DEPARTMENT OF ENVIRONMENTAL PROTECTION
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CHRISTOPHER O. WARD, COMMISSIONER

January 9, 2004

Water Docket
Environmental Protection Agency, Mail Code 4101T
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

RE: Long-Term 2 Enhanced Surface Water Treatment Rule, Proposed Rule, 68 Federal Register 47639, Docket No. OW–2002–0039

Dear Sir/Madam:

The New York City Department of Environmental Protection ("DEP") appreciates this opportunity to comment on the proposed Long-Term 2 Enhanced Surface Water Treatment Rule ("LT2"), which, when implemented will have a tremendous impact on the operation of New York City's water supply and surface water supplies nationwide. As commissioner of the nation's largest unfiltered drinking water supplier, I want to highlight several specific concerns which DEP believes should be addressed before final promulgation of the rule. These concerns will be addressed in further detail in the attached comments. However, certain issues bear highlighting and are briefly summarized below:

1) LT2 overestimates risk presented by cryptosporidium

DEP is troubled by the analysis presented by EPA as justification for the proposed rule (i.e., in the preamble to the rule and the economic analysis). DEP believes the analysis overstates the risk of illness presented by cryptosporidium in U.S. drinking water supplies; overstates the benefits to be derived from promulgation of the rule; and understates the degree of uncertainty that exists with regard to estimating these risks and benefits. In addition, DEP feels that the rule's preamble language does not fully and accurately reflect the spirit of the FACA process. Specifically, during the FACA process, the uncertainties in risk assessment were raised, but the group agreed that despite these uncertainties, certain measures could be taken as proactive steps, and this proactive context is the true basis of the Agreement in Principle. This more accurate context should be included in the preamble.

2) LT2 underestimates major capital costs

DEP believes that the rule's cost-benefit analysis *significantly* underestimates the cost of treatment options required under LT2. Both the cost estimates for UV disinfection and for reservoir covering as presented by EPA appear to be considerably lower than the City's own estimates. For example, DEP estimates capital costs for a UV facility to be $600,000,000 -- whereas, the proposed rule's Economic Analysis seems to project a cost of $92,000,000 for a facility of the same capacity. DEP's projected unit costs for reservoir covers also exceed EPA's estimate by a factor of 5 – 25.

3) LT2 should amend burdensome or redundant public notification requirements for violation of the SWTR

DEP fully recognizes the importance of public notification in instances where there are legitimate public health concerns for populations using the water supply. However, in important cases DEP believes that certain notifications now required under the SWTR lead to mis- or overapplication of this rule. Unwarranted notification may sounds an alarm in a community not directly impacted by the violation, creating the perception of a threat where there is no actual health risk. Overapplication also diminishes the impact of notification when it is in fact necessary.

4) LT2 must provide new flexibility in meeting the 1989 SWTR Filtration Avoidance Criteria either by deletion or modification of the rigid filtration-for-noncompliance mandate

DEP is most concerned with the "trap door" that threatens unfiltered water supplies who are operating under a Filtration Avoidance Determination pursuant to the SWTR but who can still be ordered to filter for even a minor divergence from the original standards. DEP – like other unfiltered surface water supply systems – has invested heavily in watershed management and protection strategies and is now implementing further costly measures to comply with LT2 *as an unfiltered system.* Still, DEP and similar unfiltered systems have no assurance against a loss of filtration avoidance as a result of a single violation of the 1989 Criteria that in many cases might represent neither a significant change in water quality nor a threat to public health. Significantly, filtration would not necessarily be the most appropriate means of addressing violations of the Criteria were they to occur. For filtered systems that experience similar disturbances, disruptions or violations, EPA's protocol is to assess the problem and determine the most appropriate means of solving it; there is no automatic trigger requiring installation of costly new treatment infrastructure. DEP argues for equivalence with filtered systems with regard to enforcement of SWTR violations. Therefore, DEP strongly urges that the 1989 SWTR Filtration Avoidance Criteria be dropped, modified, or at the very least, thoroughly reviewed, one by one, to demonstrate their current applicability.

5) Provide a variance or exemption allowance

Variances and exemptions should not be prohibited under LT2 or under the earlier surface water treatment rule.

Thank you for this opportunity to comment on a significant change to our nation's water quality standards which, if implemented with precision and balance, will go far towards improving the quality of life for all Americans.

Sincerely,
Christopher O. Ward

COMMENTS OF THE
NEW YORK CITY DEPARTMENT OF ENVIRONMENTAL PROTECTION
ON THE PROPOSED REGULATION
"LONG TERM 2 ENHANCED SURFACE WATER TREATMENT RULE"

Docket # 0W-2002-0039
January 9, 2004

The New York City Department of Environmental Protection ("DEP") appreciates this opportunity to comment on the proposed "Long Term 2 Enhanced Surface Water Treatment Rule." DEP commends the USEPA for soliciting comments from a broad spectrum of stakeholders, and for convening a FACA process for the development of these regulations. While DEP remains committed to the execution of the spirit and intent of the Agreement in Principle which was the outcome of the FACA process, we have a number of concerns with the regulations as proposed, and the documentation presented by EPA to justify and clarify the regulations. We are submitting the following comments to assist EPA in promulgating a final regulation that is consistent with good science, is transparent and supportable, and that is sufficiently flexible so as to not pose an unreasonable burden on drinking water suppliers. In summary, we find significant problems with the cost, risk, and benefit analyses which are presented by EPA as justification for the proposed regulations; and in addition, we find troublesome certain provisions of the proposed regulations. DEP suggests herein a number of modifications to the proposed regulations which we believe will, to some degree, ease the financial and operational burden created by these regulations, while in no way increasing the risk to public health.

For example, one very disturbing aspect of the proposed regulations is the provision requiring continued compliance with all of the Filtration Avoidance Criteria from the 1989 Surface Water Treatment Rule, particularly considering the rigid nature of these criteria as implemented in the 1989 rule. As a large unfiltered system, which maintains the highest quality water through vigorous (and costly) watershed protection programs, and which will be installing UV treatment (also at great cost) to comply with the proposed LT2ESWTR, DEP is very much concerned that, despite all these investments in the name of enhanced public health protection, DEP could be subjected to the unreasonable and unwarranted requirement to install filtration, as a result of failure to comply with each and every Filtration Avoidance Criterion, at all times. This requirement for continued application of the stringent 1989 Filtration Avoidance Criteria places an unreasonable burden on both DEP and on the ratepayers who consume City water, and who must shoulder the financial responsibility (not insignificant) for all enhanced treatment that is required under these rules.

We strongly urge EPA to reassess the proposed rule in light of the comments contained herein. We remain ready and willing to assist EPA in whatever manner we can to formulate a rule that provides necessary public health protection while allowing systems such as ours the flexibility to address water quality problems in the most cost-effective manner. DEP's comments are provided in 3 parts: Part I: General Comments, Part II: Additional Comments, and Part III: Attachments.

PART I – GENERAL COMMENTS

1) S.W.T.R. FILTRATION AVOIDANCE CRITERIA

The Department strongly believes that the proposed rule should be worded in such a manner that any unfiltered system's substantial investment and demonstrated success in watershed protection not be subject to costly and potentially arbitrary change due to the implicit LT2 requirement that unfiltered systems continue to comply with **all** filtration avoidance requirements of the SWTR (40 CFR 141.71). For example, the language in the LT2 in Section 141.721(a) and elsewhere conditions the applicability to the new treatment and monitoring requirements for "unfiltered systems that meet all filtration avoidance criteria of 141.71**."**

In 1989, the rigid imposition of the filtration avoidance criteria in 40 CFR 141.71 perhaps had a rational basis. During the development of the SWTR, little was known about the quality of the water supplied by unfiltered water supplies (particularly from a microbial risk perspective) and about the degree of variability in the source water microbial risk under varying environmental, demographic, and climatologic conditions. In addition, the effectiveness of watershed protection programs, as a risk management strategy, was untested. Thus, EPA imposed conditions requiring not only a program of demonstrated ownership and control within a watershed, but the requirement that source water as well as finished water meet certain objective conditions for turbidity, coliform bacteria, disinfection byproducts, etc. These criteria primarily represented parameters that acted as direct or indirect indicators of potential microbial risk and/or were parameters, such as turbidity, that affected disinfection capabilities.

