

# The Q-Net™ Monthly

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## What's News

Q-Net would like to welcome several of its newest subscribers who include healthcare practitioners in Denmark, France, Ireland, Israel, Italy, Malaysia, Saudi Arabia, Singapore, South Africa, Spain, Turkey, and the United Arab Emirates.

On August 28, 2002, the FDA posted in the *Federal Register* (Vol. 67, No. 167, pp. 55269-70) a notice soliciting information on current practices for opened-but-unused, single-use medical devices. The deadline for written comments is November 26, 2002.

## Editor-in-Chief

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## 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.

## Dear CDC, HICPAC:

This article is based on a letter written by this newsletter's editor (LFM) to the Centers for Disease Control and Prevention (CDC), in response to its "**Draft Guideline for Disinfection and Sterilization in Healthcare Facilities**," which was recently posted for comment. The CDC's final document is expected to be published later this year.



**Background:** In the April 30, 2002, issue of the *Federal Register* (Vol. 67, No. 83, p. 21252), the Centers for Disease Control and Prevention (CDC) notified the public of the publication of its *Draft Guideline for Disinfection and Sterilization in Healthcare Facilities*.<sup>1</sup> The CDC requested that the public review this document and provide comments.

Once finalized pending review of the public's submitted comments, this CDC draft guideline, referred to in this article as the *Draft*, is intended to be used by health care workers "responsible for monitoring and preventing infections in healthcare settings," especially those workers in charge of disinfecting and sterilizing reusable medical instrumentation.<sup>1</sup> The *Draft* will replace the section on disinfection and sterilization in the CDC's *Guideline for Handwashing and Hospital Environmental Control, 1985*.

The *Draft*, which is no longer available for public comment, is divided into two parts. The first provides information on chemical disinfectants and sterilization

methods used to reprocess patient-care equipment. The *Draft's* second part provides consensus recommendations of the *Healthcare Infection Control Practices Advisory Committee (HICPAC)* for the practice of disinfection and sterilization in healthcare settings.<sup>1</sup>

Although this *Draft's* guidelines and recommendations are very comprehensive and address many important infection control issues crucial to patient safety, some of its text could be modified and clarified in order to facilitate the reading and understanding of its content.

Below are some of the comments that this newsletter's editor (LFM) submitted to the CDC for consideration in response to the *Draft*. His complete response to the *Draft* can be read on this newsletter's homepage at: <http://www.myendosite.com/> Several of his submitted comments summarize conclusions previously published in this newsletter.

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## Liquid chemical sterilants (LCSs)

Throughout the *Draft*,<sup>1</sup> liquid chemical sterilants (LCSs) are described as biocidal agents that can be used not only for high-level disinfection but also for the sterilization of flexible endoscopes and other types of instruments (refer to the *Draft's* Tables 8 and 9). In particular, the *Draft* discusses at least two LCS-based automated endoscope reprocessors (AERs) labeled for sterilization. One of these AERs uses peracetic acid and was cleared by the Food and Drug Administration (FDA) almost 15 years ago and the second, which uses performic acid, was submitted to the FDA but to date has not been cleared for marketing.

Although not addressed in the *Draft*, controversy surrounds the application and labeling of LCSs and LCS-based AERs for the sterilization of flexible endoscopes and other types of instruments.<sup>2-17</sup> LCSs, unlike other sterilizing agents such as pressurized steam and ethylene oxide (EtO) gas, have several salient shortcomings that limit them from achieving sterilization, at least in the traditional sense. For instance, LCSs and LCS-based AERs, among other limitations:<sup>2-17</sup> (a) preclude instrument wrapping to maintain a shelf-life; (b) require a terminal water rinse that typically is not sterile (and therefore nor are the processed instruments) and may recontaminate the instruments with microorganisms following chemical immersion (which is why it is essential to dry the endoscope before storage); and (c) pose challenges to routine biological monitoring.<sup>10</sup>

