

Peer Review Report

Peer Review of *Development of Human Health Water Quality Criteria for the State of Idaho*

December 1, 2015

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DEQ Contract #K109



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I. INTRODUCTION

Idaho Department of Environmental Quality (DEQ) is updating their water quality criteria (WQC) for about 100 chemicals of interest using probabilistic and deterministic risk assessment methods. Derivation of human health-protective WQC is summarized in the draft report “Development of Human Health Water Quality Criteria for the State of Idaho,” which focused on fish consumption for three population groups: general population, anglers, and tribal populations in Idaho. The assessment relied on updated estimated fish intake rates for these populations, distributions for body weight and drinking water intake, and deterministic inputs for toxicity, bioaccumulation factors, and relative source contribution. Acceptable risk thresholds (10^{-6} for cancer and $HQ=1$ for non-cancer effects) were used as the basis for the probabilistic development of WQC, to be protective of the upper percentile (i.e., the 95th percentile of exposure) of the general Idaho population. For the high-end consuming tribal and angler-only populations, the intent was to ensure that the WQC would be protective of the average individual. Each chemical’s WQC was derived based on cancer and/or non-cancer toxicity values and the WQC was developed based on the toxicity value that resulted in the more stringent (i.e., lower) value.

This report, along with other documents developed by Idaho DEP, including two related to fish consumption surveys, is part of Idaho DEQ’s rulemaking effort to derive water quality criteria to be protective of human health. Additional background on the larger scope of Idaho DEQ’s efforts can be found in the Overview section of Idaho DEQ’s web site:

<http://www.deq.idaho.gov/58-0102-1201>.

The approach, methodology, parameter values used, and results from this effort are summarized in the draft document “Development of Human Health Water Quality Criteria for the State of Idaho,” authored by Windward Environmental, LLC. The purpose of this peer review was to have three experts evaluate the draft document with regards to the validity of the approach and calculations for the purpose of deriving human health water quality criteria.

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II. PEER REVIEW PROCESS

This section details the procedures that were followed to conduct this external peer review. Versar has a well-established approach for conducting peer reviews, from completion of more than 500 peer reviews of environmental risk assessment-related documents over the past 20 years for a variety of Federal and state government research and regulatory agencies. The approach covers all aspects of the peer review, from reviewer selection through completion of the peer review report. Within this approach are several quality assurance protocols to ensure that: qualified individuals are selected to participate, they are free from conflict of interest (COI) and the appearance of the lack of impartiality, and a thorough review is completed.

Reviewer Identification and Selection

Versar's approach for selecting the technical expert reviewers consisted of the following five key steps: (1) development of selection criteria, (2) identification of experts, (3) COI screening, (4) selection of peer reviewers, and (5) confirmation of peer reviewer participation.

The experts that participated in this review were identified by literature searches of scientific journals, professional societies, and scientific meetings, as well as searches of Versar's internal peer review database of more than 3,000 scientists. As a result of this search, Versar identified potential scientific experts with expertise in human health risk-based water quality criteria. These experts were contacted to determine their availability and interest in participating in the review. Interested candidates provided their curriculum vitae, which were reviewed by Versar staff to ensure that each candidate had the appropriate scientific credentials and evidence of expertise through a listing of their publications and professional affiliations. The specific disciplines/areas of expertise needed for this peer review included: (1) human health exposure and risk assessment, (2) selection of exposure factors for population-based exposure/risk assessment, (3) derivation of human health-based water quality criteria, and (4) probabilistic and deterministic risk assessment for chemicals.

Versar also conducted COI screening to make certain that the experts had no COI or appearance of the lack of impartiality that would interfere with providing a thorough critical review of the document. This screening involved sending the potential candidates a series of COI screening questions that helped us to determine if they were involved with any other work and/or organizations that might create a real or perceived conflict of interest for the current task. Additionally, each expert signed forms certifying that, to the best of their knowledge, they did not have any conflict of interest related to the task. Upon completion of the COI screening, Versar selected three experts, based on their credentials, to conduct the review. Versar requested and received consent from the Idaho DEQ and, subsequently, contacted the three reviewers to notify them that they were selected to participate in the peer review.

Conducting the Review

Following the selection process, Versar distributed to the reviewers the draft document "Development of Human Health Water Quality Criteria for the State of Idaho" and a work assignment authorization (WAA) letter, which included the charge questions, instructions, and a comment template for the preparation of written comments to ensure that each reviewer submitted their comments in a consistent format.

Versar developed a series of six charge questions to help guide and focus the review of the document. These charge questions generally asked reviewers to provide comments on the strengths, weaknesses, and overall quality of the report. The comment template instructed the reviewers to provide comments in the following three categories:

- (1) General Impressions - overall comments addressing the accuracy of information presented, clarity of presentation, and soundness of conclusions.
- (2) Response to Charge Questions - narrative responses to the six charge questions.
- (3) Specific Observations - Specific observations or comments on the document, including editorial changes, mentioning page and line.

The WAA also included Versar's confidentiality statement indicating that the peer reviewers' should not distribute or discuss their comments with any outside party, as well as the amount of time the external reviewers had to complete their reviews and submit written comments. During the review period, Versar monitored the progress of the reviewers on a regular basis to make sure there was timely delivery of the written comments.

Review of Expert Comments

At the completion of the review period, Versar received written comments from the three reviewers, evaluated the experts' comments for completeness and scientific quality, and obtained clarification or additional input as needed. The three experts all submitted thorough reviews of the draft report, providing: (1) general comments, which included their overall impressions of the document, addressing the accuracy of information presented, clarity of presentation, and soundness of the conclusions; (2) responses to six charge questions; and (3) specific observations, which included editorial corrections or factual changes to the document. The comments were compiled into a draft peer review summary report, and organized by charge question to facilitate side-by-side viewing of the reviewers' comments on the same topics.

III. CHARGE TO REVIEWERS

Charge Questions:

1. Please comment on the clarity and organization of the report. Does it present information, including tables and figures, in a clear and usable format? If not, please provide suggestions for improving the clarity of the document, which is intended to be useful to state regulators, the scientific community, and other stakeholders, including the general public.
2. Please comment on the appropriateness and application of the methodology for deriving human health water quality criteria based on fish intake only and fish and water intakes?
3. Do you agree with the populations considered in the development of WQC – general Idaho population and higher-level consumer populations (i.e., angler-only population in Idaho, the Nez Perce tribe, and the Shoshone-Bannock tribes)?
4. Please comment on the appropriateness and the approach for selecting the parameter values (e.g., body weight, fish consumption rate, drinking water intake rate, BAFs/BCFs, toxicity values) used in the calculations.
5. Are the results of the analysis scientifically sound and “valid” for the State of Idaho’s use in their proposed human health water quality criteria?
6. Do you have any other suggestions for improving the scientific quality or utility of the document?

IV. GENERAL IMPRESSIONS

Peter deFur

The document on the Human Health Water Quality Criteria is clearly presented and explains most of the information for the intended audience. As with all such technical documents of this nature, the audience is not the general public, but the intended audience is not stated in the document and it would be an improvement to have a simple statement to the effect that this document is written for agency staff, consultants, etc., or whatever target group the agency indicates. Agency staff who might be new to the topic may also be unable to follow much of the document without referring to background materials, but that situation is usually acceptable to the sponsoring agency.

There is an assumption that the Monte Carlo or probabilistic approach is sufficiently well-known that further explanation is not needed. I am not sure that assumption holds up. I suggest a couple of references to EPA guidance on the topic, SETAC publications, etc. to direct a reader who is otherwise knowledgeable with other aspects of the report, but needs more on the approach.

A fact-checking effort reveals that the data taken from EPA documents and reports is accurate, as are the equations and the scientific approach.

The conclusions are sound, given the assumptions and conditions set by IDEQ.

Two items give me concern and I raise them here and elsewhere:

(1) There is no explanation or justification for the differential protection afforded the general population and the Nez Perce in terms of fish consumption; and

(2) A number of metals are not on the list, specifically lead, copper and chromium, and lead is a known problem for fish contamination in the region. The document is silent on these chemicals and likely due to factors out of the author's control.

Angela Preimesberger

The Windward Environmental report, *Development of the Human Health Water Quality Criteria for the State of Idaho [Draft]*, dated October 6, 2015 is formatted and written in a typical technical report style. This report presents information to a well-informed or technical audience familiar with methods for risk assessment and state and U. S. Environmental Protection Agency (EPA) human health-based water quality criteria and standards. As a technical report it provides clear table of contents, tables of relevant data, and review of findings.

The report is not written in plain language and lacks sufficient background discussions to make it easily understood or usable by the general public. The focus of the report is on probabilistic and deterministic development of input parameter values to the water quality criteria (WQC) equations; however, only very limited information is provided that explains the differences and benefits of using each approach to determine parameter values.

The scope of the evaluation requested by the State of Idaho from Windward Environmental for development of WQC is not clear. The report referenced a 2015 work plan with the State of Idaho, but didn't elaborate on the scope of that work plan. Therefore, the report did not explain if the consultant's role is to just run the Monte Carlo analyses for developing WQC using the three probabilistically calculated parameter values or to more fully provide the State with additional options to improve how the WQC are developed. Based on the content of the report, the scope looks to center primarily on running the probabilistic calculations and quality control and assurance tests on the Monte Carlo model used. The information provided though could be expanded to reflect the breadth of valuable survey data available in order to better assist the State of Idaho in determining the most defensible parameter values.

Alan Stern

The authors are to be commended for applying Monte Carlo (MC) analysis to the analysis of Idaho-specific exposure. The application of MC to the estimation of exposure under circumstances of relatively complete distributional data is the appropriate use of MC in exposure assessment. However, as discussed below, there are issues of its specific use in this document. In general (and except as noted below), the document is clearly and concisely written. However, as MC is still not a widely employed or well-known concept, it might be useful to provide a brief introduction to MC if the intended audience is other than those with a specific knowledge of this methodology.

