

25th October, 2004

Mr Brian Labza
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MELBOURNE VIC 3001

Dear Brian

SAFE DRINKING WATER REGULATIONS 2004 - SUBMISSION

Thank you for the opportunity to comment on the exposure draft for the Safe Drinking Water Regulations 2004 and the associated Regulatory Impact Statement (RIS). This letter comprises a formal submission-in-response to the Victorian Government.

Goulburn Valley Water is very supportive of both the *Safe Drinking Water Act 2003* and the intent of the proposed regulations. The Authority has worked very closely with DHS representatives and the Victorian water industry to achieve positive outcomes throughout the process of establishing the legislation. This response to the RIS is also submitted with a view to maximising the net social and economic benefits for Victoria.

The issues identified in the Authority's review of the RIS and draft Regulations are detailed in Attachment 1A, including suggestions for substitute text where applicable. While many of the suggestions aim to clarify ambiguity, the issues of most importance to Goulburn Valley Water are:

- The proposed statistical reporting requirements as recommended by the Australian Drinking Water Guidelines are flawed. Their adoption will inevitably lead to unwarranted capital investment and associated operational costs. This is a complex area of mathematics which the Authority has attempted to address in Attachment 1B.
- The blanket sampling and testing requirement for all proposed standards, regardless of their relevance in treatment processes adopted will add substantially to business operating costs. In the case of the Authority, the ozone related by-products of formaldehyde and bromate will add approximately \$78,000 per annum to monitoring costs. Given only a few facilities incorporate this process across Victoria, it is recommended that the Standards be deleted from the proposed Regulations.

- Within the context of the Act, Regulation 10(c) should be applied having regard to a risk based approach. However, the wording in Section 7.2.4 of the RIS introduces a level of ambiguity. The RIS expectation to achieve a “high level of confidence” for compliance against all parameters identified in the Australian Drinking Water Guidelines potentially goes beyond qualitative risk assessment. Consequently, water businesses may incur significant additional monitoring costs that are unwarranted. The RIS will be considered as an extrinsic reference when interpreting the intent of the Regulation in future. Given this ambiguity and the risk approach of the Act providing sufficient coverage of all water quality hazards, Goulburn Valley Water believes Regulation 10(c) is redundant and should be deleted.

The impact of the draft Regulations will result in additional estimated capital costs of \$4.3 million and estimated recurrent costs of \$1.3 million per annum to Goulburn Valley Water. However these quanta exclude a number of other potential costs related to the ambiguity in the proposed regulations; for example:

- The number and extent of Water Sampling Localities and Sampling Points
- Monitoring costs associated with Regulation 10(c), and;
- Additional monitoring costs associated with increased monitoring frequency that will be driven by the currently proposed statistical reporting requirements.

A breakdown of the drivers for the quantified costs is detailed in Attachments 2A and 2B.

Goulburn Valley Water requests that each issue raised in this submission be responded to in writing by DHS. Further more Goulburn Valley Water seeks to view and provide further comment on any revisions to the Draft Regulations before they progress to Parliament.

I hope that the comments and cost details provided are of assistance in finalising the Regulations. If you require any further information or clarification of issues raised, please contact Bruce Hammond on 5832 0465.

Yours sincerely

Allen J Gale
DIRECTOR TECHNICAL SERVICES

Attachment 1A: Comments on the exposure draft for the SDW Regulations 2004 & RIS
Attachment 1B: Data Assessment for Drinking Water Quality Monitoring
Attachment 2A: Impact of the draft Regulations on Capital Costs
Attachment 2B: Impact of the draft Regulations on Recurrent Operating Costs

Comments on the Exposure Draft for the Safe Drinking Water Regulations 2004 & RIS

Regulation 1 Objective and outline

No issues.

Regulation 2 Authorising provision

No issues.

Regulation 3 Definitions

No issues.

Regulation 4 Water sampling localities

- There is considerable uncertainty regarding how the Localities will be designated. Until Localities are specified, accurate costing is not possible for activities such as analytical testing, provision of sampling points, reporting etc. There is a need to clearly define how Localities are to be assigned (eg. reference to ADWG), to eliminate subjectivity.

Suggested Change: We suggest an additional subsection(s) to Regulation 4 to:

- Define the basis or guidelines upon which Localities are to be assigned; and/or
- Restrict the number of Localities that the Secretary can specify; and/or
- Provide a mechanism for a water supplier to appeal the decision.

Regulation 5 Water Sampling Points

- It has been understood from previous advice that the intent has always been for drinking water Standards to apply at the point of supply to customers. It is ambiguous within the Act and the draft Regulations that this is the case, as there is no clear statement that water sampling points are to be representative of drinking water at the point of supply to customers.

