Letters to the Editor

A Thank You to SHEA

See page 529.

To the Editor:

The National Institute for Occupational Safety and Health respirator regulation, 42 CFR Part 84, finally cleared departmental and OMB review and was published in the *Federal Register* (60 FR 30336) on June 8, with an effective date of July 10, 1995. I have provided a brief summary of the key provisions of the final regulation. *(See this issue's Special Report on page 529.)*

I want to express my appreciation for all the help provided by SHEA and its members in educating concerned individuals and organizations on how important this regulation will be to the health of American workers. In particular, SHEA's Dr. Michael Tapper was instrumental in providing key information in a timely manner. I am especially appreciative of his understanding and support in shepherding this important rule in these difficult times.

Thank you again for all your help. I know we all look forward to the improved protection and wider range of options that 42 CFR 84 makes possible.

Linda Rosenstock, MD, MPH
Director
National Institute for Occupational Safety and Health
Washington, DC

The New 16-Towel Test Pack: Is It a Challenge to the Sterilizer?

To the Editor:

In Part II of their comprehensive evaluation of the rapid readout biological indicators for 132°C vacuum-assisted steam sterilization cycles, Dr. Vesley and his colleagues[1] used what they described as "a standard 16-towel pack recommended by AAMI." As a point of reference for that pack, the authors cite a document published by the Association for the Advancement of Medical Instrumention (AAMI) in 1993, *Good Hospital Practice: Steam Sterilization and Sterility Sterilization*.[2]

Actually, the pack was first introduced to the community in the 1988 edition of this document.[3] Detailed information on its development and qualifications is to be found in Appendix E of each edition.

Basically, the 16-towel test pack was developed to replace the traditional 12 lb, 12 in × 12 in × 20 in test pack (density, 7.2 lbs/cu ft) that was based on the work done by Perkins in 1969.[4] Although this pack configuration had been adopted by a number of professional organizations, including AAMI, the Association of Operating Room Nurses, and central service societies, difficulties in obtaining the necessary components began to emerge with the passage of time.

Through cooperative efforts among hospital personnel, industry representatives, and independent consultants, the task of developing a new biological-indicator test pack was undertaken. The objectives of the project were twofold: (1) to develop a pack that could be made of components readily available to hospital personnel, and (2) to develop a pack that would have the same performance characteristics as those of the original test pack.

So it was that a pack consisting of 16 all-cotton unwrapped huck towels, with an average size of 9.4 in × 8.9 in × 6.1 in, an average weight of 3.3 lbs, and density of 11.3 lbs/cu ft was found to be the equivalent.

In describing the original test pack, the AAMI documents indicate that, in addition to 12 huck towels, 30 gauze sponges, and 5 lap sponges, there were "no less than three Type 140 thread-count muslin (100% cotton) surgical gowns and one Type 140 thread-count muslin (100% cotton) surgical drape . . ." and that the assembled components were to "be sequentially wrapped—such that each wrapper can be removed separately—with two Type 140 thread-count muslin (100% cotton) wrappers and secured with suitable tape."

Considering the fact that this original pack already contained 12 towels, one can only conclude that the four additional towels in the new pack (that, incidentally, weigh less than 1 lb) present a challenge to the sterilizer that is equal to that presented by the three surgical gowns, one surgical drape, and two large wrappers, all of which are made of the Type 140 thread-count muslin (100% cotton) and that have a cumulative weight of 8 to 9 lbs!

Not to be overlooked is Perkins' observation, in his infamous text, to the effect that "of the various types of dry goods encountered in the operating room, the table drapes and sheets are the most difficult to sterilize. . . . Towels, on the contrary, present no special problem when included in the major pack. The towel fabric is relatively coarse and, even when ironed, it offers little resistance to the passage of steam."

Other than the comparative time-temperature profile data between the old and new test packs that appeared in the AAMI documents, to the best of my knowledge, these data have yet to be published in any healthcare-oriented journal. More importantly, it would be interesting to know whether or not they have been replicated by any clinical investigator or professional group.

Let it be clearly understood that it is not my intent to challenge or repute the results reported by Dr.

Vesley, but rather only to question their efficacy predicated on a test pack that may not be appropriate for validating the operating efficiency of the sterilizer, let alone the efficacy of a device used in a vitally critical application.