My overriding issue with this document, is that the design and intent of the WQC are not clearly stated anywhere in this document. This would seem to be essential, and I recommend that a specific section be included in the beginning of the document laying out the intent and rationale for this the WQC. In particular, since the water in question appears to be the surface water of Idaho *per se*, it is not clear how the WQC for fish consumers applies to non-angler fish consumers. If the intent is to address fish consumption in total because it is considered to be a significant source of toxicant exposure, then it is not clear why other significant sources of toxicant exposure (e.g., general diet) are not, likewise, included. If (as seems more likely) the intent is to include fish consumption because the water quality criteria for a given chemical should integrate all routes of water-derived exposure to that toxicant, then it is not clear why fish from non-Idaho waters are included.

V. RESPONSE TO CHARGE QUESTIONS

Charge Question 1

Please comment on the clarity and organization of the report. Does it present information, including tables and figures, in a clear and usable format? If not, please provide suggestions for improving the clarity of the document, which is intended to be useful to state regulators, the scientific community, and other stakeholders, including the general public.

Peter deFur

The report is well organized, well presented and clearly written as a technical document written for an audience of people who work in the fields of water quality permits or water quality in general. The presentation is clear and the information well done, with two items raised above and explained again below.

As to the question of how appropriate this document might be for the general public, per the charge question, this document is not at all appropriate for the general public and was not written nor prepared for such an application. It is clear to this reviewer that the authors of this report were following direction to prepare a technical support document for permit writers, and similar agency and private persons trained in the subject matter.

To make this document appropriate for the general public would take a substantial effort and more than a short period of time. In order to make this document a public document, the consultants would have to complete the following:

- Remove all acronyms
- Change all possible technical terms to non-technical phrasing
- Add definitions as footnotes and text boxes for every technical term
- Provide numerous references and background documents
- Expand the explanations of every term related to the WQS
- Add explanation and documentation of the WQS development process

It is not clear that a single document could or should accomplish the dual objectives of explaining to the public and informing technical staff.

Angela Preimesberger

The Windward Environmental report, *Development of the Human Health Water Quality Criteria for the State of Idaho [Draft]*, dated October 6, 2015 provides a strong technical document for evaluating data relevant to development of water quality criteria (WQC) to protect human health. For a technical report, the content and presentation of information, tables, figures, and appendices are well organized.

The report does not provide sufficient background or explanatory information to be easily usable by the general public. The report focuses on WQC analyses related to the probabilistic calculations and quality control and assurance tests using a Monte Carlo model for three

parameter values: body weight and drinking water and fish consumption intake rates. There are only brief discussions of the definition and purpose of using probabilistic parameters.

The Windward Environmental report could be improved for use by a general audience by including more background on the value and application of the Monte Carlo model. The report should better relay how the use of probabilistic parameter values improves the calculated WQC. The report should also include the WQC calculated using all deterministic parameter values to allow for a comparison of the values calculated using each approach. A quick comparison suggest that the probabilistic WQC are generally more stringent than those that would be calculated using all deterministic parameter values; and while this fits a goal of the Clean Water Act, there is less transparency in the actual exposure parameters values reflected in the final WQC using the probabilistic parameter values. This is most problematic in the application of an average drinking water intake rate for the Nez Perce tribal population WQC, which isn't the standard practice for this parameter value.

Alan Stern

For the most part, the text is clearly written, as far as it goes. However, given that the intended audience includes those without risk assessment expertise, such as state regulators and the general public, I think that the document takes too much for granted in terms of the understanding of intent and rationale for the document, the nature of the methodology applied (particularly MC) and the nature of the risk-based criteria employed. I recommend that the following sections be added to the document:

1. A description of the nature and intent of the WQC. This should include the relationship between the exposure to contaminants in the water per se and exposure to the contaminants in fish. As mentioned in my General Impressions, the rationale for including non-Idaho fish should be included in this section.
2. A brief description of the nature of risk-based criteria-setting for non-carcinogens and carcinogens, or at least a link to a more detailed description elsewhere.
3. A description of MC and the advantages of its use. Without such an explanation, the rationale for and conclusions from this methodology will likely be opaque to the great majority of readers.

Similarly, the figures showing the modeled distributions, while useful to a practitioner of MC, are likely to be entirely unclear to others. For example, the understanding of “cumulative frequency” on the y-axis requires some understanding of statistics and is not intuitive. The text should provide an explanation of what cumulative frequency means.

Charge Question 2

Please comment on the appropriateness and application of the methodology for deriving human health water quality criteria based on fish intake only and fish and water intakes?

Peter deFur

The methods for calculating two criteria based on fish consumption only or fish consumption plus water intake is perfectly logical, and not at all without precedent. Such calculations have been conducted before. And the fact is that there are certainly more than a few people who would fall into one and not the other category.

Angela Preimesberger

The scope of the Windward Environmental report is not clearly described, but is primarily based on data analyses to support Idaho's development of human health-based WQC. The WQC have to address EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)*. This is EPA Office of Water's most recent comprehensive guidance to states and tribes to develop human health-based water quality criteria or standards. The EPA also recently published 94 updated National Ambient Water Quality Criteria (AWQC) primarily based on the 2000 guidance that are also referenced in the report. An important issue relates to the development of fish consumption rates; EPA has clarified and changed their technical approach to developing these parameter values since the 2000 guidance (for more information, see USEPA 2013 and 2014b). These documents are important as EPA has to approve adopted WQC. The EPA guidance is developed to meet the requirements of the Clean Water Act, but has flexibility in regards to use of local or state data in place of national defaults and generally any other scientifically defensible information that may differ from EPA guidance, yet still ensure WQC protect designated beneficial uses.

The methods used to develop human health-based WQC in the Windward Environmental report include aspects that follow the EPA guidance and some developed based on other scientifically defensible data. The methods primarily follow the guidance and AWQC for the toxicological values, relative source contribution (RSC) factors, and bioaccumulation or bioconcentration factors (BAF/BCFs). The use of the EPA data for these parameter values should sufficiently meet EPA requirements. For the exposure parameters of body weight and drinking water and fish consumption intake rates Idaho primarily used survey data collected on State populations (general population of Idaho, Idaho anglers, and tribal populations) instead of national defaults. The use of state data is preferred by EPA. The efforts by Idaho Department of Environmental Quality (IDEQ), EPA, and Nez Perce, Shoshone-Bannock, Kootenai, and Coeur d' Alene Tribes are commendable in undertaking critical surveys, interviews, and historical research to examine fish consumption patterns and rates! Current and reliable fish consumption information on local and subsistence freshwater fishing populations for use in water quality regulations is very limited.

The development of WQC by IDEQ can consider scientifically defensible methods that differ from EPA guidance. In this case the application of probabilistic exposure parameter values using a Monte Carlo model to develop WQC is different. The Windward Environmental report

provides the scientific basis for using this method. The reason for developing WQC using probabilistic parameter values for body weight and drinking water and fish consumption intake rates is described as “to better characterize the range of potential risks to the exposed population.” The report does offer many tables of data to compare the WQC for two populations at two different “percentiles” of exposure that provides more comprehensive information for setting protective WQC than EPA’s method with all deterministic parameters. Making an estimate of WQC if all deterministic parameters values are used for some pollutants suggests that the WQC calculated using this approach are often more stringent than if all deterministic parameters are used. This is another benefit of using probabilistic rather than deterministic parameters values. The quality assurance and control measures described in Sections 2.2 are sound and valid.

Use of probabilistic parameter values is a scientifically defensible approach in risk assessment (USEPA 2014a); however, the report discussion and analyses should have been broadened to support the development of the most defensible WQC. Mainly, the very little discussion on the rationale for use of probabilistic parameter values results in a lack of transparency in the final exposure values actually used in the WQC. The reason why the WQC for water plus fish for the Nez Perce tribal population were less stringent than the general population isn’t clear until reading the discussion in Section 3.3.2, where it became apparent that not only was their average adjusted fish consumption rate used, but also an average drinking water intake rate. This didn’t match the discussions of deterministic drinking water intake rates that stated the 90th percentile is used for all populations. In addition, the tables of comparison values in Appendix B should be supplemented with WQC calculations using all deterministic parameter values to make a comparison easier and provide more transparency in the outcome.

The IDEQ set protection level goals for noncancer and cancer risk: hazard index of 1 and excess cancer risk of 1×10^{-6} , respectively; these protection level goals reflect EPA guidance and standard risk assessment practice. The EPA guidance also states that WQC should be developed to protect the majority of the general populations to also ensure adequate protection for special populations, such as high-end consumers of fish and water and people with greater susceptibilities to adverse health effects. In regards to the exposure parameter values evaluated by Windward Environmental, their analyses should be expanded to include the full breadth of Idaho survey data and associated risk estimates as described in Section 3.3 (particularly Table 3-3 and Appendix B). Notably missing in the analyses of upper-percentile survey data on two freshwater fishing populations (Idaho anglers and Shoshone-Bannock Tribe) is a similar analysis of the Nez Perce Tribe survey results. While this population is considered in the development of WQC, their drinking water and fish consumption rates are only used around the average values. A comparison of their risk estimates should also include the upper-percentiles (up to 95th percentiles) for this population.

Idaho DEQ has other options for improving WQC. Idaho could consider more recent and defensible risk assessment guidance available from EPA published after the EPA’s Office of Water 2000 guidance. The Minnesota Pollution Control Agency recently revised the methods used to develop human health-based water quality standards (Minn. R. chs. 7050 and 7052). An important foundation for our revisions was using more recent EPA risk assessment guidance and reports, with additional information available from the methods and parameter values Minnesota Department of Health used to develop Health Risk Limits for drinking water protection (Minn. R. ch. 4717). Most notably, our revisions included use of EPA guidance to improve protection to

infants and children by addressing life-stage differences in toxicity and exposure (for more information, see USEPA 2003; 2005a,b,c; 2006; and 2011). The evaluation of all life stages is particularly important for determining appropriate exposure rates, because they should match a pollutant's toxicological profile and not always be based on adult data only.