Suggested Change: We suggest that the phrase “at the point of supply to customers” be inserted at a convenient place in this Regulation. (NB. We do not believe that this in any way is paraphrasing of the Act.)

- A water supplier may have valid cause or reason to want to reject a sampling point nominated by the Secretary. Ideally, sampling point allocations should be performed through consultation between the water supplier and the Secretary.

Suggested Change: We suggest an additional subsection to Regulation 5 to provide a mechanism for a water supplier to appeal the creation of a sampling point as specified by the Secretary.

- There is considerable uncertainty regarding the number of sampling points that will be specified for each Locality.

Regulation 6 Risk Management Plan

No issues.

Regulation 7 Risk Management Plan Audits

No issues.

Regulation 8 (& Schedule 1) Audit certificate

- The format of the audit certificate only caters for an overall pass or fail. This approach could be improved upon greatly by indicating the compliance status for individual aspects of the risk management plans.

Suggested Change: We suggest enhancement of the audit certificate to indicate compliance for individual aspects of the risk management plans (eg. tick boxes), with allowance for comments relating to each aspect.

Regulation 9 Approval of Risk Management Plan Auditors

- It is not clear whether it is only the lead auditor that needs to be approved, or whether each and every member of the audit team needs to be approved.

Regulation 10 Drinking Water Quality Standards

- The current wording of the Regulations suggests that all Localities will need to be tested for all Standards, regardless of the type(s) of chemical treatment employed. Section 56 (2) (b) of the Act appears to grant specific permission for differential Standards, but this has not been taken up.

Suggested Change: We suggest that the Regulation be reworded such that Standards apply only to those Water Sampling Localities for which the relevant type(s) of chemical treatment is used.

- Regulation 10 (c) is a very open-ended and ambiguous expectation for sampling and compliance. The RIS is suggesting that all conceivable parameters would need to be tested at very high frequency in order to meet the requirements of this Regulation. This would be extremely difficult to implement, as well as being exorbitantly costly.

Standards should be prescriptive in nature, and this statement is far from prescriptive. Therefore, it should not appear within the Regulation headed “Standards”.

The intent of Regulation 10 (c) is commendable, however it is recognised that the requirement to eliminate contamination of drinking water with toxins, pathogens, chemicals or other substances is the cornerstone of the Risk Management approach underlying the Act.

Suggested Change: Delete Regulation 10 (c), as all aspects of this clause are fully catered for by Regulation 6, and the wording is not typical of a prescriptive Standard.

Regulation 11 Frequency of Sampling for Drinking Water

- It is noted that there is absolutely no mention of any requirement for the selection of weekly or monthly sampling points to be random. As Regulation 11 (2) prevents sampling from the same sampling point twice in a row, this then precludes simple random sampling. Any random selection would then become “random sampling without replacement”, which would greatly complicate any attempt at valid statistical analysis of data.

- Column 1 of the Table in Schedule 2 lists the relevant sampling frequencies for the Standards as either “one sample per week” or “one sample per month”. There is no mention in either Regulation 11, the Table in Schedule 2, or the definitions in Regulation 3 that these frequencies pertain to minima. This then precludes a water supplier from routinely taking more samples than the relevant sampling frequency in some or all of its water supply localities and/or including their results within reports.

Suggested Change: We suggest insertion of the term “minimum” within Regulation 11 to describe the required sampling frequencies, or otherwise make it clear that the values in column 2 of the Table in Schedule 2 are minima eg. “at least one sample per month”.

- The relatively low frequency of sampling/analysis will result in the data set being too small for any summary statistical analysis to be valid. (This is further emphasised in Attachment 1B.)

Schedule 2 Drinking Water Quality Standards Table

- It appears to be an oversight that there is no mention of the Standards (excepting *E.coli*) needing to be assessed over a specific time frame.

Suggested Change: We suggest adding the phrase “assessed over a rolling 12 month period, calendar month by calendar month” to relevant entries in column 3 of the Table in Schedule 2.

- The subheadings “Chlorine based chemicals” and “Aluminium based chemicals” in the Table, that are meant to represent the types of chemical treatment that would cause generation of the listed water quality parameter in drinking water, are ambiguous and imprecise. It is unclear whether “chlorine based chemicals” would include chlorine dioxide. In addition, bromine based chemicals, which would also give rise to THM and HAA generation, would not be included. Also, it may be construed that “aluminium based chemicals” would include bentonite and sand.

