

side of the membrane that remains in suspension; and C_f is the concentration of suspended particulate matter in the feed water. The magnitude of the concentration factor depends on the mode of system operation and typically ranges from 1 to 20. The Membrane Filtration Guidance Manual presents approaches for determining the volumetric concentration factor for different operating modes (USEPA 2003e).

Sensitivity of direct integrity tests that use a particulate or molecular marker is determined from the feed and filtrate concentrations of the marker. The LRV_{DIT} for this type of direct integrity test is calculated according to the following equation:

$$LRV_{DIT} = \text{LOG}_{10}(C_f) - \text{LOG}_{10}(C_p)$$

where LRV_{DIT} = maximum log removal value that can be verified by a direct integrity test; C_f = the typical feed concentration of the marker used in the test; and C_p = the filtrate concentration of the marker from an integral membrane unit. For this equation to be valid, equivalent units must be used for the feed and filtrate concentrations. An ideal particulate or molecular marker would be completely removed by an integral membrane unit.

If the sensitivity of the direct integrity test is such that LRV_{DIT} is less than LRV_{C-Test} , LRV_{DIT} establishes the maximum removal credit that a membrane filtration process is eligible to receive. Conversely, if LRV_{DIT} for a direct integrity test is greater than LRV_{C-Test} , LRV_{C-Test} establishes the maximum removal credit.

A control limit is defined as an integrity test response which, if exceeded, indicates a potential problem with the system and triggers a response. Under this proposal, a control limit for a direct integrity test must be established that is indicative of an integral membrane unit capable of meeting the *Cryptosporidium* removal credit awarded by the State. If the control limit for the direct integrity test is exceeded, the membrane unit must be taken off-line for diagnostic testing and repair. The membrane unit could only be returned to service after the repair has been completed and confirmed through the application of a direct integrity test.

The frequency of direct integrity testing specifies how often the test is performed over an established time interval. Most direct integrity tests available at the time of this proposal are applied periodically and must be conducted on each membrane unit at a frequency of not less than once every 24 hours while the unit is in operation. If

continuous direct integrity test methods become available that also meet the sensitivity and resolution criteria described earlier, they may be used in lieu of periodic testing.

EPA is proposing that at a minimum, a monthly report must be submitted to the State summarizing all direct integrity test results above the control limit associated with the *Cryptosporidium* removal credit awarded to the process and the corrective action that was taken in each case.

Continuous Indirect Integrity Monitoring

The majority of currently available direct integrity test methods are applied periodically since the membrane unit must be taken out of service to conduct the test. In order to provide some measure of process performance between direct integrity testing events, continuous indirect integrity monitoring is required. Indirect integrity monitoring is defined as monitoring some aspect of filtrate water quality that is indicative of the removal of particulate matter. If a continuous direct integrity test is implemented that meets the resolution and sensitivity criteria described previously, continuous indirect integrity monitoring is not required. Continuous indirect integrity monitoring must be conducted according to the following criteria:

- Unless the State approves an alternative parameter, continuous indirect integrity monitoring must include continuous filtrate turbidity monitoring.
- Continuous monitoring is defined as monitoring conducted at a frequency of no less than once every 15 minutes.
- Continuous monitoring must be separately conducted on each membrane unit.
- If indirect integrity monitoring includes turbidity and if the filtrate turbidity readings are above 0.15 NTU for a period greater than 15 minutes (*i.e.*, two consecutive 15-minute readings above 0.15 NTU), direct integrity testing must be performed on the associated membrane units.
- If indirect integrity monitoring includes a State-approved alternative parameter and if the alternative parameter exceeds a State-approved control limit for a period greater than 15 minutes, direct integrity testing must be performed on the associated membrane units.

• EPA is proposing that at a minimum, a monthly report must be submitted to the primacy agency summarizing all indirect integrity monitoring results triggering direct

integrity testing and the corrective action that was taken in each case.

b. *How was this proposal developed?*
The Stage 2 M-DBP Agreement in Principle recommends that EPA develop criteria to award *Cryptosporidium* removal credit to membrane filtration processes. Today's proposal and the supporting guidance are consistent with the Agreement.

A number of studies have been conducted which have demonstrated the ability of membrane filtration processes to remove pathogens, including *Cryptosporidium*, to below detection levels. A literature review summarizing the results of several comprehensive studies was conducted by EPA and is presented in Low-Pressure Membrane Filtration for Pathogen Removal: Application, Implementation, and Regulatory Issues (USEPA 2001h). Many of these studies used *Cryptosporidium* seeding to demonstrate removal efficiencies as high as 7 log. The collective results from these studies demonstrate that an integral membrane module, *i.e.*, a membrane module without any leaks or defects, with an exclusion characteristic smaller than *Cryptosporidium*, is capable of removing this pathogen to below detection in the filtrate, independent of the feed concentration.

Some filtration devices have used membrane media in a cartridge filter configuration; however, few data are available documenting their ability to meet the requirements for membrane filtration described in section IV.C.11.a of this preamble. However, in one study reported by Dwyer *et al.* (2001), a membrane cartridge filter demonstrated *Cryptosporidium* removal efficiencies in excess of 6 log. This study illustrates the potentially high removal capabilities of membrane filtration media configured into a cartridge filtration device, thus providing a basis for awarding removal credits to these devices under the membrane filtration provision of the rule, assuming that the device meets the definition of a membrane filtration process as well as the direct integrity test requirements.

Today's proposal requires challenge testing of membrane filtration processes used to remove *Cryptosporidium*. As noted in section III.D, EPA believes this is necessary due to the proprietary nature of these systems and the lack of any uniform criteria for establishing the exclusion characteristic of a membrane. Challenge testing addresses the lack of a standard approach for characterizing membranes by requiring direct verification of removal efficiency. The proposed challenge testing is product-specific and not site-specific since the