Also relevant to the WQC protection of surface water users is the issue of recreational exposure to toxic pollutants. EPA guidance has not specifically included this beneficial use in their national AWQC for toxic pollutants. However, EPA did include at least an incidental ingestion intake rate in their Great Lakes Initiative Criteria (USEPA 1995). Minnesota includes a specific evaluation of recreational exposure into their water quality standards, including decisions on RSC. Most recently an incidental intake rate based on children ages one to nine (minimum chronic exposure duration) was adopted (Minn. R. ch. 7050). For most toxic pollutants recreational exposure will not be significant, but for some classes, such as polycyclic aromatic hydrocarbons (PAHs) and cyanobacterial toxins, consideration of this exposure scenario is warranted.

Alan Stern

Presumably, the goal in setting human health water quality criteria on the basis of both fish-only and fish plus water intake is that contaminants in the surface water may bio-accumulate in the fish and therefore, exposure to these contaminants can occur either through fish consumption or through direct consumption of the water. However, this is not clearly stated anywhere in the document.

The template equations in Table 2-2 (to which probabilistic inputs are applied) appear to be standard and straightforward.

The use of BAFs in the calculation of the fish portion of the criteria is not clearly described. There is mention of trophic level BAFs and their weighting, but it is not clear how these apply to the individual species that are consumed or how the weighting factors were applied. The document also states (section 2.3.5) that, "Idaho-specific weighting factors were developed based on FCRs for the Nez Perce Tribe." As written, this indicates that the trophic level weighting factors are dependent on the fish consumption rate (FCR). This does not make sense to me since it appears that the BAF weighting is used to adjust the extent of bioaccumulation for the increased accumulation (of bioaccumulative contaminants) upward through trophic levels. This process should not be affected by the rate at which any given species is consumed.

Charge Question 3

Do you agree with the populations considered in the development of WQC – general Idaho population and higher-level consumer populations (i.e., angler-only population in Idaho, the Nez Perce tribe, and the Shoshone-Bannock tribes)?

Peter deFur

While I agree that the different groups have their own fish consumption patterns that can be quantified for the purposes of determining toxicity based WQC, the groups do not receive the

same level of protection using the methods in the document, as instructed by IDEQ. The document explains that IDEQ gave directions to determine risks differently: based on the upper 95 % consumption rate for the general population, v based on the mean for the Nez Perce.

There is no explanation and no justification.

All fish consumption rates used in the determination of the WQS need to be based on the upper 95% FCR.

Angela Preimesberger

One of the strengths of WQC being proposed by the State of Idaho is their use of new survey data collected on Idaho drinking water and fish consumers. The new survey results found similar drinking water intake rates as national surveys; this is anticipated from past knowledge. Fish consumption survey data available on freshwater, caught fish consumers in the State, including subsistence populations is extremely valuable for setting protective WQC. EPA guidance also has a hierarchy for exposure parameter data with local, state, or regional data being preferred over national defaults.

With the breadth of fish consumption survey data available, the Windward Environmental report should have developed additional evaluations and tables of information on fish consumption rate percentiles and associated risk estimates. Section 3.2 described the risks for the Idaho anglers and Shoshone-Bannock tribal population up to their 95th percentile fish consumption rate. The highest 95th percentile rate was 24.1 g/day (adjusted rate). Noticeably absent though was such an analysis up to the 95th percentile fish consumption rate for the Nez Perce tribal population of 56.6 g/day (adjusted rate). Including the analysis of hazard quotient ratio and excess cancer risk at the proposed WQC would be informative to the public and decision-makers as to the protectiveness of the criteria using the full complement of survey results.

As previously stated, EPA guidance on recommended fish consumption rates and population-specific protection goals has been clarified and also changed since the 2000 guidance. In 2013 EPA published a “frequently asked questions” document to supplement the information on development of fish consumption rates from the 2000 guidance (USEPA 2013). This document helped clarify expectations on this important exposure parameter. Also relevant was EPA’s 2014 publication of updated national fish consumption rates based on a new method (National Cancer Institute or NCI) and survey data (NHANES 2003-2010)(USEPA 2014b). The approaches described in the Windward Environmental report on the proposed fish consumption rates have scientific merits based on their use of new survey data and NCI method. Full survey details are not available in the report to provide input on the actual rates and percentiles to use in development of WQC. IDEQ should be considering all EPA guidance relative to fish consumption rates as well as State and Tribal policies on environmental standards protection levels as fish consumption is a principal route of exposure for many pollutants being updated in this rulemaking (Section 3.3.2). And unlike drinking water exposure to pollutants in surface water where treatment is most often applied and regulated in finished water or at the tap based on Safe Drinking Water Act regulations, WQC are the sole regulatory environmental standards set to limit pollutants in fish.

Regarding the use of any other scientifically defensible data to improve exposure rates, additional supporting data may be available from EPA guidance (for more information, see USEPA 2011 and 2014b). For instance, applying individual survey respondent body weight with their drinking water and fish consumption intakes to develop exposure parameter values normalized by body weight provides more accurate parameter values. The population that the average body weight was taken from is not the same population consuming fish. In addition, when developing exposure rates, the toxicological profile of the pollutant has to be considered. For developmental toxicants, use of a fish consumption rate for children or women of childbearing age may be more accurate and defensible.

Alan Stern

No specific percentile of a distribution is any more representative of the underlying population than any other percentile, and the choice of any particular percentile of the output distribution of exposure is a policy decision. Having said this, the 95th percentile of exposure is a typical and reasonable choice as a reasonably conservative (i.e., protective) point for deriving WQC intended for the protection of the general population. However, it is unclear to me why the mean value of the exposure distribution was selected as the basis for deriving WQC for the high-level consuming population (i.e., the Nez Perce). While this too is a policy decision, it appears inconsistent with the choice of the 95th percentile for the general population. Why should the fact of higher level fish consumption imply derivation of a WQC from a less inclusive/protective percentile of the distribution of exposure? The authors should present a rationale for this choice.

It is generally accepted that Native Americans living in traditional communities tend to consume more self-caught fish than the general population. However, little specific information is provided about the fish consumption patterns of these tribes, and the data from the cited studies on Nez Perce fish consumption rates are presented without discussion of the methodology or reliability of those studies. Therefore, it is difficult to assess the appropriateness of using this population as to represent high-level fish consumers.

The Nez Perce are described as the angler-only population for the purpose of deriving the WQC. However, the assumption underlying the designation of water consumption (or lack of water consumption) from the same bodies of water (presumably) from which the fish are caught are nowhere stated in the document. Is the assumption really that the Nez Perce do not drink the water in question while the general population does? If so, this requires explanation.

Charge Question 4

Please comment on the appropriateness and the approach for selecting the parameter values (e.g., body weight, fish consumption rate, drinking water intake rate, BAFs/BCFs, toxicity values) used in the calculations.

Peter deFur

The parameters and variables are both appropriate and correct to use in the manner conducted in this document. The document draws heavily on EPA's most recent technical documents for the parameters and variables, including body weight, drinking water, toxicity values.

The fish consumption rates for Idaho seem to be based on unpublished or unavailable data and analysis – which may be available by now, but is really an unacceptable situation.

Angela Preimesberger

Previous comments offer support or recommendations related to these parameter values. A summary of recommendations for improvement include:

- Use of the EPA AWQC and other sources for toxicological values would meet EPA guidance. To make the currency of those values though more apparent to interested parties the report should also cite the original source and year of the values. For example: benzene cancer slope factor is from EPA 2015 updated criteria (based on IRIS 2000), nickel reference dose is from EPA 2002 NRWQC HH calculation matrix(based on IRIS 1996), and benzo-a-pyrene cancer slope factor is from EPA 2015 updated criteria (based on IRIS 1991). Some EPA AWQC are based on dated toxicological values that for pollutants of primary concern in Idaho's water resources should be made a priority in future WQC rulemakings to develop updated toxicological values.
- Exposure parameters for drinking water and fish consumption intake rates should all be body weight normalized. Individual survey responses should be used to pair body weight with each respondent's drinking water and fish consumption rates; use of the 80 kg default does not specifically match the fish populations surveyed or recognize when exposure rates are needed for specific subpopulations (e.g., women of childbearing age when addressing a pollutant that has *in utero* developmental toxicity).
- When setting percentiles for exposure parameters, EPA has used an upper percentile of 90th percent for drinking water intake. That rate should be used when evaluating WQC for any population. The use of an average rate for this exposure parameter is not standards risk assessment practice.
- Add to the Windward report analyses of the different WQC based on using all deterministic values and of the Nez Perce tribal population fish consumption rates up to the 95th percentile.
- Consider evaluating WQC for developmental toxicants using body weight normalized fish consumption rates for women of childbearing age (typically ages 15 to 44, but in this case Idaho survey data may only be available for ages 18 and older) for each survey population. Determine if those rates are greater and should be used in place of the combined adult male and female and age group rates for those pollutants.

Alan Stern

The general approach for selecting the values for these parameters is sound. It is appropriate to use well described and empirically supported distributions in the MC approach describing exposure in the population. However, I have identified specific issues with the generation of some of the input distributions. These follow:

Body Weight

The distribution in Fig. 2-1 shows the smoothed (or perhaps idealized – based only on a mean and SD) distribution. In order to evaluate how well the data fit a given parametric (e.g., lognormal) distribution, the selected function should be shown against empirical data.

In Table 2-7, it is stated that the body weight distribution for the Nez Perce is the same as for the general population. This is generally consistent with the data presented in Table 2-4, which gives the body weights by percentile that are applied from the USEPA Exposure Factors Handbook (EFH). However, it isn't clear (and isn't further clarified) which data from the EFH are being used to support this assertion. Presumably, the EFH does not give Nez Perce-specific data. This assumption requires further justification and discussion.

Drinking Water Intake Rate

It is not clear why non-consumers are included since they are not exposed, but their inclusion would, nonetheless, result in a lower estimate of intake among consumers.

