THE UNIVERSITY OF ALABAMA IN HUNTSVILLE
SCHOOL OF PRIMARY MEDICAL CARE

FINAL REPORT
ENVIRONMENTAL CONTROL
MEDICAL SUPPORT TEAM

Submitted To:

Space Station Development Project Office
George C. Marshall Space Flight Center
National Aeronautics and Space Administration
Marshall Space Flight Center, AL 35812

Prepared By:

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and

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Technical Studies Coordinator,
Consortium for the Space Life Sciences

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INTRODUCTION

This report summarizes the activities conducted in support of the Environmental Control and Life Support Team during December 7, 1987 through September 30, 1988. The majority of the ongoing support has focused on the ECLSS area. Through a series of initial meetings with the ECLSS team and technical literature review, an initial list of critical topics was developed. These were prioritized by Dr. Randy Humphries' group. Subtasks were then identified or additional related tasks received as action items from the ECLSS group meetings and the team worked to provide the required information.

Although most of the efforts during this period were focused on providing MSFC personnel with information regarding specific questions and problems related to ECLSS issues, other efforts regarding identifying an ECLSS Medical Support Team and constructing data bases of technical information was also initiated and completed. Each of the specific tasks are discussed in the following Section.

SPECIFIC TASKS

1.0 Determine areas of need where medical consideration and design requirements interface.

Through a series of meetings with the ECLSS team and technical literature review, an initial list of critical topics was produced. These were prioritized by Dr. Randy Humphries' group and structured as an outline. Sub-tasks were then identified, and the team worked to provide the required information. The working outline that was developed is presented in Appendix A. The original prioritized tasks are presented below:

- Provide support to the mechanical design and integration of test systems as related to microbiological concerns.
- Assist with design of Human Subjects Test Protocols
- Interpretation and recommendations pertaining to air/water quality requirements
- Assist in determining the design specifications required as related to the Technical Demonstration Program
- Develop data base of all microorganisms recovered from previous subsystem testing
- Estimates of health risk of individual microbes to test subjects
- Assist with setting limits for safety of test subjects
- Health monitoring of test subjects

- o Assist in the preparation of test plans
- o Assist in the development of a QA/QC program to assure the validity, accuracy and precision of the analyses
- o Assist in developing test plans required for future "man in the loop" testing

2.0 Assemble Support Team

As the specific ECLSS questions were delineated, team members were recruited and the tasks were assigned. There was initial discussion with members of the Colleges of Science, Engineering, Nursing, Liberal Arts, and the School of Primary Medical Care as well as the Johnson Research Center within the University of Alabama in Huntsville. Contacts were also made in the Physiology Departments of the University of Alabama in Birmingham (UAB) and Vanderbilt University. In addition, further contacts have been made from the School of Biostatistics and Biomathematics at UAB, the Athletic Drug Testing Laboratory located at Vanderbilt University, the Space Research Center located at Texas A & M University and the Botany and Microbiology Department at Auburn University. Because the primary focus at this point is environmental microbial control, the personnel utilized during this period have been expert in this area.

With the past experience of these efforts in hand, a primary Medical Support team can be defined which can offer the general expertise required by the MSFC Environmental Control/Life Support team for future efforts. A brief description of the key positions is provided below:

Family Physician

The majority of medical questions arising from life support design cross traditional speciality barriers and require a systems approach. The modern specialist in Family Medicine is broadly trained in abnormalities of all organ systems, unconstrained by patient age or gender. In addition, Family Practice training includes extensive exposure to medical care as a systems issue as well as the interactions of the physical and social environment in an individual's health, performance and illness. The family physician will monitor the team's activities and provide the necessary general perspective to keep the group on target.

Environmental Health Physician

Many of the health concerns of ECLSS testing and operation are similar to ground based occupational and environmental health needs. The team member most qualified to address these issues must have training beyond the M.D. degree to include a Master's Degree or equivalent in Public Health or Occupational Medicine. This physician will become intensely involved in hardware design, integration, and operation, and will review each step for health and safety concerns.

Technical Studies Coordinator

Successful completion of many of the necessary tasks will require supplemental and adjunct activities of a variety of technical and professional personnel. This might include literature searches, laboratory based research and verification, or support to problem understanding and proposed resolutions. The technical studies coordinator will be responsible for the coordination and supervision of technical personnel. In addition, he will be responsible for the timely completion of all required sub-tasks delegated to technical and specialized personnel. The technical studies coordinator must be versed in chemistry, microbiology, toxicology, ECLSS hardware and operation as well as have a basic understanding of medical issues.

Environmental Toxicologist

A large portion of the Phase III test activities will involve the operation and performance evaluation of ECLSS hardware. A major concern of these test activities involve the safety and health maintenance of the test subjects involved. The environmental toxicologist will play a major role in the identification of health and safety concerns of the test subjects and in addition provide valuable information regarding the detection and identification of chemical and microbial contamination of the waste and product streams associated with the ECLSS.

Chemist

The methods of detection and identification of chemical contaminants will be of upmost importance to both the performance evaluation of the ECLSS hardware and the verification of water quality. An individual versed in chemical and instrumental methodology will provide the necessary inputs required for the establishment of test plans, verification of laboratory performance and assurance of test subject safety.

Microbiologist

Many of the non-medical questions which arise are related to microbiology. For this reason, it is important to have knowledgeable representation in this field with direct experience in enumeration, detection and identification of environmental as well as medically significant microorganisms. In addition, microbiologists will play important roles in the establishment of test plans and microbial control options for the ECLSS test bed.

Information Management

The large volume of scientific and technical information requires electronic collation to facilitate interpretation and information transfer. In addition, integration of sub-component reports to complete task reports will require extensive technical merging and editing. The information specialist is responsible for these activities as well as other support functions such as interfacing with contract and support personnel, preparing and delivering presentations, and coordinating and facilitating information searches.

Specialized Professionals

Because of the diversity of the potential problems which might arise during the course of the Phase III activities it will be essential to call upon specialized individuals to answer and provide insight to particular questions. These individuals, although not be needed on a full time basis, may be called upon at any time for the resolution of specific tasks. Below are some experts identified at this time.

Toxicologist/Pharmacologist
Filtration and Separation
Instrumental Design
Biostatistician

The resumes of the current team members are included in Appendix B.

3.0 Construct Data Base of Background Technical Information

At the present time, over 500 individual articles have been manually classified. This information was computerized, and is continually updated as further information is produced by the regular literature searches. A current listing of these articles is presented in bibliography format with the abstracts (if available) in Appendix C. In addition, a bibliography produced by the National Library of Medicine that provides ready access to many of the important subject headings is included in Appendix D.

4.0 Provide Ongoing Technical Support to Development Project Office

The majority of this ongoing support has actually focused in the ECLSS area, with regular contacts with Dr. Humphries' Team. Periodically, action items would be delegated to the UAH Medical Support Team. Oftentimes, these action items were specific topics within a general topic area initially defined as high priority. Presented in Appendix E is the current information obtained and recommendations for the individual topic areas and action items. All pertinent supporting information is included in Appendix F. Copies of all presentation material used by the UAH team are provided in Appendix G.

FUTURE THRUSTS

Below are areas identified from the original prioritized tasks and others which have developed which require further efforts.

- o Assist with setting limits for safety of test subjects
- o Assist in the development of test protocols necessary for institutional review
- o Assist in the establishment and preparation of test plans
- o Assist in the development of a QA/QC program to assure the validity, accuracy and precision of the analyses
- o Identify and evaluate the removal of various drugs and/or pharmacuticals by the urine reclamation system.
- o Develop data base of all microorganisms recovered from previous subsystem testing
- o Estimates of health risk of individual microbes to test subjects
- o Assist in determining the design specifications required as related to the Technical Demonstration Program
- o Assist in developing test plans required for future "man in the loop" testing

BUDGET SUMMARY

A summary of expenditures for the contract period is presented in Appendix H.

APPENDIX A
Task Outline

MASTER OUTLINE
3/3/88

TASK OUTLINE

Phase III Test Activities
Medical Aspects

1.0 Provide support to the mechanical design and integration of test systems as related to microbiological concerns.

- 1.1 General Recommendations
- 1.2 Material Recommendations
- 1.3 System Integration
- 1.4 Sampling Ports
- 1.5 Sterilization/Decontamination
- 1.6 Operational Requirements

2.0 Assist with design of Human Subjects Test Protocols

- 2.1 Test Subject Protocols
- 2.2 Human Subject Guidelines
  - 2.21 Institutional Review Board
  - 2.22 System Certification
  - 2.23 Subject Injury
  - 2.24 Supporting Documents
    - 2.241 JSC HRPPC (Appendix A)
    - 2.242 HHS (Appendix B)
    - 2.243 UAH IRB (Appendix C)

3.0 Assist in determining the design specifications required as related to the Technical Demonstration Program

- 3.1 Documentation Review
- 3.2 Current water/air quality requirements review
- 3.3 Recommendations

4.0 Interpretation of air/water quality requirements

4.1 Identify current air/water quality requirements

4.2 Develop and justify air/water quality requirements for recycled air and water

4.3 Provide recommendations pertaining to above

5.0 Develop data base of all microorganisms recovered from previous subsystem testing

5.1 Biochemical Characterization of Unknowns

5.2 Identification of Presumptive Organisms

5.3 FAME profiling of isolates

5.4 Establish data base of isolates with respect to source

5.5 Identify isolates which potentially represent health risks

5.6 Characterize isolates based on susceptibly/resistance to antimicrobials

6.0 Estimates of health risk of individual microbes to test subjects

7.0 Assist with setting limits for safety of test subjects

8.0 Health monitoring of test subjects

8.1 Delineation of parameters to monitor well subjects

8.2 Guidelines for managing sick subjects

9.0 Assist in the preparation of test plans

9.1 Microbiological

9.2 Chemical

10.0 Assist in the development of a QA/QC program to assure the validity, accuracy and precision of the analyses

11.0 Assist in developing test plans required for future "man in the loop" testing

APPENDIX B
Resumes of Key Personnel

CURRICULUM VITAE

NAME:	William J. Crump, M.D.
POSITION:	Director of Research, Family Medicine
RANK:	Associate Professor of Family Medicine
OFFICE ADDRESS:	UAH Medical Clinics Family Medicine Program 201 Governor's Drive, S.W. Huntsville, Alabama 35801
HOME ADDRESS:	230 Teakwood Drive Huntsville, Alabama 35801 (205) 882-3608
BIRTHDATE AND PLACE:	June 14, 1953 Savannah, Georgia
SEX:	Male
MARITAL STATUS:	Married, four children
SOCIAL SECURITY NUMBER:	260-82-1826

EDUCATION:

University of Georgia, 1971-1975, B.S., 1975
Vanderbilt University School of Medicine, 1975- 1979, M.D., 1979
Residency, Family Practice, University of Alabama in Birmingham, 1979-1982
Family Medicine Faculty Development Fellowship, University of North Carolina at Chapel Hill, 1982-1983

CERTIFICATION AND LICENSURE:

American Board of Family Practice, July 1982
Alabama Medical License, 1980-present
Tennessee Medical License, 1984-present

ACADEMIC APPOINTMENTS:

Associate Professor of Family Medicine, University of Alabama in Huntsville, School of Primary Medical Care, September 1986-present
Assistant Professor of Family Medicine, University of Alabama in Huntsville, School of Primary Medical Care, March 1983-September 1986
Adjunct Assistant Professor, University of Alabama in Huntsville, School of Primary Medical Care, Department of OB/GYN, June 1985-November 1985
Assistant Professor, Assistant Residency Director and Assistant Educational Director, University of Alabama in Birmingham, Department of Family Medicine, July 1982-March 1983

Instructor and Chief Resident, University of Alabama in Birmingham, Family Practice Residency Program, 1981-1982

PROFESSIONAL ORGANIZATIONS:

American Academy of Family Physicians
Society of Teachers of Family Practice
Medical Association State of Alabama
Madison County Medical Society
North American Primary Care Research Group

HONORS AND AWARDS:

First Place Award for Academic Division Research Papers, AAFP 36th Annual Assembly, October 1984
Outstanding Family Practice Faculty, University of Alabama in Huntsville, School of Primary Medical Care, Family Practice Residency Program, 1983-1984
Mead Johnson Award Alternate, 1981
Fellowship in Primary Care, Vanderbilt University School of Medicine, 1977
Justin Potter Medical Scholarship, 1975-1979[1]

GRANTS:

Principal Investigator, "Family Practice Hospital Study Mini Grant," University of Alabama in Huntsville, School of Primary Medical Care, 1986-1987
Principal Investigator, "Anxiety, Cortisol, and Pregnancy Outcome Mini Grant," University of Alabama in Huntsville School of Primary Medical Care, 1986-1987
Principal Investigator, "A Sentinel Practice Network for Obstetrics," Family Health Foundation of America, 1985-1987, $35,000
Site Coordinator and Major Contributor for (Tri-Campus) Grant for Faculty Development in Family Practice, University of Alabama in Huntsville, School of Primary Medical Care 1984-1987, $382,5571
Principal Investigator, Family Medicine Graduate Training Grant, University of Alabama in Huntsville School of Primary Medical Care, 1984-1987, $340,000
Principal Investigator, Perinatal Outcome Analysis Mini-Grant, University of Alabama in Huntsville, School of Primary Medical Care 1984-1985

[1]A four-year scholarship to Vanderbilt University School of Medicine commemorating a Nashville businessman. Selection is "for distinguished academic performance, demonstrated personal, professional, and intellectual competence, and strong potential for leadership in medicine."

Principal Investigator, "Family Practice Perinatal Outcome Project," Family Health Foundation of America, 1983
Principal Investigator, "Social Support and the Maternal Perception of the Newborn," Family Health Foundation of America, 1982

SELECTED OFFICES, COMMITTEES AND CONSULTATION:

Chief, Huntsville Hospital, Division of Family Practice, October 1987-September 1988
Vice-Chief, Huntsville Hospital, Division of Family Practice, October 1986-September 1987
Member, Alabama Journal of Medical Sciences Editorial Board, 1987-present
Board of Directors, Hope Place Shelter for Domestic Violence, 1987-present
Member, Alabama Chapter-American Academy of Family Physicians Research Committee, 1986-present
Member, University of Alabama in Huntsville Computer Users Advisory Committee, 1984-1986
Member, University of Alabama in Huntsville Joint Computer Network Access Committee, 1984-1985
Member, University of Alabama in Huntsville School of Primary Medical Care Advisory Committee on Promotions and Tenure, 1984-present
Member, University of Alabama in Huntsville School of Primary Medical Care Family Practice Residency Promotion Committee, 1984-present
Member, University of Alabama in Huntsville Human Subjects in Research Committee, September 1983-present
Chairman, University of Alabama in Huntsville School of Primary Medical Care Grants and Research Committee, 1983-present

ADMINISTRATIVE AND EDUCATIONAL POSITIONS:

Medical Director, Family Practice Clinics, University of Alabama in Huntsville School of Primary Medical Care, February 1987-present
Fellowship Coordinator, University of Alabama in Huntsville Family Medicine Program, 1986-present
Director of Research Division of Family Medicine, University of Alabama in Huntsville School of Primary Medical Care, April 1983-present
Family Medicine Faculty Development Fellowship, University of North Carolina at Chapel Hill, 1982-1983 (Concurrent with first faculty year)

Clinical Coordinator, University of Alabama in Birmingham Basic Science Clinical Correlation Conference for Freshmen Medical Students, 1981-1983

CONFERENCES, MEETINGS AND PRESENTATIONS:

"Research Problems and Methodological issues in the Assessment of Family Practice Obstetrics," North Alabama Primary Care Research Group Annual Meeting, Minneapolis, Minn., May 1987
"Doing Research in Your Private Practice - You Can Do It," Alabama Academy of Family Physicians Annual Meeting, Gulf Shores, Alabama, June 1986
"How to be an Aggressive Health Care Consumer Without Alienating Your Doctor," University of Alabama in Huntsville School of Primary Medical Care Community Seminar, May 1986
"The Premenstrual Syndrome - Medical and Psychological Aspects," Huntsville Hospital Center for Women's Health, March 1986 and May 1986
"The Alabama Family Practice Perinatal Outcome System: An Obstetrical Practice Network," North American Primary Care Research Group Annual Meeting, Baltimore, Maryland, April 1986
"The Alabama Perinatal Outcome Systems an a Model Information Network," Southeastern/Atlantic Regional Medical Library Services, Birmingham, Alabama, October 1985
"Sentinel Practice Networks: A New Idea," Second Annual Fall Invitational Scientific Symposium of the Medical Association of the State of Alabama, Birmingham, Alabama, September 1985
"Perinatal Outcome Project - The Second Year," Plenary Session Presentation at the Alabama Chapter of the AAFP, Gulf Shores, Alabama, June 1985
"Consumerism and the Iatrotrpphic Stimulus: A Paradign for Medical Students," Peer Presentation at Annual STFM Meeting, Nashville, Tennessee, May 1985
"Sentinel Practice Systems: Obstetrics," Presentation at Regional STFM Meeting, Atlanta, Georgia, October 1984
"Longitudinal Obstetric Care in a Family Practice Residency: A Pilot Study," Authored by William J. Crump, M.D. and Robert Hargraves, M.D. Presented in Absentia by Michael Harrington, M.D., AAFP 36th Annual Assembly, Kansas City, Kansas, October 1984
"Perinatal Outcome Project," Plenary Session Presentation at the Alabama Chapter of the AAFP, Gulf Shores, Alabama, May 1984
"Prenatal Risk Factor Analysis: The Psychosocial Dimension," Research Paper presented at the Annual NAPCRG/STFM Meeting, Orlando, Florida, May 1984
"Family Practice - A Career Decision," Annual Presentation to Vanderbilt University School of Medicine Students, 1982-1985

"Psychosocial Determinants of Pregnancy Outcome," Presentation at Annual Fellows Convocation, University of North Carolina at Chapel Hill, June 1983

PUBLICATIONS:

Crump, W.J.: "Family Centered Maternity Care and the Tort System: A Collision Course?," Fruits of our Labor, United North Alabamians for Safe Alternatives in Childbirth, 2(1): Summer 1987

Crump, W.J.: "The Alabama Perinatal Outcome Project: Some Methodological Issues," Fam Pract Res J, 7(1):3-11, Fall 1987

Crump, W.J.: "Obstetrical Practice Style and Clinical Policy in Residency Training," Fam Med, 19(5):378-379, 1987

Crump, W.J.: "Use of Progestins in Postmenopausal Estrogen Therapy," Family Practice Currents, Vol. 3, #5, 1987; In press

Crump, W.J.: "The Bishop Score and Labor Duration: A New Look," South Med J, In press

Crump, W.J.: "Current Use of the Pap Smear," J Am Bd Fam Pract; In press

Crump, W.J.: "Use of Antidepressants in Patients with Heart Disease," Family Practice Currents, Vol. 3, #4, 1987

Crump, W.J.: "Bacterial Sinusitis -- Two Perspectives: I. Diagnosis," Family Practice Currents, Vol. 3, #3, 1987

Crump, W.J.: "The Honeymoon Period in Non-Insulin Dependent Diabetes Mellitus," J Fam Pract, 25(1);78-82, 1987

Crump, W.J., Coleman, W.H.: "Obstetrical Issues in Family Practice," Family Medicine, Vol. 19, #2, Transactions, March-April 1987

Crump, W.J.: "Infant Crying and Parental Behavior," Family Practice Currents, Vol. 3, #2, 1987

Crump, W.J.: "Calf-Vein Thrombosis: Is Anticoagulation Necessary?," Family Practice Currents, Vol. 3, #1, 1987

Banahan, B.F. Jr, Anderson, R.L., Banahan, B.F.,III, Crump, W.J.,: "Physician Evaluation of Their Moonlighting During Residency Training," J of Med Ed, 62:351-353, April 1987

Crump, W.J., Smith, C.W.: "The Postdate Pregnancy: When to Wait, When to Induce Labor," Postgraduate Medicine, 80(5);291-297, 1986

Crump, W.J.: "Vaginitis: Some New Thoughts," Family Practice Currents, Vol. 2, #4, 1986

Crump, W.J.: "The Treatment of Reflux Esophagitis," Family Practice Currents, Vol. 2, #3, 1986

Crump, W.J.: "Automated Ambulatory Blood Pressure Monitoring," Family Practice Currents, Vol. 2, #2, 1986

Crump, W.J.: "Hypercholesterolemia: Whom to Treat and How," Family Practice Currents, Vol. 2, #1, 1986

Crump, W.J., Redmond, D.B.: "A Survey of Family Physicians Providing Obstetrical Care," Alabama Medicine, April 1986, 26-27

Crump, W.J., Redmond, D.B.: "A Survey of Family Physicians Providing Obstetrical Care: A Preliminary Report," Alabama Medicine, March 1986, 39-40

Bartlett, E, Pegues, H.U., Shaffer, C.R., Crump, W.J.: "Health Hazard Appraisal in a Family Practice Center: An Exploratory Study," J Community Health, Vol. 9, #2, Winter 1983, 135-144

Crump, W.J.: "Labor: Is It Normal?" Ortho Forum, 4:18, 1983

"Behaviorial Dimensions of Normal Childbirth," Family Centered Maternity Care (Cybele) CME Module with G. Gayle Stephens, M.D., 1981

Kochert, G, Crump, W.J.: "Reversal of Sexual Induction in Volvox Carteri by Ultraviolet Irradiation and Removal of Sexual Pheromone," Gamete Research, 2:259, 1979

Data, J.L., Gerber, J.G., Crump, W.J., et al: "The Prostaglandin System: A Role in Canine Baroreceptor Control of Renin Release," Circ Research, 42:454, 1978

RESUME

NAME: Melvin Voorees Kilgore, Jr.

POSITION: Director, Analytical Research & Testing Laboratory

RANK: Research Associate

EDUCATION:

University of Alabama in Huntsville Master's Degree, Biological Sciences	1983 - 1986 1987
Auburn University Graduate Courses: Chemistry	1978-1980
Auburn University B.S. Microbiology	1974 - 1978 1978

Short Courses and Seminars:

High Resolution Gas Chromatography, Hewlett Packard, Birmingham, AL, February, 1987

Inspecting Buildings for Asbestos, Georgia Tech, Atlanta, GA, July, 1987.

Managing Asbestos Projects, Georgia Tech, Atlanta, GA, January, 1988.

PROFESSIONAL AFFILIATIONS:

American Association for the Advancement of Science
American Society of Microbiology
American Chemical Society
Association of Official Analytical Chemists

PROFESSIONAL EXPERIENCE:

University of Alabama in Huntsville The Kenneth E. Johnson Research Center	June 1984 - Present
Southern Research Institute Biotechnology Section Position: Biochemist	June 1983 - May 1984
University of Alabama in Huntsville Kenneth E. Johnson Research Center Graduate Research Assistant	Feb 1983 - May 1983

PROFESSIONAL EXPERIENCE: (cont)

Energy Associates, Inc. — Jun 1980 - Jan 1983
Alternative Energy Division
Technical Representative

Auburn University — Sep 1978 - May 1980
Chemistry Department
Graduate Research Assistant

Alabama Water Improvement Commission — Sep 1975 - Dec 1977
Monitoring and Surveillence Section
Microbiological Technician

PUBLICATIONS:

"A Physiological Survey of the Effects of the Cis and Trans Isomers of Platinum (II) Diaminodichloride (PPD) Using the Prokaryotic System as a model," D.L. Elam, M.V. Kilgore, Jr., and P. Melius. presented at Southeastern Regional Meeting of the American Chemical Society, Oct., 1978.

"A Comparative Study on Induction of Mixed Function Oxidase Activity in the Rat, Mullet and Gulf Killifish," M.V. Kilgore, Jr., D.L. Elam and P. Melius. Alabama Academy of Sciences, Mar., 1979.

"Induction of Polyaromatic Hydrocarbon Oxidases in Marine Organisms," P. Melius, M.V. Kilgore, Jr., D.L. Elam, Jr. and W.P. Schoor. XI International Congress of Biochemistry, Jul., 1979.

"Product Pattern and Kinetic Analysis of Benzo(a) Pyrene Metabolism in Marine Organisms by HPLC," M.V. Kilgore Jr., P. Melius, B. Tan, D.L. Elam and W.P. Schoor. Southeastern Regional Meeting of the American Chemical Society, Oct., 1979.

"Biomass Conversion of Municipal Solid Wastes," D.R. Coleman, W.E. Meyers, M.V. Kilgore, Jr., C.L. Lishawa, and M.H. Eley. Miami International Symposium on the Bioshpere, Apr., 1984.

"The Production of Fuel Grade Ethanol from the Cellulose in Municipal Solid Waste," T.J. Laughlin, D.R. Coleman, M.V. Kilgore, Jr., C.L. Lishawa, and M.H. Eley. Sixth Symposium on Biotechnology for Fuels and Chemicals, May, 1984.

"The Economics of Biomass Conversion of Municipal Solid Waste to Ethanol," C.L. Lishawa, R.E. Lacey, D.R. Coleman, W.E. Meyers, M.V. Kilgore, Jr., T.J. Laughlin, and M.H. Eley. Sixth Symposium on Biotechnology for Fuels and Chemicals, May, 1984.

"Mixed Function Oxidase Inductibility and Polyaromatic Hydrocarbon Metabolism in the Mullet, Sea Catfish and Gulf Killifish," P. Melius, M.V. Kilgore, D.L. Elam, B. Tan and W.P. Schoor. Polynuclear Aromatic Hydrocarbons. Proceedings of the 4th International Symposium, 1979.

PUBLICATIONS: (cont)

"Metabolites of Benzo (a) Pyrene in Arocolor 1254 Treated mullet," B. Tan, M.V. Kilgore, D.L. Elam, P. Melius and W.P. Schoor. Aquatic Toxicology, Proceedings of the 4th ASTM Symposium, 1979.

"Indirect Atomic Absorption Method for Determining 1,2-Diols via Digested Lead Periodate," B. Tan, P. Melius and M.V. Kilgore, Jr. Analytical Chemistry (1980) 52 (3) 602-604.

"The Production of fuel Grade Ethanol from the Cellulose in Municipal Solid Waste," T.J. Laughlin, D.R. Coleman, M.V. Kilgore, Jr., C.L. Lishawa and M. H. Eley. Proceedings of the 4th Annual Solar and Biomass Workshop, 1984.

"Biomass Conversion of Municipal Solid Waste," D.R. Coleman, M.V. Kilgore, Jr., T.J. Laughlin, C.L. Lishawa, W.E. Meyers and M.H. Eley. Proceedings of the International Symposium on the Biosphere, 1984.

"Design of a Pilot for the Conversion of Municipal Solid waste to Ethanol," M.H. Eley, M.V. Kilgore, et.al., in proceedings of the Sixth Symposium on Biotechnology for Fuels and Chemicals, Gatlinburg, TN, Vol. 6, p. 80.

"The Bioconversion of Municipal Solid Waste and Sewage Sludge to Ethanol," M.H. Eley, M.V. Kilgore, Jr., et.al. in proceedings of the First Symposium on Biotechnological Advances in Processing Municipal Wastes for Fuels and Chemicals, Minneapolis, MN, Vol. 1, p. 28.

"The Utilization of Municipal-Solid-Waste and Sewage Sludge in the Production of Ethanol," M.H. Eley, M.V. Kilgore, et.al., in proceedings of the First Symposium on Bio- technological Advances in Processing Municipal Wastes for fuels and Chemicals, Minneapolis, MN, Vol 1, p. 54, 1984.

"Design of a Pilot Plant for the Conversion of Municipal Solid Waste to Ethanol," T.J. Laughlin, D.R. Coleman, W.E. Meyers, M.V. Kilgore, Jr., C.L. Lishawa, and M.H. Eley. Bioengineering and Biotechnology (in press).

"The Economics of Biomass Conversion of Municipal Solid Waste to Ethanol," C.L. Lishawa, R.E. Lacey, D.R. Coleman, W.E. Meyers, M.V. Kilgore, Jr., M.H. Eley, and T.J. Laughlin, Bioengineering and Biotechnology (in press).

RESEARCH REPORTS:

Biomass Conversion of Municipal Solid Waste (Phase II). C.L. Lishawa, M.V. Kilgore, Jr., T.J. Laughlin, D.R. Coleman, W.E. Meyers, W.J. Suling, and M.H. Eley. Final Progress Report, Commissioners of Jefferson County, Alabama, 1984.

Small Scale Grain Ethanol Demonstration Plant: Assembly and Preliminary Operation of Equipment. M.H. Eley, M. V. Kilgore, Jr., and S. Underwood. UAH Research Report No. 442, Catalytic Reactors, Inc., 1985.

Conversion of Cellulosic Wastes to Ethanol: Preliminary Studies on Enzymatic Hydrolysis of Cellulose. M.H. Eley, M. V. Kilgore, Jr., S. Underwood. UAH Research Report No. 460, Catalytic Reactors, Inc., 1985.

Establishment of Test Plans for the Advanced Development Programs. M. V. Kilgore, Jr., R. J. Zahorchak. UAH Research Report No. 476, 1986, Boeing Aerospace Company.

Chemical Support of the Urine Pretreatment Mixer (UPM) Evaluation Studies. M.V. Kilgore, Jr., W.E. Dendy, et.al., UAH Research Report No. 545, 1986, Boeing Aerospace Company.

Microbiological Support of the Urine Pretreatment Mixer Evaluation Studies. M. V. Kilgore, Jr., et.al. UAH Research Report No. 546, 1986, Boeing Aerospace Company.

Chemical Analysis of Phase I Shower Studies. M.V. Kilgore, Jr., W.E. Dendy, et.al., UAH Research Report No. 549, 1986.

Microbiological Analysis of Phase I Shower Studies. M. V. Kilgore, Jr., et.al. UAH Research Report No. 550, 1986, Boeing Aerospace Company.

Chemical Analysis of Phase II Shower Studies. M.V. Kilgore, Jr., W.E. Dendy, et.al. UAH Research Report No. 551, 1986.

Microbiological Analysis of Phase II Shower Studies. M. V. Kilgore, Jr., et.al. UAH Research Report No. 552, 1986, Boeing Aerospace Company.

Microbiological Analysis of Space Lab (D-1) Condensate. M. V. Kilgore, Jr., et.al. UAH Research Report No. 553, 1986, Boeing Aerospace Company.

Chemical Analysis of Laundry and Hygiene Water. M.V. Kilgore, Jr., W.E. Dendy, et.al. UAH Research Report No. 554, 1986.

Microbiological Analysis of Laundry and Hygiene Water. M. V. Kilgore, Jr., et.al. UAH Research Report No. 555, 1986, Boeing Aerospace Company.

RESEARCH REPORTS: (cont)

Chemical Analysis Support of the Humidity Condensate Heat Exchanger Evaluation Studies. M.V. Kilgore, Jr., W.E. Dendy, et.al., UAH Research Report No. 556, 1986.

Microbiological Support and Analysis of the Humidity Condensate Heat Exchanger Evaluation Studies. M. V. Kilgore, Jr., et.al. UAH Research Report No. 557, 1986, Boeing Aerospace Company.

Chemical Analysis and Support of the Spiral Wound Reverse Water Reclamation System. M.V. Kilgore, Jr., W.E. Dendy, et.al., UAH Research Report No. 558, 1986.

Microbiological Analysis and Support of the Spiral Wound Reverse Osmosis Water Reclamation System. M. V. Kilgore, Jr., et.al. UAH Research Report No. 559, 1986, Boeing Aerospace Company.

Chemical Analysis and Support to the Hollow Fiber Reverse Osmosis Water Reclamation System Evaluation Study. M.V. Kilgore, Jr., W.E. Dendy, et.al., UAH Research Report No. 560, 1986.

Microbiological Analysis and Support to the Hollow Fiber Reverse Osmosis Water Reclamation System Evaluation Study. M. V. Kilgore, Jr., et.al. UAH Research Report No. 561, 1986, Boeing Aerospace Company.

Chemical Analysis and Support of the Multifiltration Water Reclamation System Evaluation Study. M.V. Kilgore, Jr., W.E. Dendy, et.al., UAH Research Report No. 562, 1986.

Microbiological Analysis and Support of the Multifiltration Water Reclamation System Evaluation Study. M. V. Kilgore, Jr., et.al. UAH Research Report No. 563, 1986, Boeing Aerospace Company.

Standard Operating Procedures Document for the ECLSS Chemical Laboratory. M. V. Kilgore, Jr. UAH Research Report No. 564, 1986, Boeing Aerospace Company.

CONTRACTS AND GRANTS:

"Aquatic bioassay Testing," M. V. Kilgore, Jr., Project Director. Amoco Chemicals Corporation, January 1985 - September 1985 ($5,100.00).

"Analytical Laboratory Support for the Area Industry," M. V. Kilgore, Jr., Project Director. October 1984 - September 1985 ($20,000.00).

"Establishment of Test Plans for the Advanced Development Programs," M. V. Kilgore, Jr., Project Director. Boeing Aerospace Corporation, September 1985 - December 1985 ($8,172.00).

"Aquatic Bioassay Testing," M. V. Kilgore, Jr., Project Director. Amoco Chemical Corporation, November 1985 - September 1986 ($6,500.00).

CONTRACTS AND GRANTS: (cont)

"Independent Research and Development Testing, Microbiological Support for Space Station Development," M. V. Kilgore, Jr., and R. J. Zahorchak, Co-Directors. Boeing Aerospace Corporation, December 1986 - October 1986 ($94,400.00).

"Establishment of Test Plans for the Advanced Development Programs," M. V. Kilgore, Jr., Project Director. Boeing Aerospace Corporation, January 1986 - October 1986 ($14,902.00).

"Advanced Development Program Testing, Microbiological Support for Space Station Development," M. V. Kilgore, Jr., and R. J. Zahorchak, Co-Directors. Boeing Aerospace Corporation, January 1986 - October 1986 ($78,500.00).

"Design of a GC System for the Analysis of Reduced Sulfur Compounds," M. V. Kilgore, Jr., Project Director. Applied Technology Consultants, March 1986 - September 1986 ($7,000.00).

"Sampling and Trace Solvent Analysis of Ambient Air," M. V. Kilgore, Jr., Project Director, Intergraph Corporation, March 1986 - April 1986 ($1,900.00).

RESUME

NAME: WILLIAM F. ARENDALE

RESIDENCE: 1216 Stonehurst Dr. S.E. Phone: (205) 881-4631
Huntsville, AL 35801

BUSINESS: The University of Alabama Phone: (205) 895-6473
in Huntsville
Chemistry Department
Huntsville, AL 35899

DEGREES:

1939 Central High School, Murfreesboro, Tennessee

1942 B.S., Science and Mathematics, Middle Tennessee State University

1948 M.S. Chemistry, University of Tennessee
Thesis: The Identification of Organo-Selenium Compounds Obtained by the Oxidation of Stilbazoles with Selenium Dioxide. (With Dr. C. A. Buehler)

1953 Ph.D., Chemistry-Physics, University of Tennessee
Dissertation: Vibrational Spectra of Ketene ag Aerospacnc Deuterated Ketenes. (With Dr. W. H. Fletcher)

EMPLOYMENT HISTORY

1983- Technical consultant to United Space Boosters, Inc., Huntsville Alabama. Contracted efforts have included a study of the state-of-the-art related to sensors for Automated Weather Observing Systems, sensors for NDT/NDE systems, and materials and processes for manufacturing optical components with emphasis on fiber optic systems and optrode designs.

1978-1983 Technical Consultant to Hobgood, Calimafde et al, Patent Attorneys, New York, N.Y. Moore vs. U.S., patent infringement related to castable, elastomeric solid propellants.

1977-78 Technical consultant to Burns, Doane, Swecker and Mathis, Patent Attorneys, Washington, D. C. Moore vs U.S.

1966-70 The University of Alabama in Huntsville. Director, Division of Natural Sciences and Mathematics. Responsible for developing programs in biology, chemistry, earth sciences, mathematics and physics.

1964-66 The University of Alabama in Huntsville. Assistant Director of Research Institute.

1964- The University of Alabama in Huntsville. Professor of

Chemistry. Interaction of electromagnetic energy with matter, scattering from laser illuminated targets, and hyper-Raman spectroscopy. Th chemistry of selenium as related to the ecological cycle and selenium deficiency diseases. Most recently, interest have been directed to real time monitoring systems. Philosophy of science, epistemology, and pedagogy of science. Teaching assignmnets have included general chemistry, analytical chemistry, instrumental analysis emphasizing the design of analog and digital instrumentation, physical chemistry, environmental chemistry, and chemometrics.

1951-64 Thiokol Chemical Corporation, Huntsville, Alabama. Chief Project Chemist, Head of Research Department, Director of Research and Assistant to General Manager and Technical Director. Themodynamics related to rocket propulsion, chemistry of polysulfide and butadiene copolymers, synthesis of high energy compounds, and rheology of suspensions. New formulations developed for ablative plastics, reinforced plastics, fiberglass composites. Applications and properties of metal whiskers, titanium and high strength ferrous alloys. Supervised design of rocket otors and new plant facilities. Administrative assignments included responsibility for quality assurance program; safety program; personnel training programs; coordination of customer contacts; and preparation and monitoring of the Five-Year Plan and the Annual Operating Plan.

1950-51 University of Tennessee, Dissertation work for Ph.D.

1948-50 Union Carbide Chemicals Corporation, Oak Ridge, Tennessee. Research Chemist. Studies of the organo-metallic and phosphate complexes of iron, uranium, and vanadium as a function of proton and electron activity. Results applied to leaching of low grade uranium containing soils and processing of solutions obtained.

1948-49 University of Tennessee. Lecturer, Organic Chemistry, Oak Ridge Program.

1947-48 Chemical Warfare Service Research Fellow.

1946-47 University of Tenessee. Instructor, Organic Chemistry.

1944-46 Tennessee Eastman Corporation, Oak Ridge, Tennessee. Analytical Chemist. Laboratory Supervisor. Isotope Analysis Section. Principal Emphasis: Mass spectrometry, radiation counters, and electrochemistry.

1942-44 E. I. Dupont, Alabama Ordnance Works. Analytical Chemist. Analyses of TNT, tetryl, smokeless powder, and the acids and organic intermediates used in the manufacture of these materials.

PROFESSIONAL ACTIVITIES RELATED TO CURRENT RESEARCH INTERESTS:

I. Chemometrics and the measurement process. Applications have included: platinum and palladium complexes of compounds containing pyridine and selenium in configurations that favor five membered rings for screening as antitumor agents, and oximes and tertiary amines from selenophene as reactivators and inhibitors for phosphrylated acetyl cholinesterase. Instrumentation developments including rapid scan spectrophotometry, use of fiber optics, and optrodes for data acquisition, and real time data processing. Process monitoring in real time. New materials and processing methodes for manufacturing optical components.

A. Professional Memberships.

1. American Chemical Society

2. American Physical Society

3. Optical Society of America. Executive Committee Local Section 1969-70, 1972-74. Program Committee 1972.

4. American Rocket Society. Fellow. American Institute of Aeronautics and Astronautics. Associate Fellow. Board of Directors, Alabama Section 1965-67.

5. American Defense Prepardness Association.

B. Publications and Presentations

1. C. A. Buehler, J. O. Harris, W. F. Arendale, "Reactions of and Stilbazoles with Selenium Dioxide", J. Chem. Soc. 72, 4953-6 (1950).

2. W. F. Arendale and C. F. Coleman, Oak Ridge National Laboratory Report Y-664, October 1950, "Solubility of Uranous Toluene Sulfinate and related Compounds".

3. W. H. Fletcher, W. F. Arendale, "Geometry of Ketene". J. Chem. Phys. 21, 1898 (1953).

4. W. F. Arendale, W. H. Fletcher, "Infrared Spectra of CD_2CO and CHDCO", J. Chem. Phys. 19, 1431-2 (1951).

5. W. . Arendale, W. H. Fletcher, "Vibrational-Rotational Bands of Ketene", J. Chem. Phys. 24, 581 (1956).

6. W. F. Arendale, "Fuel-Binder Requirement for Composite Propellants", Ind. Eng. Chem. 48, 725 (1956).

7. W. F. Arendale, W. H. Fletcher, "Infrared Spectra of Ketene and Deuteroketenes", J. Chem. Phys. 26, 7937 (1957).

8. W. F. Arendale, C. F. Coleman, "Uranium-Vanadium Recovery and Separation by Phosphate Precipitation", U. S. Patent 2,797,143 (1957)

9. W. F. Arendale, T. A. Neely, "Solid Propellants", Encyclopedia of Chemical Technology, Interscience Encyclopedia of New York, 2nd Supplement Edition, 1960.

10. W.F. Arendale and Virgil V. Vaughn, Evaluation of Selected sTechniques for Raman, Hyper-Raman and Stimulated Raman Spectroscopy, UARI Research Report No. 57, May 1968.

11. W. F. Arendale and H. Jeffreys, The Reflection of Polarized Illuminating Light From Near Diffuse Surfaces, A thesis submitted by Harold B. Jeffreys in partial fullfillment of the requirements for the Master's degree, June 1986.

12. W. F. Arendale and Harold B. Jeffreys, Study of Reflected Energy From Laser Illuminated Targets, Final Report Contract DA-01-021-AMC-12250(z), also issued as UARI Research Report No. 58, December 1968. (not in print).

13. W. F. Arendale, "Chemistry of Propellants Based on Chemically Crosslinked Binders", Paropellants Manufacture, Hazards, and Testing, Advances in Chemistry Series No. 88, American Chemical Society Publication, 1969, pp 67-83.

14. W. F. Arendale, "The Selenium Dilemma" presented as Seminar to the Chemistry Department at the University of Alabama in Birmingham, February 4, 1976.

15. W. F. Arendale, "Solid Propellant Containing Ferrocene Plasticizer", U. S. Patent 4,023,994, May 17, 1977.

16. W. F. Arendale, "The Selenium Dilemma", presented as UAH Chemistry Department Seminar, September 29, 1978.

17. W. F. Arendale, "Thermometric Titrimetry as an Analytical Method", presented as a Seminar to Alabama A&M, Chemistry Department November 29, 1979.

18. W. F. Arendale, "Thermometric Titrimetry and Determination of Thermodynamic Properties", presented as a UAH Chemistry Department Seminar, November 30, 1979.

19. W. F. Arendale, "Preparation of Selenophene Derivatives For Invivo Testing, A Pilot Study", proposal to U.S. Army Medical Research and Development Command, Sept. 1982.

20. W. F. Arendale, Larry A. Parker* and Robert T.Quier Jr.*, "Handling and Disposal of Chemical Waste", Workshop UAH Campus, December 8-10, 1982. (* J. T. Baker Chemical Company).

21. W. F. Arendale, "Linpack Fortran IV Subroutines Now Available", Computer Words XII Nov 1982, p5.

22. W. F. Arendale and Phillip Franklin, "The Dissociation Constant(s) for 2,2'-Pyridyl Thiophene", presented Alabama Academy of Science Meeting, Tuscaloosa, Alabama, March 3-5, 1983. Abstract published The Journal of the Alabama Academy of Science, 54, 133 (1983).

23. W. F. Arendale, "The Transition From Analog to Digital Data Acquisition", presented to the Southeastern Analytical Chemist Association April 14-16, 1983.

24. W. F. Arendale, "A Preliminary Evaluation Of The Guided Wave, Optical Waveguide Spectrophotometer", presented to the Southeastern Analytical Chemist Association, April 26-28, 1984.

25. W. F. Arendale, "The UV Spectrum of Benzene Using a Rapid Scan Spectrophotometer", presented to the Southeastern Analytical Association, April 18-20, 1985.

26. W. F. Arendale, "Use of Target Factor Analysis to Calculate Acid Dissociation Constants", presented to Chemistry Section, Alabama Academy of Science, March 26, 1987. Abstract published The Journal of the Alabama Academy of Science, 1987, 58, 95.

II. Epistemology, philosophy of science, pedagogy of science

A. Professional memberships

1. Alabama Academy of Science. Fellow, Treasurer 1969-72, Chairman, Local Arrangements Committee Annual Meeting 1966-67 and 1972-73. Finance Committee 1969-73. President 1978-79. Delegate to National Association of Academies 1979-. Delegate to AAAS Committee X, 1979-1986, Committee Y,1986- . Special Committee on Requirements for Certification of High School Teachers, 1980-, Committee for Long Range Planning 1982- .

2. American Association of Advancement of Science. Fellow. Committee X 1979-1986, Committee Y, 1986- .

3. American Chemical Society. Member, Chemical Education and Physical Chemistry Sections. Secretary 1954, Chairman-Elect 1955 and Chairman 1956 North Alabama Secion.

4. National Science Teachers Association.

5. Society of College Science Teachers. Committee on Science and Technology 1982- .

6. Alabama Science Teachers Association. Member of Committee on Science and Technology 1982-.

7. Alabama Education Association.

8. The Gorgas Scholarship Foundation, Inc., Trustee 1973-.

9. Rotary Club, Huntsville, Alabama. Member Scholarship Committee 1972-76. Member International Relations Committee 1977-78.

10. Chemistry Department Committee for Self-Study on State Department of Education Requirements for Teacher Certification.

B. Publications and Presentations

1. W. F. Arendale, "Should Chemists Be Trained as Astronauts (Are Trained)", prepared for Chemical Education Conference, Holyoke, Massachusetts, August 1972. Invited as panelist for one session of conference. Reported J. Chem. Ed. 50, 17 (1973).

2. W. F. Arendale, "The Purpose and Content of Introductory Chemistry Courses", The Third Biennal Conference on Chemical Education, July 30, 1974.

3. W. F. Arendale, "Measured as We Measure", presented as Keynote Address, Luncheon, First Annual UAH metric Conference, January 27, 1977.

4. W. F. Arendale, "Thermodynamics a La Piaget, Weinhold and Gibbs", presented 174th ACS National Meeting, Chicage, Illinois, August 31, 1977.

5. W. F. Arendale, "A Chemist's Search for the Missing Volume", presented to Alabama Academy of Science Meeting, April 1978.

6. W. F. Arendale, "Should Chemists be Trained as Astronauts (Are Trained) - A Second Look", presented Fifth Biennial Conference on Chemical Education, Fort Collins, Colorade, July 26, 1978.

7. W. F. Arendale, Critique of papers presented in Session titled, "General Papers A", Fifth Biennial Conference on Chemical Education, Fort Collins, Colorade, July, 1978, published J. Chem. Ed. 56, 10 (1979).

8. W. F. Arendale, "The Alabama Secondary Principals Association Position on Teaching of Science", presented to Huntsville-Madison County Science Teachers December meeting, December, 1978.

9. W. F. Arendale, "The Scientific Method? An Introduction to Epistemology", talk to Huntsville Mensa, March 16, 1979. Talk arranged by the UAH Speaker's Bureau.

10. W. F. Arendale, "Safety and the Law", amd "Course Summary", concluding talks in Course on Laboratory Safety arranged by Alabama Department of Education and Huntsville-Madison County Science Teachers Association. Banquet speaker, May 7, 1979.

11. W. F. Arendale, Quantitative Analysis Laboratory Mannual. Fall Term 1979. 2nd edition, Winter Term 1980.

12. W. F. Arendale, "The Free Enterprise System". Talk to Sparkman High School students. Sponsored by Huntsville-Madison County Chamber of Commerce, March 3, 1980.

13. W. F. Arendale, Proposal to Department of Education, "Using a Personal Computer For Computer Assisted Lecturing (CAL)". Dec. 15, 1982.

14. W. F. Arendale, "Replace That Overhead Projector With Your Computer", presentation to Science Education Section, Alabama Academy of Science, April 29, 1985. Abstract published Journal of the Alabama Academy Science 56, 135, 1958.

C. Reviews of Text for Journal of Chemical Education.

1. W. F. Arendale, Book Review of C. Dodson, Chemistry for Modern Courses, J. Chem. Ed. 54, A128, (1977).

2. W. F. Arendale, Book Review of Charles G. Wade, Contemporary Chemistry, J. Chem. Ed. 55, A105, (1978).

3. W. F. Arendale, Book Review of Mary Maier, Introduction to Chemical Science, submitted Journal of Chemical Education. Editor decided that book did not deserve review.

4. W. F. Arendale, Book Review of Clyde R. Dillard and Daniel E. Goldberg, Chemistry. Reactions. Structures. and Properties, published J. Chem. Ed. 56, A223 (1979).

5. W. F. Arendale, Book Review of Audrey L. Companion. Chemical Bonding, published J. Chem. Ed. 57, A220 (1980).

6. W. F. Arendale, Book Review of Robert L. Wolke, Chemistry Explained, J. Chem. Ed. 58, A65 (1981).

7. W. F. Arendale, Book Review of Ralph S. Becker and Wayne E. Wentworth, General Chemistry, 2nd addition, J. Chem. Ed. 59 A201, (1982).

8. W. F. Arendale, Review of Software S. J. Moss, "Free Radical Polymerization Using the Rotating Sector Method." Project Seraphim and Journal of Chemical Education. Publication pending. June 1983.

9. W. F. Arendale, Review of George O. Abell and Barry Singer, Science and the Paranormal, for Journal of College Science Teaching, 1983.

10. W. F. Arendale, Review of Barbara Gastel, Presenting Science to the Public, for Journal of College Science Teaching, 1984.

11. W. F. Arendale, Review of F. W. Fifield and d. Kealey, Analytical Chemistry, submitted to Journal of Chemical Education, August 1985.

RESUME

NAME: Timothy Lee Huff

RANK: Research Analyst III

POSITION: Lead Microbiologist

EDUCATION:

B.S. in Microbiology, University of Alabama, 1980
M.S. in Microbiology, University of Alabama, 1982

Professional Societies and Honors:

Alpha Lambda Delta (Freshman Honorary)
Arts and Sciences Honors Program (inactive)
Dean's Lisst 1976, 1979
President of Pasteur Society 1979-1980
Collegiate Civitan

SKILLS:

Bacterial Culture Curator
Regulation of Antibody Responses (adjuvant studies)
T and B Cell Collaboration
Tissue Culture (including cell line and hybridoma)
Column CHromatography (including gel and affinity)
Gel Electrophoresis
Chromosomal and Plasmid DNA Isolation and Characterization
Experience in Small Animal Handling
Protein Isolation/Purification/Concentration Techniques
Experience in the use of Automated Cell Sorter
Monoclonal Antibody Maintenance and Purification
Membrane Filtration Techniques
Isolation and Identification of Clinical and Environmental Bacteria
Wet Chemistry Techniques

PROFESSIONAL EXPERIENCE:

The University of Alabama in Huntsville — Aug 1986 - Present
Kenneth E. Johnson Research Center
Position: Lead Microbiologist

Oklahoma Medical Research Foundation — Sep 1985 - June 1986
Oklahoma City, OK
Position: Research Assistant

The University of Texas — April 1982 - Aug 1985
Medical Branch
Department of Microbiology
Position: Research Associate

PROFESSIONAL EXPERIENCE: (cont)

The University of Alabama — Sep 1980 - March 1982
Department of Microbiology
Position: Graduate Teaching Assistant

PUBLICATIONS:

Articles:

Stinson, R.S., R.D. Lemmon, D.W. Bagget, T.L. Huff, J.A. Malone, G.L. Sloan, A.L. Winters. 1986. Removal of lipopolysaccharide from acellular Bordetella pertussis vaccine by detergent treatment. Journal of Biol. Stand. 14:261-271.

Weigent, D.A., E.H. Beachy, T.L. Huff, J.W. Peterson, G.J. Stanton and S. Baron. 1983. Induction of human gamma interferon by structurally defined polypeptide fragments of Group A Streptococcal M Protein. Infect. Immun. 43:122-126.

Abstracts:

Huff, T.L., D.A. Weigent, J.W. Peterson, G.J. Stanton and S. Baron. 1985. Induction of IFN gamma by Streptococcal M protein and host resistance to a bacterial challenge. Presented at the Texas branch meeting of the American Society for Microbiology.

Weigent, D.A., T.L. Huff, J.W. Peterson, S. Baron and G. John Stanton. 1985. Bacterial induced interferon (IFN) protects mice against pneumococcal infections. Presnted at FASEB Spring Meeting.

Weigent, D.A., E.H. Beachy, J.W. Peterson, T.L. Huff, et.al. 1983. Induction of human gamma interferon by peptic extracts of streptococcal M protein. Annual Meeting of the American Society for Microbiology, New Orleans, LA.

Huff, T.L., D.A. Weigent, J.W. Peterson, et.al. 1983. Isolation and characterization of an IFN inducer in Streptococcus pneumoniae. Presnted at the Texas branch meeting of the American Society for Microbiology.

Clark, J.A., T.L. Huff, A.L. Winters and R.S. Stinson. 1982. Leukocyte and macrophage responses to Bordetella pertussiss whole cell and experimental vaccine 15A-1B.

Huff, T.L. Huff., J.A. Clark, A.L. Winters and R.S. Stinson. 1982. Comparison of the protective and immunological properties of Bordetella pertussis whole cell and experimental vaccines. Federation Proc. Vol. 41:3283.

Huff, T.L., J.A. Clark, A.L. Winters and R.S. Stinson. 1982. Comparitive study of whole cell and experimental Bordetella pertussis vaccines in mice. FASEB Spring Meeting.

Abstracts (cont)

Clark, J.A. T.L. Huff, et.al. 1982. Role of peritoneal and alveolar macrophages in immunity to Bordetella pertussis. FASEB Spring Meeting.

Research Reports:

Multifiltration Unit Microbiological Analysis. Melvin V. Kilgore, Jr., Robert J. Zahorchak, Elizabeth E. Richard, and Timothy L. Huff.

Shower Water Phase II Study. Microbiological Analysis. Melvin V. Kilgore, Jr., Robert J. Zahorchak, Elizabeth E. Richard, Timothy L. Huff, Shawn E. Prince and Natalie R. Otey.

Spiral Wound Reverse Ososis Unit Microbiological Analysis. Melvin V. Kilgore, Jr., Robert J. Zahorchak, Elizabeth E. Richard and Timothy L. Huff.

Hollow Fiber Reverse Osmosis Unit Microbiological Analysis. Melvin V. Kilgore Jr., Robert J. Zahorchak, Elizabeth E. Richard, Timothy L. Huff, Shawn E. Prince and Natalie R. Otey.

Urine Pre-Treatment Mixer Microbiological Analysis. Melvin V. Kilgore Jr., Robert J Zahorchak, Elizabeth E. Richard and Timothy L. Huff.

Humidity Condensate Heat Exchanger Microbiological Analysis. Melvin V. Kilgore Jr., Robert J. Zahorchak, Elizabeth E. Richard and Timothy L. Huff.

Submitted:

Stinson, R.S., T.L. Huff, J. Robinson, G. Sloan, R. Lemmon and A. Winters. Immunomodulation of Bordetella pertussis whole cell vaccine and acellular fractions. (Submitted to Infect. Immun.).

Huff, T.L., D.A. Weigent, J.W. Peterson, S. Baron and G. John Stanton. Induction of gamma IFN by Streptococcus pyogenes M protein and its role in response to bacterial challenge. (Submitted to Infect. Immun.).

Huff, T.L., D.A. Weigent, J.W. Peterson, G.J. Stanton, E.H. Beachy and S. Baron. Isolation and characterization of a M protein-like inducer from Streptococcus pneumoniae. (Submitted to Infect. Immun.).

RESUME

NAME: Theresa Ann Curry

RANK: Research Analyst II

POSITION: Microbiologist

EDUCATION: May 1983: B.S. in Microbiology-University of Alabama in Huntsville.

HONORS AND ACTIVITIES: Alpha Lambda, Freshman Honor Society; Athletic Scholarship-1980; Alumni Association Scholarship-1981; Dean's list-five quarters; Tri-Beta National Biological Honor Society-President-1982-83; Who's Who Among Students In American Universities and Colleges; Voted "Outstanding Senior".

PROFESSIONAL AFFILIATIONS:

American Society for Microbiology
American Society for Quality Control

PROFESSIONAL EXPERIENCE:

The University of Alabama in Huntsville — Sep 1987 - Present
Kenneth E. Johnson Research Center
Position: Microbiologist

Augusta Reading Foundation — Sep 1986 - Aug 1987
School for Dyslexic & Hyperkinetic Children
Position: Biology Teacher

Kendall Company — Aug 1983 - Aug 1986
Microbiology Division
Position: Laboratory Supervisor

Employed 3 years with the Kendall Company as Microbiology Laboratory Supervisor. Main responsibilities include supervision of seven (7) technicians which perform bioburden and resistance studies, sterility testing, LAL pyrogen testing and support testing for the company. Other responsibilities include environmental monitoring, certifying equipment (including production sterilizers) and product, and validating biological indicators.

PROFESSIONAL EXPERIENCE: (cont)

The University of Alabama in Huntsville 1981 - 1983
Department of Biological Sciences
Position: Laboratory Technician

Responsibilities included: Preparation of media, buffers, microbiological reagents and stains, maintenance of stock cultures and departmental animal room. Familiar with Public Health rules for treatment of laboratory animals. Other responsibilities included supervision of other lab-assistants in microbiology prep room and assisting in laboratory instruction.

SEMINARS CONDUCTED:

Industrial Sterilization and Microbiological Quality Control-1983
Limulus Amebocyte Lysate Workshop on Testing and Regulation-1984
Statistical Process Control Methods Workshop-1985
Quality Control In The Microbiology Laboratory-1985.

PUBLICATIONS:

"The interaction between Candida albicans blastospores and murine alveolar and peritoneal macrophages." Presented at American Society for Microbiology, New Orleans, LA, March, 1983.

APPENDIX C
Current Medical Support Team
Bibliography

Scientific Papers And Posters; List Of Abstracts. Aerospace Medical Association Annual Scientific Meeting,1985.

ABSTRACT: None

Naturwissenschaften. 73:0001-0455. 1986.

ABSTRACT: None

Methods For Measuring The Acute Toxicity Of Effluents To Aquatic Organisms, 3rd Edition. Environmental Monitoring and Support Laboratory, Office of Research and Development, U.S. Environmental Protection Agency, Cincinnati.,1985.

ABSTRACT: This manual describes methods for measuring the acute toxicity of effluents to freshwater and marine macroinvertebrates and fish. The methods include a preliminary range-finding test, a screening test, and multi-concentration (definitive) static and flow-through toxicity tests. Also included are guidelines on laboratory safety, quality assurance, facilities and equipment, effluent sampling and holding, dilution water, test species selection and handling, data interpretation and utilization, report preparation, organism culturing, and dilutor and mobile bioassay laboratory design.

Streptomyces DD-Carboxypeptidase-Transpeptidases. Exopeptidases, Chapter 51,:0611-0636. .

ABSTRACT: None

Skylab Mission Report Third Visit. NASA/JSC 08963, Houston, Texas, 1974.

ABSTRACT: In addition to microbial monitoring of the crewmembers as detailed in JSC-16888, attention must be given to the reusable spacecraft and its associated hardware. This monitoring will provide a basis for implementation of appropriate prophylaxis, treatment, or replacement procedures for insuring the maximum safety of crewmenbers. The increased crew size may result in an increased microbial load within the Shuttle orbiter and thereby provide a potential for microbial contaminatin and buildup. Microbiological sampling and monitoring of selected sites and components within the confines of the spacecraft will be used for evaluation actual or potential microbial contamination. The comparison of pre- and postflight data will as a monitor of the effectiveness of cleanup procedures in preparation for a subsequent mission.

Microbial Sample Collection Handbook. NASA/JSC-18633, 1983.

ABSTRACT: None

Space Lab 3 Microbial Contamination Control Plan In Support Of DSO 0437. NASA JSC2 0381,.

ABSTRACT: This document will encompass specific guidelines and

procedures for the monitoring of crewmembers, animals, spacecraft, Spacelab, animals housing, Hangar L,and the Research Animal Holding Facility (RAHF), and animal food and water for the Spacelab 3 (SL-3) mission. The microbial sampling schedule is given in Table 1.

Test Results Operational Ninety-Day Manned Test Of A Regenerative Life Support System. Advance Biotechnology And Power Department, McDonnell Douglas Astronautics Compant For Langley Research Center, NASA. NASA CR-111881, MDC G2282,.

ABSTRACT: None

KDI Quick Test. Keystone Diagonostics, INC., 9062 Route 108, Columbia, Maryland 21045, 301-992-7592,.

ABSTRACT: The KDI QUIK TEST Drug Screens are the first practical approach to drug testing in the workplace. Rapid, economical, accurate and simple-to-use, the screening procedures will detect drugs of abuse in urine samples.

Cancer Risk of Pestivides in Agricultural Workers. JAMA, 260/7 :0959-0966. 1988.

ABSTRACT: This report discusses some of the inherent limitaions of cancer studies in animals and humans and presents a qualitative carcinogen risk assessment of a numger of pesticides based on the judgment of national and international authorities who have reviewed the availabel experimental and epidemiologic evidence. A large number of pesticidal compounds have shown evidence of genotoxicity or carcinogenicity in animal and in vitro screening tests, but no pesticiedes-except arsenic and vinyl chloride(once used as an aerosol propellant)- definitely have been proved to be carcinogenic in man. Resolution 94 (1-86), which was referred to the Board of Trustees, calls for the American Medical Association, through its scientific journals and publications, to alert physicians to the potential hazards of agricultural pesticides, to provide physicians with advice on such hazards for their patients, and to urge that these substances be appropriately labeled. This report addresses the potential carcinogenicity of pesticides by review of the available literature.

Pentoxifylline and Leukocyte Function. Pentoxifylline and Leukocyte Function, :0001-0252. 1987.

ABSTRACT: None

Essays in Microbiology. Essays Micro., :0002-0031. 1978.

ABSTRACT: None

Troubled Waters. Hippocrates, 1988.

ABSTRACT: When you discover that the very water you drink is deadly, you don't just sit back and take it. Four communities

tell their stories.

