

Response to Peer Review of the October 6, 2015 Draft Report:

“NCI Method Estimates of Usual Intake Distributions for Fish Consumption in Idaho”

The report *“NCI Method Estimates of Usual Intake Distributions for Fish Consumption in Idaho”* was prepared under the Idaho Department of Environmental Quality (DEQ) Contract K079 with Information Management Services, Inc., (IMS). Additional contract support for IMS was provided by the National Cancer Institute (NCI), and the analysis plan and results were produced as a Collaboration between DEQ, NCI, and IMS.

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1 Introduction

We provide a response regarding the comments and suggestions that peer reviewers provided after consideration of the October 6, 2015 draft technical report: “NCI Method Estimates of Usual Intake Distributions for Fish Consumption in Idaho.” The following peer review report, dated January 22, 2016, was prepared by Versar, Inc.: “Peer Review of NCI Method Estimates of Usual Intake Distributions for Fish Consumption in Idaho.” As described in that report, the peer reviewers were: Patricia M. Guenther, Ph.D., RD, Alanna J. Moshfegh, MS, RD, and Janet A. Tooze, Ph.D., M.P.H.

IMS and NCI received the peer review report as the following file: “Revised Peer Review Summary Report on NCI Method Report 012216.docx.” In addition, IMS and NCI received the following file from DEQ: “Westat Comments on Idaho's Fish Consumption Survey & Data Processing.pdf.” Some of the comments from Westat pertain to the October 6, 2015 draft technical report: “NCI Method Estimates of Usual Intake Distributions for Fish Consumption in Idaho.” DEQ, NCI, and IMS considered the reviewers’ comments and suggestions that are included in the following documents:

- Revised Peer Review Summary Report on NCI Method Report 012216.docx,
- Westat Comments on Idaho's Fish Consumption Survey & Data Processing.pdf.

We appreciate these comments and suggestions and provide the following responses and clarifications and have incorporated clarifications in an updated version of the technical report: “NCI Method Estimates of Usual Intake Distributions for Fish Consumption in Idaho” dated March 31, 2016.

2 Overview of Response to Peer Review Report by Versar, Inc. and Westat Comments

As determined by DEQ, the Biometry Research Group of NCI, and IMS, the scope of work for this analysis is limited to the application of the NCI method as implemented in the Mixtran and Distrib SAS macros, and the technical report documents the analysis decisions made by these collaborators and includes estimated usual intake distributions of interest to DEQ. Additional analyses are beyond the scope of this analysis.

The updated technical report includes the following clarification: “This report includes estimated usual intake distributions of interest to DEQ and produced using the NCI method as implemented in the Mixtran and Distrib macros. The analysis plan and results were produced as a collaboration between DEQ, the Biometry Research Group of NCI, and IMS. This report documents the analysis decisions made by these collaborators and includes the results of interest to DEQ. The SAS macros are available to the public and are documented by the NCI, so these technical details are not reproduced in this report. The NCI also provides a list of references and other resources that consider details of the statistical methods that are referred to as the NCI method. Detailed aspects of this statistical literature are not reproduced in this report.”

3 Response to Peer Review Report, General Impressions Section

Patricia M. Guenther: “The results are clearly presented; however, as described above (see peer review comments on “Idaho Fish Consumption Survey”), it seems possible that the recall data provided for these analyses represent a maximum of 2 days of intake data (not 7 or 8). If that is the case, the accuracy of the information in this report is highly doubtful.”

Response:

The data set and documentation that NWRG provided to DEQ, NCI, and IMS includes eight days of data for each contact period. Consideration of this analysis data set, provided by NWRG, demonstrates that the file includes participants with more than two days of nonzero recall values during the eight-day recall period. The analysis plan developed by DEQ, the Biometry Research Group of NCI, and IMS considered the available data provided by NWRG and applied the NCI method using these data. We provide additional clarification in this document and in the updated technical report.

Alanna J. Moshfegh: “The accuracy of the data analysis conducted is sound as the individuals listed are known for conducting this type of analysis. The extensive list of tables in the report and in Appendix A provide a thorough statement and transparency of the analysis.”