Fish Consumption Rate

The term, “angler-only population” is not self-explanatory and is not defined. Presumably, it means the portion of general population that consists of anglers, but not consumers of the same water from which they fish. However, as this analysis deals only with the Idaho population consuming fish, it does not appear that the non-angler population (i.e., the rest of the general population) should be included unless there is a commercial fishing industry in Idaho. In that case, this should be made explicit and its relevance discussed.

Section 2.3.3.2 - “...each of the tenth-of-a-percentile increments had an equal likelihood of being selected.” The methodology for specifying the distribution seems sound. However, for each quantile of the distribution to have an equal probability of selection, the distribution would have to be flat (i.e., a constant value distribution). Based on Fig. 2-3, this is not the case. Rather, it appears that what is intended here is that the distribution is divided into equal probability sections and each section is sampled an equal number of times. In that way, each quantile (including low-probability quantiles) has a probability of being sampled equal to its ordinate (y-axis) value even if it is in a low probability tail of the distribution. In @Risk, this is accomplished through specifying Latin Hypercube sampling.

Section 2.3.3.3 - By specifying the form of the distribution empirically through specifying the value at individual selected percentiles in @Risk, the unknown values at the upper end of the distribution are implicitly adjusted so as to maintain the known mean value of the distribution. This would preclude the necessity of the procedure described here.

Correlation of Fish Consumption Rate with Body Weight

The conclusion of no correlation between FCR and BW appears to be consistent with the data presented in Fig. 2-3. However, the p-value for the correlation should be provided.

RSC

The RSC of 0.2 that was applied for most of the chemicals is a conservative default. It is appropriate to diverge from this value (generally, as per EPA guidance, up to an RSC of 0.8) when there is *specific information* indicating that non-water sources account for less than 80% of the total exposure. In section 2.3.4, it is stated that an RSC of 0.4 was applied to antimony, an RSC of 0.5 was applied to gamma-HCH, and an RSC of 0.8 was applied to several chlorinated pesticides. Presumably, the choice of these non-default values is based on an analysis of sources of exposure (ideally, specific to Idaho). However, in order for readers to evaluate the validity of these choices, the report should at least provide a summary of the analyses in question with appropriate citations.

Section 3.3.1 presents a sensitivity analysis of alternative RSC values. The result of this analysis is that when values of 0.4 or 0.8 are applied instead of the default RSC of 0.2, the resulting WQC increases proportionally. It is not clear what is gained by this sensitivity analysis for two reasons. First, it is clear from the equations in Table 2-2, that this would, in fact, be the case. Second, the choice of non-default RSC value (as discussed above) should be based on chemical and location-specific information. The absence of such information should preclude altering the default value. Thus, it is not only unclear what the sensitivity analysis is intended to show, but also why one would undertake such an analysis.

Toxicity Values

Second bullet - The rationale for using the PPRTV rather than the RfD should be presented. Additionally a citation for each should be provided.

Charge Question 5

Are the results of the analysis scientifically sound and “valid” for the State of Idaho’s use in their proposed human health water quality criteria?

Peter deFur

Yes, the scientific analysis using a probabilistic assessment to yield the WQC is a valid approach that has resulted in Criteria that seem to be as protective as other possible methods. The comparison at the end indicates the outcomes are equivalent.

The points that do not have a scientific basis are the two that are raised in the opening comment section: a number of metals such as lead, copper, chromium, are not on the list of chemicals, despite the toxicity of these chemicals and the fact that there is a fish consumption advisory for lead poisoning in the region that includes the Spokane River flowing out of Idaho. The second point is that the analysis of fish consumption rates and the use of values is different for the general population of Idaho anglers and for Nez Perce tribal members. There is no scientific basis for the different statistical treatments. All angler fish consumers need to be considered in the same manner using the upper 95% consumption rate.

Angela Preimesberger

The analyses by Windward Environmental includes many aspects that follow EPA guidance for development of human health based WQC (or standards). However, there are opportunities to improve upon the limited analyses of fish consumption survey data and incorporate newer EPA risk assessment guidance. More details are provided in the previous comments and table of Specific Observations below.

Alan Stern

Other than the issues I have noted here, it appears that the results rely on scientifically sound approaches. However, it is difficult to evaluate the scientific validity of the results on their own merit. Rather, the validity of the results rests on the both the reasonableness and appropriateness of the assumptions underlying the calculations and on the validity of the calculations, themselves. Issues relating to the underlying assumptions are addressed above. I have addressed specific issues relating to the calculations in the Specific Observations section.

Charge Question 6

Do you have any other suggestions for improving the scientific quality or utility of the document?

Peter deFur

Make the changes listed above and

- (1) Include the other metals
- (2) Use a fish consumption rate for Nez Perce Tribal members of the upper 95% consumption rate.

Angela Preimesberger

As stated in EPA's 2000 guidance, WQC are based on both scientific data and policy decisions. The Windward Environmental report is based on a scope of work from the State of Idaho. The report provides sound scientific evaluations for some aspects of the parameter values used to develop WQC. Discussions with IDEQ may result in a request for additional analyses based on peer review and public comments to improve on the available data analyses for finalizing the methods for WQC.

Alan Stern

These are addressed in my various other responses.

VI. SPECIFIC OBSERVATIONS

Specific Observations on “Development of Human Health Water Quality Criteria for the State of Idaho”		
Page	Paragraph	Comment or Question
1	2	<p>In the Introduction the use of probabilistic input parameters for fish consumption rate (FCR), drinking water intake (DI), and body weight (BW) was described as “to better characterize the range of potential risks to the exposed population.”</p> <p>In EPA guidance on probabilistic risk assessment (EPA 2014a) the best use of these approaches for evaluating risk is in describing uncertainty and variability. While the Windward Environmental analyses of WQC using probabilistic parameter values provided some information on differences between populations, it was not fully utilized to assist in clearly describing variability and resulting risk differences. The evaluation should have included a full analysis of the upper percentiles of FCR for the Nez Perce Tribe and WQC using all deterministic parameter values, including use of at least the 90th percentile DI for all populations (2.4 L/d).</p>
1	First bullet	The general population is defined relative to fish consumption. What about drinking water intake?
1	Third bullet	The term “angler-only population” is unclear. What specifically does this mean? Does this mean individuals that fish locally, but don’t drink the water from the water bodies in which they fish, or does it mean individuals who travel to waterbodies distant from their drinking water sources? If the former, how is it known that these anglers are not water consumers? If the latter, why would a daily fish intake rate be appropriate?
2	Section 2.1	<p>Section 2.1 states: “Acceptable risk thresholds for the development of WQC are presented in Table 2-1. For the general Idaho population, the intent was to protect an upper percentile of the population (i.e., the 95th percentile of exposure) (Idaho DEQ 2015a). For the higher-level consumer populations (represented by the Nez Perce tribe), the intent was to ensure that the WQC would be protective of the average individual.”</p> <p>Why is there a difference between the general population and the high consuming individuals represented by the Nez Perce Tribe? The report simply states that the two segments of the target population in Idaho will be protected differently with no indication as to why the difference. Either the same level of protection needs to be provided to all the human populations or the document really need to explain why a lower level of protection is afforded one part of the public.</p>
4		In Table 2-2, the acronym WQC should have been included in the

Specific Observations on “Development of Human Health Water Quality Criteria for the State of Idaho”		
Page	Paragraph	Comment or Question
		list of acronyms and provided with units. The equations as written result in the WQC being expressed in mg/L; however in Table 3-1 (page 18) the WQC are presented in µg/L. The equations should have included a conversion factor if results were going to be presented in µg/L.
5	1	Presumably, the iterative runs involved changing only the input water concentration. However, this is not stated.
5	2	<p>“...(plus or minus one digit)...” I think the intent here is “one significant figure.”</p> <p>“The results of these simulations were evaluated using two metrics to determine whether the model runs were stable.”</p> <p>These are not really separate criteria. Since @Risk software was used, the convergence function could have been used. This function runs the simulations until the change per iteration does not change by greater than a specific amount (e.g., 5%).</p>
6	3	<p>“Following this process...” As per the previous comment, if the convergence function were used it would not be necessary to select a standard number of iterations based on a sample of COIs. However, since it does not appear that exposure parameters should have changed from one COI to another (except for the BAFs and toxicity values, neither of which were described probabilistically, and for non-cancer versus cancer based WQCs), it is not clear what was gained by doing the estimate of the necessary number of model samplings based on a selection of COIs.</p>
10	Table 2.6	The explanations in the footnotes are not sufficient to justify the choice of values. In addition, using or relying on a report that is not yet published is a major challenge to this effort because the data are not available for supporting some of the values.
13		The text does not explain why the fish consumption rate for the Nez Perce does not use the upper 95% consumption estimate, but uses the mean (with adjustment given on page 10).
14-15	Last on 14, top 15	The text at the bottom of page 14 and top of page 15 needs to provide some at least brief comment on why the RSC for the selected chemicals was adjusted upward by EPA, in part to provide context for why the RSC for other chemicals remain unadjusted.
15	Sec. 2.3.5, Third bullet	How are BAFs dependent on the FCR?
16	Table 2-7	If the goal for the Nez Perce population is to protect the average individual in the population, then this is easily accomplished by using the mean point estimate value for each parameter in the equations. Doing this probabilistically provides no additional information.

Specific Observations on “Development of Human Health Water Quality Criteria for the State of Idaho”		
Page	Paragraph	Comment or Question
16	Table 2-7	In the discussion related to Table 2-7, the DI rate for the Nez Perce population is presented as being the same as that of the Idaho general population. However, in Section 3.3.2, the DI rate used in evaluating WQS for Nez Perce was 1.0 L/d. The average rate was used because of the IDEQ “average” level protection goal for this subpopulation of high-end fish consumers. In standard risk assessment methods though everyone is assumed or known to drink water and upper-percentile rates are always used. There is no EPA guidance that would recommend use of an average DI rate. The Nez Perce WQS should have been calculated using at least the 90th percentile DI rate.
18	Table 3-1	What is meant by “Selected WQC”?
Appendix A	Tab A2	More clearly present the trophic levels used with FCRs for each population in the report Section 2.3.5 and not just Appendix A.