The rationale for the rigid application of some if not all of these criteria no longer exists. In the last 10 years, DEP has implemented comprehensive watershed monitoring, mapping, modeling and research programs that have verified that our source waters are not only of high quality, but are consistently so. Like other unfiltered systems, we have substantially enhanced watershed protection and pollution prevention measures by implementing a variety of programs, including but not limited to: acquiring additional watershed lands (having recently attained the 50,000 acre mark of new acquisitions); upgrading wastewater treatment plants; implementing engineering controls to reduce pollution from stormwater and wastewater; and promulgating enhanced watershed rules and regulations. We have also developed partnerships with watershed stakeholders that are regarded as a national model of excellence for watershed programs. DEP has conducted extensive research into the sources of cryptosporidium in the watershed, and for almost 8 years now, we have been conducting weekly source water monitoring for Cryptosporidium and Giardia with Quality Assurance (QA) requirements that are vastly more rigorous than those proposed by EPA under the LT2. By 2007, DEP will have spent or committed in excess of $1 Billion dollars for NYC's watershed protection effort. Our watershed management programs and our monitoring programs confirm that our water quality is excellent, and will remain so into the future. Through our extensive investment and achievement of the many goals set forth through EPA's filtration avoidance determinations, we have demonstrated our long term financial commitment to watershed protection, pollution prevention and a multiple barrier approach.

As clearly indicated in the Preamble to the LT2 rule, the overarching rationale for the treatment requirement for unfiltered systems in the LT2, comes from EPA's assessment of data from the ICR and other surveys which in EPA's words "do not support the finding described in the

IESTWR of equivalent risk in filtered and unfiltered systems" (p. 47649). In response, the proposed rule now provides an extra layer of protection by mandating that all unfiltered systems provide an additional 2 or 3 log removal of Cryptosporidium. Without addressing the merits of EPA's argument regarding the need for additional protection (DEP believes that EPA has overestimated the risks of Cryptosporidium and substantially underestimated the cost of compliance with the rule), as called for in the draft regulation, we are moving forward with the construction of a UV facility to provide the required additional log inactivation of Cryptosporidium. However, as the preamble to the LT2 notes, once an unfiltered system has complied with the new treatment requirements, the unfiltered systems will be "equivalent" to the filtered systems. If equivalent, then the requirements for continued compliance with the treatment technique should be equivalent to those requirements set forth for filtered systems. Specifically, if a filtered system experiences an MCL or treatment technique violation (e.g., for coliforms, DBPs) the initial compliance step is not to require the filtered system to install an entirely new treatment facility. The first steps are: (1) assess the cause of the violation, (2) determine an appropriate solution, and (3) allow the water supplier time to implement the determined solution. This same reasonable approach should be granted to unfiltered systems that are in compliance with the LT2 (or prior to the effective date of the LT2, those systems that are taking concrete steps toward compliance with LT2). For unfiltered systems that fall out of compliance with one of the Filtration Avoidance criteria, installation of a filtration plant may NOT be the most appropriate solution, and thus should not be automatically triggered.

Clearly, given all of the above and the enormous financial implications that failure to achieve the original avoidance criteria will potentially have on unfiltered systems, even after they have achieved "equivalence", the maintenance of all of the filtration avoidance requirements in an unmodified form is patently unreasonable. DEP strongly recommends that the application of the SWTR Filtration Avoidance Criteria be modified, or at the very least, that each criterion be thoroughly reviewed to demonstrate their current applicability, and those without current applicability be dropped. DEP along with other unfiltered systems would be pleased to be participate in any technical analysis EPA chooses to undertake on this matter.

2. COST-BENEFIT AND RISK ANALYSIS

While EPA has prepared an extensive and detailed compilation of background material, and conducted a rigorous risk analysis, no attempt has been made to compare the risk conclusions against public health data, or to clearly describe the uncertainties in the assessment, in relation to these data. Moreover, DEP believes that EPA has consistently overestimated risk and underestimated cost to oversell both the need for the rule and its purported benefits. The following represent some of the issues.

2.A Underestimating Cost

The LT2's Economic Analysis (EA) clearly underestimates the capital and O&M costs for compliance. DEP is specifically concerned with two areas, the cost estimate for uncovered finished water reservoirs and the cost estimate for a UV disinfection facility.

> Uncovered Reservoirs: For reservoirs in the 250-1000 MGD category, the EA estimates a capital cost of $9.4 Million (for a floating cover based on a unit cost of $2/sq. ft of reservoir surface and an annual O&M of $280,000). These estimates are unrealistically low, particularly for large reservoirs. DEP estimates the cost of a cover for its 90-acre,

900 million gallon, Hillview Reservoir, would be from $42.6 million ($10.87 per square foot) for a floating cover to $218 million ($55.60 per square foot) for a domed fabric cover (based on 1998 numbers). DEP's projected unit costs exceed EPA's estimate by a factor of 5-25.

UV Facility: The EA includes cost estimates for construction and maintenance within existing water treatment facilities, and for installing pumping facilities at many locations. The unit cost for construction used by EPA was $48.95/sq. ft. However, typical estimates for water treatment facilities in the Northeast range from $150-200 per sq. ft. or 3-4 times the cost proposed by EPA. The cost of pumping is also substantially greater than projected by EPA. For a 2000 MGD facility (that proposed by DEP), EPA would estimate the cost at approximately $120 million including pumping. The current planning cost estimate being used by DEP for the UV facility is $600,000,000. Thus, EPA has underestimated the cost for this type of facility by a factor of approximately four.

EPA makes several statements in the EA that the per capita cost for large systems should be smaller than for smaller systems but provides no documentation regarding that assumption. Nor does EPA provide any assessment about the costs likely to be incurred by larger older urban systems with aging infrastructure that have to retrofit and reconfigure the systems to support the new technology. Capital costs for such systems may be geometrically greater than for newer systems.

Based on the above information, and related information for other facilities, DEP believes that EPA should recalculate and reassess its cost analysis. That reassessment should reevaluate the basis of the cost estimates, and reassess whether the management conclusions are still supported by the analysis.

Finally, EPA's assessment does not address the substantive costs for other related water supply risk mitigation efforts that water utilities supplying very large urban systems have to consider. While the EA should be somewhat independent of these other cost demands, the information should be included as part of the evaluation of whether the health risk reduction measures are truly worth the costs, given all of the uncertainties in the analysis, and the effect of all of the other engineering projects on water rates. These other costs include those incurred from projects to improve system reliability and repair aging infrastructure. For example, DEP is spending upwards of $6 billion for Water Tunnel # 3 to enhance system reliability. Also, as a result of 9/11, large systems such as New York's have to spend additional monies for substantive new security measures. While the incremental costs of each capital measure may be small, the added effect of all of the risk reduction measures for infrastructure reliability, security, and water treatment, may exceed the financial capabilities of even the largest cities.

