Curriculum Vitae

Michael J. Daniels
Department of Statistics
University of Florida
102C Griffin-Floyd Hall
Gainesville, FL 32611

Education

AB	Applied Mathematics	Brown University (**magna cum laude**)	1991
ScD	Biostatistics	Harvard University	1995
	Thesis:	*Hierarchical Regression Models with Applications*	
	Minors:		
	Theoretical Statistics		
	Cancer Biology		

Academic Appointments

1995-1997	Visiting Assistant Professor Department of Statistics Carnegie Mellon University, Pittsburgh, PA — supported in part by Psychiatric Statistics Postdoctoral Fellowship
1997-2002	Assistant Professor Department of Statistics Iowa State University, Ames, IA
2002-2007	Associate Professor (with tenure) Department of Statistics University of Florida, Gainesville, FL
2005-	Executive Committee and Leader of Biostatistics, Data Management, and Methodology (Institute on Aging, University of Florida
2006-2007	Chief of Division of Biostatistics Associate Professor (with tenure) Department of Epidemiology and Biostatistics Department of Statistics (joint appointment)
2007-2008	Professor Department of Epidemiology and Biostatistics
2007-	Professor Department of Statistics
2008-2009	Interim Chair, Department of Statistics
2009-	Chair, Department of Statistics

Grants

NIH

PI : Covariance estimation in longitudinal cancer studies (NIH, R01), $150,000, 2001-2004.

co-PI : Analyzing complex longitudinal data in behavior science (NIH, R01), $180,000 (direct costs: subcontract from Brown University, PI on subcontract), 2004-2008.

PI : Bayesian methods for longitudinal cancer data (NIH, R01), $300,000 (direct costs), 2004-2009.

co-PI (Leader of Biostatistics and Data Management Core): Claude D. Pepper Older Americans Independence Center (OAIC), $600,000 /per year (direct costs). 2007-2012.

Co-I: ACE inhibition and physical performance in aged rats (NIH R01), $1.1 million (direct costs), 2005-2010.

co-I: Rural Lifestyle Intervention Treatment Effectiveness Trial (Rural Lite), NIH, $3.6 million (direct costs), 2008-2013.

co-PI : CMS Nonpayment for Nosocomial Injury and Risk of Falls in Hospitals (NIH, R01), $1.6 million, pending.

co-I (Leader of Data Management and Biostatistics Core), Autophagy in aging, (NIH, P01), $7.9 million, pending.

co-I: Therapeutic strategies to augment muscle rehabilitation, (NIH, P01), $6.7 million (direct costs), pending.

co-I: Magnetic Resonance Imaging and Biomarkers for Muscular Dystrophy (NIH, R01), $10.6 million, pending.

co-I: Mechanism of apoptosis in the development of sarcopenia and frailty in old age, (NIH, R01), $3.6 million, pending.

PI: Bayesian methods for (incomplete) longitudinal cancer data (NIH, R01), $320,000 (direct costs), 2009-2013.

NSF

Co-PI : Development of Conditionally Specified Statistical Models for Analysis of Environmental Studies (NSF), $300,000, 1998-2001.

co-PI : Conference on Data mining and Bioinformatics (NSF), January 2004, $17,500.

PI: Workshop on semiparametric methodology, NSF, 2008-2009, $5,000.

Other

Co-PI : Spatial Statistics Research Applied to Ecological Resource Monitoring Programs (EPA, CR822919-01-0), 1997-1998.

Co-PI: Statistical Treatment of Class Evidence (FBI through Ames Lab), $150,000 1998-1999.

PI : Improved estimation of correlations in longitudinal and spatial data (University Research Grant, Iowa State University), $12,000, 1998-1999

Co-PI : Effect of Prenatal Stress on the Health and Well-Being of Swine (USDA), $205,000, 2000-2003.

PI : Quantification of Animal Well Being, (USDA Cooperative Agreement), $33,000, 2002-2007.

Awards and Honors

Member of Sigma Xi Scientific Honor Society, 1991-1994

National Institutes of Health Training Grant Recipient, 1991-92

Generalized Linear Models Conference Travel Award, 1994

Howard Hughes Medical Institute Predoctoral Fellowship in Biological Sciences, 1992-1995

Eastern North American Region of Biometrics Society Student Travel Award, 1995

National Research Service Award in Psychiatric Statistics (NIMH), 1995-1997

Fellow of the American Statistical association (elected 2007)

Professional Societies

American Statistical Association, International Biometric Society, Institute of Mathematical Statistics, International Society for Bayesian Analysis

Research Interests

Bayesian methodology, Bayesian biostatistics, Covariance structures, Hierarchical modelling, Longitudinal data models, Missing data models, Spatial models

Applications in cancer, nutrition, health services, the environment, and forensics

Books

Daniels, M.J. and Hogan, J.W. (2008) Missing data in longitudinal studies: Strategies for Bayesian Modeling and Sensitivity Analysis. Chapman & Hall (CRC Press).

Papers

Published (Refereed)

Lenhard R, Daniels M, Oken M, Glick J, Ettinger D, Kalish L, O'Connell M (1994) An Aggressive High Dose Cyclophosphamide and Prednisone Regimen for Advanced Multiple Myeloma. *Leukemia and Lymphoma.* 13:485-489.

Devlin B, Daniels M, Roeder K. (1997) Heritability of IQ. *Nature.* 388:468-471.

Daniels M, Hughes M. (1997) Meta-Analysis for the evaluation of potential surrogate markers. *Statistics in Medicine.* 16:1965-1982.

Daniels M, Gatsonis C. (1997) Hierarchical Polytomous Regression Models with Applications to Health Services Research. *Statistics in Medicine.* 16:2311-2325.

Hughes MD, Daniels MJ, Fischl MA, Kim S, Schooley RT. (1998) CD4 cell count as a surrogate endpoint in HIV clinical trials: a meta-analysis of studies of the AIDS Clinical Trials Group. *AIDS.* 12:1823-1832.

Daniels M, Kass R. (1998) A note on first stage approximation in two stage hierarchical models. *Sankhya, Series B.* 60:19-30.

Daniels M, Gatsonis C. (1999) Hierarchical Generalized Linear Models in the Analysis of Variations in Health Care Utilization. *Journal of the American Statistical Association.* 94:29-42.

Daniels M. (1999) A prior for the variance in hierarchical models. *Canadian Journal of Statistics.* 27:569-580.

Lay, D.C., Jr., M.F. Haussman, H.S. Buchanan, and M.J. Daniels. (1999) Danger to piglets due to crushing can be reduced by the use of a simulated udder. *Journal of Animal Science.* 77:2060-2064.

Cressie N, Kaiser M, Daniels M, Aldworth J, Lee J, Lahiri S, Cox L. (1999) Spatial analysis of particulate matter in an urban environment, In *geoENV II - Geostatistics for Environmental Applications: Proceedings of the Second European Conference on Geostatistics for Environmental Applications*, eds. J. Gomez-Hernandez, A. Soares, R. Froidevaux, 41-52.

Daniels M, Kass R. (1999) Nonconjugate Bayesian estimation of covariance matrices in hierarchical models. *Journal of the American Statistical Association*, 94, 1254-1263.

Lay D., Haussmann M, Daniels M. (2000) Hoop Housing for feeder pigs offers a welfare friendly environment compared to a non-bedded system. *Journal of Animal Welfare Science*, 3:33-48.

Sidorenko, L.V., Li, X., Cocciolone, S.M., Chopra, S., Tagliani, L., Bowen, B., Daniels, M. and Peterson, T. (2000) Complex structure of a maize Myb gene promoter: functional analysis in transgenic plants. *The Plant Journal*, 22:1-14.

Daniels M, Dominici F, Samet J., Zeger, S. (2000) Estimating particulate matter-mortality dose-response curves and threshold levels: An analysis of daily time series data for the 20 largest U.S. cities (with invited commentary). *American Journal of Epidemiology*, 152, 397-406.

Haussmann, M.F., Carroll, J.A., Weesner, G.D., Daniels, M.J., Matteri, and Lay, D.C. Jr. (2000) Administration of ACTH to restrained, pregnant sows alters their pigs hypothalamic-pituitary-adrenal (HPA) axis. *Journal of Animal Science*, 78:2399-2411.

HIV Surrogate Marker Collaborative Group (2000) Human Immunodeficiency Virus Type I RNA Level and CD4 Count as Prognostic Markers and Surrogate Endpoints: A Meta-Analysis. *AIDS Research and Human Retroviruses*, 16, 1123-1133.

Daniels M, Hogan J. (2000) Reparameterizing the pattern mixture model for sensitivity analysis under informative dropout in longitudinal studies. *Biometrics*, 56, 1241-1249.

Daniels M, Cressie N. (2001) A hierarchical approach to covariance function estimation for time series. *Journal of Time Series Analysis*, 22, 253-266.

Daniels M, Lee Y-D, Kaiser M. (2001) Assessing sources of variability in measurement of ambient particulate matter. *Environmetrics*, 12, 547-558.

Hellmich, R.L., Siegfried, B.D., Sears, M.K., Stanley-Horn, D.E., Daniels, M.J., Mattila, H.R., Spencer, T., Bidne, K.G., and Lewis, L.C. (2001) Monarch larvae sensitivity to *Bacillus thuringiensis* - purified proteins and pollen. *Proceedings of the National Academy of Sciences*, 98: 11925-11930.

Carriquiry A., Daniels M. (2001) Adjusting for measurement error of a dietary risk factor in age-related maculopathy. *Bayesian Methods with Applications to Science, Policy, and Official Statistics: Selected Papers from ISBA 2000: The Sixth World Meeting of the International Society for Bayesian Analysis.*

Daniels M.J., Kass R.E. (2001) Shrinkage estimators for covariance matrices. *Biometrics*, 57: 1173-1184.

