to dedicate its efforts to respond to the best of its ability to the needs and demands of the healthcare community it serves. However, it is only the healthcare community that should be determining the level of performance they expect that technology to provide.

In the interim, it appears that it would be proper for industry to adopt one of the simple and inexpensive test methodologies described in the clinical literature[4,6,14] for the screening of materials. These data could then be submitted for the ICP's use in assessing the protective attributes of the state-of-the-art materials as well as the gowns design, construction, and cost.

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Guaiac Testing of IV Lines

To the Editor:

The article by Manian et al (1993;14:325-330) regarding the risk of transmission of bloodborne illness through needles removed from IV ports was timely and important to the management of this common occurrence.

One point that the authors did not raise involves the possibility that guaiac testing may not always detect the presence of blood. Although I do not know enough about the physics of the fluids involved to predict this with any accuracy, it would seem likely that a certain amount of sedimentation might occur naturally at the end of an IV line. If this is so, the lighter elements of the serum may be found considerably higher in the line than red cells, and the risk of infection might be significantly higher than predicted in this article.

Pamela Patrick
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The authors reply:

We appreciate Ms. Patrick's interest in our article. We do not believe sedimentation of blood in IV tubings confounds the results of our study, for several reasons.

First, it should be remembered that all needles in our study were removed from IV lines immediately after the administration of IV medications. Thus, any preexisting serum in the upper half of the IV line would not have remained undisturbed and instead would have been mixed with the red blood cells during the process of insertion and removal of the needle, and perhaps more importantly during the administration of medication.

Second, except for the heparin-locks, the tip of the needles removed from IV ports often were near the junction of the port and the main running line, and area that would not be conducive to undisturbed sedimentation of red blood cells.

Third, since some degree of hemolysis is inevitable in IV lines, even if there were significant sedimentation of blood, guaiac testing still would have detected extracorpuscular hemoglobin in the serum at the threshold level reported in the study.

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Port-a-Cath Needlestick Injuries

To the Editor:

Needlestick injuries are the major hazard for healthcare workers for acquiring human immunodeficiency virus (HIV) infection during their work.[1] Surveillance for needlestick accidents and study of the circumstances of such accidents are of critical importance when proposing preventive measures.

Recently, in our acquired immunodeficiency syndrome care center, two needlestick injuries occurred while removing needles from Port-a-Cath systems. These Port-a-Cath systems were used to administer intravenous foscarnet/gancyclovir treatment

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FIGURE. A grooved director is used to immobilize the Port-a-Cath.

in two patients with cytomegalovirus retinitis. Each healthcare worker stuck himself in the hand he used to immobilize the Port-a-Cath system while removing the needle with the other hand.

After these two accidents, we began to advise healthcare workers who use Port-a-Cath systems to use a grooved director (Figure) to immobilize the Port-a-Cath. Since then, no new Port-a-Cath needlesticks have been reported in our center.

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Biological Indicators for a Liquid Chemical Sterilizer

To the Editor:

The editorial recently written by Bond[1] is an interesting personal commentary. The editorialist takes issue not only with the use of biological indicators for a liquid chemical sterilizer as presented by Kralovic,[2] but also takes issue with the only system that employs an EPA registered sterilant and which, as a system (Processor and Sterilant), has FDA market clearance as a sterile processing system-namely, the STERIS SYSTEM 1 Processor with STERIS 20 Sterilant. He questions the EPA and FDA review process for this system. Bond offers a challenge to manufacturers of chemical germicides and reprocessing systems to "join with the infection control community in influencing governmental agencies to act accordingly under their existing regulatory authorities."[1] Further, he calls for medical instrument manufacturers to redesign devices and provide data-based instructions on access and cleaning. All this is done without providing the readers, and in general the infection control community and the public, with a sense of understanding of the progress that has and is being made to provide the practitioner with higher standards of care. Instead, he places fear and doom and gloom in not only the use of biological monitoring, but also STERIS SYSTEM 1, the process for regulatory approval, and present instrument designs.

Let's consider his discussion of biological monitoring first. He notes that to use biological monitors, designed for use with steam or ethylene oxide sterilization, by removing them from their containers and exposing them directly to a fluid environment to monitor the efficacy of a liquid chemical sterilization cycle is not warranted by the data presented by Kralovic.[2] Bond never directly addresses whether Kralovic's data are inaccurate or unwarranted. Instead, to support his conclusion, Bond attempts to refute Kralovic's argument that biological indicators can be used to monitor liquid chemical sterilization processors by stating that they do not offer proof of sterility of each individual item; conversely, he admits that they are not intended for this purpose. The purpose of a biological monitor is to demonstrate whether sterilization conditions were met.[3,4] For a liquid chemical sterilization system, that implies that the designated time of the cycle and the required concentration and temperature of the sterilant are achieved.

Regarding the issue raised by Bond of the appropriateness of the spore test species, published and accepted requirements for biological monitors are that the spores selected have demonstrable resistance to the sterilizing agent and that they be more resistant than the bioburden found on medical devices.[5] Kralovic demonstrated the resistance of *Bacillus stearothermophilus* and *Bacillus subtilis*.[2] It was shown that *B stearothermophilus* was two to three times more resistant to the sterilant than *B subtilis*.

Bond notes that spores may remain on the strip, but that 400 were removed from the *B stearothermophilus* strip (the strip chosen for subsequent use in monitoring the process). This represents only 0.2% of the total number of spores on the strip. What remained was more than "some"[1] that he notes. Why the loss of some spores may "eliminate any notion that this technique is suitable for routine monitoring of cycles in healthcare settings"[1] is not understandable. STERIS SYSTEM 1 is a closed system. Spores on the strip and any that may be separated from the strip are contained in the fluid and inactivated by the sterilant. Testing of the sterilant at the end of a sterilization cycle and tests of the rinse waters taken from the processor show that they are sterile. This indicates that even if spores are separated from the strip they are killed. The studies of Kralovic[2] point out that only a

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