

intent of this testing is to demonstrate the removal capabilities of the membrane product rather than evaluate the feasibility of implementing membrane treatment at a specific plant.

Testing can be conducted using a full-scale module or a smaller module if the results from the small-scale module test can be related to full-scale module performance. Most challenge studies presented in the literature have used full-scale modules, which provide results that can be directly related to full-scale performance. However, use of smaller modules is considered feasible in the evaluation of removal efficiency, and a protocol for challenge testing using small-scale modules has been proposed (NSF, 2002a). Since the removal efficiency of an integral membrane is a direct function of the membrane material, it may be possible to use a small-scale module containing the same membrane fibers or sheets used in full-scale modules for this evaluation. However, it will be necessary to relate the results of the small-scale module test to the nondestructive performance test quality control release value that will be used to validate full-scale production modules.

Challenge testing with either *Cryptosporidium* oocysts or a surrogate is permitted. Challenge testing with *Cryptosporidium* clearly provides direct verification of removal efficiency for this pathogen; however, several studies have demonstrated that surrogates can provide an accurate or conservative measure of *Cryptosporidium* removal efficiency. Since removal of particulate matter larger than 1  $\mu\text{m}$  by a membrane filtration process occurs primarily via a size exclusion mechanism, the shape and size distribution of the surrogate must be selected such that the surrogate is not removed to a greater extent than the target organism. Surrogates that have been successfully used in challenge studies include polystyrene microspheres and bacterial endospores. The bacterial endospore, *Bacillus subtilis*, has been used as a surrogate for *Cryptosporidium* oocysts during challenge studies evaluating pathogen removal by physical treatment processes, including membrane filtration (Rice *et al.* 1996, Fox *et al.* 1998, Trimboli *et al.* 1999, Owen *et al.* 1999). Studies evaluating cartridge filters have demonstrated that polystyrene microspheres can provide an accurate or conservative measure of removal efficiency (Long, 1983, Li *et al.* 1997). Furthermore, the National Sanitation Foundation (NSF) Environmental Technology Verification (ETV) protocol for verification testing

for physical removal of microbiological and particulate contaminants specifies the use of polymeric microspheres of a known size distribution (NSF 2002b). Guidance on selection of an appropriate surrogate for establishing a removal efficiency for *Cryptosporidium* during challenge testing is presented in the Membrane Filtration Guidance Manual (USEPA 2003e).

The design of the proposed challenge studies is similar to the design of the seeding studies described in the literature cited earlier. Seeding studies are used to challenge the membrane module with pathogen levels orders of magnitude higher than those encountered in natural waters. However, elevated feed concentrations can lead to artificially high estimates of removal efficiency. To address this issue, the feed concentration applied to the membrane during challenge studies is capped at a level that will allow the demonstration of up to 6.5 log removal efficiency if the challenge particulate is removed to the detection level.

Because challenge testing with *Cryptosporidium* or a surrogate is not conducted on every membrane module, it is necessary to establish criteria for a non-destructive performance test that can be applied to all production membrane modules. Results from a non-destructive test, such as a bubble point test, that are correlated with the results of challenge testing can be used to establish a quality control release value (QCRV) that is indicative of the ability of a membrane filtration process to remove *Cryptosporidium*. The non-destructive test and QCRV can be used to verify the *Cryptosporidium* removal capability of modules that are not challenge tested. Most membrane manufacturers have already adapted some form of non-destructive testing for product quality control purposes and have established a quality control release value that is indicative of an acceptable product. It may be possible to apply these existing practices for the purpose of verifying the capability of a membrane filtration process to remove *Cryptosporidium*.

Challenge testing provides a means of demonstrating the removal efficiency of an integral membrane module; however, defects or leaks in the membrane or other system components can result in contamination of the filtrate unless they are identified, isolated, and repaired. In order to verify continued performance of a membrane system, today's proposal requires direct integrity testing of membrane filtration processes used to meet *Cryptosporidium* treatment requirements. Direct integrity testing is required because it is a test applied to

the physical membrane module and, thus, a direct evaluation of integrity. Furthermore, direct integrity methods are the most sensitive integrity monitoring methods commonly used at the time of this proposal (Adham *et al.* 1995).

The most common direct integrity tests apply a pressure or a vacuum to one side of a fully wetted membrane and monitor either the pressure decay or the volume of displaced fluid over time. However, the proprietary nature of these systems makes it impractical to define a single direct integrity test methodology that is applicable to all existing and future membrane products. Therefore, performance criteria have been established for any direct integrity test methodology used to verify the removal efficiency of a membrane system. These performance criteria are resolution, sensitivity, and frequency.

As stated previously, the resolution of an integrity test refers to the smallest leak that contributes to the response from an integrity test. For example, in a pressure decay integrity test, resolution is the smallest leak that contributes to pressure loss during the test. Today's proposal specifies a resolution of 3  $\mu\text{m}$  or less, which is based on the size of *Cryptosporidium* oocysts. This requirement ensures that a leak that could pass a *Cryptosporidium* oocyst would contribute to the response from an integrity test.

The sensitivity of an integrity test refers to the maximum log removal that can be reliably verified by the test. Again using the pressure decay integrity test as an example, the method sensitivity is a function of the smallest pressure loss that can be detected over a membrane unit. Today's proposal limits the log removal credit that a membrane filtration process is eligible to receive to the maximum log removal value that can be verified by a direct integrity test.

In order to serve as a useful process monitoring tool for assuring system integrity, it is necessary to establish a site-specific control limit for the integrity test that corresponds to the log removal awarded to the process. A general approach for establishing this control limit for some integrity test methods is presented in guidance; however, the utility will need to work with the membrane manufacturer and State to establish a site-specific control limit appropriate for the integrity test used and level of credit awarded. Excursions above this limit indicate a potential integrity breach and would trigger removal of the suspect unit from service followed by diagnostic testing and subsequent repair, as necessary.