

whether the proprietary rapid dip stick/slide test was relied on as the gold standard (as per reference 17 in the McCoy et al. article<sup>2,3</sup>). The authors too easily explain away the occurrence of the nosocomial cases as being possibly attributed to viable but nonculturable *Legionella* and provide little to no discussion on study limitations and alternative explanations that are more plausible.

Given the alternate interpretation of the observations reported in this article, a more objective and critical review of the HACCP method (a process control system approach most commonly used in food production and processing settings) is warranted before it is recommended as a Legionnaires' disease prevention approach in nonprocess control settings, such as building water systems.

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## Reply to Shelton

*To the Editor*—We disagree with Mr Shelton<sup>1</sup> that our water management program (WMP) failed and that use of the hazard analysis and critical control point (HACCP) method is inappropriate.

The 2 legionellosis cases discussed in our article<sup>2</sup> occurred while we were developing our WMP. The Minnesota Department of Health performed extensive independent envi-

ronmental sampling and analyses using the spread plate culture method; no *Legionella* were recovered in any of its tests from the facilities associated with these cases. This confirms that mandating actions in response to “trigger levels” or to arbitrary “percent positivity” scores, which are so often recommended by those who sell culture tests for profit, are to be not recommended. The precision and accuracy of results is not sufficient to support such specifications. In other words, taking action—or not—only on the basis of results from culturing building water samples is not scientifically defensible.

Our water management team (WMT) was in place, as is required by the HACCP system, and could therefore respond systematically to coordinate prevention efforts and use the data from clinical disease surveillance to further develop specifications in the WMP. Through this effort and within the context of developing the HACCP plan, we found *Legionella* in certain locations (eg, electronic “auto” faucets and within thermal expansion tanks) and identified insufficient disinfectant (chlorine) concentrations within the facility. The WMT used this hazard analysis to establish critical control points and control limits, monitoring, corrective actions, verification, and validation of the program.

No nosocomial disease cases have occurred since implementation of our WMP. However, if a nosocomial disease case associated with our facility water systems should occur, then in that hypothetical case, the WMT will be in place to coordinate prevention efforts, reassess the plan, and, if necessary, upgrade critical control limits. The HACCP system is a structured process to assess and respond to results from clinical disease surveillance and environmental sampling (validation). This aspect of HACCP is an important reason why the system has been so successful in the prevention of environmental-source disease and injury.

An aspect of HACCP that accounts for success in this application is that it is a practical, simple, and highly effective process management methodology. Typically, high-quality treated water enters the healthcare facility water system, where it is then processed. Water processing steps in buildings may include conditioning, filtering, heating, cooling, storing, pressure regulation, distributing, and recirculating the water. Processing water can affect its quality. Water quality can become degraded and potentially hazardous. Prevention of injury and disease depends on management of building water system processes. Although often similar, every building water system is unique in its water-processing configuration. HACCP adapted to building water system management is an ideal framework in this aspect.

With regard to the microbiological methods used in our article, the ISO 11731 spread plate method for *Legionella* was used, and results were reported for every sample. In addition, field culture “dipslide” samplers were used on site, and *Legionella*-specific polymerase chain reaction was performed on every sample. The field culturing sampler provided a reliable means to obtain *Legionella* results and total heterotrophic

aerobic bacteria (a water-quality indicator) from the same samples inoculated immediately after the samples were removed from the building water system; *Legionella* culture results correlated well with results from spread plate analyses and were available far sooner (at least 80% reduction in time required to deliver results) compared with spread plate analyses of shipped water samples. Data on comparison of methods, accuracy, precision, specificity, and sensitivity have been previously published and are cited in our article.

Our WMP was effective because it (1) united the expertise of infection control, facilities operations, facilities engineering, and industrial hygiene personnel, who all have key responsibilities in providing safe potable water at our facilities; (2) resulted in systematic risk characterization of areas in the facility so that we could focus on the highest patient risk; (3) resulted in development of one consistent plan that all stakeholders could understand and follow; (4) clarified and improved the management of resources necessary to implement the plan; (5) established a process to independently confirm and document implementation of the plan (verification); (6) provided a systematic basis to decide what to test for, where to test, and how much testing was necessary to assess hazard control (validation); and (7) provided a process to make scientifically defensible decisions about how to manage our building water systems.

Several compelling facts led us to select and to now advocate the HACCP framework for building water system management: (1) the *Legionella* Outbreak Response Team from the Centers for Disease Control and Prevention has since year 2000 advised facility managers involved in outbreaks of Legionnaires' disease to develop WMPs based on HACCP principles for their facilities; (2) the World Health Organization proposed HACCP for water system management then extensively and formally recommended use of these principles as the basis for water safety plans; and (3) in response to widespread, successful use of HACCP-based water management programs for the prevention of disease and injury associated with building water systems, NSF International has developed an educational and training certificate program that is now available nationwide. The reader is referred to our article for citations of peer-reviewed journal articles and other references that document effective application of HACCP principles to building water system management.

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## The Importance of the Central Sterile Supply Department in Infection Prevention and Control

*To the Editor*—Transmission of infectious agents through unclean and unsterile medical devices is a possibility. Breakdown in the sterility of medical devices may lead to the transmission of bacterial and viral pathogens, including those associated with multidrug resistance. Since reprocessing of expensive medical devices has to be done, it is very important that the process of cleaning, disinfection, and sterilization is subjected to stringent quality control.<sup>1</sup> The central sterile supply department (CSSD) plays a critical role in ensuring that costly medical equipment is sterilized and delivered to various users in the hospital in a quality-assured environment. The objective of this study is to describe the operations of the CSSD of a 167-bed oncology center in the eastern part of India so that users of its services are aware of its vital role in ensuring safe practices within a hospital.<sup>2</sup>

The physical infrastructure of the CSSD consists of several separate work areas, including a decontamination room, a packaging room, a linen preparation room, and a sterile storage area (total floor area of CSSD at Tata Medical Center, ~3,000 square feet).<sup>2,3</sup> The equipment and accessories that are essential for its smooth functioning include automated washer disinfector, ultrasonic cleaner, disinfection tank, instrument wash basin, handwashing sink, air and water jet guns, drying cabinet, linen folding table, instrument packing