VII. INDIVIDUAL REVIEWER COMMENTS

**Review By:
Peter L. deFur, Ph.D.**

Peer Review Comments on

“Development of Human Health Water Quality Criteria for the State of Idaho”

Peter L. deFur, Ph.D.

Environmental Stewardship Concepts, LLC

November 30, 2015

I. GENERAL IMPRESSIONS

The document on the Human Health Water Quality Criteria is clearly presented and explains most of the information for the intended audience. As with all such technical documents of this nature, the audience is not the general public, but the intended audience is not stated in the document and it would be an improvement to have a simple statement to the effect that this document is written for agency staff, consultants, etc., or whatever target group the agency indicates. Agency staff who might be new to the topic may also be unable to follow much of the document without referring to background materials, but that situation is usually acceptable to the sponsoring agency.

There is an assumption that the Monte Carlo or probabilistic approach is sufficiently well-known that further explanation is not needed. I am not sure that assumption holds up. I suggest a couple of references to EPA guidance on the topic, SETAC publications, etc. to direct a reader who is otherwise knowledgeable with other aspects of the report, but needs more on the approach.

A fact-checking effort reveals that the data taken from EPA documents and reports is accurate, as are the equations and the scientific approach.

The conclusions are sound, given the assumptions and conditions set by IDEQ.

Two items give me concern and I raise them here and elsewhere:

(1) There is no explanation or justification for the differential protection afforded the general population and the Nez Perce in terms of fish consumption; and

(2) A number of metals are not on the list, specifically lead, copper and chromium, and lead is a known problem for fish contamination in the region. The document is silent on these chemicals and likely due to factors out of the author's control.

II. RESPONSE TO CHARGE QUESTIONS

1. Please comment the clarity and organization of the report. Does it present information, including tables and figures, in a clear and usable format? If not, please provide suggestions for improving the clarity of the document, which is intended to be useful to state regulators, the scientific community, and other stakeholders, including the general public.

The report is well organized, well presented and clearly written as a technical document written for an audience of people who work in the fields of water quality permits or water quality in

general. The presentation is clear and the information well done, with two items raised above and explained again below.

As to the question of how appropriate this document might be for the general public, per the charge question, this document is not at all appropriate for the general public and was not written nor prepared for such an application. It is clear to this reviewer that the authors of this report were following direction to prepare a technical support document for permit writers, and similar agency and private persons trained in the subject matter.

To make this document appropriate for the general public would take a substantial effort and more than a short period of time. In order to make this document a public document, the consultants would have to complete the following:

- Remove all acronyms
- Change all possible technical terms to non-technical phrasing
- Add definitions as footnotes and text boxes for every technical term
- Provide numerous references and background documents
- Expand the explanations of every term related to the WQS
- Add explanation and documentation of the WQS development process

It is not clear that a single document could or should accomplish the dual objectives of explaining to the public and informing technical staff.

2. Please comment on the appropriateness and application of the methodology for deriving human health water quality criteria based on fish intake only and fish and water intakes?

The methods for calculating two criteria based on fish consumption only or fish consumption plus water intake is perfectly logical, and not at all without precedent. Such calculations have been conducted before. And the fact is that there are certainly more than a few people who would fall into one and not the other category.

3. Do you agree with the populations considered for the development of WQC – general Idaho population and higher-level consumer populations (i.e., the angler-only population in Idaho, the Nez Perce tribe, and the Shoshone-Bannock tribes)?

While I agree that the different groups have their own fish consumption patterns that can be quantified for the purposes of determining toxicity based WQC, the groups do not receive the same level of protection using the methods in the document, as instructed by IDEQ. The document explains that IDEQ gave directions to determine risks differently: based on the upper 95 % consumption rate for the general population, v based on the mean for the Nez Perce.

There is no explanation and no justification.

All fish consumption rates used in the determination of the WQS need to be based on the upper 95% FCR.

4. Please comment on the appropriateness and the approach for selecting the parameter values (e.g., body weight, fish consumption rate, drinking water intake rate, BAFS/BCFs, toxicity values) used in the calculations.

The parameters and variables are both appropriate and correct to use in the manner conducted in this document. The document draws heavily on EPA's most recent technical documents for the parameters and variables, including body weight, drinking water, toxicity values.

The fish consumption rates for Idaho seem to be based on unpublished or unavailable data and analysis – which may be available by now, but is really an unacceptable situation.

5. Are the results of the analysis scientifically sound and “valid” for the State of Idaho’s use in their proposed human health water quality criteria?

Yes, the scientific analysis using a probabilistic assessment to yield the WQC is a valid approach that has resulted in Criteria that seem to be as protective as other possible methods. The comparison at the end indicates the outcomes are equivalent.

The points that do not have a scientific basis are the two that are raised in the opening comment section: a number of metals such as lead, copper, chromium, are not on the list of chemicals, despite the toxicity of these chemicals and the fact that there is a fish consumption advisory for lead poisoning in the region that includes the Spokane River flowing out of Idaho. The second point is that the analysis of fish consumption rates and the use of values is different for the general population of Idaho anglers and for Nez Perce tribal members. There is no scientific basis for the different statistical treatments. All angler fish consumers need to be considered in the same manner using the upper 95% consumption rate.

6. Do you have any other suggestions for improving the scientific quality or utility of the document?

Make the changes listed above and

(1) Include the other metals

(2) Use a fish consumption rate for Nez Perce Tribal members of the upper 95% consumption rate.

III. SPECIFIC OBSERVATIONS

Specific Observations on “Development of Human Health Water Quality Criteria for the State of Idaho”		
Page	Paragraph	Comment or Question
2	Section 2.1	<p>Section 2.1 states: “Acceptable risk thresholds for the development of WQC are presented in Table 2-1. For the general Idaho population, the intent was to protect an upper percentile of the population (i.e., the 95th percentile of exposure) (Idaho DEQ 2015a). For the higher-level consumer populations (represented by the Nez Perce tribe), the intent was to ensure that the WQC would be protective of the average individual.”</p> <p>Why is there a difference between the general population and the high consuming individuals represented by the Nez Perce Tribe? The report simply states that the two segments of the target population in Idaho will be protected differently with no indication as to why the difference. Either the same level of protection needs to be provided to all the human populations or the document really need to explain why a lower level of protection is afforded one part of the public.</p>
10	Table 2.6	The explanations in the footnotes are not sufficient to justify the choice of values. In addition, using or relying on a report that is not yet published is a major challenge to this effort because the data are not available for supporting some of the values.
13		The text does not explain why the fish consumption rate for the Nez Perce does not use the upper 95% consumption estimate, but uses the mean (with adjustment given on page 10).
14-15	Last on 14, top 15	The text at the bottom of page 14 and top of page 15 needs to provide some at least brief comment on why the RSC for the selected chemicals was adjusted upward by EPA, in part to provide context for why the RSC for other chemicals remain unadjusted.

Review By:
Angela L. H. Preimesberger, M.S.

**Peer Review Comments on
“Development of Human Health Water Quality Criteria for the State of Idaho”**

Angela L. H. Preimesberger, M.S.
Minnesota Pollution Control Agency
November 25, 2015

I. GENERAL IMPRESSIONS

The Windward Environmental report, *Development of the Human Health Water Quality Criteria for the State of Idaho [Draft]*, dated October 6, 2015 is formatted and written in a typical technical report style. This report presents information to a well-informed or technical audience familiar with methods for risk assessment and state and U. S. Environmental Protection Agency (EPA) human health-based water quality criteria and standards. As a technical report it provides clear table of contents, tables of relevant data, and review of findings.

The report is not written in plain language and lacks sufficient background discussions to make it easily understood or usable by the general public. The focus of the report is on probabilistic and deterministic development of input parameter values to the water quality criteria (WQC) equations; however, only very limited information is provided that explains the differences and benefits of using each approach to determine parameter values.

The scope of the evaluation requested by the State of Idaho from Windward Environmental for development of WQC is not clear. The report referenced a 2015 work plan with the State of Idaho, but didn't elaborate on the scope of that work plan. Therefore, the report did not explain if the consultant's role is to just run the Monte Carlo analyses for developing WQC using the three probabilistically calculated parameter values or to more fully provide the State with additional options to improve how the WQC are developed. Based on the content of the report, the scope looks to center primarily on running the probabilistic calculations and quality control and assurance tests on the Monte Carlo model used. The information provided though could be expanded to reflect the breadth of valuable survey data available in order to better assist the State of Idaho in determining the most defensible parameter values.

II. RESPONSE TO CHARGE QUESTIONS

1. Please comment the clarity and organization of the report. Does it present information, including tables and figures, in a clear and usable format? If not, please provide suggestions for improving the clarity of the document, which is intended to be useful to state regulators, the scientific community, and other stakeholders, including the general public.

The Windward Environmental report, *Development of the Human Health Water Quality Criteria for the State of Idaho [Draft]*, dated October 6, 2015 provides a strong technical document for evaluating data relevant to development of water quality criteria (WQC) to protect human health. For a technical report, the content and presentation of information, tables, figures, and appendices are well organized.

The report does not provide sufficient background or explanatory information to be easily usable by the general public. The report focuses on WQC analyses related to the probabilistic calculations and quality control and assurance tests using a Monte Carlo model for three parameter values: body weight and drinking water and fish consumption intake rates. There are only brief discussions of the definition and purpose of using probabilistic parameters.