Atlas of the Light Scattering Characteristics of Microparticles. Science Spectrum, Inc., Santa Barbara, California 93105,1975.

ABSTRACT: This Atlas is a collection of differential scattering patterns, i.e. the relative intensity of scattered light as a function of the angle of scattering. It has been prepared for use with the Differential 1 and Differential 11 light scattering photometers manufactured by Science Spectrum, Inc., Santa Barbara, California. Most of the data are presented to correspond to the use of plane-polarized green laser light of wavelength 514.5nm.

Bottled Water Study. Environmental Protection Agency PB-227 736, 1972.

ABSTRACT: Although piped water is available to at least 75 percent of the nation's population, the production and sale of bottled water has become an established and growing industry. In some parts of the country, particularly in those areas where the only available natural water is heavily mineralized, bottled water has always been an important source of drinking water. Since the recently aroused interest in our environment, the use of bottled water has rapidly increased. Fears regarding the pollution of city water supplies, whether or not founded on fact, have caused people to distrust the quality of the product issuing from the faucet. In addition, a dissatisfaction by the public with the taste and odor of their drinking waters has influenced the increase in the use of bottled waters. Rising affluence has also had a part, since people could now afford to purchase a deluxe product, supposedly much superior to the every day waters that the city water system provided. When, in 1970, a study of Community Water Supplies was published by the Water Supply Division, Environmental Protection Agency (then the Bueau of Water Hygiene, United States Public Health Service), the bottled water industry received an unexpected (and unintentional) boost. The study revealed shortcomings and potential hazards in many communtiy water supplies, and the immediate reaction of the public was distrust of piped water and an increase in sales of bottled water. The Water Supply Division recognized the importance of this increase in the use of bottled waters by the public and was interested in determining the quality and health surveillance being provided by the manufacturers. To determine existing conditons a small pilot survey was undertaken.

Bottled Water. Published by the Office of the Federal Register National Archives and Records Administration (21 Parts 100 to 169),1986.

ABSTRACT: Bottled water sold in interstate commerce is under the jurisdiction of the Food and Drug Administration, DHEW. FDA has established quality standards for bottled water which are essentiallly equivalent to the EPA standards in effect for tap water. However, there is no monitoring program for bottled water as there is for tap water, so compliance with FDA's standards

cannot be determined for a particular brand of bottled water without actually having an analysis performed. Most states also have regulations pertaining to bottled water, but few states have programs for monitoring the quality of bottled water available within their jurisdictions. Bottled water may be distilled and reconstituted to a particular formula, may be carbon filtered, ozonated, or may receive various onter kinds of treatment. These processes are intended to produce a bottled water which is pleasing to the taste and is consistent in aesthetic characteristics. While some of the types of treatment can be expected to remove contaminants, no information is available on the contaminants, no information is available on the contaminant content of any of the many brands of bottled water. Since bottled water is most frequently sold on the basis of its aesthetic characteristics, the consumer's choice is usually based on his personal taste preference. No comparison of bottled waters on the basis of purity or freedom from contaminants has been made. If a consumer is interested in the quality of a particular brand (or lot) of bottled water, he should contact the Bureau of Foods, Food and Drug Administration, DHW, Washington, D.C. 20204; or the State agency responsible for regulation of bottled water. The latter may be the health department, the departmlent of the environment, or the agriculture department depending on the individual state. If these agencies do not have the desired information, the consumer may wish to have a sample analyzed by a private water testing laboratory. It would be advisable to specify which contaminants the analyst is to look for in such cases, since the cost of the analysis is dependent on the number and nature of contaminants investigated.

Monoclonal-Based Tests for Respiratory Syncytial Virus, Adenovirus and Influenza Virus A & B. Analytab Products, Division of Sherwood Medical, 200 Express Street, Plainview, NY 118903,.

ABSTRACT: Accurate and reliable-Four times faster than indirect method, Rapid, one-step direct immunofluorescent technique

Underground Storage Tank Management. Weston-ATC Inc., 1635 Pumphrey Avenue, Auburn Al. 36830,.

ABSTRACT: EPA estimates that there are approximately 2,000,000 underground storage tanks (UTS) in the U.S. Most of these tanks contain petroleum products, petrochemicals or other chemicals. It is estimated that approximately 16,000 of these tanks contain hazardous waste. Various trade organizations and regulatory agencies have estimated that from two to 25 percent of these USTs are leaking. Products leaking from USTs can cause a variety of problems with enormous financial liabilities for the UST owner. Some products may leak from the UST and contaminate the surrounding soil and groundwater. Other products may travel through the soil as a vapor, accumulate in basements of nearby structures and reach explosive or toxic concentrations. In many cases, migration of both liquid and vapor phases will occur, endangering human health and the environment. Abandoning a nonleaking UST can cost the owner $10,000-20,000 depending on tank contents and final disposition of the tank. Remediation of

damage caused by leaking USTs can easily exceed $25,000 considering long term monitioring under an approved restoration and closure program. There are certain cases involoving extensive soil and groundwater contamination in which remediation costs have exceeded $3 million. Lawsuits in excess of $2 billon have been filed for damages due to leaking USTs at a single service station. Clearly the UST problem impacts anyone involved with property on which UST is sited. Parties to a lawsuit resulting from a leaking UST (LUST) can easily include the property owner, the tenant (if the property is leased), real estate firms, mortgage bankers and lenders. amd the tank installer.

Genetics and Biochemistry of Pseudomonas. Genetics and Biochemistry of Pseudomonas, :0001-0341. 1975.

ABSTRACT: Over the years microbial biochemists have been challenged by the diversity of the metabolic reactions catalysed by members of the genus Pseudomonas and consequently their investigation of members of this genus has played a vital part in building up our knowledge of bacterial intermediary metabolism, particularly with respect to possible degradative routes. Latterly, interest in the pseudomonads has become much wider. Not only has the relative eclipse of Gram-positive bacteria as human pathogens revealed the presence of the so-called opportunistic pathogens (of which Pseudomonas aeruginosa is a particularly vicious example), but also pseudomonads have assumed a steadily increasing importance in industrial microbiology. Much of our knowledge of modern molecular biology has come from studies on Escherichia coli, but this organism is far from universally representative. It is to try to define what is known of another group of bacterial species of potential practical importance that these contributions have been collected and published in this form.

Abe M., Higashi S. B-Glucosidase And B-Galactosidase From The Periplasmic Space Of Rhizobium trifolii Cells. J. Gen. Appl. Micro. , 28:0551-0562. 1982.

ABSTRACT: High amounts of B-glucosidase (MW 74,000) and B-galactosidase (MW 122,000) were isolated from the periplasmic space of Rhiaobium trifolii 4S (infectious strain), compared with the cell homogenated. The characterization of B-glucosidase and B-galactosidase was determined. Both enzymes were inhibited by the addition of Cu2+, Fe2+, Zn2+, Hg2+ and p-chloromercuribenzoic acid. The B-glucosidase exhibited a strong hydrolytic activity on cellobiose, sophorose and laminaribiose to glucose, and the B-galactosidase degraded lactose and O-B-D-galactosyl-1,3-D-arabinoside to their respective components. Both enzymes hydrolyzed polysaccharide only slightly.

Altman P.L., Talbot J.M. Nutrition and Metabolism in Spaceflight. J. Nutr., 117:0421-0427. 1987.

ABSTRACT: The U.S. Space Station being planned for the 1990s will

accommodate six or more crew members on 90-d flights in low earth orbit. Adequate nutrition will be essential for maintaining crew health, effectiveness and morale. Although much is known from prior space experience about in-flight metabolism, nutrition and associated food technology, important gaps in knowledge exist that need additional research, development and analysis to meet Space Station requirements. This paper is a synopsis of a report prepared be the Life Sciences Research Office (LSRO), FASEB, from a study of the nutritional and metabolic aspects of spaceflight. It reviews available data on the metabolic responses to spaceflgiht including extravehicular activity, physiological reponses to microgravity that influence metabolism and energy needs, in-flight nutritional experience, space menus, food packaging,in-flight food service methodology, water supply and disposal of food wastes. The LSRO ad hoc Working Group identified critical gaps in knowledge and suggested corresponding research approaches for acquiring essential new data. The 38 research suggestions detailed in the report address in-flight metabolic needs, nutrient requirements, for systems and nutritional countermeasures.

ames J.B., Howard G., Blanden P.D., Krygier V. Bacterial and Endotoxin Retention by Charge-modified Filters. Semiconductor International, :80-82. 1988.

ABSTRACT: A past study showed that bacteria can peretrate 0.2 um rated sterilizing grade filters during long-term water service. However, it was demonstrated that 0.1 um rated filters can retain 100% of these bacteria. Thus, the question of grow-through or penetration during periods of long-term water service can be resolved if a 0.1 rated (or finer) filter is used and properly maintained. Growthrough will not then occur. Concern over the breakdown of Gram negative bacteria collected on the filter surface, to give cell fragments which then may peretrate the filter, has been studied. These bacterial cell wall fragments, which contain endotoxins, have a negative charge in water and can be removed by a positively charged matrix.

Anderson D.J., Reschke M.F., Homick J.E., Werness S.A.S. Dynamic Posture Analysis Of Spacelab-1 Crew Members. Exp. Brain Res., 64:0380-0391. 1986.

ABSTRACT: Dynamica posture testing was conducted on the science crew of the Spacelab-1 mission on a single axis linear motion platform. Tests took place in pre- and post-flight sessions lasting approximately 20 min each. The pre-flight tests were widely spaced over the several months prior to the mission while the post-flight tests were conducted over the first, second, fourth, and sixth days after landing. Two of the crew members were also tested on the day of landing. Consistent with previous postural testing conducted on flight crews, these crew members were able to complete simple postural tasks to an acceptable level even in the first few hours after landing. Our test were designed to induce dynamic postural responses using a variety of stimuli and from these responses, evaluate subtle changes in the postural control system which had occurred over the duration of

the flight. Periodic sampling post-flight allowed us to observe the time course of readaption to terrestrial life. Our observations of hip and shoulder position, when subjected to careful analysis, indicated modificaton of the postural response from pre- to post-flight and that demonstratable adjustments in the dynamic control of their postural systems were taking place in the first few days after flight. For transient stimuli where the platform on which they were asked to stand quickly moved a few centimeters fore or aft then stopped, ballistic or open loop 'programs' would closely characterize the response. During these responses the desired target position was not always achieved and of equal importance not always properly corrected some 15 seconds after the platform ceased to move. The persistent observation was that the subjects had a much stronger dependence on visual stabilization post-flight than pre-flight. This was best illustrated by a slow or only partial recovery to an upward posture after a transient base-of-support movement with eyes open. Postural responses to peristent wideband pseudorandom base-of-support translation stimuli were modeled as time invarient linear systems arrived at by Kalman adaptive filter techniques. Derived model parameters such as damping factor and fundamental frequency of the closed loop system showed significant modification between pre- and post-flight. This phenomenon is best characterized by movement of the poles toward increasing stability. While pre-flight data tended to show shoulders and hips moving in phase with each other, post-flight data showed a more disjoint behavior. One can speculate that this change illustrates a shattered postural organizaton or an acquired strategy not designed to stabilize terestrial posture but as a carry over from optimum inflight postural control. Given our observations one can never be certain if these changes represent modifications in the physiology of posture of purposeful changes in strategy. As in other examples of motion behavior, the time domain analysis as represented by the step changes in position is not always reconcilable with the system modeling of pseudorandum responses and subsequent frequency domain analysis as represented by the pseudorandum noise stimuli. We present the observed data with arguments and some contradictions as to the nature of the adaptive changes which occur in the postural control system.

Armstrong D.W., Martin S.M. Bacterial Fermentation Of Cellulose: Effect Of Physical and Chemical Parameters. Biotech. Bioeng., 25:2567-2575. 1983.

ABSTRACT: Acetivibrio cellulolyticus converts cellulose directly to ethanol, acetate, H2, and CO2. The effects of various physical and chemical parameters, and their interdependence, including pH, temperature, redox, and ethanol toxicity on this fermentation, were studied. Controlling pH at 6.8 favored a predominance of ethanol over acetate. Supplementation of the medium with additional reductant, concomitant with a lower redox potential, increased ethanol formation. Results from ethanol-challenged cultures indicated that cell lysis occurs with growing but not with nongrowing cells. A stable strain was adapted for growth in ethanol concentrations almost sevenfold

greater than the parent organism.

Associated Press. Drug Produced On Space Flight Is Contaminated By Microbe. Microbiological Headlines,:0011. 1984.

ABSTRACT: None

Baisch F., Beck L. Body Impedance Measurement During SpaceLab Mission D1 . The Physiologist, 30/1:S0047-S0048. 1987.

ABSTRACT: Quantification of body fluid redistribution and loss during space flight and observation of the effects on the heart were the aims of this experiment. The impedance of two body segments (Z-torso and Z-body) to a 100 kHz 1mA constant current, the first derivative of the torso segment and the ECG were recorded with a 24-hs personal recorder. Data were obtained from two astronauts during launch and reentry and inflight from another two. The recumbent period prior to launch is decisive for fluid redistribution in the compartments covered by this method. The amount of fluid shifted is comparable to that produced by daily positional changes. A fluid loss of about 2.51 can be infered through the values of Z-body and anthropometric factors. Cardiac output, as assessed by dZ/dt, was increased more than 30% of control even of the 2nd inflight day; on the 4th day its values were however lower than pre-flight. It was not possible to demonstrate deconditioning effects on the heart of the payload specialists during this multidsciplinary Spacelab Mission. Heart rate and its variability strongly suggest increased cardiac parasympathetic activity.

Balazs M.K. A Summary Of New Methods For Measuring Contaminants In Ultrapure Water. Microcontamination, January:0035-0040, 0062-0063. 1987.

ABSTRACT: It has been will documented that the presence of trace quantities of materials in ultrapure water can have a devastating effect on the yield percentage of semiconductor manufacturing operations, In the past ten years, this problem has been a major focal point for bouth manufacturers of water-purifying equipment and the analytical laboratories that test the water. The results of their combined efforts have led to a severe tightening of pure-water specifications. In spite of the tremendous improvements that have been made in the quality of pure water, however, it has become apparent that water specifications need to be tightened even more because of the reduced linewidths and film thicknesses of today's ICs. In order to tighten the specifications,it must be possible to measure smaller quantities of material in pure water-something it is not always possible to do using current methods of analysis.

Balazs M.K. Current Issues in Purified-Water Contamination Control. Microcontamination, 1988.

ABSTRACT: During the next five years, we'll see much more widespread use of ozone in the semiconductor industry. More than 95% of all contamination problems that affect

semiconductor-device yields are caused by organic compounds. Specification for purified water will continue to tighten as further improvements occur in our ability to detect lower and lower levels of contaminants.

Barabas S. Monitoring Natural Waters for Drinking-Water Quality. Wld. Hlth. Statist., 391986.

ABSTRACT: Reaching the mid-way point in the International Drinking Water Supply and Sanitation Decade is a fitting occasion to review the progress to date in achieving the Decade's goals. There is still time to benefit from both successful case histories and failures by learning how to overcome certain difficulties, modify approaches or redesign strategies. This article will review an international programme which monitors water quality, from the perspectives of the safety of drinking-water supplies and the protection of water resources on which such supplies depend. The significance of this activity will be only too apparent if one bears in mind that contaminated natural waters are the predominant cause of the most widespread diseases on earth today. The availiable statistics are alarming. It is reported (1) that over one-half of the world's population, or more than 2 billion men, women and children, at one time or another, suffer from infectious diseases due to exposure to folluted wpters. Approximately 250 million new cases of waterborne or water-related diseases are reported each year, from which about 10 million die. The article will first outline the nature of waterborne diseases and the consideration of fresh water as a finite resource. The objectives, orgaization and operation of the Global Environmental Monitoring System for Water (GEMS/Water) will then be presented, Finally, the water quality data that have been gathered over the years by the GEMS/Water programme will be critically reviewed.

Barbaree J.M., Gorman G.W., Martin W.T., Fields B.T., Morrill W.E. Protocol For Sampling Environmental Sites For Legionellae. App. Env. Micro. , 53/7:1454-1458. 1987.

ABSTRACT: A protocol for sampling environmental sites was developed and used to identify possible sources of Legionella species in support of epidemiologic investigations at two hospitals. In hospital A, legionellae were isolated from 43 of 106 (40%) different sites. Three separate Legionella pneumophila serotypes and a previously unrecognized species were present in different combinations in the positive samples. Two of five cooling towers contained the same L. pneumophila serogroup 1 monoclonal type (1,2,4,5) as was isolated from patients. The same monoclonal type was also isolated from make-up water for the two cooling towers, a hot water tank, water separators in four main air compressor systems for respiratory therapy, and cold and hot water faucets. In hospital B, 13 of 37 (38%) sample sites contained legionellae, all of which were L. pneumophila serogroup 1. The monoclonal type matching isolates from patients (1,2,4,5) was found at the highest concentration in a hot water tank, but it was also present at four other sample sites. Since legionellae not related to disease may be found in many of the

sites sampled, an epidemiologic association with the probable source should be established before intervention methods, such as disinfection, are undertaken.

Barnes S., Spenney J.G. Improved Enzymatic Assays for Bile Acids Using Resazurin and NADH Oxidoreductase From Clostridium Kluyveri. Clin. Chimica., 102/2-3:0241-0245. 1980.

ABSTRACT: The recent application of resazurin as a fluorigenic electron acceptor in the enzymatic analysis of bile acids has proveded a simple and specific method for serum bile acid quantitation in clinical analysis [1,2]. The absence of blank sample fluorescence, which complicated previous enzymatic methods, has eliminated the need for preliminary solvent or resin extraction of serum [3,4] and has facilitated the application of automated methods [5]. Our studies, reported here, indicate that (a) the sensitivity can be enhanced by conducting the indicator step at pH 6.5, and (b) the assay can be quantitated by measuring changes of either absorbance or fluorescence.

Batjer J.D., Williamson L.J., Polissar L., Hamlin W.B. Effects Of Bacterial Contamination Of Reagent Water On Selected Laboratory Tests. Am. J. Clin. Path., 71:0319-0325. 1979.

ABSTRACT: The effects of three widely spaced levels of bacterial contamination of reagent water on several chemistry, radioimmunoassay, and coagulation procedures were studied. These included determinations of lactate dehydrogenase, creatin kinase, aspartate transaminase, alkaline phosphatase, blood urea nitrogen, total protein, thyroid-stimulating hormone, digoxin, thrombin time, activated partial thromboplastim time, and prothrombin time. Statistical analyses included calculations of means and coefficients of variation, and analysis of variance, as well as correlaton coefficients for test results versus logarithm of bacterial contamination. Statistically and clinically significant differences occurred together only for an elevated level of creatine kinase.

Batra K.K., Omand J., Baselt R.C. Serum Quinidine Concentrations as Measured by Direct Fluorometry, Double-Extraction Fluorometry, and Enzyme Immunoassay. Clin. Chem., 27/5:0780-0781. 1981.

ABSTRACT: We conclude from our results that the direct fluorometric procedure for serum quinidine no longer has a place in the management of quinidine therapy. The discrepancies that may arise with this method between the measured serum concentration and the actual clinical condition are simply unacceptable in view of the current availability of more specific methods.

Baugh P.J. Photodegradation and Photooxidation of Cellulose. Department of Chemistry and Applied Chemistry, University of Salford, UK,.

ABSTRACT: Progress in the study of the photodegradation and photooxidation of cellulose and to some extent cellulose

derivatives in the last decade is reviewed with those aspects in which there have been significant recent advances receiving most attention. Direct and sensitized photooxidation of cellulose are discussed and model system work is treated in a parallel fashion. In relation to both, particular attention is paid to the recent flourish in activity in the study of the nature of free radicals generated in photoirradiated celluloses. This decade has seen a decline in activity of certain aspects of the photosensitized degradation of cellulose, particularly that concerning dye seneitizers, although the controversy over the involvement of singlet oxygen in relation to the validity of the acativated oxygen theory in phototendering has continued during this period. Photoinitiated grafting is given some scope from the standpoint of the nature of the free radicals acative in initiating the polymerization of added monomer,generated in cellulose by direct photolysis and via metal ion photosensitization. Work on the photostabilization and destabilization of cellulose derivatives is also summarized.

Baumgarten R.J. European Vestibular Experiments on The Spacelab-1 Mission: 1. Overview. Exp. Brain Res., 64:0239-0246. 1986.

ABSTRACT: During the flight of Spacelab-1 a series of vestibular experiments was performed on the crew by a group of European investigators. Control experiments were carried out on the same subjects pre- and postflight. The tests included caloric stimulation of the ears, threshold measurements of response to linear acceleration, motion sickness provocative stimuli, vestibulo-ocular reflexes during linear and angular stimulation, estimation of the subjective vertical (luminous line measurements) and static ocular counterrotation at various tilt angles. The caloric experiment proved the existence of a nonthermoconvective mechanism of caloric nystagmus in space. Most of the other test results point to a greater dependence on visual and somatosensory than on otolith cues in the microgravity environment. Some results, in particular the raised threshold to perception of linear acceleration in flight and the temporary reduction of ocular counterrotation at lateral tilts postflight, suggest a decreased gain of the otolith system as a possible effect of space vestibular adaptation.

Bentle L.A., Dutta S., Metcoff J. The Sequential Enzymatic Determination of DNA and RNA. Anal. Biochem., 116:0005-0016. 1981.

ABSTRACT: Enzymatically small quantities of native DNA and RNA in crude tissue homogenates can readily be specifically determined using ethidium bromide as a fluorescent indicator. The ethidium bromide-polynucleotide complexes of DNA and RNA serve as effective substrates for deoxyribonuclease and ribonuclease, respectively. Optimal divalent metal cation requirements were determined for a commone reaction medium that is compatible for both the DNase and RNase reactions. To a single reaction mixture, that contains a biological sample, sequential addition of DNase and RNase produces a specific and rapid decrease in fluorescence that is proportional to the respective amounts of

DNA and RNA present. Levels of DNA and RNA found in six different tissues of the rat were determined enzymatically by this method and compared to that obtained by alternate techniques. Enzymatically determined values were highly reproducible and correlate well with those values obtained by more time-consuming, conventional methods. Most enzymatically determined RNA levels in tissues, however, were significantly greater than those levels obtained spectrophotometrically. Advantages of the enzymatic procedure for analysis of tissue polynucleotide content are: (1) rapid determination of both DNA and RNA within a single sample aliquot allowing maximum use of available sample; (2) extensive fractionation and extraction of the tissue are not required; (3) it is especially useful when quantities of tissue are limited; and (4) sensitivity to 0.05 and 0.25 ug of DNA and RNA, respectively. Reaction conditions developed for the assay also provide for a highly sensitive means to continuously monitor DNA hydrolysis; DNase activity is directly proportional to the amount of enzyme added.

Bergstrom I., Heinanen A., Salonen K. Comparison Of Acridine Orange, Acriflavine, And Bisbenzimide Stains For Enumeration Of Bacteria In Clear And Humic Waters. App. Env. Micro., 51/3:0664-0667. 1986.

ABSTRACT: In highly humic water, acridine orange precipitated with dissolved humic matter, resulting in such bright background fluorescnce that no bacteria could be seen. With bisbenzimide staining, a similar precipitate was nonfluorescent but obscured many cells. An acriflavine staining method proved useful and reproducible both in clear and in humic waters. Fading of fluorescence was not a problem, and stained samples could be stored after preparation. The fluorescence of cells stained with acriflavine was weaker than that with acridine orange, making counting extremely snall cells slightly more difficult with the former stain.

Berry C.A. Medical Legacy of Skylab As of May 9, 1974: The Manned Skylab Missions. Aviat. Space Environ. Med., 47/4:0418-0424. 1976.

ABSTRACT: The purpose of these summary remarks is to put into proper focus the magnificent achievement created by the Skylab Medical Team in concert with their engineering colleagues and most importantly, the astronauts who had to serve as both investigators and subjects. Indeed, by their ingenuity and capability of handling the numerous problems encountered due to engineering deficiencies, they have shcwn man to be indispensable in long-duration space flight.

Billing, E. The Value of Phage Sensitivity Tests for the Identification of Phytopathogenic Pseudomonas Spp. J. appl. Bact., 26/2:0193-0210. 1963.

ABSTRACT: To study the value of phage sensitivity tests for the identification of phytopathogenic pseudomonanda, 284 isolates from various sources were examined for their sensitivity to 9

phages. Phages came from infected plants (4), meat (2), manure (2) and from a culture of Ps. mors-prunorum, P27 (1). The main part of the study was concerned with isolates of Ps. syringae from lilac (6), stone fruits (22), pear (46), Ps. mors-prunorum (17), Ps. phaseolicola (16) and Ps. lachrymans (11), but single isolates of other phytopathogenic Pseudomonas spp. (30) were also examined. Strains of Ps. aeruginosa (5) and pseudomonads from soil, water and chicken meat (151) were included for comparison. Three of the phages 2, 12B and 33 from plant sources showed a high degree of specificity for Ps. phaseolicola, Ps. syringae (pear isolates) and Ps. syringae (lilac isolates), respectively, but in no case was this absolute. Most isolates of the 4 species studied in detail showed characteristic but not specific patterns with phages 12S, 15 and 21. Many of the phytopathogens were sensitive to phage 12S, but pseudomonads from soil, water and chicken meat were not lyzed by this phage. Of this latter group 44% were lyzed by one or more of the phages from meat or manure (14, 15, 20 and 21). Ps. aeruginosa was not lyzed by any of the phages. The ninth phage, P27, lyzed a proportion of Ps. syringae isolates from pear but none of the other pseudomonads tested. Tests for oxidase, sucrose oxidation, gelatinase and lecithinase activity were found useful in conjunction with lesion tests for screening purposes. Many of the phytopathogens, especially those having affinities with Ps. syringae, were oxidase negative. From these results and those of other workers it is concluded that phage sensitivity tests can play a useful part in the identification of phytopathogenic pseudomonads, if used in conjunction with other tests. The importance of the host in connection with phage sensitivity patterrns is emphasized; also the fact that isolates from a wide geographical area and saprophytes from the vicinity of the host plant need to be examined if an adequate assessment of the value of phage is to be obtained.

Billing, E. Further Studies on the Phage Sensitivity and the Determination of Phytopathogenic Pseudomonas spp. J. appl. Bact., 33 :0478-0491. 1970.

ABSTRACT: An interim determinative scheme for phytopathogenic Pseudomonas spp. by a variety of cultural and biochemical tests was suggested by Lelliott, Billing & Hayward (1966) following the study of 156 green fluorescent phytopathogenic pseudomonads. The phage sensitivity of these and 80 additional cultures to 20 phages from a variety of sources are described. Information on the morphology of these phages is now available (Bradley, 1963a). A few nutritional tests which seem to be of diagnostic value at the species level are also included and a relationship between the presence of a heat stable antigen (Lovrekovich et al., 1963) and phage sensitivity patterns is discussed.

Blumer M. Polycyclic Aromatic Compounds In Nature. :0035-0045. .

ABSTRACT: These multiple-ring hydrocaron molecules have been found in soils and sediments around the world. They are unusually stable, and their origins presented an intriguing puzzle.

Bolan M.P., Nieswand G.H., Singley M.E. How Research Helps The Operation Of a Compost Plant. Compost Science/Land Utilization, 1979 Conference Proceedings-Part II,20/5:0017-0021. 1979.

ABSTRACT: The research components at the Camden Composting Project reflect each operation - dewatering, mixing, aeration, screening, curing, use - as sludge is processed into compost.

Borison H.L. A Misconception of Motion Sickness Leads to False Therapeutic Expectations. Aviat. Space Environ. Med., 56 :0066-0068. 1985.

ABSTRACT: The emetic chemoreceptor trigger zone (CTZ), located in the area postrema of the medulla oblongata, is generally believed to be indispensable for the vomiting in motion sickness and by extrapolation, also in space sickness. Accordingly, it has been postulated that a "motion vomiting substance" is secreted into the cerebrospinal fluid in the emetic process. Furthermore, certain therapeutic measures against motion sickness are aimed at preventing the presumed chemical stimulation of the CTZ. This concept originated from laboratory experiments in which ablation of the area postrema protected some dogs and monkeys against motion-induced vomiting. More recent experiments, however, showed that verified lesions of the area postrema were not effective in preventing motion sickness in cats. It appears that an indispensable unidentified element close to but separate experiments. The overall evidence leads to the conclusion that the area postrema is not essential for motion-induced vomiting. Therefore, no functional basis exists for the postulation of a motion vomiting substance, and it is irrational for the treatment of motion sickness to seek pharmacologic blocking agents that act at the CTZ.

Brennan D.H., Girvin J.K. The Flight Acceptability Of Soft Contact Lenses: An Environmental Trial. Aviat. Space Environ. Med., 56 :0043-0048. 1985.

ABSTRACT: Seventeen officer aircrew, wearing soft contact lenses, were subjected to adverse conditions likely to be encountered in military aviation. The stresses included hypoxia, rapid decompression, pressure breathing, vibration, climatic extremes, G forces, and the prolonged wearing of an aircrew respirator. Their visual performance wearing contact lenses under stress did not differ significantly from the control values; either when wearing corrective flying spectacles or contact lenses when not under stress. It is considered that from the environmental standpoint soft contact lenses are suitable for aircrew. As contact lenses may not be tolerated by all, and may cause undesirable side-effects in some, their use should be restricted to the aircrew to whom they offer the maximum advantages. The group most likely to benefit are young, well motivated myopes flying fast jets.

Brorstrom E., Grennfelt P., Lindskog A. The Effect Of Nitrogen Dioxide And Ozone On The Decomposition Of Particle-Associated

Polycyclic Aromatic Hydrocarbons During Sampling From The Atmosphere. Atm. Environ., 17/3:0601-0605. 1983.

ABSTRACT: The effects of NO2 and O3 exposure on the degradation of polycyclic aromatic hydrocarbons (PAH) during high-vloume sampling of airborne particulate matter were studied. Addition of 1 ppm NO2 during ambient air sampling caused degradation of pyrene, benz(a)anthracene and benzo(a)pyrene, most probably due to nitration. Acid particles seem to enhance the reaction. The results indicate that NO2 concentrations within the range normally formed in urban air may cause degradatin of some reactive PAH. Addition of 200 ppb)3 caused degradation in one of the three experiments only.

Brorstrom E., Grennfelt P., Lindskog A. The Effect of Nitrogen Dioxide and Ozone on the Decomposition of Particle-Associated Polycylilc Aromatic Hydrocarbons During Sampling from the Atmosphere. Atm. Environ., 17/3:0601-0605. 1983.

ABSTRACT: The effects of NO2 and O3 exposure on the degradation of polycyclic aromatic hydrocarbons (PAH) during high-volume sampling of airborne particulate matter were studied. Addition of 1 ppm NO2 during ambient air sampling caused degradation of pyrene, benz(a)anthracene and benozo(a)pyrene, most probably due to nitration. Acid particles seem to enhance the reaction. The results indicate that NO2 concentrations within the range normally formed in urban air may cause degradation of some reactive PAH. Addition of 200 ppb O3 caused degradation in one of the three esperiments only.

Brundage J.F., Scott R.M., Lednar W.M., Smith D.W., Miller R.N. Building-Associated Risk OF Febrile Acute Respiratory Diseases In Army Trainees. JAMA, 259/14:2108-2112. 1988.

ABSTRACT: Airborne transmission of infectious agents and associations of indoor air pollutants with respiratory illnesses are well documented. We hypothesized that energy conservation measures that tighten buildings also increase risks of respiratory infection among building occupants. At four Army training centers during a 47 month period, incidence rates of febrile acute respiratory disease were compared between basic trainees in modern (energy-efficient design and construction) and old barracks. Rates of febrile acute respiratory disease were significantly higher among trainees in modern barracks (adjusted relative risk estimate, 1.51; 95% confidence interval, 1.46 to 1.56), and relative risks were consistent at the four centers. These results support the hypothesis that tight buildings with closed ventilation systems significantly increase risks of respiratory-tranmitted infecton among congregated, immunologically susceptible occupants.

Buchanan P. The Closing Gap Between Occupational Medicine and Flight Medicine In The Space Station Era. Biomedical Office, NASA, J. F. Kennedy Space Center, Texas, U.S.A.,:0237-0244. .

ABSTRACT: None

Bucker H., Horneck G., Reitz G., Graul E.H., Berger H., Hoffken H., Ruther W., Heinrich W., Beaujean R. Embryogenesis and Organogenesis of Carausius Morosus Under Spaceflight Conditions. Naturwissenschaften, 73:0433-0434. 1986.

ABSTRACT: None

Bungo M.W., Charles J.B., Johnson P.C. Cardiovascular Deconditioning During Space Flight And The Use of Saline As A Countermeasure To Orthostatic Intolerance. Aviat. Space Environ. Med., 56 :0985-0990. 1985.

ABSTRACT: Alterations in the physiology of the cardiovascular system have been noted during all exposures to the microgravity experienced in space flight. Of most importance to the operational function of Space Shuttle crewmembers in orthostatic intolerance. Although complex changes occur as a result of adaptation to weightlessness, the redistribution and loss of body fluid apparently plays a substantial role. Utilizing ground-based bed rest data as an analog to the absence of gravitational force excountered in orbital flight, a saline loading countermeasure was developed. In this study, 17 crewmembers consumed various amounts of salt and fluid prior to the reentry phase of Space Shuttle flights; 9 other astronauts served as control subjects. The countermeasure reduced the heart rate response to orthostatic stress 29% and reversed the fall in mean blood pressure. A Cardiovascular Index of Deconditioning (defined as CID=delta HR- delta SBP+delta DBP) equalled 21 in those who utilized the countermeasure, a significant improvement toward baseline ($p<0.003$) when compared to the control group CID= 49. The encouraging results of these investigations have led to the adoption of the countermeasure as an operational procedure by Shuttle crewmembers.

Bungo M.W., Goldwater D.J., Popp R.L., Sandler H. Echocardiographic Evaluation Of Space Shuttle Crewmembers. J. Appl. Physiol., 62/1:0278-0283. 1987.

ABSTRACT: Echocardiographic measurements were obtained before and after space flight from 17 members of four shuttle crews. Measurements obtained 1 h after landing (L+0) compared with preflight values (n=7) demonstrated an increase in heart rate (HR) (16 beats/min, 30.5%, $P < 0.05$), mean arterial pressure (12%, $P < 0.05$), and systemic vascular resistance (34% $P < 0.05$). End-diasolic volume index (EDVI) fell 17 ml/m2 (-23%, $P < 0.005$) and stroke volume index (SVI) fell 15 ml/m2 (-28%, $P < 0.05$). Repeat measurements taken 1-2 wk later (n=17) demonstrated that HR had returned to normal (4 beats/min, $P < 0.05$); however, EVDVI remained significantly below preflight levels (-11%, $P < 0.005$). End-systolic volume index (ESVI) was also still significantly lower (-23%, $P < 0.01$). This delayed recovery occurred despite ability of the subjects to fully ambulate and exercise during the postflight period. These results indicate that spaceflight induces significant changes in heart volume affecting left ventricular function. The exact rasons for these specific

changes remain unknown and will require additional measurements before, during, and after flight. The prolonged recovery period for the present subject group probably relates to their high level of aerobic conditioning.

Buoni C.M., Hill C.E., Arthur H.F., Johnson L.R., Balog P.P., Rench J.D., Coutant R.W., Rodman C.W. Space Station Contamination In Pressurized Environments: Issues And Options. Battelle Columbus Laboratories Report, NASA KSC Contract NAS10-11033,1985.

ABSTRACT: None

Canaveris G., Nau G.J. Intraventricular Conduction Disturbances In Flying Personnel: Development and Prognosis Of Bifascicular Blocks. Aviat. Space Environ. Med., 58:0683-0689. 1987.

ABSTRACT: The evolutive characteristics as well as the qualification criteria applied in 21 cases of bifascicular blocks detected in a presumably healthy population consisting of 6,915 male individuals engaged in cilvilian flying activities (prevalence: 0.3%) were studied. The cases were divided in four groups according to the type and severity of the conduction disturbance. The sequence of conduction disturbances, ages and electrical axis rotation velocity are assessed. Bifascicular blocks may be complete or incomplete. The progression towards advanced conduction disturbances may affect the involved fascicles independently. Cases with incomplete bifascicular block have better prognosis, followed by those with primary conduction system disease. The mean time between the development of first and second conduction disturbance was 3.5 years. On an individual basis, once those etiologies which by themselves imply a future risk are ruled out, and provided they do not show evolutive features in frequent repeat evaluations, they may be waivered for flying activities with a proposed maximum age of 60 years.

Carlsson A.S., Nilsson B., Walder M.H., Osterberg K. Ultraviolet Radiation and Air Contamination During Total Hip Replacement. J. Hospital Infection, 7:0176-0184. 1986.

ABSTRACT: Ultraviolet radiation of the operationg room was assessed bacteriologically in an open randomized study of 30 total hip procedures. Volumetric air-sampling demonstrated that the number of colony forming units (cfu m-3) were significantly reduced ($P<0.001$) by uv light, bouth close to the wound and in the periphery of the operationg room. No adverse effects of uv-irradiation were observed either in the patients or the staff. In operationg rooms fitted with a 'zonal ventilation' system and with an air change rate of about 70 h-1, the addition of uv irradiation during surgery may achieve 'ultra clean' air. However, in conventionally ventilated operating rooms uv-irradiation alone is probably not sufficient to do so.

Chahal D.S. Solid-State Fermentation With Trichoderma reesei For Cellulase Productio . App. Env. Micro., 49/1:0205-0210. 1985.

ABSTRACT: Cellulase yields of 250 to 430 IU/G of cellulose were recorded in a new approach to solid-state fermentation of wheat straw with Trichoderma reesei QMY-1. This is an increase of CA. 72% compared with the yields (160 to 250 IU/G of cellulose) in liquid-state fermentation reported in the literature. High cellulase activity 16-17 1U/ML) per unit volume of enzyme broth and high yields of cellulases were attributed to the growth of T. reesei on a hemicellulose fraction during its first phase and then on a cellulose fraction of wheat srraw during its later phase for cellulase production, as well as to the close contact of hyphae with the substrate in solid-state fermentation, the cellulase system obtained by the solid-state fermentation of wheat straw contained cellulases (17.2 IU/ML), B-glucosidase (21.2 IU/ML), and xylanases (540 IU/ML). This cellulase system was capable of hydrolyzing 78 to 90% of delignified wheat straw (10% concentration) in 96 H, without the addition of complementary enzymes, B-glucosidase, and xylanases.

Chambers A. Long Residence, An Uncharted Field. Astro. Aero, :0061-0063. 1983.

ABSTRACT: None

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ABSTRACT: None

Chen M., Hickey P.J. Elimination Of Overgrowth In Delayed-Incubation Membrane Filter Test For Total Coliforms By m-ST Holding Medium. App. Env. Micro., 52/4:0778-0781. 1986.

ABSTRACT: Two holding media were compared for their effects of total coliform recovery by the delayed-incubation membrane filter procedure. LES-MF holding medium contains tryptone, m-Endo broth, dipotassium hydrogen phosphate, sodium benzoate, sulfanilamide, para-aminobenzoic acid, and cycloheximide (pH 7.0). m-ST holding medium contains ethanol, sodium monophosphate, dipotassium hydrogen phosphate, sulfanilamide, and Tris (pH 8.6). In test with natural water and wastewater samples from various sources recovery with LES-MF and m-ST were similar after a 1-day holding period. With LES-MF, however, after a 2 or 3 day holding period, coliform bacteria frequently were partially or totally overgrown by noncoliforms, causing significant reductions in coliform counts. No significant overgrowth was observed with m-ST. We propose that m-ST be used for all holding periods longer than 1 day.

Christensen J.M., Talbot J.M. A Review of The Phychological Aspects of Space Flight. Aviat. Space Environ. Med., 57:0203-0212. 1986.

ABSTRACT: Instances of overt, serious functional impairment of space crews caused by adverse psychologic responses have not been scientifically documented. However, transient disorientation, spatial illusions, and visual disturbances as well as anomalous myopias, sleep disturbance, and instances of substandard

performance have been described. Moreover, anecdotal information describes significant psychologic aberrations in space flight. Adequate scientific data are lacking for optimal psychological and psychophysiological methods for crew selection, training, and performance evaluation, for identifying key psychosocial factors for crew compatibity, cohesiveness, and productivity, and for determining the effects of space flight on perceptual, intellectual, and motor skills. The ad hoc Working Group, converted to review psychological aspects of space flight, favored establishment of a comprehensive research and development program to address the deficiencies identified in the study.

Clement G., Gurfinkel V.S., Lestienne F., Lipshits M.I., Popov K.E. Changes of Posture During Transient Perturbations In Microgravity. Aviat. Space Environ. Med., 56:0666-0671. 1985.

ABSTRACT: The control of goal-directed arm movement and of body stability before, during, and 3 d after a 7-d spaceflight has been investigated. The findings show that the anticipatory and compensatory activities of the postural muscles were highly reproducible during the first days of the space mission. The sequence of these activities, studied in two situations- in which the platform either was fixed of could rotate about near the rotation exis of the ankle- was similar to a ground-based situation. The trajectory of various body segments demonstrated that a 7-d exposure to microgravity did not result in major changes in posture. Furthermore, vision seemed to play an important role in the control of standing posture at the beginning of the flight. Postural perturbatins, elicited by unexpected displacements of the foot support, involved leg muscle reflexes whose amplitudes were greatly reduced compared to those on earth.

Cohen B.L., Gromicko N. Adequacy Of Time Averaging With Diffusion Barrier Charcoal Adsorption Collectors For 222RN Measurements In Homes . Health Physics, 54/2:0195-0202. 1988.

ABSTRACT: Radon-222 Levels in homes are known to undergo short-term fluctuations over times ranging from less than an hour to a few days, as well as long-term seasonal variations. Since we are usually interested in time-averaged 222RN Levels, it is important to know how well a measurement device determines this average. Clearly the average over a full year as can be done with a Beta track detector, and that is therefore unquestionable the most meaningful measurement. However, regardless of the desires of scientists, the great majority of measurements are made for 1 MO Or less during which seasonal variations are of negligible importance. For these, it is important to know how well they average over short-term fluctuations. In this paper, we consider that question, in particular, we determine the average deviation of a single measurement from the 1-MO Average.

Collins M.D., Jones D. Distribution of Isoprenoid Quinone Structural Types in Bacteria and Their Taxonomic Implications. Micro. Reviews, 45/2:0316-0354. 1981.

ABSTRACT: Chemotaxonomic methods, such as cell wall analyses and deoxyribonucleic acid base ratio and homology determinations, now figure prominently in microbial systematics. To date, the use of lipids as chemical characters has generally received less attention by bacterial taxonomists. However, studies involving fatty acid and polar lipid analyses have yielded encouraging results. A class of terpenoid lipids with a similar inherent potential in chemotaxonomy are the isoprenoid or respiratory quinones. Isoprenoid quinones are constituents of bacterial plasma membranes and play important roles in electron transport, oxidative phosphorylation, and, possibly, active transport. The results of the early studies indicated that the inherent structural variation exhibited by isoprenoid quinones might be of value in microbial systematics. The majority of subsequent studies on the isoprenoid quinones of bacteria have been preformed by biochemists, whose primary interest is in the function of these compounds in bacterial cells and not in their value as taxnomic markers. Over the last decade, however there have been a number of comparative studies designed to assess the value of these compounds in microbial taxonomy. Thus, there is now a comparable body of material on isoprenoid quinone structural types and their distribution in a large number of bacterial genera. However a great deal of this information is fragmentary and scattered through the literature in papers not necessarily concerned with taxonomy. Therefore seemed opportune to review the literature in this field and where possible,to attempt to evaluate the data in the context of taxonomic groupings based on other criteria.

Collins M.D., Jones D. Distribution of Isoprenoid Quinone Structural Types in Bacteria and Their Taxonomic Implications. Micro Reviews, 45/2:316-354. 1981.

ABSTRACT: Chemotaxonomic methods, such as cell wall analyses and deoxyribonucleic acid base ratio and homology determinations, now figure prominently in microbial systematics. To date, the use of lipids as chemical caracters has generally received less attention by bacterial taxonomists. However, studies involving fatty acid and polar lipid analyses have yielded encouraging results. A class of terpenoid lipids with a similar inherent potertial in chemotaxonomy are the isopernoid or respiratory quinones.

Collmer A., Wilson D.B. Coding And Expression Of A Thermomonospora YX Endocellulase Gene In E. coli. Biotechnology, 1983.

ABSTRACT: A set of E. coli transformants (2,500) containing plasmid pBR322 with Thermomonospara YX DNA inserts larger than 3 kb was prepared. The transformants were screened directly for the ability to hydrolyze carboxymethyl cellulose. Two colonies exhibiting cellulase activity were found. One colony contains a plasmid (pD365) that contains a 7.6 kb insert, including the entire gene coding for the major endoglucanase activity of Thermomonospora YX. The other colony (D315) had two plasmids in it: pD316 contains a 8.5 kb insert which includes at least 80% of the major endoglucanase gene; pD315 contains a 6.6 kb insert and

does not express cellulase activity. Restriction maps were prepared for each plasmid and the endoglucanase gene was localized to a 2.3 kb Sall fragment in pD316 and to a 3.7 kb EcoRI fragment in pD365. These fragments were subcloned into plasmids containing active promotgrs regulated by the lactose repressor. The new strains each made 50 times more cellulase than the original strains. E. coli transformants containing plasmids pD316, pD365 and their dervaties secrete about 30% of their endoglucanase activity into the medium, 30% into the periplasmic space, while 40% remains in the cytoplasm. Thermomonospora YX DNA restriction digests were fractionated by agarose gel electrophoresis and the fragments which hybridized to pD315 and pD316 were detected by nitrocellulose blotting techniques. The results indicated that each plasmid contains a single contiguous segment of Thermomonospora YX DNA and that the pD315 and pD316 inserts are linked in the Thermomonospora YX genome.

Colombo G.V., Greenley D.R., Putnam D.F., Sauer R.L. Advanced Microbial Check Valve Development. The American Society of Mechanical Engineers, #81-ENAs-45,.

ABSTRACT: The Microbial Check Valve (MCV) is a flight qualified assembly that provides bacteriologically safe drinking water for the Space Shuttle. The 1-lb unit is basically a canister packed with an iodinated ion-exchange resin. The device is used to destroy organisms in a water stream as the water passes through it. It is equally effective for fluid flow in either direction and its primary method of disinfecton is killing rather than filtering. The MCV was developed to disinfect the fuel cell water and to prevent back contamination of stored potable water on the Space Shuttle. This paper reports its potential for space applications beyond the basic shuttle mission. Data are presented that indicat the MCV is suitable for use in advanced systems that NASA has under development for the reclamation of humidity condensate, wash water and human urine,

Compton, D. A. C., Hill, S. L., Wright, N. A., Druy, M. A., Piche, J., Stevenson, W. A., Vidrine, D. W. . In-Situ FT-IR Analysis of a Composite Curing Reaction Using a Mid-Infrared Transmitting Optical Fiber. In-Situ FT-IR Analysis of a Composite Curing Reaction Using a Mid-Infrared Transmitting Optical Fiber, :0002-0022. .

ABSTRACT: The use of a mid-infrared transmitting fiber to carry the infrared beam of an FT-IR spectrometer outside of the optical bench is reported. In addition it is demonstrated that it is possible to analyze samples using the fiber as an Internal Reflection Element. The fiber is covered with a protective coating which can be removed for a short region, to allow contact with the sample over a controlled length. Two examples of the use of an optical fiber for remote sampling are discussed. The first shows that a spectrum of a liquid sample (2-butanone) may be easily measured, and the second shows how a fiber may be used to monitor the progress of a curing reactions in thermoset composite materials. The spectrum of a resin was recorded before

the cure by embedding the optical fiber in the graphite fiber/polyimide matrix resin prepreg, and then the progress of the cure monitored during the curing process. This type of remote sampling shows treemendous potential for opening totally new areas of usage for FT-IR spectrometry, including the studies of hazardous materials, enclosed reactions, and processes that do not allow samples to be taken inside the spectrometer.

Connors M. Dentistry Moves Into Space. TIC, XLVI/4:0001-0003. 1987.

ABSTRACT: None

Cooper H.R., Chorpenning F.W., Rosen S. Preparation And Chemical Composition Of The Cell Walls Of Streptococcus mutans. Inf. And Imm., 11/4:0823-0828. 1975.

ABSTRACT: Purified cell walls from Streptococcus mutans strain BHT were prepared without the use of proteolytic enzymes in order to retain all cell wall constituents for chemical analysis. Of four methods employed, the Ribi cell fractionator produced disrupted cell suspensions which could be most thoroughly purified on sucrose gradients. Results of chemical analyses on purified cell walls prepared in this manner represented 99.2% recovery. They indicated the presence of 6.8% protein, 8.9% glycerol teichoic acid, 33.6% non-peptidoglycan polysaccharide, and 49.9% peptidoglycan.

Cornet P., Millet J., Beguin P., Aubert J.P. Characterization Of Two (Cellulose Degradation) Genes Of Clostridium thermocellum Coding For Endoglucanases. Biotechnology, 1983.

ABSTRACT: Two structural genes, celA and celB, coding respectively for the endoglucanases A and B of Clostridium thermocellum, were subcloned from cosmids of a gene bank into plasmid pBR322. Both genes are carried in a DNA sequence of about 2.7 kb. They share no homology and are not contiguous on the C. thermocellum chromosome. They are expressed in E. coli independenatly of their orientation in the coloning vector.

Cosman B.C., Brandt-Rauf P.W. . Infectious Disease In Antarctica And Its Relation To Aerospace Medicine: A Review. Aviat. Space Environ. Med., 58:0174-0179. 1987.

ABSTRACT: In many aspects, an Antarctic Station provides parallels to the environments encountered in space exploration, particularly with reference to infectious disease. In both instances, small groups of people live in isolation for long periods of time in a functionally sterile atmosphere. Therefore, studies of infectious disease in Antarctica should provide important insights into the experiences to be expected in spaceflight. This paper presents a summary of the information on the infectious and immunologic aspects of isolation derived over the years from research in Antarctica.

Council on Scientific Affairs. Cancer Risk of Pesticides in Agricultural Workers. JAMA, 260/7:0959-0966. 1988.

ABSTRACT: This report discusses one of the inherent limitations of cancer studies in animals and humans and presents a Qualitative carcinogen risk assessment of a number of pesticides based on the judgement of national and international authorities who have reviewed the available experimental and epidemiologic evidence. A large number of pesticidal compounds have shouwn evidence of genotoxicity or carcinogenicity in animal and in vitro screening tests, but no pestidices except arsenic and vinyl chloride (once used as an aerosol propellant)- definitely have been proved to be carcinogenic in man. Resolution 94 (I-86), which was refferred to the Board of Trustees, calls for the American Medical Association, through its scientific journals and publications, to alert physicians to the potential hazards of agricultural pesticides, to provide physicians with advice on such hazards for their patients, and to urge that these substances be appropriately labeled. This report addresses the potential carcinogenicity of pestidices by review of the available literature.

Crosse, J. E., Garrett, C. M. E. . Studies on the Bacteriophagy of Pseudomonas Mors-Prunorum, Ps. Syringae and Related Organisms. J. Appl. Bact., 26/2:0159-0177. 1963.

ABSTRACT: A group of 23 phages, mainly isolated with Pseudomonas mors-prunorum and Ps. syringae as the propagating strains, was tested against more than 200 pseudomonads including named plant pathogens and a variety of saprophytes. The majority of the phages had a wide host range, and did not distinguish between plant pathogens and saprophytes, thus confirming the close relationship between these two groups. The most reactive bacteria were 60 English isolates of Ps. mors-prunorum, 48 from cherry and 12 from plum, and 28 isolates of Ps. syringae from pear. Patterns of reaction within these 3 groups were relatively homogeneous and each group was distinct and differed from all other isolates tested. Ps. syringae isolates from other hosts were less uniform and occasionally shared reaction patterns with other species, e.g. Ps. cannabina and Ps. glycinea. Similar relationships were observed with phages at both high titre and at routine test dilution including the difference in phage sensitivity between the cherry and plum strains of Ps. mors-prunorum. On the basis of 7 biochemical tests the plum and cherry strains were indistinguishable but they differed from all Ps. syringae isolates tested by giving white growth in 5% sucrose broth and in failing to liquefy gelatin. Furthermore, unlike most Ps. syringae isolates they were also unable to hydrolyze aesculin and were tyrosinase positive. There was no clear evidence in this investigation of correlation between phage sensitivity and biochemical activity. Eleven isolates from various European countries, designated Ps. mors-prunorum, differed widely both in phage sensitivity and biochemical activity and some of them may be more appropriately called Ps. syringae. Others may be intermediate forms between these species. The relationship between Ps. mors-prunorum and Ps. syringae and the nomenclature of these organisms are discussed and a concept of ecotypes suggested as a substitute for species.

Crowley J.S. Simulator Sickness: A Problem For Army Aviation. Aviat. Space Environ. Med., 58:0355-0357. 1987.

ABSTRACT: "Simulator sickness" describes a symptom complex frequently reported by pilots durilng or after flight simulator training. There were 112 helicopter pilots at a U.S. Army AH-1 Cobra Flight Weapons Simulator (FWS) who completed a symptom-orientaed objective questionnaire. Of these, 40% reported symptoms of dysequilibrium; pilots developing simulator sickness had significantly more total and AH-1 fligth time. Adaptation of the syndrome occurred with increasing FWS experience. The history and aeromedical significance of simulator sickness are briefly reviewed, and a case report presented. A mandatory grounding policy in use locally is described. Potential treatment strategies are briefly discussed.

Dally E.L., Stokes H.W., Eveleigh D.E. A Genetic Comparison Of Strains Of Zymomonas mobilis By Analysis Of Plasmid DNA. Biotech. Let., 4/2:0091-0096. 1982.

ABSTRACT: Strains of Zymomonas mobilis were examined for their ability to act as recipients of plamid DNA and for the relatedness of native plasmids which these strains harbor. We conclude that the high ethanol producing strains CP3 and CP4 are identical.

Daniell W.E., Couser W.G., Rosenstock L. Occupational Solvent Exposure And Glomerulonephritis. A case Report and Review of the Literature. JAMA, 259/15:2280-2283. 1988.

ABSTRACT: We describe a patient who presented with renal failure after a one-year period of unprotected heavy occupational exposure to organic solvents. Renal biopsy results and serological findings were diagnostic of anti-glomerular basement membrane antibody-mediated glomerulonephritis. An analytic review of the literature revealed substantial evidence linking solvent exposure to the development of glomerulonephritis (GN), with seven of nine case-control studies demonstrating a statistically significanat association. Odds ratios were reported by or could be calculated for six of these studies, and the five positive studies detected a 2.8 to 2.9 fold increased risk for GN among solvent-exposed individuals. The findings in several of these studies of dose-response relatioships, the reports of variations in disease severity in relation to exposure intensity, and the absence of alternative explanations for the association provide additional supportive evidence for a solvent effect. In the majority of cases of anti-glomerular basement membrane antibody-mediated GN and other types of GN, there is no remarkable preceding exposure to organic solvents. However, we conclude that in the case presented herein and in cases of GN with similar exposure histories, solvent exposure may play a significant contributing role in the development of GN.

Davies I.B., Grind I.M., Pottage A., Turner P. Development of new drugs in man: a review. J. Royal Soc. Med., 79:96-99. 1986.

ABSTRACT: The period of development of a new drug averages 10-15 years from initial invention of the chemical structure to approval for general use. In the US, the current cost can approach 100 million dollars, while elsewhere it can be approximately 15-20 millon pounds sterling. Two main stages are involved in drug development: the preclinical stage comprises chemistry (synthesis, purification, patenting), pharmacology, pharmacokinetics and toxicology in animals and pharmaceutical development of dosage forms; the clinical stage includes four phases which embrace all studies done in man. The major aim of drug development is a safe and effective product. If a drug causes many minor side effects, or one serious one, development will probably be stopped unless the drug is of unique clinical benefit. However, for some drugs unusual serious adverse drug reactions (ADR) have been identified for the first time after marketing, benoxaprofen (Opren), indomethacin slow release, and zimeldine. In these cases the incidence of the ADR was so low, about 1:10,000-1:100,000 patients treated, that it was impossible to identify even in the large-scale clinical trials done before marketing; it follows that this type of rare ADR cannot be avoided even with extensive testing before ,marketing, and this must be accepted if development of new drugs is to continue. This paper rewiews the development programme of new drug (new chemical entity, NCE) taking approximately 5-7 years form initial administration to man to the point of approval for marketing by the various European and North Ametical requlatory authorities.

De Valdez G.F., De Giorgi G.S., De Ruiz Holgado A.P., Oliver G. Effect Of The Rehydration Medium On The Recovery Of Freeze-Dried Lactic Acid Bacteria. App. Env. Micro, 50/3:1339-1341. 1985.

ABSTRACT: Sixteen cultures of lactic acid bacteria were freeze-dried in 10% nonfat skim milk plus 0.75 M adonitol and rehydrated by using different rehydration media. Marked variations in their capacity to repair cellular damage after freeze-drying were observed among the species and strains under condiseration.

De Vicente A., Borrego J.J., Arrabal F., Romero P. Comparative Study Of Selective Media For Enumeration Of Pseudomonas aeruginosa From Water By Membrane Filtration. App. Env. Micro., 51/4:0832-0840. 1986.

ABSTRACT: In the present study, mPA-D and mPA-E agar, modifications of mPA-C agar that reduce background fecal strptococci that interfere with the differentaition and enumeration of the Pseudomonas aeruginosa colonies grown in other mPA media, are proposed for use in analyzing natural water samples. In addition, the efficiencies of several culture media for the recovery of P. aeruginosa in water after membrane filtration and multiple-tube techniques are compared. The degree of selectivity, precision, efficiency, and sensitivity achieved with the proposed media exeeded that achieved by current methods. Furthermore, they yielded equal rates of accuracy and specificity. Incubation at 36 C resulted in an improved recovery

of stressed P. aeruginosa. In conclusion, we propose the use of mPA-D and mPA-E agar, both incubated at 36 C for 24-48 h, for analyzing river water and seawater, respectively.

Dellinger J.A., Taylor H.L., Porges S.W. . Atropine Sulfate Effects On Aviator Performance and On Respiratory-Heart Period Interactions. Aviat. Space Environ. Med., 58:0333-0338. 1987.

ABSTRACT: In this study, 20 human volunteers received a placebo and atropine doses of 0.5, 1.0, 2.0, and 4.0, mg 75 kg-1 in a Latin Square double blind design, and effects were monitored for 3 h postinjection. The 2.0 mg and the 4.0 mg doses resulted in significant flight simulator performance decrements beginning at 1 h postinjection with only minimal recovery by 3 h postinjection. Electrocardiogram data were used to estimate the amplitude of respiratory sinus arrhythmia (RSA) which was more sensitive than mean heart period or mean heart period variance to the effects of atropine. These parasympathetic effects were relatively rapid in onset and peaked within the first 40-min period for the 2.0 and 4.0 mg doses. The onset of performance effects were delayed 1 h 40 min for the 2.0 mg and 1 h 00 min for the 4.0 mg treatments.

Dement W.C., Seidel W.F., Cohen S.A., Bliwise N.G., Carskadon M.A. Sleep And Wakefulness In Aircrew Before And After Transoceanic Flights. Aviat. Space Environ. Med, 57 (12, Suppl.):B0014-B0028. 1986.

ABSTRACT: Aircrew were studied before and after flying one of two routes: San Francisco (SFO) to London (LHR) or SFO to Tokyo (NRT). After an adaptation night, sleep and daytime sleepiness were objectively measured in SFO and during the first layover (L/O) of the target trip. Baseline sleep was slightly shorter than normally reported for similar age subjects and, for several reasons, is not an ideal basis for subsequent comparison. Nevertheless, L/O sleep periods tended to provide either less total sleep or less efficient sleep. Crewmember's estimates of their sleep duration correlated well with objectve measures, but estimates of daytime sleepiness correlated poorly with objectively measured sleepiness. During baseline there was a significant midday sleep tendency as measured by the Multiple Sleep Latency Test. This tendency occurred at almost the same time (GMT) on the second L/O day in LHR. Since sleepiness has a persistent rhythm which is maximal twice per day, it is suggested that L/O sleep periods be taken at these times of maximal sleepiness and that peak workload should coincide with the subsequent periods of maximal alertness. Although the overall quality of sleep diminished only slightly on this L/O, it is possible that if this relatively small loss accumulated over successive L/Os, the effects on daytime sleepiness could be measurable.

DeRoos R.L., Wheeler D.J. Medical uses of high-purity water. Hospitals, 46/13:0100-0104. 1972.

ABSTRACT: Providing the different kinds of water used in health

care institutions is a formidable challenge. Water is used in the cleaning of equipment, in medical support equipment such as artificial kidney machines and respiratiors, in the preparation of infant formulas and injectable soultions, and so on. As steam, water is used in heating equipment, in autoclaves, in steam cookers, and in steam sanitizers. The water needed may be ordinary municipal tap water, or it may be high-purity water. This article discusses the uses of high-purity water, some considerations for determining the type of water required, and different methods for providing these special types of water.

Detroy R.W., Rhodes R.A. Biological Conversion Of Agricultural Lignocellulosics To Ethanol And Digestible Feedstuffs. Workshop 2: Conversion Of Lignocellulosic Materials To Simple Carbohydrates ,1980.

