

III. REFERENCES

This reference list includes all cited references in the Peer Review Panel reports and key references provided to or recommended for the UDP Peer Review Panel.

16 CFR 1500. 2000. Title 16: Commercial Practices. Chapter II. Consumer Product Safety Commission. Part 1500: Hazardous Substances and Articles; Administration and Enforcement Regulations. Government Printing Office, Washington, DC.

29 CFR 1910.1200. 1998. Title 29: Department of Labor. Chapter XVII. Part 1910: Occupational Safety and Health Administration. Subpart Z: Toxic and Hazardous Substances. Section 1200: Hazard Communication. Government Printing Office, Washington, DC.

40 CFR 152. 2000. Title 40: Protection of Environment Agency. Code of Federal Regulations. Part 152: Pesticide Registration and Classification Procedures. Government Printing Office, Washington, DC.

40 CFR 156. 2000. Title 40: Protection of Environment Agency. Code of Federal Regulations. Part 156: Labeling Requirements for Pesticides and Devices. Government Printing Office, Washington, DC.

40 CFR 158. 2000. Title 40: Protection of Environment Agency. Code of Federal Regulations. Part 158: Data Requirements for Registration. Government Printing Office, Washington, DC.

40 CFR 721. 2000. Title 40: Protection of Environment Agency. Code of Federal Regulations. Part 721: Significant New Uses of Chemical Substances. Government Printing Office, Washington, DC.

49 CFR 173. 1999. Title 49: Department of Transportation. Code of Federal Regulations. Part 173: Shippers--General Requirements for Shipments and Packagings. Government Printing Office, Washington, DC.

American Society for Testing and Materials (ASTM). 1998. Standard Test Method for Estimating Acute Oral Toxicity in Rats. ASTM E1163-98. In: Annual Book of ASTM Standards, Philadelphia.

ASTM. 1987. Standard Test Method for Estimating Acute Oral Toxicity in Rats. ASTM E1163-87. In: Annual Book of ASTM Standards, Philadelphia.

BMDP Statistics Software, Inc. 1990. BMDP Statistical Software Manual. W.J. Dixon, Chief Ed. 1990 rev. or later. University of California Press, Berkeley, CA, USA.

Barlow, R.E., D.J. Bartholomew, J.M. Brenner, and H.D. Brunk. 1972. Statistical Inference Under Order Restrictions: The theory and application of isotonic regression. John Wiley & Sons, New York. 388 pp.

Bonnyns, E., M.P. Delcour, and A. Vral. 1988. Up-and-Down Method as an Alternative to the EC-Method for Acute Toxicity Testing. IHE Project No. 2153/88/11. Institute of Hygiene and Epidemiology, Ministry of Public Health and the Environment, Brussels. 33 pp.

Bruce, R.D. 1987. A Confirmatory Study for the Up-and-Down Method for Acute Toxicity Testing. Fundam. Appl. Toxicol. 8: 97-100.