The Windward Environmental report could be improved for use by a general audience by including more background on the value and application of the Monte Carlo model. The report should better relay how the use of probabilistic parameter values improves the calculated WQC. The report should also include the WQC calculated using all deterministic parameter values to allow for a comparison of the values calculated using each approach. A quick comparison suggest that the probabilistic WQC are generally more stringent than those that would be calculated using all deterministic parameter values; and while this fits a goal of the Clean Water Act, there is less transparency in the actual exposure parameters values reflected in the final WQC using the probabilistic parameter values. This is most problematic in the application of an average drinking water intake rate for the Nez Perce tribal population WQC, which isn't the standard practice for this parameter value.

2. Please comment on the appropriateness and application of the methodology for deriving human health water quality criteria based on fish intake only and fish and water intakes?

The scope of the Windward Environmental report is not clearly described, but is primarily based on data analyses to support Idaho's development of human health-based WQC. The WQC have to address EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)*. This is EPA Office of Water's most recent comprehensive guidance to states and tribes to develop human health-based water quality criteria or standards. The EPA also recently published 94 updated National Ambient Water Quality Criteria (AWQC) primarily based on the 2000 guidance that are also referenced in the report. An important issue relates to the development of fish consumption rates; EPA has clarified and changed their technical approach to developing these parameter values since the 2000 guidance (for more information, see USEPA 2013 and 2014b). These documents are important as EPA has to approve adopted WQC. The EPA guidance is developed to meet the requirements of the Clean Water Act, but has flexibility in regards to use of local or state data in place of national defaults and generally any other scientifically defensible information that may differ from EPA guidance, yet still ensure WQC protect designated beneficial uses.

The methods used to develop human health-based WQC in the Windward Environmental report include aspects that follow the EPA guidance and some developed based on other scientifically defensible data. The methods primarily follow the guidance and AWQC for the toxicological values, relative source contribution (RSC) factors, and bioaccumulation or bioconcentration factors (BAF/BCFs). The use of the EPA data for these parameter values should sufficiently meet EPA requirements. For the exposure parameters of body weight and drinking water and fish consumption intake rates Idaho primarily used survey data collected on State populations (general population of Idaho, Idaho anglers, and tribal populations) instead of national defaults. The use of state data is preferred by EPA. The efforts by Idaho Department of Environmental Quality (IDEQ), EPA, and Nez Perce, Shoshone-Bannock, Kootenai, and Coeur d' Alene Tribes are commendable in undertaking critical surveys, interviews, and historical research to examine fish consumption patterns and rates! Current and reliable fish consumption information on local

and subsistence freshwater fishing populations for use in water quality regulations is very limited.

The development of WQC by IDEQ can consider scientifically defensible methods that differ from EPA guidance. In this case the application of probabilistic exposure parameter values using a Monte Carlo model to develop WQC is different. The Windward Environmental report provides the scientific basis for using this method. The reason for developing WQC using probabilistic parameter values for body weight and drinking water and fish consumption intake rates is described as “to better characterize the range of potential risks to the exposed population.” The report does offer many tables of data to compare the WQC for two populations at two different “percentiles” of exposure that provides more comprehensive information for setting protective WQC than EPA’s method with all deterministic parameters. Making an estimate of WQC if all deterministic parameters values are used for some pollutants suggests that the WQC calculated using this approach are often more stringent than if all deterministic parameters are used. This is another benefit of using probabilistic rather than deterministic parameters values. The quality assurance and control measures described in Sections 2.2 are sound and valid.

Use of probabilistic parameter values is a scientifically defensible approach in risk assessment (USEPA 2014a); however, the report discussion and analyses should have been broadened to support the development of the most defensible WQC. Mainly, the very little discussion on the rationale for use of probabilistic parameter values results in a lack of transparency in the final exposure values actually used in the WQC. The reason why the WQC for water plus fish for the Nez Perce tribal population were less stringent than the general population isn’t clear until reading the discussion in Section 3.3.2, where it became apparent that not only was their average adjusted fish consumption rate used, but also an average drinking water intake rate. This didn’t match the discussions of deterministic drinking water intake rates that stated the 90th percentile is used for all populations. In addition, the tables of comparison values in Appendix B should be supplemented with WQC calculations using all deterministic parameter values to make a comparison easier and provide more transparency in the outcome.

The IDEQ set protection level goals for noncancer and cancer risk: hazard index of 1 and excess cancer risk of 1×10^{-6} , respectively; these protection level goals reflect EPA guidance and standard risk assessment practice. The EPA guidance also states that WQC should be developed to protect the majority of the general populations to also ensure adequate protection for special populations, such as high-end consumers of fish and water and people with greater susceptibilities to adverse health effects. In regards to the exposure parameter values evaluated by Windward Environmental, their analyses should be expanded to include the full breadth of Idaho survey data and associated risk estimates as described in Section 3.3 (particularly Table 3-3 and Appendix B). Notably missing in the analyses of upper-percentile survey data on two freshwater fishing populations (Idaho anglers and Shoshone-Bannock Tribe) is a similar analysis of the Nez Perce Tribe survey results. While this population is considered in the development of WQC, their drinking water and fish consumption rates are only used around the average values. A comparison of their risk estimates should also include the upper-percentiles (up to 95th percentiles) for this population.

Idaho DEQ has other options for improving WQC. Idaho could consider more recent and defensible risk assessment guidance available from EPA published after the EPA’s Office of

Water 2000 guidance. The Minnesota Pollution Control Agency recently revised the methods used to develop human health-based water quality standards (Minn. R. chs. 7050 and 7052). An important foundation for our revisions was using more recent EPA risk assessment guidance and reports, with additional information available from the methods and parameter values Minnesota Department of Health used to develop Health Risk Limits for drinking water protection (Minn. R. ch. 4717). Most notably, our revisions included use of EPA guidance to improve protection to infants and children by addressing life-stage differences in toxicity and exposure (for more information, see USEPA 2003; 2005a,b,c; 2006; and 2011). The evaluation of all life stages is particularly important for determining appropriate exposure rates, because they should match a pollutant's toxicological profile and not always be based on adult data only.

Also relevant to the WQC protection of surface water users is the issue of recreational exposure to toxic pollutants. EPA guidance has not specifically included this beneficial use in their national AWQC for toxic pollutants. However, EPA did include at least an incidental ingestion intake rate in their Great Lakes Initiative Criteria (USEPA 1995). Minnesota includes a specific evaluation of recreational exposure into their water quality standards, including decisions on RSC. Most recently an incidental intake rate based on children ages one to nine (minimum chronic exposure duration) was adopted (Minn. R. ch. 7050). For most toxic pollutants recreational exposure will not be significant, but for some classes, such as polycyclic aromatic hydrocarbons (PAHs) and cyanobacterial toxins, consideration of this exposure scenario is warranted.

3. Do you agree with the populations considered for the development of WQC – general Idaho population and higher-level consumer populations (i.e., the angler-only population in Idaho, the Nez Perce tribe, and the Shoshone-Bannock tribes)?

One of the strengths of WQC being proposed by the State of Idaho is their use of new survey data collected on Idaho drinking water and fish consumers. The new survey results found similar drinking water intake rates as national surveys; this is anticipated from past knowledge. Fish consumption survey data available on freshwater, caught fish consumers in the State, including subsistence populations is extremely valuable for setting protective WQC. EPA guidance also has a hierarchy for exposure parameter data with local, state, or regional data being preferred over national defaults.

With the breadth of fish consumption survey data available, the Windward Environmental report should have developed additional evaluations and tables of information on fish consumption rate percentiles and associated risk estimates. Section 3.2 described the risks for the Idaho anglers and Shoshone-Bannock tribal population up to their 95th percentile fish consumption rate. The highest 95th percentile rate was 24.1 g/day (adjusted rate). Noticeably absent though was such an analysis up to the 95th percentile fish consumption rate for the Nez Perce tribal population of 56.6 g/day (adjusted rate). Including the analysis of hazard quotient ratio and excess cancer risk at the proposed WQC would be informative to the public and decision-makers as to the protectiveness of the criteria using the full complement of survey results.

As previously stated, EPA guidance on recommended fish consumption rates and population-specific protection goals has been clarified and also changed since the 2000 guidance. In 2013 EPA published a “frequently asked questions” document to supplement the information on development of fish consumption rates from the 2000 guidance (USEPA 2013). This document

helped clarify expectations on this important exposure parameter. Also relevant was EPA's 2014 publication of updated national fish consumption rates based on a new method (National Cancer Institute or NCI) and survey data (NHANES 2003-2010)(USEPA 2014b). The approaches described in the Windward Environmental report on the proposed fish consumption rates have scientific merits based on their use of new survey data and NCI method. Full survey details are not available in the report to provide input on the actual rates and percentiles to use in development of WQC. IDEQ should be considering all EPA guidance relative to fish consumption rates as well as State and Tribal policies on environmental standards protection levels as fish consumption is a principal route of exposure for many pollutants being updated in this rulemaking (Section 3.3.2). And unlike drinking water exposure to pollutants in surface water where treatment is most often applied and regulated in finished water or at the tap based on Safe Drinking Water Act regulations, WQC are the sole regulatory environmental standards set to limit pollutants in fish.

Regarding the use of any other scientifically defensible data to improve exposure rates, additional supporting data may be available from EPA guidance (for more information, see USEPA 2011 and 2014b). For instance, applying individual survey respondent body weight with their drinking water and fish consumption intakes to develop exposure parameter values normalized by body weight provides more accurate parameter values. The population that the average body weight was taken from is not the same population consuming fish. In addition, when developing exposure rates, the toxicological profile of the pollutant has to be considered. For developmental toxicants, use of a fish consumption rate for children or women of childbearing age may be more accurate and defensible.

4. Please comment on the appropriateness and the approach for selecting the parameter values (e.g., body weight, fish consumption rate, drinking water intake rate, BAFs/BCFs, toxicity values) used in the calculations.

