Overview of Validation

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ABSTRACT

USEPA recently published the 2006 UV Disinfection Guidance Manual. Compared to the 2003 draft Guidance, the 2006 Guidance includes an updated section on UV reactor validation that reflects new developments in validation approaches and a modified approach for applying that validation data for defining pathogen inactivation credit. This paper describes what's new in the 2006 guidance and describes recent developments in UV validation methods which will impact how UV validation will be applied in the future.

KEYWORDS: UVDGM, UV disinfection, dose distributions, biodosimetry

INTRODUCTION

The 2006 USEPA *Ultraviolet Disinfection Guidance Manual for the Final Long Term 2 Enhanced Surface Water Treatment Rule* (UVDGM) (USEPA 2006) includes one chapter (Chapter 5) and five appendices (Appendices A, B, C, D and G) on UV validation. This article highlights some of the key differences between the Final 2006 UVDGM validation protocol and the 2003 Draft UVDGM, and discusses the impact of new advances in UV reactor validation methods.

What's New In The 2006 Validation Protocol?

The significant changes in the 2006 protocol were motivated by new knowledge in the art and science of UV validation and a desire to simplify the validation calculations.

The 2006 protocol specifies that the stability of the test microbe's concentration and UV dose-response should be verified during validation. This new guidance was added in response to numerous reports in the literature of phage die off during validation testing (e.g., Hargy et al. 2004).

The new protocol also lists T1, T7, and QB phages as alternates for MS2 phage for the validation of reactors for *Cryptosporidium* and *Giardia* credit. These "new" microbes are more sensitive to UV light than MS2 phage, and hence reduce the RED bias uncertainty associated with testing reactors for *Cryptosporidium* and *Giardia* credit. For UV reactors with relatively narrow UV dose distributions, the use of microbes such as T1, T7, and QB phage instead of MS2 will result in significant capital and O&M cost savings while maintaining public health protection. On the other hand, for UV reactors with UV dose distributions wider than those used to define the 2006 UVDGM RED Bias factors, a more sensitive microbe like T1 will better characterize the impact of the lower end of the reactor's UV dose distribution, and hence improve public health protection.

With the validation of polychromatic UV systems, the 2006 UVDGM specifies that the wavelength response or action spectra of the test microbe should be evaluated to determine if it matches that of the target pathogen (e.g., *Cryptosporidium*). A correction factor should be applied if the test microbe's wavelength response biases the measured RED to values higher than delivered to the pathogen. For example, action spectra data indicates that a factor of approximately 1.15 should be applied to T7 REDs measured with medium-pressure UV systems (Wright et al. 2007). Appendix D of the UVDGM provides one approach for calculating this bias.

The UVDGM states UV sensors should be germicidal. If non-germicidal UV sensors are used, the polychromatic bias caused by differences in the UVA spectrum during validation and the UVA spectrum at the WTP should be included in the calculation of the validation factor used to define pathogen credit. The guidance also states this bias should be accounted for if the germicidal sensor is located relatively far from the lamps (e.g., > 10 cm) and/or the reactor is used at low *UVT* (e.g., < 80%).

The UVDGM also provides more emphasis on the impact of non-uniform lamp aging based on the results of a recently completed Awwa Research Foundation study (Wright et al. 2007), which reported that UV dose delivery can be significantly over estimated if the UV sensors view

the lamps at locations that age the least over time. This issue should be considered by the UV system manufacturer when they locate the UV sensors within their reactors.

The 2006 UVDGM provides more emphasis on specifying the accuracy of measurements made during validation. For example, the accuracy of the flow rate and UVA measurements should be ±5 and ±10%, respectively. The protocol recommends the use of NIST[1]-traceable wavelength and absorbance standards and organic-free water to confirm UVA measurement accuracy. Duty UV sensors should match the average of two or more reference UV sensors within 10%. The accuracy of the reference sensors should be specified on the calibration certificate. Care should be taken confirming the accuracy of reference sensors. Data from another AwwaRF project, *Design and Performance Guidelines for UV Sensor Systems* shows reference sensor accuracy can vary by as much as 20 percent (Wright et al. 2005). Use of two sensors only reduces that uncertainty to (20 / √2 =) 14%. The use of three or more reference sensors is recommended.