2. B. Overestimating Endemic Risk

DEP has a number of major concerns with regard to the health impacts analysis provided by EPA to justify promulgation of the LT2ESWTR. In summary, DEP's concerns are that: (1) internal inconsistencies in EPA's analysis raise question about it's validity; (2) risk numbers presented by EPA appear to overestimate endemic risk of cryptosporidiosis, and no attempt was made to provide a reality check or to "groundtruth" the risk estimates; (3) the degrees of uncertainty in the risk analysis are not adequately acknowledged; and (4), there has been little attempt to assess

any of the various health studies, including those that might call into question EPA's risk analysis. These issues are discussed in greater depth below.

Internal Inconsistencies in Risk Projections:

Risk projections are included in a few different locations of EPA's analyses (re: LT2 and prior rules), and the projections do not all match up. For example, as is pointed out in the Stratus report prepared for AWWA (Raucher, et al., Dec 2003, pg. 5-8), based on the analysis conducted for the Regulatory Impact Analysis (RIA) for the IESWTR, the number of endemic cases of cryptosporidiosis projected to remain after implementation of the IESWTR was 59,500 to 111,000. However, the number of illnesses that EPA is now projecting it would avoid with promulgation of LT2 is 256,000 to 1.02 million illnesses -- or approximately 4 to 9 times more illness than the projected baseline. Inconsistencies such as the above call into question the credibility of EPA's risk estimates.

Overestimatation of Risk:

DEP finds EPA's risk numbers – for illnesses and deaths due to cryptosporidiosis in drinking water – to be far off the mark from empirical data which NYC has collected. While DEP acknowledges that there are limitations in the available public health data, EPA should at least have considered such empirical data, and should have compared its risk estimates with these data, as a means of "groundtruthing" and testing with the limitations of the risk analysis modeling exercise. Below we provide a review of EPA's projections for illness (morbidity) and death (mortality) and we compare these projections against available public health data.

Morbidity

As described above, EPA's Economic Analysis (as reported on page 47743 of the LT2 preamble) projected 168,000 to 547,000 cases of illness averted from Cryptosporidium for unfiltered water systems. As New York City represents 2/3 of the population served by unfiltered systems (8 million people out of 12 million total unfiltered population), presumably the number of cases of illness averted in NYC alone would be 112,000-365,000. These numbers reflect an illness rate for NYC of 1.4% to 4.6%. In other words, as many as 1 in 22 people in New York are projected by EPA to be getting ill with cryptosporidiosis from the drinking water each year (EPA's estimate is based on estimated morbidity not infection). In comparison, the average annual number of laboratory-confirmed cryptosporidiosis cases in NYC for recent years was 143 (this is an average of data from 2000, 2001 and 2002), or an annual rate of less than 2/100,000. Though NYC conducts active disease surveillance (thus insuring that essentially every single laboratory confirmed case is captured), we recognize that not all ill persons will seek medical care, and thus many, if not most cases will be missed. However, using the Corso ratio of crypto illness referenced by EPA -- of 88:11:1 for mild:moderate:severe illness -- one could predict that if there are 112,000 to 365,000 cases of illness in New York City, then at least the "severe" cases and some moderate cases would likely be picked up in the health surveillance system. (EPA defines moderate illness as patients with one or more outpatient visits to a physician or ER but not requiring hospitalization-Severe cases are those requiring hospitalization). However using EPA's above numbers and counting just the 1% of cases estimated to be classified as severe, the projection would be 1,120 to 3,650 "severe" cases in NYC, which is vastly greater than the number of cases we actually observe. Even if one looked at illness in the AIDS population (a population which receives more careful health monitoring than the general population, and for which cryptosporidiosis testing is much more likely to be conducted), NYC surveillance system

observed a total of 94 cases of cryptosporidiosis in this group in 2002, while the New York City Department of Health and Mental Hygiene's AIDS branch reported approximately 80,000 persons in NYC living with AIDS at that time (from NYCDOHMH, HIV Surveillance and Epidemiology Program, 4th Quarter Report, Oct 2003, p.2). Even if one assumed that all 94 cases per year were from water (which is clearly not the case, given the importance of other routes of infection), out of 80,000 persons living with AIDS in New York City gives an illness rate of approximate 0.1%, which is also far below EPA's illness projections.

Other data from New York City, which can be used to provide some perspective on EPA's assessment comes from a pilot program conducted by the NYCDOHMH in which cryptosporidium analyses were conducted on stool samples submitted by the Child Health Clinics and the School Health Program. While this pilot program population was not representative of the overall population (as it involved predominantly, if not entirely, school-aged children), and was known to have certain limitations, the findings do not support very high estimates of endemic cryptosporidium. Out of a total of 22,000 stools tested over a 5 year period, only 7 were found to be positive for cryptosporidium (or a rate of 0.03%). Although one of the limitations of the data is that we cannot describe the exact population tested, regardless of who was tested, if one in 20 New Yorkers had cryptosporidiosis, higher rates would have been expected.

Mortality

Again using EPA's estimates of illness averted from page 47743, and considering NYC to represent 2/3 of the total unfiltered population, EPA estimates that the LT2 could avert the number of premature deaths annually by 19 – 61. This estimate appears to be too high. In the last 6 years of National Death Registry data for NYC, cryptosporidiosis was indicated only 1 time as a cause of death. While we recognize that death certificate information is imperfect and incomplete, this finding does suggest that EPA's predicted death rate is a significant overestimation. It is also worth noting a study that was reported recently from San Francisco on causes of death among persons with AIDS, and covering the period 1994 - 1998. This study reported no deaths at all from cryptosporidiosis in the San Francisco population during the final year of the study (i.e., 1998) (Louie, et al., Journal of Infectious Disease, 2002).

Inadequate Acknowledgement of Uncertainties and Insufficient Consideration of Recent Epidemiolgy Study Results:

DEP feels that insufficient acknowledgement is given of the many uncertainties inherent at this time in cryptosporidiosis risk assessment The overall impression that a reader can get is that there is indeed a significant amount of endemic waterborne cryptosporidiosis occurring across the Unites States based on the current oocyst levels observed in source waters, and the current levels of drinking water treatment. However, we do not really know that this is the case. In fact some recent epidemiology studies designed to assess waterborne GI risk raise significant questions about this assumption. A number of research efforts which EPA should have considered in the analysis are summarized below:

- The National Estimate of Waterborne Disease -- A national effort has been underway for a number of years to estimate the amount, if any, of disease caused by water across the country. This research effort is being led by the CDC and the EPA, as mandated by the U.S. Congress. This estimate is a number of years overdue, apparently due to the fact that the authors of this report, have found the various uncertainties involved in the

estimation process to be daunting. Despite a congressional deadline and the expenditure of considerable funds for research, this group has not been able to provide a national estimate of waterborne disease.

- Melborne Study -- A study was recently conducted in Melbourne, Australia looking at gastrointestinal illness and an unfiltered drinking water supply with a protected watershed. This study utilized the "gold standard" type of protocol for assessing health effects from a drinking water supply – i.e., a randomized, blinded and controlled household intervention protocol (using a home-filtering device designed to reduce microbial/protozoan risk). The results of this investigation found no evidence of waterborne illness, and the treatment devices installed were not found to reduce illness. (Hellard, et al., Env. Hlth. Persp., August 2001).
- Davenport Study – The study that EPA and CDC were most looking towards to answer the question of whether drinking water was causing GI illness was recently completed. This study again used the "gold standard" study design of a randomized, blinded, controlled household intervention protocol, but in this case the water supply was filtered. In this study, again no illness was attributed to the drinking water, and no illness was found to be averted by installation of advanced-level household treatment devices. (Unpublished, but presented by Colford, 2003).
- Other Studies -- A case-control study was recently conducted in San Francisco among immunocompetent patients. Though this was a small study, the findings are interesting: drinking water was not found to be a risk factor for cryptosporidiosis. (Khalakdina A, Vugia DJ, Nadle J, Rothrock GA, Colford JM Jr. "Is drinking water a risk factor for endemic cryptosporidiosis?"). Finally, CDC has been working on a multi-State case-control study examining the risk factors for cryptosporidiosis, including drinking water. The study is complete and submitted for publication. Once these results are available, they should be considered by EPA, as studies such as this one can help assess the question of whether drinking water is truly a significant risk.