- Bruce, R.D. 1985. An Up-and-Down Procedure for Acute Toxicity Testing. *Fundam. Appl. Toxicol.* 5: 151-157.
- Dixon, W.J. 1991. Design And Analysis of Quantal Dose-Response Experiments (with emphasis on staircase designs). Dixon Statistical Associates, Los Angeles CA, USA.
- Dixon, W.J. 1991. Staircase Bioassay: The up-and-down method. *Neurosci. Biobehav. Rev.* 15:47-50.
- Dixon, W.J. 1965. The Up-and-Down Method for Small Samples. *J. Am. Stat. Assoc.* 60:967-978.
- Dixon, W.J. and A.M. Mood. 1948. A Method for Obtaining and Analyzing Sensitivity Data. *J. Am. Stat. Assoc.* 48:109-126.
- Durham, S.D. and N. Flournoy. 1995. Up-and-Down Designs I: Stationary treatment distributions. In: *Adaptive Designs*; Flournoy, N. and W.F. Rosenberger (Eds.). Hayward, California: Institute of Mathematical Sciences. pp. 139-157.
- Durham, S.D. and N. Flournoy. 1994. Random Walks for Quantile Estimation. In: *Statistical Decision Theory and Related Topics V*; Gupta, S.S. and J.O. Berger (Eds.). New York: Springer-Verlag. pp. 467-476.
- Durham, S.D., N. Flournoy, and A.A. Montazer-Haghighi. 1995. Up-and-Down Designs II: Exact treatment moments. In: *Adaptive Designs*; Flournoy, N. and W.F. Rosenberger (Eds.). Hayward, California: Institute of Mathematical Sciences. pp. 158-178.
- Durham, S.D., N. Flournoy, and W.F. Rosenberger. 1997. A Random Walk Rule for Phase I Clinical Trials. *Biometrics* 53:745-760.
- Ekwall, B. 1999. Overview of the Final MEIC Results: II. The *in vitro/in vivo* evaluation, including the selection of a practical battery of cell tests for prediction of acute lethal blood concentrations in humans. *Toxicol. In Vitro* 13(4-5):665-673.
- Finney, D.J. 1978. *Statistical Methods in Biological Assay*. Griffin, London.
- Finney, D.J. 1971. *Probit Analysis*. 3rd ed. Cambridge Univ. Press, Cambridge, U.K.
- Flournoy, N. 1993. A Clinical Experiment In Bone Marrow Transplantation: Estimating a percentage point of a quantal response curve. In: *Case Studies in Bayesian Statistics*; Gatsonis, C, J.S. Hodges, R.E. Kass, and N.D. Singpurwala (Eds.). New York: Springer-Verlag. pp.324-336.
- Galson, S. 2000. Historical and Current Regulatory Perspectives. Opening Plenary Session, ICCVAM International Workshop on *In Vitro* Methods for Assessing Acute Systemic Toxicity, October 17-20, 2000.
- Griffith, J.F. 1964. Interlaboratory Variations in the Determination of Acute Oral LD50. *Toxicol. Appl. Pharmacol.* 6: 726-730.
- Gross, S.B. April 18, 1989. Memorandum Subject: Comments on standard evaluation procedure. Inhalation Toxicology Testing (SEP/Inhalation).

Gross, S.B. and F.J. Vocci. August 1988. Hazard Evaluation Division Standard Evaluation Procedure Inhalation Toxicity Testing. U.S. EPA-540/09-88-101.

Halle, W. 1998. Toxizitätsprüfungen In Zellkulturen Für Eine Vorhersage Der Akuten Toxizität (LD50) Zur Einsparung Von Tierversuchen. Life Sciences/ Lebens-wissenschaften, Volume 1, 94 pp., Jülich: Forschungszentrum Jülich.

Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). 2001a. Guidance Document on Using *In Vitro* Data to Estimate *In Vivo* Starting Doses for Acute Toxicity. NIH Publication No. 01-4500. National Institute of Environmental Health Sciences. Research Triangle Park, North Carolina. Available: http://iccvam.niehs.nih.gov/methods/invidocs/guidance/iv_guide.pdf [cited October 18, 2001].

ICCVAM. 2001b. Report of the International Workshop on *In Vitro* Methods for Assessing Acute Systemic Toxicity. NIH Publication No. 01-4499. National Institute of Environmental Health Sciences. Research Triangle Park, North Carolina. Available: <http://iccvam.niehs.nih.gov/methods/invidocs/finalall.pdf> [cited October 18, 2001].

ICCVAM. 2001c. The Revised Up-and-Down Procedure: A test method for determining the acute oral toxicity of chemicals. NIH Publication 02-4501. National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina.

ICCVAM. 2000. The Revised Up-and-Down Procedure: A test for determining the acute oral toxicity of chemicals and products. Proposed test method and background review document, April 14, 2000. National Institute of Environmental Health Sciences. Research Triangle Park, North Carolina. Available: <http://iccvam.niehs.nih.gov/methods/udpdocs/AllBRDlk.pdf> [cited October 18, 2001].

ICCVAM. 1999. Evaluation of the Validation Status of Toxicological Methods: General guidelines for submissions to ICCVAM validation and regulatory acceptance of toxicological test methods: A Report of the ad hoc Interagency Coordinating Committee on the Validation of Alternative Methods. NIH Publication 99-4496. National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina. Available: <http://iccvam.niehs.nih.gov/docs/guidelines/subguide.htm> [cited October 18, 2001].

ICCVAM. 1997. Validation and Regulatory Acceptance of Toxicological Test Methods: A report of the ad hoc Interagency Coordinating Committee on the Validation of Alternative Methods. NIH Publication 97-3981. National Institute of Environmental Health Sciences, Research Triangle Park, NC. Available: <http://iccvam.niehs.nih.gov/docs/guidelines/validate.pdf> [cited October 18, 2001].

