continued from page 286

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Richard Gammon, PhD
Cynthia Boris, MS
Research Microbiologists
American Sterilizer Co.
Erie, Pennsylvania

Ms. Kotilainen and Dr. Gantz reply to Dr. Gammon and Ms. Boris.

Thank you for the opportunity to respond to the interesting, if somewhat biased, letter from Dr. Richard Gammon and Ms. Cynthia Boris of AMSCO Medical Products. Our response to each of their four concerns follows.

Their first point seems insignificant given that the difference between 10^2 microorganisms and 10^3 microorganisms is only 1 log. However, we will agree that most organisms encountered on instruments could be expected to be vegetative without any significant steam resistance. We certainly agree that spore strips have been the gold standard for cycle monitoring. Published standards from the United States Pharmacopeia (USP), however, state that BIs for steam sterilization should contain 10^4 to 10^9 spores per strip of Bacillus *stearothermophilus* Standards for flash sterilization BIs are not published, but USP does state that when another spore concentration is used and subjected to 121 ± 0.5°C, the D value should be between 1.3 and 1.9 minutes. As manufacturers do not routinely publish D values, the consumer is left wondering why Proof Flash contains 10^7 spores versus 10^5 spores. Interestingly, Proof Plus contains 10^4 spores.

We do not believe that the come-up time was excessive. In our experience with other flash units at other facilities the average come-up time is 1 minute 15 seconds. However, as Perkins and others have stated, a true sterilization-capable cycle is not achieved until the proper temperature and pressure has been met for the required time. We do not feel that users should include come-up time as part of an appropriate length cycle.

However, for the sake of discussion, even if come-up time is included in the length of the cycle, at the one-minute exposure level (total cycle length 2 minutes, 31 seconds) in run #1, only 44% of the Proof Flash became positive by seven days, and more importantly for the hospital user, 8.3% were positive by 48 hours. This slow outgrowth was also reflected in one positive control which required 36 hours for a media color change. At the time of the study, the Proof Flash product insert stated a "high degree of readout reliability at 48 hours of incubating" and suggested that for additional confidence, incubation could be extended to seven days.

The FDA guideline, which uses a sample size of 100, is intended to be used as suggested reference for industry. However, for the number of samples tested and the results generated, the data cannot be interpreted as due to chance alone. Daily readings were taken for each RI tested; these results added little to the published study and were not included on the tables because of their cluttering effect.

The Attest BI was not incubated in this study for seven days as we were following the manufacturer's instructions. However, since this time, we have repeated this evaluation for additional lots of Attest as well as Proof Flash. We found no outgrowth of Attest after 48 hours when held up to seven days.

We recognize AMSCO's concerns over user incompatibility. We did read the package inserts and did use the suggested crusher. The experiment was repeated because of our wish to give Proof Flash a fair evaluation. As stated in the article in the second run, all Proof Flash were properly cracked, sealed, and seated after a fair amount of practice. Evaporation of media before seven days was still observed.

The information about browning of media when exposed to temperatures exceeding 280°F is interesting. As a recording thermometer was threaded through the door gasket and temperature continuously monitored, we can assure you that at no time did the temperature exceed 275°C for any run. When we noted discolored media, we meant that it was brown, not light purple, on removal from the sterilizer and that it did not return to its original color.

In summary, given the conditions under which flash sterilization is usually performed, commonly without optimal preparation of the materials and user intervention of the cycle, our facility prefers not only a more resistant biological indicator but also one with a narrower survive/kill ratio. As we do not dismiss our occasional positive spore tests as nuisances or flukes and by monitoring our sterilizers daily with two BIs for each unit, we have been able to detect minor inconsistencies in cycle performance, such as poor steam quality or aging door gaskets, before a major failure occurs. In flash sterilization, a major failure can not be acted upon either because the instruments have already been used or a patient, often under anesthesia, waits for instruments to be reprocessed in a functioning sterilizer. Proof Flash was an unsatisfactory indicator system using standard methodology.

Helen Rosen Kotilainen, MA, MT(ASCP), CIC
Nelson M. Gantz, MD, FACP
Infection Control Department
University of Massachusetts Medical Center
Worcester, Massachusetts

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