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.

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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.

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