REFERENCES

1. Vesley D, Nellis MA, Allwood PB. Evaluation of a rapid readout biological indicator for 121°C gravity and 132°C vacuum-assisted steam sterilization cycles. *Infect Control Hosp Epidemiol* 1995;16:281-286.
2. Association for the Advancement of Medical Instrumentation. *Good Hospital Practice: Steam Sterilization and Sterility Assurance*. Arlington, VA: ANSI/AAMI; ST46-1993.
3. Association for the Advancement of Medical Instrumentation. *Good Hospital Practice: Steam Sterilization and Sterility Assurance*. Arlington, VA: AAMI; SSSA-1988.
4. Perkins JJ. 2nd ed. *Principles and Methods of Sterilization in Health Sciences*. Springfield, IL: Charles C. Thomas; 1969.

Nathan L. Belkin, PhD
Clearwater, Florida

The authors reply

Dr. Belkin's letter raises an important issue relative to the simulation of in-use conditions in a steam sterilizer using the standard AAMI test pack. However, our purpose was not to validate the performance of the sterilizer, but to evaluate the new rapid readout indicator developed by 3M. Indeed, a denser and larger test pack could result in additional positive indicators at the times we tested, and we would hope that AAMI will continue to seek a standard pack that realistically simulates the actual in-use conditions of these sterilizers. We do not feel qualified to pass judgment on that issue at this time.

Using the currently recommended AAMI test pack, we believe that we have demonstrated conclusively that the new biological indicator (BI) is significantly more sensitive in detecting failures of the sterilizer to maintain the prescribed time and temperature parameters than any other indicator on the market and that it can do so in a much shorter time. It was our observation that the vacuum-assisted sterilizer that we used in our studies rendered all of the tested BIs negative (killed all the spores) in a considerably shorter time than the recommended cycle. Indeed, we had some negative BIs even at zero time. Perhaps this would compensate for the lesser density of the test pack.

Donald Vesley, PhD
Melissa A. Nellis, MPH
Paul B. Allwood, MPH
Division of Environmental and Occupational Health
School of Public Health
University of Minnesota
Minneapolis, Minnesota

FDA Labeling Requirements for Disinfection of Endoscopes: A Counterpoint

To the Editor:

I would like to offer the following commentary in response to Dr. William Rutala's article, "FDA Label Requirements for Disinfection of Endoscopes: A Counterpoint."[1]

Drs. Rutala and Weber suggest that "The FDA should modify the label of the liquid germicide that requires a 45-minute immersion at 25°C to support a high-level disinfection claim. Their recommendation is for the label to state, "if cleaning is accomplished using a standard cleaning protocol, then a 20-minute immersion at 20°C will be sufficient." Their conclusions are based on the fact that investigators found that cleaning alone reduces the microbial load enough to allow such a reduction in time and temperature. No doubt, when flexible endoscopes are properly cleaned, as would be the case when an investigation or research project is undertaken, the findings would be verified.

But—and it is a big but—under less controlled conditions, such as in a busy hospital or private practice, cleaning is much less adequate. This was demonstrated clearly in an article published in 1992 in the *American Journal of Medicine*.[2] The authors draw very different conclusions from their review of actual processing of endoscopes. Through interviews and observation, they found fundamental errors in the cleaning. They also found that 23.9% of bacterial cultures obtained from the internal channels grew ⩾100,000 colonies after cleaning and disinfection of the scopes. This occurred when personnel knew they were being interviewed and observed; infection control personnel can only guess what happens when no one is checking.

But, even when personnel process these instruments conscientiously and to the best of their ability, they may not achieve the cleanliness they strive for; the structure and materials of the endoscopes hinder efforts for effective cleaning. These conclusions and concerns are voiced in the APIC Guideline for Infection Prevention and Control in Flexible Endoscopy.[3,4]

I oppose having dual label instructions for disinfection, one for instruments that are adequately cleaned and another when adequate cleaning is not achieved. First of all, no one would recognize or want to admit, even to themselves, that they are not adequately doing what they are supposed to be doing. And second, when they see the 20-minute, 20°C instructions, they may read no further.

There is a third reason I oppose such labeling. If the manufacturer feels 45 minutes' immersion at 25°C is necessary, we should not reduce the time. If anything, the time should be increased to allow for errors. And up to now, no one has yet explained to my satisfaction why the 25°C temperature is listed by the manufacturer, and yet 20°C is recommended by Drs. Rutala and Weber. I hope readers will remember, from articles I have published