Suggested Changes:

1. We suggest replacement of the subheading “Chlorine based chemicals” with “By-products from disinfectants containing chlorine and/or bromine”.
2. We suggest replacement of the subheading “Aluminium based chemicals” with “Residual chemicals from the use of aluminium-based coagulants”.

- The guideline limit for Formaldehyde is listed as “0.5 mg/L” in the ADWG. In column 3 of the Standards Table, the limit is given as “0.50 milligrams per litre”. This discrepancy would have implications for significant digits in reporting.

Suggested Change: We suggest amending the Formaldehyde limit from “0.50” to “0.5”, as stated in the ADWG.

- The notation that the Aluminium results are to represent “acid-soluble” forms is ambiguous and open to subjective interpretation, and should provide more specific detail of the required analytical methodology.

Suggested Change: We suggest inclusion in Regulation 3 as a definition, or enhancement of the text within the Table itself, the phrasing “acid-soluble aluminium is determined after acidifying the sample to pH 1.5-2, followed by filtration through a 0.45 micron membrane filter” (as stated in the ADWG).

- The detection limit for bromate analysis is typically 0.02 mg/L, and cannot be improved easily (according to information provided by Water ECOscience). Therefore, bromate results clearly cannot be reported by laboratories at a resolution low enough to be able to report summary statistics in comparison with a 0.02 mg/L limit.

In addition, the cost of bromate analysis is relatively expensive (in the order of \$100 per analysis). Considering that very few water supply systems in Victoria are ozonated, and therefore bromate and formaldehyde are not a real risk in the vast majority of water supplies, the elevation of these two parameters as Standards is not justifiable. It is believed that risk management approaches for ozonated supplies will ensure that these two parameters are kept in check, in the same way that levels of chlorite and chlorate will be kept in check for systems treated with chlorine dioxide.

Suggested Change: Remove Bromate and Formaldehyde as Standards under these Regulations.

- The absence of specific guidance or Regulation for analytical methods used for testing Standards will provide considerable ambiguity, will allow testing methodology implemented by different analysts to be open to subjective interpretation, and will potentially cause controversy concerning reporting of results. We strongly urge the Department to prepare a Regulation or guidance as soon as practicable to avoid these problems.
- The proposed method for summarising results as 95% Upper Confidence Limits of 95th percentiles or means, and the suggested guidelines in ADWG for undertaking these calculations, is extremely misguided, overly simplistic and scientifically erroneous. The reasons for this include:
 - These particular statistics are not well aligned with the (health) objectives of the data analysis.
 - There is considerable bias introduced from the nature of the proposed sampling regimes (whether randomness is included or not), which needs to be considered in statistical evaluation of the data. This would make any valid statistical analysis quite complex.
 - There is inherent uncertainty and error in all analytical test results reported by laboratories, which has not been considered in the proposed statistical calculations. In addition, the lack of standard test methodologies exacerbates this problem.
 - The validity of any proposed or alternate statistical approach to the data assessment, in consideration of the underlying statistical properties of the “population” being measured (eg. probability distribution), needs to be established by thorough assessment of assumptions inherent in these statistical approaches. The calculations suggested in ADWG are based upon the presumption of an unskewed Gaussian distribution and other invalid assumptions.
 - Inferential statistical methods require minimum data sets, which are specific to the underlying statistical properties of the “population” being measured, in order for the methods to be valid. These minima will not be met by the frequencies as specified in the Regulations.
 - There are no proposed methods or guidelines currently in place for dealing with “censored” data sets that include results below detection of quantification limits. Although there are several simplistic approaches for dealing with these non-specific results, there is no perfect method for dealing with them, and the use or endorsement of any particular methods would be highly subjective and would introduce additional error and uncertainty into any summary statistics calculated from them.

A more detailed dissertation of the problems with using the proposed summary statistics, and calculating them using the approach given in the ADWG, has been provided as a separate attachment to this submission. It provides more appropriate methods of summarising the data and determining compliance with Standards. This detailed evaluation is supported by reference to several technical documents issued by the US EPA and other reputable sources.

Regulation 12 Sample of Water must be Analysed

- This Regulation, as currently worded, does not account for situations where a sample is inadvertently lost or broken, and therefore cannot be analysed. This type of situation will be inevitable and unavoidable, especially where it is necessary to use third-parties for transportation of samples to a Laboratory for testing by an accredited analyst. Also, this Regulation does not provide provision for situations where a sample that has been taken in accordance with the Regulations is subsequently discovered to be non-representative of the drinking water supply eg. through mis-labelling or use of an improper sampling point. In these situations, it would be expected that replacement samples are taken within the required time frame. For these reasons, it would be better to specify the frequency of analysis, rather than the frequency of sampling, within Regulation 11 and the Table in Schedule 2.

