

membrane filtration process under the conditions in paragraph (b)(3) of this section.

(2) *Challenge Testing.* The membrane used by the system must undergo challenge testing to evaluate removal efficiency, and the system must submit the results of challenge testing to the State. Challenge testing must be conducted according to the criteria in paragraphs (b)(2)(i) through (b)(2)(vii) of this section. The State may accept data from challenge testing conducted prior to [Date of Publication of Final Rule in the **Federal Register**] in lieu of additional testing if the prior testing was consistent with the criteria in paragraphs (b)(2)(i) through (b)(2)(vii) of this section.

(i) Challenge testing must be conducted on either a full-scale membrane module, identical in material and construction to the membrane modules used in the system's treatment facility, or a smaller-scale membrane module, identical in material and similar in construction to the full-scale module.

(ii) Challenge testing must be conducted using *Cryptosporidium* oocysts or a surrogate that is 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; gross measurements such as turbidity may not be used.

(iii) The maximum feed water concentration that can be used during a challenge test is based on the detection limit of the challenge particulate in the filtrate and must be determined according to the following equation:

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

(iv) Challenge testing must be conducted under representative hydraulic conditions at the maximum design flux and maximum design process recovery specified by the manufacture for the membrane module. Flux is defined as the rate of 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. For the purpose of challenge testing in this section, recovery does not consider losses that occur due to the use

of filtrate in backwashing or cleaning operations.

(v) Removal efficiency of a membrane module during challenge testing must be determined as a log removal using 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. Equivalent units must be used for the feed and filtrate concentrations. If the challenge particulate is not detected in the filtrate, the term  $C_p$  is set equal to the detection limit. An LRV must be calculated for each membrane module evaluated during the test.

(vi) The removal efficiency of a membrane filtration process demonstrated during challenge testing must be expressed as a log removal value ( $\text{LRV}_{\text{C-Test}}$ ). If fewer than 20 modules are tested, then  $\text{LRV}_{\text{C-Test}}$  is equal to the lowest of the representative LRVs among the applicable modules tested. If 20 or more modules are tested, then  $\text{LRV}_{\text{C-Test}}$  is equal to the 10th percentile of the representative LRVs among the applicable modules tested. The percentile is defined by  $(i/(n+1))$  where  $i$  is the rank of  $n$  individual data points ordered lowest to highest. If necessary, the 10th percentile may be calculated using linear interpolation.

(vii) The challenge test must establish a quality control release value (QCRV) for a non-destructive performance test that demonstrates the *Cryptosporidium* removal capability of the membrane filtration process. This performance test must be applied to each production membrane module used by the system that did not undergo a challenge test in order to verify *Cryptosporidium* removal capability. Production modules that do not meet the established QCRV are not eligible for the removal credit demonstrated during the challenge test.

(viii) If a previously tested membrane is modified in a manner that could change the removal efficiency of the membrane or the applicability of the non-destructive performance test and associated QCRV, additional challenge testing to demonstrate the removal efficiency of, and determine a new QCRV for, the modified membrane must be conducted and submitted to the State.

(3) *Direct integrity testing.* Systems must conduct direct integrity testing in a manner that demonstrates a removal efficiency equal to or greater than the removal credit awarded to the membrane filtration process and meets

the requirements described in paragraphs (b)(3)(i) through (b)(3)(vi) of this section.

(i) The direct integrity test must be independently applied to each membrane unit in service. A membrane unit is a group of membrane modules that share common valving that allows the unit to be isolated from the rest of the system for the purpose of integrity testing or maintenance.

(ii) The direct integrity method must have a resolution of 3  $\mu\text{m}$  or less, where resolution is defined as the smallest leak size that contributes to a response from the direct integrity test.

(iii) The system must demonstrate that the direct integrity test can verify the log removal credit awarded to the membrane filtration process by the State using the approach in either paragraph (b)(2)(iii)(A) or (b)(2)(iii)(B) of this section as applicable based on the type of direct integrity test.

(A) For direct integrity tests that use an applied pressure or vacuum, the maximum log removal value that can be verified by the test must be calculated according to the following equation:

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

where  $\text{LRV}_{\text{DIT}}$  = maximum log removal value that can be verified by a direct integrity test;  $Q_p$  = total design filtrate flow from the membrane unit;  $Q_{\text{breach}}$  = 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 that in the feed water.

(B) For direct integrity tests that use a particulate or molecular marker, the maximum log removal value that can be verified by the test must be calculated according to the following equation:

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

where  $\text{LRV}_{\text{DIT}}$  = 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.

(iv) Systems must establish a control limit for the direct integrity test that is indicative of an integral membrane unit capable of meeting the removal credit awarded by the State.

(v) If the result of a direct integrity test is outside the control limit established under paragraphs (b)(3)(i) through (b)(3)(iv) of this section, the membrane unit must be removed from service. A direct integrity test must be