Jaeger, B. November 1984. Pesticide Assessment Guidelines Subdivision F Hazard Evaluation: Human and Domestic Animals. Office of Pesticide Programs. U.S. EPA.

Jennison, C. and B.W. Turnbull. 2000. Group Sequential Methods with Applications to Clinical Trials. Chapman & Hall/CRC: Boca Raton, FL.

Levitt, H. 1971. Transformed Up-Down Methods in Psychoacoustics. J. Acoustical Soc. America 49:467-447.

Lipnick, R.L., J.A. Cotruvo, R.N. Hill, R.D. Bruce, K.A. Stitzel, A.P. Walker, I. Chu, M. Goddard, L. Segal, J.A. Springer, and R.C. Myers. 1995. Comparison of the Up-And-Down, Conventional LD50, and Fixed-Dose Acute Toxicity Procedures. Food Chem. Toxicol. 33: 223-231.

- Litchfield, J.T., Jr. and F. Wilcoxon. 1949. A Simplified Method of Evaluating Dose-Effect Experiments. *J. Pharmacol. Exp. Ther.* 96:99-113.
- Liu, A. 1997. On the MLE for the Drift of Brownian Motion Following a Symmetric SPRT. *Comm. Statist.-Theory Meth.* 26: 977-989.
- Luttik, R. and T. Aldenberg. Extrapolation Factors for Small Samples of Pesticide Toxicity Data: Special focus on LD50 values for birds and mammals. *Environ. Toxicol. Chem.* 16:1785-1788.
- Mats, V.A., W.F. Rosenberger, and N. Flournoy. 1998. Restricted Optimality for Phase I Clinical Trials. In: *New Developments and Applications in Experimental Designs*; Flournoy, N., W.F. Rosenberger, and W.K. Wong (Eds.). IMS Monograph Series 34:50-61.
- Miller, F.J. (Ed.). 1994. *Nasal Toxicity and Dosimetry of Inhaled Xenobiotics, Implications for Human Health.* Chemical Industry Institute of Toxicology. Taylor & Francis, Washington, D.C. pp. 452-455.
- Mulder, G.J. 1986. Sex Differences in Drug Conjugation and Their Consequences for Drug Toxicity. Sulfation, glucuronidation and glutathione conjugation. *Chem. Biol. Interactions* 57:1-15.
- National Institute of Environmental Health Sciences (NIEHS). 2000a. National Toxicology Program: Request for Data and Nomination of Expert Scientists to Participate in the Independent Peer Review Evaluation of the Revised Up-and-Down Procedure for Assessing Acute Oral Toxicity. Evaluation of the Up-and-Down Procedure. 65 FR 8385. February 18, 2000.
- NIEHS. 2000b. National Toxicology Program: Notice of Peer Review Meeting on the Revised Up-and-Down Procedure (UDP) as an Alternative Test Method for Assessing Acute Oral Toxicity. Request for Comments. 65 FR 35109. June 1, 2000.
- NIEHS. 2001a. National Toxicology Program: The Revised Draft Up-and-Down Procedure for Assessing Acute Oral Toxicity. Notice of Availability and Request for Public Comments. 66 FR 33550. June 22, 2001.
- NIEHS. 2001b. National Toxicology Program: The Revised Draft Up-and-Down Procedure for Assessing Acute Oral Toxicity. Notice of Peer Review Meeting. 66 FR 36294. July 11, 2001.
- Nelson, D.R., L. Koymans, T. Kamatski, J.J. Stegeman, R. Feyereisen, D.J. Waxman, M.R. Waterman, O. Gotoh, M.J. Coon, R.W. Estrabrook, I.C. Gunsalus, and D.W. Nebert. 1996. P450 Super Family: Update on new sequences, gene mapping accession numbers and nomenclature. *Pharmacogenetics* 6:1-42.
- Organisation for Economic Co-operation and Development (OECD). 2001. *Harmonised Integrated Classification System for Human Health and Environmental Hazards of Chemical Substances and Mixture.* OECD Chemicals Committee and the Working Party on Chemicals, Pesticides, and Biotechnology, Series on Testing and Assessment, No. 33. OECD, Paris. 247 pp. Available: <http://www.oecd.org/ehs/class/HCL6.htm>. [cited October 18, 2001].
- OECD. 2000a. *Guidance Document on the Recognition, Assessment, and Use of Clinical Signs as Humane Endpoints for Experimental Animals used in Safety Evaluation*, OECD Environmental Health and Safety Publications, Series on Testing and Assessment, No. 19. OECD, Paris. 44 pp. Available: <http://www.oecd.org/ehs/test/monos.htm>. [cited October 18, 2001].