Suggested Changes:

1. We suggest an appendage to the Regulation, stating: “unless: (a) the sample is lost; (b) the sample container is damaged and the sample is irretrievable; (c) it becomes known or is suspected that the sample is not representative of the water intended to be tested.”
2. We suggest that, in Regulation 11 and the Drinking Water Quality Standards Table within Schedule 2, the words “sample” and “sampling” be replaced with terms indicating “test” or “analysis”.

Regulation 13 Accreditation of Water Analysts

- Although an analyst will need to hold appropriate qualifications and must be employed by a NATA certified body, there is no actual requirement for the analyses to be conducted using valid methodologies, according to rigorous quality assurance procedures (eg. ISO/IEC 17025 standard), in accredited facilities, or using equipment that is adequate. There is a need to reword this Regulation to close this loophole.

Regulation 14 Reports of Results of Water Samples

- No issues.

Regulation 15 Additional Details to be Included in Annual Reports

- The use of the term “annual report” is ambiguous as it may be construed to mean the corporate annual report. In the Act, it is clearly referred to as the “water quality annual report”.

Suggested Change: We suggest that the term “annual report” be replaced with “water quality annual report”.

- The spelling of the word “odour” should be in Australian English, not American English.

Suggested Change: Within Regulation 15 (1) (k), we suggest replacement of the term “odor” with “odour”.

- With respect to Regulation 15 (1) (d), it is not clear what degree of “incident or event” needs to be included in water quality annual reports. This requires greater clarity, by specifying the reporting of incidents and events that may have posed a risk to human health. By definition, these should be equivalent to the incidents and events that would have been reportable to the DHS at the time of the incident or event.

Suggested Change: We suggest including the phrase “that may have posed a risk to human health” to Regulation 15 (1) (d).

- Compared with the current standard of Water Quality Annual Reports previously published by Victorian Water Authorities, the requirements mandated by this Regulation are considerably greater in scope. In general, we support and agree with these inclusions. However, the additional impact on costs needs to be recognised. In addition, there is no mechanism proposed for the approval of water quality annual reports.

Executive Summary

Victorian water authorities are required to undertake regular monitoring of all drinking water supplies. The results for specific parameters need to be assessed against Standards given in the forthcoming Safe Drinking Water Regulations. The appropriate methodology for assessing the test data, in order to determine regulatory compliance against the Standards, is discussed here.

Guideline limits have been published in the Australian Drinking Water Guidelines (ADWG) for notable water quality contaminants and properties, including those to be used as Standards in Victoria. These guideline limits define the level of the contaminant that is safe, or constitutes no significant risk to health, if consumed over a lifetime (NHMRC/ARMCANZ 2001, p. 1.4). The average concentration is most representative of the concentration that would be contacted over time, so an estimate of the average concentration should be used in assessing the level of a contaminant (USEPA 1992, pp. 1-2).

The average concentration of a contaminant may be estimated using a descriptive summary statistic that is a simple measure of central tendency, such as the arithmetic mean or the median. If the data set available from testing of the water supply has been derived from a sampling design that is sufficiently robust and randomised to justify the calculation of inferential statistics, then an upper confidence limit (UCL) may be applied to the mean or median to provide a higher level of confidence regarding the average concentration of exposure.

There are several valid methods for calculating the 95% UCL of the mean. Those that best fit parameters with a right-skewed distribution, which would generally be the case for trace contaminants in drinking water, include the Chen, Wilcoxon Signed Rank and Land methods. In addition, there are a number of other non-parametric (distribution-free) methods available. In order to determine the feasibility, and most appropriate method, of calculating the 95% UCL of the mean, it is necessary to consider how well the sampling design and available data meets the inherent assumptions of the respective methods.

For the Standards that will be introduced within the forthcoming Regulations, it is proposed that the method of summarising the data for comparison with compliance limits be performed by one of the following two methods:

Approach 1

- a) Ensure that the sampling design is such that the calculation of inferential statistics is viable.
- b) Calculate the 95% UCL of the mean or median. (The best method for calculating this statistic should be determined following a thorough review of the available techniques.)

Approach 2

- a) For non health-related Standards, calculate the mean or median.
- b) For health-related Standards, calculate the mean or median. In addition, apply a stipulation that the Maximum Observed Value shall not exceed 1.5 times the compliance limit.