Similar to the 2003 UVDGM, the RED of the test microbe is determined from the log inactivation measured through the reactor using the test microbe's UV dose-response curve. The new guidance, however, specifies that the most UV resistant UV dose-response curve measured on a given day should be used to determine REDs if the UV dose-response curves are statistically different at a 95-percent confidence level.

The 2003 UVDGM provided a lot of detail on the UV intensity and UVT/UV intensity setpoint UV dose-monitoring approaches but provided limited information on the calculated UV dose monitoring approach, primarily because algorithms used by UV vendors were proprietary. Since 2003, numerous validations supported by CFD-models have better defined the calculated UV dose-monitoring equations (e.g., Wright et al. 2005). As such, the new UVDGM describes a general equation for the calculated UV dose-monitoring approach:

$$[1] \qquad RED = 10^{a} \times UVA^{b} \times Q^{c} \times \left(S/S_0\right)^{d} \times B^{e}$$

where UVA is the UV Absorbance (corollary to UVT) measured using the on-line UVT monitor, Q is the flow rate through the reactor, S/S_0 is the relative lamp output[2], B is the number of operating banks of lamps, and a, b, c, d, and e are constants determined by fitting the equation to the validation data.

The specific form of this equation will vary with reactor technologies depending on which functions best describe the relations between RED and UVA, flow rate, UV sensor readings, and banks. The equation used should pass through the origin (0,0) and have fit coefficients that are statistically significant at a 95% confidence level. Furthermore, if the UV sensor is optimally located within the reactor, the equation can be defined at a *UVT* value that gives conservative REDs over a wide range of water *UVT*s. In that case, an on-line *UVT* monitor is not required.

The 2003 UVDGM specified that UV dose monitoring and reporting could be based on a target test microbe RED, where that RED is defined as the product of required UV dose for pathogen credit multiplied by a "safety factor". Furthermore, the 2003 UVDGM specified two approaches for defining that safety factor, termed the Tier 1 and Tier 2 approaches. The Tier 1 approach defined MS2 REDs for pathogen credit based on compliance of the reactor and its validation to a set of QA/QC criteria. The Tier 2 approach defined an approach for calculating the "safety factor" based on the accuracy of validation and UV dose monitoring specific to the reactor.

The new UVDGM specifies that the UV dose reporting should be based on the UV dose delivered to the pathogen RED as opposed to the test microbe RED. The UV dose delivered to the pathogen RED is defined as:

$$[2] \qquad \text{Validated Dose} = \frac{\text{RED}}{\text{VF}}$$

where VF is the validation factor defined as:

$$[3] \qquad VF = B_{RED} \times \left(1 + \frac{U_{Val}}{100}\right) \quad \text{Equation 3}$$

where B_{RED} is the RED bias uncertainty factor and U_{Val} is the uncertainty of validation. These equations can either be programmed into the UV system's PLC as part of the UV dose-monitoring algorithm, programmed into the water treatment plant's SCADA system, or used off-line to determine the UV dose reported to the State.

The RED Bias uncertainty factor is determined using Appendix G of the 2006 UVDGM, which tabulates RED bias values as a function of test microbe UV sensitivity and *UVT* for various levels of log inactivation credit for *Cryptosporidium*, *Giardia*, and viruses. The RED bias can be defined either at the lowest *UVT* that can occur with the application or as a function of *UVT* measured using the on-line *UVT* monitor. The UV sensitivity is defined as the maximum ratio of RED/log I observed with all test replicates measured during validation, *i.e.*, the maximum UV sensitivity is used to determine the RED bias uncertainty factor.