Additionally, when used to reprocess complex instruments with narrow lumens, orifices, and connectors, the flow of LCSs may be impeded limiting their contact with every contaminated surface. Due in part to the difficulty microbiologically sampling all of a complex instrument's internal channels and components, validation of the effectiveness of a LCS labeled for sterilization can prove elusive.<sup>12,13</sup> Further, the survival curves of LCSs appear not to exhibit log-linear kinetics but rather their shapes are variable and depend on factors such as the LCS's stability and formulation.<sup>13</sup> Finally, available data suggest that LCSs are associated with a significantly higher sterility assurance level (SAL) than achieved by, for example, sterilization processes that use pressurized steam or EtO gas.<sup>4,13</sup> As the SAL increases, so too does the risk of instrument contamination and patient infection.

In fact, lacking are independently published reports or data that show processes that use LCSs can be used reliably to sterilize complex instruments, such as flexible endoscopes.

Ironically, the *Draft's* depiction of LCSs as chemical agents that can achieve sterilization (refer to the *Draft's* Table 9) appears to belie the FDA's current stance on the effectiveness of and appropriate label claims for LCSs. The consistent rejection over the years by the FDA of several 510(k) applications for LCSs and LCS-based processes labeled for sterilization would appear to suggest that the FDA is concerned about the marketing of these medical devices for

such applications.<sup>2-5,13</sup> In general, LCSs are used to achieve high-level disinfection.

**ANPR:** Cognizant of the inherent and aforementioned limitations of LCSs,<sup>2-17</sup> the FDA has suggested (person communication, 4-18-02) that it plans to post soon for public review an *Advance Notice of Proposed Rulemaking* (ANPR) that will address, among other issues, whether the current sterilization labeling of most LCSs is appropriate or warrants modification. Depending on the public's response to this ANPR, the FDA may consider replacing the "sterilization" claim on the labels of most currently cleared LCSs with a more limiting and justifiable "sporicidal" claim, modeling the effectiveness of LCSs after a sporicidal test developed by the *Association of Official Analytical Chemists* (AOAC).

The intent of such a proposed label change would be to eliminate confusion and to stress that LCSs are not associated with the same SAL as other traditional sterilization methods.<sup>4,13</sup> This proposed label change would also emphasize the differences between a multi-stepped *bona fide* sterilization process with built-in controls and the single-stepped process of immersing an instrument in a LCS the microbiological effectiveness of which is difficult to control and monitor.<sup>2,10,12</sup>

**AAMI:** Also raising for discussion the limitations of LCSs, the *Association for the Advancement of Medical Instrumentation* (AAMI) has indicated that it is considering modifying its Technical Information Report (AAMI TIR No. 7; 1999) document, entitled *Chemical Sterilants and High-level Disinfectants: A Guide to Selection and Use*, to be more consistent with recently published data and the FDA's current stance on LCSs. One of the topics that AAMI is likely to address during its review of this document is whether its description of LCSs and LCS-based processes labeled for sterilization is accurate and complete or warrants modification and clarification.

► *It is therefore recommended that the Draft be modified to include a discussion of the salient limitations of LCSs and how the available data do not support an instrument sterilization claim for LCSs.<sup>2-17</sup> It is further recommended that the Draft be modified as required to be consistent with the FDA's current stance on the effectiveness of LCSs.*

## Bacterial filters, sterile water?

The *Draft* discusses at least two AERs, one already cleared by the FDA and one currently under FDA review, that use a LCS (peracetic acid and performic acid, respectively) and are labeled to achieve instrument sterilization. These two AERs (and most others currently on the market) are equipped with a water filtration assembly that includes a 0.2 micron bacterial membrane. This assembly filters tap water used to rinse the

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instruments terminally after immersion in and exposure to a LCS. The water filtration assemblies of these two AERS are labeled to produce sterile rinse water.