ABSTRACT: Chemical and biological methods for delignification coupled to enzymatic bydrolysis of freed cellulose are being studied at the Northern Regional Reserach Center, Peoria, Ill. The immmediate objective is enhanced production of alcohol from biomass. The oyster mushroom, Pleurotus ostreatus, NRRL 2366, was grown on native wheat straw (WS) ammended with ammonium sulfate, urea, or oatmeal. The fungus degraded the lignocellulosec WS, as evidenced by 10 to 45% and 15 to 55% decreased in lignin and cellulose, respectively, after 36 days. The initial lignin and cellulose utilization was also greater with oatmeal amendment. Soluble reducing sugars in WS remained constant during the first 15 days of incubation; however, free reducing sugars increased twofold to threefold the remainder of the fermentation period regardless of nitrogen amendment. The in vitro digestibility of WS as measured by release of reducing sugar after cellulase treatment increased twofold to threefold after a 90 day fermentation period. Fermented WS thus would have improved digestibility in animal diets and the mycelium should contribute increased nutritional value.

Dinterfass L. Background And Development of the Space Project on "Aggregation Of Red Cells" Austral. Physical Eng. Sci. In Med., 6/4:0156-0165. 1983.

ABSTRACT: None

Dixon G.A., Adams J.D., Harvey W.T. Decompression Sickness And Intravenous Bubble Formation Using A 7.8 PSIA Simulated Pressure-Suit Environment. Aviat. Space Environ. Med., 57 :0223-0228. 1986.

ABSTRACT: The purpose of this study was to determine the minimum space-suit pressure required to prevent decompression sickness (DCS) during operational conditions in a 50% oxygen/50% nitrogen environment. In this study, 30 male volunteer subjects were exposed in groups of three, to three consecutive daily extravehicular activity (EVA) simulations at 7.8 psia (5,031 m altitude equivalent) for a continuous period of 6 h. During each altitude exposure, the subjects participated in similar exercise workloads expected to be experienced by astronauts during a

typical EVA scenario. Precordial Doppler monitoring revealed that 73.3% of the subjects had intravenous bubbling during at least 1 d of the 3h of exposure, with 26.7% remaining bubble-free during the entire study. No correlation was found between either body fat or age and incidence of bubble formation. One case of DCS occurred during the study indicating that 7.8 psia is not sufficient pressure to preclude DCS in a 50% exygen/50% nitrogen environment. The necessary pressure awaits further study.

Dolbeare F. Dynamic Assay Of Enzyme Activities In Single Cells By Flow Cytometry. J. Histochem. And Cytochem., 27/12:1644-1646. 1979.

ABSTRACT: Three enzymes in single cells were assayed dynamically by flow cytometry using four fluorogenic substrates. Acid phosphatase was determined with 7-bromo-3-hydroxy-2-naphtho-o-anisidine (naphthol AS-BI) phosphate and 4 methylumbelliferone (MU) phosphate, neutral esterase with fluorescein diacetate, and lactic dehydrogenase with NAD-sodium lactate. Fluorescence measurements obtained with the flow cytometer were converted into relative specific enzyme activities for single cells with molar fluorescence coefficients determined with a spectrofluorometer. Specific activities obtained from spectrofluorometric data were compared with activities for 4-methylumbelliferone phosphate hydrolysis and for lactic dehydrogenase than did similar assays by standard spectrofluorometry. Product diffusion may be the greatest cause for this discrepancy.

Du Moulin G.E., Coleman E.C., Whyte J.H. Bacterical Colonization and Endotoxin Content of a New Renal Dialysis Water System Composed of Acrylonitrile Butadiene Styrene. App. and Env. Micro, 53/6 :1322-1326. 1987.

ABSTRACT: We measured encotoxin and bacterial levels in tap water, in water purified by reverse osmosis, and in dialysate samples over a 4-mounth period in a new 10-bed renal dialysis unit. Water treated by reverse osmosis is conducted to 10 stations through 111 m of piping composed of acrylonitrile butadiene styrene (ABS). All determinations were made prior to the opening of the unit and after the system was purged for 35 h with all bedside station taps open. Formaldehyde disinfection of the piping system was attempted with a recommended protocol after 11 weeks by feeding 2.5 liters of 37% formaldehyde (0.85%, vol/vol) into the delivery system. Prior to water purging, 24 ng of endotoxin per ml was detected. This level decreased to 2.0 ng of endotoxin after the purging. Levels of endotoxin remained below 1.0 ng of endotoxin per ml throughout the duration of the study. In contrast, the level of viable microorganisms recovered from the trated water was approximately 3.5 times 10,0000 CFU/100 ml. Even after disinfection of the system, there was no significant decrease in culturable bacteria from the water even though endotoxin levels were lower. Species isolated from the renal dialysis system were predominately pseudomonads, whereas species isolated from the tap water were Bacillus and Flavobacterium species. ABS provides a surface suitable for

long-term colonization and growth of bacteria. Currently recommended decontamination protocols are ineffective in removing potentially pathogenic bacteria from ABS pipes and thus constitute an increased risk to patients undergoing dialysis.

Dudley R.L., Fyfe C.A., Stephenson P.J., Deslandes Y., Hamer G.K., Marchessault R.H. . High-Resolution 13C CP/MAS NMR Spectra Of Solid Cellulose Oligomers And The Structure Of Cellulose II. J. Am. Chem. Soc., 105:2469-2472. 1982.

ABSTRACT: High-resolution solid-state 13C NMR spectra of cellulose II samples and of the complete series of solid cellulose oligomers up to cellohexaose have been obtained by using cross-polarization/magic-angle spinning (CP/MAS) techniques. Comparison of the spectra of the solid oligomers whth those of cellulose II preparations indicates that the charatersitic features of cellulose II structure appear in the cellotetraose spectrum and are fully developed in those of cellopentaose and of the higher oligomers. Thus a single-crystal X-ray structure determination on one of the higher oligomers should reveal the details of the cellulose II structure that the 13 C NMR data suggest is made up of two independent chins. A comparison of the chemical shifts for samples of cellulose I, II and IV shows characteristic displacements of C-4 and C-6 carbons for each polymorph.

Evans G.P., Briers M.G., Rawson D.M. Can Biosensors Help to Protect Drinking Water. Biosensosors, :287-300. 1986.

ABSTRACT: A large proportion of drinking water is abstracted for treatment from lowland rivers-about 30% in the UK-and this water is at particular risk from sudden and poisonous industrial or agricultural pollution. To cover the range of potential pollutants it may be possible to use biosensors as broadband monitors for toxins. The underlying assumption is that some bilolgical processes, when challenged with a toxin, will be affected in a way analogous to that of man, and that therefore on-line scrutiny of such processes will provide early warning of substances liable to be detrimental to human health. Suitable processes for study might involve multi-cellular organisms, whole cells or enzymes. To date, most practical work has concentrated on fish, but enzymes and single cells hold out the promise of quicker response and, possible, easier maintenance.

Eveleigh D.E., Montenecourt B.S. Increasing Yields Of Extracellular Enzymes. Advances In Applied Microbiology, 25:0057-0073. .

ABSTRACT: None

Fan L.T., Lee Y. Kinetic Studies Of Enzymatic Hydrolysis Of Insoluble Cellulose: Derivation Of A Mechanistic Kinetic Model. Biotech. Bioeng., XXV:2707-2733. 1983.

ABSTRACT: A comprehensive mechanistic kinetic model for enzymatic hydrolysis of insoluble cellulose has been synthesized by combining models for several key aspects which have been derived

independent of each other. The model takes into account the major contributing factors: the nature of the enzyme system, the structure of cellulose, and the mode of interaction between the enzyme and cellulose molecules. It consists of set of simultaneously occurring ordinary-differential equations with ten kinetic constants. All of the kinetic constants have been determined independently by carrying out critically designed experiments, and they appear in the comprehensive model without any arbitrary manipulations. The governing equations of the model have been numerically simulated by means of the computer subroutine CSMP III. The model predicts the progress of hydrolysis of cellulose over a wide range of experimental conditions and hydrolysis times reasonably well. The model can even be applied to predict the progress of hydrolysis for intensively pretreated cellulose with a minor adjustment. The applicability of the model for the actual process development is also discussed.

Fan L.T., Lee Y.H., Beardmore D.H. Major Chemical and Physical Features of Cellulosic Materials as Substrates for Enzymatic Hydrolysis. Department of Chemical Engineering, Kansas State University, Manhattan KS 66506,.

ABSTRACT: This review emphasizes the structure and morphology of cellulose, which are pertinent to understanding the enzymatic hydrolysis of cellulose. Physical and chemical constraints on the susceptibility of cellulose to hydrolysis will be examined. In addition, the relationship between the capillary structure of cellulose fiber and enzmatic hydrolysis will be discussed.

Fang H.S., Tsai M.L., Lea I.T. Further Studies On The Application Of The Compartmentalization/Airlock Concept To Aircraft And Spacecraft. Aviat. Space Environ. Med., 56:1209-1212. 1985.

ABSTRACT: The effect of the application of the compartmentalization/ airlock on accidental decompression was studied in conscious rats, mice, and guinea pigs. It was observed that in unprotected rats and mice, 78 of 102 middle ears (76.5%) exhibited hemorrhages with their eardrums intact; and in unprotected guinea pigs, 37 of 50 eardrums (74%) revealed rupture associated with hemorrhages of all middle ears (100%). Seven cases of malleus fractures (14%) were also found in unprotected guinea pigs. On the other hand, none of the protected animals showed signs of middle ear barotrauma. The protective efffects of the tolerance of middle ears in the present study showed the same tendency as that on the tolerance of lungs in our previous study. These findings indicate that the applicaton of the compartmentalization / airlock would be of great value in protection against accidental rapid decompression of pressurized aircraft and space craft.

Favero M.S., Drake C.H. Factors Influencing The Occurrence Of High Numbers Of Iodine Resistant Bacteria In Iodinated Swimming Pools. App. Micro., 14/4:0627-0635. 1966.

ABSTRACT: It has been shown that, although iodinated

swimming-pool waters are usually free from coliform bacteria and enterococci, the total counts frequently become relatively high. Pseudomonas alcaligenes and Alcaligenes faecalis have been shown to account for most of these high counts. It was of interest, therefore, to compare the microbial flora of four alternately cholrinated and iodinated swimming pools. By means of the membrane filter method and suitable selective media, examinations were made for total viable counts, coliform bacteria, enterococci, staphylococci, Streptococcus salivarius, and P. aeruginosa. Colonies also were picked from membrane filters incubated on standard plate count agar and identified. The results showed that, although viable counts were significantly higher during the iodinated periods, the specific types of bacteria determined were either fewer than or the same as in chlorinated periods. During chlorination, the predominant microbial flora consisted of staphylococci and members of the genus Bacillus. During iodination, however, the P. alcaligenes-A. faecalis group accounted for 92 to 99% of the microbial flora. The accumulation of high numbers of these bacteria was shown to be due to thier iodine resistance and their ability to grow rapidly in pool water in the absence of free iodine.

Fennington G., Neubauer D., Stutzenberger F. Adenosine 3',5'-Cyclic Monophosphate Levels In Thermonomonspora curvata During Cellulase Biosysnthesis. Biotech. Bioeng., 25:2271-2276. 1983.

ABSTRACT: None

Ferchak J.D., Pye E.J. Effect Of Glucose And Other Sugars On The B-1,4-Glucosidase Activity Of Thermomonospora fusca. Biotech. Bioeng., 25:2855-2864. 1983.

ABSTRACT: The cell-associated b-glucosidase activity of Thermomonospora fusca, strain YX, showed both PNPGase and cellobiase activities. The cellobiase activity was found by HPLC assay to have very low product inhibition, whereas the PNPGase activity was more significantly inhibited. Of the various sugars and sugar analogs tested for inhibition of the PNPGase activity, gluconolactone had the greatest effect. The low product inhibition of the cellobiase activity was further demonstrated by the production of glucose syrups to 20% concentration from both cellobiose and swollen cellulose (Avicel). This characteristic is of practical importance in the development of a commercial process for the production of glucose syrups from cellulose. Growth experiments gave further evidence for the probability of separate enzymes for the PNPGase and cellobiase activities

Ferraris R., Carosso R., Fiorentini M.T., De La Pierre M., Marcelino M., Eandi M., Gamalero S.R. Enzymatic Determination Of Faecal Bile Acids. Bollenttino-Societa Italiana Di Biologia Sperimtale, 56/1:0015-0021. 1980.

ABSTRACT: None

Fishman N. Patient Smart. Miles Inc. Diagnostics Division,

Elkyhart, In. 46515,.

ABSTRACT: Months of data are stored in the patient's Glucometer M Blood Gulcose Meter, then reported through my office computer or the Glucofacts Data Printer. Seeing all that information at once lets me make faster, better decisions about treatment regimens.

Flach J.M., Riccio G.E., McMillian G.R., Warren R. Phychophysical Methods For Equating Performance Between Alternative Motion Simulators. Ergonomics, 29/11:1423-1438. 1986.

ABSTRACT: Psychophysical matching techniques were employed to equate the subjective experience of motion is two roll-axis motion simulation devices: the RATS, a whole-body motion environment, and the dynamic seat sub-system of the ASCOGS, presenting motion cues through a moving seat pan. Two psychophysical techniques, cross-modality matching and magnitude estimation, yielded similar results. These results indicated that motion sensitivity increased with roll angular frequency for both simulators. However, the rate of increase at high frequencies was greater for the RATS than for the dynamic seat. These results were used to design a fliter for the dynamic seat which enhanced high-frequency signal components. Tests in a roll-exis tracking task showed that performance in the dynamic seat using this filter was both quantitatively (in terms of r.m.s. error) and qualitatively (in terms of frequency characteristics) similar to performance in the whole-body motion environment.

Frein E.M., Montenecourt B.S., Eveleigh E.D. Cellulase Production By Trichoderma reesei Immobilized On K-Carrageenan. Biotech. Let., 4/5:0287-0292. 1982.

ABSTRACT: Cellulase production by Trichoderma reesei mutant RUT-C30, immobilized on 4% k-carrageenan beads, was monitored in continuous culture for 13 days. Cellulase production averaged 26.0 Filter Paper Units (FPU)/L/hr; carbon and nitrogen requirements per FPU produced were reduced to 1/4-1/2 those of conventional continuous culture.

Friederici A.D., Levelt W.J.M. Cognitive Processes of Spatial Coordinate Assignment. Naturwissenschaften, 73:0455-0458. 1986.

ABSTRACT: None

Gaid K., Cavelier C., Martin G. Mechanisms Of Biological Purification On Activated Carbon. Water Research, 16:0007-0017. 1982.

ABSTRACT: Activated carbon was used for the treatment of waste water, and a study made of the fixing-properties of the adsorbent and the part played by micro-organisms. The process of "fixing" remains to be demonstrated because it has not yet been proved that bacteria are fixed on carbon. Study of the biological mechanism of activated carbon was carried out in three stages. The first was a survey of the adsorption on this material of various products present in waste water [amino-acids, enzymes,

total organic matter (COD)]. In the course of these tests, the part played by the micro-porosity of activated carbon in regard to such molecules was observed. In the second stage, by using various techniques (electron microscope, scanning and transmission, X-ray fluorescence, Castaing micro-gauge), we determined the part played by fixation-spots initially present on carbon (surface functions, heavy metals) during bacterial development. In the third stage, we correlated the eliminated organic pollution with the bacterial mass present on the adsorbing material. The conlusions drawn were that the micro-porosity of carbon does not play a fundamental part in the adsorption of organic matter in sewage, but it does come into play in the adsorption of certain molecules taken separately (amino-acids, enzymes), and that the presence of fixation-spots (metals, surface functions) can have some influence during bacterial development. Experiments are in progress to determine the part played by the specific surface in regard to the adsorbable molecules and its correolation with the bacterial mass and also, to observe the part played the adsorbing material and the bacteria in regard to the non-adsorbable molecules (ethanol, methanol).

Gallegos J.A., Gallegos J.A. Estimation and Control Techniques for Continuous Culture Fermentation Processes. Biotech. Bioeng., 26 :0442-0251. 1983.

ABSTRACT: The use of digital computers in fermentation processes has increased in recent years. There have been several works dealing with data acquisition, parameter and state estimation, optimization, and control of such processes. There is considerable activity both in industry and research institutions in the use of digital computers for optimal control of fermentation systems. However, there still remains some unsolved problems. This article presents some results obtained when modern control techniques are applied to these processes. The article is organized as follows. A discussion about the main problems of computer control of fermentation processes is first presented. The objectives of computer-aided fermentations are mentioned. Then, a simple process model of a continuous culture fermentation process is described. This process model will be used throughout the work to test some control laws designed for a certain class of nonlinear multivariable systems. The synthesis of these control laws is detailed later. One of the main problems in the implementation of a control law is accessibility to the state vector. This problem is discussed and some methods to overcome the problem, in a fermentation process, are also presented. In particular, the design and realization of observers for the substrate concentration are described. The designed observers are included in a feedback control structure for nonlinear systems and the obtained simulation results are presented.

Garcia R., Sauer R.L., Pierson D.L. Development Program for a Zero-G Whole Body Shower. 1985.

ABSTRACT: In 1985, the Man-Systems Division at the Johnson Space

Center initated a program for the development of a whole body shower suitable for operation in a microgravity environment. Supporting this development effort has been a systematic research program focused on four critical apects of the design (i.e., human factors engineering, biomedical, mechanical, and electrical) and on the interfaces between the whole body shower system and the other systems to be aboard the Space Station (e. g., the water reclamation and air revitalization systems). A series of tests has been conducted to help define the design requirements for the whole boby shower. Crew interface research has identified major design parameters related to enclosure configurations, consumable quantities, operation timelines, displays and controls, and shower and cleanup protocols. Mechanical research has provided data on relative humidity, air and water temperatures and flow rates, liquid and gas separation, and system efficiency. Electrical research has characterized and quantified the power requirements for an optimized system. Biomedical research not only has provided data relevant to the indentification and control of microorganisms introduced into the system by human usage but also has led to a new area of research; that is, a study of the effects of biofilm within the shower system. defining the interfaces between the whole body shower system and the other Space Station systems and determining the impact of the whole body shower system on the performance of those systems are of paramount importance in this development program. In order to define these interfaces, a closed-loop test was conducted with the water reclamation system to evaluate the effects of the shower waste water on the design of the water reclamation system.

Garcia R., Verostko C.E., Pierson D.L. Zero-G Whole Body Shower Development Program Phase II Test Plan. NASA Human Research Master Protocol Information,.

ABSTRACT: A Whole body shower (WBS) can be disigned and fabricated to include the human engineering concepts necessary to satisfy the hygienic, physiological, and social needs of crewmembers engaged in long duration space missions while being compatible with the Space Station mechanical Systems (e.g., the water reclamation system). Moreover, the microbial buildup in the shower system can be maintained at a safe level by selecting components that do not harbor microorganisns and by establishing appropriate cleaning procedures.

Gazenko O.G., Grigoriev A.I., Kozlovskaya I.B. Mechanisms Of Acute and Chronic Effects of Microgravity. The Physiologist, 30/1 (Suppl):S0001-S0005. 1987.

ABSTRACT: None

Gazenko O.G., Ilyin E.A. Physiological Investigations of Primates Onboard Biosatellites Cosmos-1514 And Cosmos-1667. The Physiologist, 30/1 (Suppl):S0031-S0035. 1987.

ABSTRACT: It is known that the early period of adaptation to weightlessness occupies the first 5-7 days of space flight.

During this time period many physiological changes that constitute the so-called space adaptation syndrome develop. A comprehensive study of this syndrome was the primary goal of physiological investigations of four monkeys flown onboard Cosmos-1514 and Cosmos-1667 in 1983 and 1985. The flight duration was 5 and 7 days, respectively.

Gazenko O.G., Shulzhenko E.B., Egorov A.D. Cardiovascular Changes In Prolonged Space Flights. ACTA Physiol. Pol., 37/2:0053-0068. 1986.

ABSTRACT: In prolonged space flights, the cardiovascular function was examined at rest and during provocative tests. As compared to the preflight data the following changes were seen: higher heart rate at rest and during LBNP test, decrease of stroke volume at rest and during LBNP test and a less marked increase (or decrease) during exercise test, symptoms of a greater heart load which transformed to the syndrome of myocardial hypodynamics (preload) during LBNP test or to the syndrome of myocardial hyperdynamics (afterload) during exercise test (with other than preflight ratios of systolic and diastolic time intervals). The above cardiovascular changes did not , as a rule, aggravate with flight time and can be viewed as adaptive reactions to microgravity.

The above cardiovascular changes were primarily produced by fliud redistribution in the cranial direction, diminished participation of the muscle system in circulation, and involvement of unloading reflexes from the cardiopulmonary eeceptor zones.

Geekie D.A. Aeronautics Act Changes Medical Practice. CMAJ, 133 :0310-0313. 1985.

ABSTRACT: None

Ghose T.K., Ghosh P. Cellulase Production And Cellulose Hydrolysis. Process Biochem., 14/11:0020-0024. 1979.

ABSTRACT: More recent problems associated with cellulase production, pretreatment of cellulosic substance and their accessibility to enzymatic hydrolysis are discussed. Important aspects of mathematical models based on the kinetics of cellulose-cellulase system are briefly reviewed.

Ghosh S., Henry M.P., Sajjad A. Novel Two-Phase Anaerobic Gasification With Solid-Bed Acid Digestion in Tandem With Fixed-Film Methane Fermentation. Institute of Gas Technology, USA,.

ABSTRACT: The development and performance of a novel solid-bed two-phase anaerobic digestion system are described. The system consists of a bed of organic feed operated in tandem with an acid-phase slurry digester and a methane-phase upflow anaerobic filter. The bed and the acid-phase digesters liquefy and convert the organics to volatile fatty acids (VFA) without gas production, while a high methane-content product gas is collected

from the methane-phase filter. With municipal refuse feeds, VFA and ethanol were the major products from acid-phase digestion, A high methane content (up to 88 mol %) gas was the major product from the methane phase filter.

Giampietro P.F., Desnick R.J. Supplement ALA Dehydratase: A Sensitive Coupled-Enzyme Assay. Division of Medical Genetics, Mount Sinai School of Medicine, New York, New York,:0144-0145. .

ABSTRACT: A coupled-enzyme assay for the specific and sensitive fluorometric determination of S-aminolevulinic acid (ALA) dehydratase has been developed. This assay is at least 10 times more sensitive than the existing colorimetric methods for porphobilinogen (PBG) quantitation using p-dimethylaminobenzaldehyde. The coupled-enzyme assay for ALA dehydratase is similar to the second stage of the ALA synthase fluorometric assay detailed by Bishop et al.

Goldstein I.S. Hydrolysis Of Wood. Dept. of Wood and Paper Science, N. Carolina State University,:0413-0416. .

ABSTRACT: Although wood hydrolysis has been practiced on a commercial scale during wartime conditions and is still practiced in the USSR, renewed interest and development work has been generated by the energy crisis, with ethanol from glucose fermentation assuming the role of a leading potential liquid fuel extender for gasoline. Recent developments in both enzymatic and acidic hydrolysis of wood are reviewed.

Gordon A.S. Influence Of Alginate On Attachment Of Vibrio spp. To Stainless Steel Surfaces In Seawater. App. Env. Micro., 53/5 :1175-1177. 1987.

ABSTRACT: The influences of alginate on the attachment of Vibrio alginolyticus and Vibrio pelagius biovar II to stainless steel was investigated. When the bacteria were in stationary phase, alginate decreased the number of attached bacteria in the case of each Vibrio sp. In contrast, when V. pelagius biovar II was grown on alginate and harvested in log phase, attachment was increased. This effect may be due to nutrient availability at the surface or to receptors on the bacterial surface which interact with alginate adsorbed to the metal.

Gould M.J. Alkaline Peroxide Delignification Of Agricultural Residues To Enhance Enzymatic Saccharification. Biotech. Bioeng., 26 :0046-0052. 1984.

ABSTRACT: Approximately one-half of the lignin and most of the hemicellulose present in agricultural residues such as wheat straw and corn stover are solubilized when the residue is treated at 25 C in an alkaline solution of hydrogen peroxide. The delignification reaction is most efficient when the ratio of hydrogen peroxide to substrate is at least 0.25 (w/w) and the pH is 11.5. The supernatant fraction from a given pretreatment, after addition of makeup peroxide and readjustment of the pH, can be recycled to treat at least six additional batches of

substrate, resulting in a substantial concentration of hemicellulose and soluble lignin degradation products. Hydrolysis of the insoluble fraction with Trichoderma reesei cellulase after alkaline peroxide treatment yields glucose with almost 100% efficiency, based upon the cellulose content of the residue before treatment is a simple and efficient method for enhancing the enzymatic digestibility of lignocellulosic crop residues to levels approaching the theoretical maximum.

Graeber R.C., Lauber J.K., Connell L.J., Gander P.H. International Aircrew Sleep And Wakefulness After Multiple Time Zone Flights: A Cooperative Study. Aviat. Space Environ. Med., 57 (12 Suppl.) :B0003-B0009. 1986.

ABSTRACT: An international research team has carried out an electroencephalographic study of sleep and wakefulness in flight crews operating long-haul routes across seven or eight time zones. Following baseline recordings, volunteer crews (n=56) from four airlings spent their first outbound layover at a sleep laboratory. This paper provides an overview of the project's history, its research design, and the standardization of procedures. The overall results are remarkably consistent among the four participating laboratories and strongly support the feasibility of cooperative international sleep reseearch in the operational arena.

Grams R.R., Massey J.K., Jin Z.M., Hickey S. Medical Diagnostic Support For Spacecraft. J. Med. Systems, 10/2:0185-0194. 1986.

ABSTRACT: None

Graybiel A., Lackner J.R. Treatment of Severe Motion Sickness With Antimotion Sickness Drug Injections. Aviat. Space Environ. Med., 58:0773-0776. 1987.

ABSTRACT: This report concerns the use of intramuscular injections of scopolamine, promethazine, and dramamine to treat severely motion sick individuals participation in parabolic flight experiments. The findings indicate that a majority of individuals received benefit from 50 mg injections of promethazine or 0.5 ml injections of scopolamine. By contrast, 50-mg injections of dramamine and 25-mg injections of promethazine were nonbeneficial. The use of antimotion drug injections for treating space motion sickness is discussed.

Griffin H., Dintzis F.R., Krull L., Baker F.L. A Microfibril Generating Factor From The Enzyme Complex Of Trichoderma reesei. Biotech. Bioeng., 26:0296-0300. 1984.

ABSTRACT: Ample literature and symposia now exist which examine questions of enzymatic degradation of cellulose. The intent of this work is to describe the isolation of a factor from a commercial Trichoderma reesei preparation and to demonstrate that this factor interacts with filter paper cellulose to generate microfibrils without causing release of water-soluble carbohydrates, and synergisticaly interacts with chromatographed

cellulase protein peaks such that the amount of substrate solubilized by a specific amount of protein fraction is increased. Visual evidence of microfibril generation is demonstrated by scanning electron-micrographs (SEM).

Grindeland R., Hymer W.C., Farrington M., Fast T., Hayes C., Motter K., Patil L., Vasques M. Changes In Pituitary Growth Hormone Cells Prepared From Rats Flown on Spacelab 3. Am. J. Physiol., 252 (Regulatory Integrative Comp. Physiol. 21):R0209-R0215. 1987.

ABSTRACT: Anterior pituitaries from "small" (250 g) and "large" (400 g) rats flown on the 7 day Spacelab 3 mission were pooled and trypsinized into two single-cell suspensions. Compared with ground-based controls, flight cells appeared to contain more intracellular growth hormone (GH) but release less GH over a 6 day culture period. After implantation into hypophysectomized rats, both sets of flight cells released only 50% of the GH compared with the control cells. Glands from large flight rats conained 44% somatotrophs compared with 37% for controls; small animals showed no difference. There were no striking differences in somatotroph ultrastructure between cells in the four groups. Western blot analysis indicated that there were no major differences in immunoactive GH variants. High-performance liquid chromatography fractionation of culture media indicated that small flight cells released much less of a high-molecular weight variant rich in GH bioactivity. The results suggest that GH cells from rats exposed to microgravity may experience secretory dysfucntion. The possibility that this occurs directly at the pituitary cell level is discussed.

Guy W.W. Partially Closed System Will Save Big Money. Astro. Aero., :0050-0053. 1983.

ABSTRACT: None

Haggin J. New Generation of Membranes Developed for Industrial Separations. Chem. Eng., 1988.

ABSTRACT: For many years, membranes were confined to specialty applications, usually as delicate, often expensive, and frequently low-volume separation devices. With a few exceptions, industrial membranes were feeble imitations of the biological masterpieces found in living organisms. However, in the mid-1970s this picture changed abruptly. New membrane materials began to appear, the technique of making composite membranes was develped, and the integration of membrane separators into chemical processing technology accelerated. Today, membranes have found wide acceptance in the traditional chemical and petroeum refining industries, as well as a new role in the rapidly developing specialty chemicals industries, where highly selective catalysis is essential and where catalyst use must be intimately combined with pre-or postreaction preparation and separation. This article focuses on efforts to develop and expand applications for some of the more conventional operations employing membranes in high-volume industrial sperations. A future article will look at some of the more exotic developments

making use of membranes.

Haggin J. Membranes Play Growing Role in Small-Scale Industrial Processing. Chem. Eng., 1988.

ABSTRACT: With industrial demands growing for better separation and/or purification in chemical, pertoleum, pharmaceutical,biotechnology, and other areas, mambrane technology has been attractiong more and more attention, This article examines many of the smaller scale operations that are now using membrane technology or are seen as potential application areas. An earlier C&EN article focused on efforts to develop and expand applications for some of the more conventional operations employing membranes in high-volume industrial separations.

Halliwell G. Cellulosic Materials and Their Pre-Treatment. Proc. Bioconversion Symp., :0081-0095. 1977.

ABSTRACT: Although vast amounts of cellulosic materisls are synthesised annually the absence of mountaious regions for the polymer testify to the efficancy of cellulolytic microbes in its removal to cell protein and related products. Unfortunately, man has so far been unable to emulate in the laboratory this remarkable ability of certain baceria and fungi and has turned to pretreatment of cellulosic matter. Such procedures cover four main areas,chemical, physical, enzmic and a combination of these. Native cellulose, the form most resistant to biological degradation is readly swollen at low temperature in as little as two hours in certain acids and becomes 10-20 times more susceptible to hydrolysis, even by enzyme preparations from microorganisms not normally considered celluloytic. Susceptibility to enzyme hydrolysis can be increased even further by extending acid treatment to dissolve cellulose thence to be followed by its reprecipitation in a very finely divided form (regenerated cellulose). Enzyme preparations from either Myrothecium verrucaria or Trichoderma spp readily achieve complete dissolution of regererated cellulose within 24 hr. Unfortunately chemical treatment like the use of alkalis provides swollen material of relatively low density. An alternative procedure that might prove useful here since it provides large surface areas and is applicable not only to purer forms of cellulose but also to naturally occurring cellulosic material such as grass, straw, hay and sawdust utilises the ability of dilute peroxide and iron salts to disintergrate the substrate to very short fibers. Physical treatments including ball-milling offer considerable promises since they can increase susceptibility and yield procucts of high bulk density. Finally, the use of cellulase preparations themselves to provide increased contact surface by comminution natural fibers should be considered. This reaction constitutes and early stage through which crystalline cellulose passed before solubilisation is extensive and can be expecited considerably by agitation.Non-cellulolytic enzyme preparations from such microbes as M. verricaroa can also accomplish this stage. It is a property freely available in crude enzyme extracts of such

microbes as well as in filtrates from the cellulolytic varieties. As such it would appear to offer some advantages and interestion possibilities in view of the wider range of microbes available and recent proposals for improving the economy of enzymic saccharificatiom by recovering cellulase with fresh inputs of substrate.

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ABSTRACT: None

Hara A., Fukuyama K., Epstein W.L. Angiotensin-Converting Enzyme Measured in Mouse Tissue by Inhibition of Histidyl-Ieucine Peptidase. Biochem. Med., 26/2:0199-0210. 1981.

ABSTRACT: Angiotensin-converting enzyme (ACE) is a dipeptidyl carboxypeptidase which hydrolyzes angiotensin I to produce the vasopressor angiotensin II and degrades the vasodeepressor bradykinin (1,2). The enzyme is a vascular endothelial cell ectoenzyme (3,4) and is widely distributed in various mammalian tissues (4-7), but it is also present in parenchymal cells of kidney, where it plays a role in regulation of aldosterone formation and renal function (2,4,8). Recently, ACE was detected in epithelioid and giant cells in vivo (9), and in monocytes and macrophages in vitro (10,11). The assay of ACE in tissues usually is done spectrophotometrically as ethyl-acetate-extractable hippuric acid released from the synthetic substrate, hippuryl-L-histidyl-L-leucine (hip-His-Leu) (12). However, insensitivity of the method limits ACE measurement in some tissues (6). Roth and his co-workers (13,14) first designed a more sensitive fluorometric method using o-phthaldialdehyde-coupled L-histidyl-L-leucine (His-Leu) produced from N-benzyloxycarbonyl-L-phenylalanyl-His-Leu (15). The substrate was subsequently changed to hip-His-Leu by Yang and Neff for assay of ACE in rat brain (16). Although the assay method was further modified by Friedland and Silverstein (17), it still had a drawback. Since most animal tissues contain His-Leu peptidase (18), the apparent value obtained by fluorometric ACE assay required an adjustment for His-Leu peptidase activity. Silverstein and co-workers used a mathematical correction for measuring ACE in tissues and macrophages in man (10,11,19,20) and animals (21). We measured levels of both ACE and His-Leu peptidase in murine tissues by fluorometric assay and sought an inhibitor of His-Leu peptidase activity. Among various alcohols tested, n-butanol was found to selectively inhibit His-Leu peptidase, but not ACE. ACE levels were then established in 12 tissues and in subcellular fractions of lung, kidney, and liver by inhibiting His-Leu peptidase with n-butanol.

Harris M.I. Classification And Diagnostic Criteria For Diabetes And Other Categories Of Glucose Intolerance. Chapter II, Attachment J.8,.

ABSTRACT: Diabetes mellitus comprises a heterogeneous group of

disorders characterized by high blood glucose levels. Four major types of diabetes have been defined by the National Diabetes Data Group: insulin-dependent diabetes (IDDM), noninsulin-dependent diabetes (NIDDM), gestational diabetes (GDM), and diabetes secondary to other conditions. In addition, impaired glucose tolerance (IGT) is a class that encompasses persons whose glucose tolerance is intermediate between normal and diabetic. Diabetes can be diagnosed by the presence of classical signs and symptoms of diabetes and unequivocally elevated blood glucose levels; by a fasting plasma glucose greater than or equal to 140 mg/dl; or by an abnormal oral glucose tolerance test, with a venous plasma glucose value greater than or equal to 200 mg/dl at 2 hours after 75 grams oral glucose being a hallmark criterion for diabetes.

Harrison M.H. Athletes, Astronauts, And Orthostatic Tolerance. Sports Medicine, 3:0428-0435. 1986.

ABSTRACT: Specific alterations in autonomic functions induced by endurance training may lead to a reduced abiltiy to withstand orthostatic stress. This possibility has caused some authorities to suggest that, because of potentially greater pooling of blood in the lower extremities during gravitational loading, endurance-trained athletes may make poor astronauts. Although results from spaceflight studies have provided little evidence to support this suggenstion, data from water-immersion studies indicate that endurance-trained athletes do become more orthostatically intolerant following a few hours of simulated weightlessness. Unfortunately, other evidence supporting the hypothesis that endurance training reduces orthostatic tolerance has not received adequate publication in the open scientific literature.

One the other hand, a number of studies which have been openly reported clearly refute this hypothesis. Nevertheless, the established physiological differences between endurance athletes and non-athletes are themselves sufficient to suggest that the hypothesis could be tenable. Consequently, it has to be concluded that the presently available information is both qualitatively and quantitatively inadequate to permit any defintie statement regarding a possible relationship between aerobic power and orthostatic tolerance.

Hart L.G. Wearing Contact Lenses In Space Shuttle Operations. Aviat. Space Environ. Med., 56:1224-1225. 1985.

ABSTRACT: More and more mission specialists are being trained to operate in the Space Shuttle and to eventually maintain a permanent station in space. Since up to 48% of the general population wears a visual correction of some sort, it is logical to assume that this percentage will also be found in the astronaut population. This paper proposes that the soft contact lens can be worn successfully in the space environment. The contact lens of choice is the continuous-wear soft contact which is proving to be quite successful for the general public. These lenses must be fitted at least 6 months before space flight in order to make sure thay can be worn successfully.

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ABSTRACT: A fluorometric system to determine the kind and amount of substances derived from a biological fluid (e.g., serum or urine) or tissue in which the substances to be detected (e.g., antigen, antibody, hormone or enzyme) are coated onto a substrate suface in fluorescent form. Multiple coating areas of different samples may be employed. The fluorometric system includes a source of filtered light to excite fluorescence, optical systems for conducting the excitation light to such coating, and optical systems for receiving emitted fluorescence and for detecting the same. The system efficiency and optical characteristics disclosed avoid photobleaching; limit fading; and are especially adapted to provide accurate surface reading fluorometry.

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ABSTRACT: A fluormetric system to determine the kind and amount of substances derived from a biological fluid (e.g., serum or urine) or tissue in which the substances to be detedted (e.g., antigen, antibody, hormone or enzyme) are coated onto a substrate surface in fluorescent form. Multiple coating areas of different samples may be employed. The fluorometric system includes a source of filtered light to excite fluorsecence, optical systems for conduction the exciation light to such costing, and optical systems for receiving emitted fluorescence and for detecting the same. The system efficiency and optical charateristics disclosed avoid photo bleaching; limit fading; and are especially adapted to provide accurate surface reading fluorometry.

Henney M.R., Knopp K.D. Shuttle Air Monitoring. NIS/LSL Test Plan Number 79-875,.

ABSTRACT: None

Henriksen J.A. Good Practice For Installing Pharmaceutical Water Systems. Process Engineering, 1983.

ABSTRACT: The supply of pure water through a piping network can best be assured by following a number of validation procedures during installation.

Herson D.S., McGonigle B., Payer M.A., Baker K.H. Attachment As A Factor In The Protection Of Enterobacter cloacae From Chlorination. App. Env. Micro., 53/5:1178-1180. 1987.

ABSTRACT: Enterobacter cloacae attached to drinking water distribution particles was subjected to chlorination. Attachment resulted in the protection of these organisms from disinfection. This effect was found to be dependent upon both the level of chlorine in the system and attachment time. The results obtained in this study indicate that attached organisms may play an important role in coliform outbreaks.

Hills B.A. Compatible Atmospheres For A Space Suit, Space Station, And Shuttle Based On Physiological Principles. Aviat. Space Environ. Med., 56:1052-1058. 1985.

ABSTRACT: Fundamental physiological principles have been invoked to design compatible environments for a space suit, space station, and the space craft used to transport the astronauts from Earth. These principles include the long-term memory of tissues for a bubble-provoking decompression, the intermittent nature of blood flow in the tight connective tissues responsible for the bends whose incidence in aviators have been shown to be related to bubble volume by the Weibull distribution. In the overall design an astronaut breathing a mixture of 30% oxygen in nitrogen for 4-5 h in a space craft at 11.9 psia can transfer to a space station filled with the same mix at 8.7 psia and, after a further 4-5 h, go EVA at any time without any oxygen prebreathing at any stage. The probable incidence of decompression sickness has been estimated as less that 0.5% using the present suit operating at 4.3 psia but the risk could be reduced to zero if the suit pressure were increased to 6.5 psia.

Hunter K.W. Technological Advances in Bedside Monitoring: Biosensors. Arch. Pathol. Lab Med., 111:633-636. 1987.

ABSTRACT: The need to monitor certain key biochemical parameters in hospitallized patients is driving the development of biosensors, a new class of medical device for real-time, on-line quantitative analysis. A biosensor is a microelectronic device that utillizes a biological molecule (eg, antibody, enqyme, or receptor) as the sensing or signal-transducing element. Biosensors can be configured into simple, rapid, and cost-effective laboratory devices that will allow the clinical pathologist to become even more responsive to the primary care physician. In those instances where measurements on discrete samples do not provide the required information, continuous monitoring with implantable biosensors could provide realtime data on levels of critical endogenous or exogenous substances. By hybridizing recent advances in transdermal substance collection with the analytical capabilities of biosensors, devices for continous noninvasive monitoring at the bedside can be envisioned. The clinical pathologist can and should play a key role in the clinical evaluation and implementation of such technological addvances.

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ABSTRACT: Given the relatively short period of the space flight missions and more inexperienced personnel expected to be aloft, if the time in space should be optimized, the critical processes which occur in the body equilibrium system during the period of initial exposure to space environment must be thoroughly investigated. It is most important that improved management of space motion sickness (including the prediction, prevention and

countermeasures) is properly developed. The improvement will fully depend on advances in our research on the etiology and pathology of this debilitating condition.

Inman F.N. Filtration And Separation In Antibiotic Manufacture. Presented at a meeting of the Filtration Society on January 24, 1984 in London,1984.

ABSTRACT: The manufacture of a typical semi-synthetic antibiotic is described in detail. The preparation of the initial culture, the fermentation stage, the extraction and preparation of bulk sterile product and the final filling of vials with sterile powder or solution for injection together use many forms of filtration and separation. In this respect, antibiotic manufacture is similar to other large-scale fine chemical manufacturing processes, but there is the additional and essential requirement for contamination control as extraneous micro-organisms can adversely affect antibiotic production in many ways, and some stages have to be operated aseptically for reasons that are self-evident. The high demands made upon the equipment are discussed and practical applications described.

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ABSTRACT: A system of tangential-flow filtration was evaluated for use in the detection of Giardia cysts in drinking water. This method was more sensitive in recovering cysts than a frequently used wound-orlon system of throughfiltration

Janik D.S., Sauer R.I., Pierson D.L., Thorstenson Y.R. Quality Requirements For Reclaimed/Recycled Water. Technical Memorandum 58279,1987.

ABSTRACT: Water used during current and previous space missions has been either carried or made aloft. Future human space endeavors will require some form of water reclamation and recycling. There is little experience in the U.S. space program with this technology. Water reclamation and recycling constitute engineering challenges of the broadest nature that will require an intensive research and development effort if this technology is to mature in time for practical use of the proposed U.S. Space Station. In order for this to happen, reclaimed/recycled water specifications will need to be devised to guide engineering development. Present NASA Potable Water Specifications are not applicable to reclaimed or recycled water. Adequate specifications for ensuring the quality of the reclained of recycled potable water do not exist either within or outside of NASA. NASA experience with potable water systems is reviewed, limitations of present water specifications are examined, world experience with potable water reclamation/recycling systems and system analogs is reviewed, and an approach to developing peritinent biomedical water specifications for spacecraft is presented. Space Station water specifications should be designed to ensure the health of all likely spacecraft inhabitants

including man, animals, and plants, both separately and collectively.

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ABSTRACT: A study was performed to evaluate decompression procedures suggested for use prior to Space Shuttle extravehiclular activity. Hematological parameters were measured in 12 male human subjects before and after exposure in an altitude chamber to a 3-day staged decompression schedule, with simulated extravehicular activity. Following the exposure, significant increases occurred in white blood cell count and activated partial thromboplastin time, and platelet aggregate ratio was significantly decreased. Pre-exposure samples from subjects who were susceptible to formation of venous gas emboli (VGE) exhibited a significantly lower degree of ADP-induced platelet aggregation and a significantly higher amount of lymphocyte blastogenic transformation in response to the mitogen phytohemagglutinin than samples from VGE-resistant subjects. The results indicate that, following this decompression profile, small but significant changes occur in several hematological parameters, and that levels of certain parameters may be related to susceptibility to VCGE formation during decompression.

Jennings R.T. Women And The Hazardous Environment: When The Pregnant Patient Requires Hyperbaric Oxygen Therapy. Aviat. Space Environ. Med., 58:0370-0374. 1987.

ABSTRACT: Women are now being exposed in increasing numbers to environmental hazards. Normal operations in that environment plus accidents of training prodecures may result inconditions such as decompression sickness, air embolus, hyperoxia, or carbon monoxide poisoning occurring in a woman who also happens to be pregnant. This article examines the animal data and human experience in these conditions in both early and late gestation. The risk of these conditions to the mother and fetus is assessed compared to the problems associated with hyperbaric oxygen therapy (HBO) in pregnancy. Suggestions are made regarding the appropriate use of HBO therapy in pregnancy. Further medical investigation is requested.

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Setting . Space Medical Branch Report, American Medical Association,.

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ABSTRACT: As space missions become longer and broader in scope, and as crews become more heterogeneous, psychological and interpersonal factors will take on increasing importance. In order to isolate instructive psychosocial issues and trends, a review was made of over 60 American and Russian simulation and spaceflight studies and reports. Although the missions accomplished most of their goals, psychological and social stresses were evident in the crew members. Psychosocial problems tended to relate to mission length. There was evidence that the use of appropriate psychological testing and interpersonal sensitivity training could improve crew selection and ameliorate problems in the simulation studies. It is time to apply this knowledge to actual spaceflight conditions.

Kanas N. Psychological and Interpersonal Issues in Space. Am. J. Psychiatry, 144/6:0703-0709. 1987.

ABSTRACT: As future manned space missions become longer, and as crews become more heterogeneous, psychological and interpersonal factors will take on increasing importance in assuring mission success. On the basis of a review of more than 60 American and Soviet space simulation studies on Earth, along with reports from U.S. and Soviet space missions, the author identifies nine psychological and seven interpersonal issues, which are discussed along with pertinent research findings and examples from manned spaceflights. He concludes that more psycholgical and interpersonal research should be done under actual spaceflight conditions and offers suggestions.

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ABSTRACT: A series of vestibular experiments were performed in conjucntion with the first Spacelab mission, consisting of sets of pre-, in- and postflight tests. A multipurpose experimental apparatus used for the diverse flight and ground test is presented. Additional apparatus together with the multi-purpose package were used in the baseline data collection facility at the landing site at NASA Dryden Flight Research Facility for the ground tests. The tests involved optokinetic, caloric and mechanical (whloe-body of head -alone) stimulation. The latter included linear acceleration in the subjects's xyz axes, static roll and yaw about an earth-vertical axis. Physiological parameters such as electro-oculogram (EOG), blood-volume-pulse (BVP), respiration, as well as the stimulus variables such as acceleration and caloric temperature were transmitted to the

ground and recorded there. The flight and ground testing schedules are outlined. Problems arising from this complex venture are discussed, and some suggestions are made for future improvement.

Kaysner C.A., Abeyta C., Wekell M.M., Depaola A., Stott R.F., Leitch J.M. Virulent Strains Of Vibrio vulnificus Isolated From Estuaries Of The United States West Coast. Appl. Env. Micro., 53/6:1349-1351. 1987.

ABSTRACT: Vibrio vulnificus was isolated from United States West Coast estuaries at a low frquency (5.9%) from 529 samples of water, shellfish, and sediment. Four strains tested with iron-treated mice had 50% lethal dose values ranging from 7.6 to 360 CFU, compared with a 50% lethal dose of 4.9 CFU for a clinical isolate that caused the death of a septicemic patient. The presence of this pathogen may be a hazard to users of marine beaches and consumers of raw shellfish on the West Coast, especially to persons most susceptible to V. vulnificus septicemia. Species-specific antiflagellar serum and a gene probe for cytotoxin-hemolysin production were useful for screening these environmental isolates.

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ABSTRACT: The incidence of Vibrio cholerae in shellfish, sediment, and waters of California, Oregon, and Washington was determined during the summer of 1984. Samples from 24 distinct estuaries were analyzed qualitatively. V. cholerae non-01 was found in 23 estuaries and in 44.6% of the 529 samples examined. V. cholerae 01 Inaba was isolated from water samples from water samples in Morro Bay, Calif. Vibrio mimicus was found in 2.3% of the samples. Cholera entertoxin was not found in cell-free filtrates of the 100 isolates tested in the Y-1 mouse adrenal cell assay, but heat-labile cytotoxic activity was observed with 3% of the isolates.

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ABSTRACT: The type stain Fontaine of Clostridium thermoaceticum proliferated on H2/CO2 as energy source and was culturally adapted to grow on 100% CO in the headspace. The doubling times at 55 C on CO of H2/CO2 were 16 and 18 h, respectivly. Under these conditions, the substrate-product transformation stoichiometries observed were: 4H2 + 2.1 CO2 = 0.9 acetate and 4 CO = 2CO2 + 1.1 acetate. It is concluded that C. thermoaceticum has a single carbon growth physiology.

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ABSTRACT: In microgravity (micro-g) when the hydrostatic component of the intravascular pressure is eliminated, a redistribution of body fluids occurs leading to a fluid shift towards the cephalic parts of the body. Therefore, elevated venous pressures should be expected in the vein of the upper part of the body as compared to the values on ground. However, our measurements during the Spacelab 1 Mission failed to show this. It was thought that 22 h after entry into the micro-g environment, when we had the first chance to measure, adaptive mechanisms had already counteracted this pressure increase. Therfore, the attempt was made to measure venous pressure as early as possible during the D1 Mission.

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ABSTRACT: Existing methods for quantitating yeasts in beverages include time-consuming plate counts that detect only living cells and hemacytometer counts that are reliable only at very high concentrations (e.g., 106 to 20 x 106 cells per ml). The new method described here involves the use of fluorescence microscopy with the fluorescent stain aniline blue to differentiate yeasts (and other fungs) from backgrounds for easy conting and also may be used in conjunction with membrane filtration to concentrate yeasts from liquids before cell enumeration. Recoveries averaged 91.5% for beverages spiked with levels of 500 to 600,000 organisms per ml. The correlation coefficient of count to spike levels was 0.996%.

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ABSTRACT: Orally administered metoclopramide (REGLAN) at doses of 10 or 20 mg, 75 min prior to either stressful linear acceleration (parabolic flight) of cross-coupled accelerative semicircular canal stimulation in a rotating chair was evaluated for its ability to prevent emesis or nausea 11, respectively. Although metoclopramide is an effective antiemetic agent that enhances gastric emptying and prevents cancer chemotherapy-induced emesis, we were unable to demonstrate any significant ($p<0.05$) effects of this drug on motion sickness.

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ABSTRACT: Sympathomimetic agents are frequent components in antimotion-sickness drug combinations because of their usefulness in counteracting the sedation caused by stressful motion or resulting from the administration of other antimotion-sickness drugs. The noradrenergic neurochemistry of the brain's arousal-attentional systems prompted us to evaluate the efficacy of five new sympathomimetic drugs and to further define the role of arousal in susceptibility to motion. Subjects were orally administered methamphetamine (20 mg), phenmetrazine (25 mg), phentermine (37.5), methylphenidate (20 mg), or pemoline (75 mg) 2 h prior to taking a Staircase Profile Test. All of the drugs increased resistance to stressful coriolis stimulation by 80-120%. Methylphenidate and pemoline showed fewer side effects. These findings, interpreted in conjunction with the documented ineffecacy of most anticholinergic and antihistaminergic drugs tested to date, suggest that sympatheomimetic drugs of a generalized state of arousal can inhibit the development of motion sickness.

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biodegradation will result in ammonia production; this also exerts toxicity. Hence, nitrification of aniline should be ensured in the biological treatment before discharge into receiving streams. Aniline, however, is reported to inhibit the nitrificatin process. Aniline degradation was studied in laboratory continuous activated sludge with an acclimated culture developed in synthetic feed to determine the extent of complete biological degradation. Anilline-N (even at 400 mg/L aniline concentration) could be converted to nitrate-N with ammonium-N and nitrite-N formed as intermediates at a detention time of 24 h. The nitrification, however, was suppressed by aniline. The degradation of aniline to ammonia releases the suppression and the nitrification proceeds rapidly.

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ABSTRACT: Episodes of emesis unaccompanied by the usual prodromal signs of motion sickness have been reported by astronauts in the space shuttle program. Such reports have raised the issue whether space motion sickness has different characteristics from terrestrial motion sickness. We present evidence here from parabolic flight experiments that sudden vomiting can occur in response to a provocative vestibular stimulus even when no premonitory exposure conditions, the absence of prominent signs of symptoms of motion sickness does not necessarily mean an absence of sensitization.

Lackner J.R., Graybiel A. Head Movements In Non-Terrestrial Force Environments Elicit Motion Sickness: Implications For The Etiology of Space Motion Sickness. Aviat. Space Environ. Med., 57:0443-0448. 1986.

ABSTRACT: Space motion sickness has become an operational concern in manned space flight. Considerable evidence exists that head movements in free fall, especially pitch movements, are provocative until adaptation occurs. The question arises whether space motion sickness is an unique nosological entity of is due to body movements in a non terrestrail force environment, a force environment for which the body's dynamic sensory-motor adaptions to 1 G are no longer appropriate. To evaluate this issue, we had subjects make controlled head movements during exposure to high gravitoinertial force levels, 1.8-2.0 G, in parabolic flight maneuvers. Head movements in pitch with eyes open were most evocative of motion sickness, yaw movements with eyes covered were least provocative. This pattern is identical to that which occurs when the same types of head mevements are made in the free fall phase of parabolic maneuvers. It appears that space motion sickness is the consequence of prolonged exposure to a non-terrestrial force background rather than of exposure to free fall per se.

Lackner J.R., Graybiel A. The Effective Intensity of Coriolis, Cross Coupling Stimulation Is Gravitoinertial Force Dependent: Implications For Space Motion Sickness. Aviat. Space Environ. Med., 57:0229-0235. 1986.

ABSTRACT: Coriolis, cross-coupled angular acceleration stimulation readily induces motion sickness under terrestrial conditions. Nevertheless, the Skylab astronauts, when tested with such stimulation in-flight, sure insusceptible event though each had been susceptible preflight. It is unclear whether this decreased susceptibility was the consequence of in-flight adaptation of in part the result of immediate changes in sensory-motor and vestibulo-motor function that occur during exposure to microgravity conditions. To evaluate this issue, we have tested individuals both in the high and low force phases of parabolic flight maneuvers using constant levels 1) subjects are less susceptible when tested in 0 G than +2 Gz 2) the perceived intensity and provocativeness of Coriolis stimulation decreases in 0 G and increases in +2 Gz relative to +1 Gx baseline values; and 3) changes in the apparent intensity of Coriolis stimulation occur virtually immediately when background gravitoinertial force level is varied. These findings explain in large part why the Skylab astronauts were refractory to motion sickness during Coriolis stimulation in-flight. The general implication for space motion sickness are discussed.

Landstrom U., Lofstedt P. Noise, Vibration And Changes In Wakefulness During Helicopter Flight. Aviat. Space Environ. Med., 58 :0109-0118. 1987.

ABSTRACT: The investigation was carried out in cooperation with the helicopter school AF 1 in Boden. Measurements were made in two different types of helicopter, Hkp 3 and Hkp 6. Three different parameters were recorded during the flights: noise, vibration, and wakefulness. Noise and vibration exposures were mainly correlated to the main rotor energy and frequency. both types of exposure were dominated by lower frequencies, below 10 Hz. Analyses of wakefulness during long-distance flights, about 4 h, and short-distance flights, less than 2 h, were based on EEG and EKG recordings. As expected the level of wakefulness was influenced by the stress upon the pilots. Take-offs and landings, as well as unexpected events during the flight, were correlated to an increased level of wakefulness. In some cases flying was correlated to a gradual increase of weariness. The correlation between weariness, types of flying, and the external environmental factors of noise and vibration, is also discussed.

Lange R.D., Andrews R.B., Gibson L.A., Congdon C.C., Wright P., Dunn C.D.R., Jones J.B. Hematological Measurements In Rats Flown On Spacelab Shuttle, SL-3. Am. J. Physiol., 252 (Regulatory Intergrative Comp. Physiol. 21):R0216-R0221. 1987.

ABSTRACT: Previous studies have shown that a decrease in red cell mass occurs in astronauts, and some studies indicate a leukocytosis occurs. A life science module housing young and

mature rats was flown on shuttle mission Spacelab 3 (SL-3), and the results of hematology studies of flight and control rats are presented. Statistically significant increases in the hematocrit, red blood cell counts, and hemoglobin determinations, together with a mild neutrophilia and lymphopenia were found in flight animals. No significant changes were found in bone marrow and spleen cell differentials of erythropoietin determinations. Clonal assays demonstrated an increased erythroid colony formation of flight animal bone marrow cells at erythropoietin doses of 0.02 and 1.0 U/ml but not 0.20 U/ml. These results agree with some but vary from other previously published studies. Erythropoietin assays and clonal studies were performed for the first time.

Lantz J.B., Winkler H.E., Schubert F.A., Jensen F.C. Development Of An Advanced Combined Iodine Dispenser/Detector. The American Society of Mechanical Engineers Publication,1977.

ABSTRACT: Injection of Iodine (I2) into water is widely used to control microbial growth. An advanced, entirely automated Device for I2 injection has been developed for spacecraft application. Transfer of I2 into the water from a concentrated form is controlled electrochemically via feedback from an intergrated photometric I2 Level Detector. All components are contained within a package weighing only 1.23 kg dry, occupying only 1213 cm3 of space, and having the capcity to iodinate 10,900 kg of water to 5 ppm. These features exceed design specifications. The device performed satisfactorily during extended testing at variable water flow rates and temperatures. Designed to meet specification of the Shuttle Orbiter, the device will find application in the regenerative water systems of advanced spacecraft.

Laughlin T.J., Coleman D.R., Kilgore M.V., Lishawa C.L., Eley M.H. The Production Of Fuel-Grade Ethanol From The Cellulose In Municipal Solid Waste. .

ABSTRACT: Two systems that effectively convert the cellulose in municipal solid waste (MSW) to fuel-grade ethanol have been evaluated. These systems yield about 40 gallons per ton of MSW. Our economic analyses indicate that these systems would be cost effective at a 500-1500 MSW ton/day scale.

Leach C.S., Schneider H.J. Spacelab Life Sciences 1 And 2 Scientific Research Objectives. The Physiologicst, 30/1 (Suppl.) :S0006-S0009. 1987.

ABSTRACT: The pressurized Spacelab module was designed and built to allow investigators to conduct research in space in an environment approximating that of a ground-based laboratory. It is configured to allow multiple investigations employing both human and non-human subjects. This flexibility is exemplified by the SLS-1, SLS-2, and SLS-3 experiment complement. Twenty-one experiments will be performed on these missions; the areas to be investigated are renal-endocrine function, cardiovascular-cardiopulmonary function, hematology, immunology,

metabolic activity of muscle, calcium metabolism, the vestibular system, and general biology. A plan for integration of measurements will allow each investigation to use data from other experiments. The experiments make up a scietifically balanced payload that addresses fundamental biomedical problems associated with space flight and provides the first opportunity to study the acute effects of weightlessness in a comprehensive, interrelated fashion.

Leahy T.J., Gabler F.R. Sterile Gas Filtration. 1983.

ABSTRACT: None

Lechene C. Analysis of Attomole Quantities of Chemical Elements, Metabolites, and Enzymes in Cellular and Subcellular Volumes. Proc. Int. Workshop on Developmental Renal Physiology, :0041-0052. 1980.

ABSTRACT: This chapter reviews the different uses of a physical method, electron probe microanalysis, for the analysis of chemical elements in very small volumes of biological material. A technique is outlined for scaling down a chemical and physical method, fluorescence spectrometry, for this analysis of organic compounds in fluid volumes in the picoliter range. The examples given illustrate the different possibilities of applications as they have been used in renal, reproductive, or developmental physiology and as they could apply to renal developmental biology.

Lechevallier M.W., Schiemann D.A., Mcfeters G.A. Factors Contributing To The Reduced Invasiveness Of Chlorine-Injured Yersinia enterocolitica. App. Env. Micro., 53/6:1358-1364. 1987.

ABSTRACT: The invasion of epithelial cells in vitro and in vivo by chlorine-injured Yersinia enterocolitica was assessed by direct microscopic observations. These experiments showed that injury by chlorin inhibited invasiveness of virulent Y. enterocolitica. Two requirements appeared to be necessary for invasiveness: (i) the organism must be viable and metabolically active, and (ii) the organism must have certain surface components to initiate engulfment. Inhibition of RNA synthesis by rifampin and protein synthesis by chloramphenicol, tetracycline, and spectinomycin inhibited the invasiveness but not the attachment of Y. enterocolitica to epithelial cells. Membrane preparations from untreated and antimicrobial-agents treated Y. enterocolitica blocked the invasiveness. Chlorine did not change the hydrophobicity of surface charge of unjured Y. enterocolitica. The results indicate that invasiono was more than simple association of the bacterium with the epithelial cell and involved a specific trigger to stimulate engulfment.

Lee J.M., Woodward J. Properties And Application Of Immobilized B-D-Glucosidase Coentrappen With Zymomonas mobilis In Calcium Alginate. Biotech. Bioeng., 25:2441-2451. 1983.

ABSTRACT: The enzyme b-d-glucosidase has been immobilized on

concanavalin A-Sepharose to give a maximum loading of 2050 units/g dry weight of support material. The immobilized b-d-glucosidase was also entrapped within calcium alginate gel spheres with apparently only 35% retention of activity when assayed with 10mM cellobiose. However, it was discovered that, unlike the immobilized enzyme, the entrapped immobilized enzyme was not subject to substrate inhibition up to 100mM cellobiose, suggesting that a concentration gradient of cellobiose existed between the bulk solution and the interior of the gel sphere. Thus, the activity of the entrapped immobilized enzyme was almost twice as high as that of the immobilized emzyme when assayed with 100mM cellobiose. Concanavalin A-Sepharose- immobilized b-d-glucosidase and the bacterium Zymomonas mobilis coimmobilized in calcium alginate gel spheres converted cellobiose to ethanol in both batch and continuous-flow fermentation systems.

Lee Y.H., Fan L.T. Kinetic Studies Of Enzymatic Hydrolysis Of Insoluble Cellulose: (II). Analysis Of Extended Hydrolysis Times. Biotech. Bioeng., XXV:0939-0966. 1983.