Daniels, M.J., and Carriquiry, A.L. (2001) Computing the posterior distribution of individual level usual intakes with application to disease models. *Research in Official Statistics*, 4: 67-79.

Hogan J, Daniels M. (2002) A hierarchical modelling approach to analysing longitudinal measurements with dropout and non-compliance, with application to an equivalence trial in paediatric acquired immune deficiency syndrome. *Applied Statistics (JRSS-C)*, 51:1-21.

Dominici, F., Daniels, M., Zeger S., Samet J. (2002) National models for estimating the effect of particulate matter on mortality in U.S. cities. *Journal of the American Statistical Association*, 97:100-111.

Pourahmadi M, Daniels M. (2002) Dynamic conditionally linear mixed models. *Biometrics*, 58:225-231.

Daniels, M. Pourahmadi, M. (2002) Bayesian analysis of covariance matrices and dynamic models for longitudinal data. *Biometrika*, 89, 553-566.

Kaiser, M., Daniels, M., Furakawa, K., Dixon, P. (2002) Analysis of particulate matter air pollution using markov random field models of spatial dependence. *Environmetrics*, 13, 615-628.

Pogranichnyy, R.M., Yoon K-J., Harms, P.A., Sorden, S.D., Daniels M. (2002) Case-control study on association of porcine circovirus type 2 and other swine viruses in postweaning multisystemic wasting syndrome. *Journal of Veterinary Diagnostic Laboratory Investigation*, 14, 449-456.

Daniels, M. and Zhao, Y. (2003) Modelling the random effects covariance matrix in longitudinal data. *Statistics in Medicine*, 22, 1631-1647.

Sidorenko, L, Bruce W., Maddock, S., Tagliani, L., Li, X., Daniels, M., Peterson, T. (2003) Functional analysis of two matrix attachment region (MAR) elements in transgenic maize plants. *Transgenic Research*, 12, 137-154.

Scharfstein D, Daniels M, Robins J. (2003) Incorporating prior beliefs about selection bias into the analysis of randomized trials with missing outcomes. *Biostatistics*, 4: 495-512.

Daniels, M.J., Dominici, F., Zeger, S. (2004) Underestimation of standard errors in multi site time series studies. *Epidemiology*, 15: 57-62.

Daniels, M.J. (2005) Shrinkage priors for the dependence structure in longitudinal data. *Journal of Statistical Planning and Inference*, 127: 119-130.

Dominici F., McDermott A., Daniels, M., Zeger S.L, Samet J.M. (2005) Revised analyses of the National Morbidity, Mortality, and Air Pollution Study: mortality among resident of 90 cities. *Journal of Toxicology and Environmental Health Part A.*, 68, 1071-1092.

Daniels, M., Normand, S-L.(2006) Longitudinal profiling of health care units based on mixed multivariate patient outcomes. *Biostatistics*, 7, 1-15.

Krieger, J.W., Sitren, H.S., Daniels, M.J., Landkamp-Henken, B. (2006) Effects of variation in protein and carbohydrate intake on body mass and composition during energy restriction: a meta-analysis. *American Journal of Clinical Nutrition*, 83: 260-274.

Daniels, M., Zhou, Z, and Zou, H. (2006) Conditionally specified space-time models for multivariate processes. *Journal of Computational and Graphical Statistics*, 15, 157-177.

Botts, C., Daniels, M. (2006) A shrinkage estimator for the spectral densities. *Biometrika*, 93, 179-195.

Daniels, M.J. (2006) Bayesian modelling of several covariance matrices and some results on the propriety of the posterior for linear regression with correlated and/or heterogeneous errors. *Journal of Multivariate Analysis*, 97, 1185-1207.

Scharfstein, D.O., Halloran, M.E., Chu, H., and Daniels, M.J. (2006) On Estimation of Vaccine Efficacy Using Validation Samples with Selection Bias. *Biostatistics*, 7, 615-629.

Liu, X. and Daniels, M.J. (2006) A new algorithm for simulating a correlation matrix based on parameter expansion and re-parameterization. *Journal of Computational and Graphical Statistics*, 15, 897-914.

Pourahmadi, M., Daniels M., Park, T. (2007) Simultaneuous modelling of covariance matrices using the modified Choleski decomposition with applications. *Journal of Multivariate Analysis*, 98, 568-587.

Ilk O., Daniels, M. (2007) Marginalized transition random effects models for multivariate longitudinal binary data. *Canadian Journal of Statistics*, 35, 105-123.

Lee, K., Daniels, M.J. (2007) A class of Markov models for longitudinal ordinal data. *Biometrics*, 63, 1060-1067.

Lay, D., Kattesh, H., Cunnick, J., Daniels, M.J., McMunn, K., Toscano, M. and Roberts, M. (2008) Prenatal stress on pig development and response to weaning. *Journal of Animal Science*, 86, 1316-1324.

Roy, J. and Daniels, M.J. (2008) A General Class of Pattern Mixture Models for Nonignorable Dropout with Many Possible Dropout Times. *Biometrics*, 64, 538-545.

Lee, K. and Daniels, M.J. (2008) Marginalized models for longitudinal ordinal data with application to quality of life studies. *Statistics in Medicine*, 27, 4359-4380.

Botts, C. and Daniels, M.J. (2008) A flexible approach to Bayesian multiple curve fitting. *Computational Statistics and Data Analysis*, 52, 5100-5120.

Perri, M.G., Limacher, M.C., Durning, P.E., Janicke, D.M., Lutes, L.D., Bobroff, L.B., Dale, M.S., Daniels, M.J., Radcliff, T.A., and Martin, A.D. (2008) Treatment of Obesity in Underserved Rural Settings (TOURS): A Randomized Trial of Extended-Care Programs for Weight Management in Women. *Archives of Internal Medicine*, 168, 2347-2354.

Judge, M.K., Zhang, J., Tumer, N., Carter, C., Daniels, M.J., and Scarpace, P.J. (2008) Prolonged hyperphagia with HF feeding contributes to exacerbated weight gain in rats with adult-onset obesity. *American Journal of Physiology - Regulatory, Integrative, and Comparative Physiology*, 295, R773-R780.

Martin, D.J., Martin, T.D., Hess, P.J., Daniels, M.J., Feezor, R.J., and Lee, W.A.L. (2009) Spinal Cord Ischemia after TEVAR in Patients with Abdominal Aortic Aneurysms. *Journal of Vascular Surgery*, 49, 302-306.

Daniels, M.J. and Wang, C. (2009) Discussion of "Missing Data in longitudinal studies: A review" by Ibrahim and Molenberghs. *TEST*, 18, 51-58.

Liu, X, Daniels, M., Marcus, B. (2009) Joint models for the association of a longitudinal binary and continuous process. *Journal of the American Statistical Association*, 104, 429-439.

Daniels, M.J. and Pourahmadi, M. (2009) Modeling covariance matrices using partial autocorrelations. *Journal of Multivariate Analysis*, 100, 2352-2363.

Carter, C.S., Leeuwenburgh, C., Daniels, M.J., and Foster, T.C. (2009) Influence of calorie restriction on measures of age-related cognitive decline: Role of increased physical activity. *Journal of Gerontology: Biological Sciences*, 64, 850-859.

Lee, K., Daniels, M.J., and Sargent, D. (2009) Causal effects of treatments for informative missing data due to progression/death. To appear in *Journal of the American Statistical Association.*

Peer Reviewed

Daniels, M, Dominici F, Samet J., Zeger, S. (2004) The National Morbidity-Mortality, and Air Pollution Study Part III: Concentration Response Curves and Thresholds for the 20 Largest U.S. Cities, The Health Effects Institute, Cambridge, MA.

Dominici F., McDermott A. Daniels, M. Samet J.M. Zeger S.L. (2004) A Report to the Health Effects Institute on Reanalyses of the NMMAPS Database, The Health Effects Institute, Cambridge, MA.

Daniels M, Dominici F, Samet J., Zeger, S. (2001) Reply to the letter of Tobias and Saez re: "Estimating particulate matter-mortality dose-response curves and threshold levels: An analysis of daily time series data for the 20 largest U.S. cities." *American Journal of Epidemiology*, 153, 1027-1028.

Submitted

Wang, C. and Daniels, M.J. (2009) A Note on MAR, Identifying Restrictions, and Sensitivity Analysis in Pattern Mixture Models With and Without Covariates for Incomplete Data. Submitted.

Wang, C., Daniels, M.J., Scharfstein, D.O., and Land, S. (2009) A Bayesian Shrinkage Model for Incomplete Longitudinal Binary Data with Application to the Breast Cancer Prevention Trial. Under revision.

Yang, Y., Halloran, M.E., Daniels, M.J., and Longini, I.M. (2009) Modeling competing infectious pathogens from a Bayesian perspective: Application to influenza studies with incomplete laboratory results. Submitted.

Published (Non-Refereed)

Daniels M, Devlin B, Roeder K (1997) 'Of Genes and IQ' in *Intelligence, Genes, and Success: Scientists respond to "The Bell Curve"*, editors B Devlin, S Fienberg, D Resnick, and K Roeder, New York: Springer-Verlag.

Daniels M. (1998) Computing posterior distributions for covariance matrices in *Computing Science and Statistics, Volume 30, Proceedings of the 30th Symposium on the Interface*, editor S. Weisberg, p. 192-196.

Daniels, M., Carriquiry A. (1999) Dietary assessment and estimation of intake densities. In: Paulino, C.D., Pacheco, A., and Ferreira da Cunha, A.P. (eds.) *Afirmar a Estatistica: Um Desafio para o Seculo XXI*, Sociedade Portugeusa de Estatistica, Lisboa, Portugal.