Janet A. Tooze: “This document was entirely focused on the data analysis of the recall surveys, and really did not provide any real discussion of the implications of the results. It would have been nice to see a little bit more discussion of the assumptions made in the analysis and the implications of the covariate adjustment used, particularly the body size, which is known to be associated with measurement error, and more specific details for each outcome (e.g., were all covariates used in all analyses?). It would have been helpful to have a discussion of using the full 8 days of recall vs. a smaller number of days, and also whether utilizing all 8 days with a sequence effect might have been preferable. In general, the method appeared to have been implemented correctly, but there are some points of clarification needed, particularly for Idaho fish.”

Response:

We agree that DEQ, the Biometry Research Group of NCI, and IMS appropriately developed and implemented an analysis plan for the application of the NCI method using the publically available NCI macros and the data provided by NWRG. The scope of work for this analysis is limited to the application of the NCI method as implemented in the Mixtran and Distrib SAS macros, and the technical report documents the analysis decisions made by these collaborators and includes estimated usual intake distributions of interest to DEQ. We have updated the technical report to provide additional clarifications and to implement suggestions made by the reviewers.

4 Response to Peer Review Report, Charge Questions Section

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.

Patricia M. Guenther: “Fish consumers’ included in these analyses consumed fish at least once in the previous 7 days. Therefore, the inferred (target) population is adults who reside in Idaho and who consume fish at least once during any given week. It is not those who consume fish at all during a year as stated in the report.”

Response:

As stated in the technical report, “The DEQ is interested in consideration of fish consumers only, as defined by positive report of fish consumption in the past 12 months at the time of questioning. The collaborators, DEQ, NCI, and IMS, decided to apply the NCI method to participants with positive report of fish consumption in the past 12 months at the time of questioning. Therefore, considering the annual FFQ variable provided by NWRG, the subset of participants with annual FFQ values greater than zero were selected for the analysis.” This quotation is in the “Selection of Participants with Annual FFQ Values Greater than Zero” subsection of the report, and this subsection appears in the Methods section of the report. Therefore, we think that this analysis decision is clearly documented in the report.

Patricia M. Guenther: “The tables and graphs are clear, except for the graphs that include Non-Idaho Fish and Market Fish. The organization of the report is good, but too much of the information is repeated unnecessarily. Important information should be in both the summary and the body of the report, but nothing else needs to be stated more than once.”

Alanna J. Moshfeqh: “Specific comments on the organization of the report and the numerous places where text is duplicated are detailed below.”

Response:

We appreciate these comments regarding the draft report. We have implemented these editorial suggestions and have incorporated additional clarifications and updates to the report.

Alanna J. Moshfeqh: “The data presented in the tables are clear and the format is good.”

Janet A. Tooze: “I think the report is presented in a logical manner, and there are certainly a lot of tables and figures. The report itself is quite brief and of course could not stand on its own without the other report. It would actually be most useful if the two reports could be integrated and an overall

summary could be drafted. There is a lot of analysis presented in this report with very little interpretation.”

Response:

We appreciate these comments regarding the tables and the organization of the report. As determined by DEQ, the Biometry Research Group of NCI, and IMS, the scope of work for this analysis is limited to the application of the NCI method as implemented in the Mixtran and Distrib SAS macros, and the technical report documents the analysis decisions made by these collaborators and includes estimated usual intake distributions of interest to DEQ. The updated report includes the following clarification: “This report includes estimated usual intake distributions of interest to DEQ and produced using the NCI method as implemented in the Mixtran and Distrib macros. The analysis plan and results were produced as a collaboration between DEQ, the Biometry Research Group of NCI, and IMS. This report documents the analysis decisions made by these collaborators and includes the results of interest to DEQ.”

Charge Question 2

Please comment on the appropriateness of the application of the NCI technique to the fish consumption survey data available from the NWRG survey, based on short-term dietary recall with a reference period of 8 days, to develop usual intake distributions.

