TASK DESCRIPTION

Task 1. Acquire and evaluate the most recent cancer data available on vinyl chloride.

a. Perform literature search
b. Contact OHEA at EPA and the Department of Health Services in California to determine what activities they have ongoing and obtain data they may have on the quantitative cancer assessment of vinyl chloride.
c. Evaluate the data and determine the appropriateness of the currently accepted potency values.

Task 2. Review the air dispersion model and results, to be supplied by Vista Chemicals, and investigate the population dynamics of the area potentially at risk to vinyl chloride emissions.

a. Determine whether the appropriate model was used and whether the results are correct. (Note: If the appropriate model was not used, an appropriate model should be selected and run. This will ensure that the most accurate ground level concentration values for vinly chloride are calculated.)

Task 3. Using information from Tasks 1 and 2, determine cancer risk values at the fenceline and beyond, and if possible the expected number of cancer cases expected per year above background to the population in the plant vicinity.

Task 4. Prepare an assessment report based on the results in Tasks 1-3.

a. Draft report to be completed by the end of the second week of October, 1990. At least one contact with Vista staff is in order to keep you informed and also to obtain your input into the development of the draft assessment report
b. Finalize the assessment report after obtaining input/approval from Vista Chemical staff.

COSTS

Task 1: $3,000
Task 2: $3,000 (this does not include the cost of rerunning the model)
Task 3: $2,000
Task 4: $3,500

Note: All other direct costs including transportation, lodging, long distance calls, equipment usage, and other direct expenses normally billed to our clients will be invoiced at cost.

DAVID R. PATRICK, P.E.

EDUCATION

B.S., Chemical Engineering, Georgia Institute of Technology (1962)

PROFESSIONAL REGISTRATIONS AND CERTIFICATIONS

Professional Engineer, North Carolina (1969)

EXPERIENCE

Mr. Patrick joined Clement Associates Inc. in 1986 as a Project Manager. Mr. Patrick has over 27 years of professional experience in project management, environmental regulation and risk assessment. For over 10 years he engaged in industrial sector research and development on new hazardous chemicals and chemical production processes. Mr. Patrick then spent over 15 years with the Environmental Protection Agency (EPA) in program and project management responsible for analysis, control and regulation of air pollution, with emphasis on hazardous and toxic air pollutants and industries and processes that manufacture and use organic chemicals. He currently is a Project Manager for Clement Associates and conducts multi-media risk assessments and engineering studies. He has supervised as many as 30 people and directed programs with budgets well in excess of $1 million per year.

PROJECT MANAGEMENT

- For Clement Associates, Mr. Patrick manages air pollution and waste management public health evaluations and environmental risk assessments. Recently, he has managed a number of private client engineering and risk assessment projects. Noteworthy projects included the assessment of the risks of burning hazardous wastes in a cement kiln located in a large metropolitan area; evaluating the community risks associated with exposure to emissions from paint spraying operations at a large automotive assembly plant; assessment of the risks associated with exposure to emissions from a large Pacific Northwest aluminum smelter; and development of health assessment and regulatory support material for several chemical plants and trade associations.

- In addition to these technical projects, Mr. Patrick manages a numeber of policy related projects, including the preparation of guidance and support information for EPA's toxic air pollution program and conducting training courses on understanding and implementing sections of the emergency response and community right to know provisions of the Superfund Amendments and Reauthorization Act (SARA) of 1986.

- Prior to joining Clement Associates, Mr. Patrick spent 15 years with the EPA's Office of Air and Radiation in a variety of project management positions. He managed groups up to 30 in number in developing and promulgating air pollutant standards and directing air pollution sampling and analytical technique research and

DAVID R. PATRICK, P.E.

EXPERIENCE (cont.)

development, including field stack test and R&D laboratory supervision. He later directed a major $4 million study of the potential for and control of air pollution from the organic chemical manufacturing industry. For 2 years, he was responsible for the proposal and promulgation of all of EPA's stationary source air pollution regulations and for 6 years for EPA's policy and strategy development activities related to toxic and hazardous air pollutants.