- OECD. 2000b. OECD Guideline for the Testing of Chemicals, Revised Draft Test Guideline 420, Acute Oral Toxicity - Fixed Dose Procedure. OECD, Paris. Available: <http://www.oecd.org/ehs/test/health.htm> [cited September 12, 2001].
- OECD. 2000c. OECD Guideline for the Testing of Chemicals, Revised Draft Test Guideline 423, Acute Oral Toxicity - Acute Toxic Class Method. OECD, Paris. Available: <http://www.oecd.org/ehs/test/health.htm> [cited September 12, 2001].
- OECD. 2000d. OECD Guideline for the Testing of Chemicals, Revised Draft Test Guideline 425, Acute Oral Toxicity - Up-and-Down Procedure. OECD, Paris. Available: <http://www.oecd.org/ehs/test/health.htm> [cited September 12, 2001].
- OECD. 1998a. OECD Guideline for the Testing of Chemicals, Test Guideline 425, Acute Oral Toxicity - Up-and-Down Procedure. OECD, Paris. Available: <http://www.oecd.org/ehs/test/health.htm> [cited September 12, 2001].
- OECD. 1998b. Harmonized Integrated Hazard Classification System for Human Health and Environmental Effects of Chemical Substances as Endorsed by the 28th Joint Meeting of the Chemicals Committee and the Working Party on Chemicals in November 1998, Part 2, p. 11. Available: <http://www.oecd.org/ehs/class/HCL6.htm>. [updated August 14, 2001 -- see also OECD, 2001].
- OECD. 1996. OECD Guideline for the Testing of Chemicals, Test Guideline 423, Acute Oral Toxicity - Acute Toxic Class Method. OECD, Paris. Available: <http://www.oecd.org/ehs/test/health.htm> [cited September 12, 2001].
- OECD. 1992. OECD Guideline for the Testing of Chemicals, Test Guideline 420, Acute Oral Toxicity - Fixed Dose Procedure. OECD, Paris. Available: <http://www.oecd.org/ehs/test/health.htm> [cited September 12, 2001].
- OECD. 1987. OECD Updated Guideline for the Testing of Chemicals Test Guideline 401, Acute Oral Toxicity. OECD, Paris. Available: <http://www.oecd.org/ehs/test/health.htm> [cited September 12, 2001].
- OECD. 1981. OECD Guideline for the Testing of Chemicals 401: Acute Oral Toxicity. OECD, Paris.
- Robertson, T., F.T. Wright, and R.L. Dykstra. 1988. Order Restricted Statistical Inference, John Wiley & Sons, New York.
- SAS Institute Inc. 1990. SAS/STAT User's Guide. Version 6, Fourth Ed. or later. Cary, NC, USA.
- Salem, H. 1987. Inhalation Toxicology. Research Methods, Applications, and Evaluation. Marcel Dekker, Inc., New York.
- Schlede, E., W. Diener, U. Mischke, and D. Kayser. 1994. OECD Expert Meeting: Acute toxic class method. January 26-28, 1994, Berlin, Germany.
- Schlede, E., U. Mischke, W. Diener, and D. Kayser. 1995. The International Validation Study of the Acute Toxic Class Method (oral). Arch. Toxicol. 69: 659-670.
- Schlede, E., U. Mischke, R. Roll, and D. Kayser. 1992. A National Validation Study of the Acute Toxic Class Method - An alternative to the LD50 test. Arch. Toxicol. 66: 455-470.