Compared to the 2003 UVDGM, the RED bias uncertainty factors now vary with *UVT*, with lower values at high *UVT* and higher values at low *UVT*. This will decrease the capital and O&M costs of UV systems used for high *UVT* applications but increase those costs for UV systems used for low *UVT* applications.

The UVDGM recommends that UV facilities use one value of the RED bias uncertainty factor based on the minimum operating *UVT* of the facility. However, if the water *UVT* drops below the *UVT* value used to select the RED bias uncertainty factor, then the UV system could under dose. For example, with a reactor validated with MS2 phage, the under dosing could be a factor of 2.22/1.73 = 1.28 if the RED bias uncertainty factor is based on 90% *UVT* but the actual *UVT* is 80%. The selection of the used to define the RED bias uncertainty factor will also impact UV dose

delivery under design conditions if that *UVT* is less than the design *UVT*.

The 2006 UVDGM also lets utilities define the RED bias uncertainty factor as a function of *UVT*. If the RED bias uncertainty factor varies with *UVT*, *UVT* monitor errors can lead to over and under estimations of the RED bias uncertainty factor. For example, if a *UVT* monitor reads 98% when the true *UVT* is 95% (an out of specification because the error is greater than 2%), a UV system validated with MS2 for 3-log *Cryptosporidium* credit could under dosed by a factor of 1.38/1.19 = 1.16.

Regardless of how the RED bias uncertainty factor is defined, validation with T1, T7, or QB instead of MS2 phage notably reduces these errors.

For UV systems using the UV intensity setpoint approach, the uncertainty of validation (U_{Val}) is set to:

[4] $$U_{Val} = U_{SP}$$

However, if the UV sensor uncertainty is greater than 10 percent or the uncertainty of the UV dose-response is greater than 30 percent at 1-log inactivation, U_{Val} is calculated using:

[5] $$U_{Val} = \left(U_{SP}^2 + U_S^2 + U_{DR}^2\right)^{1/2}$$

where U_{SP} is the uncertainty of the RED measured at the setpoint, U_S is the uncertainty of the UV sensor used during validation, and U_{DR} is the uncertainty of the validation microbe's UV dose-response curve.

The uncertainty of the setpoint is calculated using:

[6] $$U_{SP} = \frac{t \times SD_{RED}}{RED}$$

where RED is the average RED measured at the setpoint, SD_{RED} is the standard deviation of replicate REDs measured at the setpoint, and *t* is a t-statistic at a 95% confidence level.

For UV systems using the calculated UV dose approach, the uncertainty of validation is set to the uncertainty of the calculated UV dose-monitoring algorithm:

[7] $$U_{Val} = U_{IN}$$

Again, if either the sensor uncertainty or the uncertainty of the UV dose-response are greater than 10 percent and 30 percent at 1-log inactivation, respectively, U_{Val} would have to include these errors as well:

[8] $$U_{Val} = \left(U_{IN}^2 + U_S^2 + U_{DR}^2\right)^{1/2}$$

The uncertainty of the calculated UV dose-monitoring algorithm is calculated using a similar approach:

[9] $$U_{IN} = \frac{t \times SD}{RED}$$

where RED is the RED predicted by the UV dose-monitoring algorithm for a given flow rate, *UVT*, and UV lamp output, and SD is the standard deviation of the difference between the UV doses predicted by the algorithm for the validation test conditions and the measured REDs, including all replicate pairs. The calculation represents the 95th percentile prediction interval about the relation between measured and predicted RED.

The uncertainty of the UV sensors (U_S) used during validation is defined as the maximum difference between the duty and reference UV sensors observed during validation. This definition does not account for the measurement uncertainty of the reference UV sensors, which may be high. For example, if the difference between the duty and reference UV sensor is 5% but the measurement uncertainty of the reference sensor is 15 %, the accuracy of the duty UV sensor may be as high as 20%. Using multiple reference UV sensors minimizes these errors.