Patricia M. Guenther: “It does not appear that the NCI method was appropriately applied. The approach taken seems to assume that 8-day recall includes *all* the fish that was consumed during the reference period, but that may not be the case. It appears that the data available include only the first day, which may or may not include fish, and only one other day, which does include fish. The second day was not chosen at random, but rather with certainty because it included fish. The survey did not determine on how many days fish was consumed during the reference period. This seems to undermine the sampling theory on which the NCI method relies. If somehow all of this does not matter, then why it does not matter should be explained. In any case, the amount reported for 8 days is actually only for a maximum of 2 days, so it cannot simply be divided by 8 to get a 1-day amount.”

Response:

The survey data, that NWRG provided, includes recall information from an eight-day recall period. For a subset of the sampled participants, recall information is also available from a second eight-day recall period. The data set and documentation that NWRG provided to DEQ, NCI, and IMS includes eight days of data for each contact. The analysis plan developed by DEQ, the Biometry Research Group of NCI, and IMS considers the available data provided by NWRG and applies the NCI method using these data.

Patricia M. Guenther: “It is misleading to say that recalling intake over a period of up to 8 days is a “short-term” recall. It is shorter than a year or 30 days, which is the reference period for many food

frequency instruments, but “short-term” recall is typically 1 day, not 8. The validity of the “8-day recall” method has not been established. It would be better to simply avoid the phrase “short-term” when describing the recall for this study. Did the authors, IDEQ, or NCI consider the possibility of estimating the usual intake distributions from just the days reported during the first contact? If not, why not?”

Alanna J. Moshfegh: “Appropriate application as the authors are well-known for conducting this type of highly specialized analysis.”

Janet A. Tooze: “In general, dietary recalls tend to exhibit less systematic error than FFQs. Fish is considered an episodically consumed food, meaning that it is not consumed every day. In addition, fish consumption data are generally positively skewed, and there may be positive correlation between the probability of consuming fish and the amount consumed, i.e., those who eat fish more frequently may consume more fish on eating occasions. The NCI Method adjusts for random error, skewed data, episodically consumed foods, and the correlation between probability of consumption and amount. It also may incorporate covariates to adjust for sequence effects, and make estimates for certain population strata. Therefore, the NCI Method is appropriate to use for fish consumption estimates for this survey. However, it is important to note that for this particular implementation of the NCI method, consumption day probability and amount were not allowed to be correlated with each other, but were assumed to be independent. The report states this was due to ‘data limitations.’ It would be helpful to give further information on these ‘limitations.’ It may be without having consumption day level data that the correlation cannot be estimated as well as with using 24-hour recalls. Furthermore, the Box-Cox parameter was estimated outside the macro also due to ‘data limitations.’ This would not be anticipated to have a large impact on the results. In addition, the ‘sequence’ effect was limited to comparing the two 8-day recalls, but there appear to be sequence effects within the 8-d recalls. It would be helpful to provide a discussion of the impact of these decisions on the results.”

Response:

We appreciate this suggestion to avoid using the phrase “short-term.” We have implemented this suggestion in the updated report. We have provided additional clarification and removed the phrase “data limitations.”

As planned by the collaborators, DEQ, NCI, and IMS, the recall data from each eight-day recall period was used as the response variable in the measurement error model (i.e. as the response variable for the NCI Mixtran macro). In the updated report, we clarified that this decision was informed by relevant recall data considerations and potential convergence issues discussed by Kipnis et al. (2009). In the updated report, we provide additional clarifications and state the following: “To avoid the convergence issues discussed by Kipnis et al. (2009), the Idaho data from each eight-day recall period was used as the response variable in the Mixtran macro, so the response variables have the following units: grams of intake per 8 days.” The updated report clarifies that these collaborative decisions were made, so the NCI method could be successfully applied using the NCI macros and the available data. Consideration of additional statistical analyses and approaches was beyond the scope of the analysis planned by the collaborators: DEQ, NCI, and IMS.

Janet A. Tooze: “It is not clear why gender was not stratified by or included as a covariate in any analyses, particularly since there appear to be gender effects, and most national dietary intake data are stratified by gender.”

Response:

In the updated report, we have clarified that gender was used as a covariate. Results were not reported separately by gender because these results were not of interest to DEQ.