Daniels, M., Zhang, Y, Erdman, M., Harris IT. (2001) Experience with the Danish Mix-ELISA in the United States. *Proceedings of the 4th International Symposium on the Epidemiology and Control of Salmonella and other food-borne pathogens in Pork (Salinpork 2001)*, ed. PJ van der Wolf, 492-495.

Daniels, MJ, Zhang, Y., Erdmann, M., Harris, IT (2002) Estimating the accuracy of the DME in the U.S. *Proceedings of the 17th International Pig Veterinary Society (IPVS) Congress*, Ames, Iowa, June 2-5, 2002, p. 243.

Daniels, MJ (2003) Review of "Contemporary Statistical Models for the Plant and Soil Sciences" for *Journal of the American Statistical Association*, 98, 1080-1082.

Editorial Boards

Corresponding Editor for Institute of Mathematical Statistics Bulletin, 1998-2001

Associate Editor for Biometrics, 2003-2010 (3 terms)

Associate Editor for Journal of the American Statistical Association, Applications and Case Studies, 2005-2010

Associate Editor for Statistics & Probability Letters, July 2007-June 2010

Professional activities

Member of EPA FIFRA Scientific Advisory Panel, September, 1999

Review Committee for ENAR Student Paper Awards, 1999-2000

Co-organized ENAR invited session on informative missing data, 2000.

NIH Study Section (Small grants program for cancer), Spring and Fall 2001

Member of EPA Scientific Advisory Panel on Water Quality, December 2001

Organized ENAR invited session on longitudinal data, 2002.

ENAR Regional Advisory Board, 2003-2005.

Organized JSM invited session on modelling dependence, 2004.

ad hoc member, NIH BMRD Study Section, 2004, 2006.

HPSS Section Representative to ENAR, 2004-2005.

Member of ENAR Program Committee, 2005

Organized invited session on Bayesian Biostatistics, International Workshop/Conference on Bayesian Statistics and its Applications, India, January, 2005.

Organized JSM invited session on longitudinal data, 2005.

Biometrics section program chair for JSM 2006

Nominated to stand for election as member of International Society for Bayesian Analysis (ISBA) Board, Spring 2007 (election).

Review Committee for Student Paper Awards for Section on Bayesian Statistical Science (SBSS) of the ASA, 2007.

Program Chair Elect, Section on Bayesian Statistical Science (SBSS) of the ASA, 2008 (elected in 2007).

Savage Thesis Award Committee, 2007-2008, 2008-2009

Council of Sections Representative, Biometrics Section of the ASA, 2008 (elected in 2007).

ad hoc member, NIH ACE Study Section, 2008.

Program Chair, Section on Bayesian Statistical Science (SBSS) of the ASA, 2009.

Program Chair, ENAR Spring Meetings 2010, New Orleans.

Refereeing/Reviewing

Refereed papers for JASA,JRSS-B,Environmetrics,Canadian Journal of Statistics,JCGS, JBES, JABES, Archives of General Psychiatry, Case Studies in Bayesian Statistics, Journal of Clinical Oncology, Statistics in Medicine, Biostatistics, American Journal of Epidemiology, Biometrics, Health Services and Outcomes Research Methodology, Annals of Internal Medicine, Psychological Bulletin, Journal of Statistical Planning and Inference, Statistical Science, Environmental Health Perspectives, Science for the Total Environment, Biometrika, Statistical Modelling, Lifetime Data Analysis, Biometrical Journal, JRSS-A, Atmospheric Environment, Statistica Sinica, Annals of Statistics, Ecology, Journal of Clinical Epidemiology, Bayesian Analysis, Statistics and Computing

Grant reviewer for NSF, NIH, and HEI (Health Effects Institute)

Reviewed manuscripts for Springer-Verlage, Duxbury Press, and Addison Wesley Longman

External thesis examiner for F.K. Wong's PhD thesis, Australian Graduate School of Management, 2004

Consulting/Collaborations

Boston Medical Area (Consulting Lab), 1993-1994

Western Psychiatric Institute and Clinic, in designing and analyzing studies, grant preparation, 1995-1996

Legal Firm (Freedman and Lockhart), analysis of data regarding potentially forged document, 1996

Carnegie Mellon History Department, analysis of educational data, 1996-1997

HIV RNA Surrogate Marker Collaborative Group, analysis of surrogate markers in AIDS trials, 1997-1999

Iowa State University, Department of Animal Science, Agronomy, Zoology and Genetics, and Veterinary Medicine, 1997-

Des Moines hospitals, analysis of perinatology data, design of survey on factors related to having genetic counseling, 1998-

Pfizer, study design and data analysis for drug testing, 1998-1999

Nextran, risk factors in Xenotransplantation, 1999-

Iowa State University, Department of Microbiology and School of Veterinary Medicine: project involving eventual eradiction of multi-drug resistant salmonella in swine, 2001-

Environomics, review document on water quality regulations, 2004

Asthmatx, Member of Mock FDA panel, 2009.

Miscellaneous

discussed 1997 Nature paper on radio shows in Texas and Minnesota

January 7, 2009

Supplement to Cal/EPA External Scientific Peer Review Guidelines – "Exhibit F" in Cal/EPA Interagency Agreement with University of California
Gerald W. Bowes, Ph.D.

Guidance to Staff:

1. Revisions. If you have revised any part of the initial request, please stamp "Revised" on each page where a change has been made, and the date of the change. Clearly describe the revision in the cover letter to reviewers, which transmits the material to be reviewed. The approved reviewers have seen your original request letter and attachments during the solicitation process, and must be made aware of changes.

2. Documents requiring review. All important scientific underpinnings of a proposed science-based rule must be submitted for external peer review. The underpinnings would include all publications (including conference proceedings), reports, and raw data upon which the proposal is based. If there is a question about the value of a particular document, or parts of a document, I should be contacted.

3. Documents not requiring review. The Cal/EPA External Peer Review Guidelines note that there are circumstances where external peer review of supporting scientific documents is not required. An example would be "A particular work product that has been peer reviewed with a known record by a recognized expert or expert body." I would treat this allowance with caution. If you have any doubt about the quality of such external review, or of the reviewers' independence and objectivity, that work product – which could be a component of the proposal - should be provided to the reviewers.

4. Implementation review. Publications which have a solid peer review record, such as a US EPA Criteria document, do not always include an implementation strategy. The Cal/EPA Guidelines require that the implementation of the scientific components of a proposal, or other initiative, must be submitted for external review.

5. Identity of external reviewers. External reviewers should not be informed about the identity of other external reviewers. Our goal has always been to solicit truly independent comments from each reviewer. Allowing the reviewers to know the identity of others sets up the potential for discussions between them that could devalue the independence of the reviews.

6. Panel Formation. Formation of reviewer panels is not appropriate. Panels can take on the appearance of scientific advisory committees and the external reviewers identified through the Cal/EPA process are not to be used as scientific advisors.

7. Conference calls with reviewers. Conference calls with one or more reviewers can be interpreted as seeking collaborative scientific input instead of critical review. Conference calls with reviewers are not allowed.

January 7, 2009

Guidance to Reviewers from Staff:

1. Discussion of review.

   Reviewers are not allowed to discuss the proposal with individuals who participated in development of the proposal. These individuals are listed in Attachment 3 of the review request.

   Discussions between staff and reviewers are not permitted. Reviewers may request clarification of certain aspects of the review process or the documents sent to them.

   Clarification questions and responses must be in writing. Clarification questions about reviewers' comments by staff and others affiliated with the organization requesting the review, and the responses to them, also must be in writing. These communications will become part of the administrative record.

   The organization requesting independent review should be careful that organization-reviewer communications do not become collaboration, or are perceived by others to have become so. The reviewers are not technical advisors. As such, they would be considered participants in the development of the proposal, and would not be considered by the University of California as external reviewers for future revisions of this or related proposals. The statute requiring external review of science-based rules proposed by Cal/EPA organizations prohibits participants serving as peer reviewers..

2. Disclosure of reviewer Identity and release of review comments.

   Confidentiality begins at the point a potential candidate is contacted by the University of California. Candidates who agree to complete the conflict of interest disclosure form should keep this matter confidential, and should not inform others about their possible role as reviewer.

   Reviewer identity may be kept confidential until review comments are received by the organization that requested the review. After the comments are received, reviewer identity and comments must be made available to anyone requesting them.

   Reviewers are under no obligation to disclose their identity to anyone enquiring. It is recommended reviewers keep their role confidential until after their reviews have been submitted.

3. Requests to reviewers by third parties to discuss comments.

   After they have submitted their reviews, reviewers may be approached by third parties representing special interests, the press, or by colleagues. Reviewers are under no obligation to discuss their comments with them, and we recommend that they do not.

   All outside parties are provided an opportunity to address a proposed regulatory action during the public comment period and at the Cal/EPA organization meeting where the proposal is considered for adoption. Discussions outside these provided avenues for comment could seriously impede the orderly process for vetting the proposal under consideration.

4. Reviewer contact information.

The reviewer's name and professional affiliation should accompany each review. Home address and other personal contact information are considered confidential and should not be part of the comment submittal.

Condensed Curriculum Vitae

STEVE E. HRUDEY

CURRENT APPOINTMENTS:

Title: Professor Emeritus
Division of Analytical and Environmental Toxicology
Department of Laboratory Medicine and Pathology
Faculty of Medicine and Dentistry
University of Alberta
Edmonton, Alberta T6G 2G3

Title: President, Steve E. Hrudey & Associates Ltd.
1016 Lawrence Grassi Ridge
Canmore, AB T1W 3C2

Recent and Other Appointments

Title: Chair, Environmental Appeals Board (July 2005 – July 2009)
306 Peace Hills Trust Tower
10011 – 109 St.
Edmonton, AB T5J 3S8

Titles: Adjunct Professor
School of Public Health &
Preventive Medicine
Monash University,
Melbourne, Australia

Visiting Professor of the University
Cranfield University
Cranfield, England
U.K.