ABSTRACT: The kinetics of enzymatic hydrolysis of pure insoluble cellulose by means of unpurified culture filtrate of Trichoderma reesei was studied, emphasizing the kinetic characteristics associated with the extended hydrolysis times. The changes in the hydrolysis rate and extent of soluble protein adsorption during the progress of reaction, either apparent of intrinsic, were investigated. The hydrolysis rate declined drastically during the initial hours of hydrolysis. The factors causing the reduction in the hydrolysis was examined; these include the transformation of cellulose into a less digestible form and product inhibition. The structural transformation can be partially explained by changes in the crystallinity index and surface area. The product inhibition was caused by the deactivation of the adsorbed soluble protein by the products, which essentially represents the so-called "un-competitive" inhibition. The kinetics of B-glucosidase were also studied. The result has shown that the action of B-glucosidase in competitively inhibited by glucose. It has been found that the integrated form of the initial rate expression cannot be used in predicting the progress of reaction because the digestibiltiy of cellulose changes drastically as the hydrolysis proceeds, and that the rate expression for enzymatic hydrolysis of cellulose cannot be simplified or approximated by resoration to the pseudo-steady-state assumption. A mechanistic kinetic model of cellulose hydrolysis should include the following major influencing factors: 1) mode of action of enzyme, 2) structure of cellulose, and 3) mode of interaction between the enzyme and cellulose molecules.

Leigh R.J., Daroff R.B. Space Motion Sickness: Etiological Hypotheses and a Proposal For Diagnostic Clinical Examination. Aviat. Space Environ. Med., 56:0469-0473. 1985.

ABSTRACT: The general notion that space motion sickness (SMS) is due to a "conflict" between vestibular, visual, and other sensory inputs has gained popular acceptance. We have reviewed three

specific hypotheses for SMS and identified characteristic disorders of ocular motility that each hypothesis would predict. Accurate recording of horizontal and verical eye movements during free head movements in space craft presents technical difficulties. We suggest that careful clinical examination may be useful, provided the examinaton is directed towards detection those specific abnormalities predicted by each hypothesis.

Linko M. An Evaluation of Enzymatic Hydrolysis of Cellulosic Materials. Technical Research Center of Finland, Biotechnical Laboratory, Box 192, SF-00121 Helsinki 12, Finland,.

ABSTRACT: The diminishing one-way resorces must be replaced by renewable, plentiful organic materials such as cellulose. Enzymatic hydrolysis of cellulose has been intensively studied in recent years, since acid hydrolysis of cellulose has not proved to be economically fesible. In spite of the abundance of cellulose, it is not very easy to find suitable cellulosic materials that could be collected from a limited area and would be cheap enough, taking into account collecting, transport, handling, and storage costs. the correct choice of material depends on local conditions. For example, sugarcane bagasse would be useful in certain areas. An enzyme preparation capable of completely breaking down cellulose is needed for the hydrolysis. Trichoderma viride is the most efficient producer of extracellular cellulases known at present. Since several types of cellulases are needed, it is possible that two or more organisms will be used in the future. Pretreatment of cellulosic materials prior to hydrolysis is inevitable, but all the known methods, such as alkali treatment or ball-milling, are rather costly. The product of complete hydrolysis is glucose, which can be used as such for various purposes or as raw material for other products. The economic feasibility of processes based on enzymatic hydrolysis of cellulosic materials is uncertain so far, but the potential of these processes encouages further developmental work.

Linnarsson D. The Esa Anthrorack Project: Integrated Research In Human Physiology. The Physiologist, 30/1 (Suppl.):S0010-S0012. 1987.

ABSTRACT: The evolution of terrestial life has taken place under the constant influence of gravity, but in all fields of life sciences there is a lack of knowledge about the importance and nature of the influence of gravity on life processes. This is true also for the area of human physiology. A new exciting tool for experimentation became available with the onset of the manned exploration of space. The men and women who were exposed to microgravity could be observed as experimental subjects. Areas where new insights could be gained were in the control of balance and locomotion, in cardiovascular dynamics, in fluid balance and in bone mineralization.

Lockwood, R., Furusawa, E., Furusawa, S. Toxicity of Pretazettine in Rats and Cats. Prox. West. Pharmacol. Soc., 24:0259-0260. 1981.

ABSTRACT: Pretazettine is an alkaloid from Narcissus tazetta having therapeutic activity in mice against Rauscher erythrocytic leukemia (1) and spontaneous AKR lymphocytic leukemia (2). This activity may be due partly to reverse transcriptase inhibition ('antiviral effect') and partly to protein biosynthesis inhibition ('cytostatic effect') (3). We now report an investigation of toxicity and associated pharmacological effects of PTZ in rats and cats.

Lornzi G., Fuchs-Bislin P., Cogoli A. Effects of Hypergravity On "Whole-Blood" Cultures of Human Lymphocytes. Aviat. Space Environ. Med., 57:1131-1135. 1986.

ABSTRACT: The purpose of this paper is to present a detailed description of the effects of hypergravity on the mitogenic response of human lymphocytes to concanavalin A. The effect of cultures of lymphocytes isolated from periphral blood are compared with those on whole-blood cultures obtained by diluting fresh blood with culture medium 1:10. Whole-blood cultures of lymphocytes from crew members will be investigated inflight on the Spacelab missions D1 in 1985 and SLS1 in 1987. In hypergravity there is an increase in lymphocyte activation of up to 500%. A similar increase can be induced by pre-incubating the cultures in hypergravity prior to exposure to concanavalin A at 1G. The effect is less evident in cultures of isolated lymphocytes. The influence of autologous plasma and erythrocytes has also been investigated. Plasma and hypergravity have a synergistic and positive effect of lymphocyte activation, i.e. cultures of separated lymphocytes show the highest activations when incubated at G and supplemented with autologous plasma. Conversely, erythrocytes depress lymphocyte activation.

Lum M. A Family Physician's Guide to Toxnet. Center for Disease Control, Agency for Toxic Substances and Disease Registry, Chambless, 28 South, F38, 1600 Clifton Road, NE, Atlanta, GA 30333,.

ABSTRACT: Toxnet is a computerized system of toxicologically oriented data banks operated by the National Library of Medicine (NLM). This minicomputer-based system permits efficient access to valuable data on potentially toxic or otherwise hazardous chemicals.

Lutzen M.W., Nielsen M.H., Oxenboell K.M., Schulein M., Stentebjerg-Olesen B. Cellulases And Their Application In The Conversion Of Lignocellulose To Fermentable Sugars. Phil. Trans. R. Soc. Lond., B300:0283-0291. 1983.

ABSTRACT: Several processes have been developed for the enzymic conversion of lignocellulose to fermentable sugars. Most of these processes have employed the cellulolytic enzyme system from Trichoderma reesei. The action of a commercial cellulase preparation, Celluclast, from T. reesei on microcrystalline cellulose is compared with that of cellulolytic enzymes from other microorganisms. It is concluded that the Trichoderma system is not unique. More effective enzyme complexes can be

produced from other microorganisms. In particular, systems from different Aspergillus species are shown to be more effective. The enzymic conversion of lingocellulose to fermentable sugar has not yet been scaled up, undoubtedly for technical and economic reasons. The cellulose substrate is very inaccessible, and furthermore the enzymic hydrolysis involves several consecutive reactions, each of which may be rate limiting. Enzyme costs have a great impact on process economy. The conversion of cellulose into fermentable sugar requires approximately 100 times more enzyme protein than the corresponding hydrolysis of gelatinized starch. Therefore, with today's enzyme technology, the use of cellulose as a raw material is not competitive with processes based on starch.

Marco R., Vernos I., Gonzalez J., Calleja M. Embryogenesis and Aging of Drosophila Melanogaster Flown In The Space Shuttle. Naturwissenschaften, 73:0431-0432. 1986.

ABSTRACT: None

Marmur J. A Procedure For The Isolation Of Deoxyribonucleic Acid From Micro-organisms. J. Mol. Biol., 3:0208-0218. 1961.

ABSTRACT: A method has been described for the isolation of DNA from micro-organisms which yields stable, biolgically active, highly polymerized preparations relatively free from protein and RNA. Alternative methods of cell disruption and DNA isolation have been described and compared. DNA capable of transfroming homologous stains has been used to test various steps in the procedure and preparations have been obtained possessing high specific activities. Representative samples have been characterized for their thermal stability and sedimentation behaviour.

Marmur J., Doty P. Thermal Renaturation Of Deoxyribonucleic Acids. J. Mol. Biol., 3:0585-0594. 1961.

ABSTRACT: The conditions that produce the optimal re-formation of the native DNA conformation from denatured DNA have been examined. The restoration of the native conformation, called thermal renaturation, has been found to depend markedly on the source of the DNA; mammalian DNA coming from cells with very large DNA content renatures only slightly, bacterial DNA with greatly reduced DNA content per cell undergoes extensive renaturation, and the very smallest bacteria together with bacteriophage, having the lowest DNA contents, show nearly complete renaturation. With a given DNA, the optimal renaturation was found to occur at about 25 degrees below the denaturation temperature, Tm. The extent of renaturation was optimal above 0.4 m-NA+ and increased with molecualr weight. The identity of the renatured DNA and the native material can be shown in two ways: the similarity of the absorbance-temperature curves and the similarity of the rate of thermal inactiviation of biological markers at temperatures somewhat above Tm. This reproduceability of the helix-coil transition and the course of thermal inactivation demonstrates that the same secondary

structure has reformed and that non-specific hydrogen bonding is not involved.

Marmur J., Doty P. Determination of the Base Composition of Deoxyribonucleic Acid from its Thermal Denaturation Temperature. J. Mol. Biol., 5:0109-0118. 1962.

ABSTRACT: The previously discovered linear relation between the base composition of DNA, expressed in terms of percentage of guanine plus cytosine bases, and the denaturation temperature, Tm, has been further investigated. By means of measurements on 41 samples of knouwn base composition the previously observed relation has been confirmed. It can be summarized thus: for a solvent containg 0.2m-Na+, Tm=69.3+0.41(G-C where Tm is in degrees Centigrade and G-C refers to the mole percentage of guanine plus cytosine. The deviations of experimental points from this relation are no more than that expected from the uncertainties of base analysis and the variations of a half degree in the reproducibility of determining the Tm. Consequently it appears that the measurement of the Tm is a satisfactory means of determining base composition in DNA. The Tm values are most simply measured by following the absorbance at 260 mu as a function of temperature of the DNA solution and noting the midpoint of the hyperchromic rise. Only 10-50 ug of DNA are required. A number of other DNA samples of unknown base composition have been examined in this manner and their base compositions recorded.

Martin E.A. An Investigation Regarding The Use of a Dynamic Seat-Pan Display For Training And As a Device For Communicating Roll-Axis Motion Information. Aviat. Space Environ. Med., 57:1189-1193. 1986.

ABSTRACT: This paper describes a research program conducted to determine the feasibility of providing useful angular onset-motion information via a broad-area tactual seat-pan display. The experiment was designed to evaluate the utility of the display as a training device as well as its efficacy for imparting motion information. The results indicate that, with proper attention given the drive law, the tactual display can elicit both prformance and control behavior indistinguishable from that observed in a whole-body motion environment. Unfortunately, the training transfer results were not as encouraging. These results indicated that the seat-pan display as used in this study was not adequate for training naive subjects to properly interpret and use the motion information available in a whole-body motion environment.

Martyak J.E. Reverse Osmosis/Deionized Water Bacterial Control At The Central Production Facility. Microcontamination, January :0034-0037, 0055. 1988.

ABSTRACT: None

Matsumoto T., Suzuki O., Katsumata Y., Oya M., Nimura Y., Akita M., Hattori T. A Fluorometric Assay for Total Diamines in Human Urine

Using Human Placental Diamine Oxidase. Clin. Chimica., 112/2 :0141-0148. 1981.

ABSTRACT: The detailed procedure for a new fluorometric assay for total diamines in human urine is described. The diamines were purified from the urine by cation-exchange chromatography and incubated with human placental diamine oxidase. Hydrogen peroxide formed in the diamine oxidase reaction was measured fluorometrically by converting homovanillic acid to a highly fluorescent compound in the presence of peroxidase. Because of its simplicity and high sensitivity, our present method seems useful for routine clinical investigation. The data obtained from normal subjects and patients suffering from various forms of cancer are also presented.

Matsuyama T., Sogawa M., Yano I. Direct Colony Thin-Layer Chromatography And Rapid Characterization Of Serratia marcescens Mutants Defective In Production Of Wetting Agents. App. Env. Micro., 53/5:1186-1188. 1987.

ABSTRACT: A bacterial mass (ca. 1 mg) was placed directly on a thin-layer chromatography plate and developed shortly in chloroform-methanol (2:1 vol/vol). After being dried, the bacterial mass was developed in chlorofrom-methanol-5 M ammonia (80:25:4 vol/vol). The obtained chromatogram indicated the characteristic lipid compositions of the bacteria. So, it became possible to examine bacterial colonies at once for the identification of mutants defective in the production of specific lipids.

McDonald L.C., McFeeters R.F., Daeschel M.A., Fleming H.P. A Differential Medium For The Enumeration Of Homofermentative And Heterofermentative Lactic Acid Bacteria. App. Env. Micro., 53/6 :1382-1384. 1987.

ABSTRACT: A medium was developed for the differential enumeration of homofermentative and heterofermentative lactic acid bacteria. Essential components of the medium included fructose (14mM), KH2PO4 (18mM), bromcresol green (as a pH indicator), and other nutrients to support growth. In agar medium, homofermentative colonies were blue to green, while heterofermentative colonies remained white. A total of 21 Lactobacillus, Pediococcus, Leuconostoc, and Streptococcus species were correctly classified with the medium.

McFeters G.A., Kippin J.S., Lechevallier M.W. Injured Coliforms In Drinking Water . App. Env. Micro., 51/1:0001-0005. 1986.

ABSTRACT: Coliforms were enumerated by using m-Endo agar LES and m-T7 agar in 102 routime samples of drinking water from three New England community water systems to investigate the occurrence and significance of injured colforms. Samples included water collected immediately after conventional treatment, during the backwash cycle, at various points in the distribution system, and 1 week after the break and subsequent repair of a distribution main. Injured coliforms in these samples average >95%. m-T7

agar yielded 8-38 fold more coliforms than did m-ENdo agar LES. The geometric mean of coliforms recovered by m-Endo agar LES was <1 confirmed coliform per 100 ml, although m-T7 agar yielded 5.7 to 67.5 confirmed coliforms per 100 ml. In addition, the majority of these samples giving positive results on m-T7 agar produced no detectable counts on m-Endo agar LES. These findings indicated that coliforms were injured and largely undetected by use of accepted analytical media in the system examined.

McHale A., Coughlan M.P. Properties Of The B-Glucosidases Of Talaromyces emersonii. J. Gen. Micro, 128:2327-2331. 2/5/1982.

ABSTRACT: The thermophilic fungus Talaromyces emersonii when grown on cellulose-containing medium produces three extracellular forms of B-glucosidase, I(Mr 135000), II (Mr, 100000), III (Mr,45700), and one intracellular form, B-glucosidase IV (Mr, 57600). With the exception of B-glucosidase II which has yet to be isolated in quantities for characterization each has been shown to be a glycoprotein and to exist as a single polypeptide. Each of the purfied enzyme preparations catalysed cellobiose hydrolysis but only B-glucosidase IV, at the concentrations of substrates used, also catalysed glucosyl transfer to cellobiose.

McInerney M.J., Bryant M.P. Syntrophic Associations Of H2-Utilizing Methanogenic Bacteria And H2-Producing Alcohol And Fatty Acid-Degrading Bacteria In Anaerobic Degradation Of Organic Matter. Anaerobes Anaerobic Infect. Symp. Int. Congr. Microbiol.,1978.

ABSTRACT: None

Mednieks M.I., Hand A.R. Salivary Gland Ultrastructure and Cyclic AMP-Dependent Reactions In Spacelab 3 Rats. AM. J. Physiol., 252 (Regulatory Integrative Comp. Physiol. 21):R0233-R0239. 1987.

ABSTRACT: Environmental stimuli influencing catecholamine levels induce changes in cyclic AMP-dependent reactions and cell morphology in the rat parotid. Responses of salivary glands to spaceflight were determined by measurement of cyclic AMP-mediated reactions in fresh-frozen salivary glands and by microscopic evaluation of ultrastructure in fexed parotid glands. Decreased cell-free protein phosphorylation accurred in parotid glands in three of five flight anumals. Protein kinase activity ratios were decreased in the soluble and increased in the particulate fractions of Apcelab 3 (SL-3) rat sublingual glands, compared with ground controls. Biochemical analyses show that effects of space flight on salivary glands are similar to those induced experimentally by physiological manipulation of alteration of catecholamine levels. Morphological evaluation of three SL-3 rat parotid glands showed increased numbers of lysosomes, autophagic vacuoles containing degenerating secretory product, and accumulation of lipid droplets. Since these animals lost weight, consistent with disruption of food and water consumption, morphological changes may in part be due to decreased masticatory stimulation, as occurs with reduced food intake of a liquid diet.

The observed changes may reflect physiological responses of the gastrointestinal and autonomic systems to effects of spaceflight.

Merrill A.H., Wang E., Jones D.P., Hargrove J.L. Hepatic Function In Rats After Spaceflight: Effects on Lipids, Glycogen, And Enzymes. Am. J. Physiol., 252 (Regulatory Integrative Comp. Physiol. 21) :R0222-R0226. 1987.

ABSTRACT: The inclusion of rats aboard Spacelab 3 (SL-3) allowed analyses of liver lipids, glycogen, hepatic enzymes of cholesterol, glycerolipid and sphingolipid biosynthesis, and other enzyme activities. Glycogen content was markedly elevated in livers from the flight animals compared with controls. Cholesterol was 24% ($P < 0.04$) lower in livers from the experimental groups, whereas blood cholesterol was 19% higher ($P < 0.05$). The activity of 3-hydroxy-3-methylglutaryl-CoA reductase, the rate-limiting exzyme of steroid biosynthesis, was 80% lower ($P < 0.01$). Total phospholipids and sphingolipid levels did not differ significantly. The specific activity of fatty acyl-CoA synthetase, which is responsible for activation of fatty acids, was 37% ($P < 0.02$) there was no difference per gram of liver. The initial exzymes of sphingolipid and glycerolipid biosynthesis were assayed; serine palmitoyltransferase was 40% lower ($P < 0.01$), and glycerol 3-phosphate acyltransferase did not differ. Hepatic cytochrome P-450 content decreased by 50% after spaceflight. Enzymes that did not differ significiantly between the two groups include cytochrome b5, glutathione S-transferase, tyrosine aminotransferase, aspartate aminotransferase, and cystathionase. These findings suggets that space flight alters hepatic metabolism of several classes of conpounds.

Michels D.B., West J.B. Distribution Of Pulmonary Ventilation And Perfusion During Short Periods Of Weightlessness. J. Appl. Physiol., 45/6:0987-0998. 1978.

ABSTRACT: Information of the distributions of pulmonary ventilation and perfusion was obtained from four subjects on board a Learjet during 112 weightless periods lasting up to 27 s each. Zero gravity (G) was obtained during all or part of each test by varying the aircraft flight profile. Single-breath N2 washouts were performed with the test inspiration containing an initial bolus of argon at residual volume (RV). When the test inspiration was at 0 G with the washout at 0 G or greater, the terminal rises and the cardiogenic oscillations in both N2 and argon were small and often absent. If instead the test inspiration was at 1 G with the washout at 0 G, the terminal rises were again small or absent but the cardiogenic oscillations remained. The terminal rese and the cardiogenic ascillations for N2 but not argon, were also nearly eliminated by performing just the preliminary exhalation to RV at 0 G with the test inspiration and washout following at 1 G. Alveolar plateaus for N2 sloped upward at 0 G apparently due to nontopographical inequalities of ventilation. In further tests during air breathing, recordings were made of expired partial pressure of oxygen (PO2) and carbon dioxide (PCO2) following a brief hyperventilation and a 15 s

breath hold. These recordings revealed marked cardiogenic ascillations in PO2 and PCO2 at 1 G that were enhanced at 2 G but almost eliminated at 0 G. The results suggest that virutally all the topographical inequality of ventilation, blood flow, and lung volume seen under 1 G conditions are abolished during short periods of 0 G.

Mid-South Testing. Bioassay Testing Procedures For NASA. Quarterly Report,DSN001, DSN0031986.

ABSTRACT: None

Miller G.L., Blum R., Glennon L.E., Burton A.L. Measurement Of Carboxymethylcellulase Activity. Anal. Biochem., 2:0127-0132. 1960.

ABSTRACT: None

Mishra C., Rao M., Seeta R., Srinivasan M.C., Deshpande V. Hydrolysis Of Lignocelluloses By Penicillium funiculosum Cellulase. Biotech. Bioeng., 26:0370-0373. 1984.

ABSTRACT: This commumication reports the studies on saccharification of lignocelluloses by P. funiculosum cellulase and certain studies on the kinetic aspects.

Mittelman M.W. Biological Fouling of Purified-Water Systems: Part 1, Bacterial Growth and Replication. Microcontamination, October :0051-0055, 0070. 1985.

ABSTRACT: The efficiency of many industrial operations is often closely tied to the quality of purified water used. The tie is particularly strong in the microelectronics industry, where ultrapure water is essential to a number of manufacturing processes. Clearly, it is important that contaminants that may affect water quality-and, ultimately, product quality and systems operations-be identified and isolated from the water system.

Mittelman M.W. Biological Fouling of Purified-Water Systems: Part II, Detection and Enumeration. Microcontamination, November :0044-0058. 1985.

ABSTRACT: The unique ability of microorganisms to adapt to their environment allows them to survive under extremely nutrient-limited conditions. This unusual physiology contributes to a number of difficulties associated with the analysis of these contaminants. This column will describe various microbiological testing methods designed for application to high-purity waters.

Mittelman M.W. Biological Fouling of Purified-Water Systems: Part III, Treatment. Microcontamination, January:0030-0070. 1986.

ABSTRACT: This column will provide insight into the factors involved in the selection of biofouling treatments. Biological fouling presents a number of special treatment problems. Purified-water systems contain both planktonic and adherent

bacterial populations; since the latter make up the bulk of the total bacteria present, the treatment used must be capable of killing the bacteria in biofilms as well as those in the overlying water, In addition, the attached bilofilms must be removed from surfaces and flushed from the system in order to prevent organic or ionic contamination. Other essential factors in treatment selection are product, process, and system-component compatibility. Finally, since most treatments for biological fouling employ chemicals, safety and environmental considerations are of great importance.

Mittelman M.W., Geesey G.G., Hite R.R. Epifluorescence Microscopy. Microcontamination, 1983.

ABSTRACT: None

Mohler S.R. Case From The Aerospace Medicine Resident's Teaching File, #4. Aviat. Space Environ. Med., :0271-0274. 1985.

ABSTRACT: An airline captain with a presenting sign of some premature ventricular contractions. The clinical presentation, evaluation, and diagnosis of the pilot are discussed. The aeromedical disposition and prognosis of this patient are provided.

Mohler S.R. Age and Space Flight. Aviat. Space Environ. Med., 56 :0714-0717. 1985.

ABSTRACT: Criteria for space flight crew and passenger selection should be based on the following three considerations: (1) freedom from impairing disease, (2) ability to perform mission requirements and (3) motivation to undertake the mission. Chronologic age of itself is not a valid criterion. Forecast life expectancy and vitality relative to mission duration are valid criteria and can be applied on an individual basis using modern assessment techniques. The good health and vitality characterizing the upper ages of today's population widens the opportunity to utilize increasingly broad fields of experience and skills in future space flights, further enhancing the odds for total mission accomplishment.

Moloney A., Coughlan M.P. Sorption Of Talaromyces emersonii Cellulase On Cellulosic Substrates. Biotech. Bioeng., XXV:0271-0280. 1983.

ABSTRACT: The sorption characterstics of the cellulase system of Talaromyces emersonii on various cellulosic substrates were examined. Analysis of reaction mixture supernatants by electrophoresis and enzyme assay showed that all components of the cellulase system were rapidly adsorbed by cellulose and then gradually returned to the liquid phase as the hydrolysis of the substrate progressed. The extent of adsorption in the rapid phase was influenced by pH, temperature, the nature of the substrate, and its concentration.

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The Cellulases Produced By Talaromyces emersonii When Grown On Different Inducing Substrates. Biotech. Bioeng., XXV:1169-1173. 1983.

ABSTRACT: Pulp obtained from the processing of subar beet at a local factory is mixed with molasses and sold as cattle food. However, the value of the pulp would be increased considerably if its constituent cellulose and hemicellulose fractions could be converted to fermentable sugars. To this end we are investigating the enzymic hydrolysis of beet pulp using the cellulase system produced by the termophilic fungus, Talaromyces emersonii. In this Communication, we report on the initial results of such studies.

Moloney A.P., Hackett T.J., Considine P.J., Coughlan M.P. Isolation Of Mutants Of Talaromyces emersonii CBS 814.70 With Enhanced Cellulase Activity. Enzyme Micro. Technol., 5 1983.

ABSTRACT: By a combination of genetic mutation and modification of growth medium the cellulase activity of culture filtrates of Talaromyces emersonii CBS 814.70 has been increased four-fold to approximately 2 U ml-1 and a productivity of 20-25 Ul-1h-1. At 50 degrees C this system was completely stable for at least 24 hours. At 60 degrees C in static reaction mixtures 19% of the original activity was lost compared with 21% when mixtures were shaken. At 70 degrees C the loss of activity after 4 hours was 64% without shaking and 70% when shaken. The cellulase system from Trichoderma reesei was deciedly less than that of Talaromyces emersonii under each of the above conditions. The ability of each enzyme system, separately and together, to digest beet pulp was investigated.

Montenecourt B.S., Eveleigh D.E. Preparation Of Mutants Of Trichoderma reesei With Enhanced Cellulase Production. App. Environ. Micro., 34/6:0777-0782. 1977.

ABSTRACT: The development of an agar plate screening technique has allowed the isolation of a range of mutants of Trichoderma reesei capable of synthesizing cellulase under conditions of high catabolite repression, The properties of one of these mutants (NG-14) is described to illustrate the use of this technique. NG-14 produced five times the filter paper-degrading activity per ml of culture medium and twice the specific activity per mg of excreted protein in submerged culture when compared with the best existing mutant, QM9414. NG-14 also showed enhanced endo-B-glucanase and B-glucosidase production, Although these mutants were isolated as cellulase producers in the presence of 5% glycerol on agar plates, in similar liquid medium, NG-14 exhibits only partial derepression of the cellulase comples. Since the proportions of filter paper activity, endo-B-glucanase, and cellobiase were not the same in mutants NG-14 and QM9414, and the yields of each enzyme under conditions repressive for cellulase synthesis were different, differential control of each enzyme of the cellulase complex is implied. These intial results suggest that the selective technique for isolating hyper-cellulase-producing mutants of Tricholerma will be of

considerable use in the development of commercially useful celluloytic strains.

Montenecourt B.S., Eveleigh D.E. Production And Characterization Of High Yielding Cellulase Mutants Of Trichoderma reesei. Department of Biochemistry And Microbiology Cook College, Rutgers The Stat University of New Jersey, New Brunswick, New Jersey 08903,.

ABSTRACT: Biological conversion of cellulosic materials to glucose by the use of microbial cellulase enzymes is an attractive alternative to chemical hydrolysis since enzmes generally are non-polluting, reusable, energy sparing and catayze high conversion efficiencies without undesirable side products. Enzymatic conversions to date have not been economical due to the high production costs and low yield of the enzymes produced by the available microbial strains. In an effort to overcome these economic bottlenecks, improved strains of trichoderma reesei have been isolated by mutation and selection which are capable of overcoming some of the rigid controls on enzyme synthesis and activity. The selection techniques and the characteristics of several high yielding mutants are discussed. These mutants hyperproduce all of the enzymes in the cellulase complex. One mutant C-30 is resistant to catabolite repression and appears to have a partially end-product resistant B-glucosidase.

Montenecourt B.S., Eveleigh D.E. Semiquantitative Plate Assay for Determination of Cellulase Production by Trichoderma viride. App. Env. Micro, 33/1:0178-0183. 1977.

ABSTRACT: A plate clearing assay was devised to screen for high-producing cellulase mutants of Trichoderma viride. The method employs (i) the use of either rose bengal or oxgall to limit colony size and (ii) Phosfon D (tributyl-2,4-dichlorobenzylphosphonium chloride) to enhance cellulase detection, in combination with acid-swollen cellulose on agar plates. The method was used to isolate constitutive cellulase mutants of T. viride and should prove useful for isolationg high-producing mutants from a range of organisms. This technique has been also used to determine the concentration at which glucose and glycerol inhibit cellulase synthesis by catabolite repression in the wild-type strains.

Morris N.J.H. Air, Gas And Liquid Filtration In The Pharmaceutical Industry. 1984.

ABSTRACT: The production of proteins, vaccines, antibodies, hormones vitamins and enzymes involves high technology proceses which require aseptic and sterile supplies of gases or liquids throughout the manufacturing cycle. Recent advances in methods of filtration for compressed air, gases and liquids are leading to longer service life with higher retention efficiencies. This paper highlights the need for filtration in pharmaceuticals and describes test programmes designed to establish the value of hollow fibres as a superior filter medium.

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ABSTRACT: Recent advance in preventaive medicine offer practitioners exceptional opportunities to help patients and their families have longer, healthier, and more enjoyable lives. Those involved in aerospace medicine are uniquely qualified by their training and experience to apply this enhanced prevention armamentarium. The discussion considers a number of activities and techniques which can provide important patient benefits at acceptable costs.

Mowery R.A. Automated LC Allows Engineers to Monitor Ongoing Processes. Indust. Research and Devel., June:0102-0105. 1983.

ABSTRACT: Process liquid chromatography analyzes streams of reactants and products, permitting quick process changes when needed.

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ABSTRACT: None

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ABSTRACT: Nosocomial Legionnaires disease can be acquired by exposure to the organism from the hospital water distribution system. As a result, many hospitals have instituted eradication procedures, including hyperchlorination and thermal eradication. We compared the efficacy of ozonation, UV light, hyperchlorination, and heat eradication using a model plumbing system constructed on copper piping, brass spigots, Plexiglas reservoir, electric hot water tank, and a pump. Legionella pneumophila was added to the system at 10 7 cfu/ml. Each method was tested under three conditions; (i) nonturbid water at 25 C, (ii) turbid water at 25 C, and (iii) maintenance. Both UV light and heat (60 C) produced a 5 log kill in less than 1 h. In contrast, both chlorine and ozone required 5 h of exposure to produce a 5 log decrease. Neither turbidity nor the higher temperature of 43 C impaired the efficacy of any of the disinfectant methods. Surprisingly, higher temperature enhanced the disinfecting efficacy of chlorine. However, higher temperature accelerated the decomposition of the chlorine residual such that an additional 120% volume of chlorine was required. All four methods proved efficacious in eradicating L. pneumophila from a model plumbing system.

Musial C.E., Arrowood M.J., Sterling C.R., Gerba C.P. Detection Of Cryptosporidium In Water By Using Polypropylene Cartridge Filters. App. Env. Micro., 53/4:0687-0692. 1987.

ABSTRACT: Members of the genus Cryptosporidium are protozoan parasites that cause gastroenteritis in humans and animals and

appear to be spread largely by the fecal-oral route. A method was developed for the concentration and detection of Cryptosporidium oocysts in water to assess their occurance in the environment and potential for waterborne disease transmission. This method was developed by using spun polypropylene cartridge filters. Optimal conditions for concentration, filter elution, filter porosity, and detection were determined. Fluoresceinated monoclonal antibodies were used for oocyst detection. Experiments also were conducted to study the effect of flow rate, low oocyst numbers, and the additon of detergents of recovery and retention of oocysts. The method that was developed was sensitive enough to detect oocysts at levels of less than 1 per liter. Using this method, we isolated Cryptosporidium oocysts from secondarily treated sewage.

Nair G.B., Misra S., Bhadra R.K., Pal S.C. Evaluation Of The Multitest Medium For Rapid Presumptive Identification Of Vibrio cholerae From Environmental Sources. App. Env. Micro., 53/5 :1203-1205. 1987.

ABSTRACT: The multitest V. cholerae medium (VC medium) for rapid presumptive identification of V. cholerae was evaluated. On the basis of reactions in the VC medium, 379 strains recovered during a yearlong ecological study in Calcutta were presumptively identified as V. cholerae. Further phenotypic characterization of these strains revealed that the reactions of 371 (97.9%) isolates were consistent with that of V. cholerae. False-positive reactions were exhibited by eight (2.1%) strains, three of which were identified as V. fluvialis biotype 1. By slightly varying the basic formulation of the VC medium, we could elimiate some false-positive reactions. On the basis of the present evaluation, we recommend the routine use of the VC medium.

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ABSTRACT: An amplified enzyme-linked immunosorbent assay (A-ELISA) for detecting and quantifying hepatitis A virus in estuarine water samples is described. The test was five times more sensitive than a standard ELISA and at least two times more sensitive than radioimmunoassay. Test sensitivity was unaffected by the procedures used to concentrate the virus in estuarine samples or by the presence of humic and tannic acids in test samples. Nonspecific reactions were not encountered with an number of enteroviruses or with a rotavirus. A high sensitivity and specificity combined with speed, low cost, and freedom from radiolabels made the A-ELISA useful for detecting hepatitis. A virus in environmental samples. The virus was detected in 3 of 20 estuarine water samples examined by A-ELISA.

Natelson B.H., Goldwater D.J., De Roshia C., Levin B.E. Visceral

Predictors Of Cardiovascular Deconditioning In Late Middle-aged Men. Aviat. Space Environ. Med., 56:0199-0203. 1985.

ABSTRACT: A major task for space biologist is to try to delineate methods which can be used to predict the degree of cardiovascular deconditioning that given individuals might develop while in space. Toward that end, we have studied a number of different visceral and behavioral variables in a group of late middle-aged men (55-65 years) on day 1 and day 5 of a bedrest regimen. During each 8-h study period, data were collected every 15 min. Mean arterial blood pressure and plasma cortisol and norepinephrine concentrations were significantly higher on the day 5 than on the day 1 of bedrest; heart rate, core temperature, plasma epinephrine and subjective arousal were unchanged. Pairwise correlations between each of these variables and the time to blackout on a +3-Gz test of acceleration tolerance administered on day 9 of bedrest (mean decrease in latencies from prebedrest was 52%) revealed a significant correlation for the mean arterial blood pressure variable. Thus, these data indicate that men in this age span with relatively low resting blood pressures are at greater risk for developing clinical signs relating to their cardiovascular deconditioning than other men with higher basal blood pressures.

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ABSTRACT: Treatment of a wide variety of lignocellulosic biomass with gaseous ozone results in greatly enhanced susceptibility to cellulase enzyme hydrolysis and to digestion by rumen microorganisms so that it can be used as ruminant animal feed or for the production of glucose via enzymatic hydrolysis. By use of appropriate reaction conditions a useful degree of such pretreatment may be obtained in 1-2 h contact time with an ozone consumption of ca.4-6% of the dry weight of the biomass.

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ABSTRACT: Effects of hyperbaric oxygen (HBO) on tumor growth and lung metastases were investigated using the Lewis lung squamous carcinoma in a mouse model. Ninety Swiss white mice were injected with 1 mm3 of the tumor in a standardized fashion and randomly assigned to a control or HBO group. Mice receiving HBO were treated at 2.5 ATA for 90 min twice a day for 7 d. Tumor volumes, tumor weights, and lung metastaes were analyaed at specified times by a "blinded" researcher. Results indicated that there were no significat differences between HBO and control groups on any of the parameters measured. Results of the current study indicate that HBO does not enhance tumor growth or lung metastases.

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ABSTRACT: There are two overriding concerns in the design of schedules for aircrew who have to cope with irregularity of their sleep due either to work at unusual times of the day or to time zone changes. The first is that aircrew must be able to achieve an acceptable sleep pattern, and this is likely to involve short periods of sleep and naps. These, inturn, depend on limits to duty hours. The second is that the arrangement of work must bear in mind that prolonged duty and duty at certain times of the day may both involve relatively low levels of performance, and modelling can identify the adverse interactions of these influences. It is also important that the quality of the sleep of the individual pilot is taken into consideratin when there are undue difficulties in coping with irregularity of work.

Nicholson A.N., Pascoe P.A., Spencer M.B., Stone B.M., Green R.L. Nocturnal Sleep And Daytime Alertness of Aircrew After Transmeridian Flights. Aviat. Space Environ. Med., 57 (12, Suppl.):B0043-B0052. 1986.

ABSTRACT: The nocturnal sleep and daytime alertness of aircrew were studied by electroencephalography and the multiple sleep latency test. After a transmeridian flight from London to San Francisco, sleep onset was faster and, although there was increased wakefulness during the second half of the night. sleep duration and efficiency over the whole night were not changed. The progressive decrease in sleep latencies observed normally in the multiple sleep latency test during the morning continued throughout the day after arrival. Of the 13 subjects, 12 took a nap of around 1-h duration in the afternoon preceding the return flight. These naps would have been encouraged by the drowsiness at this time and facilitated by the departure of the aircraft being scheduled during the early evening. An early evening departure had the further advantage that the circadian increase in vigilance expected during the early part of the day would occur during the latter part of the return flight.

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ABSTRACT: None

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ABSTRACT: Sixty-eight halobacteria, including both culture collection strains and fresh isolates from widely differing geographical areas, were tested for susceptibility to arsenate, cadmium, chromium, cobalt, copper, lead, mercury, nickel, silver, and zinc ions by an agar dilution technique. The culture

collection strains showed different susceptibilities, clustering into five groups. Halobacterium mediterranei and Halobacterium volcanii were the most metal tolerant, whereas Haloarcula californiae and Haloarcula sinaiiensis had the highest susceptibilities of the culture collection strains. Different patterns of metal susceptibility were found for all the halobacteria tested, and there was a uniform susceptibilty to mercury and silver. All strains tested were multiply metal tolerant.

Nojima S. The Development Of Continuous Alcohol Fermentation By Immobilized Living Cells. Chem. Econ. Eng. Rev., 15/4:0017-0022. 1983.

ABSTRACT: Technology for a continuous alcohol fermentation process was developed by means of immobilized living cells using yeast cells and specially designed artificial resins. Yeast which has the ability to make alcohol was screened from Saccharomyces genus and mixed with prepolymers of photo-crosslinkable resin, then illuminated with an active ray (for example, chemical lamp) to change the prepolymers into three dimensional cross-linked polymers in which yeast was entrapped. Specially shaped immobilized yeast was packed in an fermentor and a diluted molasses solution fed to the fementor. The fermentation temperature was kept at about 30-31 C and the pH at 4-5. As a result of a bench scale test (10 liters of ethanol a day) and pitot plant test (250 liters of ethanol a day), the constant activity of the yeast and high alcohol yield on sugar during long-term operation was confirmed and it was also established that the alcohol productivity was several times that of conventional suspended state batch system fermentation.

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ABSTRACT: The concept of transforming municipal, agricultural, and industrial cellulosic wastes into usable resources has long exicited the scientific community. Our new found awareness of our depleting resources has been repsonsible for the support, both scientific and political, given to the development of many cellulose utilising technologies. In a process conceived at the US Army Natick Research and Development Command, cellulose is hydrolysed to glucose via the action of a complex of enzymes known as 'cellulase'. A small pilot facility has been built and operated to develop an economic process technology for both the production of enzymes and the hydrolysis of various cellulosic materials. A highly instrumented concept with designed processing flexibility has greatly accelerated the development efforts. Improved processing techniques have led to both enhanced production of cellulase via submerged fermentation of Trichoderma viride and more optimum use of these biological catalysts in enzyme reactors.

O'Sullivan J.B. Gestational Diabetes: Factors Influencing The Rates Of Subsequent Diabetes. Attachment J.9,:0425-0435. .

ABSTRACT: The design of our initial study of gestational diabetes provided both an intervention trial and a longitudinal study. The results of the intervention trial, which concerned the effects of insulin treatment on the outcome of pregnancy, were summarized in the First Colloquium on Carbohydrate Metabolism in Pregnancy and the Newborn in 1973 (O'Sullivan, 1975). On the occasion of the Second Colloquium, my comments will be confined to data from the longitudinal study providing current information on the rates of subsequent diabetes from that initial study and to some of the factors that determine these rates.

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Odum H.T. Limits of Remote Ecosystems Containing Man. Am. Biol. Teacher, 25:429-443. 1963.

ABSTRACT: Considering a controversy among those attemptiong to provide support for man in Space, three kinds of systems are contrasted: A. the conventional engineering approach with pipes, electrical circuits, fuel, and maintenance parts sent from earth; B. the physiological approach with a few biological species in culture to complement man in a simple ecosystem, which also requires heavy subsidies in energy materials, controls, and parts from earth; C. the ecological approach with a complex multispecies climax ecosystem self sufficient with all its maintenance and control functions in the form of many highly minaturized and specialized biogeochemical circuits. Some fallacies in previous estimates of the amount of solar energy required to support man in space are described: A. the incorrect use of theoretical reversible high effciencies for computing potentials in defiance of the great body of empirical data on the noderately low efficiency of successful self maintaining ecosystems; B. the omission of the energetic costs of the accompanying species necessary for stable chemical cycles and system maintenance; C. the neglect of the high trophic position of man and the necessity of heat losses during food chain transfers to him. The extimated minimum solar area for a closed and stable climax ecosystem supporting man without outside subsidies is estimated as 2 acres. To develop such a system including man for space encapsulation, the multiple seeding method is recommended.

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ABSTRACT: Ten aviators with cardiac symptoms or electrocardiographic abnormalities underwent electrocardiographic testing. Four patients were studied because of symptoms including palpitaitons, near-syncope, and sudden cardiac death. Six patients were studied because of electrocardiographic abnormalities including AV block, right bundle branch block, sinus bradycardia, ventricular tachycardia, and questionable Wolff-Parkinson-White syndrome. Three patients with bradycardia and/or AV block were found to have increased vagal tone. A fourth patient had near-syncope and intra-Hisian block. Of four patients evaluated for palpitations and/or tachycardias; one had nonsustained ventricualr tachycardia; one had easily inducible ventricualr tachycardia and fibrillation; one had a normal study, and one had coronary artery disease with an unanticipated prolonged HV interval. The diagnosis of congenital right bundle branch block and Wolff-Parkinson-White syndrome were confirmed in the final two patents. Performance of electrophysiologic testing provided objective data to allow appropriate therapeutic and administrative decisions in these aviators.

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ABSTRACT: Pure cellulose (Avicel) was hydrolyzed batchwise at 50 C and pH 4.8 by cellulase from Trichoderma viride (Meicelase CEP). Then the effects of the crystallinity of cellulose as well as the thermal deactivaton and product (cellobiose and glucose) inhibition to cellulase on the hydrolysis rate were quantitatively investigated. While these factors had evidently retarded the enzymatic hydrolysis of cellulose to a significant extent, the hydrolysis rates observed could not be explained. For practical purposes, an empirical, simple rate expression was developed which included only one parameter: an overall rate retardation constant. This empirical rate expression held for the hydrolysis of at least two kinds of cellulosic materials: Avicel and tissue paper.

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ABSTRACT: Space sickness symptoms were observed by 4 specially trained observers on Spacelab-1. Three reported persistent symptoms, and vomited repeatedly during the first and/or second day of flight. Head movements on all axes were provocative, particularly in pitch and roll. Head acceleration data recorded

from 2 symptomatic crewmen showed that after several hours of physical activity in orbit, symptoms appeared, and thereafter both crewmen were compelled to limit head movements. Firm body contact with motionless surfaces helped alleviate symptoms. When crewmembers floated into unfamiliar body orientations in the cabin, inherent ambiguities in static visual orientation cues sometimes produced spatial reorientation episodes which were also provocative. Symptoms largley resembled those of other forms of prolonged motion sickness, superimposed upon other sypmtoms attributable to fluid shift. All 4 eventually used anti-motion sickness drugs. When they did, vomiting frequency was reduced. By the 4th day, symptoms subsided,and head accelerations again increased in magnitude and variability. Sickness intensity in orbit was not predicted by statistically concordant results of 6 acute preflight susceptiblity tests. However, results from a longer duration preflight prism goggles test showed an apparent correlationl All subjects were asymptomatic making head movements in parabolic flight 4 days after the mission, but not 1 year later. Overall, results support the view that space sickness is a motion sickness.

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ABSTRACT: The adsorption of cellulase from trichoderma viride (Meicelase CEP) on the surface of pure cellulose was studied. The adsorption was found to obey apparently the Langmuir isotherm. From the data concerning the effects of temperature and the crystallinity of cellulose on the Langmuir adsorption parameters, the characteristics of the adsorption of the individual cellulase components, namely CMCase (endoglucanase) and Avicelase (exoglucanase), were discussed. While B-glucosidase also absorbed on the surface of cellulose at 5 degrees C, it did not at 50 degrees C.

Owen A.J. The Diode-Array Advantage in UV/Visible Spectroscopy. The Diode-Array Advantage in UV/Visible Spectroscopy, Hewlett-Packard Co.,:1-60. 1988.

ABSTRACT: The development of diode-array spectrophotometers was a major advancement in UV/Visible spectorphotometer technology. In 1979, Hewlett-Packard introduced the HP 8450A, the world's first commercially available diode-array spectrophotometer. It possessed a revolutionary new optical system and introduced the concept of total intergration of spectrophotometer, microprocessor control and data processing. Compared to conventional, serial scanning spectrophotometers, a diode-array instrument acquires the spectral data simultaneously without mechanically moving parts. The most obvious benefit to the user is speed. However, the design differences result in a series of other advantages, which will be discussed in this booklet. As a result, diode-array spectrophotometers can not only replace conventional instruments in most applications, but their benefits clearly make them superior in most cases. Initially, because of the high price, the advantages of diode-array spectroscopy could

only be appreciated by a relatively small number of specialized laboratories. Now, the HP 8452A diode-array spectrophotometer is available at a price that is comparable to that of conventional instruments. This has been achieved through a combined effort in optimizing the design, developing now technologies and new manufacturing concepts.

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ABSTRACT: In recent years several efforts have been made to investigate the sources of volatile organic chemicals (VOCs) in offices and residential buildings. However, the largest data base by far has been compiled by NASA (McDonnell Douglas, contractor), who have tested the VOC Emmissions for over 5,000 Materials used in the space program. Many of these (paints, epoxies, pens, cosmetics, etc.) are available commercially and are used in homes and offices across the United Stated. By utilizing this unique data base, stored on a personal computer, we calculated emission rates of ten common VOCs using the test results from a large number of materials and household products found in most U.S. buildings. Ongoing analysis efforts using this important data set are also presented.

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ABSTRACT: The analysis of a continuous aerobic, fixed-film bioreactor is performed by simulating the behavior of penicillin production in a three-phase fluidized bed. Rigorous mathematical models are developed for a fluidized-bed fermentor in which bioparticles are fluidized by the liquid medium and air. The steady-state performance of the fluidized-bed reactor is appraised in terms of penicillin productivity and outlet concentration by considering the two extremes in contacting patterns, complete back-mix and plug flow, in the absence of a growing biofilm. The results show that the complete back-mix contacting pattern is preferred over that of plug flow due to the nature of the penicillin kinetic relationships. It is also shown that for the dual-nutrient (glucose and oxygen) penicillin reaction system the optimum biofilm thickness does not equal the peretration depth of a limiting nutrient, but depends upon the total reactor configuration.

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ABSTRACT: The dynamic analysis of a contionous,aerobic,

fixed-film bioreactor has been performed. Rigorous mathematical models have been developed for a fluidized-bed fermentor with biofilm growth. The transient performance of the reactor is appraised in terms of outlet penicillin concentration for constant, as well as variable carbon substrate feed rates. The effect of the reactor oxygen transfer capacity is elucidated for those cases employing substrate feeding strategies. The results show that penicillin production in a continuous, fixed-film bioreactor reaches a maximum with processing time, but subsequently decreases as cell mass accumulates and substrate deficiencies occur. The maximum production level can be maintained for increased operating times if the substrate supply is continuously increased. The duration of this prolonged production is a direct function of the rate of increase and the operating time at which the increase is initiated. The oxygen transfer capacity of the reactor was found to be important to the effectiveness of a feeding strategy.

Parker D.E., Reschke M.K., Arrott A.P., Homick J.L., Lichtenberg B.K. Otolith Tilt-Translation Reinterpretation Following Prolonged Weightlessness: Implications For Preflight Training. Aviat. Space Environ. Med., 56:0601-0606. 1985.

ABSTRACT: Observations with three astronauts yielded two major findings. First, perceived self-motion during sinusoidal roll differed immediately postflight from preflight. Between 70 and 150 min after landing, roll was perceived primarily as linear translation. Secondly, more horizontal eye movement was elicited by roll stimulation immediately postflight relative to both preflight observations. These results support as "otolith tilt-translation reinterpretation" hypothesis, which has clear implications for understanding astronaut reports of space motion sickness during the early period of orbital flight. A proposal for "prophylatic adaptation training" which may provide preflight adaptation to weightlessness, derives from this research.

Patterson-Buckendahl P., Arnaud S.B., Mechanic G.L., Martim R.B., Grindeland R.E., Cann C.E. Fragility and Composition of Growing Rat Bone After One Week In Spaceflight. Am. J. Physiol., 252 (Regulatory Integrative Comp. Physiol. 21):R0240-R0246. 1987.

ABSTRACT: To gain some in8sight into the early effects of spaceflight on skeletal metabolism, we quantified the major chemical constituents and a noncollagenous protein, osteocalcin, in the third-lumbar verebrae and humeri from 8-wk old rats that were part of the 7-day NASA Spacelab 3 flight experiments. The ratio of calcium to hydroxyproline in the humeral diaphysis increased from 8.5 in preflight to 9.8 in ground simulation control and only to 8.9 in flight bones. There was no demonstrable change in the fraction of nonmineralized collagen. Osteocalcin content was reduced in the humerus and vertabra. Reduced accumulation of mineral and osteocalcin with no associated decrease in collagen in flight animals suggests that both mineralization and collagen metabolism are impaired in growing animals during spaceflight within a few days after launch. Strength tests of the humeri of flight rats showed

substantial deficits that appeared to be related, not only to the reduced bone mass, but also to the composition and quality of new bone formed.

Perin M.M. Space Nursing. Nurs. Clin. N. Am., 20/3:0497-0503. 1985.

ABSTRACT: The challenge is to have man living and working in a permanently based space station. Nursing is on the threshold of expanding the health care role to man's adaptation in outer space. Elements of man's physioligic and psycholigic responses are involved in determining the most productive use of man and machines in the space environment. Curricular considerations for a career in space nursing can produce effective contributions toward health care maintenance of the space station personnel. The challenge for nursing is to become a collaboration team participant in the exploration of living and working in space.

Perry T.W., Reid D.H. Spacelab Mission 4-The First Dedicated Life Sciences Mission. Aviat. Space Environ. Med., 54/12:1123-1128. 1983.

ABSTRACT: Spacelab is a large,versatile laboratory carried in the bay of the Shuttle Orbiter. The first Spacelab mission dedicated entirely to life sciences is Spacelab-4. It is scheduled for launch in late 1985 and will remain aloft for 7 days. All of the investigations are currently classified as "tentatively selected," with "final selection" and confirmation planned for late 1983. The 24 tentatively selected investigation have been combined into a comprehensive, integrated exploration of the effects of acute weightlessness on living systems. An emphasis is placed on studying physiological changes previously observed in manned space flight. This payload has complementary designs in both human and animal investigations in order to validate animal models of human physiology in weightlessness. The experimental subjects include humans, squirrel monkeys, laboratory rats, two species of plants, and frog eggs. The primary scientific objectives include study of the acute cephalic fluid shift, cardiovascular adaptation to weightlessness (including postflight reductions in orthostatic tolerance and exercise capacity), and changes in vestibular function (including space motion sickness), associated with weightlessness. Secondary scientific objectives include the study of red cell mass reduction, negative nitrogen balance, altered calcium metabolism, suppressed in vitro lymphocyte reactivity, gravitropism and phototropism in plants, and fertilization and early development in frog eggs. The rationale behind this payload, the selection process, and details of the individual investigations are presented in this paper.

Pettitt D.J., Bennett P.H., Knowler W.C., Baird R., Aleck K.A. Gestational Diabetes Mellitus And Impaired Glucose Tolerance During Pregnancy: Long-Term Effects On Obesity And Glucose Tolerance In The Offspring. Diabetes, 34 (Suppl. 2):119-122. 1985.

ABSTRACT: The effects of disturbances in carbohydrate metabolism

during gestation were studied in the offspring of 1049 Pima Indian women who had no previous diagnosis of diabetes. Rates of fetal and maternal complications of pregnancy among women with diabetes first diagnosed during the pregnancy were similar to those among women in whom diabetes was recognized before gestation. Offspring, aged 5-19 yr, of women with abnormal glucose tolerance during pregnancy had a higher mean percent desirable weight and a higher mean postchallenge plasma glucose concentration than did offspring of women with normal glucose tolerance. Percent desirable weight and glucose concentration, however, were both lower than found in offspring of women with diabetes diagnosed before the pregnancy. Thus, metabolic events during pregnancy, as indicated by the detection of abnormal glucose tolerance during gestatin, appear to have long-term effects on obesity and glucose tolerance in the offspring.

Pickett M.J. Gram Negative Rods, Genus Psuedomonas. Specific Microbial Agents of Disease, :0365-0374. .

ABSTRACT: None

Pierson D.L., Cintron M.N. Microbiological Requirements And Specifications For Space Station. Johnson Space Center,1985.

ABSTRACT: None

Pipes W.O., Minnigh H.A., Moyer B., Troy M.A. Comparison Of Clark's Presence-Absence Test And The Membrane Filter Method For Coliform Detection In Potable Water Samples. App. Env. Micro., 52/3:0439-0443. 1986.

ABSTRACT: A total of 2,601 water samples from six different water systems were tested for coliform bacteria by Clark's presence-absence (P-A) test and by the membrane filter (MF) method. There was no significant difference in the fraction of samples positive for coliform bacteria for any of the systems tested. It was concluded that the two tests are equivalent for monitoring purposes. However, 152 samples were positive for coliform bacteria by the MF method but negative by the P-A test, and 132 samples were positive by the P-A test but negative by the MF method. Many of these differences for individual samples can be explained by random dispersion of bacteria in subsamples when the colifrom density is low. However, 15 samples had MF counts greater than 3 and gave negative P-A results. The only apparent explanation for most of these results is that coliform bacteria were present in the P-A test bottles but did not produce acid and gas. Two other studies have reported more samples positive by Clark's P-A test than by the MF method.

Popendorf W. Report On Agents. Am. J. Indust. Med., 10:0251-0259. 1986.

ABSTRACT: Recommendations were formulated on sampling strategies and characteristics of different sampling methods. Microbiological products, such as endotoxins and proteases were suggested to be included apart from traditional dust

measurements. It was recommended that priority should be given to establishing dose-response relationships and that the importance of anaerobic organisms be evaluated. A summary of components within organic dust suspected of contributing to respiratory disease was presented.

Popova I.A., Afonin B.V., Davydova N.A., Grigoriev A.I. Hormonal Regulation In Space Flights of Varying Duration . The Physiologist, 30/1 (Suppl):S0042-S0044. 1987.

ABSTRACT: In the course of adaptation to space flight effects and subsequent readaptation to Earth gravity regulatory systems, adevelop significant changes. This gives an impetus to the study of changes in hormonal regulation as a function of flight time. In this context the key problem, which is the subject of the present report, is the blood content of hormones and responses to them of target organs.

Putnam D.F., Thomas E.C., Colombo G.V. Water Management Results for the 90-Day Space Station Simulator Test. MDAC Paper WD 1582, 1971.

ABSTRACT: Water management subsystem data are presented for a four-man 90-day test conducted in the Space Station Simulator with closed water and oxygen loops and no resupply. All expendables including food, urine pretreatment chemicals, filter beds, and machinery spare parts were stored onboard and no pass-ins were made during the test. Elements of the subsystem were: (1) isotope-heated VD-VF unit; (2) wick evaporator and humidity control unit; (3) detoxification-multifiltration unit; (4) potable water storage and distribution system; (5) backup potable water supply; and (6) wash water recovery unit. The performance data include mass and energy balances, water chemistry, and microbiological profiles. Pretest qualification procedures are covered as well as operating protocol used during the manned test.

Pycraft C.H. The Pulping Of Straw By Enzymatic Degradation. Paper Tech. Ind., :0130-0135,0439. 1979.

ABSTRACT: In recent years, attention has been focused not only on re-cyclilng of waste paper but also on other indigenous sources of fibre. Studies have shown that cereal straw is the most promising such source and, supposing a system of collection can be contructed, the author considers an oblique approach to the still unsatisfactorily-solved question of how best to degrade the unwanted part of straw to retain suitable fiber. He proposed the use of enzymes-collectively cellulases-and explains how they act and considers the practicability of the idea.

Pyle B.H., McFeters G.A. Effect Of Growth Medium On Sensitivity Of Pseudomonads To Iodine And Their Recovery After Desinfection. 1987.

ABSTRACT: This study was initiated to examine the sensitivity of Pseudomonas spp. to iodine and their ability to recover after

disinfection. It has been shown that the degree of bacterial resistance to disinfection may be related in part to the conditions under which the organisms had been growing before disinfection. In this investigation we have examined the sensitivity of two Pseudomonas spp. to iodine after growth in rich nutrient media (brain heart infusion and mineral salts supplemented with glutamate and glucose) and low nutrient conditions (phosphate buffered water and reverse osmosis water). The ability of these species to recover after iodination was also examined because this may be a significant factor in the detection of pseudomonads after disinfection.

Raddin J.H. A Perspective On Human Performance As The Limiting Factor In Aircraft Performance. Aviat. Space Environ. Med., 58 :0393-0394. 1987.

ABSTRACT: The popular notion appears to be growing that the human is the limiting factor in aircraft performance. Proponents cite recent instances of pilot loss of consciousness during maneuvers. The aerospace medicine perspective differs, seeing the aircraft not as a vehicle in which to make hard turns, but as a mission-directed weapon system for which the pilot is the enabling factor. Various "human limition factors" are described among requirements staffs, developers, researchers, trainers, and operators. A plea is made to pursue available avenues to improve manned weapon system performance and to see even our most sophisticated weapons as human instruments.

Rao M.A., Mithal B.M., Thakur R.N., Sastry K.M. Productions Of Cellulase From Pestalotiopsis versicolor. Biotech. Bioeng., 25 :2395-2398. 1983.

ABSTRACT: Production of cellulase from Pestalotiopsis versicolor was studied in a shake flask culture. The cellulase system was found to be rich in B-glucosidase. Kinetic parameters such as pH and temperature have been optimized for the varioius enzyme components.

Ray R.J., Retzlaff S.E., Radke-Mitchell L., Newbold D.D., Price D.F. A Membrane-Based Subsystem for Very High Recoveries of Spacecraft Waste Waters. NASA Technical Memorandum 860984,:0645-0659. No Date.

ABSTRACT: This paper describes the continued development of a membrane-based subsystem designed to recover up to 99.5 % of the water from various spacecraft waste waters. Specifically discussed are 1) the design and fabrication of an energy-efficient reverse osmosis (RO) breadboard subsystem; 2) data showing the performance of this subsystem when operated on a synthetic wash-water solution--including the results of a 92 day test; and 3) the results of pasteurization studies, including the design and operation of an in-line pasteurizer. Also included in this paper is a discussion of the design and performance of a second RO stage. This second stage results in higher-purity product water at a minimal energy requirement and provides a substantial redundancy factor to this subsystem.

Raymond C.A. Unearthly Medicine Demands Special Devices. JAMA, 259/17:2514-2515. 1988.

ABSTRACT: The tools NASA is developing for the Health Maintenance Facility have some of the flavor of science fiction, because they will need to be adapted to the conditions of microgravity. The core diagnostic component of the facility will include capability to do a complete blood count, urinalysis, clinical chemistry and electrolyte measurements, basic microbilolgy, and diagnostic imaging.

Razin A., Razin S. Methylated Bases In Mycoplasmal DNA. Nucleic Acids Research, 8/6:1383-1390. 1980.

ABSTRACT: The DNAs of four Mycoplasma and one Acholeplasma species were found to contain methylated bases. All of the five species contained 6-methyladenine (m6Ade), the methylated base characteristic of prokaryotic DNA. The extent of methylation of adenine residues in the mycoplasmal DNA ranged from 0.2% in mycoplasma capricolum to about 2% in Mycoplasma arginini and Acholeplasma laidlowii DNAs. About 5.8% of the cytosine residues in M. hyorhinis DNA were methylated also. Analysis of cell culture DNA for the presence of m6Ade as a means for detection of contamination by mycoplasmas, and the phylogenetic implications of the finding of methylated bases in mycoplasmal DNAs are discussed.

Reanney D. Extrachromosomal Elements As Possible Agents Of Adaptation And Development. Bact. Reviews, :0552-0590. 1976.

ABSTRACT: None

Reysa R.P., Price D.F., Olcott T., Gaddis J.L. Hyperfiltration Wash Water Recovery Subsystem - Design And Test Results. SAE Technical Paper Series NO.831112,1983.

ABSTRACT: The hyperfiltration Wash Water Recovery Subsystem is considered the most promising water recovery process for the large quantities of wash water needed for a Space Station. A preprototype Hyperfiltration Subsystem has been developed by Lockheed Missiles and Space Corporation (LMSC) to satisfy projected wash water recovery requirements of 10.9 Kgms/hr (24 lbs/hr) utilizing a hyper filtration module consisting of cintered metal tubes having a polymeric filtration layer. Two hyperfiltration module designs, manufactured by Abcor, Inc. and Carre, Inc., are currently being evaluated at NASA JSC. This paper presents a description of the preprototype subsystem design and important design features, configuration, module test results comparisons and recommemdations for future development and testing.