Previous comments offer support or recommendations related to these parameter values. A summary of recommendations for improvement include:

- Use of the EPA AWQC and other sources for toxicological values would meet EPA guidance. To make the currency of those values though more apparent to interested parties the report should also cite the original source and year of the values. For example: benzene cancer slope factor is from EPA 2015 updated criteria (based on IRIS 2000), nickel reference dose is from EPA 2002 NRWQC HH calculation matrix(based on IRIS 1996), and benzo-a-pyrene cancer slope factor is from EPA 2015 updated criteria (based on IRIS 1991). Some EPA AWQC are based on dated toxicological values that for pollutants of primary concern in Idaho's water resources should be made a priority in future WQC rulemakings to develop updated toxicological values.
- Exposure parameters for drinking water and fish consumption intake rates should all be body weight normalized. Individual survey responses should be used to pair body weight with each respondent's drinking water and fish consumption rates; use of the 80 kg default does not specifically match the fish populations surveyed or recognize when exposure rates are needed for specific subpopulations (e.g., women of childbearing age when addressing a pollutant that has *in utero* developmental toxicity).
- When setting percentiles for exposure parameters, EPA has used an upper percentile of 90th percent for drinking water intake. That rate should be used when evaluating WQC

for any population. The use of an average rate for this exposure parameter is not standards risk assessment practice.

- Add to the Windward report analyses of the different WQC based on using all deterministic values and of the Nez Perce tribal population fish consumption rates up to the 95th percentile.
- Consider evaluating WQC for developmental toxicants using body weight normalized fish consumption rates for women of childbearing age (typically ages 15 to 44, but in this case Idaho survey data may only be available for ages 18 and older) for each survey population. Determine if those rates are greater and should be used in place of the combined adult male and female and age group rates for those pollutants.

5. Are the results of the analysis scientifically sound and “valid” for the State of Idaho’s use in their proposed human health water quality criteria?

The analyses by Windward Environmental includes many aspects that follow EPA guidance for development of human health based WQC (or standards). However, there are opportunities to improve upon the limited analyses of fish consumption survey data and incorporate newer EPA risk assessment guidance. More details are provided in the previous comments and table of Specific Observations below.

6. Do you have any other suggestions for improving the scientific quality or utility of the document?

As stated in EPA’s 2000 guidance, WQC are based on both scientific data and policy decisions. The Windward Environmental report is based on a scope of work from the State of Idaho. The report provides sound scientific evaluations for some aspects of the parameter values used to develop WQC. Discussions with IDEQ may result in a request for additional analyses based on peer review and public comments to improve on the available data analyses for finalizing the methods for WQC.

III. SPECIFIC OBSERVATIONS

Specific Observations on “Development of Human Health Water Quality Criteria for the State of Idaho”		
Page	Paragraph	Comment or Question
1	2	<p>In the <i>Introduction</i> the use of probabilistic input parameters for fish consumption rate (FCR), drinking water intake (DI), and body weight (BW) was described as “to better characterize the range of potential risks to the exposed population.”</p> <p>In EPA guidance on probabilistic risk assessment (EPA 2014a) the best use of these approaches for evaluating risk is in describing uncertainty and variability. While the Windward Environmental analyses of WQC using probabilistic parameter values provided some information on differences between populations, it was not fully utilized to assist in clearly describing variability and resulting risk differences. The evaluation should have included a full analysis of the upper percentiles of FCR for the Nez Perce Tribe and WQC using all deterministic parameter values, including use of at least the 90th percentile DI for all populations (2.4 L/d).</p>
4		In Table 2-2, the acronym WQC should have been included in the list of acronyms and provided with units. The equations as written result in the WQC being expressed in mg/L; however in Table 3-1 (page 18) the WQC are presented in µg/L. The equations should have included a conversion factor if results were going to be presented in µg/L.
16		In the discussion related to Table 2-7, the DI rate for the Nez Perce population is presented as being the same as that of the Idaho general population. However, in Section 3.3.2, the DI rate used in evaluating WQS for Nez Perce was 1.0 L/d. The average rate was used because of the IDEQ “average” level protection goal for this subpopulation of high-end fish consumers. In standard risk assessment methods though everyone is assumed or known to drink water and upper-percentile rates are always used. There is no EPA guidance that would recommend use of an average DI rate. The Nez Perce WQS should have been calculated using at least the 90 th percentile DI rate.
Appendix A	Tab A2	More clearly present the trophic levels used with FCRs for each population in the report Section 2.3.5 and not just Appendix A.

Supporting References:

Minnesota Rules Chapter (Minn. R. ch.) 4717. *Environmental Health*. Minnesota State Office of the Revisor of Statutes. Minnesota Department of Health. Retrieved November 25, 2015. <https://www.revisor.mn.gov/rules/?id=4717>

Minn. R. ch. 7050. *Waters of the State*. Minnesota State Office of the Revisor of Statutes. Minnesota Pollution Control Agency. Retrieved November 25, 2015. <https://www.revisor.mn.gov/rules/?id=7050>

Minn. R. ch. 7052. *Lake Superior Basin Water Standards*. Minnesota State Office of the Revisor of Statutes. Minnesota Pollution Control Agency. Retrieved November 25, 2015. <https://www.revisor.mn.gov/rules/?id=7052>

U.S. Environmental Protection Agency (USEPA). 1995. *Final Water Quality Guidance for the Great Lakes System: Final Rule*. Federal Register. Vol. 60(56): 15366-15385. http://www.access.gpo.gov/nara/cfr/waisidx_05/40cfr132_05.html

USEPA. 2000. *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)*. Office of Water. EPA /822/B-00/004. October 2000. <http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf>

USEPA. 2003. *Critical Periods in Development*. Office of Children's Health Protection . EPA 2003-2. February 2003. <http://www2.epa.gov/children>

USEPA. 2005a. *Final Guidelines for Carcinogenic Risk Assessment*. Risk Assessment Forum. EPA/630/P-03/001F. March 2005. http://www2.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf

USEPA. 2005b. *Supplemental Guidance for Assessing Cancer Susceptibility from Early-Life Exposure to Carcinogens*. Risk Assessment Forum Technical Panel. EPA/630/R-03/003F. March 2005. http://www.epa.gov/ttn/atw/childrens_supplement_final.pdf

USEPA. 2005c. *Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants*. Final. Risk Assessment Forum. EPA/630/P-03/003F. November 2005. <http://www2.epa.gov/sites/production/files/2013-09/documents/agegroups.pdf>

USEPA. 2006. *A Framework for Assessing Health Risk of Environmental Exposures to Children (Final)*. National Center for Environmental Assessment. EPA/600/R-05/093F. September 2006. <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=158363>

USEPA. 2011. *Exposure Factors Handbook: 2011 Edition*. Office of Research and Development and National Center for Environmental Assessment. EPA/600/R-090/052F. September 2011. <http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252>

USEPA. 2013. *Human Health Ambient Water Quality Criteria and Fish Consumption Rates Frequently Asked Questions*. January 18, 2013.

<http://water.epa.gov/scitech/swguidance/standards/criteria/health/methodology/upload/hhfaqs.pdf>

USEPA. 2014a. *Risk Assessment Forum White Paper: Probabilistic Risk Assessment Methods and Case Studies*. Risk Assessment Forum. EPA/100/R-09/001A. July 2014.

<http://www2.epa.gov/sites/production/files/2014-12/documents/raf-pra-white-paper-final.pdf>

USEPA. 2014b. *Estimated Fish Consumption Rates for the U.S. Population and Selected Subpopulations (NHANES 2003-2010)*. EPA/820/R/14/002. April 2014.

<http://www2.epa.gov/fish-tech/estimated-fish-consumption-rates-reports>

USEPA. 2015. *Final Updated Ambient Water Quality Criteria for the Protection of Human Health*. *Federal Register*, vol. 80 (124): 36,986-36,989. <http://www.gpo.gov/fdsys/pkg/FR-2015-06-29/html/2015-15912.htm>

**Review By:
Alan H. Stern, Dr.P.H., D.A.B.T.**

**Peer Review Comments on
“Development of Human Health Water Quality Criteria for the State of Idaho”**

Alan H. Stern, Dr.P.H., D.A.B.T.
Independent Consultant
November 19, 2015

I. GENERAL IMPRESSIONS

The authors are to be commended for applying Monte Carlo (MC) analysis to the analysis of Idaho-specific exposure. The application of MC to the estimation of exposure under circumstances of relatively complete distributional data is the appropriate use of MC in exposure assessment. However, as discussed below, there are issues of its specific use in this document. In general (and except as noted below), the document is clearly and concisely written. However, as MC is still not a widely employed or well-known concept, it might be useful to provide a brief introduction to MC if the intended audience is other than those with a specific knowledge of this methodology.

My overriding issue with this document, is that the design and intent of the WQC are not clearly stated anywhere in this document. This would seem to be essential, and I recommend that a specific section be included in the beginning of the document laying out the intent and rationale for this the WQC. In particular, since the water in question appears to be the surface water of Idaho *per se*, it is not clear how the WQC for fish consumers applies to non-angler fish consumers. If the intent is to address fish consumption in total because it is considered to be a significant source of toxicant exposure, then it is not clear why other significant sources of toxicant exposure (e.g., general diet) are not, likewise, included. If (as seems more likely) the intent is to include fish consumption because the water quality criteria for a given chemical should integrate all routes of water-derived exposure to that toxicant, then it is not clear why fish from non-Idaho waters are included.

II. RESPONSE TO CHARGE QUESTIONS

1. Please comment the clarity and organization of the report. Does it present information, including tables and figures, in a clear and usable format? If not, please provide suggestions for improving the clarity of the document, which is intended to be useful to state regulators, the scientific community, and other stakeholders, including the general public.

For the most part, the text is clearly written, as far as it goes. However, given that the intended audience includes those without risk assessment expertise, such as state regulators and the general public, I think that the document takes too much for granted in terms of the understanding of intent and rationale for the document, the nature of the methodology applied (particularly MC) and the nature of the risk-based criteria employed. I recommend that the following sections be added to the document:

1. A description of the nature and intent of the WQC. This should include the relationship between the exposure to contaminants in the water *per se* and exposure to the contaminants in fish. As mentioned in my General Impressions, the rationale for including non-Idaho fish should be included in this section.