AIR POLLUTION REGULATION AND ENGINEERING

- Mr. Patrick spent 15 years with the Office of Air Quality Planning and Standards in EPA, where he was involved in all aspects of air pollution control, evaluation, and regulation. In his early years with the Agency Mr. Patrick developed and promulgated the Agency's first hazardous air pollutant standards. He then was in charge for 2 years of all stationary source air pollution sampling equipment and analytical technique development, and he supervised a research and development laboratory. In this capacity, Mr. Patrick became familiar with all types of sampling equipment and analytical techniques for air pollution. Following several years conducting special engineering studies, he served as the Branch Chief responsible for the proposal and promulgation of stationary source air pollution regulations and, in his final 6 years in the Agency, served as Branch Chief responsible for all EPA activities on toxic and hazardous air pollutants. Mr. Patrick is thoroughly familiar with the Clean Air Act and all aspects of the analysis, control, measurement and regulation of air pollution. He was an Assistant to EPA's Deputy Assistant Administrator for Air and Radiation when he left EPA.

RISK ASSESSMENT/RISK MANAGEMENT

- Mr. Patrick was at the forefront in developing EPA's risk assessment/risk management process. For example, he managed for six years all risk assessment activity on toxic air pollutants for EPA. He also was an original member of EPA's Risk Assessment Forum, an internal Agency scientific forum established to develop new risk assessment methodologies and present them to Agency management, and a member of the Task Group that developed EPA's Risk Assessment Guidelines (published in 1986).

- Mr. Patrick currently is a Project Manager in Clement Associates Risk Assessment Division and directs numerous risk assessment activities, including a number of multi-media assessments. Current projects include risk assessments for a large automotive paint spraying operation, an aluminum smelter, and an electric utility located adjacent to a municipal incinerator.

DAVID R. PATRICK, P.E.

EXPERIENCE (cont.)

POLICY DEVELOPMENT

- Mr. Patrick had extensive policy related experience while with EPA For example, he was a member of the team that developed EPA's Air Toxics Strategy and chaired a long range planning committee for air toxics. He also represented EPA's air office on numerous agency planning and working groups implementing CERCLA, SARA, RCRA, TSCA, CWA, and SDWA.

- Since joining Clement Associates, Mr. Patrick has also conducted policy related projects for EPA and DOE. These include support to EPA's Office of Air Quality Planning and Standards in developing the toxic air pollutant program and support to the Office of Air and Radiation in preparing the Report to Congress on Indoor Air Pollution.

ENVIRONMENTAL REGULATION

- Although he is most knowledgeable in the Clean Air Act, Mr. Patrick also has extensive experience in the implementation of other environmental regulation. In particular, he served on internal EPA Working Groups charged with implementing CERCLA, RCRA, TSCA and CWA. His responsibility was to become familiar with the other Agency laws and to assure that the actions taken under those acts coordinated properly with the goals and regulations under the Clean Air Act. Mr. Patrick serves as a focal point within Clement Associates for air pollution related matters because of his extensive background in this field.

- Mr. Patrick also has extensive experience with the process for developing, proposing, and promulgating Federal environmental regulations. While with EPA he both participated in and managed the preparation of environmental regulations.

- He also has interfaced with and supported State and local pollution control agencies in preparing and defending environmental regulation. As part of this he had management responsibility while at EPA for the development of the National Air Toxics Information Clearinghouse, an EPA service to State and local Agencies as well as others.

ENVIRONMENTAL AUDITS

- Mr. Patrick currently leads environmental audit teams in evaluating the potential environmental liabilities associated with property transactions. Recent audits range from large industrial facilities to small commercial enterprises. These audits make excellent use of Mr. Patrick's strong background in hazardous waste, water pollution, toxic substances and air pollution.

DAVID R. PATRICK, P.E.

PROFESSIONAL AFFILIATIONS

Air and Waste Management Association (formerly the Air Pollution Control Association)
-Chairman of the Intercommittee Task Force on Air Toxics
-Member of Technical Council
American Institute of Chemical Engineers
Society for Risk Analysis

AWARDS

EPA Silver Medal, awarded December 1985, in recognition of outstanding managerial leadership and initiative in publishing twenty regulatory decisions on toxic air pollutants between May 1984 and October 1985.

SELECTED PUBLICATIONS AND PRESENTATIONS

Served for 6 years as EPA's principal spokesperson on air toxics by giving speeches, lectures and workshops, and being interviewed for publication and television.