EDUCATIONAL QUALIFICATIONS:

D.Sc (Eng), Environmental Health Sciences and Technology,
University of London, 2002 (higher doctorate degree based on career research publications)

Ph.D., Public Health Engineering,
University of London, 1979 (Advisor: Professor Roger Perry)

M.Sc., Public Health Engineering
Imperial College, University of London, 1971 (Advisor: Professor Roger Perry)

B.Sc., Mechanical Engineering (with electives in life sciences)
University of Alberta, 1970

PROFESSIONAL AFFILIATIONS:

- Canadian Public Health Association
- Society for Risk Analysis
- International Water Association
- American Water Works Association
- Association of Environmental Engineering and Science Professors
- Association of Professional Engineers, Geologists and Geophysicists of Alberta

AWARDS AND HONOURS

2007 Fellow of the Society for Risk Analysis

2006 Fellow of the Royal Society of Canada, Academy of Science

2006 Donald R. Stanley Best Environmental Paper Award, Canadian Society of Civil Engineering, for: "*Occurrence of N-nitrosamines in Alberta public drinking water distribution systems.*" J.W.A. Charrois, J.M. Boyd, K.L. Froese and S.E. Hrudey. 2007. *J. Environ. Eng. Sci.* 6: 103-114.

2006 National Water Research Institute (Canada) Distinguished Speaker for 2006

2006 TD Canada Trust Walter Bean Visiting Professor in Environment, University of Waterloo

2005 Inaugural Schultz Oration for the Donal Herbert Schultz Endowment to the Flinders Research Centre for Coastal and Catchment Environments, Flinders University, Adelaide, Australia

2003-04 Killam Annual Professor, University of Alberta.

2002 D.Sc (Eng), Environmental Health Sciences and Technology, University of London, (higher doctorate degree award based on career research publications)

2002: Honorary Professor, Department of Epidemiology and Preventive Medicine, Monash University Medical School. Melbourne, Australia.

1997: Association of Environmental Engineering Professors Distinguished Lecture: "*Health Risk Assessment and Risk Management for Algal Toxins in Drinking Water Supplies* "at the American Water Works Association Annual Conference in Atlanta, June.

1995: Emerald Award for Environmental Research Advances, Alberta Foundation for Environmental Excellence

1993-98 *Eco-Research* Chair in Environmental Risk Management – NSERC-SSHRC-MRC

1991: Albert E. Berry Medal for significant contributions to Environmental Engineering in Canada, Canadian Society for Civil Engineering

1990: The Owen Holmes Science Lecture, The University of Lethbridge.

1989: National Lecture Tour, Environmental Engineering Division, Canadian Society for Civil Engineering.

1987-88: McCalla Research Professorship, University of Alberta

SCIENTIFIC AND PROFESSIONAL JOURNAL EDITORIAL BOARDS

Associate Editor
Environmental Reviews
published by the National Research Council of Canada, Ottawa, 1993-present

Member of Editorial Committee
Environmental Health
published by the Australian Institute of Environmental Health, 2000 - present

Editorial Board Member
Environmental Technology ,
published in London, U.K., 1985-2002
(Regional Editor for Canada, 1979-1985)

Associate Editor,
Environmental Engineering Science, 1997 - 2000
formerly Editorial Board Member,
Hazardous Wastes and Hazardous Materials,
published in New York, 1988-1997

Editor and Member of Editorial Review Board,
Water Environment Research, (formerly, *Res. J. Water Pollut. Control Fed.*)
published by the Water Environment Federation,Washington, D.C., 1989-1993

Associate Editor for Environmental Engineering,
Canadian Journal of Civil Engineering,
published by the National Research Council of Canada, Ottawa, 1988-1992

PUBLIC AND PROFESSIONAL SERVICE (~ last 10 years):

Chair, Expert Panel on Environmental and Health Impacts of Canada's Oil Sands Industry, Royal Society of Canada, October 2009 to present.

Member, Expert Advisory Panel on Water Quality, Washington Aqueduct drinking water supply, U.S. Army Corps of Engineers, Washington, D.C., September 2009 to present.

Testimony at Legislative Council, Western Australian Parliamentary Review into Recreational Access in Drinking Water Catchments and Storages, Perth, Australia, November 24, 2009.

External Peer Review, Draft Drinking Water Health Advisory on NDMA, U.S. Environmental Protection Agency, August 2009.

Invited Testimony at the Standing Senate Committee on Energy, the Environment and Natural Resources, Victoria Building, Ottawa regarding Bill S-206, An Act to amend the Food and Drugs Act (Clean Drinking Water), 29 April, 2008.

Member, Technical Advisory Committee to the Minister of Health, British Columbia Ministry of Health on Turbidity and Microbial Risk in Drinking Water, November 2007 to February 2008.

Member, Expert Panel on Groundwater Management in Canada, Council of Canadian Academies, Ottawa, May 2007 to May 2009.

Invited Testimony at the Standing Senate Committee on Aboriginal Peoples, Houses of Parliament, Ottawa regarding the Expert Panel Report on Safe Drinking Water for First Nations, May 15, 2007.

Member, Expert Panel reporting to the Minister of Indian and Northern Affairs to conduct public hearings and report on regulatory options to assure safe drinking water in First Nations communities in Canada, May 2006 – November 2006. Report tabled in the House of Commons on December 7, 2006.

Member, Sub-committee for a Professional Guideline on Risk Management, Association of Professional Engineers, Geologists and Geophysicists of Alberta 2004 – 2006

Member of Research Advisory Panel to the Walkerton Inquiry, August 2000 – May 2002

Chair, International Expert Panel for Health Canada, To Identify Critical Endpoints for Assessment of Health Risks Related to Trihalomethanes (THMs) in Drinking Water. September 2002 to March 2003.

Peer Review, Health Canada, CDBP (Chlorinated Disinfection By-Products) Task Force
Water Quality Issues Sub-Group Final Report

Member, Independent Peer Review Panel for the Giant Mine Task Force of Indian Northern Affairs Canada review of risk management options for arsenic trioxide dust (237,000 tonnes) stored in the mined out areas of the Giant Yellowknife Mine., Yellowknife, September 2002 - 2005

Member of Working Party to the National Health and Medical Research Council on developing a Framework for Water Quality Management – From Catchment to Consumer for the current revisions to the Australian Drinking Water Guidelines and Research Collaborator with the Cooperative Research Center for Water Quality and Treatment, Adelaide, Australia, 2000-2003

Chair, Expert Review Panel, Royal Society of Canada, Socio-Economic Modelling for the Canada Wide Standards for Respirable Particulate and Ozone, November 1999 to January 2001.

Independent Reviewer, Alberta Environment air quality studies of intensive livestock operations in the Lethbridge region and resulting critique by the Chinook Health Region., September 2000.

Member, Science Advisory Committee to Alberta Health and Wellness on Environmental Health Risk Advisories, January 1998 -

Member, Sour Gas Advisory Panel to the Energy and Utilities Board, January 2000 – November 2000

Member, National Advisory Panel on Environment, Canadian Chemical Producer's Association, November 1994-November 1999.

Expert Panel Member reporting to the World Health Organization for preparation of a monograph addressing management of health risks from cyanobacterial toxins in drinking water supplies. 1997-1999.

Review of Environmental Risk Assessment for Resolution Island PCB Cleanup. The Nunavut Impact Review Board. Cambridge Bay, Nunavut, December 1999.

Review of Precautionary Principle Application to Disinfection By-Products in Drinking Water, Pollution Probe, Ottawa, October 1999.

Member, Syncrude Landscape Reclamation Technical Advisory Panel, November 1995 – January 2000.

Expert Panel Member reporting to the Laboratory Centres for Disease Control on evaluation of human health risks from drinking water disinfection by-products, 1997-98.

ACADEMIC AND RESEARCH SERVICE (~last 10 years):

Management Advisory Board, Alberta Water Research Institute, March 2007 to October 2009.

Visiting Consultant, Ontario Council on Graduate Studies, to assess the proposed MPH at the University of Guelph, October 2008.

Visiting Consultant, Ontario Council on Graduate Studies, to assess the proposed MPH at the University of Waterloo, March 2006.

Member, Science Advisory Council, Public Health National Collaborating Centres, Public Health Agency of Canada, Ottawa, July 2005 – 2007

Program Leader, Protecting Public Health, Canadian Water Network NCE. May 2001 – June 2005.

Reviewer of the NSERC – SSHRC Chair in Population Health Risk Assessment, University of Ottawa, 31 Oct, 2005.

Member, College of Reviewers, Special Research Opportunity program, NSERC, Ottawa, 2003-present

Member, College of Reviewers, Canada Research Chairs, Ottawa, 2002-present

Reviewer for the National Research Council, Board on Environmental Studies and Toxicology, U.S. National Academy of Sciences, 2002

Member, NSERC Advisory Group on Interdisciplinary Research, Ottawa, October 2000 -

Member, STAR Graduate Fellowship Selection Panel, U.S. Environmental Protection Agency, Washington, D.C. October 2000 – January 2001.

Chair, Expert Advisory Panel, Metals in the Environment Research Network, NSERC-funded, Guelph, 1999-2002.

Member, Project Advisory Committee, Removal of Cyanobacterial Toxins from Drinking Water (Adelaide

INVITED PRESENTATIONS (last 5 years):

Prevention is Painfully Easy in Hindsight - Fatal E. coli O157:H7 & Campylobacter Outbreak in Walkerton, Canada *2000. Global Issues in Water, Sanitation and Health. Institute of Medicine, U.S. National Academy of Sciences*, Washington, D.C., U.S.A., 23 Sep 2008.