The uncertainty of the UV dose-response, U_{DR}, is defined in Appendix C as a 95-percent confidence interval about the fit to the UV dose-response data. While not mentioned in the UVDGM, confidence interval is calculated as (Draper and Smith 1998, page 80-93):

[10] $$CI = \left[\frac{1}{n} + \frac{(x_i - \bar{x})^2}{\sum_{i=1}^{n}(x_i - \bar{x})}\right]^{1/2} \times t \times \sigma$$

where *n* is the number of data sets of UV dose and log inactivation, x_i is a specific value of log inactivation, *x* is the mean value of log inactivation for the data set, y_i is the predicted UV dose for x_i, t is the Students T-statistic for *n*-1 degrees of freedom, and σ is the standard error of the difference between the predicted and measured UV doses.

Because of the challenge calculating confidence intervals using Equation 8, the UVDGM provides an alternate simplified calculation:

[11] $$U_{DR} = \frac{t \times SD}{UV\ Dose}$$

where SD is the standard deviation of the differences between the UV dose predicted using the fit to the UV dose response data and the measured UV dose delivered by the collimated beam apparatus for all test points in the UV dose-response curve. Compared to Equation 10, Equation 11 approximates a prediction interval and hence is conservative.

With U_{IN}, U_{SP}, and U_{DR}, the value of the uncertainty increases geometrically at lower REDs. For example, if U_{DR} is 30% at 1-log inactivation of MS2 phage, it is 60% at 0.5-log inactivation. Therefore, care should be taken calculating the validation factor for REDs less than that the equivalent RED for one log inactivation.

Lastly, unlike the 2003 UVDGM, the validation factor does not include terms for UV dose monitoring uncertainty at the WTP. Instead, Chapter 6 of the UVDGM specifies QA/QC criteria for UV dose monitoring. Duty UV sensors should match reference UV sensors within 20%, on-line *UVT* monitors should match lab *UVT* measurements within 2% *UVT*, and utilities using UV systems with fewer UV sensors than lamps (e.g,. most low-pressure high-output systems) should swap out lamps to ensure the UV sensors are not reading the lamp with the highest output. The

uncertainty due to a 2% error measuring *UVT* is small at low *UVT* but becomes significant at high *UVT*. For example, with one validated UV system, the UV dose-monitoring equation can predict a UV dose 1.8 times higher if the on-line *UVT* reads 98% but the actual *UVT* is 96%. The large error occurs because changes in *UVT* have a large impact on UV dose delivery at high *UVT*.

What's New In Validation?

The development of the UVDGM over the last five years was strongly influenced by developments in UV technologies, their validation, and the availability of data. In 2002, the only test facilities were in Germany and Austria and they only validated reactors using the UV intensity setpoint approach. Limited data was available on validation, calculated UV dose monitoring algorithms, properties of UV sensors, and the performance of installed drinking water systems. Today, North America has two validation test facilities, most vendors have validated their product lines, and AwwaRF and other research institutions have completed numerous drinking water UV disinfection projects. However, the world of UV disinfection continues to advance. Two advances in the last year are the use of T1 phage and the determination of UV dose distributions.

T1 phage has been used to validate at least eight UV reactor technologies over the last year. T1 phage has inactivation kinetics without curvature from 0 to 5-log inactivation. The UV sensitivity is approximately 5 mJ/cm^2 per log inactivation. Hence, the RED bias uncertainty factor for 3 log *Cryptosporidium* credit with T1 ranges from 1.05 at 98% *UVT* to 1.21 at 75% *UVT*. This is notably less than the RED bias uncertainty with MS2, which for 3-log *Cryptosporidium* credit, ranges from 1.18 at 98% *UVT* to 2.24 at 75% *UVT*. Because T1 phage is more sensitive to UV light than MS2 phage, it will better characterize reactors for *Cryptosporidium* and *Giardia* credit, evening the playing field between reactors with narrow UV dose distributions and those with wide UV dose distributions.