Rickloff J.R. An Evaluation Of Sporicidal Activity Of Ozone. App. Env. Micro., 53/4:0683-0686. 1987.

ABSTRACT: This study was undertaken to determine the feasibility

of sterilizing surfaces with ozone-saturated water by the methods of the Association of Official Analytical Chemists (AOAC). Initially, it was determined that there was no apparent difference in ozone resistance between spores of Bacillus subtilis and Clostridium sporogenes when they are suspended in water. Both species were inactivated by a 10-min exposure at ambient temperature. Resistance was increased when the spores were dried on AOAC carriers. Viable organisms were recovered after an exposure of 40 min at ambient temperature. An increase in the reactor water temperature to 60 C did not improve the effectiveness of the ozone in sterilizing AOAC carriers. Dried spores of C. sporogenes were more resistant than B. subtilis spores because of a greater accumulation of organic matter on the carriers. No significant sporicidal activity was demonstrated after 40 min for spores of either species when they were inoculated on silk suture loops. The data suggest that organic loading and poor ozone penetrability are key factors in effecting the ability of ozone to sterilize surfaces rapidly.

Roberts K.P., August C.M., Nelson J.D. Relative Sensitivities Of Environmental Legionellae To Selective Isolation Procedures. App. Env. Micro., 53/12:2704-2707. 1987.

ABSTRACT: A survey of water samples to determine the efficacy of standard procedures for the isolation of environmental legionellae was conducted. Marked variations in intraspecies resistance to selective agents and treatments were observed, and in experiments with one of the isolates, the response was modified by culture conditions. Five selective prodedures incorporating acid (pH 2.2) and heat (50 C, 30 min) treatments, with and without plating on buffered charcoal-yeast extract agar supplemented with vacomycin (5 ug/ml), polymyxin B (60 U/ml), and cycloheximide (80 ug/ml), caused 5 to 99% decreased in viable counts of pure clutures in water suspensions. The differences in the responses of the cultures to the five treatments were statistically significant. Cells in retained samples of naturally contaminated water from which the original cultures had been isolated were significantly less sensitive than artifically grown isolates. The sensitivities of the laboratory-grown cells to the treatments were affected by the length of incubation of buffered charcoal-yeast extract agar. Whereas acid resistance increased after 24 h of incubation, resistance to the antiboitic mixture decreased.

Robins J. Measuring Esposures and Assessing Health Effects. Environmental Tobacco Smoke, Committee on Passive Smoking Board on Environmental Studies and Toxicology National Research Council,:294-337. 1986.

ABSTRACT: This appendix gives an approach to risk assessment that considers both the epidemiologic data and some measures of exposure to the constituents of ETS.

Roser D.J., Bavor H.J., McKersie S.A. Application Of Most-Probable Number Statistics To Direct Enumeration Of Microorganisms. App. Env. Micro., 53/6:1327-1332. 1987.

ABSTRACT: A novel method for rapid determination of total microbial cell numbers was investigated. The method involves the application of most-probable-number estimation statistics to direct microscopic counting of microbial cells by using a particle sizing graticule. Its accuracy and reliability were tested with computer simulations of bacterial cell distributions encountered in ecological studies. Good estimates of cell numbers were obtained when the cell density varied from 3-6000 cells per field, i.e., over 3 orders of magnitude. Low levels of contagion did not markedly influence cell estimates, althouhg high levels, corresponding to discrete scattered microcolonies, did. However, these could be recognized visually. Estimates of cell numbers in Breed smears confirmed its speed and good correlationo with the standard quadrat counting technique under real experimental conditions.

Ross H.E., Schwartz E., Emmerson P. Mass Discrimination In Weightlessness Improves With Arm Movements of Higher Acceleration. Naturwissenschaften, 73:0453-0454. 1986.

ABSTRACT: None

Ross M.D. Anatomic Evidence For Peripheral Neural Processing In Mammalian Graviceptors. Aviat. Space Environ. Med., 56 :0338-0343. 1985.

ABSTRACT: Ultrastructural study of utricular and saccular maculas demonstrates that their innervation patterns are complex. There is a clustering of type 1 and type 2 hair cells based upon a sharing of afferents, a system of efferent-type beaded fibers that is of intramacular (mostly calyceal) origin, and a plexus-like arrangement of afferents and efferents at many sites in the neuroepithelium. Results suggest that information concerning linear acceleration is processed peripherally, beginning at the hair cell level, before being sent to the central nervous system. The findings may supply a structural basis for peripheral adaptation to a constant stimulus, and for lateral inhibition to improve signal relative to noise.

Russo, D. M. Behavioral Technology and its Application to Fire Toxicology Research. Southwest Foundation for Research and Education, San Antonio, Texas 78284, N79-12037,:0160-0179. .

ABSTRACT: The application of behavioral technology to the toxicity testing of pyrolysis/combustion (P/C) products is discusseed and two categories of behavioral tests commonly employed in fire toxicology programs are reviewed. Data are presented from a comparison of carbon monoxide (CO) induced incapacitation in rats performing in a rotating wheel or under a Sidmon free-operant schedule of shock avoidance. Rats performing in the rotating wheel were behaviorally incapacitated at CO concentrations and carboxyhemoglobin levels significantly lower than those which incapacitated operant avoidance animals. It is concluded that different measures of behavioral incapacitation may vary since incapacitation is a function of the particular

toxic mechanism at work and the behavioral requirements of the specific task employed in the test procedure.

Russo, D. M., Kaplan H. L. Effects of-Carbon Monoxide on Two Behavioral Measures in the Rat. Proc. West. Pharmacol. Soc., 21 :0419-0425. 1978.

ABSTRACT: During the past decade numerous behavioral end points have been used in toxicological evaluations of thermal decomposition products. However, little research has been conducted which allows a comparison of these different end points. Such comparisons should provide useful information about the susceptibility of different behaviors to toxic incapacitation, supply further knowledge about specific mechanisms of incapacitation, and ultimately provide a guideline by which appropriate behavioral end points may be chosen. The following two experiments were part of a preliminary assessment of the applicability of two different behavioral methodologies to the toxicological evaluation of pyrolysis and combustion products. The purpose of the experiments was to compare the course of changes in two behaviors in animals exposed to increasing concentrations of carbon monoxide (CO). Specifically, the experiments were designed to compare CO induced incapacitation of simple motor behavior in a rotating wheel with CO induced changes in a more complex operant avoidance behavior.

Russo, D. M., Sgro, P., Schneider, H. J. Effects of Polyurethane and Polyimide Thermal Decomposition Products on Shock Escape and Avoidance Behavior. Neurobehavioral Tox. Teratology, 3 :0265-0270. 1981.

ABSTRACT: Thirty-six male Sprague-Dawley rats were exposed for 15 minutes to the decomposition products of either a polyurethane or polyimide foam while performing an unsignalled shock escape-avoidance task. These products were generated by placing 1g samples of the foams on a conductive plate heated to either 435, 605, or 775 degrees Celcius. The decomposition products and behavioral toxicity of the 2 foams varied differentially with test temperature. At the 2 lower temperatures, the decomposition products of polyurethane proved to be more behaviorally disruptive than those of polyimide, while at 775 degrees Celcius the reverse was true. These results indicate that operant behavior technology brings a sensitivity to material testing which may prove quite useful for future assessments of potential behavioral toxicity.

Ryu D.Y., Kim C., Mandels M. Competitive adsorption of cellulase Components And Its Significance In A Synergistic Mechanism. Biotech. Bioeng., XXVI:0488-0496. 1984.

ABSTRACT: Some studies on the adsorption of cellulase on cellulose revealed part of the mechanisms involved in the enzymatic hydrolysis of cellulose and provided some clues to the synergistic mechanism of cellulase complex. The adsorption of cellulase was significantly affected by the reaction conditions and physical chemical characteristics of cellulose.

Endoglucanase consisted of adsorbable and nonadsorbable components. Cellobiohydrolase had the strongest adsorption affinity. Each cellulase component is postulated to have distinctly different adsprption sites on cellulose, corresponding to the activesites in the hydrolysis reaction, Competitive adsorption kinetics between cellulase componets were also observed during the adsorption process. The degree of competitive adsorption was most remarkable when the composition of cellulase components was nearly the same as that in the crude cellulase complex. This seems to show the optimal relative composition of cellulase components. The synergism between cellobiohydrolase and endoglucananse could be elucidated more clearly by this competitive adsorption model of the reaction mechanism.

Saeman J.F. Key Factors In The Hydrolysis Of Cellulose . Biomass As A Nonfossil Fuel Source, Chapter 9,:0186-0197. 1981.

ABSTRACT: None

Safarik J., Rogers D.M., Ridgway H.F. Effects Of Biocidal Agents Of Bacterial Adhesion To Reverse Osmosis Membranes. .

ABSTRACT: The flux and mineral rejection of reverse osmosis (RO) membranes are advesely affected by microbial surface fouling. Because fouling translates into increased operation costs, the Orange County Water District is conducting studies on the mechanism of biofouling in RO systems. Our experiments have focused on the use of chemical biocides to reduce biofilm formation. The effects of biocidal agents were quantified by measuring attachment of radiolabeled fouling microorganisms (Mycobacteria BT2-4) to RO membrane surfaces in response to biocide treatment. A variety of biocides including quaternary ammonium compounds and chlorine were tested. The effects of compounds on adhesion depended on their chemical structures and concentrations, as well as on the bacterial type and polymer structure of the RO membrane. Results will be used to formulate more effective membrane cleaners of inhibitors of biofilm development.

Sagan L. On The Origin Of Mitosing Cells. J. Theoret. Biol., 14 :0225-0274. 1967.

ABSTRACT: A theory of the origin of eukaryotic cells ("higher" cells which divide by classical mitosis) is presented. By hypothesis, three fundamental organelles: the mitochondria, the photosynthetic plastids and the (9+2) basal bodies of flagella were themselves once free-living (prokaryotic) cells. The evolution of photosynthesis under the anaerobic conditions of the early atmosphere to form anaerobic bacteria, photosynthetic bacteria and eventually blue-green algae (and protoplastids) is described. The subsequent evolution of aerobic metabolism in prokaryotes to form aerobic bacteria (protoflagella and photomitochondria) presumably occurred during the transition to the oxidizing atmosphere. Classical mitosis evolved in protozoan-type cells millions of years after the evolution of

photosysnthesis. A plausible scheme for the origin of classical mitosis in primitive amoeboflagellets is presented. During the course of the evolution of mitosis, photosynthetic plastids (themselves derived from prokaryotes) were symbiotically acquired by some of these protozoans to form the eukaryotic algae and the green plants. The cytoligical, biochemical and paleontological evidence for this theory is presented, along with suggestions for further possible experimental verification. The implications of this scheme for the systematics of the lower organisms is discussed.

Sandler H., Krotov V.P., Hines J., Magadev V.S., Benjamin B.A., Badekeva A.M., Halpryn B.M., STone H.L., Krilov V.S. Cardiovascular Results From A Rhesus Monkey Flown Aboard the Cosmos 1514 Spaceflight. Aviat. Space Environ. Med., 58 :0529-0536. 1987.

ABSTRACT: Pressure and flow relationships to the head were measured before and during space flight by means of a chronically implanted cuff placed about the left common carotid artery in one of two rhesus monkeys flown aboard cosmos 1514. Measurements were obtained daily for 4 min every 2 h during the 5-d spaceflight and compared to identical recordings obtained during a 35 h pre-flight control period 9-d before flight and a 12 h period while on the launch pad. Mean arterial pressure demonstrated a 10% increase compared to control levels immediately on insertion into orbit and maintained a 16-27% increase over the first few fours of flight before returning to baseline levels. Blood flow velocity showed a marked increase (approximately 8 cm/s) compared to pre-flight control while on the launch pad which was maintained over the duration of the flight. Blood flow showed reciprocal changes to pressure on orbital insertion. Cardiovascualr system changes persisted into the second day of flight and were most cleasrly indicated by a decrease in relative differences between blood flow to the head and total cardiac output as measured by impedance plethysmography. Signs of adaptation appeared on days 3-5 of flight.

Sartor G., Schersten B., Carlstrom S., Melander A., Norden A., Persson G. Ten-Year Follow-Up Of Subjects With Impaired Glucose Tolerance Prevention Of Diabetes By Tolbutamide And Diet Regulation. Diabetes, 29:41-49. 1980.

ABSTRACT: In a diabetes detection survey carried out between 1962 and 1965, 2477 (1.1%) of 228,883 subjects had Clinistix-positive glucosuria after a carbohydrate-rich luncheon meal. Of these 2477, 578 displayed impaired tolerance to oral glucose without having manifest diabetes. From this group, 267 men were divided into five groups and subjected to the following treatments and controls: (a) diet regulation and 0.5 g tolbutamide t.i.d. (N=49), annual oral glucose tolerance test (OGTT); (b) diet regulation and one placebo tablet t.i.d. (N=48), anuual OGTT; (c) diet regulation only (N=50), annual OGTT; (d) no treatment (N=61), annual OGTT; and (e) no treatment, OGTT at follow-up (N=59 at follow-up). In addition, a control group was included

comprised of men with normal OGTT (N=52). At follow-up, 29% of these without diet regulation and medication (group e; N=59) had developed diabetes. Of those on diet regulation, but without active medication (group b plus group c, N=98), 13% had diabetes. No individual maintaining tolbutamide and diet regulation (N=23) had progressed to diabetes. In this group, 80% of those later examined (N=11) had serum tolbutamide concentrations in the therapeutic range. No individual with initially normal OGTT developed diabetes or impaired OGTT. The findings suggest that normal oral glucose tolerance signifies little risk of progress to impaired glucose tolerance and manifest diabetes, whereas impaired glucose tolerance is associated with a high risk of progression to diabetes. In addition, it seems possible that treatment with diet regulation, in combination with tolbuamide, may prevent or postpone progression from impaired glucose tolerance to manifest diabetes.

Sasaki M., Kurosaki Y., Mori A., Endo S. Patterns Of Sleep-Wakefulness Before And After Transmeridian Flight In Commercial Airline Pilots. Aviat. Space Environ. Med., 57 (12 Suppl.):B0029-B0042. 1986.

ABSTRACT: The study investigated changes in sleep-wake rhythms due to time zone changes. The subjects were 12 commercial airline cockpit crewmembers on active duty who spents their baseline nights in a sleep facility in Tokyo. After flying from Tokyo to San Francisco, they underwent two consecutive nights of sleep polysomnography and daytime sleep latency tests (MSLTl). During the San Francisco layover, slight changes in sleep quality were obsrved. REM sleep (%) was decreased, while slow wave sleep (%) tended to increase during the major sleeps. Subjective sleep quality assessments also exhibited a decrease in comparison to the baseline values. Daytime sleepiness as measured by MSLTs was generally greater in the latter half of the awake period during layover as compared with baseline. When the subjects were divided into "morning" or "evening" types, the daytime MSLTs of each type showed different patterns. The former displayed a decreasing L-shaped pattern. These results suggest that further investigation of the individual differences in circadian phase position may be important for understanding the effects of multiple time zone flights.

Sato M., Takahashi H. Fermentation Of C14-Labeled Cellobiose By Cellulomonas fimi. Agr. Biol. Chem., 31/4:0470-0474. 1967.

ABSTRACT: Crude cell-free extracts from Cellulomonas fimi contains cellobiose phosphorylase which cleaves cellobiose into glucose and glucose-1-phosphate in the presence of inorganic phosphate. With the aid of this enzyme, two samples of C14-cellobiose labeled in reducing or non-reducing glucosyl moiety were prepared from uniformly labeled C14-glucose or C14 glucose-1-phosphate as substrate, respectively. The labeled preparations have been shown to be radiochemically pure. Analyses of the anaerobic fermentation products from C14-cellobiose by resting cell suspensions showed that both glucose moieties were fermented almost equivalently. However,

relatively small difference in specific activities of the products revealed that significantly larger amounts of formic acid were produced form the reducing glucose moiety than from the other half of the molecule. Succinic and lactic acids appeared to be produced almost equally from both mpieties.

Sawada Y., Fujii R., Igami I., Kawai A., Kamiki T., Niwa M. Removal Of Endotoxin From Water By Microfiltration Through A Microporous Polyethylene Hollow-Fiber Membrane. App. Env. Micro., 51/4 :0813-0820. 1986.

ABSTRACT: The microporous polyethylene hollow-fiber membrane has a unique microfibrile structure throughout its depth and has been found to possess the functions of filtration and adsorption of endotoxin in water. The menbrane has a maximum pore diameter of approximately 0.04 um, a diameter which is within the range of microfiltration. Approximately 10 and 20% of the endotoxin in tap water and subterranean water, respectively, polyethylene hollow-fiber membrane. Escherichia coli 0113 culture broth contained 26.4 % of endotoxin smaller than 0.025 um which was also removed. Endotoxin was leaked into the filtrate only when endotoxin samples were successively passed through the membrane. These results indicate that endotoxin smaller than the pore size of the membrane was adsorbed and then leaded into the filtrate because of a reduction in binding sites. Dissociation of 3H-labeles endotoxin from the membrane was performed, resulting inthe removal of endotoxin associated with the membrane by alcoholic alkali at 78% efficiency.

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ABSTRACT: Rhodospirillum rubrum and Rhodopseudomonas capsulata were able to grow anaerobically in the dark either by a strict mixed-acid fermentation of sugars or, in the presence of an appropriate electron acceptor, by an energy-linked anaerobic respiration. Both species fermented fructose without the addition of accessory oxidants, but required the initial presence of bicarbonate before fermentative growth could begin. Major products of R. rubrum fermentation were succinate, acetate, propionate, formate, hydrogen, and carbon dioxide; R. capsulata produce major amounts of lactate, acetate, succinate, hydrogen, and carbon dioxide. R. rubrum and R. capsulata were also capable of growing strictly through anaerobic, respiratory mechanisms. Nonfermentable substrates, such as succinate, malate, or acetate, supported growth only in the presence of an electron acceptor such as dimethyl sulfoxide or trimethlamine oxide. Carbon dioxide and dimethyl sulfide were produced during growth of R. rubrum and R. capsulata on succinate plus dimethyl sulfoxide. Molar growth yields from cultures grown anaerobically in the dark on fructose plus dimethyl sulfoxide were 3.8 to 4.6 times higher than values obtained from growth on fructose alone and were 56 to 60% of the values obtained from aerobic, respiratory growth with fructose. Likewise, molar growth yields from anaerobic, respiratory growth conditions with succinate plus dimethyl sulfoxide were 51 to 54% of the valuse obtained from aerobic, respiratory growth with succinate. The data indicate that dimethyl sulfoxide or trimethylamine oxide as a terminal oxidant is approximately 33 to 41 % as efficient as oxygen in conserving energy through electron transport-linked respiration.

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ABSTRACT: The proposed revisions to the total coliform regulations under the National Primary Drinking Water Regulations may specify that a heterotrophic bacteria count must be taken and that the bacterial density must be below a specified value to avoid interference with the total coliform test. The Standard Plate count (PCA or TGE pour plate), has been used for years as a

useful procedure for determining the heterotrophic bacterial density of potable waters and for quality control studies of water treatment processes. It also has been used for monitoring changes in the bacteriological quality of finished water throughout a distribution system.(1) Standard Methods (16 ed. 2) states the problems in using the Standard Plate Count. All viable bacteria present in a water sample cannot be recovered with any single procedure growth medium, or set of physical conditions. Three Alternative methods and two new media are presented in Standard Methods (2) to improve recovery of heterotrophic bacteria. The purpose of this evaluation was to compare the heterotrophic bacteria recoveries using these new media and methods with recoveries obtained using the previously accepted method in order to assess heterotrophic bacteria levels in various drinking water samples.

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flavefaciens, Bactercides succinogenes, Butyrivibrio fibrisolvens, Clostridium lochheadii, CI. longisporum and other Closiridium spp. Cellulolytic cocci were present in smaller numbers than rod forms in the rumen of wheat-straw-fed buffaloes, whereas the cocci outnumbered rod forms in sorghum and berseem-fed buffaloes.

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ABSTRACT: An endo-B-1,4-GLUCANASE (EC 3.2.1.4) was obtained in high yields in purified form from a culture filtrate of Fisarium lini by an extremely simple method. The method consists of precipitation of the culture filtrate with ammonium sulphate (290 g/L), followed by chromatography of the precipitated fraction on Biogel P-150. The purification is based on the unusual property of the enzyme being eluted after cytochrome C, even though its molecular weight is 2.8 X 10 (4) (by SDS PAGE). The yield of pure enzyme was 6.8 mg/L culture broth. The homogeneity of the enzyme was established by ultracentrifugation, isoelectric focusing, and electrophoresis in polyacrylamide gels containing SDS. The enzyme was isoelectric at PH 8.3 and contained 2.9% carbohydrate. The Km value for carboxymethyl (CM) cellulose was 11.6 mg/mL. The enzyme Showed high viscosity reducing activity towards CM cellulose but very low activity with Walseth cellulose and crystalline celluloses such as Avicel and cotton. The purified enzyme has activity towards xylan. The amino acid analysis showed a predominance of acidic and neutral amino acids and low contents of histidine, arginine, and methionine. One-half of the cysteine content was 1 residues/mol enzyme, and no free-SH group was detectable.

Verostko C.E., Garcia R., Peirson D.L., Reysa R.P., Irbe R. Results On Reuse Of Reclaimed Shower Water. NASA TM 860983 ,.

ABSTRACT: A microgravity whole body shower (WBS) and a waste water recovery system (WWRS) were used in a closed loop test at the Johnson Space Center. The WWRS process involved chemical pretreatment, phase change distillation and post-treatment. A preprototype Thermoelectric Intergrated Hollow Fiber Membrane Evaporation Subsystem (TIMES) was used for distillation after

pretreatment and the post-treatment was accomplished with activated carabon, mixed ion exchange resin beds and bactericide dispensing units. The purposes of this test were to evaluate a NASA approved Shuttle soap for whole body showering comfort; evaluate the effects of the shower water on the WBS and the TIMES; and evaluate purification qualities of the recovered water in a closed loop operation. This paper describes the test hardware, the controls exercised for whole body showering, shower water collection and chemical pretreatment for microorganism control, TIMES operation and recovered water post-treatment. During the closed loop test, samples were taken to evaluate the water quality for both chemical and microbial impurities at selected locations in the water purification process. The water was recycled five times, thus demonstrating the feasibility of reusing reclaimed shower water in Space Station. Chemical pretreatment effectively controlled microorganism growth in the raw shower water and the TIMES with post-treatment effectively reduced the organic impurities and provided adequate and positive disinfectant.

Verostko C.E., Price D.F., Garcia R., Pierson D.L., Sauer R. L., Reysa R.P. Test Results of a Shower Water Recovery System. SAE Technical Paper #871512,1987.

ABSTRACT: A shower test was conducted recently at NASA-JSC in which waste water was reclaimed and reused. Test subjects showered in a prototype whole body shower following a protocol similar to that anticipated for Space Station. The waste water was purified using reverse osmosis followed by filtration through activated carbon and ion exchange resin beds. The reclaimed waste water was maintained free of microorganisms by using both heat and iodine. This paper discusses the test results, including the limited effectiveness of using iodine as a disinfectant and the evaluation of a Space Station candidate soap for showering. In addition, results are presented on chemical and microbial impurity content of water samples obtained from various locations in the water recovery process.

Vico L., Chappard D., Bakulin A.V., Novikov V.E., Alexandre C. Effects of 7 Day Space Flight on Weight Bearing And Nonweight Bearing Bones In Rats (Cosmos 1667). The Physiologist, 30/1 (Suppl):S0045-S0046. 1987.

ABSTRACT: Previous 3-week COSMOS spaceflights indicated a significant reduction of bone mass in weight- and non-weight-bearing bones probably due to a decrease in bone formation activity. On COSMOS 1667, 7 flight and 7 control male rats were studied by bone histomorphometric methods. 1) Weight-bearing bones: in proximal tibial metaphysis, the trabecular bone volume was markedly declined in flight animals. Trabeculae were decreased in number and thickness; this probably leads to an alteration of bone mechanical properties. Formation activity (reflected by osteoid seam thickness and osteoid surface measurements) was decreased at the trabecular and endosteal levels. Resorption activity (osteoclast number and active resorption surfaces measured by a histoenzumologic method)

remained unchanged. The imbalance that appeared to occur between these cellular activities may be responsible for the loss of trabecular bone mass. In proximal femoral metaphysis, trabecular bone volume was measured in area located under muscular insertions. Deleterious effects of weightlessness were not observed. Therefore, muscular tractory may have a protective effect on weight-bearing bones. 2) Non-weight-bearing bones: in thoracic and lumbar vertebrae, no change was found neither in bone mass nor in bone cellular parameters. The short flight appeared to confirm that non-weight-bearing bones are not as much at risk as weight-bearing bones during spaceflight. Futhermore, marked differences observed between areas with and without muscular insertions, emphasize the most important role of mechanical factors in trabecular bone mass preservation.

Vico L., Chappark D., Alexandre C., Palle S., Minaire P., Riffat G., Novikov V.E., Bakulin A.V. . Effects of Weightlessness on Bone Mass and Osteoclast Number In Pregnant Rats After A Five-Day Spaceflight (Cosmos 1514). Bone, 8:0095-0103. 1987.

ABSTRACT: Five pregnant growing rats were orbited for 5 days aboard the Soviet COSMOS 1514 biologic satellite. The bone effects of weightlessness were studied and compared to those of five pregnant rats. Bone histomorphometric studies were performed to investigate the early effects of weightlessness in loaded (tibia-femur) and unloaded (thoracic and lumbar vertebrae) bones. A short exposure to weightlessness does not induce any change in bone mass and inner structure in either type of bone. In unloaded bones, the number of osteoclasts per square millimeter of the trabecular surface significantly increased when measured after histochemical demonstration of tartrate-resistant acid phosphatase. It is likely that a stimulation of bone resorption activity occurs in the trabeculae of unloaded bones during the early phase of a spaceflight. In tibia, osteoid seam thickness and total osteoclastic resorption surfaces at the endosteal level were not modified.

Voge V.M. A Comparison of U.S. Air Force And U.S. Navy Flight Surgeon Philosophies. Military Medicine, 150:0542-0545. 1985.

ABSTRACT: The author compares the Flight Surgeon utilization/training philosophies of the U.S. Air Force and the U.S. Navy. These two programs are compared as to general philosophies, basic and advanced training programs, continuing medical education opportunities, career opportunities, peer prestige, practice modalities, retention rates, and special aircrew member evaluations/follow-up. Some proposals for improving the programs are put forth. It is concluded that, in many ways, the aviation medicine problems faced by the USAF and the USN Flight Surgeons are quite similar. However, their programs, philsophies and aeromedical policies are seen to be quite divergent. Each service could learn from the other.

Vogel J.M., Whittle M.W. Bone Mineral Changes: The Second Manned Skylab Mission. Aviat. Space Environ. Med., 47/4:0396-0400. 1976.

ABSTRACT: The mineral content of the central os calcis, and distal radius and ulna was measured by the monenergetic photon absorptiometric technique pre- and postflight on the SL-3 crewmen. No significant changes were observed in the radius and ulna. Only the SPT showed a loss in calcaneal mineral which slowly returned to preflight levels by the 87th postflight day.

Volkmann D., Behrens H.M., Junk P. Flight Hardware For Chemical Fixation Of Living Material In The Microgravity Environment . Naturwissenschaften , 73:0435-0437. 1986.

ABSTRACT: None

Walch M., Mitchell R. Hydrogen Uptake By Metals In The Presence Of Bacterail Films. Sixth International Biodeterioration Symposium, 1984.

ABSTRACT: None

Wald S., Wilke C.R., Blanch H.W. Kinetics Of The Enzymatic Hydrolysis Of Cellulose. Biotech. Bioeng., 26:0221-0230. 1984.

ABSTRACT: Enzymatic hydrolysis of cellulose for sugar production offers advantages of higher conversion, minimal by-product formation, low energy requirements, and mild operating conditions over other chemical conversions. The development of a kinetic model, based on observable, macroscopic properties of the overall system, is helpful in design and economic evaluation of processes for sugar conversion and ethanol production. A kinetic model is presented, incorporating enzyme adsorption, product inihibition, and considers a multiple enzyme and substrate system. This model was capable of simulation saccharification of a lignocellulosic material, rice straw, at high substrate (up to 333 g/L) and enzyme concertrations (up to 9.2 FPU/mL) that are common to proposed process designs.

Waldron C.R., Frein E.M., Eveleith D.E. Prevention of Phosphate Interference in HPLC Sugar Analysis Studies. Biotech. Bioeng., 25:2091-2092. 1983.

ABSTRACT: The use of high performance liquid chromatography (HPLC) is a common tool for the separation and quantitation of saccharification products in cellulase research. Many of the columns used both commercial and homemade, employ the cation exchange resin Dowex(Aminex)50WX4. A problem with this procedure is the interference to the response of the refactometer by certain ions (e.g. phosphate and citrate). These inons are present in culture media and hence in crude extracellular enzyme preparations. Their removal via dialysis poses the question of the degree of loss of the cellulase enzyme via adsodrption to the dialysis membrane. These ions may also be used in the saccharification buffers and can produce peak responses with similar retention times to the sugars being analyzed. Phosphate ion produces a peak with approximately the same retention time as cellobiose when the 50W-X4 resin is used in its Ca2+,Pb2+, or H+

forms. Depending on the concentration of both the phosphate ion and the disaccharide, there can be interference with or even total obliteration of the cellobiose peak. This interference can be eliminated by precipitation of the phosphate by the addition of heavy metals.

Walia S.K., Carey V.C., All B.P., Ingram L.O. Self-Transmissible Plasmid In Zymomonas mobilis Carrying Antibiotic Resistance. App. Env. Micro., 47/1:0198-0200. 1984.

ABSTRACT: The cryptic plasmid pRUT41 from Zymomonas mobilis was examined for its biological properties. This plasmid was found to be conjugally transferred from Z. mobilis CP4 toE. coli BM21 and to carry genes for antibiotic resistance (gentamicin, kanamycin, and streptomycin). Covalently closed circular plasmid DNA was isolated from eight transconjugants of E. coli BM21. These plasmids were identical in mobility on agarose gels and exhibited the same restriction patterns as the native pRUT41 plasmid isolated from Z. mobilis. The plasmid location of the antibiotic resistance genes was further confirmed by transforming E. coli BM21 with isolated pRUT41 plasmid from strain CP4 and with plasmids from the transconjugants of BM21. Resistance to streptomycin, kanamycin, and gentamicin was tightly linked and transferred together in all cases.

Wallis C., Melnick J.L. An Instrument For The Immediate Quantification Of Bacteria In Potable Waters. .

ABSTRACT: A new semi-automated instrument is described which quantifies the number of bacteria in potable waters within 3 minutes, providing a permanent colorimetric record of the results. The bacterial-detection device can measure as few as 100 CFU/ml in potable waters. In brief, a 100-1000 ml sample of tap water is drawn thru a large surface, customized filter housed in the device, and bacteria, rust and humic acid in the water are concentrated there on. A reducing agent is used to remove the rust and humic acid from the filter. The filter is inverted and backflushed to elute the bacteria which are collected and reconcentrated onto a 7 mm diameter filter surface. The reconcetrated bacteria are stained, and the fiter fibers are preferentially decolorized without removing the dye from the bacteria. The color intensity of the filter surface is compared to a color guide to determine the amount of bacteria in the test water.

Wang D.C., Cooney C.L., Wang S.D., Gordon J., Wang G.Y.,. Anaerobic Biomass Degradation to Produce Sugars, Fuels and Chemicals. Department of Nutrition and Fooc Scinece, Massachusetts Institute of Technology, Cambridge, MA 02139,1978.

ABSTRACT: The degradation of cellulosic biomass by an anaerobic and thermophillic bacterium, Clostridium thermocellum, has been under investigation. It has been found that this organism is able to degrade cellulose and accumulate reducing sugars in the fermentation broth. The degradation of cellulose and the utilization of the sugars has been tested in mixed-cultures where

the second organism is used to produce acetic acid. The direct production of a chemical (acetic acid) and a liquid fuel (ethanol) from cellulosic biomass-by a pure culture of C. thermocellum also appears possible. Although the conversion efficiency is quite good, the product concentration must be increased. A selection and adaptation technique has been used where a strain capable of tolerating 5 volume % ethanol has been isolated.

Warzywoda M., Ferre V., Pourquie J. Development Of A Culture Medium For Large-Scale Production Of Cellulolytic Enzymes By Trichoderma reesei. Biotech. Bioeng., 25:3005-300. 1983.

ABSTRACT: Culture filtrates of CL-847 strain of Trichoderma reesei grown on different carbon sources have been compared. The highest enzyme production is obtained with Watman CC 41 cellulose: 17.9 mg/mL of soluble proteins and 13.7 units fo filter paper (FP) activity. Wood pulps gave lower production values and more viscous culture media. About one-third of maximal enzyme production is obtained on lactose as the sole carbon source. Addition of 0.5% cellulosic inducer to 6% lactose media enhances enzyme production up to the following levels: 14.1 mg/mL of soluble proteins and 8.4 units of FP activity.

Waterfield M.D., Scrace D.T., Whittle N., Stroobant P., Johnsson A., Wasteson A., Westermark B., Heldin C.H., Huang J.F., Deuel T.F. Platelet-Derived Growth Factor Is Structurally Related To The Putative Transforming Protein P28 Of Simian Sarcoma Virus. Nature, 304/7:0035-0037. 1983.

ABSTRACT: A partial amino acid sequence of human platelet-derived growth factor, the major mitogen in serum for cells of mesenchymal origin has been determined. A region of 104 contiguous amino acids shows virtual identity with the predicted sequence of p28 sis, the putative transorming protein of simian sarcoma virus (SSV). This similarity suggests a mechanism for transformation by SSV and other agents, involving expressing of growth factors.

Watson R.D. Prevention Of Dust Exposure. Am. J. Indust. Med., 10 :0229-0243. 1986.

ABSTRACT: Dust exposure on farms can be prevented by changes in work practices and by informing and educating farmers. Ventilation control during handling and prevention of growth of microbes are feasible measures and could be included in regulation schemes. Apart from information on existing work practices, an increased awareness of new technology is necessary.

Wegmann H.M., Gundel A., Naumann M., Samel A., Schwartz E., Vejvoda M. Sleep, Sleepiness, And Circadian Rhythmicity In Aircrews Operating On Transatlantic Routes. Aviat. Space Environ. Med., 57 (12 Suppl.):B0053-B0064. 1986.

ABSTRACT: This study was performed on B-747 aircrews operation on

regular passenger flights between Frankfurt and the U.S. west coast (9 h time difference). In an initial phase, sleep behavior was surveyed by daily logs in 38 erewmembers. The results for the layover period indicate congruent sleep patterns with shifts in sleep onset distinctly less than 9 h. In comparison with preflight control data, sleep duration was significantly prolonged and, on average, no sleep deficits were experienced before commencing the return flight. The main part of the study consisted of polygraphic sleep recordings and multiple sleep latency tests (MSLT) applied to four complete cockpit crews (12 members total) in a baseline period, during layover, and after return to homebase. In addition, body temperature and ECG were continuously recorded. during layover, mean bed times were shifted by 4.5 h at maximum. Sleep was disturbed by early and prolonged avakenings which led to a reduction of sleep efficiency. In contrast, no sleep deficits nor increases in daytime sleepiness occurred. Night duty associated with the return flight caused sleep deprivaton which conversely resulted in good sleep during the first night back in Germany. However, during the second night after return, impaired sleep was observed, at least in part caused by the rhythm disturbances. As predicted by our resynchronization model, ECG and rectal temperature recordings gave evidence for a desynchronization of the circadian system and an internal dissociation of different body functions.

Whinnery J.E., Burton R.R. +Gz-Induced Loss Of Consciousness: A Case For Training Exposure To Unconsciousness. Aviat. Space Environ. Med., 58:0468-0472. 1987.

ABSTRACT: +Gz-induced loss of consciousness (G-LOC) continues to be a threat to aircrew flying high-performance fighter aircraft. All avenues to prevent G-LOC, and to reduce the resulting incapacitation should G-LOC occur, must be explored. Research has begun to accurately quantify all aspects of the G-LOC phenomenom. The emerging pattern from this research indicates that, theoretically, G-LOC incapacitation could be significantly reduce. Comparison of G-LOC with LOC induced by acute arrest of cerebral circulation reveals that the G-LOC incapacitation could be reduced by as much as 17 s. Results also indicate that the relative incapacitation period (confusion and disorientation) following unconsciousness could be reduced by at least 9 s for an individual who has previously experienced G-LOC. This suggests that exposure to G-LOC during centrifuge training could provide this orientatione to G-LOC and potentially reduce the incapacitiation period should it occur inflight. This expposure may be likened to the current altitude-hyposia training requirement for aircrew. Experience to date supports the contention that such training may be accomplished with an acceptable safety margin.

Whinnery J.E., Glaister D.H., Burton R.R. +Gz-Induced Loss Of Consciousness And Aircraft Recovery. Aviat. Space Environ. Med., 58:0600-0603. 1987.

ABSTRACT: Aircrew incapacitation resulting from very high onset

sustained +Gz stress has resulted in significant losses of aircraft and aircrew. Enhanced protection and training toward prevention of +Gz-induced loss of consciousness (G-LOC) will continue to be vital. Techniques for reduction of the time of incapacitation, should G-LOC occur, must also be explored and developed. Current capabiltiy of aircraft autorecover as demonstrated by the Advanced Fighter Technology Intergration F-16 (AFTI/F-16) promises to enhance safety from the acute incapacitation resulting form G-LOC (and spatial disorientation). Physiologic monitoring for determining G-LOC has certain advantages especially in the aerial combat arena. The optimum physiologic monitoring technique would be direct determination of failure of brain cell function at the cellular of subcellular level. Complete investigation of G-LOC is necessary to understand the phenomenon and to develop methods for physiologic monitoring of G-LOC. Intergration of physiologic monitoring techniques into aircraft autorecovery systems requires a broad approach for optimal development.

White S.C. The Aerospace Medical Research Laboratory: A Leader In The Development Of Life Support. Aviat. Space Environ. Med., 57 (10 Suppl):A0044-A0048. 1986.

ABSTRACT: The progress in the development of life support for the crewman parallels the changing flight envelope of the airplane and spacecraft. A constant in this history is man. In spite of elaborate attempts to refine the selection of the crew, the basic lists of requirements has not changed. Only the urgency and the need for providing the entire list of requirements have been seen. Generally, progress in the flight envelope has demanded more reliable and often more complex provisions to support the crew. The debate as to how this should be done has often centered on the argument about having man wear or carry the life support elements versus integration of these provisions into the vehicle. This debate initiated the concept of risks/benefits, a debate that has now reached all aspects of man's endeavors, including his medical care. This paper will disuss the major milestones of providing life support, some of the key contributors (a role that General Armstrong played in a great way), and how this has provided the base for the next steps in aviation and space operations.

Whitley K.M., McGriff C.F. Test Plan For VCD Subsystem Checkout And Performance Testing. No Date.

ABSTRACT: None

Willis C.E., Schultz J.R. Spacecraft Water System Disinfection Technology: Past, Present, and Future Needs. SAE Technical Paper Series 871487,1987.

ABSTRACT: The lessons of past and present manned space programs are clear. Successful design and operation of a spacecraft water system is contingent upon consideration of traditional saitary engineering principles in the context of unique mission requirements. However, the aerospace solution to the traditional

terrestrial problem often requires an innovative desigh approach to succeed in the spacecraft environment. Future long duration space missions will require the same attention to basic principles, the same degree of innovation, and an extra measure of caution, because of the lack of terrestrial experience with direct human reuse of reclaimed water.

Wolfe R.S. Respiration In Methanogenic Bacteria. Diversity Of Bacterial Respiratory Systems 1, :0161-0186. 1980.

ABSTRACT: None

Wolff H.S. Animal Experiments. Proc. R. Soc. Lond. B., 199 :0479-0483. 1977.

ABSTRACT: Towards the end of 1980 the first Spacelab will be launched. It represents the culmination of a major cooperative project between the nations subscribing to the European Space Sgency and N.A.S.A. The Spacelab module contains a laboratory inside which a wide range of experiments can be carried out in an environment which, apart from the absence of gravity,is not unlike that of a terrestrial laboratory. From the point of view of the life scientist it represents an opportunity to carry out experiments to investigate the effect of xero gravity or modulated gravity on biolgical preparations including amn. Thefirst mission will last seven days, but subsequent missions planned for the decade 1980-1990 may last up to thirty days. The purpose of the paper is to introduce participants to the facilities whech are available in Spacelab and to explain the procedure by which experiments may be proposed. There is also a discussion of the present funding arrangements int he United Kingdom.

Wolin M.J. The Rumen Fermentation: A Model For Microbial Interactions In Anaerobic Ecosystems. Division of Laboratories and Research, New York State Department of Health, Albany, New York 12201, USA,:0049-0077. .

ABSTRACT: A ruminant can be thought of as a fermentation factory. The animal ingets plant polymers (in grass, hay, corn, silage, etc.) which are the raw material for its fermentation. Preliminary processing occurs in the oral cavity and consists mainly of comminution of food by mastication. The plant material is then swallowed and transported to the ruminant's complex stomach. The stomach, called the rumen reticulum or, more simpley, rumen, is the site of fermentation.

Wood C.D., Manno J.E., Manno B.R., Redetzke H.M., Wood M.J., Mims M.E. Evaluation of Antimotion Sickness Drug Side Effects On Performance. Aviat. Space Environ. Med., 56:0310-0316. 1985.

ABSTRACT: This project has employed a computerized pursuit meter which has a high correlation with operational performance to test the principal antimotion sickness drugs. Proficiency scores on the pursuit meter task were improved over placebo scores in subjects with d-amphetamine 10 mg and 5 mg, the combination of

promethazine 25 mg plus scopolamine 0.4 mg with d-amphetamine 10 mg, and the combination of scopolamine 1 mg with d-amphetamine 10 mg. Scores were not significantly different from placebo scores in tests with scopolamine 0.25 mg, 0.5 mg, or 0.6 mg; marezine 50 mg; meclizine 50 mg; or dimenhydrinate 50 mg. This was also true for the combination of scopolamine 1 mg with d-amphetamine 5 mg, and that of promethazine 25 mg with d-amphetamine 10 mg. A statistically significant decrement of performance scores was seen with scopolamine 1 mg or 0.8 mg, and with promethazine 25 mg oral or 25 mg I.M. The combination of promethazine 25 mg with scopolamine 0.4 mg, and that of promethazine 25 mg oral plus 25 mg I.M. with d-amphetamine 10 mg, also gave significant decrements from placebo scores. These results indicate that selected doses and combination of antimotion sickness drugs can be used without loss of operational proficiency.

Wood E.H. Contributions Of Aeromedical Research To Flight and Biomedical Science. Aviat. Space Environ. Med, 57/10(Suppl.) :A0013-A0023. 1986.

ABSTRACT: Pilot and plane capabilities to withstand high-Gz combat maneuvers are tactically important. Sustained 10-15 Gz capabilities of current and future planes outstrip safe physiologic limits in spite of the combined use of World War 11 -vintage straining maneuvers and relatively ineffective anti-G suits to prevent losses of vision and consciousness. However, the extreme arterial pressure increases needed to maintain cerebral blood frow (e.f. 400 mm Hg at heart level during exposures to 13.5 G when sitting upright) carry risks of anatomic damages to the circulatory system and rupture of air-containing, essentially unprotectable, lungs. These could be minimized, and incapacitating losses of consciousness avoided, by use of horizontal positions designed to eliminate heart-to-head hydrstatic gradients. Development of a prone-position cockpit with a counterweighted, forward-looking head support plus optical-electronically aided all-directional visibility is the most physiologic, safest, and surest way to achieve this goal.

Woodard E.D., Friedlander B., Lesher R.J., Font W., Kinsey R., Hearne T.F. Outbreak of Hypersensitivity Pneumonitis in an Industrial Setting. JAMA, 259/13:1965-1969. 1988.

ABSTRACT: Systoms consistent with hypersensitivity pneumonitis developed in several wokers in two multistory buildings in an industrial complex. A health questionnaire survey was conducted to determine the extent of the problem. Eightyseven percent of the population of 1050 employees completed the health questionnaire. Serological testing identified 152 positive precipitin reactors to the fungus Aureobasidium pullulans; 115 reactors were symptomatic. The clinical and laboratory features at the time of the acute illness and during four years of follow-up are described. The agent, A pullulans, was identified as a contanimant of the heating-cooling ventilation units containing open waterspray chambers. Control was accomplished by replacement of the ventilation systems. A secondary source of antigen was found to be corrugated cardboard. Some sensitized

employees required removal from work exposure to corrugated cardboard to prevent recurrent symptoms.

Wronski T.J., Morey-Holton E.R., Doty S.B., Maese A.C., Walsh C.C. Histomorphometric Analysis of Rat Skeleton Following Spaceflight. Am. J. Physiol. , 252 (Regulatory Integrative Comp. Physiol. 21):R0252-R0255. 1987.

ABSTRACT: Male Sprague-Dawley rats were placed in orbit for 7 days aboard the space shuttle. Bone histomorphometry was performed in the long bones and lumbar vertebrae of flight rats and compared with data derived from ground-based control rats. Trabecular bone mass was not altered during the 1st week of weightlessness. Strong trends were observed in flight rats for decreased periosteal bone formation in the tibial diaphysis, reduced osteoblast size in the proximal tibia, and decreased osteoblast surface and number in the lumbar vertebra. For the most part, histological indexes of bone resoption were normal in flight rats. The results indicate that 7 days of weightlessness are not of sufficient duration to induce histologically detectable loss of trabecular bone in rats. However, cortical and trabecular bone formatin appear to be diminished during the 1st wk of spaceflight.

Yotis W.W., Zeb M., Kubak B., Wu-Yuan C., Yotis E., McNulty J. Cytoplasmic Proteins Of Streptococcus mutans (Serotype C) And Their Interaction With Fluoride. App. Env. Micro., 47/3 :0506-0512. 1984.

ABSTRACT: The protein profile of the cytoplasmic proteins of Streptococcus mutans GS-5 was determined by two-dimensional gel electrophoresis. Use of this recently developed, high-resolution analytical tool showed in excess of 140 cytoplasmic proteins. The profile consisted of mostly acidid components with pI values between 3.70 and 5.30 and relative moecular weights mainly in the 13,000 to 90,000 range. With sodium dodecyl sulfate-polyacrylamide get electrophoresis, the proteins were resolved into 40-45 components. The binding of fluoride by the proteins reached a maximum value in 15 miln., and it was linear with exogenous F- doses of up to 60-80 ppm per mg of protein (60-80 ug/g). The proteins bound 22 to 138 times more F- from assay mixtures containing 1 mM CaCl2 than from assay mixtures containing such ions as HgCl2, ZnCl2, CuCl2, MgCl2, MnCl2, or SnCl2. When NaF, SnF2, NH4F, CsF, (CH4)3NF, and Na2PO3F were used as sources of F- (adjusted to 10 ppm of F- in all cases), the proteins bound 2.1, 1.8, 1.6, 1.4, and 0.3 ppm of F- per mg of protein, respectively. Initial fractionation of the plasma proteins by preparative column isoelectric focusing indicated that proteins with pI values of 4.1 to 4.5 as well as thaose with pI values of 5.0 to 5.3 bound twice as muc F- as did the proteins utside these pI values.

Young L.R., Oman C.M., Watt D.G.D., Money K.E., Lichtenberg B.K. Spatial Orientation In Weightlessness And Readaptation To Earth's Gravity. Science, 225:0205-0208. 1984.

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ABSTRACT: Unusual vestibular responses to head movements in weightlessness may produce spatial orientation illusions and symptoms of space motion sickness. An integrated set of experiments was performed during Spacelab 1, as well as before and after the flight, to evaluate responses mediated by the otolith organs and semicircular canals. A variety of measurements were used, including eye movements, postural control, perception of orientatin, and susceptibility to space sickness.

Young, R. B., McConnell, D. G., Suelterr, C. H., Phillips, T. A. . Normal and Dystrophic Embryonic Chicken Pectoralis Muscle Cultures: I. Cell Differentiation, Protein Synthesis, and Enzyme Levels. Muscle and Nerve, :0117-0124. 1981.

ABSTRACT: Normal (line 200) and dystrophic (line 307) embryonic chicken pectoralis muscle cells were studied in cell culture over a period of 2 weeks. During the first 4 days, normal and dystrophic cultures exhibited similar developmental increases in the number of nuclei within multinucleated myotubes; however, dystrophic muscle cells degenerated approximately twice as fast as normal cells once the initial burst of myoblast fusion was complete. The apparent synthesis rate of nonmyofibrillar proteins was similar in normal and dystrophic cells throughout development, but the apparent synthesis rates of myosin heavy chain and the myofibrillar protein fraction were 50%-90% higher in dystrophic muscle cultures once maturity had been reached (days 6-14). The specific activities of creatine kinase and phosphofructokinase were not affected by the dystrophic condition; however, specific activity of AMP-deaminase was depressed 25%-40% in the dystrophic muscle cultures.

Young, R. B., Schneible, P. A. . Myosin Heavy Chain Concentration, Synthesis Rate and Degradation Rate in Normal and Dystrophic Chicken Muscle Cells in Culture. Euro. J. Cell Biol., 34 :0075-0079. 1984.

ABSTRACT: Myosin heavy chain concentrations, synthesis rates and degradation rates were studied in muscle cell cultures prepared from the breast muscle of 13-day normal (white leghorn) and dystrophic (line 307) chicken embryos. Muscle cells were studied after 7 days in culture, at which time they had reached a steady state with respect to myofibrillar protein synthesis and degradation. The quantity of myosin heavy chain was 10.5 + 0.9 ug/culture (n=32) in normal cells and 8.10 + 1.2 ug/culture (n=31) in dystrophic cells. However, the myosin heavy chain synthesis rate was 23 500 molecules/min/nucleus in normal cells and 39 900 molecules/min/nucleus in dystrophic cells, as deteermined by pulse labeling with [3H]leucine and measurement of the specific radioactivity of tRNA precursor pools. Myosin heavy chain half-lives rates were calculated to be 30.6 h in normal cells and 15.6 h in dystrophic cells when corrections were made for reutilization of [3H[leucine. Thus, dystrophic muscle cultures accumulate less myosin heavy chain, despite their faster synthesis rate, because of faster degradation of myosin heavy chain.

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Yu V.L., Beam T.R., Lumish R.M., Vickers R.M., Fleming J., McDermott C., Romanmo J. Routine Culturing for Legionella in the Hospital Environment May Be a Good Idea: A Three-Hospital Prospective Study. Am. J. Med. Sci., 294:97-99. 1987.

ABSTRACT: The source for nosocomial Legionnaires' disease is the water distribution system. However, the implications for legionella contamination in a hospital without known Legionnaires' disease is unclear. Therefore, culturing for Legionella pneumophila in the environment has not been routinely recommended. The authors conducted a prospective pneumonia study in three hospitals, none of which was known to have a major problem with endemic legionellosis. The water system of Hospital 1 was colonized with L. pneumophila, serogroup 1; Hospital 2 was colnized by L. pneumophila, serogroup 5 (which is rarely associated with disease); Hospital 3 was essentially free of L. pneumophila. Sputum culture on selective legionella media, direct fluorescent antibody testing, and serology were performed for all nosocomial pneumonias regardless of clinical impression. At the end of the study the incidence of nosocomial legionnaires' disease was found to be 9%, 0%, and 0% in Hospitals 1, 2, and 3, respectively, In Hospital 1, monoclonal antibody subtyping confirmed that the patient isolates were identical to the environmental isolates. The authors conclude that environmental culturing, despite the absence of known Legionnaires' disease, is useful. Positive cultures from the hospital water supply would mandate the introduction of legionella testing into the laboratory and stimulate physicaians to consider Legionnaires' disease when encountering nosocomial pnemonias.

Zamost B.L., McClary D.O. The Effects Of Plant Growth Regulators On Cellulase Production By Trichoderma reesei . Biotech. Let., 5/3 :0179-0184. 1983.

ABSTRACT: The plant growth regulators, indole-3-acetic acid (IAA) and gibberellic acid (GA3), were tested for their effects on spore germinaton and cellulase (B-1-4-endogluconase) producton by Trichoderma reesie. The addition of 10 -5 M IAA of GA3 enhanced cellulase production whereas higher concentration were inhibitory, both to spore germination and cellulase production.

Zayed S.M.A.D., Mastafa I.Y., Farghaly M.M., Attaby H.S.H., Adam Y.M., Mahdy R.M. Microbial Degradation Of Trifluralin By Aspergillus carneus, Fusarium oxysporum, And Trichoderma viride. J. Environ. Sci Health, B18/2:0253-0267. 1983.

ABSTRACT: None

Zdankiewicz E.M., Chu J. Phase Change Water Recovery For Space Station Parametric Testing And Analysis. .

ABSTRACT: Vapor compression distillation (VCD) technology for phase change recovery of potable water from wastewater has evolved as a technically mature approach for use aboard the space station. A program to parametrically test an advance

preprototype vapor compression life systems for the national aeronautics and space administration (NASA) Johnson Space Center (JSC) During 1985. In parallel with parametric testing, a hardware improvement program was initiated to incorporate and verify certain key improvements into the advance preprototype VCDS following initial parametric tests. Specific areas of improvements included long-life, self-lubricated berings, a lightweight, highly-efficient compressor and a long-life magnetic drive. These improvements are now incorporated and verification testing started. The advance preprotype VCDS Was designed to reclain 95% of the available wastewater at a nominal water recovery rate of 1.36 KG/H (3.0 LB/HR) And 308 K (95 F) condenser temperature. While this performance was maintained for the initial testing, a 300% improvement in water production rate (4.1 KG/H(9.0 LB/HR)) with a corresponding lower specific energy was achieved following incorporation of the improvements. The paper presents a summary of the results of the parametric test program conducted. Testing involved the characterization of key VCDS Performance factors (water production rate, water quality and specific energy) as a function of recycle loop solids concentration, distillation unit temperature and fluids pump speed. The objective of this effort was to expand the VCDS data base to enable defining optimum performance characteristics for flight hardware development. Based upon the parametric testing results which were obtained. Projections are made for a phase change water recovery subsystem for the space station based upon the VCD concept. The projected unit processes 18.1 KG/Day (40.0 LB/Day) of wastewater, weighs 36.1 KG (79 LB), has a volume of only 0.21M3 (7.4 FT3) and requires only 84 W of electrical power for a specific energy of 76.8 W-H/KG (35 W-HR/LB).

Zeikus. Use Of Co-Cultures In The Production Of Ethanol By The Fermentative Of Biomass . U.S. Patent 4,400,470,.

ABSTRACT: Production of ethanol and enzymes by fermentation of biomamss with co-culture of Clostridium thermocellum and C. thermohydrosulfuricum

Zeikus J.G. Microbial Populations In Digesters. Anaer. Dig. Proc. Int. Symp.,:0061-0089. 1981.

ABSTRACT: None

Zeikus J.G. Thermophilic Bacteria: Ecology, Physiology And Technology. Reviews, Department of Bacteriology, University of Wisconsin, Madison, Wisconsin 53706, USA,.

ABSTRACT: Thermophilic bacteria are common in soil and volcanic habitats and have a limited species composition. Yet they possess all the major nutritional categories and metabolize the same substrates as mesophilic bacteria. The ability to proliferate at growth temperature optima well above 60 C is associated with ectremely thermally stable macromolecules. As a consequence of growth at high temperature and unique macromolicular properties, thermophilic bacteria can possess high metabolic rates, physically and chemically stable enzymes, and

lower growth but higher end product yields than similar mesophilic species. Thermophilic processes appear more stable, rapid and less expensive, and facilitate reactant activity and product recovery. Thermophilic bacteria have application in chemical feedstock and fuel production, bioconversion of wastes, enzyme technology, and single cell protein production. This paper reviews the fundamental and applied aspects of thermophilic bacteria that are of potential industrial interest.

Zeikus J.G. Microbial Intermediary Metabolism In Anaerobic Digestion. Anaerobic Digention, Proceedings Of The International Symposium, :0023-0035. 1982.

ABSTRACT: Effective biodegradation of oranic wastes into methane requires the coordinated metabolic activities of different microbial populations. The intermediary metabolism of multicarbon and uni- and dicarbon transforming bacteria is described in mono- and co-culture fermentations. The results of physiological and biochemical experiments are presented in order to explain the fundamentals of mixed culture metabolism and to identify key control parameters which influence the rate of organic degradation, the yield of reduced metabolites, and thermodynamic efficiency in the anaerobic digestion process.

APPENDIX D
Space Medicine
Bibliography

SBS No. 1986 - 3

SPACE MEDICINE

SPECIALIZED BIBLIOGRAPHY SERIES

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November 1986

SPECIALIZED BIBLIOGRAPHY SERIES

This is one of a series of Specialized Bibliographies prepared and distributed by the Public Services Division of the National Library of Medicine (NLM). These bibliographies are usually the result of a combination of manual and computerized searching, utilizing databases produced by NLM and others. Specialized Bibliographies are therefore generally more comprehensive in coverage than those bibliographies produced under NLM's Literature Search series. The only criterion for inclusion of a published work in a Specialized Bibliography is its relevance to biomedicine. The format, ownership, or location of the materials are not considered.

SPACE MEDICINE

This bibliography was prepared in conjunction with the colloquium "Space Medicine: Newest Frontier of the Health Sciences" held at the National Library of Medicine on November 13, 1986. The colloquium was one of a series held in celebration of the Library's sesquicentennial.

Because there is a large volume of literature on space flight which covers all disciplines of science, this selective bibliography is limited, for the most part, to references on the biomedical aspects as they relate to the human factor in space flight or the space environment. These include physiological, biological, and behavioral functions. There are a limited number of references of a more general nature relating to equipment design, life support systems, environmental control, radiation effects, life sciences, and international cooperation. In general, references to animal and cell culture studies have been excluded.

This bibliography covers the ten-year period from 1977 to the present and includes only English language publications. Sources for the references include NLM's MEDLINE and CATLINE databases as well as BIOSIS, EMBASE, Aerospace Database, Dissertation Abstracts Online, Mental Health Abstracts, NASA RECON, PSYCHINFO, and Social SciSearch. All types of publications have been included: monographs, journal articles, technical reports, conference proceedings, and dissertations. This bibliography is extensive but not exhaustive; the exclusion of particular items is no reflection on their quality or usefulness.

"Space Medicine" has been divided into seven broad categories: bone metabolism, the cardiovascular system, general physiology, motion sickness, psychological/behavioral aspects, radiation effects, and other. The latter includes broad general publications as well as specific ones which fall outside the categories listed above.

For a comprehensive publication on the pre-1977 aspects of space medicine, the reader is referred to:

> Foundations of space biology and medicine: joint USA/USSR publication. Melvin Calvin and Oleg G. Gazenko, general editors. Washington: Scientific and Technical Information Office, National Aeronautics and Space Administration, 1975. 3v. (NASA Special Publication no. 374)

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APPENDIX E
Task Statements

1.0 Provide Support To The Mechanical Design And Integration Of Test Systems As Related To Microbiological Concerns

These are preliminary design recommendations for the integration and material compatibility of water reclamation subsystems as they relate to microbial concerns. These criteria are based on an ideal system and as such are subject to change depending on actual design implementation.

1.1 General

A major microbiological concern in a water-related system is the attachment of bacteria to surfaces and subsequent biofouling. The degree of attachment is dependent upon surface area and the nutrient conditions present. Although these factors cannot be eliminated, steps can be taken to reduce their influence in most cases. A second concern involves the ability to detect bacterial presence quickly and accurately. Proper preventive measures should be taken and problem areas identified and detected quickly. Some general recommendations are outlined below.

1.1.1 Bacterial Attachment and Biofilming

Surface areas available for bacterial attachment should be minimized. Plumbing runs, number of elbows, and storage tank size should be reduced wherever possible. Joints should be welded by automatic orbital welding techniques to eliminate the creation of internal surface areas and subsequent attachment sites for bacteria. Component materials (Section 1.2) and Subsystem Integration (Section 1.3) considerations are also important to reducing biofouling.

In addition, nutrient concentrations available to support microbial growth should be reduced. Component materials should not contribute nutrients to the system. Growth-promoting factors may be reduced in the water supply by physical or chemical means. For example, organic carbon, the single most important factor in biofilm formation, can be reduced by reverse osmosis membranes UV irradiation and activated carbon beds.

1.1.2 Holding Time

A holding (storage) period is needed in order to validate and verify the quality of water before use. This time period is dictated by the time required to perform the necessary tests for verification. However, as long as a holding time is required it is not possible to verify the water quality just prior to use. In addition, a holding time requires not only the maintenance of water quality during the hold period but also during the use period as well. Finally, the greater the holding time which is placed on the water prior to use the more tank capacity that is required to store the water. At the present time, the minimum time required is estimated to be 24 hours. Although it is conceivable that the chemical parameters can be concluded and reported within an eight hour shift, the microbiological parameters will require at least 24 hours. A holding time greater than 24 hours is <u>not</u> recommended. In order to allow for the minimal holding time possible, viable plate counts should be performed on those parameters which can be completed within 24 hours and also provide the necessary information required for verification of water quality (Section 3.2). In addition, a near real-time method for total bacterial counts will be necessary.