A Risk Context for Assessing Drinking Water Disinfection. *Ontario Drinking Water Advisory Council International Workshop on Disinfection Alternatives.* Toronto, ON, 22 Sep 2008.

Why Water Safety Plans are Essential to Safe Drinking Water. *Keynote Address – World Health Organization – International Water Association Specialty Conference on Water Safety Plans*. Lisbon, Portugal, 12 May 2008.

Disinfection By-Products A Health Risk Assessment Perspective. *Keynote Address to the Annual LaRonge Drinking Water Conference*. LaRonge, SK, 17 Apr 2008.

Turbidity and Microbial Health Risk in Drinking Water, *B.C. Medical Officers of Health Meeting*. Victoria, BC, 1 Apr 2008.

Risky Business – Bridging the Barriers Between Science and Public Health. Keynote Address to the First Annual Research Symposium of the University of Alberta School of Public Health. Edmonton, AB, 15 Nov 2007.

Drinking Water Safety in Smaller Communities. *Public Health Works – Capital Health Authority* (with video conferencing across Alberta and to 3 other provinces. Edmonton, AB, 16 Oct 2007.

Why "Effective" Risk Management is Essential to Safe Drinking Water. *Keynote Address to National Workshop of the National Health and Medical Research Council on the Implementation of the Australian Drinking Water Guidelines*, Adelaide, Australia, 2 Oct 2007.

Safe Drinking Water - Walkerton 7 Years On. *Special Seminar for the Water Corporation of Western Australia*, Perth, Australia, 28 Sep 2007.

Safe Drinking Water – What Makes People Sick? *Knowledge Translation Workshop for the Canadian Water Network Project on Safe Drinking Water for Small Communities*. Walkerton, ON, 10 Sep 2007.

Lessons from Recent Drinking Water Outbreaks. *Ontario Ministry of Environment Annual Drinking Water Conference*. Toronto, ON, 24 Apr 2007.

Safe Drinking Water for First Nations Communities – Challenges and Opportunities, B.C. *Centres for Disease Control –Monthly Rounds*. Vancouver, BC, 16 Mar 2007.

When Organisations Fail – Insights from Walkerton and Other Drinking Water Disasters. *Cranfield University – Professional Short Course on Risk Management*, Cranfield, U.K., 22 Jan 2007

Challenges in Providing Safe Drinking Water for Small Systems. *TD Canada Trust Visiting Professor in Environment*. Department of Civil and Environmental Engineering, University of Waterloo. 29 Nov 2006.

Perspectives on Risk, Water Quality and Public Health. *Watersheds and Source Protection: Governance, Science and Health*. The Peter Wall Institute, UBC, Vancouver, 24 Nov 2006.

Role of Science and Best Judgement in the Walkerton Inquiry. National Conference of the Canadian Water Network, Montreal, 21 Nov 2006.

Safe Drinking Water from Walkerton to Kasechewan. Water in Canada and the World: Rising Tensions in the 21st Century – Issues and Solutions. The Royal Society of Canada. 17 Nov 2006.

Challenges for Safe Drinking Water in Small Systems. International Network on Small Community Water Management. Kelowna. 19 Sep 2006.

Safe Drinking Water for Small Systems. Infrastructure Workshop, Canadian Water Network, Toronto. 18 Sep 2006.

Risk Analysis for Better and More Credible Utility Decisions. AwwaRF Technology Transfer Workshop. San Francisco. 13 Sep 2006.

Keynote Speaker: Disinfection By-Products and Alternative Disinfection - Where Are We and How Did We Get Here? Enviro 06, Melbourne, Australia, 9 May 2006.

Banquet Speech: "150 Years and Counting - Drinking Water Safety Lessons are Learned Slowly" *Annual Banquet for the TD Canada Trust Walter Bean Visiting Professorship in Environment*, University of Waterloo, 2 Mar 2006.

Keynote Speaker: "From Walkerton to Kashechewan – Is Safe Drinking Water Really so Difficult?" *National Water Research Institute Distinguished Speaker for 2006*, February 13, 2006.

"Role of the Environmental Appeals Board in Alberta." International Institute for Resource Industries & Sustainability Studies Serminar Series, Haskayne School of Business, University of Calgary, 16 Dec 2005.

Keynote Speaker. "Safe Drinking Water and Risk Management – Converting Hindsight into Foresight" Emerging Trends in Environmental Law, Municipal Governments Seminar, Brownlee-Fryett, Edmonton, 7 Dec, 2005.

Inaugural Schultz Oration: "150 Years Later - How Are We Doing with Drinking Water Safety?" *Donal Herbert Schultz Endowment to the Flinders Research Centre for Coastal and Catchment Environments*, Flinders University, Adelaide, Australia, 22 Nov 2005.

"The Alberta Environmental Appeals Board – A Primer for Practitioners" *Canadian Bar Association – Edmonton Branch*, Monthly Meeting, 10 Nov, 2005.

"Risk Analysis Strategies for Better and More Credible Utility Decisions" *Advancing the Science of Water – The Future of Water Utilities: Reading the Crystal Ball, American Water Works Association Research Foundation*, Detroit, 21 Oct, 2005

Keynote Presentation: "Turning Hindsight into Foresight – Lessons from Recent Drinking Water Outbreaks" *Annual Conference of the Atlantic Canada Water Works Association*, Halifax, 17 Oct, 2005.

Keynote Presentation: "A Nose for Trouble - The Role of Off-Flavours in Assuring Drinking Water Safety" *7th International Water Association Specialty Conference on Off Flavours in the Aquatic Environment*, Cornwall, Ontario, 6 Oct, 2005.

"Risk Analysis Strategies for Better and More Credible Utility Decisions" *Advancing the Science of Water – The Future of Water Utilities: Reading the Crystal Ball, American Water Works Association Research Foundation*, St. Louis, 27 Sept, 2005.

Keynote Presentation: "Drinking Water Disease Outbreaks – Legal Perspectives of Problems and Resolutions" *Annual Conference of Environmental Lawyers in Government*, Edmonton, 12 Sept, 2005.

Keynote Presentation: "Safe Drinking Water – Protecting the Public's Health" *Rural Community Action Partnership 2005 Conference – Rural Issues and Best Practices*, Washington, D.C., 23 Aug, 2005

"Safe Drinking Water - Converting Hindsight into Foresight" *Special Presentation to the State Water Council of Western Australia*, Perth, Australia, 29 July, 2005
"Safe Drinking Water – Walkerton 5 Years On." *Special Seminar of the Australian Water Association - Western Branch*, Perth Australia, 28 July, 2005

"Safe Drinking Water - Converting Hindsight into Foresight" *Special Seminar for the Water and Rivers Commission of Western Australia*, Perth, Australia, 28 July, 2005
"Current DBP Issues –A Health Risk Assessment Perspective" *Cooperative Research Centre for Water Quality and Treatment Research Symposium*, Brisbane, 26 July, 2005

"Drinking Water Safety in Canada Saving a Victim of Success" Water Education Institute, Kananaskis, Alberta, 8 July 2005.

"Preventing Drinking Water Emergencies – Water Quality Monitoring Lessons from Recent Outbreak Experience" UK Conference, Manchester UK, 14 June, 2005.

"The Lessons Learned? Converting Hindsight into Foresight" *Symposium on Converting Hindsight into Foresight - Walkerton 5 Years On - Canadian Water Network Public Health Workshop*, Walkerton, May 31, 2005

Keynote Presentation: "Waterborne Disease Outbreaks in Affluent Societies" Public Forum for *Walkerton 5 Years On - Canadian Water Network Public Health Workshop*, Walkerton, May 30, 2005

"Recent Drinking Water Disease Outbreaks in Developed Countries, *Special Seminar, Beijing University*, 18 May, 2005

"Quantitative Risk Assessment – Useful Insight or Misleading Disinformation?" *2nd Chinese International Symposium on Persistent Toxic Substances*, Beijing, 17 May, 2005

"A Population Health and Drinking Water Safety Perspective on Guidelines for Canadian Drinking Water Quality" *Federal-Provincial-Territorial Committee on Drinking Water*, St. Johns,Nfld, 2 May 2005.

"Risk Management – Lessons for More Credible Decision-Making" *AwwaRF International Workshop on Risk Analysis Strategies for Better and More Credible Decision Making*, Banff, Alberta, 6 April 2005.

"Safe Drinking Water – Converting Hindsight into Foresight", Invited Seminar in the Series - *Shaping Future Water Policy: The Role of Science*, Michigan State University, East Lansing, Michigan, 25 March 2005.

Invited Testimony: on Safe Drinking Water before the *Standing Senate Committee on Energy, Environment and Natural Resources*, Edmonton, 9 March 2005

Keynote Speaker: "Waterborne outbreaks in affluent nations - causal themes common to small systems", *Federal Drinking Water Providers, First Annual Workshop*, Health Canada, 9 Feb, 2005.

"Safe Drinking Water – Confronting the Truth" *Edmonton Section, Canadian Bar Association*, 14 Dec 2004.

Keynote Speaker: "Safe Drinking Water – Turning Hindsight into Foresight" *Breakfast for MPs and Senators, Parliament Hill, 15th Annual Meeting of the Networks of Centres of Excellence*, Ottawa, 2 Dec 2004.

"Environmental Health Risk Management – Understanding Reality." *Air and Waste Management Association*, Edmonton, 30 Nov, 2004.

Special Seminar: "Safe Drinking Water – Lessons for Australians from Recent Outbreaks in Affluent Nations." *Australian Water Association – South Australia Branch*, Adelaide, 25 Nov, 2004.

"Water Quality Monitoring Evidence for Drinking Water Risk Management" *Workshop on Developing Evidence-Based Water Quality Monitoring Systems, Monash University*, Melbourne, 22 Nov, 2004.

