

In considering the appropriate confidence bounds to use for developing the CT tables in today's proposal, EPA was primarily concerned with accounting for uncertainty in the regression and for true variability in the inactivation rate. Variability associated with experimental error was a lesser concern, as the purpose of the CT tables is to ensure a given level of inactivation and not predict the measured result of an individual experiment.

Because confidence in the prediction accounts for all variability in the data sets (both true variability and experimental error), it may provide a higher margin of safety than is necessary. Nevertheless, in other disinfection applications, the use of confidence in the prediction may be appropriate, given limited data sets and uncertainty in the source of the variability. However, the high doses of ozone and chlorine dioxide that are needed to inactivate *Cryptosporidium* create an offsetting concern with the formation of DBPs (e.g., bromate and chlorite). In consideration of these factors and the statutory provision for balancing risks among contaminants, EPA attempted to exclude experimental error from the confidence bound when developing the CT tables in today's proposal (i.e., used a less conservative approach than confidence in the prediction).

In order to select confidence bounds reflecting potential true variability between different oocyst populations (lots) but not variability due to measurement and experimental imprecision, it was necessary to estimate the relative contributions of these variance components. This was done by first separating inactivation data points into groups having the same *Cryptosporidium* oocyst lot and experimental conditions (e.g., water matrix, pH, temperature). Next, the variance within each group was determined. It was assumed that this within-group variance could be attributed entirely to experimental error, as neither of the factors expected to account for true variability in the inactivation rate (i.e., oocyst lot or water matrix) changed within a group. Finally, comparing the average within-group variance to the total variance in a data set provided an indication of the fraction of total variance that was due to experimental error (see Sivaganesan 2003 and Messner 2003 for details).

In carrying out this analysis on the Li *et al.* (2001) and Rennecker *et al.* (1999) data sets for ozone inactivation of *Cryptosporidium*, EPA estimated that 87.5% of the total variance could be attributed to experimental error

(Sivaganesan 2003). A similar analysis done by Najm *et al.* (2002) on the Oppenheimer *et al.* (2000) data set for ozone produced an estimate of 89% of the total variance due to experimental error. For chlorine dioxide inactivation of *Cryptosporidium*, EPA estimated that 62% of the total variance in the Li *et al.* (2001) and Ruffle *et al.* (1999) data sets could be attributed to experimental error (Messner 2003). The different fractions attributed to experimental error between the chlorine dioxide and ozone data sets presumably relates to the use of different experimental techniques (e.g., infectivity assays).

EPA employed estimates of the fraction of variance not attributable to experimental error (12.5% for ozone and 38% for chlorine dioxide) in a modified form of the equation used to calculate a bound for confidence in prediction (Messner 2003). These were applied to the regression equations developed by Clark *et al.* (2002a and 2002b) in order to estimate CT values for an upper 90% confidence bound (Sivaganesan 2003, Messner 2003). These are the CT values shown in Tables IV-19 and IV-20 for ozone and chlorine dioxide, respectively.

Since the available data are not sufficient to support the CT calculation for an inactivation level greater than 3 log, the use of Tables IV-19 and IV-20 is limited to inactivation less than or equal to 3 log. In addition, the temperature limitation for these tables is 1 to 25 °C. If the water temperature is higher than 25 °C, temperature should be set to 25 °C for the log inactivation calculation.

EPA recognizes that inactivation rates may be sensitive to water quality and operational conditions in the plant. To reflect this potential, systems are given the option to perform a site specific inactivation study to determine CT requirements. The State must approve the protocols or other information used to derive alternative CT values. However, EPA has provided guidance for systems in making such demonstrations in the Toolbox Guidance Manual.

During meetings of the Stage 2 M-DBP Advisory Committee, CT values were used in the model for impact analysis of different regulatory options (the model Surface Water Analytical Tool (SWAT), as described in Economic Analysis for the LT2ESWTR, USEPA 2003a). Those preliminary CT values were based on a subset of the data from the Li *et al.* (2001) study with laboratory waters and were adjusted with a factor to match the mean CT values derived from the Oppenheimer *et al.* (2000) study with natural waters. In comparison, the CT

values in today's proposal are higher. However, the current CT values are based on larger data sets and more comprehensive analyses. Consequently, they provide more confidence in estimates of *Cryptosporidium* log inactivation than the preliminary estimates used in earlier SWAT modeling. EPA has subsequently re-run analyses for LT2ESWTR impact assessments with the updated CT values (USEPA 2003a).

c. *Request for comments.* EPA requests comment on the proposed approach to awarding credit for inactivation of *Cryptosporidium* by chlorine dioxide and ozone, including the following specific issues:

- Determination of CT and the confidence bounds used for estimating log inactivation of *Cryptosporidium*;
- The ability of systems to apply these CT tables in consideration of the MCLs for bromate and chlorite; and
- Any additional data that may be used to confirm or refine the proposed CT tables.

15. Ultraviolet Light

a. *What is EPA proposing today?* EPA is proposing criteria for awarding credit to ultraviolet (UV) disinfection processes for inactivation of *Cryptosporidium*, *Giardia lamblia*, and viruses. The inactivation credit a system can receive for each target pathogen is based on the UV dose applied by the system in relation to the UV dose requirements in this section (see Table IV-21).

To receive UV disinfection credit, a system must demonstrate a UV dose using the results of a UV reactor validation test and ongoing monitoring. The reactor validation test establishes the operating conditions under which a reactor can deliver a required UV dose. Monitoring is used to demonstrate that the system maintains these validated operating conditions during routine use.

UV dose (fluence) is defined as the product of the UV intensity over a surface area (fluence rate) and the exposure time. In practice, UV reactors deliver a distribution of doses due to variation in light intensity and flow path as particles pass through the reactor. However, for the purpose of determining compliance with the dose requirements in Table IV-21, UV dose must be assigned to a reactor based on the degree of inactivation of a microorganism achieved during a reactor validation test. This assigned UV dose is determined through comparing the reactor validation test results with a known dose-response relationship for the test microorganism. The State may