Janet A. Tooze: “It is also confusing that the report states that ‘models were fit separately for the angler and non-angler strata,’ but results are presented overall. Does this mean they were also run overall, or were the two strata combined? If not, how were anglers treated in the overall analysis? Obviously they have different rates of consumption of Idaho fish from non-anglers. How were the per kg estimates calculated if body weight is included as a covariate?”

Response:

The following clarification is included in the report: “For estimation of a usual intake distribution involving both anglers and non-anglers, the Monte Carlo data sets, produced for each stratum, were combined. Combining Monte Carlo data sets from different strata and estimating the usual intake distribution as described, is an example of an established approach that has been used as part of the NCI statistical methodology, i.e. the NCI method.”

The following clarification is included in the report: “The DEQ is also interested in consideration of estimated usual intake distributions reported using the units of grams per day per kg of body weight. The collaborators, DEQ, NCI, and IMS, produced these distributions by including body weight as a covariate as described in Section 3.5 and then performing the required calculation to obtain the units of interest within the Monte Carlo data sets produced by the NCI method.”

Janet A. Tooze: “The type of backtransformation used and how well data were transformed to normality should be addressed, particularly for the Idaho fish analyses.”

Response:

We have provided the following additional detail regarding version 2.1 of the Distrib macro: ‘Version 2.1 of the Distrib macro includes the following update described in the Release Notes on the NCI website: “A 9-point approximation method has replaced the Taylor linearization method in the back-transformation of the amount consumed. For most cases, the new method will produce estimates very similar to those produced using the older Taylor linearization method, but for cases where the Box-Cox parameter is small (e.g., for more extreme transformations), the 9-point approximation method is considered more accurate (Tooze et al., 2010).”’

We have provided the following additional detail: “In an initial attempt to fit the measurement error models for this analysis, the Box-Cox transformation parameter (i.e. lambda) could not be estimated by the Mixtran macro, so the collaborators, DEQ, NCI, and IMS, decided to use another approach. The BoxCox_Survey SAS macro, available from the following NCI website:

http://epi.grants.cancer.gov/diet/usualintakes/boxcox_survey_macro.v1.1.sas (accessed on March 31, 2016), was used to estimate the Box-Cox transformation parameter for the recall variables. Quantile-Quantile plots from this macro were examined to ensure that the Box-Cox transformation was appropriately selected, and the Box-Cox transformation parameter estimate from the BoxCox_Survey SAS macro was used as input for the Mixtran macro instead of estimating this parameter using the Mixtran macro. This established approach utilizes an input option of the Mixtran macro.”

Charge Question 3

Please comment on the presented usual intake means for the populations of interest, Idaho adults and Idaho adult anglers, for all fish, Idaho fish, non-Idaho fish, and market fish. Do you have any comments on the reported 50th and 95th percentile intake rates?

Patricia M. Guenther: “The report would be more useful if an explanation would be offered for why the consumption rates of non-Idaho fish and of market fish separately are of interest.”

Response:

In the updated report, we provided the following clarification regarding the scope of work for this analysis and the results of interest to DEQ: “As requested by DEQ, the estimated distributions of usual intake were produced separately using the following intake variables provided by NWRG: intake of *All Fish*, intake of *Idaho Fish*, intake of *Non-Idaho Fish*, and intake of *Market Fish*.”

Patricia M. Guenther: “The decision to analyze the data for anglers as a separate stratum seems to be based on the mistaken belief that that angler data were collected using a separate sampling frame. This decision should be re-visited. The original intent was to have a separate sampling frame, but it was not implemented as explained in the companion report.”

Response:

The following clarification is included in the report: “The collaborators, DEQ, NCI, and IMS, decided to fit the measurement error models separately for the angler and non-angler strata, so the variance components and other parameters in the measurement error models were estimated separately for the angler and non-angler strata. DEQ is interested in estimation of usual intake distributions for consideration of the Idaho adult angler population and the general population of Idaho adults, age 18 years or older.”

Also, the following technical detail is included in the report: “For estimation of a usual intake distribution involving both anglers and non-anglers, the Monte Carlo data sets, produced for each stratum, were combined. Combining Monte Carlo data sets from different strata and estimating the usual intake distribution, using the combined Monte Carlo data set, is an example of an established approach that has been used as part of the NCI statistical methodology, i.e. the NCI method.”