It is also interesting to note that efforts to study cryptosporidiosis have been limited by the fact that it is too difficult to find people with the illness to conduct the needed studies. Several years ago, the CDC and DEP co-funded a cross-sectional study of cryptosporidiosis in the HIV-infected population, in an attempt to determine the prevalence of current infection and past exposure to *Cryptosporidium* and to study risk factors, including exposure to drinking water. (The study was conducted at the New York Hospital-Cornell Medical Center, in collaboration with the NYCDOHMH). The study was conducted from 1995 to 1997, and it was during this period that the new anti-retroviral therapies (HAART) became available. As a result, the researchers found it difficult to find an adequate number of HIV-infected patients with cryptosporidiosis to conduct the study

Table IV-5 in the preamble to the rule summarizes the estimated annual risk of crypto infection as a function of source water oocyst concentration and treatment efficiency. This table suggests that the annual risk of infection at a source water concentration of 0.01 oocyst/liter and 2 log removal capability is 3.7 x 10-3. From this table it can be inferred that an unfiltered system with no log removal capability would have an annual risk of infection of 3.7 x 10-1 or 37%. As this source water concentration is representative of a levels found in NYC's source water (this is higher than NYC's average, but close enough for this example), this number seems not supportable, given some of the other data noted above. EPA should make some effort to include in the discussion of uncertainty, some comparison of the results of the risk estimates with measured determinations of waterborne disease illness and infection rates.

The above-mentioned findings suggest that the level of concern indicated by the LT2 as currently proposed, may be not in line with the actual public health findings.

Conclusion:

Given all of the above, DEP feels that in its LT2 proposal and supporting documents, EPA has overestimated and overstated the level of endemic risk presented by cryptosporidium in U.S. drinking water supplies, and has insufficiently conveyed the degree of uncertainty which remains with regard to this organism. EPA should provide better discussion of the above topics so that the public and other stakeholders have some perspective on the issues and uncertainties associated with the reported risks and benefits of the regulation.

2.C. Overestimating Benefit

In addition to overestimating risk, and underestimating cost, EPA has also overestimated benefit. The overestimation of benefit is directly related, of course, to EPA's overestimation of risk which we have discussed above. However, beyond those issues, EPA makes certain assumptions for its benefits analysis which we believe to be questionable. First, EPA applies rates of morbidity and mortality from the Milwaukee incident, and uses these rates to derive the cost of illness and death. The benefits are thus derived from avoiding these costs. DEP believes that the application of the lessons learned from a large-scale outbreak like Milwaukee, to projections of costs and benefits for situations such as in the typical U.S. drinking water supply, is not appropriate. In EPA's own words (p. 5-14 of the EA), the "mortality rate from the Milwaukee outbreak may not reflect the overall mortality rates from low-level endemic exposure". Second, approximately half the benefit is derived from the value of reduced mortality. In other words, the benefit of avoiding up to as many as an estimated 91 premature deaths is approximately equal to the benefits from avoiding up to 500,000 cases of illness. Given the sensitivity of the overall benefit calculation to the estimate of mortality, DEP does not understand why the mortality rate is a fixed number rather than a statistical distribution as was used in other parts of the risk, cost, and benefit analysis. EPA compounds the problem by using the ICR data (despite EPA's stated concerns about the quality of the ICR data), which drives the upper bound estimates of fatalities, and by extension maximizes the predicted net benefits of the rule.

DEP also has concerns about the methodology used to estimate benefits through the value of life analysis. As noted in the Proposed Rule, EPA used the value of statistical life [VSL] methodology to calculate mortality benefits. Specifically VSL estimates from 26 studies were used to get a mean VSL of $ 6.3 million. Some details on this analysis were presented in EPA's "Guidelines for Preparing Economic Analyse" and the report "The Benefits of the Clean Air Act, 1990-2010." The latter report notes how complex and controversial VSL estimates can be, and points out that the majority of the 26 studies utilized middle-age working populations. Since these working populations differ dramatically from the AIDS population of greatest concern in the LT2 Rule mortality calculation, both in terms of health status and statistical life expectancy, it would appear that the calculation provided needs to take this difference into account. While the Clean Air Act report discusses the problems of life expectancy citing the value of statistical life year [VSLY] concept and life quality citing the quality- adjusted life years [QALY] concept, it appears that these approaches were ignored in the report's VSL calculations. In fact, these concerns and approaches were not mentioned or discussed at all in the Proposed Rule. It is recommended that this substantial issue be reviewed, discussed, and if warranted (as appears to be the case) the mortality benefits analysis be re-calculated and adjusted accordingly.

Overall, with the large number of charts and analyses, DEP found it difficult to determine what is EPA's judgement regarding a realistic assessment of costs and benefits associated with the rule,

for different size systems, and the degree of uncertainty. This problem was compounded by EPA's modeling of risk cost and benefit using different categories of systems sizes (i.e. number of people served). For example, as indicated on page 4-10 of the EA, in some analyses nine system size categories are used, and in other analyses four sizes or even (for net benefit estimates) two sizes are used. The rationale for grouping different size systems in different ways is not readily apparent. The analysis would be more transparent if EPA aggregated the different type of systems in a consistent manner in the cost, benefit, and risk analyses sections. After EPA incorporates any comments, it should be explicit as to whether the response to comments changes any of the Agency's conclusions regarding the net benefits.

3) PUBLIC NOTIFICATION

DEP is deeply concerned that EPA's public notification requirements -- under the existing microbial regulations and the proposed LT2 rules -- are too restrictive, with little to no flexibility for discretion by the primacy agency. While DEP fully recognizes the critical importance of public notification in circumstances where warranted, DEP is also acutely aware of the problem of "over-notification" (or in other words "crying wolf"). There is significant danger to the public, in addition to a real financial cost, of making notifications in circumstances where notification is not warranted. Therefore, DEP strongly suggests that EPA modify the regulations as needed to provide for greater discretion, and it appears that such a modification could be made via LT2. Specifically, DEP is concerned with the requirement that "Tier 2" violations require quarterly public notification, and that per CFR 141.203, primacy agencies are directed NOT to permit notification at a frequency less than every 3 months, in the case of treatment technique violations under the SWTR, or IESWTR.

DEP firmly believes that quarterly notification is neither necessary nor helpful to consumers in the case of certain treatment technique violations. For example, as an unfiltered system, DEP is concerned that a violation of the SWTR Filtration Avoidance Criteria, even after providing for 2 or 3 log inactivation with UV under LT2, may trigger a Tier 2 notice addressing microbial risk, whether or not the SWTR criteria violation relates at all to such risk. Certainly, primacy agencies should be given some discretion in determining the frequency and need of the Tier 2 notification, when the violation does not affect the level of risk from Cryptosporidium.

In addition, DEP is deeply troubled by the requirement that it issue quarterly public notices with regard to the Croton system's temporary status of non-compliance with the SWTR requirement for filtration. DEP *strongly* requests that EPA modify its reporting requirements such that: in the case of systems with high quality source waters which are not yet in compliance with the SWTR filtration requirement but which are under an administrative order or consent decree from the Primacy agency or USEPA to construct filtration, public notice on an annual basis shall suffice, rather than quarterly notification. DEP currently spends $200,000 per year on mandated quarterly notices regarding the DEP's Croton System and its noncompliance with the SWTR. These notices are not only an unnecessary expenditure of limited city funds, but they also can frighten consumers unnecessarily, so they should be eliminated as they do not serve a useful purpose.