1.1.3 Storage Tanks

Storage tanks, with their large volumes of water, can be especially difficult to control. Limiting the size of the tank and minimizing storage time will effectively reduce the attachment of bacteria to tank walls and eliminate a major reservoir for bacterial contamination and growth. Refrigeration of the storage tanks and their contents will usually slow the process of bacterial growth and subsequent fouling. Direct heat sterilization of the tank and its contents will control bacterial development. In addition, heat sterilization can be mechanically validated and thus the sterility easily verified. At lower temperatures than is normally required for conventional heat sterilization a process known as tyndallization may be used. Tyndallization is a series of daily heat spikes which destroys vegetative cells present and then allows for the subsequent germination of spores which may be present. These new vegetative cells are then destroyed by repeating the process.

1.1.4 Control of problem areas

Those areas which are especially prone to bacterial contamination such as sampling sites, replacement units (e.g. reverse osmosis unit, resin beds, activated carbon beds and particulate filters) and storage tanks will require special considerations. These areas should be easily accessible for periodic checking, routine maintenance and scheduled replacement. This will serve to reduce system down time when a problem is encountered or components need to be cleaned or replaced.

1.2 Material Recommendations

The choice of materials used in the construction of pharmaceutical and semiconductor water supplies remains the best source of information on system components. Wherever possible materials should be those which are flight approved. Listed below are recommendations applicable to the test system from these sources.

1.2.1 Stainless steel (316L)

Stainless steel (316L) is recommended for all applicable hardware components. Advantages are listed below:

- low carbon content
- low trace metal content
- highly resistant to pitting and corrosion
- able to tolerate high salt concentrations
- acceptable resistance to bacterial attachment

1.2.2 Gaskets

Use of Teflon gasket material is recommended.

1.2.3 Storage Tanks

Bellows tanks with an external piston are recommended. These tanks will eliminate the possibility of water entrapment in the piston mechanism which would serve as a reservoir for bacterial contamination.

1.2.4 Valves

Packless diaphagm valves are recommended in order to prevent water entrapment in the valve mechanism and a potential site for bacterial contamination.

1.2.5 Activated Carbon

Many grades of activated carbon are available. The highest quality anthracite is recommended.

1.2.6 Material compatibility with disinfectant

Care must be taken to ensure that the decontamination processes chosen are compatible with the hardware materials used. All hardware materials (RO membranes, ion exchange resins, etc.) should be compatible with proposed pretreatment processes, other subsystem components and proposed disinfection procedures and/or agents.

Stainless steel is suitable for disinfection with dry/moist heat procedures. In addition, 316L stainless steel can withstand treatment with hot water, chlorine, and iodine. Fiberglas-reinforced plastics (FRP) can tolerate hydrogen peroxide, ozone, and formaldehyde. Polyvinyl decaflouride (PVDF) compounds are resistant to gluteraldehyde and ultraviolet (UV) light.

1.3 System Design and Subsystem Integration

The ability to produce acceptable product water depends on the integration of basic structural and implemented hardware designs to discourage bacterial growth. Listed below are some problems likely to be encountered and recommendations to help govern them.

1.3.1 Stasis

Any segment of pipe containing water that is not recirculated on a frequent basis provides an area for nutrient deposition and eventual bacterial growth. These areas, often referred to as a "dead legs" can potentially serve as internal sites for system contamination.

Distribution lines should be plumbed as close to the point of use as possible. This will decrease the physical length of pipe required and reduce the amount of dead space present when the system is not in use. Minimize the use of elbows, valves, and use points in order to reduce possible "dead legs". Also, electronic water level indicators instead of a sight tube is recommended to eliminate standing water.

Recirculation or continuous operation is recommended to reduce static conditions and minimize "dead legs".

Point of use sites such as hand washers serve as potential reservoirs for bacterial growth due to contaminants from skin oils, hair, and respiratory droplets. Circulating pumps at these sites help reduce standing water and thereby help to eliminate the build-up of required nutrients necessary for the propagation of microorganisms. Circulation within water storage tanks would help to reduce bacterial populations. Circulation reduces the settling of growth-promoting substrates from materials and water sources which normally provide a primary layer for biofilm formation. Circulation will ensure uniform mixing of chemical biocides, if employed. It allows for increased filtration and exposure to UV. irradiation (or disinfection).

1.3.2 Tank Vent Filters

1.3.2.1 Composition

The composition of the filter should be of a hydrophobic membrane to reduce water entrapment on the surface.

1.3.2.2 Placement

Place the unit in a vertical position to reduce further the possibility of water collection on the filter and subsequent microbial growth.

1.4 Sampling Ports

Sampling ports as will use points provide a place of entry for contaminating microorganisms. The ability to control such areas is based on a combination of design considerations and physical treatments. Recommendations are listed below.

1.4.1 Implementation of sterilization or disinfection procedures (Section 1.5).

1.4.2 Circulation to prevent water stagnation.

1.4.3 Elimination of gooseneck designs which may trap water.

1.5 Sterilization/Decontamination

In order to retard bacterial growth the system should be sterilized or decontaminated at the onset as well as during actual usage. This may include separate cleaning of specific hardware especially susceptible to the growth of microorganisms. Periodic cleaning or replacement of some materials would also be indicated. Below are listed recommendations for sterilization and decontamination of the system.

1.5.1 Routine removal of the outer length of outlet pipe for physical cleaning and sterilization (or disposal) would allow mechanical cleaning of biofilm formation.

1.5.2 Point of Use/Sampling Port Sterilization

Routine point of use/sampling port sterilization or decontamination is recommended. These measures will help eliminate environmental contamination to the system. Below are presented several possible means to accomplish this.

1.5.2.1 Ultraviolet (UV) irradiation

1.5.2.2 Routine and periodic treatment of the sampling ports with H2O2 or other acceptable disinfecting solution reduces the possibility of environmental contamination between uses.

1.5.2.3 Microbial Check Valve (MCV)

1.5.2.4 Flaming

1.5.3 Sterilization of hardware

1.5.3.1 R/O Membranes

Reverse osmosis membranes can be treated with high temperature (95C) to remove bacteria attached to them.

1.5.3.2 Activated Carbon Beds

Activated carbon beds can be steam sterilized to reduce bacterial levels.

1.5.3.3 Ion-exchange Resins

Ion-exchange resins can be sterilized with a 0.5% solution of formaldehyde. Regeneration of the beds with 2% sulfuric acid and 4% sodium hydroxide solutions will also help to control bacterial growth

1.6 Operational Requirements

To operate efficiently, conditions must be maintained that will not overburden the system and cause premature failure of components. Recommendations for maintaining an efficient system are given below.

1.6.1 Water pretreatment

The R/O membrane and activated carbon bed are a major site for bacterial attachment due to 1) the large surface areas present and 2) the nutrient accumulation. Bacterial growth here will not only affect the efficiency of these components but all other subsystems downstream. Therefore, effective pretreatment of water entering these units will greatly extend the life of the of these subsystems by reducing the bacterial burden placed upon them.

1.6.2 Filters

Periodic replacement of air filters, vent filters, prefilters and particulate filters will decrease the possibility of airborne contamination and reduce the particulate burden placed on the reclamation system.

1.6.3 Continuous Operation

Continuous or semi-continuous operation, as opposed to batch processing, is recommended (Section 1.3.1). In addition to eliminating static conditions continuous operation will allow for increased observation of the system over an extended period of time to detect areas of weakness. It will also allow for the greater capacity for producing water if required for test evaluation and it will better simulate the operating conditions to be encountered aboard the Space Station.

1.6.4 Constant Flow

Maintenance of constant flow rates are recommended. Optimum flow rates of similar systems are reported to be between 5-10 ft./sec. Maintaining a constant flow is reported to help reduce the number of free-floating bacteria and nutrients available for attachment to surfaces.

2.0 Assist with the design of Human Subjects Test Protocols

2.1 Test Subject Protocols

The Boeing Aerospace Company (BAC) will identify potential subjects and route the names and contact information (work area, mail code, work phone number) to the BAC health nurse. The BAC health nurse will contact the potential subject and set up an appointment for initial screening. This initial screening will include a description of the project and completion of an informed consent form. The nurse will obtain a health questionnaire (HQ), a Duke University Health Profile (DUHP), and have the subject begin a symptom diary. The subject will be given an appointment with the examining physician (EP), and the HQ and DUHP results will be routed to the examining physician by the health nurse. The subject will bring the diary to the EP on the day of the initial examination.

At the initial examination, a full history and physical will be performed and recorded on the initial examination form. The laboratory will be drawn and the skin tests placed. When these results are available, the EP will indicate his/her opinion concerning the subject's medical qualification for involvement and route all the information to the Environmental Health Physician (EHP). Guidelines for this determination are outlined in 2.12 below.

For the subject selected to be involved in the test, an appointment will be made with the EP one week before he/she is scheduled to participate. At this time, the brief pre-test examination will be done and recorded on the form. The repeat laboratory will also be drawn. When the results are available, the EP will again verify qualification, based on the guidelines presented in 2.14 below. The EP will then notify the EHP by telephone of the status of the subject, and route all the materials to the EHP. Each day of the testing, the EHP will notify the project manager of any changes in subject status.

Throughout the period from initial evaluation through testing and for six months beyond, the subject will continue the symptom diary. Each subject will be seen by the EP one week after each involvement, one month later and six and twelve months later. These follow-up visits will include review of any intercurrent illnesses or symptoms and a brief physical examination as indicated. Each month after involvement for 24 months, the health nurse will obtain the records of any visit to a physician other than the EP and route them to the EP. All records will then be routed to the EHP on all subjects monthly.

2.11 Initial Evaluation

2.111 Name of personal physician

2.112 Recent illnesses

2.113 Past medical history

2.1131 Chronic illnesses (Hypertension, Diabetes, etc.)

2.1132 Regular medicines, including OCP's and OTC

2.1133 Menstrual history

2.1134 Regular cream, ointment, oil use

2.1135 Other drugs, alcohol, tobacco

2.1136 Active skin or hair disorder

2.1137 Frequency of minor infectious diseases

2.11371 Respiratory (colds, pharyngitis, bronchitis)

2.11372 GI (gastroenteritis)

2.11373 UTI (bladder, kidney)

2.11374 GU (vaginitis, urethritis)

2.11375 Skin (acne, impetigo, cellulitis, athlete's foot)

2.114 Physical Exam

2.1141 Skin

2.1142 Heart

2.1143 Lungs

2.1144 Heart

2.1145 Abdomen

2.1146 GU (including pelvic)

2.1147 Neuro/Musculo Skeletal

2.115 Health Profile (DUHP)

2.116 Laboratory

2.1161 CBC

2.1162 U/A and culture

2.1163 Wet prep/GM Stain (if indicated)

2.1164 Serum pregnancy test

2.1165 Stool culture

2.1166 Special studies

2.117 Skin test anergy pack and PPD (Reading required in 48 hours)

2.118 Begin symptom diary

2.12 Disqualification Criteria for Initial Evaluation

2.121 No personal physician

2.122 Any chronic illness or regular medicine intake

2.123 Frequent minor illnesses

2.1231 > 4 colds/yr.

2.1232 > 2 GE/yr.

2.1233 > 1 UTI/yr.

2.1234 > 2 Vaginitis/yr.

2.1235 > 1 Active Skin Infection/yr.

2.124 Abnormal physical finding

2.125 Poor DUHP score

2.126 Abnormal lab

2.13 Pre-Test Evaluation

2.131 Review symptom diary

2.132 Review recent menstrual history

2.133 Review recent topical use

2.134 Brief physical exam

2.135 Laboratory

2.1351 U/A and culture

2.1352 Wet prep/GM stain (if indicated)

2.1353 Serum pregnancy test

2.1354 Urine drug screen (legal ramifications)

2.1355 Special Studies

2.14 Disqualification Criteria for Pre-test Evaluation

2.141 Significant new symptoms of infection

2.142 Testing likely to occur during menses (policy decision)

2.143 Any topical use on prohibited list

2.144 Abnormal physical finding

2.145 Positive urine culture (>10,000/ml of each organism)

2.146 Positive wet prep/GM stain

2.147 Positive or indeterminate serum pregnancy test

2.148 Positive urine drug screen (legal)

2.15 Post-Test Evaluation

2.151 Review symptom diary

2.152 Review menstrual history

2.153 Brief physical exam

2.154 Repeat health profile (DUHP)

2.155 Laboratory

2.1551 U/A and culture

2.1552 Wet prep/GM stain (if indicated)

2.1553 Serum pregnancy test

2.1554 Stool culture

2.1555 Special studies

2.16 Detection of Sick Subjects

2.161 Continue symptom diary

2.162 Monitor visits to personal physician (by permission)

2.163 Subject notifies

2.17 Medical Staffing Options for Project Evaluations

2.171 Boeing/NASA Physician

POSITIVE	NEGATIVE
1) Good adherence to protocols	1) Low subject acceptability ?
2) Low additional cost	2) Objectivity

2.172 Personal Physician

1) High subject acceptability	1) Objectivity
2) Awareness of involvement	2) High cost
	3) Low adherence to protocol

2.173 Contract Physician

1) Objectivity	1) cost
2) High adherence to protocol	

2.174 Responsibility for subject problems, accidents, injuries, exposure

2.1741 Human subjects guidelines

2.1742 JSC guidelines

2.175 Certification process

2.2 Human Subject Guidelines

2.21 Institutional Review Board

There are several large policy issues that require early decisions in order to continue to work on further details. The first of these is an approval of human subjects in general. The JSC Document provides the same categories of "minimal" and "reasonable" risk that are used by the UAH Institutional Review Board. These are guidelines published by the Department of Health and Human Services that clearly outline what is to be done. In the JSC document, it is made clear that the testing of ground-based projects does not come under the JSC HRPPC review. It is stated that this review would be carried out by the Institutional Review Board "of the Institution at which the test procedure development takes place". This review board is a group of persons with widely diverse backgrounds which reviews protocols for human subjects. At this point, we have not identified a MSFC IRB. An IRB should be designed for this review. If the MSFC legal department approves of delegating this authority to the UAH IRB, Dr. Crump can facilitate that process, as he is on the University-wide board. Dr. Crump could also facilitate designing an IRB for MSFC if one is needed.

2.22 System Certification

Certification prior to system use is another major policy issue. The JSC document makes it clear that the principal investigator for the project is the person whose signature certifies that 1) the system is safe, and 2) the subjects are medically qualified to participate. Certainly, one role of the Medical Support Team is to delineate and accept some of this risk. However, the principal investigator for this project must be specified, as it is clear that this person signs the "bottom line". The Medical Support Team can be advisory to that principal investigator and can go on record as having recommended to the principal investigator that all is well.

2.23 Subject Injury

Concerning the issue of injury or harm to the test subjects, the JSC Document states that (in HRPPC reviews) since the subjects are NASA employees, NASA accepts responsibility under the Federal Employee's Compensation Act or the Federal Tort Claims Act. If Boeing employees are to be the subjects in our tests, this line of responsibility will have to be clarified before we can proceed.

2.24 Supporting Documents (Appendix H)

2.241 JSC HRPPC

2.242 HHS

2.243 UAH IRB

2.244 Duke University Health Profile

3.0 Interpretation and recommendations pertaining to water quality requirements.

3.1 Identify current air/water quality requirements.

3.1.1 Johnson Space Center Requirements

The proposed requirements for potable and hygiene water as specified by the Johnson Space Center (JSC) are presented in Table 3-1.

3.1.2 Environmental Protection Agency (EPA)

The current recommended priority pollutants as established by the EPA are presented in Table 3-2.

3.1.3 State of Alabama

The current State of Alabama requirements for drinking water are presented in Table 3-3.

3.2 Recommend which chemical parameters should be monitored in order to verify water quality prior to use.

The current parameters recommended for water quality verification are listed in Table 3-4. The chemical parameters recommended for routine monitoring are based on the identification of these compounds as toxic by the EPA, the recommendation by EPA that these compounds be monitored for pharmacutical products, the existence of standardized methods for their evaluation and the potential for rapid analysis (8 hours or less).

3.3 Identify the instrumentation and methodology to be used for water quality verification.

Based on the recommendations made pertaining to Section 3.2, Table 3-5 lists the instrumentation and methods required for chemical parameter verification.

3.4 Provide recommendations pertaining to microbiological monitoring of the potable and hygiene water loops in order to verify water quality.

The current microbiology requirements are presented in Table 3-6. The parameters recommended for water quality verification are presented in Table 3-7. The microbiological parameters recommended are based on standard microbiological procedures, current water quality requirements and the need for rapid results (6-24 hours). Determination of total bacteria will be conducted by an epifluorescence method in order to facilitate rapid results (4-6 hours). Conventional viable plate counts requiring a maximum incubation of 24 hours will also be conducted. The standard heterotrophic plate count (72-120 hours) will be used for after the fact verification and identification of isolates as required. Legionellae, fungi and yeast will be monitored routinely at a frequency to be determined at a later time.

Specific recommendations pertaining to viral monitoring will also be addressed at a later time.

3.5 Development of a method for total bacterial counts.

In order to detect the presence of bacteria on a near real-time basis a direct method for their detection and enumeration must be developed. It is recommended that an epifluorescence method be used. At present, personnel at the CSLS are reviewing current methods and will make a final recommendation upon completion of this review. It is estimated that approximately $4,000.00 in equipment upgrades and four man-months will be required for method development. Table 3-8 summarizes the current methods for enumeration and the current recommendations.

3.6 Provide information pertaining to laboratory analysis required for Legionella and AIDS screening.

The information outline below details pertinent information regarding the Legionellae and HIV (AIDS) virus.

3.6.1 Legionellae

A. General

1. gram negative rod 0.3-0.9 x 2-20 um
2. usually motile
3. Ten(10) species determined by 1984 (Legionella symposium) nine(9) of which had been implicated in human disease (legionellosis)
4. More than one serogroup in some species
5. Incubation is at 35C for 4-7 days in a humid environment usually requiring 2.5% CO_2

B. Nomenclature

1. Partial list of species
   * a. L.pneumophilia(pneumonia;also called Legionnaires disease;less severe infection termed Pontiac Fever)
   b. L. bozemanii pneumonia)
   c. L. micdadei (pneumonia)
   * d. L. dumoffii (pneumonia)
   * e. L. gormanii (pneumonia)
   f. L. longbeachae (?)
   * g. L. jordanis (pneumonia)
   * h. L. oakridgensis (not implicated)
   i. L. wadsworthii (pneumonia)
   * j. L. feelii (Pontiac Fever)

2. Species a,d,e,g,h and j have been isolated from environmental sources (water and soil)

C. Habitats

1. Pertaining to our areas of interest
   a. water heaters, especially those at low temperatures (<55C)
   b. water storage tanks
   c. potable water distribution outlets
      1. shower heads
      2. faucets
      3. showers
   d. evaporator condensers
   e. air compressor lines (at water separator)
   f. "dead legs" in piping

D. Ecological interactions

1. Interaction with other organisms

   a. Studies indicate L. pneumophilia may derive many of its nutritional requirements from various species of green and blue-green algae. This may help explain the preponderance of Legionellae in cooling towers where conditions favoring algal growth i.e. direct or indirect sunlight, warmth and moisture are present. Dissemination of the organism in aerosols may also be enhanced by protection from desiccation due to the mucilage produced by the algae.

   b. L. pneumophilia has been shown to grow intracellularly in some freshwater protozoans such as tetrahymena pyriformis which normally feed on bacteria. In this way the bacteria are protected from certain environmental factors.

   c. Certain species of the bacteria also appear to grow within vacuoles of ameba ubiquitous to the same aquatic environment and therefore may also protected as above.

E. Sampling from Environmental Sites

1. Water

a. The volume of water sampled is dependent on site
   1. Potable water sources including holding tanks, cooling tower blowdowns and circulating pumps require at least 2-3 one(1) liter volumes
   2. Water condensers require about 3 one hundred (100) ml. volumes
   3. Other sites must be assessed individually based on probability of isolation

b. All samples should be collected in sterile polypropylene containers

c. Potable water from faucets should be collected after allowing steady flow for two(2) minutes

d. Samples are processed within 30 hours

2. Air

The ability of legionellae to survive in aerosols generated from evaporative condensers, cooling towers, etc. indicates that sampling at any aerosol generating site should be considered.

a. Methods

   1. The use of an air sampler such as a six-stage Andersen unit at a rate of 0.0283 cubic millimeters per minute for 10 minutes (ambient air) up to 24 minutes (air/water lines). In general, a selective media for air impact is not recommended but is necessary here to reduce background organisms. Examples of such media are listed below.

   2. A glass impinger containing 0.25% yeast extract set to collect air at a rate of 0.0108 cubic millimeters per minute for 10 minutes may also be considered. The broth can be stained by direct fluorescence antibody procedures and plated on a selective media for examination of legionella-like organisms.

F. Isolation from Environmental Sites

1. A variety of isolation techniques have been used to select for Legionellae from environmental sources by reducing the number of background organisms.

   a. Buffered charcoal-yeast extract (BCYE) agar containing a-ketoglutarate
   b. BCYE supplemented with antibiotics
   c. BCYE containing cysteine and ferric pyrophosphate
   d. Acid pretreatment of the water sample
   e. Heat pretreatment of the water sample
   f. Any combination of the above

2. Although useful for initial isolation , only a and c should be considered for subculturing, as some studies have shown even 24 hour cultures become sensitive to these procedures

3. Incubation time requires 4-7 days

G. Identification

Procedures involved in the identification of Legionellae include both colonial characterization and specific antigen-antibody responses.

1. Colony Characterization
   a. Colonies are presumptively identified on selective media by their ground glass appearance
   b. Their specific requirement for L-cysteine is used as a determinant i.e. will only see a colony on media containing a cysteine source

2. Antigen-Antibody Reactions

   a. Based primarily on F.1.b., isolates are confirmed by direct fluorescent monoclonal antibody assays for L. pneumophilia
   b. Other Legionellae species and serogrouping within all species requires a polyclonal antibody not commercially available

3. Because of the unusual abundance of branched-chain fatty acids, a library of known Legionellae species fatty acid profiles may serve as a basis for the separation from non-legionella organisms as well as differentiation within the genus

H. Environmental Control

The detection of Legionellae does not necessarily mean it is also a reservoir for the organism. The ability to infect is dependent upon concentrations of the bacteria usually in the form of aerosols. Regardless, strategies can be employed to reduce the possibility of supporting its growth.

1. Material/Design
   a. Dead legs in piping or any area of stasis will increase the ability of the bacteria to grow
   b. Some investigators have found rubber gaskets in shower heads, tap faucets and fittings to harbor legionellae even after chlorination procedures because of the inability to reach these areas adequately. Replacement with inert materials discourage initial colonization in these areas

2. Disinfection
   a. Because legionellae has shown a symbiotic existence with other organisms standard methods such as chlorination to reduce these organisms will also affect growth of the bacteria
   b. Ultraviolet(UV.) light is effective in removing legionellae from water sources and would be of greatest use in areas of low flow or stasis
   c. Because low hot water temperatures (38-46C) favor colonization of legionellae elevation to 70C will eliminate most if not all activity. Even at a temperature of 60-63C the electron transport system of the organism is compromised

3.6.2 AIDS

Testing of the HIV (AIDS) Virus in Hygiene Loop Studies

Routine monitoring for the AIDS virus from the various ECLSS sources is not recommended for the following reasons:

A. The virus is transmissible through very limited means

1. Sexual intercourse with an infected person
2. Blood contamination including transfusion and the sharing of needles, razors, etc. by drug users
3. Passage from an infected mother to her fetus or through breastmilk

B. The virus is infectious in only certain body fluids

1. Blood
2. Semen and vaginal secretions
3. Breast milk

C. The virus is environmentally unstable

D. There is no evidence supporting the transmission of AIDS through any of the following routes:

1. Coughing
2. Sneezing
3. Sweat exposure
4. Saliva exposure
5. Teardrop exposure
6. Urine exposure

E. Studies of transmission of the virus to close but non-sexual contacts of AIDS patients living in the same household and sharing household items, facilities and washing items continue to support the absence of transmission of the virus in this setting

F. The virus is extremely sensitive to commonly used disinfectants including household bleach at a 1:10 dilution, alcohol, hydrogen peroxide, paraformaldehyde and heat (56C for 10min.)

G. The virus has only been recovered from blood or serum and commercial test kits are designed to look for antibody to the virus in these fluids. No other sources have been recognized by the Center for Disease Control (CDC) as viable recovery sites

3.7 Determine what parameters should be determined on a real-time, near real-time and delayed time basis in order to drink the potable water or to use the hygiene water.

Table 3-9 illustrates the analysis frequency possible for water quality verification. These are optimum frequencies possible and are directly related to laboratory equipment available, number of samples collected and number of qualified laboratory personnel available.

3.8 Explain what value results obtained from real time monitoring will provide in determining whether the water is usable.

Results obtained from real time (on line) monitoring will provide little information toward verifying water quality (due to low sensitivity and limited parameters currently available). It will, however, be useful in the operation of the reclamation system and identification of upset conditions.

3.9 Development and justify comprehensive air/water quality requirements for recycled air and water.

Recommendations concerning air/water quality requirements were made and a delineation of specific requirements were outlined by three general categories. A current listing of these compounds are presented at the end of this section.

3.7.1 Primary Requirements

3.7.2 Secondary Requirements

3.7.3 Mission Specific Requirements

3.10 Determine the short and long term effects of toxicants.

Not fully addressed at this time.

Table 3-1

WATER QUALITY REQUIREMENTS

QUALITY PARAMETERS	POTABLE	HYGIENE
PHYSICAL PARAMETERS		
TOTAL SOLIDS (mg/l)	100	500
COLOR, TRUE (Pt/Co units)	15	15
TASTE & ODOR (TTN/TON)	3	3
PARTICULATES (max size-microns)	40	40
pH	6.0-8.0	5.0-8.0
TURBIDITY (NTU)	1	1
DISSOLVED GAS (free @ 35°F)	None	TBD
FREE GAS (@ STP)	None	TBD
INORGANIC CONSTITUENTS (mg/l)		
AMMONIA	0.5	0.5
ARSENIC	0.01	0.01
BARIUM	1.0	1.0
CADMIUM	0.01	0.01
CALCIUM	30	30
CHLORIDE	250	250
CHROMIUM	0.05	0.05
COPPER	1.0	1.0
IODINE (TOTAL)	15	15
IRON	0.3	0.3
LEAD	0.05	0.05
MAGNESIUM	50	50
MANGANESE	0.05	0.05
MERCURY	0.002	0.002
NICKEL	0.05	0.05
NITRATE (NO3-N)	10	10
POTASSIUM	340	340
SELENIUM	0.01	0.01
SILVER	0.05	0.05
SULFATE	250	250
SULFIDE	0.05	0.05
ZINC	5.0	5.0
BACTERICIDE (mg/l)		
RESIDUAL IODINE (minimum)	0.5	0.5
RESIDUAL IODINE (maximum)	4.0	6.0

WATER QUALITY REQUIREMENTS (continued)

QUALITY PARAMETERS	POTABLE	HYGIENE
AESTHETICS (mg/l)		
CATIONS	30	--
ANIONS	30	--
CO2	15	--
MICROBIAL		
BACTERIA (CFU/100ml)		
TOTAL COUNT	1	1
ANAEROBES	1	1
AEROBES	1	1
GRAM NEGATIVE	1	1
GRAM POSITIVE	1	1
E-COLI	1	1
ENTERIC	1	1
VIRUS (PFU/100ml)	1	1
YEAST & MOLD (CFU/100ml)	1	1
RADIOACTIVE CONSTITUENTS (pCi/l)	Note 1	TBD
ORGANIC PARAMETERS (ug/l)		
TOTAL ACIDS	500	TBD
CYANIDE	200	TBD
HALOGENATED HYDROCARBONS	10	TBD
PHENOLS	1	1
TOC (Less Non-Toxicants)	100	1,000
TOTAL ALCOHOLS	500	TBD
TOTAL ORGANIC CARBON (TOC)	500	10,000
ORGANIC CONSTITUENTS (mg/l)		
SPECIFIC TOXICANTS	TBD	TBD

Note 1: The maximum contaminant levels for radioactive material in potable and personal hygiene water shall conform to Nuclear Regulatory Commission (NRC) regulations (10CFR20, et al.) for control of dose to the public from the extant 1200+ man-made radionuclides. These maximum contaminant levels are listed in the Federal Register, Vol. 51, No. 6, 1986, Appendix B, as Table 2 (Reference Level Concentrations) Column 2 (Water).

Table 3-2

SPECIFIC TOXICANTS

PRIMARY REQUIREMENTS

	Compound	Source	Amt detected
	VOLATILES		
*	Acetyl benzene	1	16 (20ppb est amt)
		3	30
	Acrolein		
	Acrylonitrile		
	Alkylbenzene	4	50
	Benzene		
*	Bromochloromethane	1	500
*	Bromochloropropane	1	500
	Bromoform		
	Bromomethane	1	100
	dibromomethane	3	10
	Bromodichloromethane		
	Carbontetrachloride		
	Chlorobenzene	3	5
	Chlorodibromomethane		
	Chloroethane		
	2-chloroethyl vinyl ether		
	Chloroform	4	10
		3	4
	Chloromethane	1	100
	Dibromochloromethane		
*	Dichlorobutane	1	500
	1,1-dichloroethane		
	1,2-dichloroethane		
	1,1-dichloroethylene		
	trans 1,2-dichloroethylene		
*	Dichlorofluoromethane	1	50
	1,2-dichloropropane		
	1,3-dichloropropene	1	100
	1,2-dichloropropylene		
*	Dimethylbenzene-methanamine	1	230
	ethyl benzene		
	methyl bromide		
	methyl chloride		
	methylene chloride	8	200
	propa-di-ene chloride	4	30
	1,1,2,2-tetrachloroethane		
	tetrachloroethylene		
	toluene		
	1,2-trans-dichloroethylene		
	1,1,1-trichloroethane		
	trichloroethylene		
	trichlorofluoromethane	1	50
	vinyl chloride		

PRIMARY REQUIREMENTS (CONT.)

	Compound	Source	Amt detected	
	ACID COMPOUNDS			
	0-cresol	8	160	
	p-chloro-m-cresol			
	4,6-dinitrocresol			
	phenol	8	150	
		3	3	
	2-chlorophenol			
	dichlorophenol	4	55	
	2,4-dichlorophenol			
	2,4,6-trichlorophenol	1	200	
		4	25	
	pentachlorophenol			
	chloromethylphenol	4	30	
	4-chloro-3-methylphenol			
	2,4-dimethylphenol			
	2-nitrophenol	4	265	
	4-nitrophenol			
	2,4-dinitrophenol			
	2-methyldinitrophenol	1	40	
	methylphenol	4	1000	
*	2-methyl phenol	1	650	
*	4-methyl phenol	1	10	
*	phenol, 2,6-di -t-butyl-4-methyl-	1	16	(20ppb est amt)
*	phenol, 4-(1,1-dimethylethyl)	1	13	
*	phenol cmpds	4	2,200	
*	phenol cmpds (8)	6	600	
*	phenol cmpds (6)	2	275	
*	phenol,2,6-di -t-butyl-4-methyl-	8	150	
	phenol (carbolic acid)	4	460	
	phenol, chloro- adduct	4	100	
	phenol, dichloromethyl	4	100	
	phenol, t-butyl	4	150	

PRIMARY REQUIREMENTS (CONT.)

Compound	Source	Amt Det.
BASE/NEUTRALS		
acenaphthene	1	100
acenaphthylene		
anthracene		
benzidine		
benzo-a-anthracene		
benzo-a-pyrene	1	100
benzo-b-fluoranthene		
3,4-benzofluoranthene		
benzo(g,h,i)perylene		
benzo(k)fluoranthene	1	40
bis(2-chloro ethoxy)methane		
bis(2-chloroethyl)ether		
bis(2-chloroisopropyl)ether		
4-bromophenyl phenyl ether		
butylbenzyl phthalate		
2-chloro naphthalene		
4-chlorophenyl phenyl ether		
chrysene	1	100
dibenzo(a,h)anthracene		
1,2-dichlorobenzene		
1,3-dichlorobenzene		
1,4-dichlorobenzene		
3,3'-dichlorobenzidine		
diethyl phthalate	1	200
dimethyl phthalate	1	240
di-n-butyl phthalate	1	9
2,4-dinitro toluene		
2,6-dinitro toluene		
di-n-octyl phthalate		
1,2-diphenylhydrazine (as azobenzene)		
flouranthene		
fluorene		
hexachlorobenzene		
hexachlorobutadiene		
hexachlorocyclopentadiene		
hexachloroethane		
indeno(1,2,3-od)pyrene		
isophorone		
* 2-methyl naphthalene	1	40
naphthalene	1	100
nitrobenzene		
N-nitrosodimethylamine		
N-nitrosodi-n-propylamine		
N-nitrosodiphenylamine		
phenanthrene		

PRIMARY REQUIREMENTS (CONT.)

Compound	Source	Amt Det.
BASE/NEUTRALS (CONT.)		
• phthalate, diethyl pentyl-	1	49
• phthalate esters (2)	6	350
• phthalate esters	1	140-15,000
phthalate ester cmpds (4)	3	75
phthalate ester cmpds (3)	8	20
• phthalate, bis(2-ethyl hexyl)-	8	103
• phthalate, bis(2-ethyl hexyl)-	1	4600
pyrene		
1,2,4-trichlorobenzene		
2,3,7,8-tetrachlorodibenzo-p-dioxin		
PESTICIDE COMPOUNDS		
Aldrin		
alpha-BHC		
beta-BHC		
gamma-BHC		
delta-BHC		
chlorodane		
4,4'-DDD		
4,4'-DDE		
4,4'-DDT		
dieldrin		
endosulfan I		
endosulfan II		
endosulfan sulfate		
endrin		
endrin aldehyde		
heptachlor		
heptachlorepoxide		
toxaphene		
PCB-1016		
PCB-1221		
PCB-1232		
PCB-1242		
PCB-1248		
PCB-1254		
PCB-1260		

TABLE 3-3

STATE OF ALABAMA

DRINKING WATER STANDARDS

Primary Standards

Inorganics		
Arsenic	.05	mg/l
Barium	1.0	mg/l
Cadmium	0.01	mg/l
Chromium	0.05	mg/l
Lead	0.05	mg/l
Mercury	0.002	mg/l
Nitrate	10.0	mg/l
Selenium	0.01	mg/l
Silver	0.05	mg/l
Fluoride	4.0	mg/l
Organics		
Endrin	.0002	mg/l
Lindane	.004	mg/l
Methoxy	0.1	mg/l
Toxaphene	.005	mg/l
2,4 D	0.1	mg/l
2,4,5,TP Silvex	0.01	mg/l
Trihalomethanes	0.1	mg/l
Volatile Organic Carbons		
Benzene	5	ug/l
1,4 dichlorobenzene	75	ug/l
Carbontetrachloride	5	ug/l
1,2 dichloroethane	5	ug/l
1,1 dichloroethylene	7	ug/l
Trichloroethylene	5	ug/l
Vinyl chloride	2	ug/l
1,1,1 trichlorethene	200	ug/l

Secondary Standards

Chloride	250	mg/l
Color	15	NTU
Copper	1	mg/l
Iron	0.3	mg/l
Manganese	0.5	mg/l
Sulfate	250	mg/l
Total Dissolved Solids	500	mg/l
Zinc	5.0	mg/l

TABLE 3-4

RECOMMENDATIONS FOR MONITORING

PHYSICAL

- CONDUCTIVITY
- COLOR
- pH
- TURBIDITY

INORGANIC

Non-Metals

- Ammonia
- Chloride
- Bromide
- Iodide
- Nitrate
- Phosphate
- Sulfate

Metals

- Arsenic
- Barium
- Cadmium
- Chromium
- Copper
- Iron
- Lead
- Manganese
- Mercury
- Selenium
- Silver
- Zinc

ORGANICS

- CYANIDE
- TOC
- TOX
- Total Toxic Organics (TTO)

MICROBIOLOGICAL

- TOTAL BACTERIA
- TOTAL COLIFORMS
- HETEROTROPHS
- NON-SAPROPHYTIC

TABLE 3-5

METHODS AND INSTRUMENTATION FOR WATER QUALITY VERIFICATION

PARAMETER	METHOD	INSTRUMENTATION
PHYSICAL		
CONDUCTIVITY	EPA 120.1	Cond. Meter
COLOR	EPA 110.3	UV-VIS
pH	EPA 150	pH Meter
TURBIDITY	EPA 180	Nephelometer
INORGANIC		
Non-Metals		
Ammonia	EPA 350.2	UV-VIS
Chloride	EPA 300.0	Ion Chromatograph
Bromide	EPA 300.0	Ion Chromatograph
Iodide	EPA 300.0	Ion Chromatograph
Nitrate	EPA 300.0	Ion Chromatograph
Nitrogen, Total	EPA 351.3	UV-VIS
Phosphate	EPA 300.0	Ion Chromatograph
Sulfate	EPA 300.0	Ion Chromatograph
Metals		
Arsenic	EPA 206.3	AAH
Barium	EPA 200.7	ICP
Cadmium	EPA 213.2	AAG
Chromium	EPA 200.7	ICP
Copper	EPA 200.7	ICP
Iron	EPA 200.7	ICP
Lead	EPA 239.2	AAG
Magnesium	EPA 200.7	ICP
Manganese	EPA 200.7	ICP
Mercury	EPA 245.1	Hg Analyzer
Nickel	EPA 249.2	AAG
Potassium	EPA 258.1	AAF
Selenium	EPA 270.3	AAH
Silver	EPA 272.2	AAG
Zinc	EPA 200.7	ICP
ORGANICS		
Cyanide	EPA 335.2	UV-VIS
Halogenated Hydrocarbon	EPA 612	GC/ECD
Organic Acids		HPLC
Organic Alcohols		HPLC
Pesticides	EPA 608	GC/ECD
Phenols	EPA 604	GC/FID
TOC	EPA 415.2	TOC Analyzer
Total Toxic Organics	EPA 624, 625	GC/MS

TABLE 3-6

MICROBIOLOGICAL REQUIREMENTS

Drinking Water

State of Alabama

Total Coliforms	<4 CFU/100 ML
Fecal Coliforms	<1 CFU/100 ML

Recreational Waters

American Public Health Association

Total Plate Count	<100 CFU/ML
Turbidity	1 NTU

TABLE 3-7

RECOMMENDATIONS FOR MICROBIOLOGICAL MONITORING

BACTERIA

- TOTAL BACTERIA
- TOTAL COLIFORMS
- HETEROTROPHS
- NON-SAPROPHYTIC
- LEGIONELLAE

FUNGI AND YEAST

VIRUSES

To Be Determined

TABLE 3-8

METHODS FOR ENUMERATION

VIABLE PLATE COUNTS	18-120	HOURS
DIRECT MICROSCOPIC COUNTS	4	HOURS
FLUORESCENCE MICROSCOPY	6	HOURS
SCANNING ELECTRON MICROSCOPY	8-12	HOURS
PARTICLE COUNTS	4	HOURS

RECOMMENDATION:

FLUORESCENCE MICROSCOPY

REQUIREMENTS:

APPROXIMATELY $4,000 UPGRADE OF PHASE MICROSCOPE AND 4 MAN-MONTHS LABOR

TABLE 3-9

SAMPLING FREQUENCY REQUIRED FOR WATER QUALITY VERIFICATION

PARAMETERS	REAL-TIME	NEAR REAL TIME	DELAYED (24 HRS)
PHYSICAL			
Conductivity	X	X	X
Color		X	X
pH	X	X	X
Turbidity	X	X	X
INORGANIC			
Non-Metals			
Ammonia		X	X
Chloride		X	X
Bromide		X	X
Iodide		X	X
Nitrate		X	X
Phosphate		X	X
Sulfate		X	X
Metals			
Arsenic		X	X
Barium		X	X
Cadmium		X	X
Chromium		X	X
Copper		X	X
Iron		X	X
Lead		X	X
Manganese		X	X
Mercury		X	X
Selenium		X	X
Silver		X	X
Zinc		X	X
ORGANICS			
Cyanide		X	X
TOC	X	X	X
TOX		X	X
Total Toxic Organics (TTO)		X	X
BACTERIA			
Total Bacteria		X	X
Total Coliforms			X
Heterotrophs			X
Non-Saprophytic Legionellae			X
FUNGI AND YEAST			

SPECIFIC TOXICANTS

PRIMARY REQUIREMENTS

	Compound	Source	Amt detected
	VOLATILES		
*	Acetyl benzene	1	16
	Acrolein		
	Acrylonitrile		
	Benzene		
*	Bromochloromethane	1	500
*	Bromochloropropane	1	500
	Bromoform		
	Bromomethane	1	100
	Bromodichloromethane		
	Carbontetrachloride		
	Chlorobenzene		
	Chlorodibromomethane		
	Chloroethane		
	2-chloroethyl vinyl ether		
	Chloroform		
	Chloromethane	1	100
	Dibromochloromethane		
*	Dichlorobutane	1	500
	1,1-dichloroethane		
	1,2-dichloroethane		
	1,1-dichloroethylene		
	trans 1,2-dichloroethylene		
*	Dichlorofluoromethane	1	50
	1,2-dichloropropane		
	1,3-dichloropropene	1	100
	1,2-dichloropropylene		
*	Dimethylbenzene-methanamine	1	230
	ethyl benzene		
	methyl bromide		
	methyl chloride		
	methylene chloride		
	1,1,2,2-tetrachloroethane		
	tetrachloroethylene		
	toluene		
	1,2-trans-dichloroethylene		
	1,1,1-trichloroethane		
	trichloroethylene		
	trichlorofluoromethane	1	50
	vinyl chloride		

PRIMARY REQUIREMENTS (CONT.)

	Compound	Source	Amt detected
	ACID COMPOUNDS		
	p-chloro-m-cresol		
	4,6-dinitrocresol		
	phenol		
	2-chlorophenol		
	2,4-dichlorophenol		
	2,4,6-trichlorophenol	1	200
	pentachlorophenol		
	4-chloro-3-methylphenol		
	2,4-dimethylphenol		
	2-nitrophenol		
	4-nitrophenol		
	2,4-dinitrophenol		
	2-methyldinitrophenol	1	40
*	2-methyl phenol	1	650
*	4-methyl phenol	1	10
*	phenol, 2,6-di -t-butyl-4-methyl-	1	16
*	phenol, 4-(1,1-dimethylethyl)	1	13
*	phenol cmpds	4	2,200
*	phenol cmpds (8)	6	600
*	phenol cmpds (6)	2	275
*	phenol,2,6-di -t-butyl-4-methyl-	8	150

PRIMARY REQUIREMENTS (CONT.)

Compound	Source	Amt Det.
acenaphthene	1	100
acenaphthylene		
anthracene		
benzidine		
benzo-a-anthracene		
benzo-a-pyrene	1	100
benzo-b-fluoranthene		
3,4-benzofluoranthene		
benzo(g,h,i)perylene		
benzo(k)fluoranthene	1	40
bis(2-chloro ethoxy)methane		
bis(2-chloroethyl)ether		
bis(2-chloroisopropyl)ether		
bis(2-ethylhexyl)phthalate	8	103
4-bromophenyl phenyl ether		
butylbenzyl phthalate		
2-chloro naphthalene		
4-chlorophenyl phenyl ether		
chrysene	1	100
dibenzo(a,h)anthracene		
1,2-dichlorobenzene		
1,3-dichlorobenzene		
1,4-dichlorobenzene		
3,3'-dichlorobenzidine		
diethyl phthalate		
dimethyl phthalate		
di-n-butyl phthalate		
2,4-dinitro toluene		
2,6-dinitro toluene		
di-n-octyl phthalate		
1,2-diphenylhydrazine (as azobenzene)		
flouranthene		
fluorene		
hexachlorobenzene		
hexachlorobutadiene		
hexachlorocyclopentadiene		
hexachloroethane		
indeno(1,2,3-od)pyrene		
isophorone		
* 2-methyl naphthalene	1	40
naphthalene	1	100
nitrobenzene		
N-nitrosodimethylamine		
N-nitrosodi-n-propylamine		
N-nitrosodiphenylamine		
phenanthrene		
• phthalate, diethyl pentyl-	1	49
• phthalate esters (2)	6	350
• phthalate esters	1	140-15,000
* phthalate, bis(2-ethyl hexyl)-	8	103
pyrene		
1,2,4-trichlorobenzene		
2,3,7,8-tetrachlorodibenzo-p-dioxin		

PESTICIDE COMPOUNDS

Aldrin
alpha-BHC
beta-BHC
gamma-BHC
delta-BHC
chlorodane
4,4'-DDD
4,4'-DDE
4,4'-DDT
dieldrin
endosulfan I
endosulfan II
endosulfan sulfate
endrin
endrin aldehyde
heptachlor
heptachlorepoxide
toxaphene
PCB-1016
PCB-1221
PCB-1232
PCB-1242
PCB-1248
PCB-1254
PCB-1260

SECONDARY REQUIREMENTS

Compound	Source		Amt.	Toxicity
Acetic Acid	5		300	orl hmn TDLo 1470 ug GIT ihl hmn TDLo 816ppm/3min
acetic acid, phenyl	4		400	
acetate, ethanol ethoxy	1		180	
acetate, vinyl	1		50	
acetone	3		3300	orl hmn TCLo 500ppm Eye
diacetone alcohol	1		19ppb	
acetone cmpds (2)	4		250ppb	
acrylate, 3-methoxy-butyl	3		130ppm	
azepin-2-one, hexahydro	1	SL1	73ppb	
	1	SL3	4.3ppm	
aniline	1		20ppb	
2-nitroaniline	1		200ppb	
3-nitroaniline	1		200ppb	
4-nitroaniline	1		200ppb	
Adipic Acid				orl rat LDLo 3600mg
adipate, tetramethylene	1		6ppb	
amide, butyl benzenesulfon	1		6ppb	
amide, N,n-di-n-butylform-	1		60ppb	
amide, N-methyl-N-ethyl form-	1		1,103ppb	
4-chloroaniline	1		100ppb	
amide, N,n-dimethyl form-	1		541ppb	
amides (4)	1		3190ppb	
amides (2)	2		400ppb	
amine, dimethyl				orl rat LD_{50} 698mg
amine, N,n-dimethyl benzyl-	1		80ppb	
amine, di-n-butyl	1		74ppb	
amines (2)	1		200ppb	
alcohol cmpds (2)	3		5000ppb	
alkene ($C_{29}H_{58}$)	3		10ppb	
Butyric Acid				orl rat LD_{50} 2940mg
butyrates, 3-hydroxy -trimethylpentyliso	1		300ppb	
1-butanamine, n-butyl-	1		180ppb	
butanoate,2 methoxymethyl-2-	1		55ppb	
2-butanone	1		900ppb	
butanone, 3-methyl-2-	1		60ppb	
benzoic acid	1		500ppb	orl rat LD_{50} 3040mg
	3		848ppb	
benzoic acid cmpds (2)	4		3000ppb	
	6		150ppb	
benzaldehyde	3		1000ppb	orl rat LD_{50} 1300mg
benzaldehyde cmpds (3)	4		150ppb	
benzyl alcohol	1		4700ppb	orl rat LD_{50} 1330mg
benzisoxazole	1		100ppb	

SECONDARY REQUIREMENTS (CONT.)

Compound	Source	Amt.	Toxicity
caprylic acid	1	273ppb	ivn mus LD_{50} 600mg
cyanurate, triallyliso-	1	12ppb	
carboxylic acids	4	40,800ppb	
carboxylic acids	2	92,210ppb	
carboxylic acids	3	81,500ppb	
carboxylic acids (5)	7	3,500ppb	
carboxylic acid cmpds (4)	6	52,000ppb	
carboxylic acids (5)	1	43,000ppb	
unknown carboxylic acids	1	2,633ppb	
Caproic Acid			orl rat LDLo 3000mg
caprolactam	1	15,000ppb	
carbon disulfide	1	14-722ppb	
Decanal			orl rat LD_{50} 3730mg
decan cmpds (2)	4	280ppb	
Dodecyl alcohol			ipr rat LD_{50} 800mg
dodecanol	3	100ppb	
dibenzofuran	1	20	
dimethyl-benzene methanol	1	16ppb	
dioxalane cmpds	3	600ppb	
ether, ethyl propyl	1	34ppb	
ether, ethylene glycol monobutyl-	1	100ppb	
ether, p-chlorophenyl methoxyisobutyl	4	400ppb	
ethers, glycol (2)	1	550ppb	
	3	900ppb	
furfuryl alcohol	5	200	orl rat LD_{50} 275mg
Heptanoic Acid			orl mus LD_{50} 160mg
4-heptanone	6	100ppb	
heptanone cmpds (2)	4	60ppb	
Hexanol			orl rat LD_{50} 720mg
hexanol, 2-ethyl-1-	6	100ppb	
hexanol, 5-methyl-1-	1	150ppb	
2-hexanone	1	50ppb	
cyclohexanone	1	35ppb	
isophorone	1	3ppb	
lactone cmpds	3	130ppb	
morpholine, 4-ethyl	1	470ppb	
morpholine, n-ethyl	1	400ppb	
nonanedioate, bis(2-ethyl hexyl)-	1	1,100ppb	
nonanedioic acid	1	6ppb	
octanoate, methyl-	3	200ppb	

SECONDARY REQUIREMENTS (CONT.)

Compound	Source	Amt.	Toxicity
palmitic acid	7	10	ivn mus LD_{50} 57mg
pentane, 2,3-dimethyl-	1	50	
pentane, 2,2,4-trimethyl-	1	100	
4-methyl-2-pentanone	1	50	
2-methyl-2,4-pentanediol	1	410	
pentene, 4,4-dimethyl-1-	1	100	
phosphate, diethyl pentyl-	1	67	
phosphate, triethyl-	1	12	
phosphate, tertamethylpyro-	1	2	
phosphate, tetramethylpyro-	2	100	
1-propene	1	100	
propionic acid	1	6,000-17,222	orl rat LD_{50} 1510mg
propylene glycol	1	300	
Pyrrolidine			orl rat LD_{50} 800mg
pyrrolidine, N-methyl-	1	71	
pyrrolidone	1	100	
styrene	1	50	ihn hmn TCLo 376ppm
salicylic acid	6	350000	orl rat LD_{50} 891mg
thiophene, tetrahydro-1,1-dioxide	1	15	
thiourea	1	300-500	
thiourea, tetramethyl	1	35	
urea	1	<16,000	
Undecanoic Acid			ivn mus LD_{50} 140mg
n-undecane	4	200	
vanillan	6	200	orl rat LD_{50} 1580mg
Xylenol			orl mus LD_{50} 1070mg
xylenes, total	1	50	

4.0 Assist in determining the design specifications required as related to the Technical Demonstration Program

This topic has not been addressed.

5.0 Develop data base of all microorganisms recovered from previous subsystem testing

This topic was not addressed. An outline is presented below indicating pertinent areas which must be defined.

5.1 Biochemical Characterization of Unknowns

5.2 Identification of Prcsumptive Organisms

5.3 FAME profiling of isolates

5.4 Establish data base of isolates with respect to source

5.5 Identify isolates which potentially represent health risks

5.6 Characterize isolates based on susceptibly/resistance to antimicrobials

6.0 Estimates of health risk of individual microbes to test subjects

This topic was not addressed. The completion of 5.0 above must first be completed.

7.0 Assist with setting limits for safety of test subjects

This topic was addressed in 3.0 above.

8.0 Health monitoring of test subjects

8.1 Delineation of parameters to monitor well subjects

This topic was addressed in 2.15 above.

8.2 Guidelines for managing sick subjects

This topic was addressed in 2.16 above.

9.0 Assist in the preparation of test plans

9.1 Microbiological

This topic was in progress when funding ran out.

9.2 Chemical

This topic was not addressed.

10.0 Assist in the development of a QA/QC program to assure the validity, accuracy and precision of the analyses

This topic was not addressed but is related to both 9.1 and 9.2 above.

11.0 Assist in developing test plans required for future "man in the loop" testing

This topic was not addressed.

APPENDIX F
Supporting Documents

OPRR Reports

NIH PHS HHS

PROTECTION OF HUMAN SUBJECTS

CODE OF FEDERAL REGULATIONS

45 CFR 46

Revised as of March 8, 1983

NATIONAL RESEARCH ACT
PUBLIC LAW 93-348
JULY 12, 1974

INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM

SEC. 212. (a) Part I of title IV of the Public Health Service Act, as amended by section 103 of this Act, is amended by adding at the end the following new section:

"INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM

"SEC. 474. (a) The Secretary shall by regulation require that each entity which applies for a grant or contract under this Act for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant or contract assurances satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an 'Institutional Review Board') to review biomedical and behavioral research involving human subjects conducted at or sponsored by such entity in order to protect the rights of the human subjects of such research.

"(b) The Secretary shall establish a program within the Department under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately."

(b) The Secretary of Health, Education, and Welfare shall within 240 days of the date of the enactment of this Act promulgate such regulations as may be required to carry out section 474(a) of the Public Health Service Act. Such regulations shall apply with respect to applications for grants and contracts under such Act submitted after promulgation of such regulations.

THE CODE OF FEDERAL REGULATIONS,
45 CFR 46, IMPLEMENTS THESE AMENDMENTS
TO THE PUBLIC HEALTH SERVICE ACT.

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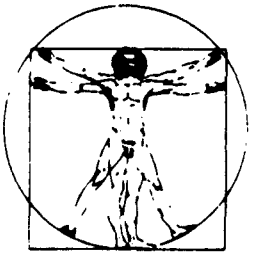
CODE OF FEDERAL REGULATIONS

TITLE 45
PUBLIC WELFARE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
OFFICE FOR PROTECTION FROM RESEARCH RISKS



PART 46—PROTECTION OF HUMAN SUBJECTS
REVISED AS OF MARCH 8, 1983

PART 46—PROTECTION OF HUMAN SUBJECTS

Subpart A—Basic HHS Policy for Protection of Human Research Subjects

Subpart B—Additional Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization

Subpart C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

Subpart D—Additional Protections for Children Involved as Subjects in Research

Authority: 5 U.S.C. 301; sec. 474(a), 88 Stat. 352 (42 U.S.C. 289*l*-3(a)).

Subpart A—Basic HHS Policy for Protection of Human Research Subjects

Source: 46 FR 8386, January 26, 1981, 48 FR 9269, March 4, 1983.

§ 46.101 To what do these regulations apply?

(a) Except as provided in paragraph (b) of this section, this subpart applies to all research involving human subjects conducted by the Department of Health and Human Services or funded in whole or in part by a Department grant, contract, cooperative agreement or fellowship.

(1) This includes research conducted by Department employees, except each Principal Operating Component head may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or funded by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (e) of this section waive the applicability of some or all of the requirements of these regulations for research of this type.

(b) Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from these regulations unless the research is covered by other subparts of this part:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if

information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(3) Research involving survey or interview procedures, except where all of the following conditions exist: (i) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (ii) the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (iii) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. All research involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.

(4) Research involving the observation (including observation by participants) of public behavior, except where all of the following conditions exist: (i) observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, (ii) the observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and (iii) the research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

(5) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(6) Unless specifically required by statute (and except to the extent specified in paragraph (i)), research and demonstration projects which are conducted by or subject to the approval of the Department of Health and Human Services, and which are designed to study, evaluate, or otherwise examine: (i) programs under the Social Security Act, or other public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(c) The Secretary has final authority to determine whether a particular activity is covered by these regulations.

(d) The Secretary may require that specific research activities or classes of research activities conducted or funded by the Department, but not otherwise covered by these regulations, comply with some or all of these regulations.

(e) The Secretary may also waive applicability of these regulations to specific research activities or classes of research activities, otherwise covered by these regulations. Notices of these actions will be published in the *Federal Register* as they occur.

(f) No individual may receive Department funding for research covered by these regulations unless the individual is affiliated with or sponsored by an institution which assumes responsibility for the research under an assurance satisfying the requirements of this part, or the individual makes other arrangements with the Department.

(g) Compliance with these regulations will in no way render inapplicable pertinent federal, state, or local laws or regulations.

(h) Each subpart of these regulations contains a separate section describing to what the subpart applies. Research which is covered by more than one subpart shall comply with all applicable subparts.

(i) If, following review of proposed research activities that are exempt from these regulations under paragraph (b)(6), the Secretary determines that a research or demonstration project presents a danger to the physical, mental, or emotional well-being of a participant or subject of the research or demonstration project, then federal funds may not be expended for such a project without the written, informed consent of each participant or subject.

§ 46.102 Definitions.

(a) "Secretary" means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(b) "Department" or "HHS" means the Department of Health and Human Services.

(c) "Institution" means any public or private entity or agency (including federal, state, and other agencies).

(d) "Legally authorized representative" means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(e) "Research" means a systematic investigation designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute "research" for purposes of these regulations, whether or not they are supported or funded under a program which is considered research for other purposes. For example, some "demonstration" and "service" programs may include research activities.

(f) "Human subject" means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. "Intervention" includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(g) "Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(h) "Certification" means the official notification by the institution to the Department in accordance with the requirements of this part that a research project or activity involving human subjects has been reviewed and approved by the Institutional Review Board (IRB) in accordance with the approved assurance on file at HHS. (Certification is required when the research is funded by the Department and not otherwise exempt in accordance with § 46.101(b)).

§ 46.103 Assurances.

(a) Each institution engaged in research covered by these regulations shall provide written assurance satisfactory to the Secretary that it will comply with the requirements set forth in these regulations.

(b) The Department will conduct or fund research covered by these regulations only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the Secretary that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB. This assurance shall at a minimum include:

(1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of source of funding. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of these regulations applicable to Department-funded research and is not applicable to any research in an exempt category listed in § 46.101.

(2) Designation of one or more IRBs established in accordance with the requirements of this subpart, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

(3) A list of the IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the Secretary.[1]

(4) Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; (iii) for insuring prompt reporting to the IRB of proposed changes in a research activity, and for insuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the subject; and (iv) for insuring prompt reporting to the IRB and to the Secretary[1] of unanticipated problems involving risks to subjects or others.

(c) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by these regulations, and shall be filed in such form and manner as the Secretary may prescribe.

(d) The Secretary will evaluate all assurances submitted in accordance with these regulations through such officers and employees of the Department and such experts or consultants engaged for this purpose as the Secretary determines to be appropriate. The Secretary's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be

[1] Reports should be filed with the Office for Protection from Research Risks, National Institutes of Health, Department of Health and Human Services, Bethesda, Maryland 20205.

involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(e) On the basis of this evaluation, the Secretary may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The Secretary may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

(f) Within 60 days after the date of submission to HHS of an application or proposal, an institution with an approved assurance covering the proposed research shall certify that the application or proposal has been reviewed and approved by the IRB. Other institutions shall certify that the application or proposal has been approved by the IRB within 30 days after receipt of a request for such a certification from the Department. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.

§ 46.104 [Reserved]

§ 46.105 [Reserved]

§ 46.106 [Reserved]

§ 46.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members' backgrounds including consideration of the racial and cultural backgrounds of members and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, including but not limited to subjects covered by other subparts of this part, the IRB shall include one or more individuals who are primarily concerned with the welfare of these subjects.

(b) No IRB may consist entirely of men or entirely of women, or entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in nonscientific areas; for example: lawyers, ethicists, members of the clergy.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participating in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

§ 46.108 IRB functions and operations.

In order to fulfill the requirements of these regulations each IRB shall:

(a) Follow written procedures as provided in § 46.103(b)(4).

(b) Except when an expedited review procedure is used (see § 46.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

(c) Be responsible for reporting to the appropriate institutional officials and the Secretary[1] any serious or continuing noncompliance by investigators with the requirements and determinations of the IRB.

§ 46.109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by these regulations.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with § 46.116. The IRB may require that information, in addition to that specifically mentioned in § 46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with § 46.117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification

[1] Reports should be filed with the Office for Protection from Research Risks, National Institutes of Health, Department of Health and Human Services, Bethesda, Maryland 20205.

a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by these regulations at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

§46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary has established, and published in the *Federal Register*, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, through periodic republication in the *Federal Register*.

(b) An IRB may review some or all of the research appearing on the list through an expedited review procedure, if the research involves no more than minimal risk. The IRB may also use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized. Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in § 46.108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The Secretary may restrict, suspend, or terminate an institution's or IRB's use of the expedited review procedure when necessary to protect the rights or welfare of subjects.

§46.111 Criteria for IRB approval of research.

(a) In order to approve research covered by these regulations the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by § 46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by § 46.117.

(6) Where appropriate, the research plan makes adequate provision for monitoring the data collected to insure the safety of subjects.

(7) Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§ 46.112 Review by institution.

Research covered by these regulations that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§ 46.113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Secretary. [1]

[1] Reports should be filed with the Office for Protection from Research Risks, National Institutes of Health, Department of Health and Human Services, Bethesda, Maryland 20205.

§ 46.114 Cooperative research.

Cooperative research projects are those projects, normally supported through grants, contracts, or similar arrangements, which involve institutions in addition to the grantee or prime contractor (such as a contractor with the grantee, or a subcontractor with the prime contractor). In such instances, the grantee or prime contractor remains responsible to the Department for safeguarding the rights and welfare of human subjects. Also, when cooperating institutions conduct some or all of the research involving some or all of these subjects, each cooperating institution shall comply with these regulations as though it received funds for its participation in the project directly from the Department, except that in complying with these regulations institutions may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort.

§ 46.115 IRB records.

(a) An institution, or where appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members as required by § 46.103(b)(3).

(6) Written procedures for the IRB as required by § 46.103(b)(4).

(7) Statements of significant new findings provided to subjects, as required by § 46.116(b)(5).

(b) The records required by this regulation shall be retained for at least 3 years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Department at reasonable times and in a reasonable manner.

§ 46.116 General requirements for informed consent.

Except as provided elsewhere in this or other subparts, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) programs under the Social Security Act, or other public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in these regulations are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in these regulations is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

§ 46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by § 46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A "short form" written consent document stating that the elements of informed consent required by § 46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the "short form."