Alanna J. Moshfegh: “Usual intake means for all of the fish categories are quite similar (about ¾ of an ounce) with the exception of Idaho fish that is much lower, even for the Idaho adult anglers. The low amount for Idaho fish is what I expected to see based on reports being much less frequent. I have no comments on the 50th and 95th percentile intake rates as they are also similar with the exception of Idaho fish. Also, anglers has the highest intake at the 95th percentile which is expected since their mean intakes were higher than all subjects.”

Janet A. Tooze: “It appears that the NCI method was implemented correctly, and the estimates of usual fish intake appear to be reasonable. The Idaho fish rates are a bit confusing, however. First of all, the analysis was done on those who reported fish intake, but it would be very helpful to know how many people reported Idaho fish consumption intake, and how many people had it on both 8-d recalls, and how many people reported it on the FFQ. It is a little surprising there would be enough people with consumption on both recalls to use the NCI method, and it would be helpful to add this information into the report.”

Response:

We agree that the NCI method was implemented correctly. In the updated report we included the following: “In Section 3.3, the convergence issues discussed by Kipnis et al. (2009) are considered and related to the decision by DEQ, NCI, and IMS to define the Mixtran macro response variable using the total intake from each eight-day recall period. Considering the Idaho Fish response variables for the 1175 Idaho adult anglers who reported fish consumption in the past 12 months, only seven participants have a positive response variable value for two of the eight-day recall periods. This count suggests that convergence problems could have been encountered if the response variable from each recall period had been defined using fewer than the eight days of available data provided in the file from NWRG. Considering the All Fish response variables for the 1175 Idaho adult anglers who reported fish consumption in the past 12 months, 124 participants have a positive response variable value for two of the eight-day recall periods.”

Charge Question 4

Please comment on the analysis and differences in the usual intake means, estimated using the NCI method, to the weighted mean estimates directly from the recall data (without using the NCI method).

Patricia M. Guenther: “An individual’s intake during a particular time period is an unbiased estimate of his/her usual intake; therefore, the expected value of the population mean usual is the same for both methods. The small differences found are negligible. Within-person variation out does not affect the mean; however, it does affect the other points of the usual intake distribution, and the NCI accounts for that variation. Both methods use the sampling weights.”

Alanna J. Moshfegh: “I may have overlooked this in both reports but I did not find mean intakes from the recall data, just mean intakes from the FFQ. In comparison to the FFQ data, the usual mean intakes are about 10 grams larger. While it is stated that the mean intakes from the recall data are very close to the usual intake means, it seems for this type of report, such values should be included. In usual intake analysis, mean intakes computed through the usual intake process are usually very close to those estimated directly from recall data. It would be important to look at the mean intakes from the recall data and include these values in the report.”

Janet A. Tooze: “The differences between the usual intake means from the NCI method and the weighted mean estimates directly from the recall data were small, as expected. Under normality, the mean of the distribution from estimated by the NCI method and the unweighted mean should be the same. This is because the random measurement error does not affect the estimate of the mean, but impacts the estimate of the tails of the distribution, resulting in a more variable distribution, and hence overestimates of the tails of the distribution. Due to small departures from normality (of the transformed data) and due to the backtransformation, the two means may differ somewhat.”

Response:

We agree and have included similar comments and comparisons in the Discussion of the report.

Charge Question 5

Are the results of the NCI analysis of usual intake rates scientifically sound and are the results for Idaho fish “valid” for use in derivation of water quality criteria to be protective of human health for the general population and recreational anglers?

Patricia M. Guenther: “Because of the question raised about the maximum number of days for each respondent, it cannot be concluded that the results are scientifically sound or fit for use.”

Response:

The survey data, that NWRG provided, includes recall information from an eight-day recall period. For a subset of the sampled participants, recall information is also available from a second eight-day recall period. The data set and documentation that NWRG provided to DEQ, NCI, and IMS includes eight days of data for each of these contacts. The analysis plan developed by DEQ, the Biometry Research Group of NCI, and IMS considers the available data provided by NWRG and applies the NCI method using these data.