But bacterial filters are not designed to produce sterile water from a hospital's tap water supply. Only under ideal conditions might they produce bacterial-free water. Moreover, because the water filtration process is not typically monitored microbiologically, the effectiveness of the filtration process, and therefore the microbial quality of the filtered rinse water, are generally unknown. Indeed, the quality of an instrument reprocessed by an AER is limited by and can only be as good as the quality of the AER's terminal water rinse. Contaminated rinse water yields contaminated instruments. Absent the sampling data necessary to evaluate the effectiveness of the filtration process and confirm that the filtered rinse water is sterile, as required to be consistent with an AER's sterilization label claim, it would seem necessary to conclude that the filtered rinse water, and therefore the terminally rinsed instruments, are unsterile (although not necessarily unsafe).<sup>6</sup> (A similar model applies to the use of biological indicators [BIs] for monitoring sterilization processes. When a steam sterilizer is not routinely monitored using BIs, then its effectiveness is in doubt and the processed instruments assumed to be unsterile.)

Indeed, there are no published reports in the medical literature that support the claim of sterility for unprocessed tap water that has been passed through a bacterial filter. The FDA has acknowledged that these data are lacking during discussions with and letters written to manufacturers through the years. The FDA has also recently expressed its concern that filtered rinse water claimed to be sterile may be mislabeled.<sup>15</sup>

Consider this: If bacterial filters were capable of reliably producing *bona fide* sterile water, then hospitals would be inclined to replace their hemodialysis units' expensive reverse osmosis (RO) water treatment systems with these relatively inexpensive bacterial filters. But bacterial filters by themselves are not used in hemodialysis applications, because they would be expected to place patients at a significantly increased risk of nosocomial infection from mycobacteria and gram-negative bacteria found in hospitals' water supplies.

► *It is therefore recommended that the Draft discuss in more detail the limitations of bacterial filters and their inability to produce sterile rinse water from a hospital's tap. It is also recommended that the Draft clarify the differences between the definitions and microbial qualities of: sterile water from a bottle, bacterial-free water, 0.2 micron filtered water, and tap water.*

### Monitoring the rinse water

In three recently published articles, this newsletter's editor recommends that U.S. facilities monitor the rinse water used

during endoscope reprocessing, particularly for bronchoscopes and ERCP endoscopes, for several reasons including to evaluate the effectiveness of an AER's water filtration system and to determine more reliably when the bacterial filters require changing<sup>6,15,16</sup> Although the merits of this practice have not been fully substantiated, several endoscopy organizations (but none in the U.S.) recommend it.<sup>18,19</sup>

Although not discussed in the *Draft*, the recommendation to sample routinely the rinse water used during endoscope reprocessing is germane to the *Draft's* guidelines and recommendations, particularly the sections that discuss the label claims of AERs. Future reports and guidelines that discuss the effectiveness of AERs and their label claims are encouraged to recognize that, because the rinse water contacts the instrument after chemical immersion and just prior to completion of the AER's cycle, the outcome of the reprocessed instrument (e.g., high-level disinfected, sterilized) is limited by and can only be as good as the quality of the AER's terminal water rinse. Part and parcel of the AER's label claim is the quality of the rinse water. If the rinse water is not monitored to confirm its microbial quality, then the AER's claim arguably cannot be supported.<sup>15</sup>

► *It is therefore suggested that the Draft discuss the potential merits of routinely sampling the rinse water used during endoscope reprocessing.*

### Updating the CDC *Draft's* references

The clear intent of the final publication of the *Draft's* guidelines and recommendations, as with all medical guidelines, is to provide a document that is comprehensive, accurate, and can be frequently cited and relied upon by healthcare practitioners. This goal may be better achieved, however, by updating some of the *Draft's* references.

#### Disinfecting rigid endoscopes, altering routine instrument reprocessing regimens?

For instance, the *Draft* uses the results of surveys published almost ten years ago to suggest that healthcare facilities today: (1) routinely high-level disinfect rigid endoscopes, such as arthroscopes and laparoscopes; and, (2) may alter their routine reprocessing regimen when an instrument is used on a patient known or suspected to be infected with a blood-borne pathogen, such as HCV or HIV.