2. A brief description of the nature of risk-based criteria-setting for non-carcinogens and carcinogens, or at least a link to a more detailed description elsewhere.
3. A description of MC and the advantages of its use. Without such an explanation, the rationale for and conclusions from this methodology will likely be opaque to the great majority of readers.

Similarly, the figures showing the modeled distributions, while useful to a practitioner of MC, are likely to be entirely unclear to others. For example, the understanding of “cumulative frequency” on the y-axis requires some understanding of statistics and is not intuitive. The text should provide an explanation of what cumulative frequency means.

2. Please comment on the appropriateness and application of the methodology for deriving human health water quality criteria based on fish intake only and fish and water intakes?

Presumably, the goal in setting human health water quality criteria on the basis of both fish-only and fish plus water intake is that contaminants in the surface water may bio-accumulate in the fish and therefore, exposure to these contaminants can occur either through fish consumption or through direct consumption of the water. However, this is not clearly stated anywhere in the document.

The template equations in Table 2-2 (to which probabilistic inputs are applied) appear to be standard and straightforward.

The use of BAFs in the calculation of the fish portion of the criteria is not clearly described. There is mention of trophic level BAFs and their weighting, but it is not clear how these apply to the individual species that are consumed or how the weighting factors were applied. The document also states (section 2.3.5) that, “Idaho-specific weighting factors were developed based on FCRs for the Nez Perce Tribe.” As written, this indicates that the trophic level weighting factors are dependent on the fish consumption rate (FCR). This does not make sense to me since it appears that the BAF weighting is used to adjust the extent of bioaccumulation for the increased accumulation (of bioaccumulative contaminants) upward through trophic levels. This process should not be affected by the rate at which any given species is consumed.

3. Do you agree with the populations considered for the development of WQC – general Idaho population and higher-level consumer populations (i.e., the angler-only population in Idaho, the Nez Perce tribe, and the Shoshone-Bannock tribes)?

No specific percentile of a distribution is any more representative of the underlying population than any other percentile, and the choice of any particular percentile of the output distribution of exposure is a policy decision. Having said this, the 95th percentile of exposure is a typical and reasonable choice as a reasonably conservative (i.e., protective) point for deriving WQC intended for the protection of the general population. However, it is unclear to me why the mean value of the exposure distribution was selected as the basis for deriving WQC for the high-level consuming population (i.e., the Nez Perce). While this too is a policy decision, it appears inconsistent with the choice of the 95th percentile for the general population. Why should the fact of higher level fish consumption imply derivation of a WQC from a less inclusive/protective percentile of the distribution of exposure? The authors should present a rationale for this choice.

It is generally accepted that Native Americans living in traditional communities tend to consume more self-caught fish than the general population. However, little specific information is provided about the fish consumption patterns of these tribes, and the data from the cited studies on Nez Perce fish consumption rates are presented without discussion of the methodology or reliability of those studies. Therefore, it is difficult to assess the appropriateness of using this population as to represent high-level fish consumers.

The Nez Perce are described as the angler-only population for the purpose of deriving the WQC. However, the assumption underlying the designation of water consumption (or lack of water consumption) from the same bodies of water (presumably) from which the fish are caught are nowhere stated in the document. Is the assumption really that the Nez Perce do not drink the water in question while the general population does? If so, this requires explanation.

4. Please comment on the appropriateness and the approach for selecting the parameter values (e.g., body weight, fish consumption rate, drinking water intake rate, BAFs/BCFs, toxicity values) used in the calculations.

The general approach for selecting the values for these parameters is sound. It is appropriate to use well described and empirically supported distributions in the MC approach describing exposure in the population. However, I have identified specific issues with the generation of some of the input distributions. These follow:

Body Weight

The distribution in Fig. 2-1 shows the smoothed (or perhaps idealized – based only on a mean and SD) distribution. In order to evaluate how well the data fit a given parametric (e.g., lognormal) distribution, the selected function should be shown against empirical data.

In Table 2-7, it is stated that the body weight distribution for the Nez Perce is the same as for the general population. This is generally consistent with the data presented in Table 2-4, which gives the body weights by percentile that are applied from the USEPA Exposure Factors Handbook (EFH). However, it isn't clear (and isn't further clarified) which data from the EFH are being used to support this assertion. Presumably, the EFH does not give Nez Perce-specific data. This assumption requires further justification and discussion.

Drinking Water Intake Rate

It is not clear why non-consumers are included since they are not exposed, but their inclusion would, nonetheless, result in a lower estimate of intake among consumers.

Fish Consumption Rate

The term, “angler-only population” is not self-explanatory and is not defined. Presumably, it means the portion of general population that consists of anglers, but not consumers of the same water from which they fish. However, as this analysis deals only with the Idaho population consuming fish, it does not appear that the non-angler population (i.e., the rest of the general population) should be included unless there is a commercial fishing industry in Idaho. In that case, this should be made explicit and its relevance discussed.

Section 2.3.3.2 - “...each of the tenth-of-a-percentile increments had an equal likelihood of being selected.” The methodology for specifying the distribution seems sound. However, for each

quantile of the distribution to have an equal probability of selection, the distribution would have to be flat (i.e., a constant value distribution). Based on Fig. 2-3, this is not the case. Rather, it appears that what is intended here is that the distribution is divided into equal probability sections and each section is sampled an equal number of times. In that way, each quantile (including low-probability quantiles) has a probability of being sampled equal to its ordinate (y-axis) value even if it is in a low probability tail of the distribution. In @Risk, this is accomplished through specifying Latin Hypercube sampling.

Section 2.3.3.3 - By specifying the form of the distribution empirically through specifying the value at individual selected percentiles in @Risk, the unknown values at the upper end of the distribution are implicitly adjusted so as to maintain the known mean value of the distribution. This would preclude the necessity of the procedure described here.

Correlation of Fish Consumption Rate with Body Weight

The conclusion of no correlation between FCR and BW appears to be consistent with the data presented in Fig. 2-3. However, the p-value for the correlation should be provided.

RSC

The RSC of 0.2 that was applied for most of the chemicals is a conservative default. It is appropriate to diverge from this value (generally, as per EPA guidance, up to an RSC of 0.8) when there is *specific information* indicating that non-water sources account for less than 80% of the total exposure. In section 2.3.4, it is stated that an RSC of 0.4 was applied to antimony, an RSC of 0.5 was applied to gamma-HCH, and an RSC of 0.8 was applied to several chlorinated pesticides. Presumably, the choice of these non-default values is based on an analysis of sources of exposure (ideally, specific to Idaho). However, in order for readers to evaluate the validity of these choices, the report should at least provide a summary of the analyses in question with appropriate citations.

Section 3.3.1 presents a sensitivity analysis of alternative RSC values. The result of this analysis is that when values of 0.4 or 0.8 are applied instead of the default RSC of 0.2, the resulting WQC increases proportionally. It is not clear what is gained by this sensitivity analysis for two reasons. First, it is clear from the equations in Table 2-2, that this would, in fact, be the case. Second, the choice of non-default RSC value (as discussed above) should be based on chemical and location-specific information. The absence of such information should preclude altering the default value. Thus, it is not only unclear what the sensitivity analysis is intended to show, but also why one would undertake such an analysis.

Toxicity Values

Second bullet - The rationale for using the PPRTV rather than the RfD should be presented. Additionally a citation for each should be provided.

5. Are the results of the analysis scientifically sound and “valid” for the State of Idaho’s use in their proposed human health water quality criteria?

Other than the issues I have noted here, it appears that the results rely on scientifically sound approaches. However, it is difficult to evaluate the scientific validity of the results on their own merit. Rather, the validity of the results rests on the both the reasonableness and appropriateness of the assumptions underlying the calculations and on the validity of the calculations,

themselves. Issues relating to the underlying assumptions are addressed above. I have addressed specific issues relating to the calculations in the Specific Observations section.

6. Do you have any other suggestions for improving the scientific quality or utility of the document?

These are addressed in my various other responses.

III. SPECIFIC OBSERVATIONS

Specific Observations on “Development of Human Health Water Quality Criteria for the State of Idaho”		
Page	Paragraph	Comment or Question
1	First bullet	The general population is defined relative to fish consumption. What about drinking water intake?
1	Third bullet	The term “angler-only population” is unclear. What specifically does this mean? Does this mean individuals that fish locally, but don’t drink the water from the water bodies in which they fish, or does it mean individuals who travel to waterbodies distant from their drinking water sources? If the former, how is it known that these anglers are not water consumers? If the latter, why would a daily fish intake rate be appropriate?
5	1	Presumably, the iterative runs involved changing only the input water concentration. However, this is not stated.
5	2	<p>“(plus or minus one digit)...” I think the intent here is “one significant figure.”</p> <p>“The results of these simulations were evaluated using two metrics to determine whether the model runs were stable.”</p> <p>These are not really separate criteria. Since @Risk software was used, the convergence function could have been used. This function runs the simulations until the change per iteration does not change by greater than a specific amount (e.g., 5%).</p>
6	3	“Following this process...” As per the previous comment, if the convergence function were used it would not be necessary to select a standard number of iterations based on a sample of COIs. However, since it does not appear that exposure parameters should have changed from one COI to another (except for the BAFs and toxicity values, neither of which were described probabilistically, and for non-cancer versus cancer based WQCs), it is not clear what was gained by doing the estimate of the necessary number of model samplings based on a selection of COIs.
15	Sec. 2.3.5, Third bullet	How are BAFs dependent on the FCR?
16	Table 2-7	If the goal for the Nez Perce population is to protect the average

Specific Observations on “Development of Human Health Water Quality Criteria for the State of Idaho”		
Page	Paragraph	Comment or Question
		individual in the population, then this is easily accomplished by using the mean point estimate value for each parameter in the equations. Doing this probabilistically provides no additional information.
18	Table 3-1	What is meant by “Selected WQC”?