In the updated report we included the following: “In Section 3.3, the convergence issues discussed by Kipnis et al. (2009) are considered and related to the decision by DEQ, NCI, and IMS to define the Mixtran macro response variable using the total intake from each eight-day recall period. Considering the Idaho Fish response variables for the 1175 Idaho adult anglers who reported fish consumption in the past 12 months, only seven participants have a positive response variable value for two of the eight-day recall periods. This count suggests that convergence problems could have been encountered if the

response variable from each recall period had been defined using fewer than the eight days of available data provided in the file from NWRG. Considering the All Fish response variables for the 1175 Idaho adult anglers who reported fish consumption in the past 12 months, 124 participants have a positive response variable value for two of the eight-day recall periods.”

Alanna J. Moshfegh: “I would say yes. The data collection and statistical analysis to estimate usual intakes used the best methodology available for this type of assessment.”

Janet A. Tooze: “From what I can tell, the NCI method appeared to have been implemented correctly. I did provide a few points above for which I’d like clarification to make this conclusion. The rates of consumption for Idaho fish in general seem very low, and it is a bit concerning that there were so few consumers of these fish. In general, the NCI method should provide a better estimate of usual intake adjusted for measurement error compared to methods that do not adjust for measurement error, zero intake days, and the skewness of the data. However, the method can be sensitive to small sample sizes, and the sample size should have been small for Idaho fish. I’d like to see the results for Idaho fish consumers only if possible. Also, I am concerned about treating all 8 recall days as ‘equal.’”

Response:

We provide the following clarification regarding the scope of work for this analysis: “The recall data provided to DEQ by NWRG include dietary recalls with a reference period of eight days, and these data include two recall periods for some participants. The NCI method, implemented in the publicly available Mixtran and Distrib macros, was applied to the recall data provided by NWRG. As planned by the collaborators, DEQ, NCI, and IMS, these statistical methods and SAS macros were used without modification for this analysis.”

As previously stated in this document, in the updated report we included the following details, “In Section 3.3, the convergence issues discussed by Kipnis et al. (2009) are considered and related to the decision by DEQ, NCI, and IMS to define the Mixtran macro response variable using the total intake from each eight-day recall period. Considering the Idaho Fish response variables for the 1175 Idaho adult anglers who reported fish consumption in the past 12 months, only seven participants have a positive response variable value for two of the eight-day recall periods. This count suggests that convergence problems could have been encountered if the response variable from each recall period had been defined using fewer than the eight days of available data provided in the file from NWRG.”

Charge Question 6

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

Patricia M. Guenther: “If it turns out to be true that a maximum of 2 days are available from the 7-day reference, it may still be possible to analyze the data in a scientifically sound manner, using the NCI method, if the individual days are the observation periods. However, many of the second days will be consecutive to the first. Either this should be stated as a limitation, or perhaps the analysis could account for any correlation concerns (consider the ISU method for 3 consecutive days). Another option would be to use only the repeat observations that are at least 2 days distant from the first. This information should be available in the dataset.”

“Under this scenario, the value of the ‘recontact’ survey is unclear. If the authors have reason to believe that additional observations from some of the same people can be used to improve the estimates and, therefore, wish to include some of the data from the second (‘recontact’) phase, respondents who had recall data in the both the ‘main’ and ‘recontact’ phases could be used. Another perhaps more useful option would be to treat the ‘recontact’ sample in the same manner as the “main” sample, and cut the sampling weights of people who appear in both samples in half.”

“Regardless of the analytic approach taken, assumptions have to be made. For this study, they should all be in the direction of yielding conservative (i.e., high estimates). Assuming the 2 days reported represents all fish consumed during 8 days goes against that principle.”

Alanna J. Moshfegh: “Specific comments provided below.”

Janet A. Tooze: “I think I have given all my specific suggestions elsewhere in this response.”

Response:

We agree with various review comments made by Dr. Janet Tooze and Ms. Alanna J. Moshfegh conveying that the NCI method was implemented correctly as documented in the technical report. The technical report is described as follows: “This report includes estimated usual intake distributions of interest to DEQ and produced using the NCI method as implemented in the Mixtran and Distrib macros. The analysis plan and results were produced as a collaboration between DEQ, the Biometry Research Group of NCI, and IMS. This report documents the analysis decisions made by these collaborators and includes the results of interest to DEQ.”