A more recent survey conducted by this newsletter's editor indicates, however, that today these two practices may not be as prevalent as the *Draft* suggests.<sup>20</sup> Rather, the published data from this more recent survey suggest that in today's healthcare facilities: (1) high-level disinfection of rigid endoscopes is no longer routinely practiced and is being replaced more and more with steam sterilization; and (2) routine instrument reprocessing regimens are rarely

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altered for patients suspected of carrying blood-borne pathogens. These two apparent changes in practice during the past decade mark significant improvements in infection control.

► *It is therefore recommended that the Draft's references be updated as required to reflect accurately current practice vis-à-vis the high-level disinfection of rigid endoscopes and the alteration of instrument reprocessing regimens when a patient is suspected of carrying a blood-borne pathogen.*

### Low-temperature sterilizing agents

Although the *Draft* acknowledges that: (a) thermal sterilization processes have the widest margin of safety; (b) low-temperature sterilization processes, such as those that use LCSs, gases, plasmas or vapors, require direct contact with the instrument's surfaces to be effective and are likely to fail in the presence of patient debris; and, (c) understanding the limitations imposed by complex instrument designs is essential to the proper application and use of low-temperature sterilizing agents, the *Draft* also suggests that low-temperature sterilization processes, particularly those that use a LCS, are associated with the same SAL as thermal sterilization processes (refer to the *Draft's* Table 9).<sup>4</sup> Helpful for the reader would be inclusion in the *Draft* of data that highlight the significant differences between the reliability, effectiveness, and SALs of thermally-based sterilization processes compared to low-temperature sterilization processes, particularly those that use a LCS.

In order to reduce the risk of patient infection from a contaminated instrument, it is crucial to understand that all sterilization processes are not alike.<sup>4</sup> Whereas thermal sterilization processes are typically associated with a SAL of 10<sup>-6</sup>, low-temperature sterilization processes are expected, due in part to their more limiting physical properties, to have a significantly higher SAL.<sup>4</sup> Processes associated with a higher SAL would be expected to be associated with a higher risk of instrument contamination and therefore patient infection.

Moreover, understanding that all sterilization processes are not alike is important when deciding for a specific instrument which is the best process to use. For heat-sensitive instruments, gases and vapors are typically recommended. When use of these sterilizing agents is not feasible, then LCSs are recommended. For instruments not damaged by heat, pressure, and moisture, pressurized steam is recommended.<sup>4</sup> (Refer to this newsletter's September 1997 issue.)

► *It is therefore recommended that the Draft emphasize that pressurized steam is the sterilizing agent of choice and superior in comparison to low-temperature sterilizing agents, particularly LCSs. Low-temperature sterilizing agents are only appropriate for use with critical and semi-critical instruments damaged by heat, pressure, or moisture.*

### Reprocessing the endoscope's valves

It appears that some manufacturers may not have evaluated how effectively their AER reprocesses the endoscope's suction and air/water valves, even though each is an integral component of the endoscope. Without the data to demonstrate that both of these reusable valves can be successfully reprocessed, the effectiveness, labeling, and intended uses of the AER would arguably be in doubt. Indeed, the literature contains reports documenting nosocomial infections linked to contaminated endoscope valves. The importance of successfully reprocessing these valves should not be overlooked.

► *It is therefore recommended that the Draft's section on endoscopes include a discussion of the difficulty associated with reprocessing the endoscope's suction and air/water valves and the importance of taking the necessary measures to ensure both of these valves are adequately reprocessed.*

Purchasers of AERs may want to consider contacting each manufacturer and requesting the microbiological data that confirm not only that each of the endoscope's channels can be reprocessed, but also that both of the endoscope's valves can be adequately reprocessed. *The End*

References to this article are available at:  
<http://www.myendosite.com/refs08902.htm>



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, Editor in Chief.* Please direct all correspondence to:

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