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National Shellfish Sanitation Program
U.S. Food and Drug Administration
Shellfish Safety Team
Division of Cooperative Programs
Office of Compliance

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Guidance Documents, Systematic Random Sampling Monitoring Strategy

Key Words:

Systematic Random Sampling, Estimated 90th Percentile, Intermittent Nonpoint Pollution Events, 12-tube, single dilution MPN

Question:

Is it acceptable to apply the formula currently used in Systematic Random Sampling to calculate the estimated 90th percentile of data derived from a 12-tube, single dilution MPN test?

Interpretation:

It is not acceptable to apply the formula currently used in Systematic Random Sampling to calculate the estimated 90th percentile of data derived from a 12-tube, single dilution MPN test.

Rationale:

The purpose of the estimated 90th percentile is to provide a tool to measure the impact of intermittent nonpoint pollution events on growing area water quality under the Systematic Random Sampling monitoring strategy. It does this by providing an estimate of the variability of the data. If water quality is affected by intermittent nonpoint pollution events, the effect of these events will be reflected in the variability of the data and through the use of suitable calculations this variability can be captured as the estimated 90th percentile.

Currently the procedure for calculating the estimated 90th percentile requires the use of at least 30 samples. With a data set of this size, a significant impact on the variability of the data and as a consequence, its estimated 90th percentile from the effects of intermittent nonpoint pollution events can only be detected by the occurrence of several high to very high bacterial counts in the data set. Therefore, in order to use the estimated 90th percentile as intended, the method of bacterial enumeration must be capable of operating over a wide range in counts.

A 5-tube, decimal dilution MPN test operates over a count range of <2 to >1,600. The 3-tube, decimal dilution test operates over a count range of <3 to >1,100. Both of these MPN tests have a wide count range and are capable of measuring the higher count levels necessary for the estimated 90th percentile to function. The 12-tube, single dilution MPN test on the other hand, operates over a count range of <9 to >248 for total coliforms and <2 to >50 for fecal coliforms. Both of these count ranges are quite limited and obviously are not capable of measuring the higher counts necessary for the estimated 90th percentile to function in the same manner as the 5 and 3-tube, decimal dilution MPN tests.

The *Model Ordinance* requires the use of at least 30 samples to calculate 90th percentile values when using Systematic Random Sampling. With a data set of this size, it is impossible for the 12-tube, single dilution MPN test with its limited count range to measure bacterial densities when they occur at the levels necessary to demonstrate an impact from intermittent nonpoint pollution events. As a consequence, any significant effect on water quality that may occur as a result of these intermittent nonpoint pollution events is unlikely to be detected when using the 12-tube, single dilution MPN test for monitoring under Systematic Random Sampling. Therefore, the 12-tube, single dilution MPN test is inappropriate for use with the Systematic Random Sampling monitoring strategy. Only test procedures which generate a broad range of counts should be used to monitor for the effects of intermittent nonpoint pollution events within the context of the Systematic Random Sampling strategy. Currently these testing procedures are limited to multiple dilution MPN tests and the mTEC membrane filter procedure when filtering multiple (half log) dilutions.

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