previously, that 25°C, or 78°F, is achievable *only* by heating the solution. This can only be accomplished safely in an enclosed machine that cools the liquid before the machine is opened. If the manufacturer recommends 25°C for 45 minutes' immersion, if we use a reduced temperature of 20°C (68°F to 70°F), then should not the immersion time be extended to achieve the same result?

Although I have the utmost admiration and respect for Dr. Rutala, I disagree with his and Dr. Weber's recommendations for dual labeling unless each person who allows the 20-minute immersion at 20°C is 100% certain that the endoscopes in their healthcare facility are impeccably cleaned every time they are used. Even that may not be enough until the structure and materials of these instruments are improved to facilitate and guarantee adequate removal of microorganisms if the instrument is cleaned properly.

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To the Editor:

Rutala and Weber (April 1995 issue) provide a thoroughly researched rationale for their proposal that Cidex (Johnson & Johnson Medical Inc) be considered to produce high-level disinfection of cleaned endoscopes after a 20-minute immersion at 25°C. Do they extend this proposal to all glutaraldehyde preparations achieving a sterilant and tuberculocidal label claim, regardless of the exposure time required to produce 100% *Mycobacterium* tuberculocidal activity? Do they extend this proposal to all other disinfectants with a tuberculocidal and sterilant claim? Would they extend this proposal further to bleach or pasteurization, neither of which are likely to achieve FDA registration?

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The authors reply

In response to Ms. Gurevich's comments, we agree that proper cleaning of endoscopes following each use is a critical and essential step that must precede high-level disinfection and sterilization. All hospitals should adhere rigorously to a standard cleaning protocol.[1] As noted in our paper, high-level disinfection without proper cleaning, even with a 45-minute immersion at 25°C, is not an acceptable practice.[2] We do not believe that having dual label instructions would be confusing, because longer immersion times at a higher temperature would be advised only for the unusual circumstances when cleaning of the endoscope was delayed or performed improperly. Although there is a direct relationship between improved tuberculocidal activity of glutaraldehydes and elevated temperature,[3] excellent tuberculocidal activity has been demonstrated at 20°C temperature (see Table 2 of our paper). Specifically, these studies demonstrated that glutaraldehyde solutions inactivated 4.0 to 6.4 logs of *Mycobacterium tuberculosis* at 20 minutes.

We also believe that longer immersion times at a higher temperature may have several adverse outcomes, including the potential hazard to hospital personnel resulting from higher ambient air levels of glutaraldehyde that may result from use of higher temperature soaks, the increased possibility of chemical colitis in patients due to release of glutaraldehyde from endoscopes subject to more prolonged immersion (ie, prolonged immersion at high temperature may result in absorption of glutaraldehyde by scope material),[4] decreased equipment life expectancy due to moisture damage or corrosion, and increased cost of endoscopic procedures due to increased processing time.

In response to Dr. Rhame's questions regarding the extension of our proposal to other chemical sterilants with a tuberculocidal and sporicidal claim (eg, other 2% glutaraldehydes, 6% hydrogen peroxide), we offer the following comments. Chemical sterilants, prior to having their tuberculocidal label claim cleared by the Food and Drug Administration, should be shown to inactivate reliably at least 5.0 logs of *M tuberculosis* (and other microorganisms, with the exception of bacterial endospores) within 20 minutes at 20°C. Based on current data, all 2% glutaraldehyde preparations should possess similar tuberculocidal activity.[5,6] However, because of the risk of approving an ineffective agent, the tuberculocidal claim for each agent should be independently verified. Any agent or process that is demonstrated scientifically to achieve the above tuberculocidal activity (ie, >5-log reduction) following proper cleaning, is safe for use on endoscopes and other semicritical medical devices, and does not represent an occupational hazard could be an acceptable alternative to glutaraldehyde.

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Correction

Recommendations for Preventing the Spread of Vancomycin Resistance

It has come to our attention that an organism was cited incorrectly in the Special Report "Recommendations for Preventing the Spread of Vancomycin Resistance" (1995;16:105-113). On page 106, column 1, paragraph 1, the last sentence should read, "Although vancomycin resistance in clinical strains of *S epidermidis* or *S aureus* has not been reported, vancomycin-resistant strains of *Staphylococcus haemolyticus* have been isolated."

NIOSH to Issue User Guidelines

by Gina Pugliese, RN, MS
Medical News Editor

The National Institute of Occupational Safety and Health (NIOSH) recently developed a draft user's guideline to assist with selection of the new nonpowered particulate filter respirators that will be certified under NIOSH's recently revised testing and certification procedures. These revised procedures, contained in 42 CFR 84, introduced three new classes (N-, R-, and P-series) of particulate filters for respirators and replaced the old regulations under 30 CFR 11. Each class may have filters certified at 95%, 99%, and 99.97%, for a total of nine classes of air-purifying particulate respirators. These new filter types eventually will replace the dust-mist, dust-mist-fume, high-efficiency, and other types of particulate filters. Manufacturers of respirators certified under the old regulations (30 CFR 11) will be allowed to sell them until July 1998. The NIOSH user's guidelines will help respirator purchasers, users, and program managers to determine which of the new filter types to use in different work environments. NIOSH jointly sponsored an open meeting on July 10-12, 1995, with the American Industrial Hygiene Association to receive comments on the draft user's guidelines. Comments were requested on a number of topics, including the duration of use and reuse of respirators.

How will all this affect TB respirators? These long-awaited revised certification procedures will allow users to select from a large universe of certified respirators that meet the CDC performance criteria for respiratory protection devices used in healthcare facilities for protection against tuberculosis. According to the NIOSH draft user's guideline, "all nine classes of air-purifying particulate respirators" certified under NIOSH's revised procedures (42 CFR 84) "will meet or exceed CDC requirements for TB, and several of these respirators will be less expensive and more comfortable than the HEPA filter respirators."

FROM: Department of Health and Human Services. NIOSH announces workshop in user's guideline for Part 84 nonpowered air-purifying particulate respirators. *Federal Register.* June 30, 1995; vol 60 (126) p 34385.