Introduction

Victorian Water Authorities are obliged to undertake regular monitoring for each of their drinking water supply systems for a number of microbiological and physico-chemical parameters. In the forthcoming Regulations under the Safe Drinking Water Act 2004, it is being proposed that testing for specific parameters be conducted on a weekly or monthly basis, with comparison of summary statistics against stated quality Standards (generally derived from the Australian Drinking Water Guidelines) intended to determine regulatory compliance.

By reference to the well-regarded principles of Data Quality Objectives (DQO) and Data Quality Assessment (DQA), it is intended to provide a structured and robust dissertation of the assessment of water quality data monitoring results in respect of water quality guideline limits, through consideration of the:

- Objectives of the sampling program and data assessment in respect of public health;
- Uncertainty and bias associated with the nature of the proposed sampling program design;
- Methods of dealing with “censored” data sets that include results below detection limits;
- Validity of proposed and alternate statistical approaches to assessment of the data, in consideration of underlying statistical properties and assumptions;
- Minimum number of samples required to form a statistically valid conclusion;
- Interpretation of the derived summary statistics.

Data Quality Objectives (DQO)

The Data Quality Objectives (DQO) process has been developed by the United States Environmental Protection Agency (USEPA) as the recommended planning process for determining the type, quantity and quality of data needed to reach defensible decisions in regard to assessment of environmental data. It is used to “*develop Data Quality Objectives that clarify study objectives, define the appropriate type of data, and specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions*” (USEPA 2000a, p. i).

The DQO process is based upon a systematic seven-step planning approach to develop sampling designs for data collection activities that support decision making. The seven steps are:

1. State the Problem
2. Identify the Decision
3. Identify the Inputs to the Decision
4. Define the Boundaries of the Study
5. Develop a Decision Rule (ie. define the statistical parameter and specify the action level)
6. Specify Tolerable Limits on Decision Errors
7. Optimise the Design for Obtaining Data

The DQO process uses hypothesis testing to differentiate between two or more clearly defined alternatives. When data are to be used in decision making by selecting between two clear alternative conditions (eg. compliance or non-compliance with a Standard), the DQO process is the USEPA's recommended planning methodology (USEPA 2000a, p. 0.5). The EPA QA/G-4 guidance document (USEPA 2000a) is a useful resource that would be helpful in developing and rationalising the objectives of the Standards, the decision rules for compliance, and the sampling requirements for the Safe Drinking Water Regulations.

According to the USEPA, an estimate of the average concentration should be used in assessing the level of a contaminant, unless acute toxicity is of concern, as carcinogenic and chronic toxicity criteria are based on lifetime average exposures, and average concentration is most representative of the concentration that would be contacted over time. For contaminants posing acute toxicity concerns, the focus should be to estimate short-term, peak concentrations (USEPA 1992, pp. 1-2).

With regard to drinking water contaminants, it is generally only the presence of microbiological agents, as indicated by the detection of *E.coli*, that would pose acute toxicity concerns. For each of the other proposed regulated Standards (turbidity, aluminium, THMs, HAAs, formaldehyde, bromate), the contaminants are either not health risks at all or are known to cause health problems only from long-term, chronic exposure. Therefore, estimates of the average concentrations of these contaminants are most appropriate.

Sampling Design

For use in conjunction with the DQO process, the USEPA has developed the EPA QA/G-5S guidance document for choosing a sampling design for data collection (USEPA 2002a). The general types of sampling designs possible are:

- Judgmental Sampling
- Simple Random Sampling
- Stratified Sampling
- Systematic and Grid Sampling
- Ranked Set Sampling
- Adaptive Cluster Sampling
- Composite Sampling

Each type of sampling design has relative advantages and disadvantages. Importantly, each sampling design will have its own set of limitations and assumptions which need to be recognised, and in general, the methods needed to assess the data will be highly dependant upon the nature of the sampling design. Therefore, the validity and method of calculating any statistical parameter is highly dependant upon which sampling design is employed. The most appropriate sampling design for the particular situation should be selected through a thorough DQO process.

The sampling design for drinking water in Victoria proposed within the draft Regulations has both a temporal (time) component and a spatial component. The temporal component of the proposed sampling design is essentially “systematic” in nature, as a sample will be taken once per week or once per month, and the samples will generally be taken at the same time of day.

The spatial component of the proposed sampling design adds considerably more complexity to the situation. For each water quality zone, there will be a number of sampling points assigned to (hopefully) provide a representative coverage of the zone (spatial grid). If each of these sampling points were to be sampled each week or month, then the entire sampling design could be legitimately classified as “systematic/grid sampling”. However, as only one sample is to be taken every week or month, and the location from which that sample is to be taken is to be different on each occasion, the spatial component of the sampling design should probably be considered as “simple random sampling, without replacement”.