Gave keynote technical address at Air and Waste Management Association (formerly the Air Pollution Control Association) convention in San Francisco, 1985.

Chaired initial plenary session on Toxic Air Pollution at Air and Waste Management Association convention in Minneapolis, 1986.

Member of the EPA team that participated in Tacoma, Washington, in 1983 with citizens, regulatory officials, medical advisors and the press in communicating information on the cancer risks associated with releases to the air from a local industry. The series of meetings have been preserved in video tape as an exemplary example of risk communication for the Agency.

Has briefed Congressional staff and prepared testimony for Congressional hearings.

Won Toastmaster's International Serious Speech contest for State of Utah, 1967.

PETER E. VOYTEK

EDUCATION

1963	B.A., Chemistry, University of Vermont
1969	PhD., Biochemistry, University of Vermont
1980	Program in Environmental Policy and Management, Harvard University

POSITIONS AND AFFILIATIONS

Senior Science Advisor and Vice President, Clement International

Consultant to the Center for Environmental Health and Human Toxicology, affiliated with Georgetown and George Washington Universities

Guest research scientist, Laboratory of Molecular Microbiology, NIAID,NIH

Member of the Senior Executive Service, Acting Deputy Director of EPA's Office of Health and Environmental Assessment; Director of EPA's Reproductive Effects Assessment Group

Senior toxicologist/Pharmacologist and Science Advisor to the Deputy Assistant Administrator for the Office of Toxic Substances, EPA

Senior Toxicologist in the Criteria and Standards Division, Water office, EPA

Senior Research Fellow at NIEHS, NCI, NIH

Research Associate/Instructor Department of Pharmacology, Yale University

AWARDS

Selected into the Federal government senior executive service 1980, EPA.

Bonus for Outstanding Achievement, 1980.

NSF undergraduate summer grant for research in Physical Chemistry 1962.

SOME EXAMPLES OF MANAGEMENT EXPERIENCE

Was responsible for EPA's risk assessment program for Genetic, developmental and reproductive effects. This involved directing a group of senior scientists responsible for the development of Agency Guidelines and for conducting and overseeing all risk assessments related to mutagens and reproductive--developmental toxicants. These assessments were used to make policy decisions in regulating environmental toxicants.

Forty six assessment documents were written by the group of which many were published in scientifically peer reviewed journals.

Was responsible for initiating new health research directives for the Agency in cancer, mutagenicity, and reproductive research, and was assigned by the Assistant Administrator to develop an overall future health research strategy for the Agency.

As director, dealt directly with other government agencies, special interest groups, and the public on risk assessment policy issues.

Answered congressional inquiries for my own office, the EPA Assistant Administrator, Deputy Administrator, and Administrator dealing with health issues.

Testified on health issues at congressional hearings and dealt with the press on issues regarding health risk assessments for genetic diseases and other reproductive effects matters.

Interacted with other federal agencies (e.g., was the chairperson for the Interagency Regulatory Liaison Group which was made up of members from FDA, CPSC, USDA, EPA, and OSHA. A few other members were taken from non-regulatory agencies also).

Was the scientist of a five-membered team in 1977 that was responsible for setting up the Premanufacture Notice Division for screening new chemical substances under Section 5 of TSCA.

PROFESSIONAL SOCIETIES

Elected as a member of the American Society for Biochemistry and Molecular Biology in 1976.

Elected as a member of the American Association for Cancer Research in 1980.

Member of the American College of Toxicology and Editorial Board for the Journal of the College of Toxicology, 1984.

SOME PROFESSIONAL ACTIVITIES

Formed and chaired a workgroup made up of 15 noted expert scientists from government, academia, and industry which addressed toxicological testing requirements and risk assessments for new chemical substances under Section 5 of the Toxics Substance Control Act, 1978.

Invited participant representing EPA in the national subchronic toxicity workshop, 1979.

Selected to participate in EPA's Congressional Briefing Conference, 1979.

Organized and operated a workshop on reproductive effects. This lead to the publication of the Workshop proceedings, 1980-81, which played a major role in EPA being the first regulatory agency to publish guidelines for developmental and reproductive effects.

Selected to represent EPA on the genetic Toxicology Group on genetic risks conducted by the National Academy of Science, 1981.