4) VARIANCES AND EXEMPTIONS

Variances and exemptions are important tools permitted under the Safe Drinking Water Act to allow for flexibility and Primacy Agency discretion, under limited circumstances. However, EPA proposes under the LT2ESWT Rule to exclude variances and exemptions. DEP feels strongly that variances and exemptions should be permitted under the LT2 rule (and as well, under the 1989 Surface Water Treatment Rule). Note that DEP is NOT asking for a variance or exemption from the basic cryptosporidium inactivation requirement specified in LT2 for unfiltered systems, however DEP is suggesting that there may be certain circumstances, for filtered and unfiltered systems, that a variance or exemption would be appropriate, and that granting of such would not present an undue risk to public health. EPA's stated reasons for exclusion of variances and exemptions under LT2, and DEP's argument against these reasons, are provided below.

- EPA lists one condition under which a primacy State may grant a variance from a specified treatment technique to be a situation where the system demonstrates that the treatment technique is not necessary to protect public health because of the nature of the system's raw water source. (In such case, EPA may prescribe monitoring and other requirements as conditions of the variance.) EPA states its belief that this reason for a variance is not applicable here because the LT2ESWTR cryptosporidium treatment technique requirements account for the degree of source water contamination. This is true, however, this does not take into account the fact that it is quite possible that a water system may develop scientific data, beyond oocyst concentrations, which could assure public health protection at a treatment level lower than specified by the rule. For example, it could potentially be determined that in a given watershed, all (or most) of the oocysts detected are non-viable (e.g., due to environmental degradation), or that the vast majority of oocysts are of a species that is not infectious to humans. Therefore DEP feels that the variance option is appropriate, and should be made available.

  EPA asks for comments in particular on the exclusion of the variance option in the case of unfiltered systems. NYC opposes this exclusion particularly, and strongly requests that EPA modify this exclusion. EPA indicates the theoretical possibility that an unfiltered system would determine its oocyst levels to be considerably lower than those levels on which EPA based its LT2 analysis; however, EPA then states that data that would be of relevance could not reasonably be obtained (due to economic or technologic limitations). DEP disagrees with this analysis for the following reasons. First of all, though it may be unlikely that a system could collect data indicating that its cryptosporidium concentrations are two or three logs below the values EPA used for the LT2 analysis, it may be feasible for a water system to collect data indicating that its oocyst concentrations are one log lower, and thus only 1 log of inactivation may be needed to achieve EPA's public health goal. (NYC's data at this time would not support such a treatment reduction, however it is conceivable data from some other unfiltered systems might.) In addition, there is the possibility, as described above, of data other than oocyst concentration (i.e., species identification, oocyst viability analysis) which could provide assurance of adequate public health protection, and thus a variance may be warranted.

- With regard to exemptions, EPA states its belief that "granting an exemption to the Cryptosporidium treatment requirements of the LT2ESWTR would result in an unreasonable risk to health....Cryptosporidium causes acute health effects, which may be severe in sensitive subpopulations and include risk of mortality." While DEP shares EPA's commitment to public health protection, DEP takes issue with these statements. First of all, it

is possible, as described above, that further scientific examination could, in some cases, reveal that public health is not at risk to the degree suggested by oocyst presence (e.g., if oocysts are not viable or not infectious). Secondly, there is still a significant degree of uncertainty about whether current oocyst levels in typical US drinking waters are resulting in any endemic illness, and if so, at what level (see our discussion of "Overestimation of Risk" above, including the discussion of the findings of the Melbourne study and the Davenport study, where no reduction in GI illness was observed in the groups that received enhanced drinking water treatment).

In addition, DEP feels that the characterization of cryptosporidiosis as causing "acute health effects, which may be severe in sensitive subpopulations and include the risk of mortality" is not a balanced and fair description. Specifically, as is stated in EPA's analysis, most cases of cryptosporidiosis result in mild gastrointestinal symptoms (in fact EPA considers that most people who become ill do not consider themselves sufficiently ill to seek any sort of medical treatment, and thus they are not detectable under even the most sensitive health surveillance systems). It is interesting to note that one of the reasons that it is so difficult to assess whether drinking water results in gastrointestinal illness is that there is such a high baseline of GI illness in the population from all causes (travel, food, person-to-person contact, etc.), yet GI illness does not appear to be one of the top concerns of the public health community. Also, while DEP fully acknowledges the potentially severe consequences of cryptosporidium exposure for sensitive populations (DEP has aided the NYC Department of Health and Mental Hygiene over the years to educate its HIV/AIDS population on this topic), it is conceivable that, in certain circumstances, or at least for certain restricted periods of time, that a more reasonable/economical alternative means of protecting the sensitive subpopulation may be available than compliance with the specific LT2 treatment requirement in question. For example, if a system is having difficulty achieving the required crypto log inactivation for a period and rectification of the problem will unavoidably take some time, a reasonable solution might be for that system to operate under a variance or exemption temporarily, and that provisions for bottled water could be made to serve persons in sensitive subpopulations (and this population appears to be those with advanced AIDS). While this solution may sound unusual, it might be determined to be the most appropriate and reasonable one, and fully protective of public health. Also, it is important to consider that any monies spent by a municipality for projects such as water treatment plant construction or operation, means money that is taken away from other critical needs, like HIV/AIDS education, and other public health programs. Again, all we are saying is that there should be some flexibility for alternative compliance strategies, where warranted, as long as public health is adequately protected.

Though NYC is committed to installing treatment to meet the 2 log cryptosporidium inactivation requirements of the proposed LT2 rule, NYC does have some concerns with regard to consistent compliance with the LT2, and specifically with the Filtration Avoidance Criteria of the 1989 Surface Water Treatment Rule which are carried forth under the proposed LT2. As described in our comment #1 above, DEP has major concerns with regard to the continued strict adherence to the 1989 SWTR Filtration Avoidance Criteria, which is currently proposed under LT2. While it is our firm belief that the 1989 Filtration Avoidance Criteria should be deleted or modified as discussed in #1 above, in the very unfortunate case that this goal can not be achieved, there should, at a minimum, be the possible allowance for a variance or exemption for certain types of minor violations. While DEP has consistently met all of the Avoidance Criteria since the SWTR became effective, and DEP intends to continue to meet these criteria, DEP feels that some flexibility and/or discretion should be permitted under these rules. By 2007, NYC will have

invested over $1Billion on watershed protection for SWTR compliance, and under LT2 will be investing an estimated $600 Million for UV treatment. Given these huge financial commitments, there must be some provision for a minor and/or temporary exceedance of one of the Filtration Avoidance Criteria (e.g., a minor exceedance of the raw water turbidity standard, or an exceedance of the DBP regulations), so that such an exceedance does not automatically and unavoidably trigger filtration.

As EPA is fully aware, there is a difficult task now before the drinking water industry -- that is to reduce both microbial risk and disinfection byproduct risk, in addition to meeting other NPDW Regulations, while insuring system reliability and security, and while at the same time, keeping drinking water rates at a reasonable level, such that obtaining water from the local municipal supply does not a present an undue financial burden for customers. Meeting all of these objectives can be a difficult balancing act, therefore it is essential that provisions be made for flexibility and application of discretion. This brings us to another example of a NYC concern, involving the balancing of DBP risks and system reliability, and relating to the City's Third Water Tunnel project. This tunnel is being constructed at the cost of approximately $6 Billion, and the purpose is to improve infrastructure reliability. Analysis has recently indicated that, at least during the period of project completion, NYC may experience DBP levels above the recently proposed levels (under the D/DBP2 rule) in certain areas. The somewhat elevated DBP levels would result from increased water age, which would occur until the new tunnel is fully completed, projected for the year 2020, at which time one of the other tunnels to be taken out of service and the water aging problem will be reduced. DEP is concerned that under the rules as proposed, a DBP violation resulting from this tunnel construction project would count as a violation of the 1989 SWTR Filtration Avoidance Criteria, and thus would automatically trigger filtration. DEP believes it is consistent with the intent of the SDWA to allow primacy agencies to grant exemptions for systems that experience MCL compliance problems as a result of efforts to improve system reliability, depending on the magnitude and frequency of exceedances of the DBP rule, the ability of the System to come into compliance via operational changes and other means, and the long-term projections for water quality (after the infrastructure improvements have been realized).