The overall complexity of the proposed sampling design will make any legitimate assessment of the data quite onerous, if any statistical inferential methods are to be employed or if statistics based upon probability distributions are intended to be calculated. Some advice on how to approach this, using a more complicated method for determining “pooled” standard deviations for these types of data sets, is provided by IUPAC (1997, section 2.3). In consideration of this, it is suggested that assessment of the data might best be limited to descriptive summary statistics such as simple measures of central tendency (eg. mean, median, mode), relative standing (eg. quantiles/ percentiles) and dispersion (eg. standard deviation).

Data Quality Assessment (DQA)

Data Quality Assessment (DQA) is a process developed by the USEPA for assessing data quality criteria and performance specifications for decision making. It involves the scientific and statistical evaluation of data to determine whether the type, quantity and quality of data needed to support their intended use has been achieved. “*DQA is built on a fundamental premise: data quality, as a concept, is meaningful only when it relates to the intended use of the data. Data quality does not exist in a vacuum; one must know in what context a data set is to be used...*” (USEPA 2000b, p. 0.1).

The use of DQA is intended to allow two fundamental questions to be answered:

- Can the decision/estimate be made with the desired confidence, given the quality of the data?
- How well can the sampling design be expected to perform over a wide range of possible outcomes? (USEPA 2000b, p. 0.1)

The DQA process involves five steps that would roughly parallel the actions of an environmental statistician when analysing a set of data. These steps are:

1. Review the DQOs and Sampling Design
2. Conduct a Preliminary Data Review
(ie. draw graphs and calculate basic descriptive summary statistics)
3. Select the Statistical Test
(including identification of key underlying assumptions that must hold for the statistical procedures to be valid)
4. Verify the Assumptions of the Statistical Test
5. Draw Conclusions from the Data (USEPA 2000b, p. 0.2-0.3).

The information presented in the EPA QA/G-9 guidance document for the DQA process (USEPA 2000b) is highly relevant to the assessment of drinking water quality in Victoria. This guidance document provides a structured methodology for assessing the applicability of a wide range of statistical procedures based upon their inherent assumptions, as well as providing detailed calculation methods for these statistical procedures.

Statistical Calculations for Assessment of Data

The ADWG (Australian Drinking Water Guidelines, NHMRC/ARMCANZ 2001) provides an extensive coverage of statistical principles and calculations within section 6.3. In spite of the otherwise high quality of the ADWG document, the discussion on statistics is overly simplistic and misleading. Its blanket application of an unskewed Gaussian probability distribution to all situations, without due consideration of the underlying assumptions of the distribution function or the nature of the real probability distribution of the “population”, would make the validity of these guidelines highly dubious under most likely circumstances.

For each of the proposed drinking water Standards, the application of an unskewed Gaussian distribution function for inferential statistical calculations would be highly contentious, particularly for turbidity and aluminium (which are clearly heavily right-skewed). The statistical methods given in the ADWG, based on a one-sample *t*-Test, fail to adequately recognise the assumptions and limitations of the methods employed. In addition to the improbability of the parameters approximating a Gaussian distribution, the presence of any outliers in the data set will adversely affect the applicability of any *t*-Test method (as the *t*-Test is not robust in respect of outliers). The *t*-Test methods endorsed by ADWG also have great difficulty dealing with “less-than” values where reported results are below detection or quantification limits.

Upper Confidence Limits for the Mean

For determining Upper Confidence Limits for the Mean, an alternative calculation method, the Wilcoxon Signed Rank Test for the Mean, is more robust to outliers and is able to deal with “less-than” values (USEPA 2000b, pp. 3.4-3.14). Similarly, the Chen Test for the Mean is strongly promoted by the USEPA as being a preferable test for a broad class of distributions when the data come from a right-skewed distribution (USEPA 2000b, pp. 3.15-3.17). The Chen Test is a generalisation of the t -Test, with slightly more complicated calculations involving calculation of the mean, standard deviation and skewness. This test can have some difficulties in dealing with “less than” values, but a substitute value (eg. one half of the detection limit) will suffice if the threshold/compliance value is much larger than the detection limit.

It has also been suggested that an appropriate probability distribution for estimation of the true nature of many environmental parameters is the Lognormal distribution (USEPA 1992, pp. 3-4). There may also be other distribution functions that may be applicable, such as the gamma or chi-square distributions. The Upper Confidence Limits (UCL) for the Mean, assuming a Lognormal distribution, should be calculated using the Land method which employs use of the H -statistic (USEPA 2002b, pp. 9-11), or the Chebychev Inequality method (USEPA 2002b, pp.11-14).