Member ofthe Steering Committee for the Intergovernmental Colloquia on Environmental Sciences organized by Brookhaven National Laboratory and Associated Universities, Inc., 1981.

Thesis Advisor in genetics, George Washington University--Examination of physical/chemical changes and enzymatic activities in a mammalian enzyme that has been chemically mutated whose function is involved in the synthesis of DNA. Student successfully defended his doctorate thesis in February 1982.

Cochaired and organizer a teaching workshop on Genetic Damage Tests and Their Uses for Regulatory Action. Sponsored by the College of Toxicology, 1982.

Chaired and organized a workshop made up of scientists from government, academia, and industry on Biological Effects Monitoring held at the National Academy of Sciences. This workshop lead to a publication and to the Agency creating a laboratory center for biological effects monitoring, 1982.

Member of the Steering organization committee for the 5th Annual Rocky Mountain Center for Occupational and Environmental Health Conference, 1982.

Chaired the planning committee for an international symposium on human and animal aneuploidy caused by chemical and physical agents. This symposium was published as a book, 1984.

PUBLISHED ARTICLES

Voytek, P., Gjessing, E.C.: Studies of an anionic trypsinogen and its active enzyme from procine pancreas. J. Biol. Chem. 246:608-516

Voytek, P., Chang, P., and Prusoff, W.H.: Purification of Deoxythymidine Kinase by Preparative Disc Gel Electrophoresis and the Effects of Various Halogenated Nucleoside Triphosphates on Its Enzymatic Activity. J. Biol. Chem. 246:1432-1438, 1971

Voytek, P., Chang, P., and Prusoff, W.H.: Kinetic and photochemical studies of 2-N-methyl 5 iode 2 deoxyuridine and other halogenated analogs of thymidine. J. Biol. Chem. 247:367-372, 1972

Voytek, P.: Conversion of an analytical polyacrylamide gel electrophoresis apparatus into a small preparative electrophores apparatus. Anal. Biochem. 47:879-899, 1972

Goz, B., and Voytek, P: Arginyl-tRNA protein transferase in cultured mammalian cells: properties of the enzyme and characterization of endogenous acceptor proteins by analytical acrytical acrylamide gel electrophoresis. J. Biol. Chem. 247:5829-5897, 1972

Voytek, P., Cysck, R., and Prusoff, W.H.: Photopharmocology of halogenated deoxyribonucliosides. Adv. Antimicrobial Antiplastic Chemotherapy. 2:329-331, 1972

Weisberg, J., and Voytek, P: Liver and red cell porpholbilinogen synthatase in the adult and fetal guinea pig. Biochm. Biophys. Acta 364:304-319, 1974

Voytek, P.: Purification of thymidine phosphorylase and its photoinactivation in the presence of thymine and some halogenated analogs. J. Biol. Chem. 75:3660-3665, 1974

Ku, K., Moustafa, L., and Voytek, P.: Induced DNA repair synthesis by ultraviolet radiation in mature mouse ocytes arrested in metaphase II. International Research Communications System. 3:607, 1975

Clive, D., and Voytek, P.: Evidence for Chemically-Induced Structural Gene Mutations at the Thymidine Kinase Locus in Cultured Gene L5178Y Mouse Lymphoma Cells. Mutation Research. 44:269-278, 1977

Voytek, P., Beisler, J. Driscoll, J., and Wolpert-DeFilippes, M.K.: Studies on the cytotoxic action and metabolism of 5,6-dehydro-azacytidine and 5-azacytidine in L1210 mouse cells. Cancer Res. 37:2956-1977

Futterman, B., Wolpert-DeFilippes, M.N., and Voytek, P.: Inhibition of HeLa cell growth by 5-azacytidine and 5,6-dehydro-5-azacytidine in combination with the potent cytidine decaminase inhibitor, 3,4,5,6-tetrahydrouridine, Biochemical Pharmacology. 27:907, 1978

DiAugustine, R.P., Abe, T., and Voytek, P.: Purification and comparative properties of the glycoprotein NAD glycohydrolase from rat liver microsomal and plasma membranes. Biochem. Biochem. Biophs. Acta. 526:518, 1978