To address the concerns of Dr. Patricia M. Guenther, we have included clarifications in this document and in the updated report.

In the updated report we included the following details.

“The survey data from NWRG includes recall information from an eight-day recall period. For a subset of the sampled participants, recall information is also available from a second eight-day recall period. As planned by the collaborators, DEQ, NCI, and IMS, the recall data from each eight-day recall period was used as the response variable in the measurement error model (i.e. as the response variable for the NCI

Mixtran macro). This decision was informed by relevant recall data considerations and potential convergence issues discussed by Kipnis et al. (2009).”

“Considering the available data from NWRG and considering the data requirements and convergence issues discussed by Kipnis et al. (2009), the collaborators decided to use the Idaho data from each eight-day recall period as the response variable in the Mixtran macro, so the response variables have the following units: grams of intake per 8 days. This approach was used for each of the following intake variables of interest to DEQ: intake of *All Fish*, intake of *Idaho Fish*, intake of *Non-Idaho Fish*, and intake of *Market Fish*. As introduced in Section 2.3 an “Overview of the NCI Method and Its Application to Estimating Usual Intake Distributions for Fish Consumption in Idaho,” the estimated usual intake distributions were produced using each of these intake variables, the Mixtran macro, and the Distrib macro. As part of this approach, implemented by DEQ, NCI, and IMS, the Monte Carlo data sets, produced by the NCI method, were appropriately rescaled to reflect the usual intake using the units of grams per day.”

“In Section 3.3, the convergence issues discussed by Kipnis et al. (2009) are considered and related to the decision by DEQ, NCI, and IMS to define the Mixtran macro response variable using the total intake from each eight-day recall period. Considering the Idaho Fish response variables for the 1175 Idaho adult anglers who reported fish consumption in the past 12 months, only seven participants have a positive response variable value for two of the eight-day recall periods. This count suggests that convergence problems could have been encountered if the response variable from each recall period had been defined using fewer than the eight days of available data provided in the file from NWRG. Considering the All Fish response variables for the 1175 Idaho adult anglers who reported fish consumption in the past 12 months, 124 participants have a positive response variable value for two of the eight-day recall periods.”

5 Response to Peer Review Report, Specific Observations Section

We appreciate the suggestions and comments that the reviewers provided in the “Specific Observations” section of the Peer Review Report, and we have incorporated many of these suggestions and have provided clarifications as discussed throughout this document.

Reviewer comment:

“The questionnaire indicates that the reference period is 7 days, not 8.”

Response:

The data set and documentation that NWRG provided includes eight days of data for each contact period.

Reviewer comment:

“The statistical approach used seems to assume that 8-day recall includes all the fish that was consumed during those 8 days; but, according to the questionnaire, that was not the case. The recall includes only the first day, which may or may not include fish, and only one other day which does include fish. The second day was not chosen at random.”

Response:

The analysis data set provided by NWRG includes participants with more than two days of nonzero recall values during the eight-day recall period. As previously stated, the data set and documentation that NWRG provided to DEQ, NCI, and IMS includes eight days of data for each contact period. We provided additional clarification in this document and in the updated technical report.

Reviewer comment:

“Not clear why the Kipnis discussion is needed here. Understand that lines 44-45 and 1-2 on page 9 are needed.”

Response:

We have clarified the relevance of the convergence issues and related details discussed by Kipnis et al. (2009).

6 Response to Westat's Comments

Reviewer comment:

"The covariates used in the NCI model are listed in the report (page 11). No justification for using these covariates is provided. In addition to these covariates, three other variables that are apparently available are: gender, household composition (single versus multi-person, see page 40 of the survey report), and amount consumed from the FFQ."

Response:

The updated report includes the following clarification regarding the covariates used in the analysis.

"In addition to the use of this stratification variable, covariates were used. The choice of covariates allowed for the estimation of additional usual intake distributions of interest to DEQ and included in this report. The same covariates were used in each of the measurement error models that were fit for this analysis."