In addition, there are several non-parametric methods available for calculating upper confidence limits for the mean. These include the Adjusted Central Limit Theorem method for large sample sizes, the Bootstrap Resampling method, and the Jackknife method (USEPA 2002b, pp. 14-19).

Another possibility is the use of a statistical test for the median. The Wilcoxon Signed Rank Test may be applied to the median instead of the mean, and this is the preferred method for determining a 95% UCL for the median (USEPA 2000b, pp. 3.18-3.20).

It must always be remembered that the assumptions underlying each of these statistical tests must be verified before the method can be used legitimately.

Upper Confidence Limits for Percentiles

The ADWG describes a t -statistic method for determining the 95% UCL of the 95th percentile (NHMRC/ARMCANZ 2001, p. 6.13-6.14). This method of assessing water quality data is highly inappropriate, both from a data quality objectives standpoint and a statistical validity standpoint.

The ADWG itself states that guideline values for contaminants are levels that are considered safe to drink over a lifetime, with no significant risk to health (NHMRC/ARMCANZ 2001, p. 1.4). Considering that the average concentration is most representative of the concentration that would be contacted over time (USEPA 1992, pp. 1-2), it is only sensible and reasonable to use an estimate of the average concentration, not the 95th percentile.

Even if one wanted to calculate a 95% UCL of the 95th percentile, the method described in the ADWG is dangerously flawed, due to its basis on an unskewed Gaussian distribution. For determining confidence intervals for proportions or percentiles, it is not recommended to use a method based upon a continuous distribution function, unless the exact distribution function can be identified. The generally recommended procedure involves a non-parametric method whereby each datum is categorised as being either above or within the compliance/threshold value (Hogg & Craig 1978, pp. 304-307; USEPA 2000b, pp. 3.18-3.20). This methodology will often generate highly conservative (high) UCL values, and can require very large data sets (typically several hundred data values) before the method can be considered valid. It is therefore impractical to attempt to determine 95% UCLs of the 95th percentiles for Victorian drinking water supplies where it is proposed to use relatively modest sample sizes.

Dealing with “less than” Values

There is no perfect way to deal with “less than” values. Sometimes results are reported in this manner because they are genuine “non-detects” and the real value may be approximated by zero. In other cases, they may be reported this way because they are detected at a level below the practical quantification level (PQL) of the analytical instrument or test. In these cases, the use of a substituted value would be appropriate for data analysis. A detailed review on how and why results may be reported as “less than” values is provided by IUPAC (1997, section 18.4.3.7).

The USEPA (2000b, pp. 4.42-4.51) provides excellent guidance on how to deal with “censored” data sets containing “less than” results. These include various substitution methods and guidance on preferred methods depending upon the proportion of these values in the data set. Overall, it is best to avoid the uncertainty of this type of data, and seek a statistical method that is not heavily affected by the choice of method for dealing with “less than” values.

Conclusions

The overview presented here provides clear evidence that the proposed statistics for assessing compliance with the proposed regulatory Standards for drinking water in Victoria, and the methods for calculating them as given in the ADWG, would not be appropriate or valid.

The most appropriate statistical methods will undoubtedly contain an element of subjectivity, and there would be several valid approaches that may be employed, depending upon personal preference. Two possible approaches for assessing data in relation to the proposed threshold/compliance values are provided here.

Approach 1

- a) Ensure that the sampling design is such that it maximises the randomness of the sampling, so that any inferential statistical methods can be validated. (This would require some reworking of Regulation 11, including ensuring that randomness is a cornerstone of the sampling design and removing any reference to “sampling without replacement”).

- b) For all proposed Standards (except for *E.coli*), use 95% Upper Confidence Limits for the Mean or Median in assessment of the data over a defined time period and a minimum number of samples. The calculation method to be employed, which may be the Chen, Wilcoxon Signed Rank or Land method, should be determined following a thorough DQA process, and formal instructions on how to perform the calculation are provided.

Approach 2

- a) For non health-related Standards (ie. turbidity, aluminium), use a simple descriptive summary statistic for measuring central tendency (eg. Arithmetic Mean or Median) in assessment of the data over a defined time period and minimum number of samples. Formal instructions on how to perform the calculation are provided.
- b) For health-related Standards other than *E.coli* (ie. disinfection by-products), use a simple descriptive summary statistic for measuring central tendency (eg. Arithmetic Mean or Median) in assessment of the data over a defined time period and minimum number of samples. Formal instructions on how to perform the calculation are provided.

Also, provide an additional stipulation regarding the dispersion of results, such as the Maximum Observed Value over a defined time period not exceeding 1.5 times the threshold/compliance limit.