Linnoila, I., Abe, T., Voytek, P., and DeAugustine, R.P.: The coupling of putrescine and other amines to endogenous acceptors and evidence for the cross-linking of endogenous proteins by transglutaminase. Biochemical Pharmacology 28:1601-1608, 1979

Voytek, P.: Aspects of Risk Assessment Strategies, From Assessment of Health Effects At Chemical Disposal Sites, proceedings of a symposium held on June 1-2, 1981, at the Rockefeller University, New York City, edited by W., Lowrance, copyrighted and published by the Rockfeller University 148-162, 1981

Voytek, P.: Policy and Procedure for Using Mutagenicity Data in Assessing genetic Risk. In Genetic Toxic Effects of Airborn Agents. Edits by R.R. Tice, D.L. Coota, and K.M. Schiach. Environmental ScienceResearch, Vol. 25, 1982.

Jackson, E., Fowle, J.R., Voytek, P.E. (1983). Some research needs to support mutagenicity risk assessments from whole mammal studies. In: DeSerres, F.J., Sheridan, W. (eds), Whole mammal mutation studies. Plenum, New York. Pp. 53-68

Christian, M., and Voytek, P.: In vivo reproductive and mutagenicity test. In Guide to General Toxicology. Edited by F. Humberger, J. Hayes, and E. Pelican. 1983

Voytek, P.: Approaches for Regulating for Regulating Mutagenic Agents. In the Proceedings of the University of Utah's Rocky Mountain Center for Occupational and Environmental Health 1983

Voytek, P.: Genetic Monitoring in Man: The Environmental Point of View: Inthe Toxicology Forum 1983 Annual Summer Meeting, Given Institute of Pathobiology , Aspen Colorado. Pages 217-222, and 378-387

Russell, L.B., Aaron, S., deSerres, F., Generoso, W.M., Kannan, K.L. Shelby, M., Springer, J., and Voytek, P.: Evaluation of Existing Mutagenicity Bioassays for Purposes of Genetic Risk Assessment. Mutation Res. 134:143-157

Dellarco, V.L., Voytek, P.E., Hollaender A., (eds). Aneuploidy: etiology and mechanisms. Plenum, New York (1985)

Voytek, P.E. (1985). Introduction to Aneuploidy: Etiology and Mechanisms. Edited by Dellaro, V.L., Voytek, P.E., Hollaender, A. Pp. 1-7. In: Aneuploidy: Etiology and Mechanisms. Plenum, New York. 1985.

Clegg, E.D., Sakai, C.S., Voytek, P.E. 1985. Reproductive risk assessments. Biology of Reproductive 34:5-16. 1986.

Voytek, P., and Kozak, C. HoMuLV: A Novel Pathogenic Ecotropic Virus Isolated form the European Mouse, Mus hortulanus, Virology 165:469-475. 1988.

Kozak, C., Villar, C.J., and Voytek, P: Genetic Aspects of Viral Oncogenesis in Wild Mice. Critical Reviews in Oncogenesis 1:127-143, 1989.

Voytek, P., and Kozak. Molecular Characterization of a Novel Pathogenic Ecotropic virus Isolated from Mus hortulanus. Accepted for Publication in Virology. 1989.

Voytek , P., Anver, M. and Thorslund, T. Mechanisms of Asbestos Carcinogenicity. Accepted for publication in the "Journal of the American College of Toxicology." 1990.

Voytek, P. and Thorslund, T. Benzene Risk Assessment: Status of Quantifying the Leukemogenic Risk Associated with Low Dose Inhalation of Benzene. Accepted of publication in "Risk Analysis." 1990.

Ryer-Powder, J. and Voytek, P. Review of the Health Effects of Exposure to Chronic Levels of Ammonia. (in preparation), 1990.

SOME RECENT ACTIVITIES (DOCUMENTS)

1. Quantitative re-evaluation of the human leukemia risk associated with inhalation exposure to benzene (final report-1989)

2. Summary of the workshop on the evaluation of empirical and biologically based dose response models for inhaled benzene induced leukemia (final report-1989)

3. Weight of evidence considerations for the carcinogenic potency of isophorone (final report-1989)

4. Use of the two stage model for estimating the carcinogenic risk of DEHP (draft reports-1989)

5. Derivation of improved relative potency estimates for PAHs (draft report-1989)

6. Health effects assessment of ammonia (draft report-1989)

7. Molecular aspects of asbestos carcinogenicity (final report, 1990)

8. Determination of the Inhalation RfD for Ammonia for systemic and Portal of Entry Effects (draft report, 1990)

SOME INVITED SYMPOSIUM SPEAKER ENGAGEMENTS

Voytek, P.: Enhances photoinactivation of thymidine phosphorylase by halogenated reactants accompanied by changes in physical properties of the enzyme. Presented at the International Symposium on Protein and other Adducts to DNA, May, 1975.

