

LT2ESWTR: (1) They can collect 24 monthly samples over a 2 year period and calculate their bin classification using the highest 12 month running annual average, or (2) They can collect 2 or more samples per month over the 2 year period and use the mean of all samples for bin classification.

These proposed requirements reflect recommendations by the Advisory Committee and are based on analyses of misclassification rates associated with different monitoring programs that were considered. EPA is concerned about systems with high concentrations of *Cryptosporidium* being misclassified in lower bins as well as systems with low concentrations being misclassified in higher bins. The first type of error could lead to systems not providing an adequate level of treatment while the second type of error could lead to systems incurring additional costs for unnecessary treatment.

A primary way that EPA analyzed misclassification rates was by considering the likelihood that a system with a true mean *Cryptosporidium* concentration that is a factor of 3.2 (0.5 log) above or below a bin boundary would be assigned to the wrong bin.

Probabilities were assessed for two cases:

- False negative: a system with a mean concentration of 0.24 oocysts/L (i.e., factor of 3.2 above the Bin 1 boundary of 0.075 oocysts/L) is misclassified low in Bin 1.
- False positive: a system with a mean concentration of 0.024 oocysts/L (i.e., factor of 3.2 below the Bin 1 boundary of 0.075 oocysts/L) is misclassified high in Bin 2.

Table IV-6 provides false negative and false positive rates as defined previously for different approaches to monitoring and bin classification that were evaluated. Results are shown for the following approaches:

- 48 samples with bin assignment based on arithmetic mean (i.e., average of all samples).
- 24 samples with bin assignment based on highest 12 sample average, equivalent to the maximum running annual average (Max-RAA).
- 24 samples with bin assignment based on arithmetic mean.
- 12 samples with bin assignment based on the second highest sample result.
- 8 samples with bin assignment based on the maximum sample result.

These estimated misclassification rates were generated with a Monte Carlo analysis that accounted for the volume assayed, variation in source water *Cryptosporidium* occurrence, and variable method recovery. See Economic

Analysis for the LT2ESWTR (USEPA 2003a) for details.

TABLE IV-6.—FALSE POSITIVE AND FALSE NEGATIVE RATES FOR MONITORING AND BINNING STRATEGIES CONSIDERED FOR THE LT2ESWTR  
[In percentages]

Strategy	False positive <sup>1</sup>	False negative <sup>2</sup>
48 sample arithmetic mean .....	1.7	1.4
24 sample Max-RAA .....	5.3	1.7
24 sample arithmetic mean .....	2.8	6.2
12 sample second highest .....	47	1.1
8 sample maximum .....	66	1.0

<sup>1</sup> False positive rates calculated for systems with *Cryptosporidium* concentrations 0.5 log below the Bin 1 boundary of 0.075 oocysts/L.

<sup>2</sup> False negative rates calculated for systems with *Cryptosporidium* concentrations 0.5 log above the Bin 1 boundary of 0.075 oocysts/L.

The first two of these approaches, the 48 sample arithmetic mean and 24 sample Max-RAA, were recommended by the Advisory Committee and are proposed for bin classification under the LT2ESWTR because they have low false positive and false negative rates. As shown in Table IV-6, these strategies have false negative rates of 1 to 2%, meaning there is a 98 to 99% likelihood that a plant with an oocyst concentration 0.5 log above the Bin 1 boundary would be correctly assigned to Bin 2. The false positive rate is near 2% for the 48 sample arithmetic mean and 5% for the 24 sample Max-RAA. These rates indicate that a plant with an oocyst concentration 0.5 log below the Bin 1 boundary would have a 95 to 98% probability of being correctly assigned to Bin 1. Bin misclassification rates across a wide range of concentrations are shown in Economic Analysis for the LT2ESWTR (USEPA 2003a).

The 24 sample arithmetic mean had a slightly lower false positive rate than the 24 sample Max-RAA (2.8% vs. 5.3%) but the false negative rate of the arithmetic mean was almost 4 times higher. Consequently, a plant with a mean *Cryptosporidium* level above the Bin 1 boundary would be much more likely to be misclassified in Bin 1 using a 24 sample arithmetic mean than with a 24 sample Max-RAA. In order to increase the probability that systems with mean *Cryptosporidium* concentrations above 0.075 oocysts/L will provide additional treatment, EPA is proposing that if only 24 samples are taken, the maximum 12 month running annual average must be used to determine bin assignment.

Monitoring strategies involving only 12 and 8 samples were evaluated to determine if lower frequency monitoring could provide satisfactory bin classification. The results of this analysis indicate that these lower sample numbers are not adequate and could unfairly bias excessive treatment requirements. For example, results in Table IV-6 show that if plants were classified in bins based on the second highest of 12 samples or the highest of eight samples then low false negative rates could be achieved. A system with a mean *Cryptosporidium* level 0.5 log above the Bin 1 boundary would have a 99% chance of being appropriately classified in a bin requiring additional treatment under either strategy.

However, the false positive rates associated with these low sample numbers are very high. A system with a mean oocyst concentration 0.5 log below the Bin 1 boundary would have a 47% probability of being incorrectly classified in Bin 2 using the second highest result among 12 samples, or a 66% likelihood of being misclassified in Bin 2 using the maximum result among 8 samples. Due to high false positive rates, these strategies are not proposed.

EPA also evaluated lower frequency monitoring strategies that had lower false positive rates, such as bin classification based on the mean of 12 samples, the third highest result of 12 samples, and the second highest of 8 samples. Each of these strategies, though, had an unacceptably high false negative rate, meaning that many systems with mean oocyst concentrations greater than the Bin 1 boundary would be misclassified low in Bin 1. Consequently, these strategies are inconsistent with the public health goal of the LT2ESWTR for systems with mean levels above 0.075 oocysts/L to provide additional treatment.

Increasing the number of samples used to compute the maximum running annual average above 24 also increased the number of annual averages computed, so it did not reduce the likelihood of false positives. Raising the number of samples used to compute an arithmetic mean above 48 did reduce bin misclassification rates, but the rates were already very small (1 to 2% for plants with levels 0.5 log above or below bin boundaries). For sources with *Cryptosporidium* concentrations very near or at bin boundaries, increasing the number of samples did not markedly improve the error rates, which remained near 50% at the bin boundaries.

In summary, EPA believes that the proposed sampling designs perform well for the purpose of classifying plants in LT2ESWTR risk bins and,