References

Hogg, R.V. & Craig, A.T. 1978, "Introduction to Mathematical Statistics" 4th Edition, Macmillan Publishing, New York.

IUPAC 1997, "Compendium of Analytical Nomenclature" 3rd Edition, International Union of Pure and Applied Chemistry.

NHMRC/ARMCANZ 2001, "Australian Drinking Water Guidelines" 2001 Update, National Health and Medical Research Council and the Agriculture and Resource Management Council of Australia and new Zealand, Canberra.

USEPA 1992, "Supplemental Guidance to RAGS: Calculating the Concentration Term", United States Environmental Protection Agency – Office of Solid Waste and Emergency Response, Washington D.C.

USEPA 2000a, "EPA QA/G-4 Guidance for the Data Quality Objectives Process", United States Environmental Protection Agency – Office of Environmental Information, Washington D.C.

USEPA 2000b, “EPA QA/G-9 Guidance for Data Quality Assessment – Practical Methods for Data Analysis”, United States Environmental Protection Agency – Office of Environmental Information, Washington D.C.

USEPA 2002a, “EPA QA/G-5S Guidance on Choosing A Sampling Design for Environmental Data Collection”, United States Environmental Protection Agency – Office of Environmental Information, Washington D.C.

USEPA 2002b, “OSWER 9285.6-10 Calculating Upper Confidence Limits for Exposure Point Concentrations at Hazardous Waste Sites”, United States Environmental Protection Agency – Office of Emergency and Remedial Response, Washington D.C.

CAPITAL

SITE	a Turbidity	b+c THMs/ HAAs	d ozone related	e Aluminium	comments
All systems					
Colbinabbin					
Corop *****	non potable				
Dookie					
Girgarre	100,000				
Katandra West					
Kyabram					
Merrigum					
Mooroopna					
Murchison					
Rushworth					
Shepparton					
Stanhope					
Tatura					
Tongala					
Toolamba					
Avenel					
Broadford		50,000			
Euroa					
Kilmore					
Longwood		150,000			
Nagambie		50,000			
Pyalong		150,000			
Seymour					
Strathbogie *****	Non potable				
Tallarook					
Trawool		50,000			
Violet Town					
Wallan					
Waterford Park		50,000			
Baxters Rd *****	non potable				
Kirwans Bridge *****	non potable				
Alexandra					
Bonnie Doon	1,100,000	100,000			
Buxton					
Eildon	1,200,000				
Mansfield					
Marysville					
Molesworth *****	non potable				
Upper Delatite					
Thornton	900,000	100,000			
Woods Point *****	non potable				
Yea	300,000			10,000	
Barmah					
Cobram					
Katamatite					
Katunga					
Numurkah					
Nathalia					
Picola					
Strathmerton					
Wunghu					
TOTAL	3,600,000	700,000	0	10000	\$4,310,000.00 SUB TOTAL
Risk Management Plans establishment		(already doing or planned RMPs)			\$0.00
TOTAL					\$4,310,000.00 TOTAL

Recurrent

SITE	a Turbidity	b+c THMs+HAA	d ozone related	e Aluminium	
All systems			80000		
Colbinabbin					
Corop *****	non potable				
Dookie	0				
Girgarre	10,000				
Katandra West					
Kyabram					
Merrigum					
Mooroopna					
Murchison					
Rushworth					
Shepparton					
Stanhope	0				
Tatura					
Tongala					
Toolamba					
Avenel					
Broadford		2,500			
Euroa					
Kilmore					
Longwood		8,000			
Nagambie		2,500			
Pyalong		7,500			
Seymour					
Strathbogie *****	non potable				
Tallaroook					
Trarool		2,500			
Violet Town					
Wallan					
Waterford Park		2,500			
Baxters Rd *****					
Kirwans Bridge *****					
Alexandra					
Bonnie Doon	100,000	5,000			
Buxton					
Eildon	100,000				
Mansfield					
Marysville					
Molesworth *****					
Upper Delatite					
Thornton	60,000	5,000			
Woods Point *****					
Yea	15,000			3,000	
Barmah					
Cobram					
Katamatite					
Katunga					
Numurkah					
Nathalia					
Picola					
Strathmerton					
Wunghu					
TOTAL	285,000	35,500	80,000	3,000	\$403,500 SUB TOTAL
Maintenance Risk Management Plans for Regs					\$490,000
Monitoring additional					\$181,564
Auditor Costs					\$80,000
Reporting					\$75,000
Independent samplers NATA approved					\$90,000
TOTAL RECURRENT					\$1,320,064 TOTAL