T1 phage has a notably lower uncertainty of validation than MS2 phage. Calculated UV dose monitoring algorithms that span a wide range of flow rates and *UVT*s have been developed using T1 phage with R-squared values of >0.98. The uncertainty of the UV dose-monitoring equation at a 95-percent prediction level is about 1 mJ/cm^2 with T1, which compares to 5 to 10 mJ/cm^2 with MS2 validation. The uncertainty of the UV dose-response is also notably lower.

Another development in UV validation has been the determination of UV dose distributions and the prediction of microbe log inactivation and RED using those UV dose distributions. Two methods have been developed. The first uses microspheres to measure the UV dose distribution (Shen et al. 2007). The second predicts UV dose distributions from biodosimetry data (Wright 2007). The second approach has been applied to a range of commercial LPHO and MP UV reactors. Figure 1 shows UV dose distributions predicted using MS2 biodosimetry. Figure 2 compares T1 REDs predicted using UV dose distributions determined from MS2 biodosimetry data to measured T1 REDs. Predicted T1 REDs are typically within 1 mJ/cm^2 of the measured values. Ideally, both the MS2 and T1 RED data would be used to determine the UV dose distributions to improve the accuracy of the method.

The ability to determine UV dose distributions provides a new paradigm for UV dose delivery and monitoring. In particular, UV dose-monitoring equations can be expressed in terms of log inactivation credit, instead of validated REDs that need to be correlated to log inactivation credit tables:

$$[12]\quad \text{Pathogen Log Credit} = \frac{10^{a} \times UVA^{b} \times \left(S/S_0\right)^{c} \times Q^{d} \times B^{e}}{1 + U}$$

where the constants *a, b, c, d,* and *e* are obtained by fitting the equation to pathogen log inactivation predicted from UV dose distributions defined as a function of flow rate, *UVT*, UV sensor readings, and banks of lamps. The pathogen UV dose requirements in the Long Term 2 Enhanced Surface Water Treatment Rule would be used to determine the log inactivation from the UV dose. The uncertainty factor *U* would account for the uncertainty of the UV dose distributions, the validation data, and the duty UV sensors used for UV dose monitoring at the WTP. While this method eliminates the need for an RED bias, a polychromatic bias may still apply if the action spectrum of the validation method differs from that of the pathogen.

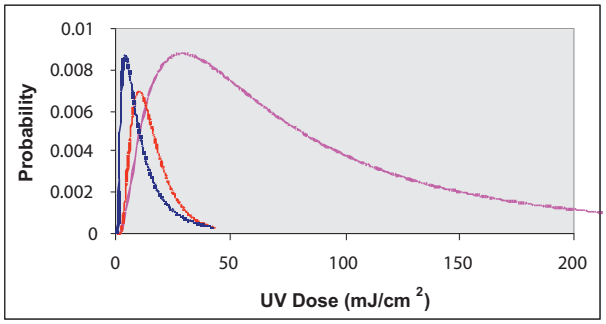

Figure 1. *UV dose distributions determined from MS2 biodosimetry.*

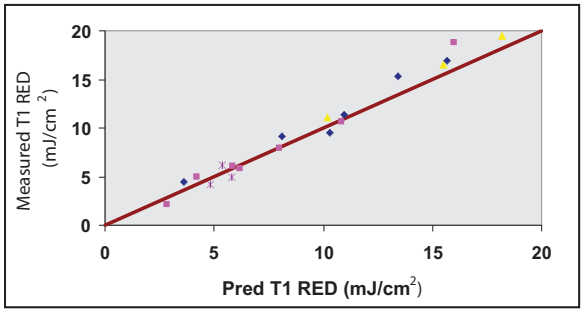

Figure 2. *Comparison of T1 REDs predicted using UV dose distributions determined using MS2 biodosimetry to measured T1 REDs.*

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[1] National Institute of Standards and Technology

[2] The expected UV sensor reading for that UVT with new lamps operating at 100% ballast power setting with clean sleeves and UV sensor port windows.