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

§ 46.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to the Department with the knowledge that subjects may be involved within the

period of funding, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants (including bloc grants) where selection of specific projects is the institution's responsibility; research training grants where the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research described in § 46.101(b), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in these regulations, and certification submitted to the Department.

§ 46.119 Research undertaken without the intention of involving human subjects.

In the event research (conducted or funded by the Department) is undertaken without the intention of involving human subjects, but it is later proposed to use human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in these regulations, a certification submitted to the Department, and final approval given to the proposed change by the Department.

§ 46.120 Evaluation and *disposition of applications and* proposals.

(a) The Secretary will evaluate all applications and proposals involving human subjects submitted to the Department through such officers and employees of the Department and such experts and consultants as the Secretary determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the proposed research to the subjects and others, and the importance of the knowledge to be gained.

(b) On the basis of this evaluation, the Secretary may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§ 46.121 Investigational new drug or device 30-day delay requirement.

When an institution is required to prepare or to submit a certification with an application or proposal under these regulations, and the application or proposal involves an investigational new drug (within the meaning of 21 U.S.C. 355(i) or 357(d)) or a significant risk device (as defined in 21 CFR 812.3(m)), the institution shall identify the drug or device in the certification. The institution shall also state whether the 30-day interval required for investigational new drugs by 21 CFR 312.1(a) and for significant risk devices by 21 CFR 812.30 has elapsed, or whether the Food and Drug Administration has waived that requirement. If the 30-day interval has expired, the institution shall state whether the Food and Drug Administration has requested that the sponsor continue to withhold or restrict the use of the drug or device in human subjects. If the 30-day interval has not expired, and a waiver has not been received, the institution shall send a statement to the Department upon expiration of the interval. The Department will not consider a certification acceptable until the institution has submitted a statement that the 30-day interval has elapsed, and the Food and Drug Administration has not requested it to limit the use of the drug or device, or that the Food and Drug Administration has waived the 30-day interval.

§ 46.122 Use of Federal funds.

Federal funds administered by the Department may not be expended for research involving human subjects unless the requirement of these regulations, including all subparts of these regulations, have been satisfied.

§ 46.123 Early termination of research funding; evaluation of subsequent applications and proposals.

(a) The Secretary may require that Department funding for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the Secretary finds an institution has materially failed to comply with the terms of these regulations.

(b) In making decisions about funding applications or proposals covered by these regulations the Secretary may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person who would direct the scientific and technical aspects of an activity has in the judgment of the Secretary materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not Department funds were involved).

§ 46.124 Conditions.

With respect to any research project or any class of research projects the Secretary may impose additional conditions prior to or at the time of funding when in the Secretary's judgment additional conditions are necessary for the protection of human subjects.

Subpart B—Additional Protections Pertaining to Research Development, and Related Activities Involving Fetuses, Pregnant Women, and Human in Vitro Fertilization

SOURCE: 40 FR 33528, Aug. 8, 1975, 43 FR 1758, January 11, 1978, 43 FR 51559, November 3, 1978

§ 46.201 Applicability.

(a) The regulations in this subpart are applicable to all Department of Health, Education, and Welfare

grants and contract supporting research, development, and related activities involving: (1) The fetus, (2) pregnant women, and (3) human *in vitro* fertilization.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will in any way render inapplicable pertinent State or local laws bearing upon activities covered by this subpart.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.202 Purpose.

It is the purpose of this subpart to provide additional safeguards in reviewing activities to which this subpart is applicable to assure that they conform to appropriate ethical standards and relate to important societal needs.

§ 46.203 Definitions.

As used in this subpart:

(a) "Secretary" means the Secretary of Health, Education, and Welfare and any other officer or employee of the Department of Health, Education, and Welfare to whom authority has been delegated.

(b) "Pregnancy" encompasses the period of time from confirmation of implantation (through any of the presumptive signs of pregnancy, such as missed menses, or by a medically acceptable pregnancy test), until expulsion or extraction of the fetus.

(c) "Fetus" means the product of conception from the time of implantation (as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or a medically acceptable pregnancy test), until a determination is made, following explusion or extraction of the fetus, that it is viable.

(d) "Viable" as it pertains to the fetus means being able, after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heart beat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the FEDERAL REGISTER guidelines to assist in determining whether a fetus is viable for purposes of this subpart. If a fetus is viable after delivery, it is a premature infant.

(e) "Nonviable fetus" means a fetus *ex utero* which, although living, is not viable.

(f) "Dead fetus" means a fetus *ex utero* which exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord (if still attached).

(g) "*In vitro* fertilization" means any fertilization of human ova which occurs outside the body of a female, either through admixture of donor human sperm and ova or by any other means.

§ 46.204 Ethical Advisory Boards.

(a) One or more Ethical Advisory Boards shall be established by the Secretary. Members of these board(s) shall be so selected that the board(s) will be competent to deal with medical, legal, social, ethical, and related issues and may include, for example, research scientists, physicians, psychologists, sociologists, educators, lawyers, and ethicists, as well as representatives of the general public. No board member may be a regular, full-time employee of the Department of Health, Education, and Welfare.

(b) At the request of the Secretary, the Ethical Advisory Board shall render advice consistent with the policies and requirements of this Part as to ethical issues, involving activities covered by this subpart, raised by individual applications or proposals. In addition, upon request by the Secretary, the Board shall render advice as to classes of applications or proposals and general policies, guidelines, and procedures.

(c) A Board may establish, with the approval of the Secretary, classes of applications or proposals which: (1) Must be submitted to the Board, or (2) need not be submitted to the Board. Where the Board so establishes a class of applications or proposals which must be submitted, no application or proposal within the class may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

(d) No application or proposal involving human *in vitro* fertilization may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Ethical Advisory Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

§ 46.205 Additional duties of the Institutional Review Boards in connection with activities involving fetuses, pregnant women, or human in vitro fertilization.

(a) In addition to the responsibilities prescribed for Institutional Review Boards under Subpart A of this part, the applicant's or offeror's Board shall, with respect to activities covered by this subpart, carry out the following additional duties:

(1) Determine that all aspects of the activity meet the requirements of this subpart;

(2) Determine that adequate consideration has been given to the manner in which potential subjects will be selected, and adequate provision has been made by the applicant or offeror for monitoring the actual informed consent process (e.g., through such mechanisms, when appropriate, as participation by the Institutional Review Board or subject advocates in: (i) Overseeing the actual process by which individual consents required by this subpart are secured either by approving induction of each individual into the activity or

verifying, perhaps through sampling, that approved procedures for induction of individuals into the activity are being followed, and (ii) monitoring the progress of the activity and intervening as necessary through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen);

(3) Carry out such other responsibilities as may be assigned by the Secretary.

(b) No award may be issued until the applicant or offeror has certified to the Secretary that the Institutional Review Board has made the determinations required under paragraph (a) of this section and the Secretary has approved these determinations, as provided in § 46.120 of Subpart A of this part.

(c) Applicants or offerors seeking support for activities covered by this subpart must provide for the designation of an Institutional Review Board, subject to approval by the Secretary, where no such Board has been established under Subpart A of this part.

§ 46.206 General limitations.

(a) No activity to which this subpart is applicable may be undertaken unless:

(1) Appropriate studies on animals and nonpregnant individuals have been completed;

(2) Except where the purpose of the activity is to meet the health needs of the mother or the particular fetus, the risk to the fetus is minimal and, in all cases, is the least possible risk for achieving the objectives of the activity.

(3) Individuals engaged in the activity will have no part in: (i) Any decisions as to the timing, method, and procedures used to terminate the pregnancy, and (ii) determining the viability of the fetus at the termination of the pregnancy; and

(4) No procedural changes which may cause greater than minimal risk to the fetus or the pregnant woman will be introduced into the procedure for terminating the pregnancy solely in the interest of the activity.

(b) No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the activity.

[40 FR 33528, Aug. 8, 1975, as amended at 40 FR 51638, Nov. 6, 1975]

§ 46.207 Activities directed toward pregnant women as subjects.

(a) No pregnant woman may be involved as a subject in an activity covered by this subpart unless: (1) The purpose of the activity is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus is minimal.

(b) An activity permitted under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if: (1) The purpose of the activity is to meet the health needs of the mother; (2) his identity or whereabouts cannot reasonably be ascertained; (3) he is not reasonably available; or (4) the pregnancy resulted from rape.

§ 46.208 Activities directed toward fetuses in utero as subjects.

(a) No fetus *in utero* may be involved as a subject in any activity covered by this subpart unless: (1) The purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

(b) An activity permitted under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's consent need not be secured if: (1) His identity or whereabouts cannot reasonably be ascertained, (2) he is not reasonably available, or (3) the pregnancy resulted from rape.

§ 46.209 Activities directed toward fetuses ex utero, including nonviable fetuses, as subjects.

(a) Until it has been ascertained whether or not a fetus ex utero is viable, a fetus ex utero may not be involved as a subject in an activity covered by this subpart unless:

(1) There will be no added risk to the fetus resulting from the activity, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means, or

(2) The purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability.

(b) No nonviable fetus may be involved as a subject in an activity covered by this subpart unless:

(1) Vital functions of the fetus will not be artificially maintained,

(2) Experimental activities which of themselves would terminate the heartbeat or respiration of the fetus will not be employed, and

(3) The purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

(c) In the event the fetus *ex utero* is found to be viable, it may be included as a subject in the activity only to the extent permitted by and in accordance with the requirements of other subparts of this part.

(d) An activity permitted under paragraph (a) or (b) of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's informed consent need not be secured if: (1) his identity or whereabouts cannot reasonably be ascertained, (2) he is

not reasonably available, or (3) the pregnancy resulted from rape.

§ 46.210 Activities involving the dead fetus, fetal material, or the placenta.

Activities involving the dead fetus, mascerated fetal material, or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable State or local laws regarding such activities.

§ 46.211 Modification or waiver of specific requirements.

Upon the request of an applicant or offeror (with the approval of its Institutional Review Board), the Secretary may modify or waive specific requirements of this subpart, with the approval of the Ethical Advisory Board after such opportunity for public comment as the Ethical Advisory Board considers appropriate in the particular instance. In making such decisions, the Secretary will consider whether the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant such modification or waiver and that such benefits cannot be gained except through a modification or waiver. Any such modifications or waivers will be published as notices in the FEDERAL REGISTER.

Subpart C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

Source: 43 FR 53655, Nov 16, 1978

§ 46.301 Applicability.

(a) The regulations in this subpart are applicable to all biomedical and behavioral research conducted or supported by the Department of Health, Education, and Welfare involving prisoners as subjects.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will authorize research involving prisoners as subjects, to the extent such research is limited or barred by applicable State or local law.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 46.302 Purpose.

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

§ 46.303 Definitions.

As used in this subpart:

(a) "Secretary" means the Secretary of Health, Education, and Welfare and any other officer or employee of the Department of Health, Education, and Welfare to whom authority has been delegated.

(b) "DHEW" means the Department of Health, Education, and Welfare.

(c) "Prisoner" means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

(d) "Minimal risk" is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

§ 46.304 Composition of Institutional Review Boards where prisoners are involved.

In addition to satisfying the requirements in § 46.107 of this part, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:

(a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.

(b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

§ 46.305 Additional duties of the Institutional Review Boards where prisoners are involved.

(a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:

(1) The research under review represents one of the categories of research permissible under § 46.306(a)(2);

(2) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

(3) The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

(4) Procedures for the selection of subjects within the prison are fair to

all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

(5) The information is presented in language which is understandable to the subject population;

(6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

(7) Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) The Board shall carry out such other duties as may be assigned by the Secretary.

(c) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

§ 46.306 Permitted research involving prisoners.

(a) Biomedical or behavioral research conducted or supported by DHEW may involve prisoners as subjects only if:

(1) The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under § 46.305 of this subpart; and

(2) In the judgment of the Secretary the proposed research involves solely the following:

(A) Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(B) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(C) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology medicine and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or

(D) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology medicine and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research.

(b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHEW shall not involve prisoners as subjects.

Subpart D—Additional Protections for Children Involved as Subjects in Research.

Source: 48 FR 9818, March 8, 1983

§ 46.401 To what do these regulations apply?

(a) This subpart applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services.

(1) This includes research conducted by Department employees, except that each head of an Operating Division of the Department may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or supported by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (e) of § 46.101 of Subpart A, waive the applicability of some or all of the requirements of these regulations for research of this type.

(b) Exemptions (1), (2), (5) and (6) as listed in Subpart A at § 46.101(b) are applicable to this subpart. Exemption (4), research involving the observation of public behavior, listed at § 46.101(b), is applicable to this subpart where the investigator(s) does not participate in the activities being observed. Exemption (3), research involving survey or interview procedures, listed at § 46.101(b) does not apply to research covered by this subpart.

(c) The exceptions, additions, and provisions for waiver as they appear in paragraphs (c) through (i) of § 46.101 of Subpart A are applicable to this subpart.

§ 46.402 Definitions.

The definitions in § 46.102 of Subpart A shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) "Children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

(b) "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) "Permission" means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) "Parent" means a child's biological or adoptive parent.

(e) "Guardian" means an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.

§ 46.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

§ 46.404 Research not involving greater than minimal risk.

HHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in § 46.408.

§ 46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being only if the IRB finds that:

(a) The risk is justified by the anticipated benefit to the subjects;

(b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

(c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in § 46.408.

§ 46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

(a) The risk represents a minor increase over minimal risk;

(b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

(c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

(d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in § 46.408.

§ 46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

HHS will conduct or fund research that the IRB does not believe meets the requirements of §§ 46.404, 46.405, or 46.406 only if:

(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either: (1) That the research in fact satisfies the conditions of §§ 46.404, 46.405, or 46.406, as applicable, or (2) the following:

(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

(ii) The research will be conducted in accordance with sound ethical principles;

(iii) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in § 46.408.

§ 46.408 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment

may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with § 46.116 of Subpart A.

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by § 46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under §§ 46.404 or 46.405. Where research is covered by §§ 46.406 and 46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in § 46.116 of Subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by § 46.117 of Subpart A.

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

§ 46.409 Wards.

(a) Children who are wards of the state or any other agency, institution, or entity can be included in research approved under §§ 46.406 or 46.407 only if such research is:

(1) Related to their status as wards; or

(2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

NOTICES

HUMAN SUBJECTS
Minimum Criteria Identifying the Viable Fetus

On March 13, 1975, regulations were published in the FEDERAL REGISTER (40 FR 11854) relating to the protection of human subjects in research, development, and related activities supported by Department of Health, Education, and Welfare grants and contracts. These regulations are codified at 45 CFR Part 46.

Elsewhere in this issue of the FEDERAL REGISTER, the Secretary is amending 45 CFR Part 46 by, among other things, adding a new Subpart B to provide additional protections pertaining to research, development, and related activities involving fetuses, pregnant women, and in vitro fertilization.

Section 46.203(d) of Subpart B provides inter alia as follows:

> The Secretary may from time to time, taking into account medical advances, publish in the FEDERAL REGISTER guidelines to assist in determining whether a fetus is viable for purposes of this subpart.

This notice is published in accordance with § 46.203(d). For purposes of Subpart B, the guidelines indicating that a fetus other than a dead fetus within the meaning of § 46.203(f) is viable include the following:

> an estimated gestational age of 20 weeks or more and a body weight of 500 grams or more.

RESEARCH ACTIVITIES WHICH MAY BE REVIEWED THROUGH EXPEDITED REVIEW PROCEDURES

Research activities involving no more than minimal risk and in which the only involvement of human subjects will be in one or more of the following categories (carried out through standard methods) may be reviewed by the Institutional Review Board through the expedited review procedure authorized in 46.110 of 45 CFR Part 46.

(1) Collection of: hair and nail clippings, in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

(2) Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

(3) Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

(4) Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

(5) Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

(6) Voice recordings made for research purposes such as investigations of speech defects.

(7) Moderate exercise by healthy volunteers.

(8) The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

(9) Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

(10) Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

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HUMAN RESEARCH POLICY
AND
PROCEDURES FOR SPACE FLIGHT INVESTIGATIONS

PREPARED BY: Medical Sciences Division — Date: October 1987

APPROVED BY: _____ — 22 Oct 87
S. L. Pool, M.D. — Date
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APPROVED BY: _____ — 26 Oct 1987
L. F. Dietlein, M.D. — Date
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CONCURRED BY: _____ — Nov 30, 1987
C. L. Huntoon, Ph.D. — Date
Director, Space and Life Sciences

CONCURRED BY: _____ — JANUARY 29, 1988
Donald R. Puddy — Date
Director, Flight Crew Operations

Revision	Date	Approval		Pages
		SD	SA	
				Reissue

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ACRONYMS AND ABBREVIATIONS

AAALAC	American Association for Acceleration of Laboratory Animals
AALAS	American Association of Laboratory Animal Science
CDR	Commander
Co-PI	Co-Principal Investigator
DSO	Detailed Supplemental Objective
FAA	Federal Aviation Administration
FDA	Federal Drug Administration
GPWS	General Purpose Work Station
HRPPC	Human Research Policy and Procedures Committee
IND	Investigational New Drug
IRB	Institutional Review Board
JSC	Johnson Space Center
MS	Mission Specialist
NASA	National Aeronautics and Space Administration
PI	Principal Investigator
PLT	Pilot
PS	Payload Specialist
RAHF	Research Animal Holding Facility
SMRB	Science Management Review Board
SPF	Specific Pathogen Free
SR&QA	Safety Reliability and Quality Assurance
STS	Space Transportation System

1.0 INTRODUCTION

All flight investigations, domestic or foreign, involving human subjects which are funded, sponsored, or implemented by National Aeronautics and Space Administration (NASA), conducted in NASA facilities, aircraft or spacecraft, or which involve NASA participation to any degree, must be approved by the NASA-Johnson Space Center (JSC), Human Research Policy and Procedures Committee (HRPPC). The authority for this requirement is NMI 7100.8A and implementing NASA/JSC policy instructions. The HRPPC has the responsibility for ensuring the medical safety, health, and well-being of all human subjects in all preflight, inflight, and postflight activities and early supporting ground-based investigations associated with human flight experiments or Detailed Supplemental Objectives (DSOs). This responsibility extends to human investigative roles whether as subject or operator (experimenter).

The responsibility of HRPPC also includes all JSC human investigations, whether conducted on site or off site (e.g., medical centers, hospitals, etc.), in which JSC personnel participate as subjects, Principal Investigators (PIs) or Co-Principal Investigators (Co-PIs). JSC-funded human research at all other institutions in which no JSC personnel participation is directly involved, shall be reviewed by the Institutional Review Board (IRB) of the institution performing the research as prescribed in the JSC procurement document (see article G, JSCM 5100A, Rev. 14). It is recognized that some institutions will require that their own IRB also review the use of flight personnel as test subjects at their institutions. Such a review does not supplant the review by the JSC/HRPPC. This duplication of effort is unavoidable, because two different sets of requirements must be met.

This issuance is designed to detail the documentation requirements and the basis for these requirements in order to facilitate the approval process and allow the investigators to devote their energies to the conduct of their studies. The Committee has learned from past experience that providing the required documentation can be somewhat difficult; however, failure on the part of the PI to provide appropriate documentation in a usable form can lead to disapproval of some experimental protocols, disruption of training schedules, and unnecessary loss of time. Therefore, the Committee urges all persons associated with human research to adhere to the letter and spirit of the requirements set forth in this document.

2.0 WORKING PRINCIPLES FOR THE HRPPC

A. Ensuring the health, well-being, and safety of human research subjects is the fundamental basis for the entire process. The Committee approves only those investigations involving "minimal" or "reasonable risk." "Minimal risk" means that the harm or discomfort anticipated in the proposed research is not greater, considering probability and magnitude, than that encountered in the daily lives of healthy individuals, including the recognized risks inherent in a chosen occupation, such as spaceflight and ground support. Examples of "minimal risk" are found in Appendix 1. "Reasonable risk" means that the risks of harm anticipated in the proposed research are greater than those ordinarily encountered in daily life or during the performance of routine tests, but considered to be proper when weighed against the anticipated benefits or importance of the knowledge to be gained from the research.

B. The HRPPC does not duplicate the efforts of the Space Transportation System (STS) Payload Safety Review Panel in its review of inflight equipment or the efforts of Safety, Reliability and Quality Assurance (SR&QA) in its

review of ground-based equipment, but the Committee does require documentation of such safety analyses.

C. Space flight personnel are viewed in the special light of their involvement in a mission. They will, on many occasions, act as test subjects or operators of tests in an environment potentially involving more risk than that on Earth due to the unusual aspects of space flight such as microgravity, alterations in atmospheric composition and pressure, multiple tasks being performed by a single subject, confined living conditions, timeline constraints, and remoteness from medical surveillance. Because of these factors, a more vigorous review process is required for spaceflight experiments than for similar ground-based investigations.

D. Protocols submitted to this Committee are of two types: Master and Training. A Master Protocol consists of a detailed description of all aspects of an investigation and is used for Spacelab studies, mid-deck experiments, Detailed Supplemental Objectives (DSOs), and ground-based investigations. The Master Protocol is the first document to be submitted to the Committee for approval. A Training Protocol consists of a detailed description of the activities of a specific training tour and will generally be used only by Spacelab investigators. It will include objectives of the specific tour as well as a daily schedule of the training procedures (protocols) and equipment to be used. The basis for this requirement is that Spacelab life sciences experiments are expected to be evolutionary in nature; the experiences from training tours and baseline data collections are expected to mandate changes in protocols. Therefore, the HRPPC requires that the exact protocol for each training tour/baseline data collection be reviewed and approved on a tour-by-tour basis. Training protocol approvals in any event are valid for only a

12-month period. The PI must submit a statement to the HRPPC 30 days prior to the expiration of the 12-month period that no changes have been made and request an approval renewal.

E. Although ground-based training/baseline data collections are likely to involve less risk than in-flight experiments, the HRPPC requires that the rigor and discipline necessary for space flight experimentation be instituted to the extent possible during the ground-based phases to ensure familiarity with these procedures during flight.

F. The Committee meets regularly in executive session and utilizes written documentation exclusively in its evaluation of protocols. Verbal assurances or explanations are not acceptable.

G. All members of the HRPPC are voting members. The Chairman will vote only in the event of a tie. A member will abstain from voting only in case of conflict of interest. A quorum of the Committee shall consist of the Chairperson and six additional members. Members of the Committee will include six life scientists appointed by the Chairperson (including a secretary-recorder), and a representative from each of the following organizations: Chief Counsel; Director of Safety, Reliability and Quality Assurance; and the Astronaut Office. The Committee will also include one "lay" or non-life sciences member and one non-NASA, full-time, federal employee. Up to three ad hoc members in specialized disciplines may be added to the Committee on a temporary basis as deemed appropriate by the Chairperson.

3.0 PROCEDURES AND REQUIREMENTS FOR INVESTIGATIONS

A. Investigators shall provide to the Committee 20 loose-leaf copies of a complete Master Protocol of preflight, in-flight, and postflight activities.

(For Spacelab studies, these should be routed through the Mission Manager.) Master Protocols should be submitted no later than 6 months prior to a mission, for original approval. The format presented in Appendix 2 shall be employed. It is designed to elicit efficiently the appropriate information required by the Committee to grant approval and also to emphasize to the investigators certain responsibilities that must be considered when dealing with human subjects. If the protocol changes, the investigator must provide dated replacement pages with the changed sections indicated by bars in the margin as shown here and dated at the bottom of the page. The replacement pages will be submitted to the Committee by the Mission Manager.

B. As a matter of general practice, all human research protocols prior to submission to the HRPPC will have been approved by the SA Scientific Merit Review Committee (for JSC investigations), peer reviewed, and submitted to one or more of the following committees as appropriate:

1) JSC Radiation Safety Committee;
2) Medical Isotopes Operations Subcommittee;
3) STS Payload Safety Review Panel (for in-flight equipment);
4) Safety Reliability and Quality Assurance (for ground-based equipment).

C. At least 6 weeks prior to a training tour, the investigator shall provide the HRPPC with 20 copies of the Training Protocol to be used in the tour. If the experiment is to fly in the mid-deck or Spacelab, the Training Protocol will be routed through the Mission Manager to the HRPPC. On the other hand, if a DSO is involved, it will be submitted to the HRPPC by a representative of the Science Management Review Committee (SMRC). The headings and contents of this protocol are detailed in Appendix 3. Again the format is

designed to improve the efficiency of information transfer and the elimination of unnecessary paperwork.

D. All protocols, training tours, and DSOs submitted to the Committee must be signed and dated by the PI.

E. After initial approval of a DSO, resubmittals of the same DSO can be in the form of a letter or memorandum to the Committee, stating any changes or problems with the DSO and the date of the original approval by the Committee.

F. Once the Secretary of the Human Research Policy and Procedures Committee has received a satisfactory and complete Master Protocol and/or subsequent Training Protocols for specific tours, the investigator will be officially informed in writing of the meeting date at which the protocol will be reviewed.

G. The Committee meets on the first and third Thursday of each month. Although the Committee works only from written documentation, it may be desirable to have a representative, who is intimately familiar with the study and its protocol, available to answer questions regarding details of the protocol and to deal with actions required by the HRPPC.

H. If the protocol is deemed deficient in some category, the PI will be informed directly or through the Mission Manager if additional information is required. Upon receipt by the Secretary of the Committee, the new information will be reviewed at the next scheduled meeting, <u>if</u> it is received 10 working days before such a meeting. It is imperative, therefore, that the process of protocol review be initiated at least 6 weeks before the anticipated training tour in order to allow for the possible exchange of questions and answers.

I. If the protocol is approved at the initial or subsequent meeting, the PI will be informed of such approval. In some cases, where minor deficiencies are found, the approval may be qualified with some stipulation that requires follow-up reports. Ordinarily, these should be sent to the Secretary within 2 weeks after the completion of the training tour. (For Spacelab investigations, such reports should be routed through the Mission Manager.)

J. During the conduct of human research, all activities will be immediately suspended (unless such suspension would endanger the subject), and the Center Director and the Chairman, Alternate Chairman, or Crew Surgeon immediately informed in the event of:

(1) Any injury to or illness of a subject;

(2) Any change in the environment or the subject's response that could lead to some medical disturbance;

(3) Any substantive change from the approved protocol.

Furthermore, any one of the following individuals has the authority to terminate the test and insist on a review of the circumstances prior to the resumption of test activities: 1) Principal Investigator; 2) Medical Officer; 3) Test Engineer or Director; 4) Test Subject; or 5) Mission Manager. A decision to terminate the test by any one of the above is binding upon the other responsible individuals.

K. A Medical Officer of the HRPPC will attend as many training tours as deemed necessary by the HRPPC. The Officer will receive the minutes from

training debriefing sessions. The Medical Officer may be the Crew Surgeon or other Flight Surgeon, an HRPPC member, or an appropriate representative designated by the HRPPC.

L. As indicated above, the Medical Officer attending a training session may terminate any experimental procedure that he/she determines to be unsafe or presents a medical hazard to the experimental subject. Minor equipment and procedure changes may be approved by the Medical Officer during the training tour. Any changes that the representative wishes to defer to the full HRPPC will delay that portion of the training until the HRPPC has ruled on the changes.

M. If, during a training tour, there is any (even minor) anomalous incident involving human subjects, the incident must be reported via telephone within 24 hours, and a written Incident Report submitted within one week to the Chairman. Such incidents might include adverse reactions to drugs or electrode paste, trauma, eye irritations, equipment failure (anomalous operation), animal bites or scratches, hematomata, etc.

N. All human research requiring data collection aboard the KC-135 will be reviewed and approved by the HRPPC at least 6 weeks prior to the scheduled flight. This approval applies as well to all payloads which may be potentially hazardous to the health of the crew and/or investigators, such as those utilizing toxic or radioactive substances.

O. The Mission Manager of a given integrated payload involving human investigations will ensure that the Science Manager presents the total medical/experimental requirements for the integrated payload to the HRPPC. This activity will be coordinated with the crew flight surgeon, and will

include medical operational (clinical) blood/fluid requirements, as well as total crew time scheduling requirements for all phases of the mission (i.e., pre-, in-, and postflight periods).

P. Research involving STS flight personnel requires that the NASA HUMAN RESEARCH MINIMAL RISK INFORMED CONSENT FORM 1416, acknowledging "minimal risks" be completed (Appendix 4). In some cases, when the Committee feels a study involves "reasonable risk", the crewmembers will be asked to complete the NASA HUMAN RESEARCH REASONABLE RISK INFORMED CONSENT FORM 1416A (Appendix 5). This form will also be used for JSC studies, including those funded, sponsored, or implemented by JSC, using test subjects other than crewmembers. Either the NASA HUMAN RESEARCH MINIMAL RISK INFORMED CONSENT FORM 1416 or NASA HUMAN RESEARCH REASONABLE RISK INFORMED CONSENT FORM 1416A must be signed by the STS flight personnel involved in the research, before the start of any training tour. These forms must then be sent to the Chairman of HRPPC and a copy to the Flight Medicine Clinic.

Q. No crew training or ground-based investigation is permitted to commence unless a Master Protocol has received original approval, the detailed procedures have been approved 6 weeks prior to a training tour, and consent forms have been obtained from the human subjects and filed with the HRPPC.

R. Studies involving animals must adhere to the guidelines which are outlined in Appendices 6 and 7. Appendix 6 describes animal handling procedures for preflight crew training activities. Flight simulations and space flight procedures are described in Appendix 7.

S. If animals are used in an experiment, the investigator must include the following information in Section 8 of the Master Protocol:

(1) Precautions to be used to maintain the Specific Pathogen-Free (SPF) status and tests used to ascertain SPF status prior to training or flight.

(2) Potential biohazards from cold-blooded vertebrates must be analyzed.

4.0 APPENDIX 1

EXAMPLES OF RESEARCH ACTIVITIES INVOLVING NO MORE THAN "MINIMAL RISK"

The following research activities (performed by standard methods) are considered to involve no more than "minimal risk".

(1) Collection of hair and nail clippings, in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

(2) Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

(3) Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject, or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echosonography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

(4) Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an 8-week period and no more than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

(5) Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth, and the process is accomplished in accordance with accepted prophylactic techniques.

(6) Voice recordings made for research purposes such as investigations of speech defects.

(7) Moderate exercise by healthy volunteers.

(8) The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

(9) Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

(10) Research on drugs or devices for which an investigational exemption is not required.

5.0 APPENDIX 2

HUMAN RESEARCH MASTER PROTOCOL*

Spacelab or Shuttle Flight Designation _____

Experiment Designation _____

Functional Objective Designation _____

1. TITLE

2. ORGANIZATION CONDUCTING THE RESEARCH

Normally the institution with which the PI is affiliated.

3. INVESTIGATORS

A. List all investigators starting with the PI, their addresses, and phone numbers. Attach a Curriculum Vitae for each investigator at the end of the protocol.

B. List technical personnel who will aid in and/or conduct the research. Attach qualifications at the end of the protocol. The Committee is interested in the qualifications of the technical staff that will be interacting with the test subjects, because they will be operating equipment or performing procedures on them.

4. HYPOTHESIS(ES)

The hypotheses should be clearly and succinctly stated. The Committee must consider scientific merit as a factor in weighing risks vs. benefits. This summary should abstract the details to be included in Section 5.

*All headings or statements in **bold** are to be included in the protocol and in the order listed.

5. PURPOSE OF RESEARCH

This section may be handled by attachment (as an appendix) of information submitted in the original proposal. However, the investigator should ensure that the following information is included:

A. HISTORICAL BACKGROUND

A brief background statement should trace development of key factors or principles which led to formulation of the hypothesis. Reference to pertinent scientific literature is essential.*

B. NEW INFORMATION EXPECTED

6. JUSTIFICATION FOR USE OF HUMAN SUBJECTS

Explain why humans are a necessary part of the study.

7. STUDY PLAN AND SCHEDULE

Give an overview of what will be accomplished during preflight training/baseline data collection sessions, in-flight experimentation, and postflight data acquisitions. For example, familiarization with the concepts of the experiment, procedures to be learned, equipment to be used, data collection, etc.

A. DATES/DURATION

Give as close an approximation as possible. Detailed schedules for Spacelab investigations should be included in Training Protocols.

B. PLACE(S) OF TRAINING/TEST

*Not required for a DSO.

C. SUBJECTS

Provide names, if known, or flight personnel designation; e.g., Mission Specialist (MS) MS1, MS2, Payload Specialist (PS) PS1, PS2, PS Backup, Commander (CDR), Pilot (PLT).

8. EXPERIMENTAL PROTOCOLS AND EQUIPMENT

This section contains some of the most important information used by the Committee. It is from this section that the Committee may identify potential problems that might be overlooked by the investigators. Experience has shown that incompleteness of this section is one of the major reasons for HRPPC disapproval.

A. PREFLIGHT TRAINING AND BASELINE DATA COLLECTION

Describe preflight training and baseline data collection in terms of step-by-step procedures and equipment used. All equipment items must be identified. In those instances where any hardware is used for training or ground-based testing, the PI is responsible for providing detailed descriptions and hazard analyses as an attachment to the protocol submittal. The PI is also responsible for maintaining configuration control of the hardware to prevent any modifications that would compromise the hazard analyses. Inspection records must be provided to assure the hardware configuration and to assure adherence to test requirements/procedures. Functional test and check-out of equipment utilizing non-flight-crew personnel is required. All equipment whether commercial, modified commercial or custom designed, used in fit and functional testing must be inspected by the SR&QA. These results, together with equipment safety certification must be submitted by the PI to the HRPPC prior to flight crew usage.

B. INFLIGHT ACTIVITIES

List step-by-step procedures and equipment used, approximate duration of the testing, how many flight personnel are necessary, and how many times the experiment will be performed.

C. POSTFLIGHT ACTIVITIES

If postflight testing of flight personnel is necessary, note how many times the test will be done, when, where, and what procedures and equipment will be used.

9. HAZARDS ANALYSES AND SAFETY PRECAUTIONS

Detail the conceivable hazards that might be encountered during the study and the precautions that will be taken to avoid them. For research involving animal handling, list precautions employed for minimizing zoonoses (see page 9 of handbook).

A. PREFLIGHT ACTIVITIES

1. POTENTIAL HAZARDS
2. PROTECTION TO MINIMIZE RISKS
3. ASSESSMENT OF RESIDUAL RISKS

B. IN-FLIGHT ACTIVITIES

1. POTENTIAL HAZARDS
2. PROTECTION TO MINIMIZE RISKS
3. ASSESSMENT OF RESIDUAL RISKS

C. POSTFLIGHT ACTIVITIES

1. POTENTIAL HAZARDS
2. PROTECTION TO MINIMIZE RISKS
3. ASSESSMENT OF RESIDUAL RISKS

10. POSSIBLE INCONVENIENCES OR DISCOMFORTS TO SUBJECTS

List additional factors that do not fall into the category of hazards but that should be considered.

11. EXTENT OF PHYSICAL EXAMINATIONS

In many cases, reliance on the annual physical examination for flight personnel is all that need be stated. If a special physical examination or special test is required, describe it and state why it is needed.

12. AVAILABILITY OF A PHYSICIAN AND MEDICAL FACILITIES

13. REQUIRED STATEMENTS FOR HUMAN RESEARCH SUBJECTS

A. The subject will be free to withdraw from the research at any time. [Except...(describe any circumstances under which it would be hazardous or unwise to do so.)]

B. The identity of human subjects will not be released to the general public without his or her consent unless specifically required by law.

C. There will be no additional wage, salary, or other remuneration of any form paid, given, or in any manner delivered to the test subjects of this investigation where the subjects are NASA employees or NASA contractor employees and the terms of the contracts with NASA provide for participation as subjects in approved experiments.

D. The human research subjects are NASA employees, NASA contractor employees or independent contractors, and the training/testing is part of their employment or contractual circumstances. Therefore, NASA is responsible for compensation for injury, death, or property damage to the extent required by the **Federal Employees Compensation Act** or the **Federal Tort Claims Act**.

14. REQUIRED ATTACHMENTS

A. Include information concerning the human research to be communicated to the subjects in the course of obtaining their informed consent. Along with a signed consent form, attach a summary, signed by the subject, describing in layman's terms the procedures the subject will undergo. Should the subject be flown on the KC-135 airplane, include the following statement in the summary: "Since the KC-135 is considered to be a public aircraft within the meaning of the Federal Aviation Act of 1958, as amended, and as such, does not hold a current airworthiness certificate issued by the Federal Aviation Administration (FAA), any individual manifested to board the KC-135 should determine before boarding whether his/her personal life or accident insurance provides coverage under such conditions."

B. If required, attach the appropriate **JSC Consent Form** to be employed (see Appendices 4 & 5). Specify the appendix designation in this section. If not required, so state.

C. Attach a copy of the **Approval by the PI's Institutional Review Board** (Human Research or Ethics Committee). Specify the appendix designation.

D. Attach a copy of the **Institutional Safety Authority's** most recent certification of all ground-based equipment. Specify appendix designation(s).

E. If external radiation sources or radionuclides are employed (see Appendix 8), their use must have the approval of the JSC Radiation Safety Committee. Attach a copy of the **Approval of the JSC Radiation Safety Committee.** Specify appendix designation.

F. Research use of drugs for indications not in the package insert is subject to Federal Drug Administration (FDA) restrictions. Prior to shipping

the drug in interstate commerce, either its sponsor (the manufacturer) or the clinical investigator must file form **FDA 1571, "Notice of Claimed Investigational Exemption For A New Drug (IND)"** with the FDA. The FDA regulations also require each clinical investigator who uses investigational drugs in humans to file with the sponsor of the Investigational New Drug (IND) either form **FDA 1572** or form **FDA 1573, "Statement of Investigator"** (See Section 12.0 Appendix 9). Attach a copy of each form that has been filed and proof of submission date (e.g. certified mail receipt) or a statement of not having received a written reply from the FDA 60 days after the submission of forms. Attach a copy of the FDA reply, if it had been received.

6.0 APPENDIX 3

TRAINING PROTOCOL*

Spacelab Designation _____

Experiment # _____

Training Tour # _____

Location of Training _____

Dates of Training _____

Subjects _____

1. TITLE

2. ORGANIZATION CONDUCTING THE RESEARCH

3. INVESTIGATORS AND TECHNICAL PERSONNEL

List the name of the PI, address, and phone number. Reference to the Master Protocol may be made for other investigators and technical personnel. If changes have been made, note the changes and supply qualifications if not already on file.

4. OBJECTIVES OF THIS TOUR

Stating the objectives of the specific training session will aid those who are conducting the tour to focus on what they wish to accomplish and help the Committee to understand the intent of an individual training tour. Relate the objectives to the results of previous training tours (if any).

5. DETAILED DAILY SCHEDULE OF TRAINING ACTIVITIES

The schedule will provide the Committee an idea of the intensity and duration of each day of training as well as the step-by-step procedures and

*All headings in bold are to be included in the protocol as listed.

equipment to be employed. Reference can be made to the Master Protocol for details, but each step must be listed and any deviation from the Master Protocol must be noted. If substantive or permanent changes from the Master Protocol have been made, supply dated and marked replacement pages for the Master Protocol. (See page 5 of this handbook.)

6. HAZARDS

Restate all of the potential hazards for the specific training tour as extracted from the Master Protocol.

7. INFORMED CONSENT FORM

If required, attach the appropriate consent form to be used. List information to be provided to the subjects. Reference may be made to Master Protocol. If a consent form is not required, so state.

8. ADDITIONAL ATTACHMENTS

A. Updated Safety Certificates (inspection and certification of ground-based equipment should be performed annually).

B. Updated IRB Certificates.

C. Qualifications of New Personnel.

7.0 APPENDIX 4

• NASA HUMAN RESEARCH
MINIMAL RISK
INFORMED CONSENT FORM

1. I, the undersigned, do voluntarily give my informed consent for my participation as a test subject to the following test, experiment, or other evaluative procedure.

NAME OF EXPERIMENT _____

TRAINING TOUR NUMBER _____

FLIGHT TO WHICH ASSIGNED _____

NAME OF DESIGNATED PRINCIPAL INVESTIGATOR _____

NAME OF RESPONSIBLE NASA PROJECT SCIENTIST _____

I understand that:

(a) This procedure is part of an experiment approved by NASA.

(b) I am performing these duties as part of my employment, with _____.

(c) This procedure has been reviewed and approved by the JSC Human Research Policy and Procedures Committee (HRPPC) and determined that the procedure involves no more than minimal risk to the subject.

(d) "Minimal risk" means that the harm or discomfort anticipated in the proposed research is not greater, considering probability and magnitude, than those encountered in the daily lives of healthy individuals, including the recognized risks inherent in a chosen occupation, such as spaceflight and ground support.

(f) I am medically qualified to participate in the procedure.

(g) I may withdraw from the procedure at any time unless, as recommended by the Principal Investigator, or his/her designee, the withdrawal is dangerous or impossible.

(h) In the event of physical injury resulting from the procedure and calling for immediate action or attention that NASA will provide, or cause to be provided, the necessary treatment. I also understand that NASA will pay for any claims of injury, loss of life or property damage to the extent required by the Federal Employees' Compensation Act or the Federal Tort Claims Act. My agreement to participate shall not be construed as a release of NASA or any third party from any future liability which may arise from, or in connection with, the above procedures.

2. I, the undersigned, the Principal Investigator of the experiment designated above, certify that:

   (a) I have accurately described the procedure to the test subject.

   (b) The test set-up involves minimal risk to the test subject. All equipment used has been inspected and certified for safe and proper operation.

   (c) The test subject is medically qualified to participate.

   (d) The test protocol has not been changed from that approved by the JSC Human Research Policy and Procedures Committee (HRPPC).

APPROVED:

Test Subject	Date
Principal Investigator	Date
Project Scientist	Date

This consent form is valid for a 60-day period from the date of signature by the subject and the Principal Investigator (which dates should be identical). A signed, dated copy of the form should be forwarded to the JSC Human Research Policy and Procedures Committee, Mail Code SA, Lyndon B. Johnson Space Center, Houston, Texas 77058.

8.0 APPENDIX 5

NASA HUMAN RESEARCH
REASONABLE RISK
INFORMED CONSENT FORM

1. I, the undersigned, do voluntarily give my informed consent for my participation as a test subject in the following test, experiment, or other evaluative procedure:

NAME OF EXPERIMENT _____

TRAINING TOUR NUMBER _____

FLIGHT TO WHICH ASSIGNED _____

NAME OF DESIGNATED PRINCIPAL INVESTIGATOR _____

NAME OF RESPONSIBLE NASA PROJECT SCIENTIST _____

I understand that:

(a) This procedure is part of an experiment approved by NASA.

(b) I am performing these duties as a part of my employment, with _____.

(c) This procedure has been reviewed and approved by the JSC Human and Research Policy Procedures Committee (HRPPC) and determined that the procedure involves reasonable risk to the subject.

(d) "Reasonable risk" means that the risks of harm anticipated in the proposed research are greater than those ordinarily encountered in daily life or during the performance of routine tests, but considered to be proper when weighing the anticipated benefits and the importance of the knowledge to be gained from the research.

(e) The procedure has been explained to me prior to the execution of this form. I was afforded an opportunity to ask questions, and all questions asked were answered.

(f) I am medically qualified to participate in the procedure.

(g) I may withdraw from the procedure at any time unless, as recommended by the Principal Investigator, or his/her designee, the withdrawal is dangerous or impossible.

(h) In the event of physical injury resulting from the procedure and calling for immediate action or attention that NASA will provide, or cause to be provided, the necessary treatment. I also understand that NASA will pay for any claims of injury, loss of life or property damage to the extent required by the Federal Employees' Compensation Act or the Federal Tort Claims Act. My agreement to participate shall not be construed as a release of NASA or any third party from any future liability which may arise from, or in connection with, the above procedures.

2. I, the undersigned, the Principal Investigator of the experiment designated above, certify that:

   (a) I have accurately described the procedure to the test subject.

   (b) The test set-up involves reasonable risk to the test subject. All equipment used has been inspected and certified for safe and proper operation.

   (c) The test subject is medically qualified to participate.

   (d) The test protocol has not been changed from that approved by the JSC Human Research Policy and Procedures Committee (HRPPC).

APPROVED:

Test Subject	Date
Principal Investigator	Date
Project Scientist	Date

This consent form is valid for a 60-day period from the date of signature by the subject and the Principal Investigator (which dates should be identical). A signed, dated copy of the form should be forwarded to the JSC Human Research Policy and Procedures Committee, Mail Code SA, Lyndon B. Johnson Space Center, Houston, Texas 77058.

9.0 APPENDIX 6

GUIDELINES RELATIVE TO USE OF EXPERIMENTAL ANIMALS DURING PREFLIGHT CREW TRAINING ACTIVITIES

These guidelines specifically address the training activities at the home institutions (medical centers/universities) of the PI conducting experiment-specific training and similar training activities at pertinent NASA facilities. Guidelines relative to animal standards and procedures for training simulations utilizing the flight Research Animal Holding Facility (RAHF), altitude chamber simulations (closed environments), and actual space flight are addressed in a separate appendix.

1. All animal holding facilities or breeding colonies will generally adhere to the guidelines and recommendations of the American Association of Laboratory Animal Science (AALAS) and the American Association for Acceleration of Laboratory Animal Care (AAALAC).

RATS

2. The Specific Pathogen-Free (SPF) criteria for rats are given in Enclosure 1. Certification by reliable commercial suppliers that their animals are free of these pathogens is acceptable to the Committee. Periodic inspection of the animals for clinical signs of illness by animal handlers is required. Should animals become clinically ill, they should be excluded from the colony and all reasonable attempts made to establish an etiologic diagnosis. In these circumstances, the remaining animals must be recertified pathogen-free, or, alternatively, a new supply secured from the vendor.

3. For training with rats at the above facilities, acceptable laboratory attire is recommended. Ordinarily, this means only a laboratory coat. The use of surgical masks and gloves is crew optional.

SQUIRREL MONKEYS

Specific Pathogen-Free (SPF) certification will be valid for a period of 6 months. Should hands-on training with squirrel monkeys be required at any of the above facilities, the SPF criteria for space flight animals shall apply (Enclosure 2). It must be re-emphasized here that the crew will not be permitted to come in contact with Herpesvirus saimiri-positive squirrel monkeys at any time.

FROGS

The risk of amphibian zoonosis is almost non-existent. Acceptable laboratory attire is recommended, viz., a laboratory coat. Other protective measures are crew optional.

SPF CRITERIA FOR RATS

MICROORGANISM	CULTURE SITE/MATERIAL OR IDENTIFICATION TEST
BACTERIA:	
Streptobacillus moniliformis	Oral
Streptococcus pyogenes	Oral, Nasal
Salmonella sp.	Fecal
Leptospira sp.	Urine
Campylobacter sp.	Fecal
VIRUSES:	
Lymphocytic choriomeningitis virus	Blood (Serology)
FUNGI:	
All Dermatophytes	Skin (Clinical Inspection)
ECTOPARASITES:	Skin, Hair
ENDOPARASITES:	Feces, Caecal Contents

Enclosure 1

SPF CRITERIA FOR SQUIRREL MONKEYS

MICROORGANISM	CULTURE SITE/MATERIAL OR IDENTIFICATION TEST
BACTERIA:	
Shigella sp.	Fecal
Salmonella sp.	Fecal
Streptococcus pneumoniae	Oral, Fecal
Mycobacterium tuberculosis	Skin Test, X-Ray
Pasteurella multocida	Nasal, Fecal
Campylobacter sp.	Fecal
Leptospira sp.	Urine
Streptococcus pyogenes	Oral, Nasal
VIRUSES:	
Lymphocytic choriomeningitis virus	Blood (Serology)
Herpes tamarinus	Blood (Serology)
Herpesvirus saimiri	Blood (Serology)
ENDOPARASITES:	
Trichomonas	Oral
Acanthocephlans	Feces
Strongyloides	Feces
Entamoeba histolytica	Feces
Hemoprotozoa	Blood
FUNGI:	
All Dermatophytes	Skin

10.0 APPENDIX 7

GUIDELINES RELATIVE TO USE OF EXPERIMENTAL ANIMALS DURING CREW TRAINING SIMULATIONS UTILIZING THE FLIGHT RESEARCH ANIMAL HOLDING FACILITY (RAHF) AND GENERAL PURPOSE WORK STATION (GPWS), ALTITUDE CHAMBER SIMULATIONS (CLOSED ENVIRONMENTS), AND ACTUAL SPACEFLIGHT

This memorandum summarizes the HRPPC's current requirements and recommendations regarding subject standards and procedures as viewed in the context of past advisory group meetings on this and related topics.

(1) All animal holding facilities and/or breeding colonies will generally adhere to the guidelines and recommendations of the American Association of Laboratory Animal Science (AALAS) and the American Association for Acceleration of Laboratory Animal Care (AAALAC).

(2) Only Specific Pathogen-Free (SPF) rats and squirrel monkeys will be utilized for subject training and flight activities. The SPF criteria for rats are given in Enclosure 1, and for squirrel monkeys in Enclosure 2. The risk of amphibian zoonosis is almost non-existent, therefore no special certification is required.

(3) Other animal species proposed for approved flight experiments will be considered by the Committee on an individual basis.

(4) The following general guidelines will be followed where applicable:

A. Standard Microbiological Practices

1. Work surfaces will be decontaminated with a suitable disinfectant after use or at least daily.

2. All waste liquids, solids, tissues, syringes and needles will be placed in durable, leakproof, puncture-resistant, sealed containers for eventual autoclaving, incineration, or other appropriate decontamination/disposal procedure post-training, post-simulation or postflight. Such materials will not be transported between Spacelab and Orbiter.

3. Hypodermic needles and syringes shall be used only for the parenteral injection or aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable needle syringe units (i.e., the needle is integral to the syringe) are to be used for the injection or aspiration of fluids. Needles should not be bent, sheared or removed from the syringe following use. Needles should not be replaced in the plastic sheath or guard prior to disposal. Needle and syringe should be promptly placed in puncture-proof container for eventual decontamination, preferably by autoclaving, before final discard.

4. Personnel will use appropriate antiseptic wet wipes or other available means for cleaning hands after handling animals, when departing the laboratory, and especially before eating.

5. Laboratory coat (or equivalent) will be worn when animals are handled.

B. Animal Certification

1. Animals will be certified SPF by the supplier for the proscribed organisms listed in Enclosures 1 and 2. The rats will be housed together in pairs in filtered cages. One animal or each pair will be sampled for microbial screening 72 hours prior to crew contact. Presumptive results will be available in 24 hours and definitive results in 72 hours. The crew will not be exposed to either animal in a given cage if the sampled animal cultures are positive for a proscribed organism. Rat viral serology will be completed two weeks prior to crew exposure according to established protocols.

2. The Squirrel Monkeys will be screened for proscribed organisms at six-month intervals. The flight animals selected will have viral serology screening completed one month before use and will be cultured for proscribed bacteria 96 hours prior to crew contact. All microbiological test results will be forwarded to the Committee as part of the Operational Readiness Review (ORR).

3. SPF certified Squirrel Monkeys will at all times be housed in their own dedicated vivarium apart from other non-certified sub-human primates. The dedicated vivarium will be provided with a separate ventilation system so as to preclude contamination from other animals.

C. Research Animal Holding Facility (RAHF) and General Purpose Work Station (GPWS) Inflight Guidelines

1. With the improved integrity of animal enclosures and associated flight procedures, THE ROUTINE USE OF LABORATORY ATTIRE IS NOT REQUIRED.

If anomalous situations should develop which produce free contaminants, all crewmembers will use suitable protective measures (viz., surgical masks) until the particular experiment or procedure is terminated and the contaminant removed from the spacecraft. This precaution is necessary in the closed microgravity environment, since contamination does not remain localized in the continuous atmosphere of the Spacelab and Orbiter.

Particular care should be exercised during the following procedures:

a. Rats: Waste tray and food canister changeout; cage removal; condensate bottle changeout; GPWS operations involving animals.

b. Squirrel Monkeys: Waste tray changeout; urine canister changeout; food canister changeout; blood sample collection.

2. HEPA filtration system of the RAHF and GWPS will filter all particles greater than 0.3 microns.

3. Biological samples from animals shall not contaminate the spacecraft or crew at any time including collection, transport and storage procedures.

4. Animals transported between the RAHF and GPWS must be enclosed in a carrier.

5. Equipment and procedures for the housing, transport, and experimental protocol must preclude any possibility of animal escape into the spacecraft.

SPF CRITERIA FOR RATS

MICROORGANISM	CULTURE SITE/MATERIAL OR IDENTIFICATION TEST
BACTERIA:	
Streptobacillus moniliformis	Oral
Spirillum minus	Oral
Streptococcus pneumoniae	Oral, Nasal
Streptococcus pyogenes	Oral, Nasal
Bacillus piliformis	Liver (Invoke with Cortisone)
Corynebacterium kutscheri	Fecal, Oral
Salmonella sp.	Fecal
Pasteurella pneumotropica	Oral, Nasal
Leptospira sp.	Urine
Campylobacter sp.	Fecal
VIRUSES:	
Lymphocytic choriomeningitis virus	Blood (Serology)
Rat parvoviruses	Blood (Serology)
Rat coronavirus	Blood (Serology)
Sialodacryadenitis virus	Blood (Serology)
Sendai virus	Blood (Serology)
FUNGI:	
All Dermatophytes	Skin
ECTOPARASITES:	Skin, Hair
ENDOPARASITES:	Feces, Caecal Contents

SPF CRITERIA FOR SQUIRREL MONKEYS

MICROORGANISM	CULTURE SITE/MATERIAL OR IDENTIFICATION TEST
BACTERIA:	
Shigella sp.	Fecal
Salmonella sp.	Fecal
Streptococcus pneumoniae	Oral, Fecal
Mycobacterium tuberculosis	Skin Test, X-Ray
Pasteurella multocida	Nasal, Fecal
Campylobacter sp.	Fecal
Leptospira sp.	Urine
Streptococcus pyogenes	Oral, Nasal
VIRUSES:	
Lymphocytic choriomeningitis virus	Blood (Serology)
Herpes tamarinus	Blood (Serology)
Herpesvirus saimiri	Blood (Serology)
ENDOPARASITES:	
Trichomonas	Oral
Acanthocephlans	Feces
Strongyloides	Feces
Entamoeba histolytica	Feces
Hemoprotozoa	Blood
FUNGI:	
All Dermatophytes	Skin

SPF CRITERIA FOR *MACACA MULATTA*

VIRUSES	BACTERIA
Herpesvirus simiae	*Mycobacterium tuberculosis*
Yaba	*Shigella sp.*
Yaba-like viruses (OrTeCu, BEMP, and Tanapox)	*Salmonella sp.*
Monkey pox	*Pasturella multocida*
Measles (Rubeola)	*Yersinia pseudotuberculosis*
Lymphocytic choriomeningitis	*Yersinia enterocolitica*
Rabies	*Streptococcus pyogenes*
SAIDS (SRV-1, SRV-2)	*Campylobacter sp.*
HIV	
STLV III	

PARASITES	SPIROCHETES
Hymenolepsis nana	*Leptospira sp.*
Entamoeba histolytica	
Giardia intestinitis	
Giardia lamblia	*Fungi*:
Balantidium coli	All dermatophytoses
Trichomonas hominis	
Ascaris sp.	
Strongyloides sp.	
Acanthocephalans	

GUIDELINES FOR
RADIONUCLIDE USE IN SPACE FLIGHT PAYLOADS

The large number of permutations of radionuclide type, amount, chemical and physical form, and degree of containment requires that each experiment involving radionuclides be evaluated on its own merit. Nonetheless, some general guidelines can be set forth. These guidelines are not hard and fast and may be waived if other safety features or procedures are deemed adequate.

1. No payload containing radioactive material or other sources of ionizing radiation shall create a situation whereby:

   a. Radiation levels which, if an individual were continuously present in the area, could result in the individual's receiving a dose in excess of 2 millirems in any 1 hour, or

   b. Radiation levels which, if an individual were continuously present in the area, could result in the individual's receiving a dose in excess of 100 millirems in any 7 consecutive days, or in excess of 5,000 millirems in a 365-day period.

2. No payload or experiment, by design, shall cause quantities of radioactive material to be released into an occupied space which could result in uniform air concentrations in excess of the values specified in Appendix B, table I, column 1 of title 10, Code of Federal Regulations, part 20. For calculation purposes, the volume of the crew compartment is 65 m^3 and that of the Spacelab is 77 m^3.

The maximum permissible dose and the maximum permissible concentrations of radionuclides as recommended are primarily for the purpose of keeping the average dose to the crewmembers as low as reasonably achievable and not because of the likelihood of specific injury to an individual.

3. General rules for safe use of radioactive materials shall be followed:

   a. Wear disposable gloves and a surgical-type mask at all times while handling radioactive liquids or powders. The gloves should prevent contamination of the hands where a mask should reduce chances of inhalation and/or ingestion.

   b. Do not eat or drink in any area where radioactive material is being used.

   c. Wipe all work surfaces after use of radioactive materials.

   d. Practice good personal hygiene habits by always thoroughly cleaning hands after handling radioactive sources.

   e. Never mouth-pipette liquids containing radioactive materials. To the maximum extent possible minimize handling and transfers of radioactive materials in flight.

   f. Dispose of radioactive waste only in specifically designated receptacles that are properly shielded and labeled.

   g. Confine radioactive solutions, specimens, powders, and waste in double containment, plainly identified and labeled. Containment must be leakproof and puncture resistant. (Hood, glove box, or vented

workbench could be considered one of the containers, but not stowage bins.)

h. All transfers of radioactive liquids should be accomplished by the "buddy system." The individual performing the transfer will be assisted by an assistant to catch or trap droplets, aerosols, etc., with absorbent material to ensure that no trap droplets or aerosols are released into the occupied areas.

4. Contingency plans for all conceivable off-nominal situations shall be developed and tested.

5. Individuals trained in Health Physics shall be involved with the stowage, the post-mission handling of payloads utilizing radioactive materials capable of producing radioactive contamination, and post-mission survey for contamination of the spacecraft.

Adherence to the guidelines is important for radiological protection of the operator and other crewmembers in the Spacelab or crew compartment. Moreover, such adherence is important in minimizing contamination buildup in the spacecraft which can interfere with other investigators' experiments.

APPENDIX >

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

NOTICE OF CLAIMED INVESTIGATIONAL EXEMPTION FOR A NEW DRUG

Form Approved; OMB No. 0910-0014
Expiration Date: February 29, 1984.

NOTE: No drug may be shipped or study initiated unless a complete statement has been received. *(21 CFR 312.1(a)(2)).*

Name of Sponsor _____ Date _____

Address _____ Telephone ( )

Name of Investigational Drug _____

FOR A DRUG:

Food And Drug Administration
Office of New Drug Evaluation *(HFN-106)*
5600 Fishers Lane
Rockville, Maryland 20857

FOR A BIOLOGIC:

Food and Drug Administration
Office of Biologics *(HFN-823)*
8800 Rockville Pike
Bethesda, Maryland 20205

Dear Sir:

The sponsor, _____, submits this notice of claimed investigational exemption for a new drug under the provisions of section 505(i) of the Federal Food, Drug, and Cosmetic Act and § 312.1 of Title 21 of the Code of Federal Regulations.

Attached hereto in triplicate are:

1. The best available descriptive name of the drug, including to the extent known the chemical name and structure of any new drug substance, and a statement of how it is to be administered. (If the drug has only a code name, enough information should be supplied to identify the drug.)

2. Complete list of components of the drug, including any reasonable alternates for inactive components.

3. Complete statement of quantitative composition of drug, including reasonable variations that may be expected during the investigational stage.

4. Description of source and preparation of, any new-drug substances used as components, including the name and address of each supplier or processor, other than the sponsor, or each new-drug substance.

5. A statement of the methods, facilities, and controls used for the manufacturing, processing, and packing of the new drug to establish and maintain appropriate standards of identity, strength, quality, and purity as needed for safety and to give significance to clinical investigations made with the drug.

6. A statement covering all information available to the sponsor derived from preclinical investigations and any clinical studies and experience with the drug as follows:

a. Adequate information about the preclinical investigations, including studies made on laboratory animals, on the basis of which the sponsor has concluded that it is reasonably safe to initiate clinical investigations with the drug: Such information should include identification of the person who conducted each investigation; identification and qualifications of the individuals who evaluated the results and concluded that it is reasonably safe to initiate clinical investigations with the drug and a statement of where the investigations were conducted and where the records are available for inspection; and enough details about the investigations to permit scientific review. The preclinical investigations shall not be considered adequate to justify clinical testing unless they give proper attention to the conditions of the proposed clinical testing. When this information, the outline of the plan of clinical pharmacology, or any progress report on the clinical pharmacology, indicates a need for full review of the preclinical data before a clinical trial is undertaken, the Department will notify the sponsor to submit the complete preclinical data and to withhold clinical trials until the review is completed and the sponsor notified. The Food and Drug Administration will be prepared to confer with the sponsor concerning this action.

b. If the drug has been marketed commercially or investigated (e.g. outside the United States), complete information about such distribution or investigation shall be submitted, along with a complete bibliography of any publications about the drug.

c. If the drug is a combination of previously investigated or marketed drugs, an adequate summary of preexisting information from preclinical and clinical investigations and experience with its components, including all reports available to the sponsor suggesting side-effects, contraindications, and ineffectiveness in use of such components: Such summary should include an adequate bibliography of publications about the components and may incorporate by reference any information concerning such components previously submitted by the sponsor to the Food and Drug Administration. Include a statement of the expected pharmacological effects of the combination.

d. If the drug is a radioactive drug, sufficient data must be available from animal studies or previous human studies to allow a reasonable calculation of radiation absorbed dose upon administration to a human being.

