input from the public in order to improve the evaluation process for liquid chemical germicides. Comments should be submitted to: *Chief, Infection Control Devices Branch, 9200 Corporate Boulevard, HFZ-480, Room 350P, Rockville, MD 20850*. The deadline for comments is mid-July, 1997.

GI: 'General Interest'



We have received many requests for our book, "Q-Net 96: Questions and Answers in Infection Control and Endoscopy, Part 1," which is a collection of all of Q-Net's 1996 newsletters. To obtain a copy, please call or fax your order. The cost is \$9.95. This monthly newsletter is free!

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 to not only ask good questions but to also 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.

Limitations of flash sterilization, liquid chemical sterilants

This article discusses the quality and infection control limitations associated with both flash sterilization and liquid chemical sterilants.

Flash sterilization

To save time and eliminate the need to transport instruments to a central location, point-of-use processes, like flash sterilization, are increasing in popularity.

Although capable of destroying highly resistant bacterial endospores during a short exposure time, flash sterilization has its limitations. Arguably, it compromises sterility assurance for the benefit of time and convenience.

For example, a 3 minute flash sterilization cycle may be ineffective against bacterial spores completely destroyed by a 10 minute standard steam sterilization cycle (270° F at 30 psi).¹ As a result, flashing may only be appropriate in 'emergency situations'^{1,2} and is not for routine use.³

Moreover, proper quality and infection controls require wrapping the instrument in a protective material *prior* to sterilization to prevent environmental recontamination *after* sterilization. But flashed instruments are not wrapped and are removed wet from the sterilizer, making them susceptible to recontamination during their delivery to the patient.

Flash sterilization is technique-dependent and relies on the diligence and skills of the health-care facility's staff in order to be successful. If proper precautions are not taken, a flashed instrument may be unsterile (although not necessarily unsafe) at the time of its use.

Liquid chemical sterilants

Similar to flashing, processing an instrument in a liquid chemical sterilant, such as 2% glutaraldehyde for several hours, lacks important quality controls necessary to ensure a sterile instrument. Consider the following limitations:

(1) Instrument wrapping: Wrapping provides the instrument with a shelf-life. But, like with flashing, instruments processed in a liquid sterilant are not wrapped (and are wet) and are therefore susceptible to recontamination during handling.

(2) Biological indicators (BIs): BIs provide health care facilities with another important quality and infection control. Using BIs to reliably monitor the effectiveness of liquid sterilants, however, has been questioned.⁴ Immersing a BI in the liquid sterilant, rather than placing it at a difficult-to-access site, arguably yields data of little value.⁴

Other issues, including the possible violation of the BI's integrity when it is manually removed from its sterile packaging and dropped into the liquid sterilant, and the possibility that the liquid sterilant may inadvertently rinse away, rather than destroy, the bacterial spores on the BI (i.e., the 'wash-off' effect),

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contribute to the limited application of using BIs to monitor liquid chemical sterilants⁴ (refer to this newsletter's January 1996 issue.)

(3) Filtered vs. sterile(?) rinse water: Unlike with pressurized steam and ethylene oxide (EtO) gas sterilization, the outcome of instruments processed in a liquid chemical sterilant may be compromised by poor rinse water quality. (Rinse water, of course, is needed to remove residues remaining on the instrument after chemical immersion.) Reports document recontamination of endoscopes during the final water rinse with opportunistic microorganisms indigenous to the water supply of some health care facilities.

Bacterial filters are often used to improve the quality of the rinse water. When properly maintained, a bacterial filter can minimize the likelihood of instrument recontamination during water rinsing. But filters are not failsafe, and their performance after only a few uses may be less than ideal.

For example, water filtered through a bacterial filter, designed to produce 'bacteria-free' water, has been reported to contain bacteria.⁵ Filtered hospital water is not typically sterile because it can contain viruses, endotoxins, pyrogens,^{6,7} and bacteria that may have colonized on, and penetrated through, the filter's 0.2 micron bacterial membrane.

(4) Instrument design: The success of all sterilization processes depends on the adequacy of the cleaning process.* But manual pre-cleaning is difficult to standardize, control and monitor. And the physical design of some complex instruments may prevent cleaning all of its internal surfaces.

Flexible endoscopes, for example, contain a complex valve system and may have several internal channels that cannot be easily accessed or cleaned with a brush. The ability to reliably sterilize any instrument whose internal surfaces may not be adequately cleaned is often questioned.** The need to design complex instruments that can be properly cleaned and sterilized with pressurized steam cannot be overemphasized.

Recommendations

To compensate for the quality control limitations associated with flash sterilization and liquid chemical sterilants, the following measures, when appropriate, are recommended:

- As always, thoroughly clean the instrument using an appropriate detergent solution.
- Ensure that your flashed instruments meet the same cleaning standards as established in your sterile processing department.
- Flash sterilization provides a low margin of safety⁸ and may only be appropriate in emergency situations.^{1,3}

- Unwrapped instruments should be handled in a strict aseptic manner and used immediately.⁹ (Remember that unwrapped instruments do not have a shelf-life.)
- A bacterial water filter, used in conjunction with a sediment filter (e.g., 5 or 25 microns), is recommended to improve the quality of the rinse water. Also, instituting a written procedure to ensure that the filters are properly maintained and replaced when necessary is essential.
- As a final step, flush the endoscope's channels with 70% alcohol followed by forced air, even when using a filtered water rinse, to prevent bacterial growth in the endoscope's internal channels during storage.

* *If cleaning is inadequate, the sterilization process is likely to fail, which may explain why low-temperature sterilization processors, such as the STERRAD™ and ABTOX™ systems, are not currently marketed for 'sterilizing' flexible endoscopes (refer to references 10 and 11, below).*

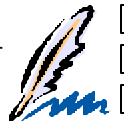
** *I anticipate that, because of their limitations, future liquid sterilants will likely be cleared by the FDA for high-level disinfection (not 'sterilization') of complex instruments.*

References

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Thank you for reading this newsletter. *I have addressed the above issues to the best of my ability. Respectfully, the*
 Publisher: *Lawrence F. Muscarella, PhD.* Please direct all correspondence to:

Lawrence F Muscarella, PhD, Publisher
 Director, Research and Development
 Chief, Infection Control



Custom Ultrasonics, Inc.
 144 Railroad Drive, Ivyland, PA 18974
 Tele: 215.364.1477; Fax: 215.364.7674



E-mail: q-net@msn.com

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