

scale module, if testing meets the other requirements listed in this section.

- Challenge testing must be conducted using *Cryptosporidium* oocysts or a surrogate that has been determined to be removed no more efficiently than *Cryptosporidium* oocysts. The organism or surrogate used during challenge testing is referred to as the challenge particulate. The concentration of the challenge particulate must be determined using a method capable of discretely quantifying the specific challenge particulate used in the test. Thus, gross water quality measurements such as turbidity or conductivity cannot be used.

- The maximum allowable feed water concentration used during a challenge test is based on the detection limit of the challenge particulate in the filtrate, and is determined according to the following equation:

$$\text{Maximum Feed Concentration} = 3.16 \times 10^6 \times (\text{Filtrate Detection Limit})$$

This will allow the demonstration of up to 6.5 log removal during challenge testing if the challenge particulate is removed to the detection limit.

- Challenge testing must be conducted under representative hydraulic conditions at the maximum design flux and maximum design system recovery as specified by the manufacturer. Flux is defined as the flow per unit of membrane area. Recovery is defined as the ratio of filtrate volume produced by a membrane to feed water volume applied to a membrane over the course of an uninterrupted operating cycle. An operating cycle is bounded by two consecutive backwash or cleaning events. In the context of this rule, recovery does not consider losses that occur due to the use of filtrate in backwashing or cleaning operations.

- Removal efficiency of a membrane filtration process is determined from the results of the challenge test, and expressed in terms of log removal values as defined by the following equation:

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

where LRV = log removal value demonstrated during challenge testing; C_f = the feed concentration used during the challenge test; and C_p = the filtrate concentration observed during the challenge test. For this equation to be valid, equivalent units must be used for the feed and filtrate concentrations. If the challenge particulate is not detected in the filtrate, then the term C_p is set equal to the detection limit. A single LRV is calculated for each membrane module evaluated during the test.

- The removal efficiency of a membrane filtration process demonstrated during challenge testing is expressed as a log removal value ($\text{LRV}_{\text{C-Test}}$). If fewer than twenty modules are tested, then $\text{LRV}_{\text{C-Test}}$ is assigned a value equal to the lowest of the representative LRVs among the various modules tested. If twenty or more modules are tested, then $\text{LRV}_{\text{C-Test}}$ is assigned a value equal to the 10th percentile of the representative LRVs among the various modules tested. The percentile is defined by $[i/(n+1)]$ where i is the rank of n individual data points ordered lowest to highest. It may be necessary to calculate the 10th percentile using linear interpolation.

- A quality control release value (QCRV) must be established for a non-destructive performance test (e.g., bubble point test, diffusive airflow test, pressure/vacuum decay test) that demonstrates the *Cryptosporidium* removal capability of the membrane module. The performance test must be applied to each production membrane module that did not undergo a challenge test in order to verify *Cryptosporidium* removal capability. Production membrane modules that do not meet the established QCRV are not eligible for the removal credit demonstrated during challenge testing.

- Any significant modification to the membrane filtration device (e.g., change in the polymer chemistry of the membrane) requires additional challenge testing to demonstrate removal efficiency of the modified module and to define a new QCRV for the nondestructive performance test.

Direct Integrity Testing

In order to receive removal credit for *Cryptosporidium*, the removal efficiency of a membrane filtration process must be routinely verified through direct integrity testing. A direct integrity test is defined as a physical test applied to a membrane unit in order to identify and isolate integrity breaches. An integrity breach is defined as one or more leaks that could result in contamination of the filtrate. The direct integrity test method must be applied to the physical elements of the entire membrane unit including membranes, seals, potting material, associated valving and piping, and all other components which under compromised conditions could result in contamination of the filtrate.

The direct integrity tests commonly used at the time of this proposal include those that use an applied pressure or vacuum (such as the pressure decay test and diffusive airflow test), and those that measure the rejection of a particulate or molecular marker (such as

spiked particle monitoring). Today's proposal does not stipulate the use of a particular direct integrity test. Instead, the direct integrity test must meet performance criteria for resolution, sensitivity, and frequency.

Resolution is defined as the smallest leak that contributes to the response from a direct integrity test. Any direct integrity test applied to meet the requirements of this proposed rule must have a resolution of 3 μm or less. The manner in which the resolution criterion is met will depend on the type of direct integrity test used. For example, a pressure decay test can meet the resolution criterion by applying a net test pressure great enough to overcome the bubble point of a 3 μm hole. A direct integrity test that uses a particulate or molecular marker can meet the resolution criterion by applying a marker of 3 μm or smaller.

Sensitivity is defined as the maximum log removal value that can be reliably verified by the direct integrity test (LRV_{DIT}). The sensitivity of the direct integrity test applied to meet the requirements of this proposed rule must be equal to or greater than the removal credit awarded to the membrane filtration process. The manner in which LRV_{DIT} is determined will depend on the type of direct integrity test used. Direct integrity tests that use an applied pressure or vacuum typically measure the rate of pressure/vacuum decay or the flow of air through an integrity breach. The response from this type of integrity test can be related to the flow of water through an integrity breach (Q_{breach}) during normal operation, using procedures such as those described in the Membrane Filtration Guidance Manual (USEPA 2003e). Once Q_{breach} has been determined, a simple dilution model is used to calculate LRV_{DIT} for the specific integrity test application, as shown by the following equation:

$$\text{LRV}_{\text{DIT}} = \text{LOG}_{10}(Q_p / (\text{VCF} \times Q_{\text{breach}}))$$

where LRV_{DIT} = maximum log removal value that can be verified by a direct integrity test; Q_p = total design filtrate flow from the membrane unit; Q_{breach} = flow of water from an integrity breach associated with the smallest integrity test response that can be reliably measured; and VCF = volumetric concentration factor.

The volumetric concentration factor is the ratio of the suspended solids concentration on the high pressure side of the membrane relative to the feed water, and is defined by the following equation:

$$\text{VCF} = C_m / C_f$$

where C_m is the concentration of particulate matter on the high pressure