In summary, DEP is not asking for a variance from the log removal requirement for unfiltered systems, only that there be the option of variances and exemptions, under limited circumstances, and at the discretion of the primacy agency.

5) DISINFECTION REQUIREMENTS FOR UNFILTERED SYSTEMS

The proposed language which defines disinfection requirements for unfiltered systems appears to be unreasonably restrictive and should be modified. While the proposed language poses no difficulty for DEP under the City's current and planned disinfection regimes (i.e., chlorination and UV for DEP's Catskill/Delaware supplies), the proposed language unnecessarily limits disinfection options – and this could pose a difficulty for various water systems (including DEP, should we want to modify our disinfection strategy in the future).

The LT2 proposed disinfection requirement is included below, and the particularly troublesome clause is highlighted in bold print. In the LT2 (p. 47679, column 3 under "treatment requirements") it states:

> *"In addition, unfiltered systems are required to use at least two different disinfectants to meet their overall inactivation requirements for viruses (4 log), Giardia lamblia (3 log),*

and cryptosporidium (2 or 3 log). ***Further, each of the two disinfectants much achieve by itself the total inactivation required for one of these three pathogen types…..****In all cases unfiltered systems must continiue to meet disinfectant residual requirements for the distribution system."*

This limitation goes beyond the wording of the AIP which on this matter merely requires that "overall inactivation requirements must be met using a minimum of 2 disinfectants." If the basis of the LT2 is public health protection, as long as the required pathogen inactivation levels are achieved, it should not matter which disinfection process achieves which portion of the inactivation? The restriction is troublesome given the goal to reduce DBP levels . The proposed language could limit a water system's options for reducing DBP levels.

6) U.V. DISINFECTION: OFF-SPECIFICATION REQUIREMENTS

The Rule states that '*…disinfection treatment… must ensure at least 99 percent inactivation of* Cryptosporidium *in at least 95 percent of the water delivered to the public every month. Systems are required to report periods when UV reactors operate outside of validated conditions on a monthly basis…(LT2ESWTR IV.B.1)."* This has the same intent as previously regulated disinfection requirements (i.e. one day per month out of compliance), but this requirement for UV disinfection will be difficult to monitor and enforce without further details. AWWA's comments (see Preliminary Draft of Formal Comments of the AWWA on the LT2ESWTR, 12/8/2003; p 51 line 31 and following 3 paragraphs) correctly state the inconsistencies with the LT2ESWTR and the previous rules and with the difficulty of determining the severity of the 'off-specification' violation. Separating off-specification from down time (e.g. treatment failure due to a power interruption or lamp failure) will aid in defining the requirements of what constitutes off-specification treatment. Leaving the rule as it is currently worded will allow for different States to enforce this requirement in significantly different ways and has the potential of requiring overly stringent requirements to ensure satisfactory treatment is achieved to meet the regulation, rather than the goal of ensuring satisfactory treatment to protect public health.

The analysis that AWWA has made comparing the requirements of providing 95% of treated water to be within validated specifications to the 90% required for chemical disinfection (i.e. t_{10}) is erroneous. The comparison of the 95% on-spec treatment should be made to the one day per month out of compliance for CT (or approximately 97% compliance). The t_{10} for CT compliance relates to a distribution of dose for chemical disinfection (i.e. at least 90% of the water will achieve the required CT), which is analogous to the dose distribution in a UV reactor. Properly designing for t_{10} in order to achieve CT compliance is done by assuming a conservative baffling factor for a clearwell. In UV disinfection, the dose distribution is accounted for in the validation testing by assuming a conservative dose distribution factor in developing the safety factors. That being so, the requirements for CT compliance of all but one day per month are in truth more restrictive than the 95% requirement for UV disinfection.

7. U.V. GUIDANCE MANUAL

The methodology outlined in UVDGM is based on conservative assumptions of UV unit performance and ensures that the reduction equivalent dose (RED) will still be conservative (as compared to dose). The requirements for the Tier 1 approach are overly stringent and will be a challenge for most utilities to meet. In addition, when compared to Tier 2, there does not appear to be a great deal of difference between the two approaches. The mandatory validation

procedures in the manual should be simplified and made more understandable. The validation method should be changed from the reduction equivalent dose (which is a UV dose with safety factors included), to one that is based on the UV dose and individual safety factors that can be evaluated separately rather than being lumped together. Developing individual safety factors will allow utilities that do extensive testing to have more flexibility in determining dose. A "tiered" approach can be created using criteria dictating whether default safety factors are used or whether a utility will need to develop specific safety factors for a UV reactor.

Additional comments concerning the UV Guidance Manual, prepared by DEP's consultants, the Joint Venture of Hazen and Sawyer and CDM are provided as Attachment 1.

Part II-Other Comments

Reservoir Covers:

DEP supports the EPA's proposal to allow existing finished water storage facilities to remain uncovered under the conditions specified. The proposed rule recognizes the substantial costs that may be associated with covering reservoirs or providing storage (though we believe significantly underestimated these costs), and has offered reasonable alternatives.

DEP does, however feel that a certain clarification is appropriate, regarding the definition of an Uncovered Reservoir. According to LT2ESWTR, the definition of an uncovered finished storage water facility in 40 CFR 141.2 is a tank, reservoir, or other facility used to store water that will undergo no further treatment except residual disinfection and is open to the atmosphere (p.47719). Many water utilities provide post filtration treatment to uncovered finished water storage facilities, such as pH adjustment for corrosion control. Such corrosion control treatment does not represent treatment to remove contaminants (e.g. filtration) or provide primary disinfection. Therefore, an uncovered reservoir still meets the definition of "facilities where water is stored after it has already undergone all filtration and primary disinfection to satisfy microbial treatment technique requirements for *Giardia lamblia, Cryptosporidium,* and most viruses," if corrosion control is added after storage. Further, it is in the best interest of public health and infrastructure maintenance for systems to provide corrosion control at the optimal location to provide these benefits. The optimal location for corrosion control is immediately downstream of Hillview Reservoir in the New York City drinking water system. Consequently, DEP suggests that EPA clarify its definition of an uncovered finished water storage facility to allow corrosion control treatment following storage.