"The 2959 participants in the analysis includes 1505 females and 1454 males. As discussed in Section 3.4, the collaborators, DEQ, NCI, and IMS, decided to apply the NCI method to participants with positive report of fish consumption, so the subset of participants, selected for the analysis, have positive values for the annual FFQ variable provided by NWRG. This annual FFQ variable was Box-Cox transformed and used as a covariate in the measurement error models. The covariates in the measurement error model include an indicator variable for males, the Box-Cox transformed annual FFQ variable, an indicator variable to adjust for recall sequence effects, and the following covariates described in Table 2: age, race/ethnicity, annual household income, education, health district, and self-reported body weight. Table 2 provides the distributions of these covariates."

Reviewer comment:

"At a minimum, compared to using only the last 24 hours, the estimates are biased without an adjustment for the decreasing frequency of reported fish consumption as the length of the recall period increases. See the general comments above."

Response:

The scope of work for this analysis is limited to the application of the NCI method as implemented in the Mixtran and Distrib SAS macros. The updated technical report includes the following clarification: "This report includes estimated usual intake distributions of interest to DEQ and produced using the NCI method as implemented in the Mixtran and Distrib macros. The analysis plan and results were produced as a collaboration between DEQ, the Biometry Research Group of NCI, and IMS. This report documents the analysis decisions made by these collaborators and includes the results of interest to DEQ. The SAS macros are available to the public and are documented by the NCI, so these technical details are not reproduced in this report. The NCI also provides a list of references and other resources

that consider details of the statistical methods that are referred to as the NCI method. Detailed aspects of this statistical literature are not reproduced in this report.”

Reviewer comment:

“The details of how the NCI macros were applied to the data files are not completely clear. For each type of fish consumption, we suspect the NCI method was applied to the data from the angler and non-angler subpopulations in separate runs, that all runs used the survey weights, and the summary statistics calculated from the simulated usual intake values for each respondent (from the DISTRIB macro) were calculated using the survey weight associated with the first recall for each respondent. The summary statistics can be calculated after combining the output files from the runs of the DISTRIB macro. If these procedures were used, we believe the calculations were done appropriately.”

Response:

We included additional details to clearly convey that the NCI method was appropriately applied as suggested by the reviewer’s comment. The following clarification is included in the report: “For estimation of a usual intake distribution involving both anglers and non-anglers, the Monte Carlo data sets, produced for each stratum, were combined. Combining Monte Carlo data sets from different strata and estimating the usual intake distribution as described, is an example of an established approach that has been used as part of the NCI statistical methodology, i.e. the NCI method.”

Reviewer comment:

“The report provides no information on the values of Box-Cox transformation parameter... In our experience, setting lambda instead of fitting lambda in the model and ignoring the correlation parameter has little effect on the results when calculating usual intake of fish. Given the relatively large number of respondents with two recalls with reported fish consumption we are surprised that lambda and the correlation parameter could not be fit using the MIXTRAN macro; at the same time, we have no reason to question this result.”

Response:

We have provided the following additional detail: “In an initial attempt to fit the measurement error models for this analysis, the Box-Cox transformation parameter (i.e. lambda) could not be estimated by the Mixtran macro, so the collaborators, DEQ, NCI, and IMS, decided to use another approach. The BoxCox_Survey SAS macro, available from the following NCI website: http://epi.grants.cancer.gov/diet/usualintakes/boxcox_survey_macro.v1.1.sas (accessed on March 31, 2016), was used to estimate the Box-Cox transformation parameter for the recall variables. Quantile-Quantile plots from this macro were examined to ensure that the Box-Cox transformation was appropriately selected, and the Box-Cox transformation parameter estimate from the BoxCox_Survey SAS macro was used as input for the Mixtran macro instead of estimating this parameter using the Mixtran macro. This established approach utilizes an input option of the Mixtran macro.”

7 Conclusion

We appreciate the comments and suggestions provided by the reviewers. As discussed in this document, we have provided clarifications and additional details in the updated technical report. The technical report includes the estimated usual intake distributions of interest to DEQ and documents the analysis decisions made by the collaborators: DEQ, the Biometry Research Group of NCI, and IMS. The scope of work for this analysis is limited to the application of the NCI method as implemented in the Mixtran and Distrib SAS macros.