Voytek, P.: Biological adducts of RNA and DNA with polycyclic hydrocarbon epoxides. Fall Meeting of American Society for Pharmacology and Experimental Therapeutics. August, 1976.

Voytek, P.: Use of Genetic Data for Assessing Genetic Risk. Second Annual Meeting of the American College of Toxicology. December 1980.

Voytek, P.: Approaches to assessment of mutagenic Risk as a consequence of exposure to Environmental Chemicals. Genetic Toxicology Association. May, 1981.

Voytek, P.: Guidance for solid waste site disposal health assessments. The Rockefeller University Symposium on Criteria for Assessment of Health Effects and Chemical Disposal Sites. June, 1981.

Voytek, P.: Status of Reproductive Toxicity for Use in assessing human risk. Reproductive Workshop Symposium sponsored by The American College of Toxicology. December, 1981.

Flamm, W.G. and Voytek, P.: Co-Moderators for the Joint Symposium of the Society of Toxicology and Environmental Mutagen Society on the "The Role Today for Mutagenicity Testing in The Safety Evaluation of Chemicals." February, 1982.

Voytek, P.: Regulatory Needs and Concerns. National Institute of Environmental Health Sciences' Conference on utilization of Mammalian Specific Locus Studies in Hazard Evaluation and The Estimate of Genetic Risk. March, 1982.

Voytek, P.: Lecturer, Workshop on Mutagenicity nd Carcinogenicity Testing. Sponsored by the United Nations Environmental Programme. World Health Organization-Nairobi, Kenya. 1/24-2/5/83.

Voytek, P. and Christian, M.: Co-sponsors for Teaching Symposium of Reproductive Toxicology Testing. Fall 83' Meeting of the College of Toxicology.

Voytek, P. and Flamm, G.: Regulation Considerations of Mutagenicity Studies. Satellite Environmental Mutagen Society Meeting on Mutagenicity Studies: Three Areas of Industrial Concern. Sponsored by the University of Texas Medical Branch, Galveston. March 1-2, 1983.

Voytek, P.: Approaches for Regulatory Mutagenic Agents; Assessment of Reproductive and Genetic Monitoring in Occupational Settings. Symposium on "Reproduction The New Frontier in Occupational and Environmental Health Research." Sponsored by the University of Utah and NIOSH Sponsored Educational Resource Center. 4/5-4/8/83.

Voytek, P.: Invited speaker at the Summer Toxicology Forum for the Testing of Chemical Carcinogens/Mutagens, held 6/27-7/1/83.

Invited Symposium Speaker on Asbestos Carcinogenicity sponsored by the Risk Analysis Society, May, 1990.

SOME AREAS OF SCIENTIFIC INTEREST AND EXPERTISE

1. Protein purification (column purification procedures, isoelectric focusing, analytical and preparative electrophoresis, etc.)
2. Enzyme inhibition and kinetics.
3. Antimetabolite research.
4. DNA repair synthesis - mutation studies.
5. Interaction of chemical carcinogens and mutagens with DNA.
6. Studies on cell toxicity in tissue culture systems.
7. Synthesis, metabolism and identification of pyrimidine analogs using HPLC in cell systems - elucidation of the cytotoxic mechanisms of antimetabolites.
8. Influence of radiation on the function of macromolecules in the presence of sensitizers.
9. Effects of ionizing radiation and alkylating agents on mammalian embryonic processes.
10. Analysis of interspecies metabolic processes.
11. Determination of sensitive individuals to cancer.
12. Molecular cloning in bacterial and mammalian cells.
13. DNA purification procedures.
14. Restriction mapping.
15. DNA sequencing.
16 Induction of viral disease in mice.

17. Modelling of cancer mechanisms of action for determining dose response relationships