Recovery and Infectiousness

For the purposes of bin assignments (and presumably for determining whether unfiltered systems require 2 or 3 log removal) EPA proposes that no adjustments be made for method recovery or percentage of oocysts that are infectious (p. 47673). EPA's basic premise is that recovery for the ICRSS averaged approximately 40%, and that percent infectiousness was about 37% and thus these values are of opposite sign and are therefore offsetting. For the purposes of the risk analysis, EPA assumed that the percent infectiousness of the ICRSS data could be modeled as a triangular distribution with a mode of 40 percent and bounds of 30 and 50%. The estimate for percentage of oocysts that are infectious is derived from the work of LeChevallier. DEP believes that EPA's approach biases the analysis towards overestimating the risks for some systems which get greater recoveries of oocysts, and lower rates of infectious oocysts. For example, DEP achieves an average recovery of approximately 50+%. LeChevallier, too, demonstrated much higher recoveries than 40% were achievable in the six watersheds that were studied in the paper cited by EPA. Further, EPA's assignment of a narrowly defined triangular distribution (Mode of 40%) for the percentage of oocysts that are infectious suggests that all watersheds are alike with regard to the type and degree of infectiousness of the oocysts. EPA could have calculated a lower bound, using the LeChevallier data indicating that, for example, the relatively pristine watershed in Oregon had a percentage of infectious oocysts that was closer to 20%. By their nature, the source waters of unfiltered supplies are significantly more likely to have a higher fraction of older, more degraded, and non-infectious oocysts. While for the purpose of the binning procedure in the proposed rule, the unfiltered systems agreed with the simplifying approach to

treat all enumerated oocysts as if they were the same, they are not. Many filtered systems have direct discharges of sewage treatment effluent to their sources, in some cases in large volumes and in close proximity to their intakes, presenting an opportunity for fresh, human infectious oocysts to arrive quickly at their treatment plants. This is not the case for unfiltered systems. The detention time in most unfiltered systems is substantial: not hours or days from pollutant source to intake, but months or years. The physical nature of these systems serves to allow for natural degradation, reducing the potential of any given enumerated oocyst to be infectious. And certainly, watershed characteristics, vulnerability to point sources of human fecal material (e.g. wastewater treatment plants and CSOs), and potential sensitivity to environmental degradation such as travel time from the watershed to the distribution system, should have been considered by EPA as part of the modeling exercise and sensitivity analysis and as to whether recovery and infectiousness are offsetting.

Additionally, EPA should factor in, at least for risk modeling purposes data on the different types of crypto genotypes that might be found in different watersheds. For example, DEPDEP has worked in collaboration with the CDC and applied a PCR-RFLP technique based on the small sub-unit rRNA gene to storm water samples collected in two sub-basins of the DEP watershed (Ashokan Brook and Malcolm Brook). Of the 59 PCR positive samples from storm water, 54 (91.5%) were linked to either known or unknown animal sources. The exceptions were three samples collected from Malcolm Brook within a two week period, where genotypes were discovered from non-human animal sources along with a few typed as *C. hominus*, suggesting a human source. Malcolm Brook storms were monitored for the next year; however, *C. hominus* was not recovered again. Several genotypes were discovered in both watersheds including: W4 (cervid) genotype from deer, W7 (muskrat) genotype, W11 (snake) genotype and W1 genotype from an unknown animal source (probably rodents). Several *Cryptosporidium* genotypes were commonly seen in Ashokan Brook: a type from birds, two types from opossum, and some from unknown animals; however, these were not seen in Malcolm Brook. Likewise, there were a few types recovered from Malcolm Brook that were not seen at Ashokan Brook – fox, rodent, and an unknown animal source.

In summary, DEP believes that EPA has not made a case that recovery and degree of infectiousness are off-setting for all systems, and with the implied conclusion that all watersheds are alike. As part of an uncertainty analysis, EPA should look at the sub-set of systems that are unfiltered to determine whether there are differences in filtered and unfiltered systems (such as recovery and infectiousness) that should be accounted for in determining relative risks between filtered and unfiltered systems, and the need for additional treatment.

p. 47645. EPA indicates that it is not proposing any changes to the MCLG for cryptosporidium at this time. At a minimum, EPA should restate the MCLG to be zero <u>oocysts that are infective in humans.</u> While at this time, the testing methods are not adequate to distinguish the degree of infectivity of each oocyst, such methods may be available in the future.

p. 47645. EPA concludes that it is not currently economically or technologically feasible for PWSs to determine the level of Cryptosporidium in finished drinking water. This statement, as worded, is misleading. DEP's experience is that the current method is generally reliable and reproducible at the 1 particle per 50 liter range. Regarding cost, the cost for sampling and analysis is relatively small compared with the decision that the sampling results rest upon. (Consider the cost of sampling, say, with the cost of the decision that the results of sampling determine). What EPA should clarify, is that it has been unable to develop an acceptable level (or an MCL) for Cryptosporidium, and that the analytical methodologies are not sensitive enough

within the lower range of concentrations that might be considered appropriate MCLs. Note that for the purposes of assessing a Microbial Index, EPA indicates (p 4-51 of the Occurrence and Exposure Assessment (OEA), a Cryptosporidium "level of concern" of 0.075 oocysts/L. This is equivalent to 3.5 oocysts/50 L, a level similar to the lowest alert level proposed by DEP as part of its Cryptosporidium Action Plan. DEP has a substantial amount of data, based on seven years of weekly source water sampling, which shows that this number can be reliably detected. DEP carefully monitors crypto recovery in source water samples, by analyzing at least one matrix spike per week (or per sampling event). Matrix spike duplicates are included at a rate of once per month. Rather than use broad generalizations about the method limitations, DEP believes that the Agency has sufficient data to define, quantitatively, a practical quantitation limit or method detection limit that at least the best laboratories or water systems are capable of achieving. Even EPA's regional laboratories (at least EPA Region II) has been able to establish precision and accuracy control limits that provide acceptance criteria for crypto analyses. That is not consistent with the statement about not feasible for determining the level of Cryptosporidium in drinking water.

p. 47647. EPA cites some reports regarding the potential influence of an immune response but indicates, "The implications of these data for studies of Cryptosporidium infectivity are unclear". In contrast, in other areas, such as estimates of mortality from Cryptosporidium, where the data are equally sparse (the Milwaukee incident whose implications for endemic risk are also unclear), EPA has had no trouble in using the sparse data in the risk estimates. As the question of an immune response is likely to have a substantive impact on the dose-response estimates (particularly at low dose), and the benefits of the proposed rule, the Agency should have included a more in-depth analysis of this issue. At the very least, the issue of immunity should be addressed (preferably quantitatively) in an uncertainty analysis.

p. 47651 EPA utilizes a limited set of data from 3 separate infectivity studies to model the crypto dose-response. That information coupled with estimates of exposure for filtered and unfiltered systems is then used to estimate cases of illness. As EPA has provided a lot of discussion about the inadequacy of the methods used to analyze crypto in water samples at low dose, EPA should address the adequacy and accuracy of the dose estimates used in the infectivity studies. Certainly, this should be discussed in the uncertainty analysis. For example, the low doses used for the Iowa and Tamu strains (10 oocysts) coupled with the few number of subjects seem to drive the dose-response estimates. EPA should report on and evaluate how the dose was determined, what the accuracy and precision of the method was, and the impact, if any that any potential variance in determining the delivered dose may have on the calculation of the risk of infection. DEP's experience with conducting cryptosporidium log removal studies for wastewater treatment, with EPA Region II oversight, indicates the need to pay careful attention to experimental design when determining dose.