Keynote Speaker: "Drinking Water and Risk Management". *Victorian Department of Human Services Special Conference for Drinking Water Authorities*. Melbourne, 19 Nov, 2004.

Special Meeting: "Outbreaks in Small Systems" *Ontario Advisory Council on Drinking Water Standards*. Toronto, Nov, 2004.

Keynote Address: "Safe Drinking Water – Lessons from Recent Outbreaks." *2004 Annual Conference Saskatchewan Water and Wastewater Association*. Saskatoon, 5 Nov 2004.

Keynote Address: "Water System Factors that Have Contributed to Human Illness: An International Review." *2004 Drinking Water Conference for B.C. Drinking Water System Regulators*. Vancouver, 3 Nov. 2004.

"Safe Drinking Water and Emergency Preparedness" *Specialty Conference, Australia Water Association – Tasmania Section*. Hobart, Sept 28, 2004.

Special Symposium: "Safe Drinking Water – Lessons from Walkerton and Beyond" *Annual Conference of the Australian Society of Microbiology*. Sydney, Sept 26, 2004.

Keynote Address: "Safe Drinking Water – Lessons from Walkerton and Beyond" *Safe Drinking Water Conference of the New South Wales Department of Health*. Sydney, 24 Sept 2004.

"Safe Drinking Water" *Special Section Meeting of the Australian Water Association*. Brisbane, 20 Sept 2004.

Keynote Address: "Safe Drinking Water – Lessons from Recent Outbreaks in Affluent Nations" *Annual Conference of the Canadian Science Writers Association*. Toronto, 7 June 2004.

Keynote Address: "Risk of Source Water Contamination Impairing Drinking Water Safety – Learning Lessons from Past Failures." *Source Water Protection Specialty Conference Alberta Environment and Western Canada Water and Wastewater Association*. Red Deer, 18 May 2004.

Keynote Address: "Walkerton and the Inquiry – A Human Tragedy and Wakeup Call for Canadians." *U.S. EPA sponsored International Colloquium Protecting Public Health in Small Water Systems, Montana State University*, Bozeman, Montana, 10 May 2004.

"Safe Drinking Water – Lessons from Recent Outbreaks in Affluent Countries." *Society for Environmentally Responsible Land Ownership*, Red Deer, 17 Jan 2004.

PUBLICATIONS:

Books:

Hrudey, S.E. & E.J. Hrudey. 2004. *Safe Drinking Water – Lessons from Recent Outbreaks in Affluent Nations*. IWA Publishing, London. 514pp.

Thomas, S. P. & S. E. Hrudey. 1997. *Risk of Death in Canada- What We Know and How We Know It*. University of Alberta Press, Edmonton, 292 pp.

Hrudey, S.E., Chen, W. & C. Rousseaux. 1995. *Bioavailability in Environmental Risk Assessment*. Lewis Publishers, CRC Press, Boca Raton, Florida, 291 pp.

Vandermeulen, J.H. & Hrudey, S.E. 1987. **Ed.** *Oil and Freshwater: Chemistry, Biology and Countermeasure Technology*, Pergamon Press, 510 pp.

Barnes, D., Forster, C.F. & Hrudey, S.E. 1987. **Ed.** *Surveys in Industrial Wastewater Treatment: Manufacturing and Chemical Industries*, Vol.**3**, Longmans Ltd., London, 217 pp.

Barnes, D., Forster, C.F. & Hrudey, S.E. 1984. **Eds.** *Surveys in Industrial Wastewater Treatment: Petroleum and Organic Chemical Industries*, Vol.**2**, Pitmans Ltd., London, 233 pp.

Barnes, D., Forster, C.F. & Hrudey, S.E. 1984. **Ed.** *Surveys in Industrial Wastewater Treatment: Food and Allied Industries*, Vol.**1**, Pitmans Ltd., London, 326 pp.

Book Chapters and Specialty Proceedings Publications

Hrudey, S.E. & E.J. Hrudey. 2009. Prevention is Painfully Easy in Hindsight: Fatal *E. coli* O157:H7 and Campylobacter outbreak in Walkerton, Canada, 2000. Global Issues in Water, Sanitation and Health. Institute of Medicine of the National Academies. National Academies Press. pp. 127-152.

Bradshaw, R.A., Pollard, S.J.T., Jalba, D.I., Charrois, J.W., S.E. Hrudey and N.J. Cromar. 2009. Evaluating cause-effect relationships and impact of incidents – a learning approach for operations and asset management. In: *Water Contamination Emergencies – Collective Responsibility*, Gray, J. and Thompson K.C. (eds.) Royal Society of Chemistry, Special Publication No. 317, pp. 82-116.

Hrudey, S.E. 2006. Fatal Disease Outbreak from Contaminated Drinking Water in Walkerton, Canada. In: *Case Studies in Environmental Engineering and Science*. Eds: A. Bhandari & M.A. Butkus, Association of Environmental Engineering and Science Professors, Champaign, Illinois. pp. 4-18.

Hrudey, S.E. 2006 Waterborne Outbreak of Cryptosporidiosis – North Battleford, Canada. In: *Case Studies in Environmental Engineering and Science*. Eds: A. Bhandari & M.A. Butkus, Association of Environmental Engineering and Science Professors, Champaign, Illinois. pp. 19-34.

Hrudey, S.E. and S. Rizak. 2006. Preventing drinking water emergencies – water quality monitoring lessons from recent outbreak experience In: *Water Contamination Emergencies: Enhancing our Response*. Eds. K.C. Thompson and J. Gray, Royal Society of Chemistry, Special Publication No. 302, pp.42-52.

Pollard, S.J.T., J.E. Strutt, B.H. MacGillivray, J.V. Sharp, S.E. Hrudey and P.D. Hamilton. 2006. Risk management capabilities – Towards 'Mindfulness' for the international water utility sector. In: *Water Contamination Emergencies: Enhancing our Response*. Eds. K.C. Thompson and J. Gray, Royal Society of Chemistry, Special Publication No. 302, pp. 70-80.

Leiss, W. and S.E. Hrudey. 2005 *On Proof and Probability, Introduction to Law and Risk*, Chap 1, 1-19, Law Commission of Canada. University of British Columbia Press and Les Presses de l'Universite Laval, 208pp.

Hrudey, S.E. and E.J. Hrudey. 2004.*Converting Hindsight into Foresight – Understanding the Causes of Waterborne Outbreaks,* Chap. 9 In: *Microbial Waterborne Pathogens*, **Ed**. Cloete, T.E., J. Rose, L.H. Nel and T. Ford. IWA Publishing, London. 205-217..

Hrudey, S.E. **Ed**. 2003. *Drinking Water Safety – A Total Quality Management Approach.* Proc. Inter. Conf. Water & Health, Ottawa, Sept 23-25, 2002, NERAM – IRR, University of Waterloo.476pp.

Hrudey, S.E. 2000. Limits to Science for Assessing and Managing Environmental Health Risks. *Science, Truth and Justice.* Canadian Institute for the Administration of Justice, Les Éditions Thémis. Faculté de Droit. Université de Montréal. ISBN 2-89400-151-7 pp. 127-150

Hrudey, S.E., M. Burch, M. Drikas and R. Gregory. (1999). Remedial Measures. Chapter 9. In: *Toxic Cyanobacteria in Water – A Guide to Public Health Consequences and their Management in Water Resources and Supplies.* **Eds**: I. Chorus and J. Bartram, World Health Organization. E & F.N. Spon. London. 275-312.

Jardine, C.G. and S.E. Hrudey. (1999). "What is Risk?" Chap 17. *Environmental Health For All.* Kluwer Academic Publishers. 205-211.

Jardine, C.G. and S.E. Hrudey. (1999). "Promoting Active Public Particiipation?" Chap 13. *Environmental Health For All.* Kluwer Academic Publishers. 157-168.

Hrudey, S.E. 1998. "Quantitative Cancer Risk Assessment - Pitfalls and Progress." *Issues in Environmental Science and Technology.*Eds. R.E. Hester and R.M. Harrison **9**: 57-90, Roy. Soc. Chem. Pub., Cambridge

Leiss, W. and S. E. Hrudey. (1997). "Dioxins or Chemical Stigmata." Chapter 3. *Mad Cows and Mother's Milk: The Perils of Poor Risk Communication*, **Eds**: D. Powell and W. Leiss. McGill-Queens University Press, pp 41-76.

Hrudey, S.E., Whitfield, F.B. & McGuire, M.J. (1995). **Ed**. "Off-Flavours in Drinking Water and Aquatic Organisms" International Association on Water Quality, Pergamon Press, Oxford, England., 280 pp.

Hrudey, S.E. (1991). "Specific problems in risk analysis and environmental monitoring" In: *Hazardous Waste Incineration Calculations*. **Eds**. Reynolds, J.P., Dupont, R.R. and Theodore, L., Wiley Interscience, pp 31-37, 131-142.

Fedorak, P.M. & Hrudey, S.E. (1988). "Anaerobic Degradation of Phenolic Compounds with Applications to Treatment of Industrial Wastewaters" In: *Biotechnology Applied to Environmental Problems: A. Bioenvironmental Systems* **Ed**. Wise, D.L., CRC Press, pp 169-225.

Vernick, A.S., Langer, B.S., Lanik, P.D. & Hrudey, S.E. (1984). "Petroleum Refining Industry Wastewater Management." Chapter 1. *Surveys in Industrial Wastewater Treatment: Petroleum and Organic Chemical Industries,*, **Vol. 2**, **Eds**. Barnes, Forster & Hrudey, Pitmans Ltd., London, pp 1-64.