- Sheehan P.J., A. Baril, P. Mineau and D. Paustenbach. 1995. Predicting the Effects of Pesticides on Aquatic Systems and the Waterfowl that Use Them. Chapter 30 in Fundamentals of Aquatic Toxicology. Second edition, G.M. Rand (Ed.), Taylor and Francis, North Palm Beach, Florida. pp. 827-857.
- Shiryaev, A.N and V.G. Spokoiny. 2000. Statistical Experiments and Decisions. Statistical inference for autoregressive models of the first order asymptotic theory. Vol 8, chapter 5. World Scientific Publ., London, Singapore.
- Sitter, R.R. and C.F.J. Wu. 1993. Optimal Designs for Binary Response Experiments - Fieller, D, and A criteria. Scandinavian J. Statistics 20:329-341.
- Spielmann, H., E. Genschow, M. Liebsch, and W. Halle. 1999. Determination of the Starting Dose for Acute Oral Toxicity (LD50) Testing in the Up-and-Down Procedure (UDP) from Cytotoxicity Data. ATLA 27:957-966.
- Stylianou, M. 2000. A New Approach to Dose Finding for Phase I Clinical Trials. Dissertation. American University.
- Stylianou, M. and N. Flournoy. 2000. A New Approach to Dose Finding for Phase I Clinical Trials. Technical Report Number 2000-2. Department of Mathematics and Statistics. American University.
- Technical Committee of the Inhalation Specialty Section. 1992. Society of Toxicology Recommendations for the Conduct of Acute Inhalation Limit Tests. Fundam. Appl. Toxicol. 18: 321-327.
- Trevan, J.W. 1927. The Error of Determination of Toxicity. Proc. Royal Soc. 101B: 483-514.
- U.S. EPA. Health Effects Test Guidelines, OPPTS 870.1100, Acute Oral Toxicity. Washington, DC: U.S. Environmental Protection Agency, 1998. Available: http://www.epa.gov/docs/OPPTS_Harmonized/870_Health_Effects_Test_Guidelines/Series/ [cited October 18, 2001].
- U.S. EPA. Health Effects Test Guidelines, OPPTS 870.1300, Acute Inhalation Toxicity. Washington, DC: U.S. Environmental Protection Agency, 1998. Available: http://www.epa.gov/docs/OPPTS_Harmonized/870_Health_Effects_Test_Guidelines/Series/ [cited October 18, 2001].
- van den Heuvel, M.J., D.G. Clark, R.J. Fielder, P.P. Koundakjian, G.J.A. Oliver, D. Pelling, N.J. Tomlinson, and A.P. Walker. 1990. The International Validation of a Fixed-Dose Procedure as an Alternative to the Classical LD50 Test. Food Chem. Toxicol. 28: 469-482.
- van den Heuvel, M.J., A.D. Dayan, and R.O. Shillaker. 1987. Evaluation of the BTS Approach to the Testing of Substances and Preparations for Their Acute Toxicity. Human Toxicol. 6: 279- 291.
- Weil, C.S. 1983. Economical LD50 and Slope Determinations. Drug Chem. Toxicol. 6:595-603.
- Weil, C.S. 1975. Toxicology Experimental Design and Conduct as Measured by Interlaboratory Collaborative Studies. J. Off. Anal. Chem. 58: 683-688.
- Weil, C.S. 1952. Tables for Convenient Calculation of Median-Effective Dose [LD50 or ED50] and Instructions in Their Use. Biometrics 8:249-263.

Weil, C.S., C.P. Carpenter, and H.F. Smyth. 1953. The Median Effective Dose. *Ind. Hyg. Q.* 14: 200-206.

Weil, C.S., C.P. Carpenter, J.S. West, and H.F. Smyth. 1966. Reproducibility of Single Oral Dose Toxicity Testing. *Am. Ind. Hyg. Assoc. J.* 27: 483-487.

Weil, C.S. and G.J. Wright. 1967. Intra- and Interlaboratory Comparative Evaluation of a Single Oral Test. *Toxicol. Appl. Pharm.* 11: 378-388.

Whalan, J.E. and J.C. Redden. Interim U.S. EPA Policy for Particle Size and Limit Concentration Issues in Inhalation Toxicity Studies.

Woodroffe, M. 1982. Nonlinear Renewal Theory in Sequential Analysis. BMS-NSF Regional Conference Series in Applied Mathematics 39, Section 1.3. SIAM.

Yam, J., P.J. Reer, and R.D. Bruce. 1991. Comparison of the Up-and-Down Method and the Fixed-Dose Procedure for Acute Oral Toxicity Testing. *Food Chem. Toxicol.* 29:259-263.

Zbinden, G. and M. Flury-Roversi. 1981. Significance of the LD50 Test for the Toxicological Evaluation of Chemical Substances. *Arch Toxicol.* 47: 77-99.