P. 47655. EPA makes a point that there was greater variability in occurrences of Cryptosporidium in flowing stream sources than in reservoir and lakes. Given this greater variability, EPA should discuss why the proposed sampling frequency for binning purposes is the same for reservoirs and lakes, and why the same log credit for watershed protection is given for systems on reservoirs and lakes compared with flowing streams. By ignoring the fact that some watersheds are more stable than others regarding the potential for episodic crypto events, such as the watersheds of unfiltered systems, EPA undervalues the benefits of robust watershed protection programs, such as those developed by unfiltered systems, and overvalues the protections afforded by engineered solutions.

p. 47659. EPA requests comments on conducting the analysis for each data set (ICR and ICRSS) recognizing that the choice has a significant effect on exposure, cost, and benefit estimates of the LT2. Given what the agency has said about the ICR data, DEP believes that the ICR data should not be used for the cost and benefit analysis.

p. 47660 (and p. 47663). EPA notes the limitations of early UV disinfection studies using only in vitro assays such as excystation and vital dye staining to measure loss of infectivity. EPA indicates that these early studies were inconclusive and shown to overestimate the UV dose required. More accurate results were provided through in vivo assays and cell culture techniques. In that context, Exhibit 2.4 lists the disinfectants tested against Cryptosporidium, and for chlorine lists only excystation tests (to demonstrate chlorine's ineffectiveness). It would help enhance EPA's argument about chlorine if the Agency included data assessing chlorine's effectiveness or lack thereof, based on the same benchmark tests (in vivo assays and cell culture) used for UV.

p. 47731. DEP believes that EPA should re-evaluate the requirement for matrix spiking under Method 1623 that systems must have **only** 1 matrix spike for each 20 source water samples. Specifically, DEP believes that it would be prudent to require 1 matrix spike per sampling event per source water, if the samples are collected for the purposes of binning or log removal requirements. Considering the criticality to which these data will be used and the low cost of matrix spiking in relation to the overall cost of the decision (rule compliance), a spiking frequency of 1 per 20 would result in only two matrix spikes for a given source water over a 24 month sampling period. For the last several years, DEP has performed analyzed matrix spikes at a frequency of once per week, at our source water keypoints. Matrix spike duplicates are analyzed at a rate of once per month. Through this extensive QA effort, on at least one occasion, we identified a transient recovery problem that appeared to be related to the algal assemblages in the source water. We would be glad to share that data with EPA, upon request. Therefore, DEP believes that the proposed protocol of one matrix spike per 20 is inadequate for the purposes of binning. There should be one matrix spike per separate source water per month.

Comments on Cryptosporidium Sampling and Analysis Procedures

- Comments on Preamble Section IV.K.1.b.

DEP concurs with the proposed alternate matrix spike sample collection for samples greater than 10 liters (i.e. field filtering 40L and spiking 10L in the laboratory) and it should be included in Method 1623 (6/03, USEPA 2003k). However, DEP also recommends that a notation be included here, as well as within Method 1623, in order to notify laboratories to what extent this will/may change laboratory matrix spike percent recoveries since spiking 10L is different than spiking 50L. (DEP recalls that during the study the HV filter mean MS recovery for a 50L spike was 56 %, whereas the mean MS recovery for the 10L spikes was 72%.).

Since there are differences in recovery between spiking 10L and spiking 50L, DEP is wondering if EPA has considered changing the OPR spiking method to 40L + 10L as well to match MS samples in the same batch? If a 50L MS can now be collected as 40L filtered in the field, followed by 10L spiked in the lab and run through the same filter; then shouldn't the OPR samples for that same batch also be analyzed in the same fashion (40L DI filtered, then 10L spiked and filtered through the same filter)? The OPR is often referred to as the recovery attainable without matrix interference. Therefore, at times, the MS recovery is compared to the OPR recovery. For example, when an OPR recovery is 60% and the matrix recovery is 40%, it is generally considered that the matrix studied interfered with recovery by about 20%. If the OPR is performed spiking 50L, but the MS is performed spiking 10L then differences between the recovery of an MS and an OPR may be more related to spiking different volumes rather than being a measure of matrix interference.

Some utilities will be collecting 10L, others 50L. There are noted recovery differences between these volumes especially in difficult matrices. Is it being considered that two utilities with similar water quality could generate different results solely based on the volume they choose to collect for the LT2?

DEP is finding that there may be reduced recovery when samples are collected at higher pressures, even if the sample is collected within the 60psi recommended by the filter manufacturer. DEP feels strongly that recording sample collection pressure is critical in data analysis and thinks it would be very beneficial for EPA to require, at a minimum, that utilities record the pressure during sample collection if not even perhaps limit collection pressure. If pressure is recorded now for the LT2 samples (a minor task), then additional valuable information may be culled from the LT2 effort at a later date if collection pressure is confirmed to have an effect on recovery.

The 2 day sample retake time frame is too short, especially for labs with numerous clients. It is quite reasonable that resamples may need to be taken within the time frame that other samples are needed to be taken for the first time within a week if only 2 days are allowed. Extending this time frame to 4 or 5 days would still keep the resample with in the same "week" and still be collected before the next weeks samples are needed if a weekly schedule is chosen by the utility.

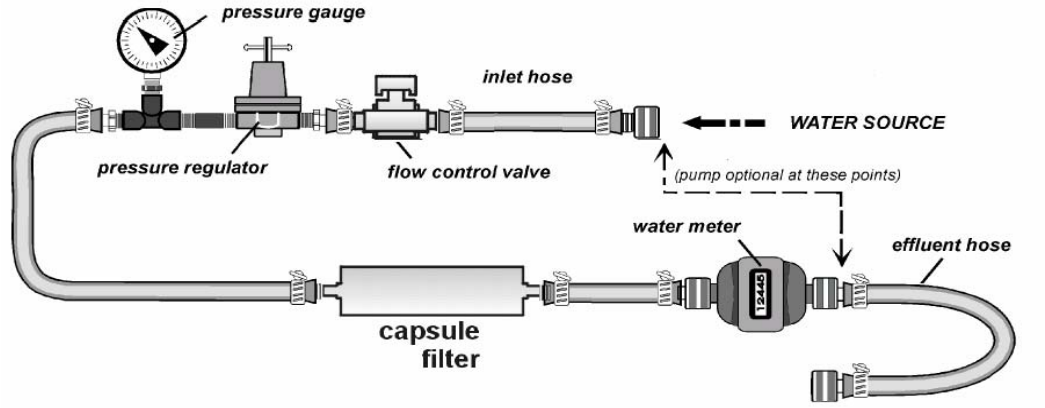
- Comments on Method 1623 (USEPA 2003k):

DEP highly recommends that EPA include a detailed procedure for field sample collection, for samples to be analyzed using Method 1623, within the final version of Method 1623. Including

sample collection procedures in the method has been done in previous *Cryptosporidium* (and *Giardia*) enumeration Methods: 1) The Information Collection Rule (ICR) Microbial Laboratory Manual (EPA/600/R-95/178 April 1996) and 2) Standard Methods for the Examination of Water and Wastewater, 19th Edition (American Public Health Association, Washington D.C., 1995).

Currently, Method 1623, Section 8 – Sample Collection, does not provide enough information to properly collect a sample - it refers elsewhere for more detail. DEP feels it is beneficial to include complete sample collection and analysis procedure in one related document. Right now, the detailed procedure for sample collection for Method 1623 is in the appendices of a separate document - Appendix E and F of The Source Water Monitoring Guidance Manual for Public Water Systems for the Long Term 2 Enhanced Surface Water Treatment Rule (LT2 Rule). These examples provided for sample collection may best be documented within the method, rather than just part of the LT2 source water monitoring.

Additionally, it should be emphasized that these example procedures for field collection, are in fact examples, and that there is flexibility; albeit minimal, for alternate collection methods to accommodate multiple study objectives and locations. An example of an alternate sampling apparatus is presented below.



Field Filtration Apparatus

Section 10.6.3 indicates a QC minimum of a monthly group analysis of a prepared slide to show analyst comparability. Counting the slide and comparing the number of organisms and the DAPI results between all analysts is a good idea, and DEP has this as part of current routine QC. However, for the entire group of analysts to do the above, and now in addition, take turns looking at 10 individual organisms one by one to characterize the DIC interpretation is quite excessive and time consuming, especially every month. Both the proposed number of examinations, and the frequency of this group exercise are beyond what is necessary to ensure analyst comparability. DEP recommends reducing the DIC characterization by the group of analysts to only 3 organisms a month, or, decreasing the frequency of this QC to quarterly.

Page 32 has a typo - need to delete 8 degrees.

Appendix D #1 - temperature still says 0-8 degrees and should be changed to 0 to <10 degrees.

Part III-Additional Comments on UV Guidance Manual

[See our comments sent as PDF file, under by separate e-transmission.]