Hrudey, S.E. (1984). "Meat and Poultry Products Industry Wastewater Management." Chapter 3. *Surveys in Industrial Wastewater Treatment: Food Processing Industries,* Vol.**1**, **Eds**: Barnes, Forster & Hrudey, Pitmans Ltd., London, pp 128-208.

Smith D.W. and Hrudey, S.E.(1981), **Eds.** "Design of Water and Wastewater Services for Cold Climate Communities", In: *Water Science and Technology.* **13**(supp.) 184 pp., Pergamon Press Ltd., London.

Hrudey, S.E. (1977). General Sampling Techniques, Chapter 1. *Handbook of Air Pollution Analysis,* , **Eds**: R. Perry & R. Young. pp.1-83, Chapman and Hall Ltd., London, J. Wiley & Sons Inc., New York.

Expert Panel Reports

Bruce , J.P., W. Cunningham, A. Freeze, R. Gillham, S. Gordon, S. Holysh, S.E. Hrudey, W. Logan, K. MacQuarrie, P. Muldoon, L. Nowlan, J. Pomeroy, S. Renzetti, B. Sherwood Lollar, R. Therrien. (Expert Panel on Groundwater) 2009. Sustainable Management of Groundwater in Canada. Council of Canadian Academies. Ottawa.

Hrudey, S.E. (Chair), M.J. Allen, R.W. Brecher, R. Copes, P. Turbidity and microbial risk in drinking water. Ministerial Technical Advisory Committee for the Minister of Health pursuant to Section 5 of the Drinking Water Act (S.B.C. 2001).

Swain, H., Louttit, S. and S.E. Hrudey. 2006. Report of the Expert Panel on Safe Drinking Water for First Nations. Minister of Indian and Northern Affairs, Ottawa, November 2006 (Vol. 1 and 2) www.eps-sdw.gc.ca/rprt/index_e.asp

Fazil, A., Paoli, G., Lammerding, A.M., Davidson, V., Hrudey, S., Isaac-Renton, J. and M. Griffiths. 2005. Microbial Risk Assessment as a Foundation for Informed Decision-Making. Microbial Food Safety Assessment Unit, Public Health Agency of Canada, Guelph, ON.

Hrudey, S.E. (Panel Chair), Bathija, A., Bull, R.J., Dodds, L., Jenkins, G., King, W., Murphy, P., Narotsky, M., Reif, J., Savitz, D. and B. Thomas. 2003. Executive Summary. International Expert Workshop for Health Canada to Identify Critical Endpoints for Assessment of Health Risks Related to Trihalomethanes (THMs) in Drinking Water. March 2003.

Langley, A. et al. 2002. *Environmental Health Risk Assessment – Guidelines for Assessing Human Health Risks from Environmental Hazards*. En Health: Department of Health and Ageing. Canberra, Australia.

Callan, P., Cunliffe, D., Howard, J., Hrudey, S.E., Rizak, S., Sinclair, M. and R. Vulcano. 2002. *Framework for Management of Drinking Water Quality – A Total Quality Management Approach from Catchment to Consumer*. (Incorporated into the Australian Drinking Water Guidelines) Working Party to the National Health and Medical Research Council. Canberra, Australia.

Sinclair, M., Bull, R., Froese, K., Hrudey, S.E., Nieuwenhuijsen, M. and S. Rizak. 2002. Disinfection By-Products and Health Effects. Summary of an International Expert Workshop. CRC for Water Quality and Treatment. Occasional Paper No. 5. Salisbury, South Australia.

Adamowicz, V., Dales, R., Hale, B.A. Hrudey, S.E. (**Panel Chair**), Krupnick, A., Lippmann, M., McConnell, J., and P. Renzi. 2001. *Expert Panel to Review the Socio-Economic Models and Related Components Supporting the Development of Canada-Wide Standards for Particulate Matter and Ozone*. The Royal Society of Canada. Ottawa. 240pp.

WHO. 2001. *Meeting on Effective Approaches to Regulating Microbial Drinking-Water Quality*. Adelaide, Australia, 14-18 May 2001.

Yoo, R.S., Carmichael, W.W., Hoehn, R.C. and S.E. Hrudey. 1995. *Cyanobacterial (Blue-Green Algal) Toxins: A Resource Guide*. American Water Works Association Research Foundation. Denver.

Hrudey, S.E., Coutts, R.T., Kratochvil, B., Bernhardt, H., Foley, P.D., Huck, P.M., Logsdon, G.S., Smith, D.W., Snoeyink, V.L., Trussell, A.R., Bull, R.J., Munro, I.C., Payment, P., Rogers, R.E., Tobin, R.S., Toft, P. 1986. *A Critical Assessment of Drinking Water in Edmonton*. Steve E. Hrudey & Associates Ltd. Edmonton.

Hrudey, S.E., Kratochvil, B.G., Markham, J.W., Orford, R.R. and R.K. Shaw. 1983. Scientific Methodology Assessment Committee Report to the Honourable Fred D. Bradley, Minister of the Environment, Government of Alberta. Edmonton. 42 pp.

Refereed Journal Articles:

Published or In Press

156. Jalba, D.I., Cromar, N.J., Pollard, S.J.T., Charrois, J.W.A., Bradshaw, R. & S.E. Hrudey. 2010. Safe drinking water: critical components of effective interagency relationships. *Environ. Int.* 36: 51-59.

155. Hrudey, S.E. 2009. Chlorination disinfection by-products, public health risk tradeoffs and me. [Invited career perspective – peer reviewed] *Water Res.* 43: 2057-2092.

154. Zhou, W.J., J.M. Boyd, F. Qin, S.E. Hrudey & X.F. Li. 2009. Formation of N-nitrosdiphenylamine and two new N-containing disinfection byproducts from chloramination of water containing diphenylamine. *Environ. Sci. Technol.* 43: 8443–8448.

153. Hrudey, S. 2009. Public health wonder or unwitting vector of disease: the challenge of delivering safe water supplies. *Rev. Environ. Sci. Biotechnol.* 8: 235-237.

152. Zhang, W., Gabos, S. Schopflocher, D., Li, X.F., Gati, W.P. & S.E. Hrudey. 2009. Validation of Urinary Trichloroacetic Acid as a Biomarker of Exposure to Drinking Water Disinfection By-Products. *J. Water Health.* 7(3): 359-371.

151. Zhang, W., Gabos, S. Schopflocher, D., Li, X.F., Gati, W.P. & S.E. Hrudey. 2009. Reliability in using urinary and blood trichloroacetic acid as a biomarker of exposure to chlorinated drinking water disinfection by-products. *Biomarkers.* **14**(6): 355-365.

150. Wu, S., Hrudey, S.E., French, S., Bedford, T., Soane, E. and Pollard, S. 2009. A role for human reliability analysis in preventing drinking water incidents and securing safe drinking water, *Water Res.* 43: 3227-3238.

149. Liu, Y., Wang, C., Tyrrell, G., Hrudey, S.E. and X.-F. Li. 2009. Induction of Escherichia coli O157:H7 into the viable but non-culturable state by chloraminated water and river water and subsequent resuscitation. *Environ. Microbiol. Rep.* 1(2): 155-161.

148. Rizak, S. & S.E. Hrudey. 2008. Drinking water safety – challenges for community-managed systems. *J. Water Health.* 6(S1): 33-41.

147. Zhao,Y.-Y., Boyd, J.M., Woodbeck, M., Andrews, R.C., Qin, F. Hrudey, S.E., and X.-F. Li. 2008. Formation of *N*-nitrosamines from eleven disinfection treatments of seven different surface waters. *Environ. Sci. Technol.* 42(13): 4857-4862.

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December 11, 2008

FINDINGS AND RECOMMENDATIONS of the BDCM EXPERT PANEL MEETING SEPTEMBER 22nd and 23rd, 2008

Context:

Health Canada leads the development of the Guidelines for Canadian Drinking Water Quality to establish maximum acceptable concentrations (MAC) of contaminants in drinking water, based on up-to-date scientific and technical information. The Guideline Technical Document for trihalomethanes (THMs) in drinking water, which includes a specific guideline for Bromodichloromethane (BDCM), was published in May 2006. The document establishes a MAC of 0.1 mg/L (100 µg/L) for THMs, as a running annual average of quarterly samples. This MAC is based on the health effects of chloroform, and applies to the total concentration of chloroform, BDCM, dibromochloromethane (DBCM) and bromoform.

The Guideline Technical Document also establishes a MAC of 0.016 mg/L (16 µg/L) for BDCM in drinking water. This MAC is based on a cancer endpoint and is designated as a "not-to-exceed" value as a precaution for potential adverse reproductive effects. Health Canada had used the 1987 NTP study, which used corn oil as a vehicle, as the key study to derive a MAC based on BDCM's carcinogenic potential.

Since the development of the MACs, several new relevant scientific papers have been published on the health effects of BDCM and of THMs. The 2006 NTP study on BDCM used drinking water as the vehicle, and it suggests that BDCM in drinking water may not cause cancer in laboratory animals, which contradicts the findings from the 1987 NTP study. New epidemiological studies have been published on the reproductive effects of BDCM, which are not showing an association between exposure to BDCM and adverse reproductive results.

Consequently, Health Canada has identified a need to review the scientific evidence now available to ensure the approach used to derive the BDCM guideline is still appropriate and to determine whether a MAC specific to BDCM is still necessary and if so, at what level.

As part of this review, Health Canada commissioned three reports (two consultant reports and one internal report) to assess current science. The first report, entitled "*Evaluation of the vehicle effects on the internal dose and carcinogenicity of BDCM based on PBPK modeling and mode-of-action*" (Krishnan, 2008a), examined the NTP 1987 and 2006 data, in addition to the current literature on the potential carcinogenic effects of BDCM exposure. The second report entitled *"Potency estimation for BDCM based on PBPK models"* (Walker, 2008) focussed on the statistical manipulation of the data and modeling to calculate tumorogenic doses (TDs), the increases in tumor rates over background. The final report, *"Cancer dose-response analysis for BDCM"* (Krishnan, 2008b), converted the TDs from Walker's report into human environmental doses using a PBPK model.

These reports were used as a starting point for discussions with experts, which marks the beginning of the review process of this guideline. A panel of experts was convened in September 2008 to provide expert advice and to make recommendations to Health Canada and to the Federal-Provincial-Territorial Committee on Drinking Water (CDW) regarding BDCM in drinking water. Advice was sought from the Expert Panel on three specific issues of concern:

1- Reproductive and developmental toxicity of BDCM;
2- Carcinogenicity of BDCM;
3- Risk assessment approach to develop BDCM guideline.

The Expert Panel reached a consensus on all key issues identified, and its main conclusions and recommendations to Health Canada and the Federal-Provincial-Territorial Committee on Drinking Water on each issue are provided below.

Expert Panel Members:

Linda Dodds, Dalhousie University, Canada
Kannan Krishnan, Université de Montréal, Canada
Rex Pegram, U.S. Environmental Protection Agency, USA
Robert Tardiff, The Sapphire Group, Inc., USA
Richard Bull, Pacific Northwest National Laboratory, USA
John Fawell, Independent Consultant on Drinking Water and Environment, UK

Issue 1: Reproductive and developmental effects

Epidemiological evidence

At the time of the update of Health Canada's Guideline Technical Document on THMs, there was some epidemiological evidence for an association of BDCM exposure with reproductive and developmental effects (i.e., spontaneous abortion). The MAC of 16 µg/L for BDCM in drinking water was based on a cancer endpoint, but identified as a "not-to-exceed" value as a precautionary approach for potential reproductive effects.

Recent evidence, from epidemiological studies with improved protocols and exposure assessment technologies, demonstrates no or inconsistent association for most reproductive or developmental endpoints with BDCM exposure at current levels.

Based on their knowledge of the science at the time of the meeting, the expert panel on BDCM agreed to the following consensus responses to Health Canada's questions:

Question from Health Canada: Does the current weight of evidence from epidemiological studies support an association between adverse reproductive and developmental effects in human and environmental exposure to BDCM?

Response from the Expert Panel: *"Overall, the evidence from epidemiological studies is inconsistent and by international standards, the current weight of evidence is not sufficient to support an association between adverse reproductive and developmental effects in humans and environmental exposures to BDCM.*

Question from Health Canada: Do you know of any new or upcoming studies that could have an impact on the weight of evidence for an association of adverse reproductive and developmental effects in human with environmental exposure to BDCM?

Response from the Expert Panel: L. Dodds identified four groups of studies currently underway whose findings will need to be considered in the future, once they are completed and published:

- Levallois et al.
- U.S. EPA, National Center for Environmental Assessment, Dr. Michael Wright
- Nieuwenhuijsen et al.
- Dodds et al.

Toxicological evidence

As cancer was considered to be the endpoint of concern to derive the 2006 MAC for BDCM, the toxicological effects of BDCM on reproduction and development in animals were not considered in the derivation of the guideline value. In animal models, the adverse reproductive and developmental effects of BDCM were observed only at very high doses and were inconsistent among animal models. Results also varied according to the method of BDCM administration and only limited data explore modes of action for reproductive and developmental toxicity.

Based on their knowledge of the science at the time of the meeting, the expert panel on BDCM agreed to the following consensus responses to Health Canada's questions:

Question from Health Canada: Does the current weight of evidence from toxicological studies support an association between adverse reproductive/developmental effects and BDCM exposure in animals?

Response from the Expert Panel: *"Although BDCM has been shown to cause adverse reproductive effects in animals, these have only been observed at maternally-toxic doses which are 5000 to 15000 times higher than levels found in drinking water. Overall, the current weight of evidence from toxicological studies does not support an association between adverse reproductive/developmental effects and exposure to BDCM at concentrations that occur in chlorinated drinking water.* "

Question from Health Canada: Do you know of any new or upcoming studies that could have an impact on the weight of evidence for an association of adverse reproductive and developmental effects in animals with exposure to BDCM?

Response from the Expert Panel: R. Pegram identified several new studies, that are underway but not yet published, and whose findings will need to be considered in the future:

- Lasley et al., (University of California, Davis). 1. Further analysis of the effect of BDCM on human placental cell differentiation in vitro. 2. Effects of DBP mixtures on human placental cell function in vitro.
- Bielmeier et al., (U.S. EPA). BDCM-induced reduction in LH secretion in the SD rat.
- Narotsky et al. (U.S. EPA). Effects of inhaled BDCM on pregnancy and relevant endocrine functions.

Issue 2: Carcinogenicity

The current guideline for BDCM in drinking water was developed using the 1987 NTP study as the key study, which used corn oil as a vehicle, and found increased tumours in F344/N rats. The 2006 NTP study found no evidence of increased carcinogenic activity of BDCM in male F344/N rats or female B6C3F1 mice when BDCM was administered via drinking water.

Based on their knowledge of the science at the time of the meeting, the expert panel on BDCM agreed to the following consensus responses to Health Canada's questions:

Question from Health Canada: Considering the findings from the new NTP (2006) study and from other recent toxicological data, does the current weight of evidence support BDCM carcinogenicity in animals?

Response from the Expert Panel: *"The evidence from a lifetime study of BDCM given to rodents by corn oil gavage is that it is an animal carcinogen. However, a second NTP lifetime study,*

which tested lower doses of BDCM in drinking water does not support this determination. The combined data from the two studies do not support a linear dose response."

"Some shorter term studies demonstrate the development of aberrant crypt foci in the rat large intestine when BDCM is given in drinking water, which suggests that BDCM may play a role in carcinogenesis."

Question from Health Canada: At the time of the expert panel meeting, BDCM was classified in Group II − probably carcinogenic to humans, with sufficient evidence in animals and inadequate evidence in humans (Health Canada, 1994). Should BDCM still be considered probably carcinogenic to humans?

Response from the Expert Panel: *The NTP 2006 drinking water study diminishes the weight of the evidence that BDCM is "probably" carcinogenic in humans. However, the possibility that a mutagenic mode of action contributes to the carcinogenic effects of BDCM in the intestine cannot be dismissed. Therefore, the Panel concluded that the NTP (2006) data alone are not sufficient to change the classification to "possibly" carcinogenic in humans.*

Issue 3: Risk assessment

BDCM is classified in Group II, "*probably carcinogenic to humans"*, based on sufficient evidence in animals, but insufficient evidence from human epidemiological studies. Because BDCM is considered to be "probably" carcinogenic to humans, the MAC is derived based on the estimated lifetime cancer risk. Health Canada considers a lifetime cancer risk range of 10^{-5} to 10^{-6} to be "essentially negligible". The 2006 guideline was derived using the Linear Multistage [LMS] method of Howe (1995), based on the results from the 1987 NTP key study. The MAC for BDCM in drinking water is considered as a "not-to-exceed" value, rather than an annual average, as a precautionary approach for potential reproductive effects.

Based on their knowledge of the science at the time of the meeting, and on the previous discussions on Issue Sheets 1 and 2, the expert panel on BDCM agreed to the following consensus responses to Health Canada's questions:

Question from Health Canada: Is the current science sufficient to justify re-assessment of the BDCM guideline?

Response from the Expert Panel: "*Sufficient new evidence exists to support the reassessment of the BDCM guideline."*

Question from Health Canada: Given the total THMs MAC, is the individual MAC for BDCM in drinking water still necessary?

Response from the Expert Panel: *"At this time, it is unlikely to be necessary to retain a BDCM guideline, however, the risk assessment needs to be completed."*

Question from Health Canada: Is the overall proposed approach for risk assessment of BDCM based on carcinogenicity appropriate? If not, what do you recommend? Are there any factors/considerations we omitted?

Response from the Expert Panel: "*Carcinogenicity is the key endpoint for risk assessment. The appropriate dose metric is internal dose, and issues related to human metabolism and kinetics need to be considered in the assessment. Two low dose extrapolation approaches should be considered for illustrative purposes (linear vs non-linear). An approach based on carcinogenicity is most likely to be protective of non-cancer health effects including reproductive/developmental effects.*"

Question from Health Canada: Should reproductive and developmental effect be considered as key endpoints when deriving the MAC for BDCM? If yes, which animal model would be appropriate, which key study should be used for reproductive/developmental effects in animals, and what would be the NOAEL?

Response from the Expert Panel: "*Reproductive and developmental effects must be considered in the risk assessment, although they are unlikely to be the key endpoint. Two drinking water studies could be used (Christian et al., 2001 & 2002); each study generated a NOAEL.*"

Question from Health Canada: Should "not-to-exceed" still be applied to the BDCM guideline value to protect the Canadian population against potential adverse reproductive and developmental effects of BDCM in drinking water?

Response from the Expert Panel: "*Since the current weight of evidence does not support the need for a BDCM guideline based on reproductive/developmental toxicity, the concept of "not-to-exceed" for BDCM is no longer applicable.*"

Additional Comments from Expert Panel

Based on their knowledge of the science at the time of the meeting, and on the discussions held during the meeting, the expert panel on BDCM suggested that Health Canada also take into consideration the following comments when updating its Guideline Technical Document:

- *"Water suppliers should keep disinfection by-products as low as possible at all times without compromising disinfection."*
- *"New human data on the absorption of THMs via inhalation and skin contact may need to be considered to further inform the risk characterization."*
- *It was noted that an association between exposure to total THMs and adverse reproductive outcomes may exist.*
- *"It remains important that Health Canada continue to monitor the emerging scientific evidence in order to ensure that the guidelines for DBPs are kept up to date within a reasonable timeframe."*