7. A total (one in each of the three copies of the notice) of all informational material, including label and labeling, which is to be supplied to each investigator: This shall include an accurate description of the prior investigations and experience and their results pertinent to the safety and possible usefulness of the drug under the conditions of the investigation. It shall not represent that the safety or usefulness of the drug has been established for the purposes to be investigated. It shall describe all relevant hazards, contraindications, side-effects, and precautions suggested by prior investigations and experience with the drug under investigation and related drugs for the information of clinical investigators.

8. The scientific training and experience considered appropriate by the sponsor to qualify the investigators as suitable experts to investigate the safety of the drug, bearing in mind what is known about the pharmacological action of the drug and the phase of the investigational program that is to be undertaken.

9. The names and a summary of the training and experience of each investigator and of the individual charged with monitoring the progress of the investigation and evaluating the evidence of safety and effectiveness of the drug as it is received from the investigators, together with a statement that the sponsor has obtained from each investigator a completed and signed form, as provided in subparagraph (12) or (13) of this paragraph, and that the investigator is qualified by scientific training and experience as an appropriate expert to under-

FORM FDA 1571 (10/83) PREVIOUS EDITION ARE OBSOLETE.

take the phase of the investigation outlined in section 10 of the "Notice of Claimed Investigational Exemption for a New Drug." (In crucial situations, phase 3 investigators may be added and this form supplemented by rapid communication methods, and the signed Form FD-1573 shall be obtained promptly thereafter.)

10. An outline of any phase or phases of the planned investigations and a description of the institutional review committee, as follows:

a. Clinical pharmacology. This is ordinarily divided into two phases: Phase I starts when the new drug is first introduced into man - only animal and in vitro data are available - with the purpose of determining human toxicity, metabolism, absorption, elimination, and other pharmacological action, preferred route of administration, and safe dosage range; phase 2 covers the initial trials on a limited number of patients for specific disease control or prophylaxis purposes. A general outline of these phases shall be submitted, identifying the investigator or investigators, the hospitals or research facilities where the clinical pharmacology will be undertaken, any expert committees or panels to be utilized, the maximum number of subjects to be involved, and the estimated duration of these early phases of investigation. Modification of the experimental design on the basis of experience gained need be reported only in the progress reports on these early phases, or in the development of the plan for the clinical trial, phase 3. The first two phases may overlap and, when indicated, may require additional animal data before these phases can be completed or phase can be undertaken. Such animal tests shall be designed to take into account the expected duration of administration of the drug to human beings, the age groups and physical status, as for example, infants, pregnant women, premenopausal women, of those human beings to whom the drug may be administered, unless this has already been done in the original animal studies. If a drug is a radioactive drug, the clinical pharmacology phase must include studies which will obtain sufficient data for dosimetry calculations. These studies should evaluate the excretion, whole body retention, and organ distribution of the radioactive material.

b. Clinical trial. This phase 3 provides the assessment of the drug's safety and effectiveness and optimum dosage schedules in the diagnosis, treatment, or prophylaxis of groups of subjects involving a given disease or condition. A reasonable protocol is developed on the basis of the facts accumulated in the earlier phases, including completed and submitted animal studies. This phase is conducted by separate groups following the same protocol (with reasonable variations and alternatives permitted by the plan) to produce well-controlled clinical data. For this phase, the following data shall be submitted:

i. The names and addresses of the investigators. (Additional investigators may be added.)

ii. The specific nature of the investigations to be conducted, together with information or case report forms to show the scope and detail of the planned clinical observations and the clinical laboratory tests to be made and reported.

iii. The approximate number of subjects (a reasonable range of subjects is permissible and additions may be made), and criteria proposed for subject selection by age, sex, and condition.

iv. The estimated duration of the clinical trial and the intervals, not exceeding 1 year, at which progress reports showing the results of the investigations will be submitted to the Food and Drug Administration.

c. Institutional review board (IRB). The sponsor must give assurance that an IRB that complies with the requirements set forth in Part [redacted] of this chapter will be responsible for the initial and continuing review and approval of the proposed clinical study. The sponsor must also provide assurance that the investigators will report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others, and that the investigators will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazard to the human subjects. FDA will regard the signing of the Form FDA-1571 as providing the necessary assurances above.

(The notice of claimed investigational exemption may be limited to any one or more phases, provided the outline of the additional phase or phases is submitted before such additional phases begin. A limitation on an exemption does not preclude continuing a subject on the drug from phase 2 to phase 3 without interruption while the plan for phase 3 is being developed.)

Ordinarily, a plan for clinical trial will not be regarded as reasonable unless, among other things, it provides for more than one independent competent investigator to maintain adequate case histories of an adequate number of subjects, designed to record observations and permit evaluation of any and all discernible effects attributable to the drug in each individual treated, and comparable records on any individuals employed as controls. These records shall be individual records for each subject maintained to include adequate information pertaining to each, including age, sex, conditions treated, dosage, frequency of administration of the drug, results of all relevant clinical observations and laboratory examinations made, adequate information concerning any other treatment given and a full statement of any adverse effects and useful results observed, together with an opinion as to whether such effects or results are attributable to the drug under investigation.

11. A statement that the sponsor will notify the Food and Drug Administration if the investigation is discontinued, and the reason therefor.

12. A statement that the sponsor will notify each investigator if a new-drug application is approved, or if the investigation is discontinued.

13. If the drug is to be sold, a full explanation why sale is required and should not be regarded as the commercialization of a new drug for which an application is not approved.

14. A statement that the sponsor assures that clinical studies in humans will not be initiated prior to 30 days after the date of receipt of the notice by the Food and Drug Administration and that he will continue to withhold or to restrict clinical studies if requested to do so by the Food and Drug Administration prior to the expiration of such 30 days. If such request is made, the sponsor will be provided specific information as to the deficiencies and will be afforded a conference on request. The 30-day delay may be waived by the Food and Drug Administration upon a showing of good reason for such waiver; and for investigations subject to institutional review committee approval as described in item 10c above, and additional statement assuring that the investigation will not be initiated prior to approval of the study by such committee.

15. When requested by the agency, an environmental impact analysis report pursuant to § 25.1 of this chapter.

16. A statement that all nonclinical laboratory studies have been, or will be, conducted in compliance with the good laboratory practice regulations set forth in Part 58 of this chapter, or, if such studies have not been conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in conducting the study and those required in the regulations.

Very truly yours,

SPONSOR	PER
	INDICATE AUTHORITY

(This notice may be amended or supplemented from time to time on the basis of the experience gained with the new drug. Progress reports may be used to update the notice.)

ALL NOTICES AND CORRESPONDENCE SHOULD BE SUBMITTED IN TRIPLICATE.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
5600 FISHERS LANE
ROCKVILLE, MARYLAND 20852

STATEMENT OF INVESTIGATOR
(Clinical Pharmacology)

Form Approved
OMB No. 57-R0031

TO: SUPPLIER OF THE DRUG: *(Name and address, include ZIP Code)*

NAME OF INVESTIGATOR *(Print or Type)*

DATE

NAME OF DRUG

Dear Sir:

The undersigned, _____, submits this statement as required by section 505(i) of the Federal Food, Drug, and Cosmetic Act and § 312.1 of Title 21 of the Code of Federal Regulations as a condition for receiving and conducting clinical pharmacology with a new drug limited by Federal (or United States) law to investigational use.

1. A STATEMENT OF THE EDUCATION AND TRAINING THAT QUALIFIES ME FOR CLINICAL PHARMACOLOGY

2. THE NAME AND ADDRESS OF THE MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL PHARMACOLOGY WILL BE CONDUCTED

3. If the experimental project is to be conducted on institutionalized subjects or is conducted by an individual affiliated with an institution which agrees to assume responsibility for the study, assurance must be given that an institutional review committee is responsible for initial and continuing review and approval of the proposed clinical study. The membership must be comprised of sufficient members of varying background, that is, lawyers clergymen, or laymen as well as scientists, to assure complete and adequate review of the research project. The membership must possess not only broad competence to comprehend the nature of the project, but also other competencies necessary to judge the acceptability of the project or activity in terms of institutional regulations, relevant law, standards of professional practice, and community acceptance. Assurance must be presented that the investigator has not participated in the selection of committee members; that the review committee does not allow participation in its review and conclusions by any individual involved in the conduct of the research activity under review (except to provide information to the committee); that the investigator will report to the committee for review any emergent problems, serious adverse reactions, or proposed procedural changes which may affect the status of the investigation and that no such change will be made without committee approval except where necessary to eliminate apparent immediate hazards; that reviews of the study will be conducted by the review committee at intervals appropriate to the degree of risk, but not exceeding 1 year, to assure that the research project is being conducted in compliance with the committee's understanding and recommendations; that the review committee is provided all the information on the research project necessary for its complete review of the project; and that the review committee maintains adequate documentation of its activities and develops adequate procedures for reporting its findings to the institution. The documents maintained by the committee are to include the names and qualifications of committee members, records of information provided to subjects in obtaining informed consent, committee discussion on substantive issues and their resolution, committee recommendations, and dated reports of successive reviews as they are performed. Copies of all documents are to be retained for a period of 3 years past the completion or discontinuance of the study and are to be made available upon request to duly authorized representatives of the Food and Drug Administration. (Favorable recommendations by the committee are subject to further appropriate review and rejection by institution officials. Unfavorable recommendations, restrictions, or conditions may not be overruled by the institution officials.) Procedures for the organization and operation of institutional review committees are contained in guidelines issued pursuant to Chapter 1-40 of the Grants Administration Manual of the U.S. Department of Health, Education, and Welfare, available from the U.S. Government Printing Office. It is recommended that these guidelines be followed in establishing institutional review committees and that the committees function according to the procedures described therein. A signing of the Form FD-1572 will be regarded as providing the above necessary assurance; however, if the institution has on file with the Department of Health, Education, and Welfare, Division of Research Grants, National Institutes of Health, an "accepted general assurance," and the same committee is to review the proposed study using the same procedures, this is acceptable in lieu of the above assurances and a statement to this effect should be provided with the signed FD-1572. (In addition to sponsor's continuing responsibility to monitor the study, the Food and Drug Administration will undertake investigations in institutions periodically to determine whether the committees are operating in accord with the assurances given by the sponsor.)

FORM FD 1572 (1/76) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

4. THE ESTIMATED DURATION OF THE PROJECT AND THE MAXIMUM NUMBER OF SUBJECTS THAT WILL BE INVOLVED

5. A GENERAL OUTLINE OF THE PROJECT TO BE UNDERTAKEN *(Modification is permitted on the basis of experience gained without advance submission of amendments to the general outline, but with the approval of the review committee and upon notification of the sponsor.)*

6. THE UNDERSIGNED UNDERSTANDS THAT THE FOLLOWING CONDITIONS GENERALLY APPLICABLE TO NEW DRUGS FOR INVESTIGATIONAL USE GOVERN HIS RECEIPT AND USE OF THIS INVESTIGATIONAL DRUG

a. The sponsor is required to supply the investigator with full information concerning the preclinical investigation that justifies clinical pharmacology.

b. The investigator is required to maintain adequate records of the disposition of all receipts of the drug, including dates, quantity, and use by subjects, and if the clinical pharmacology is suspended, terminated, discontinued, or completed, to return to the sponsor any unused supply of the drug. If the investigational drug is subject to the comprehensive Drug Abuse Prevention and Control Act of 1970, adequate precautions must be taken, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.

c. The investigator is required to prepare and maintain adequate case histories designed to record all observations and other data pertinent to the clinical pharmacology.

d. The investigator is required to furnish his reports to the sponsor who is responsible for collecting and evaluating the results, and presenting progress reports to the Food and Drug Administration at appropriate intervals, not exceeding 1 year. Any adverse effect which may reasonably be regarded as caused by, or is probably caused by, the new drug shall be reported to the sponsor promptly; and if the adverse effect is alarming it shall be reported immediately. An adequate report of the clinical pharmacology should be furnished to the sponsor shortly after completion.

e. The investigator shall maintain the records of disposition of the drug and the case reports described above for a period of 2 years following the date the new-drug application is approved for the drug; or if no application is to be filed or is approved until 2 years after the investigation is discontinued and the Food and Drug Administration so notified. Upon the request of a scientifically trained and specifically authorized employee of the Department, at reasonable times, the investigator will made such records available for inspection and copying. The names of the subjects need not be divulged unless the records of the particular subjects require a more detailed study of the cases, or unless there is reason to believe that the records do not represent actual studies or do not represent actual results obtained.

f. The investigator certifies that the drug will be administered only to subjects under his personal supervision or under the supervision of the following investigators responsible to him,

_____

_____

_____

_____

and that the drug will not be supplied to any other investigator or to any clinic for administration to subjects.

g. The investigator certifies that he will inform any patients or any persons used as controls, or their representatives, that drugs are being used for investigational purposes, and will obtain the consent of the subjects, or their representatives, except where this is not feasible or, in the investigator's professional judgment, is contrary to the best interests of the subjects.

h. The investigator is required to assure the sponsor that for investigations involving institutionalized subjects the studies will not be initiated until the institutional review committee has reviewed and approved the study. (The organization and procedure requirements for such a committee should be explained to the investigator by the sponsor as set forth in Form FD-1571, division 10, unit c.)

Very truly yours,

Name of Investigator _____

Address _____

_____

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION 5600 FISHERS LANE ROCKVILLE, MARYLAND 20857	**STATEMENT OF INVESTIGATOR**	*Form Approved* *OMB No. 57-R0029* *Use of this form is prohibited after May 31, 1982.*

NOTE: No drug may be shipped or study initiated unless a completed statement has been received (21 *CFR 312.1(a) (12)*).

TO: SUPPLIER OF DRUG *(Name and address, include Zip Code)*	NAME OF INVESTIGATOR *(Print or Type)*
	DATE
	NAME OF DRUG

Dear Sir:

The undersigned, _____ submits this statement as required by section 505(i) of the Federal Food, Drug, and Cosmetic Act and §312.1 of Title 21 of the Code of Federal Regulations as a condition for receiving and conducting clinical investigations with a new drug limited by Federal *(or United States)* law to investigational use.

1. STATEMENT OF EDUCATION AND EXPERIENCE

a. COLLEGES, UNIVERSITIES, AND MEDICAL OR OTHER PROFESSIONAL SCHOOLS ATTENDED, WITH DATES OF ATTENDANCE DEGREES, AND DATES DEGREES WERE AWARDED

b. POSTGRADUATE MEDICAL OR OTHER PROFESSIONAL TRAINING *(Indicate dates, names of institutions, and nature of training)*

c. TEACHING OR RESEARCH EXPERIENCE *(Indicate dates, institutions, and brief description of experience)*

d. EXPERIENCE IN MEDICAL PRACTICE OR OTHER PROFESSIONAL EXPERIENCE *(Indicate dates, institutional affiliations, nature of practice, or other professional experience)*

e. REPRESENTATIVE LIST OF PERTINENT MEDICAL OR OTHER SCIENTIFIC PUBLICATIONS *(Indicate titles of articles, name of publications and volume, page number, and date)*

FORM FDA 1573 (4/79) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

2a. If the investigation is to be conducted on institutionalized subjects or is conducted by an individual affiliated with an institution which agrees to assume responsibility for the study, assurance must be given that an institutional review committee is responsible for initial and continuing review and approval of the proposed clinical study. The membership must be comprised of sufficient members of varying background, that is, lawyers, clergymen, or laymen as well as scientists, to assure complete and adequate review of the research project. The membership must possess not only broad competence to comprehend the nature of the project, but also other competencies necessary to judge the acceptability of the project or activity in terms of institutional regulations, relevant law, standards of professional practice, and community acceptance. Assurance must be presented that the investigator has not participated in the selection of committee members; that the review committee does not allow participation in its review and conclusions by any individual involved in the conduct of the research activity under review (except to provide information to the committee); that the investigator will report to the committee for review any emergent problems, serious adverse reactions, or proposed procedural changes which may affect the status of the investigation and that no such change will be made without committee approval except where necessary to eliminate apparent immediate hazards; that reviews of the study will be conducted by the review committee at intervals appropriate to the degree of risk, but not exceeding 1 year, to assure that the research project is being conducted in compliance with the committee's understanding and recommendations; that the review committee is provided all the information on the research project necessary for its complete review of the project; and that the review committee maintains adequate documentation of its activities and develops adequate procedures for reporting its findings to the institution. The documents maintained by the committee are to include the names and qualifications of committee members, records of information provided to subjects in obtaining informed consent, committee discussion on substantive issues and their resolution, committee recommendations, and dated reports of successive reviews as they are performed. Copies of all documents are to be retained for a period of 3 years past the completion or discontinuance of the study and are to be made available upon request to duly authorized representatives of the Food and Drug Administration. (Favorable recommendations by the committee are subject to further appropriate review and rejection by institution officials. Unfavorable recommendations, restrictions, or conditions may not be overruled by the institution officials.) Procedures for the organization and operation of institutional review committees are contained in guidelines issued pursuant to Chapter 1-40 of the Grants Administration Manual of the U.S. Department of Health, Education, and Welfare, available from the U.S. Government Printing Office. It is recommended that these guidelines be followed in establishing institutional review committees and that the committees function according to the procedures described therein. A signing of the Form FD 1573 will be regarded as providing the above necessary assurances; however, if the institution has on file with the Department of Health, Education, and Welfare, Division of Research Grants, National Institutes of Health, an "accepted general assurance," and the same committee is to review the proposed study using the same procedures, this is acceptable in lieu of the above assurances and a statement to this effect should be provided with the signed FD 1573. (In addition to sponsor's continuing responsiblity to monitor the study, the Food and Drug Administration will undertake investigations in institutions periodically to determine whether the committees are operating in accord with the assurances given by the sponsor.)

b. A description of any clinical laboratory facilities that will be used. (If this information has been submitted to the sponsor and reported by him on Form FD 1571, reference to the previous submission will be adequate).

3. The investigational drug will be used by the undersigned or under his supervision in accordance with the plan of investigation described as follows: (Outline the plan of investigation including approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; clinical uses to be investigated; characteristics of subjects by age, sex and condition; the kind of clinical observations and laboratory tests to be undertaken prior to, during, and after administration of the drug; the estimated duration of the investigation; and a description or copies of report forms to be used to maintain an adequate record of the observations and test results obtained. This plan may include reasonable alternates and variations and should be supplemented or amended when any significant change in direction or scope of the investigation is undertaken.)

4. THE UNDERSIGNED UNDERSTANDS THAT THE FOLLOWING CONDITIONS, GENERALLY APPLICABLE TO NEW DRUGS FOR INVESTIGATIONAL USE, GOVERN HIS RECEIPTS AND USE OF THIS INVESTIGATIONAL DRUG:

a. The sponsor is required to supply the investigator with full information concerning the preclinical investigations that justify clinical trials, together with fully informative material describing any prior investigations and experience and any possible hazards, contraindications, side-effects, and precautions to be taken into account in the course of the investigation.

b. The investigator is required to maintain adequate records of the disposition of all receipts of the drug, including dates, quantities, and use by subjects, and if the investigation is terminated, suspended, discontinued, or completed, to return to the sponsor any unused supply of the drug. If the investigational drug is subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970, adequate precautions must be taken including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.

c. The investigator is required to prepare and maintain adequate and accurate case histories designed to record all observations and other data pertinent to the investigation on each individual treated with the drug or employed as a control in the investigation.

d. The investigator is required to furnish his reports to the sponsor of the drug who is responsible for collecting and evaluating the results obtained by various investigators. The sponsor is required to present progress reports to the Food and Drug Administration at appropriate intervals not exceeding 1 year. Any adverse effect that may reasonably be regarded as caused by, or probably caused by, the new drug shall be reported to the sponsor promptly, and if the adverse effect is alarming, it shall be reported immediately. An adequate report of the investigation should be furnished to the sponsor shortly after completion of the investigation.

e. The investigator shall maintain the records of disposition of the drug and the case histories described above for a period of 2 years following the date a new-drug application is approved for the drug; or if the application is not approved, until 2 years after the investigation is discontinued. Upon the request of a scientifically trained and properly authorized employee of the Department, at reasonable times, the investigator will make such records available for inspection and copying. The subjects' names need not be divulged unless the records of particular individuals require a more detailed study of the cases, or unless there is reason to believe that the records do not represent actual cases studied, or do not represent actual results obtained.

f. The investigator certifies that the drug will be administered only to subjects under his personal supervision or under the supervision of the following investigators responsible to him,

_____

_____

_____

and that the drug will not be supplied to any other investigator or to any clinic for administration to subjects.

g. The investigator certifies that he will inform any subjects including subjects used as controls, or their representatives, that drugs are being used for investigational purposes, and will obtain the consent of the subjects, or their representatives, except where this is not feasible or, in the investigator's professional judgment, is contrary to the best interests of the subjects.

h. The investigator is required to assure the sponsor that for investigations involving institutionalized subjects, the studies will not be initiated until the institutional review committee has reviewed and approved the study. (The organization and procedure requirements for such a committee should be explained to the investigator by the sponsor as set forth in Form FD 1571, division 10, unit c.

Very truly yours,

_____

(Name of Investigator)

_____

(Address)

_____

(This form should be supplemented or amended from time to time if new subjects are added or if significant changes are made in the plan of investigation.)

NASA-JSC

UAH IRB 2.243 3-22-95 Sec

I.

INTRODUCTION

An institution of higher education is eligible to receive funds for research from the Department of Health and Human Services (HHS) only if the institution complies with certain policies designed to protect human research subjects. This eligibility is secured initially by submission for HHS approval of an institutional assurance, which is a written document committing the institution to policy and procedural requirements in research. Specifically, the assurance must include a statement of principles for the protection of human subjects of research conducted at or sponsored by the institution (regardless of funding source), designation of an institutional review board (IRB) with certain prescribed research review functions, an identification of IBR members, and written procedures to be followed by the IRB in carrying out its functions. The purpose of this document is to put in place at The University of Alabama in Huntsville the foregoing policies, procedures, and mechanisms as the predicate for an approved assurance.

II.

INSTITUTIONAL REVIEW BOARD - STRUCTURE AND ROLE

A. Establishment and Composition.

1. The Use of Human Subjects in Research Committee (hereinafter referred to as the "UHSRC") has been established as the Institutional Review Board (hereinafter referred to as the "IRB") for The University of Alabama in Huntsville.

2. The UHSRC shall be composed of at least five (5) members, with diverse backgrounds possessing the professional competence to promote complete and adequate review of research activities and ascertain acceptability in terms of institutional commitments and regulations, applicable law and standards of professional conduct and practice.

3. Representation on the UHSRC shall include:

   a. Men and women,
   b. Representation of more than one profession,
   c. At least one member whose primary concerns are non-scientific, i.e., lawyer, ethicist, clergy member,
   d. At least one member who is not affiliated with UAH, either personally or by immediate familial relationship.

4. No person shall serve as a member of the UHSRC where such service would constitute a conflict of interest involving the proposed research project under review.

5. The UHSRC will invite individuals with specific competencies to assist in its review of complex issues. Within the scope of their

invitation, these invited individuals will serve as full members of the UHSRC, except that they shall not have a vote.

B. Function and Operation.

1. The UHSRC shall follow written procedures for full review at convened meetings at which a majority of members are present, which shall include at least one member whose primary concerns are in non-scientific areas. In order for research to be approved it shall receive the approval of a majority of those members present at the meeting.

2. The UHSRC shall be responsible for reporting to the appropriate University officials and the Secretary of the Department of Health and Human Services (hereinafter referred to as "HHS") any serious or continuing non-compliance by investigators with the requirements and determinations of the UHSRC.

3. The following definitions apply through-out these procedures:

a. "Certification" means the official notification by the University to the HHS in accordance with the requirements of the applicable federal regulations that a research project or activity involving human subject has been reviewed and approved by the UHSRC in accordance with the approved assurance on file at HHS.

b. "Human Subject" means a living individual about whom an investigator conducting research obtains either date through intervention or interaction with the individual, or identifiable private information.

c. "Interaction" includes communication or interpersonal contact between investigator and subject.

d. "Intervention" includes both physical procedures by which data are gathered in manipulation of the subject or subject's environment that are performed for research purposes.

e. "Minimal Risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

f. "Private Information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information which has been provided for specific purposes by an individual in which the individual can reasonably expect will not be made public. Private information must be individually identifiable in order for obtaining the information to constitute research involving human subjects.

g. "Research" means a systematic investigation designed to

develop or contribute to generalizable knowledge. Activities which meet this definition constitute "research" for purposes of these procedures, whether or not they are supported or funded under a program which is considered "research" for other purposes.

C. Records

The UHSRC shall maintain the following records:

1. A statement of principles governing the University in the discharge of its responsibilities for protecting the right and welfare of human subjects of research conducted at, or sponsored by, the University, regardless of source of funding.

2. Records reflecting that the UHSRC has been designated by the University as its IRB and that provisions have been made for meeting space and sufficient staff to support review and record keeping duties.

3. A list of the UHSRC members identified by name, earned degrees, representative capacity, indications of experience such as board certification, licenses, etc. sufficient to describe each members chief anticipated contributions to the UHSRC deliberations and any employment or other relationship between each member and the institution. Changes in the UHSRC membership shall be reported to the Secretary of HHS.

4. Written procedures which the UHSRC will follow:

   a. For conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and to the University;

   b. For determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous review by the UHSRC;

   c. For insuring prompt reporting to the UHSRC of proposed changes in a research activity, and for insuring that changes in approved research, during the period for which UHSRC approval has already been given may not be initiated without UHSRC review and approval except where necessary to eliminate apparent immediate hazards to the subject; and

   d. For insuring prompt reporting to the UHSRC and to the Secretary of HHS of unanticipated problems involving risks to subjects or others.

5. The assurance which shall be executed by an individual authorized to act for the University and to assume on behalf of the University the obligations imposed by applicable federal regulations.

6. Copies of all applications or proposals submitted to HHS. Within sixty (60) days after the date of submission to HHS of an application or

proposal, the UHSRC shall certify that the application or proposal has been reviewed and approved.

III.

INSTITUTIONAL REVIEW BOARD REVIEW PROCESS

A. Exempt Review.

1. Certain research activities are considered exempt from the usual process of the UHSRC. As listed below, these activities do not require informed consent unless the Secretary of HHS specifically determines that the project presents a danger to the physical, mental, or emotional well-being of a participant of the project. Projects of an institutional or training grant nature that may eventually involve human subjects do not require UHSRC review for the initial request for funds. However, any activities that are not exempt as listed below must have UHSRC review and HHS certification before human subjects are actually involved in the project.

2. The following activities are considered exempt from UHSRC review:

a. Research to be conducted in established or commonly accepted educational settings, involving normal educational practices, such as

i. research on regular or special educational instructional strategies, or

ii. research on the effectiveness of, or the comparison among, instructional techniques, curricular, or classroom management methods.

b. Research which will involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), if the information taken from these sources is to be recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

c. Research which will involve survey or interview procedures. No exemption can be given under this subsection if

i. the research involves children as subjects, or

ii. the subjects could be identified directly or through identifiers linked to the subjects and

Number One. The subject's responses if known outside the research could place them at risk of civil or criminal liability, damage their financial standing or employability, or

Number Two. The research deals with sensitive areas

such as illegal conduct, drug or alcohol use or sexual behavior.

d. Research which will involve survey or interview of elected or appointed officials or candidates for public office.

e. Research which will involve the observation (including observation by participants) of public behavior. No exemption can be given under this subsection

i. for research involving children in which the investigator participates in the activities being observed.

ii. if the subjects could be identified directly or through identifiers linked to the subjects and

Number One. The subject's responses if known outside the research could place them at risk of civil or criminal liability, damage their financial standing or employability or

Number Two. The research deals with sensitive areas such as illegal conduct, drug or alcohol use or sexual behavior.

f. Research which will involve the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens if these sources are publicly available or if the information is to be recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

B. Expedited Review.

Expedited review is allowed of research activities which involve no more than minimal risks to human subjects and which can be placed in one or more or the ten categories noted below. Expedited review is not allowed for research involving children except for collections which are part of the usual diagnostic or therapeutic regimen of children. The following activities may be considered for expedited review:

1. Collection of hair and nail clippings in a non-disfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

2. Collection of excreta and external secretions of sweat, uncannulated saliva, placenta removal at delivery and amniotic fluid at the time of rupture of membranes prior to or during labor.

3. Recording of data from subject 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter of

significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electorretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18years of age or older and who are in good health and not pregnant.

5. Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

6. Voice recordings made for research purposes such as investigations of speech defects.

7. Moderate exercise by healthy volunteers.

8. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

9. Research on individual or group behavior or characteristics of individuals,such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects. Research involving sensitive matters such as sexual or political behavior may require full review. Expedited review is not appropriate if the subject's responses, if known outside the research, could place them at risk of civil or criminal liability or damage their financial standing or employability.

10. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

The expedited review may be carried out by the UHSRC chair person or by one or more experienced reviewers designated by the chair person from among members of the UHSRC. These reviewers exercise all the authorities of the UHSRC for approval of research, but disapproval requires subsequent full review. Proposals approved in this manner will be discussed at the next regular meeting of the UHSRC. The use of the expedited review may be suspended or terminated by the Secretary of HHS when necessary to protect the rights or welfare of subjects.

C. Full Review.

1. In general, full review of all proposed research projects involving the use of human subjects will be required for all non-exempt research projects which do not qualify for an expedited review.

a. In the event research is undertaken without the intention of involving human subjects, but it is later proposed to use

human subjects in the research, at the time of the proposal to use human subjects the research shall then be reviewed and approved by the UHSRC and a certification submitted to, and approved by, the HHS.

b. Cooperative research projects are those projects, normally supported through grants, contracts, or similar arrangements, which involve institutions in addition to the grantee or prime contractor. In the case of a cooperative research project in which the University is the grantee or prime contractor, then the University will remain responsible to HHS for safeguarding the rights and welfare of human subjects. Also, when the University joins with another institution in a cooperative research project, the University will comply with these procedures as though it received funds for its participation in the project directly from HHS. In cases involving cooperative research projects, the University may use joint review, reliance upon the review of another qualified IRB or similar arrangements aimed at avoidance of duplication of effort.

2. Criteria for approval of research.

a. In order to approve research covered by these procedures the UHSRC shall determine that all of the following requirements are satisfied:

i. risks to subjects are minimized:

Number One. By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risks, and

Number Two. Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

ii. risks to subjects are reasonable in relation to anticipated benefits, if any, to subject, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the UHSRC will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapy subjects would receive even if not participating in the research). The UHSRC will not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

iii. selection of subjects is equitable. In making this assessment the UHSRC will take into account the purposes of the research and the setting in which the research

will be conducted.

iv. informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, the provisions of Section III (C)(3).

v. informed consent will be appropriately documented, in accordance with the provisions of Section III (C)(3).

vi. where appropriate, the research plan makes adequate provision for monitoring the data collected to insure the safety of subjects.

vii. where appropriate, there are adequate provisions to protect privacy of subjects and to maintain the confidentiality of data.

b. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards must be included in the study to protect the rights and welfare of these subjects.

3. Informed consent.

a. Except as provided elsewhere in these procedures, no investigator may involve a human being as a subject in research covered by these procedures unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

b. Except as provided elsewhere in this section, in seeking informed consent the following information shall be provided to each subject:

i. a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description

of the procedures to be followed, and identification of any procedures which are experimental;

ii. a description of any reasonably foreseeable risks or discomforts to the subject;

iii. a description of any benefits to the subject or to others which may reasonably be expected from the research;

iv. a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

v. a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

vi. for research involving more than minimal risks, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

vii. an explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject; and

viii. a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

c. When appropriate, one or more of the following elements of information shall also be provided to each subject:

i. a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

ii. anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

iii. any additional cost to the subject that may result from participation in the research;

iv. the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

v. a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

vi. the approximate number of subjects involved in the study.

d. The UHSRC may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided that the UHSRC finds and documents that:

i. the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

Number One: Programs under the Social Security Act, or other public benefit or service program;

Number Two: Procedures for obtaining benefits or services under those programs;

Number Three: Possible changes in or alternatives to those programs or procedures; or

Number Four: Possible changes in methods or levels of payment for benefits for services under those programs; and

ii. the research could not practicably be carried out without the waiver or alteration.

e. The UHSRC may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent provided the USHRC finds and documents that:

i. the research involves no more than minimal risk to the subjects;

ii. the waiver or alteration will not adversely effect the rights and welfare of the subject;

iii. the research could not practicably be carried out without the waiver or alteration; and

iv. whenever appropriate, the subjects will be provided with additional pertinent information after participation.

f. Nothing in these procedures is intended to limit the

authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state or local law.

g. Except as otherwise provided, informed consent shall be documented by the use of a written consent form approved by the UHSRC and signed by the subject or subject's legally authorized representative. A copy shall be given to the person signing the form.

h. Except as otherwise provided, the consent form may be either of the following:

   i. a written consent document that embodies the elements of informed consent required by Section III(C)(3) of these procedures. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

   ii. a "short form" written consent document stating that the elements of informed consent required by Section III(C)(3) have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the oral presentation shall include those items contained in a written summary, which has received the prior approval of the UHSRC, of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative in addition to a copy of the "short form."

i. The UHSRC may waive the requirement for the investigator to obtain a signed consent form for some or all of the subject if it finds either:

   i. that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

   ii. that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

j. In cases where the documentation requirement for informed consent is waived, the UHSRC may require the investigator to provide such subjects with a written statement regarding the research.

4. The UHSRC shall have authority to suspend or terminate approval of research that is not being conducted in accordance with UHSRC's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the UHSRC's action and shall be reported promptly to the investigator, appropriate institutional officials, and the Secretary of HHS at the Office for Protection from Research Risks, National Institutes of Health, Department of Health and Human Services, Bethesda, Maryland, 20205.

5. Procedures.

IV.

SPECIAL REQUIREMENTS - RESEARCH INVOLVING FETUSES, PREGNANT WOMAN AND HUMAN IN VITRO FERTILIZATION

A. The UHSRC has special responsibilities in research involving fetuses, pregnant women, and human in vitro fertilization. This includes monitoring the actual informed consent process and may extend to approval of procedures for induction of individuals into the activity. The Secretary of HHS, through a specific Ethical Advisory Board, has the responsibility for final review of these activities.

B. In general, the following criteria must be satisfied for UHSRC approval of research projects involving fetuses, pregnant women and human in vitro fertilization;

1. Appropriate studies on animals and nonpregnant individuals must have been completed.

2. The risk to the fetus is minimal.

3. The investigator must have no role in determining viability of the fetus or decision-making at the termination of the pregnancy.

4. No inducements may be made for pregnancy termination.

5. Maternal and paternal informed consent is required, except that the paternal consent need not be secured if:

a. the identity or whereabouts of the father cannot reasonably be ascertained,

b. the father is not reasonably available, or

c. the pregnancy resulted from rape.

6. Ex utero fetuses may be involved if no added risks results from the activity and if the purpose of the activity is to obtain knowledge which

cannot be obtained by other methods or to enhance the possibility of survival of the fetus.

7. Non-viable ex utero fetuses can be involved only if the activity does not affect vital functions and there is no way to obtain the knowledge in any other way.

8. Dead fetal material may be included in studies in accordance with state and local law.

C. Upon the request of an applicant and with UHSRC approval, the Secretary of HHS may modify or waive these criteria, with the approval of the Ethical Advisory Board. This will be done after an appropriate opportunity for public comment, and consideration will be given to whether the risk to the subject are so out weighed by the sum of the benefit as to warrant such action.

V.

SPECIAL REQUIREMENTS - RESEARCH INVOLVING CHILDREN

A. For purposes of this part of the procedures, the following definitions shall apply:

1. "Children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, which under the law of the State of Alabama at the time of the adoption of these procedures is nineteen (19) years of age.

2. "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

3. "Permission" means the agreement of parent(s) or guardian to the participation of their child or ward in research.

4. "Parent" means a child's biological or adoptive parent.

5. "Guardian" means an individual who is authorized under the law of this state to consent on behalf of a child to general medical care.

B. The UHSRC will approve research not involving greater than minimal risk to children only if the UHSRC finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians as described below.

C. The UHSRC will approve research in which the UHSRC finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the UHSRC finds that:

1. The risk is justified by the anticipated benefit to the subject;

2. The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

3. Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians as set forth below.

D. The UHSRC will approve research involving greater than minimal risks and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition, only if the UHSRC finds that:

1. The risk represents a minor increase over minimal risk;

2. The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

3. The intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for the understanding amelioration of the subject's disorder or condition; and

4. Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians as set forth below.

E. If research is not otherwise approvable pursuant to the provisions of Sections V(B)-(D), then the UHSRC will approve the proposed research only if:

1. The UHSRC finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

2. The proposed research has been approved by the Secretary of HHS.

F. Requirements for permission by parents or guardian and for assent by children.

1. In addition to the determinations required under other applicable sections of these procedures, the UHSRC shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the UHSRC the children are capable of providing assent. In determining whether children are capable of assenting, the UHSRC shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the UHSRC deems appropriate. If the UHSRC determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted without the interventional or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the UHSRC determines that the subjects are capable of assenting,

the UHSRC may still waive the assent requirements under circumstances in which consent may be waived in accordance with Section _____.

2. In addition to the determinations required under other applicable sections of these procedures, the UHSRC shall determine, in accordance with and to the extent that consent is required by Section _____, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the UHSRC may find that the permission of one parent is sufficient for research to be conducted under Sections V(B) or V(C). Where research is covered by Section V(D) and V(E) and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

3. In addition to the provisions for waiver contained in Section _____, if the UHSRC determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status and condition.

4. Permission by parents or guardians shall be documented in accordance with and to the extent required by Section_____.

5. When the UHSRC determines that assent is required, it shall also determine whether and how assent must be documented.

Duke-UNC Health Profile

Instructions:

Here are a number of questions about your health and feelings. Please read each question carefully and check (✓) your best answer. You should answer the questions in your own way. There are no right or wrong answers.

DURING THE PAST WEEK: How much trouble have you had with:

	None	Some	A Lot
1) Eyesight	___	___	___
2) Hearing	___	___	___
3) Talking	___	___	___
4) Tasting food	___	___	___
5) Appetite	___	___	___
6) Chewing food	___	___	___
7) Swallowing	___	___	___
8) Breathing	___	___	___
9) Sleeping	___	___	___
10) Moving your bowels	___	___	___
11) Passing water/urinating	___	___	___
12) Headache	___	___	___
13) Hurting or aching in any part of your body	___	___	___
14) Itching in any part of your body	___	___	___
15) Indigestion	___	___	___
16) Fever	___	___	___
17) Getting tired easily	___	___	___
18) Fainting	___	___	___
19) Poor memory	___	___	___
20) Weakness in any part of your body	___	___	___
21) Feeling depressed or sad	___	___	___
22) Nervousness	___	___	___

DURING THE PAST MONTH how much trouble have you had with:

	None	Some	A Lot
23) Undesired weight loss	___	___	___
24) Undesired weight gain	___	___	___
25) Unusual bleeding	___	___	___
26) Sexual performance (Having sex)	___	___	___

DURING THE PAST WEEK how often did you:

	Not at All	1-4 Days	5-7 Days
27) Do your usual work (either inside or outside the home)	_____	_____	_____
28) Get your work done as carefully and accurately as usual ...	_____	_____	_____
29) Socialize with other people (talk or visit with friends or relatives)	_____	_____	_____
30) Take part in social, religious or recreation activities (meetings, church, movies, sports, parties)	_____	_____	_____
31) Care for yourself (bathe, dress, feed yourself)	_____	_____	_____

DURING THE PAST WEEK:

	None	1-4 Days	5-7 Days
32) How many days did you stay *in your home* because of sickness, injury or health problems?	_____	_____	_____
33) How many days were you *in bed* most of the day because of sickness, injury or health problems?	_____	_____	_____

TODAY would you have any physical trouble or difficulty:

	None	Some	A Lot
34) Peeling an apple	_____	_____	_____
35) Combing your hair	_____	_____	_____
36) Walking to the bathroom	_____	_____	_____
37) Walking up a flight of stairs	_____	_____	_____
38) Running the length of a football field	_____	_____	_____
39) Running a mile	_____	_____	_____
40) Running 5 miles	_____	_____	_____

Instructions:

Here are some statements you could use to describe how you feel about yourself. Please read each statement carefully and place a check (✓) in the blank that best fits how the statement describes you.

Here is an example:

	Yes, describes me exactly	Somewhat describes me	No, doesn't describe me at all
I like T.V. soap operas		✓	

(If you put a check where we have, it means that liking T.V. soap operas describes you more than "somewhat" but not "exactly".)

Answer each item as best you can. There are NO right or wrong answers.

	Yes, describes me exactly	Somewhat describes me	No, doesn't describe me at all
41) I am a pleasant person			
42) I don't feel useful			
43) I get on well with people of the opposite sex ..			
44) My family doesn't understand me			
45) I like who I am			
46) I feel hopeful about the future			
47) I try to look my best			
48) I am a clumsy person			
49) I have difficulty making decisions			
50) I like meeting new people			
51) I'm not an easy person to get along with			
52) I'm a failure at everything I try to do			
53) I'm basically a healthy person			
54) I wish I had more sex appeal			
55) I give up too easily			
56) I like the way I look			
57) I'm not as smart as most people			
58) I have difficulty concentrating			
59) I'm satisfied with my sexual relationships			
60) I am happy with my family relationships			
61) I don't treat other people well			
62) I am comfortable being around people			
63) I can take care of myself in most situations			

APPENDIX C

Daily Health Record

DAILY HEALTH RECORD

DAY # 1

An example Health Record is included in your folder

DAY OF THE WEEK _____

DATE _____

TIME _____

1 How did you feel <u>physically</u> today? *(Put an "X" in the box which best describes how you felt)*

1	2	3	4	5	6	7	8	9	10

TERRIBLE WONDERFUL

2 **Did you have any <u>symptoms or discomforts today</u>?** *(Fill out the chart below from left to right for each symptom or set of symptoms)*

☐ 1 Yes ↓ ☐ 5 No symptoms or discomforts at all → *Go to Question 6*

SYMPTOM CHART

NUMBERS BELOW CAN BE USED IN Qs 3 AND 4	2a SYMPTOMS & DISCOMFORTS Write symptoms of the same health problem in one box.	2b CAUSE <u>Illness</u>, name the illness. <u>Injury</u>, name part of body hurt and type of injury.	<u>Not illness or injury</u>, write what you think caused the symptoms.	2c SERIOUSNESS In your opinion, how serious was this condition or set of symptoms today?
1				☐ 1. Very Serious ☐ 3. Somewhat Serious ☐ 5. Not Very Serious
2				☐ 1. Very Serious ☐ 3. Somewhat Serious ☐ 5. Not Very Serious
3				☐ 1. Very Serious ☐ 3 Somewhat Serious ☐ 5 Not Very Serious
4				☐ 1 Very Serious ☐ 3 Somewhat Serious ☐ 5 Not Very Serious
5				☐ 1 Very Serious ☐ 3. Somewhat Serious ☐ 5. Not Very Serious

3 Because of today's symptoms, did you cut down on the things you usually do?

☐ 1 Yes ☐ 5 No ● *Go to Question 4*

Answer 3a through 3e			For which symptom, illness, or injury? *(Write in number from symptom chart, question 2)*
3a. Did you stay in bed?	☐ No	☐ Yes ●	
3b. Did you cut down on household chores or errands?	☐ No	☐ Yes ➡	
3c. Did you miss work?	☐ No	☐ Yes ●	
3d. Did you miss school?	☐ No	☐ Yes ➡	
3e. Did you cut down on other activities you planned to do (sports, clubs, church, etc.)?	☐ No	☐ Yes ●	

4 Did you seek medical or dental help about today's symptoms?

☐ 1 Yes ☐ 5 No ➡ *Go to Question 5*

Answer 4a through 4e			For which symptom, illness, or injury? *(Write in number from symptom chart, question 2)*
4a. Did you make an appointment with a doctor or dentist?	☐ No	☐ Yes ●	
4b. Did you telephone a clinic, doctor's office or dentist's office and get advice?	☐ No	☐ Yes ➡	
4c. Did you visit a clinic, doctor's or dentist's office or an emergency room?	☐ No	☐ Yes ●	
4d. Did you get admitted to a hospital?	☐ No	☐ Yes ➡	
4e. Was there anything else you did? (IF YES: What was that?)	☐ No	☐ Yes ●	

5 **Did you talk with anyone else today — such as relatives, neighbors, friends — about your symptoms?**

☐ 1. Yes ☐ 5. No ➡ *Go to Question 6*

5a. Who did you talk with? *(Check all boxes that apply.)*

☐ A. Your husband/wife

☐ B. Other member of your household

☐ C. Relative not living with you

☐ D. Neighbor, coworker, friend (who is not a relative or household member)

☐ E. Other person (druggist, minister, priest, etc.) Who did you speak with? _____

_____

6 **Did you visit or telephone a clinic, doctor or dentist's office, or hospital today for any reason besides symptoms you might have had today?**

☐ 1. Yes ☐ 5 No ➡ *Go to Question 7*

6a. For what reasons?

_____

_____

_____

_____

7 **Did you take any pills, medicine, or treatments for your health today — to treat a symptom, prevent illness, or to become more healthy in general?** *(Fill out the chart below from left to right)*

☐ 1 Yes ▼

☐ 5 No pills, medicine or treatment taken at all ● *Go to Question 8*

	7a PILLS, MEDICINE, TREATMENTS If pills or medicine, write the brand name from the label and the type of drug. Use one box for each pill, medicine or treatment	7b REASONS FOR TAKING PILLS, MEDICINE, TREATMENTS *(Check all boxes that apply)* A To treat symptoms bothering you today B For other health problem not bothering you today C To prevent illness or to become more healthy in general D Other reasons	7c SYMPTOM OR CONDITION What was the symptom, health problem, or other reason for taking pills, medicine, or treatment?
1		☐ A ☐ B ☐ C ☐ D Go to 7c ●	
2		☐ A ☐ B ☐ C ☐ D Go to 7c ➡	
3		☐ A ☐ B ☐ C ☐ D Go to 7c ●	
4		☐ A ☐ B ☐ C ☐ D Go to 7c ●	
5		☐ A ☐ B ☐ C ☐ D Go to 7c ➡	

8 **How were your spirits today?** *(Put an "X" in the box which best describes how you felt today)*

1	2	3	4	5	6	7	8	9	10

TERRIBLE WONDERFUL

9 **Did anything happen – for better or worse – to make today different than usual?**

☐ 1 Yes ☐ 5 No ➡ *Go to Question 10*

9a. **What happened?** *(Check all boxes that apply.)*

- ☐ A. Birthday, holiday, or special social event
- ☐ B. Trip or vacation
- ☑ C. Emergency
- ☐ D. Trouble with family or friends
- ☐ E. Something extra nice with family or friends
- ☐ F. A lot of extra work
- ☐ G. Guests
- ☐ H. Other: What happened? _____

10 **Any other comments:** _____

REMINDER:

IF you had any symptoms today
Be sure you answered Questions 1, 2, 3, 4, 5, 6, 7, 8, and 9

IF you had no symptoms today
Be sure you answered Questions 1, 2, 6, 7, 8, and 9.

APPENDIX D
MEDICAL EVALUATION, SUBJECTS
FOR WATER RECOVERY TEST, MSFC

NAME: _____ _____ _____
LAST FIRST MIDDLE

ADDRESS _____

_____

AGE_____ DATE OF BIRTH_____

WORK AREA_____ WORK PHONE_____

HOME PHONE_____ MAIL CODE_____

IN CASE OF EMERGENCY, CONTACT:_____

_____ PHONE_____

PERSONAL PHYSICIAN_____

ADDRESS_____ PHONE_____

INITIAL EVALUATION

	NL	ABNL	COMMENTS
PMH	___	___	_____
CHRONIC ILLNESSES	___	___	_____
MEDS	___	___	_____
MENSTRUAL HISTORY	___	___	_____
RECENT ILLNESSES	___	___	_____
TOPICAL USE	___	___	_____
HABITS (D, T, A)	___	___	_____
SKIN/HAIR DISORDER	___	___	_____
MINOR ILLNESS FREQUENCY	___	___	_____
PHYSICAL EXAM			
SKIN	___	___	_____
HEENT	___	___	_____
LUNGS	___	___	_____

INITIAL EVALUATION (CONTINUED)

	NL	ABNL	COMMENTS
HEART	___	___	_____
ABD	___	___	_____
GU	___	___	_____
NEURO/MS	___	___	_____
HEALTH PROFILE	___	___	_____
LABORATORY			
ROUTINE	___	___	_____
SPECIAL	___	___	_____
SKIN TEST			
PPD	___	___	_____
ANERGY	___	___	_____
SYMPTOM DIARY	___	___	_____

I have examined the above named subject and believe he/she (is) (is not) qualified to be involved in the water recovery test at MSFC.

_____ M.D. ___/___/___
DATE

APPENDIX D
MEDICAL EVALUATION, SUBJECTS
FOR WATER RECOVERY TEST, MSFC

NAME: _____ _____ _____
LAST FIRST MIDDLE

ADDRESS _____

_____

AGE_____ DATE OF BIRTH_____

WORK AREA_____ WORK PHONE_____

HOME PHONE_____ MAIL CODE_____

IN CASE OF EMERGENCY, CONTACT:_____

_____ PHONE_____

PERSONAL PHYSICIAN_____

ADDRESS_____ PHONE_____

PRE-TEST EVALUATION

	NL	ABNL	COMMENTS
SYMPTOM DIARY	___	___	_____
MENSTRUAL HISTORY	___	___	_____
TOPICAL USE	___	___	_____
PHYSICAL EXAM			
_____	___	___	_____
_____	___	___	_____
_____	___	___	_____
LABORATORY			
ROUTINE	___	___	_____
SPECIAL	___	___	_____

I have examined the previous named subject and believe he/she (is) (is not) qualified to be involved in the water recovery test at MSFC.

_____ M.D. ___/___/___
DATE

APPENDIX E

2.12 Disqualification Criteria for Initial Evaluation

- 2.121 No personal physician
- 2.122 Any chronic illness or regular medicine intake
- 2.123 Frequent minor illnesses
  - 2.1231 > 4 colds/yr
  - 2.1232 > 2 GE/yr
  - 2.1233 > 1 UTI/yr
  - 2.1234 > 2 Vaginitis/yr
  - 2.1235 > 1 Active Skin Infection/yr
- 2.124 Abnormal physical finding

2.14 Disqualification Criteria for Pre-test Evaluation

- 2.141 Significant new symptoms of infection
- 2.142 Testing likely to occur during menses (phase dependent)
- 2.143 Any topical use (phase dependent)
- 2.144 Abnormal physical finding
- 2.145 Positive urine culture (>10,000/ml of each organism)
- 2.146 Positive wet prep/GM stain
- 2.147 Positive or indeterminate serum pregnancy test
- 2.148 Positive urine drug screen

APPENDIX G
Presentation Material

Presentation made on April 4, 1988

CURRENT KEY ISSUES

1. DETERMINATION OF RISK BY SKIN/M.M. EXPOSURE TO:
   a) CHEMICAL CONTAMINANTS
   b) MICROBIAL CONTAMINANTS (unusual pathogen.
   c) URINARY METABOLITES AFTER PRE-TREATMENT

2. DETERMINATION OF RISK BY INGESTION

3. SAMPLING ALGORITHMS
   a) SAMPLE SIZE & PROBABILITY MORE DATA POINTS
   b) TYPE II (β) ERROR

4. ~~MASS BALANCE~~
   a) ~~BRINE LOSS~~
   b) ~~SAMPLING LOSS~~

2.15 Post-Test Evaluation

2.151 Review symptom diary

2.152 Review menstrual history

2.153 Brief physical exam

2.154 Repeat health profile (DUHP)

2.155 Laboratory

2.1551 U/A and culture

2.1552 Wet prep/GM stain (if indicated)

2.1553 Serum pregnancy test

2.1554 Stool culture

2.1555 Special studies

2.16 Detection of Sick Subjects

2.161 Continue symptom diary

2.162 Monitor visits to personal physician (by permission)

2.163 Subject notifies

CURRENT KEY ISSUES

5. LEGAL RISK
   a) SUBJECT POOL SIZE
   b) FEDERAL VS. PRIVATE TORT SYSTEM

6. MONITORING ILLICIT DRUGS

7. INCLUDING MENSTRUATING SUBJECT

8. INCLUDING PREGNANT SUBJECT

9. MANAGEMENT OF INJURED SUBJECT

- CLEAN SYSTEM
  ALLOWED MEDICATION LIST

INSTITUTIONAL REVIEW BOARD - COMPOSITION

1. The use of human subjects in research committee (UHSRC) shall be composed of at least five (5) members, with diverse backgrounds possessing the professional competence to promote complete and adequate review of research activities and ascertain acceptability in terms of institutional commitments and regulations, applicable law and standards of professional conduct and practice.

2. Representation on the UHSRC shall include:

   a. Men and women.
   b. Representation of more than one profession.
   c. At least one member whose primary concerns are non-scientific, i.e., lawyer, ethicist, clergy member.
   d. At least one member who is not affiliated with the institution, either personally or by immediate familial relationship.

3. No person shall serve as a member of the UHSRC where such service would constitute a conflict of interest involving the proposed research project under review.

4. The UHSRC will invite individuals with specific competencies to assist in its review of complex issues. Within the scope of their invitation, these invited individuals will serve as full members of the UHSRC, except that they shall not have a vote.

W. J. Crump, M.D.
3/28/88

APPENDIX 6

CONSENT FORM
FOR APPROVED NASA HUMAN RESEARCH

1. I, the undersigned, do voluntarily give my informed consent for my participation as a test subject in the following test, experiment, or other evaluative procedure:

   NAME OF EXPERIMENT _____

   FLIGHT TO WHICH ASSIGNED _____

   NAME OF DESIGNATED PRINCIPAL INVESTIGATOR _____

   NAME OF RESPONSIBLE NASA PROJECT SCIENTIST _____

I understand that:

(a) This procedure is part of an experiment approved by NASA.

(b) I am performing these duties as a part of my employment, with _____.

(c) This procedure has been reviewed and approved by the JSC Human Research Policy and Procedures Committee (HRPPC) and determined that the procedure involves reasonable risk to the subject.

(d) "Reasonable risk" means that the risks of harm anticipated in the proposed research are greater than thos ordinarily encountered in daily life or during the performance of routine tests, but considered to be proper when weighing the anticipated benefits and the importance of the knowledge to be gained from the research.

(e) The procedure has been explained to me prior to the execution of this form. I was afforded an opportunity to ask questions, and all questions asked were answered.

(f) I am medically qualified to participate in the procedure.

(g) I may withdraw from the procedure at any time unless, as recommended by the Principal Investigator, or his/her designee, the withdrawal is dangerous or impossible.

(h) In the event of physical injury resulting from the procedure and calling for immediate action or attention that NASA will provide, or cause to be provided, the necessary treatment. I also understand that NASA will pay for any claims of injury, loss of life or property damage to the extent required by the Federal Employees' Compensation Act or the Federal Tort Claims Act. My agreement to participate shall not be construed as a release of NASA or any third party from any future liability which may arise from, or in connection with, the above procedures.

2. I, the undersigned, the Principal Investigator of the experiment designated above, certify that:

   (a) I have accurately described the procedure to the test subject.

   (b) The test set-up involves reasonable risk to the test subject. All equipment used has been inspected and certified for safe and proper operation.

   (c) The test subject is medically qualified to participate.

   (d) The test protocol has not been changed from that approved by the JSC Human Research Policy and Procedures Committee (HRPPC).

APPROVED:

Test Subject	Date
Principal Investigator	Date
Project Scientist	Date

This consent form is valid for a 60-day period from the date of signature by the subject and the Principal Investigator (which dates should be identical). A signed, dated copy of the form should be forwarded to the JSC Human Research Policy and Procedures Committee, Mail Code SA, Lyndon B. Johnson Space Center, Houston, Texas 77058.

2.11 Initial Evaluation

2.111 Name of personal physician

2.112 Recent illnesses

2.113 Past medical history

2.1131 Chronic illnesses (Hypertension, Diabetes, etc.)

2.1132 Regular medicines, including OCP's and OTC

2.1133 Menstrual history

2.1134 Regular cream, ointment, oil use

2.1135 Other drugs, alcohol, tobacco

2.1136 Active skin or hair disorder

2.1137 Frequency of minor infectious diseases

2.114 Physical Exam

2.115 Health Profile (DUHP)

2.116 Laboratory

2.1161 CBC

2.1162 U/A and culture

2.1163 Wet prep/GM Stain (if indicated)

2.1164 Serum pregnancy test

2.1165 Stool culture

2.1166 Special studies

2.117 Skin test anergy pack and PPD (Reading required in 48 hours)

2.118 Begin symptom diary

2.12 Disqualification Criteria for Initial Evaluation

- 2.121 No personal physician
- 2.122 Any chronic illness or regular medicine intake
- 2.123 Frequent minor illnesses
  - 2.1231 > 4 colds/yr
  - 2.1232 > 2 GE/yr
  - 2.1233 > 1 UTI/yr
  - 2.1234 > 2 Vaginitis/yr
  - 2.1235 > 1 Active Skin Infection/yr
- 2.124 Abnormal physical finding
- 2.125 Poor DUHP score
- 2.126 Abnormal lab

2.13 Pre-Test Evaluation

2.131 Review symptom diary

2.132 Review recent menstrual history

2.133 Review recent topical use

2.134 Brief physical exam

2.135 Laboratory

2.1351 U/A and culture

2.1352 Wet prep/GM stain (if indicated)

2.1353 Serum pregnancy test

2.1354 Urine drug screen (legal ramifications)

2.1355 Special Studies

2.14 Disqualification Criteria for Pre-test Evaluation

2.141 Significant new symptoms of infection

2.142 Testing likely to occur during menses (policy decision)

2.143 Any topical use on prohibited list

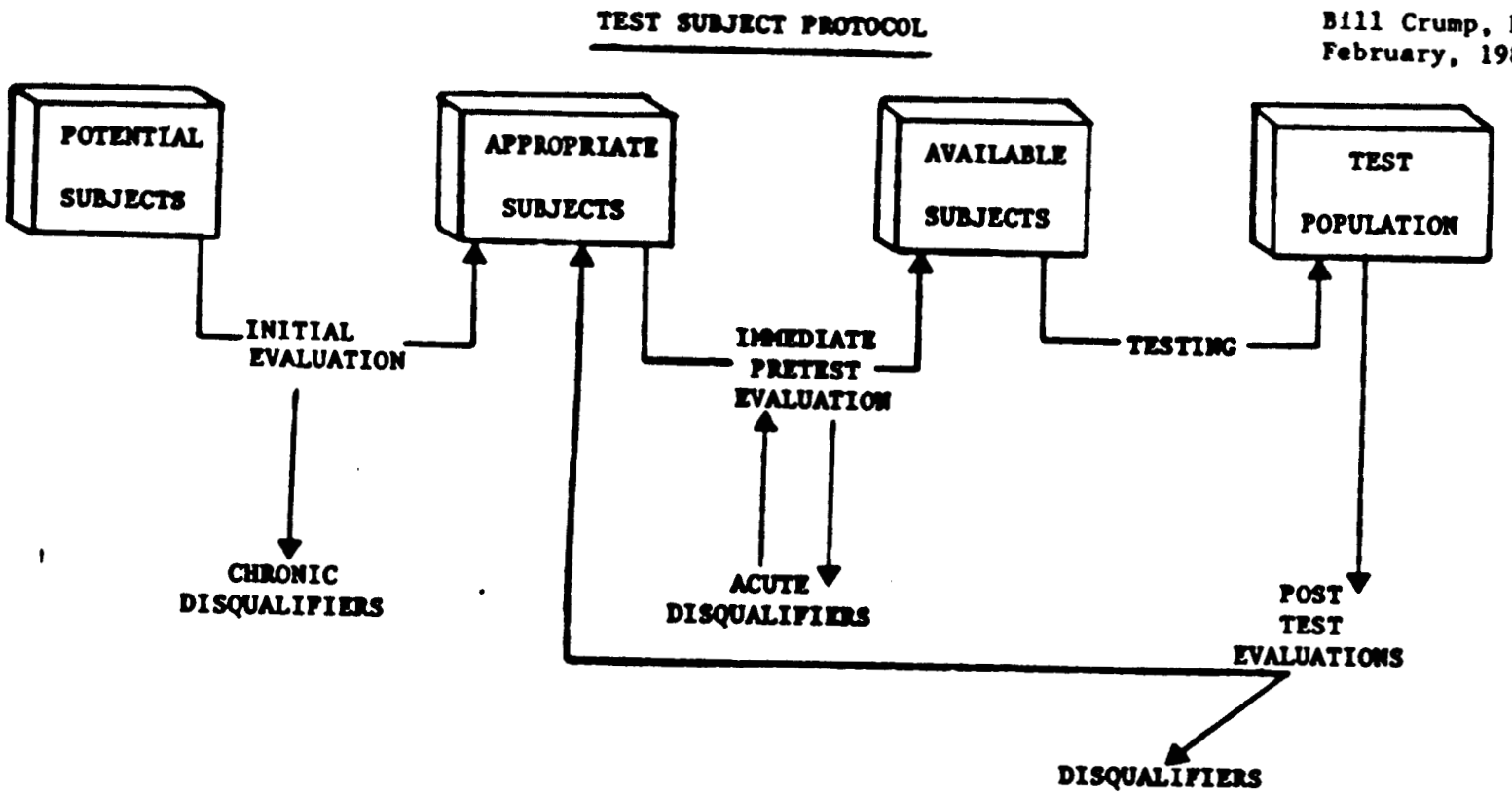
2.144 Abnormal physical finding

2.145 Positive urine culture (>10,000/ml of each organism)

2.146 Positive wet prep/GM stain

2.147 Positive or indeterminate serum pregnancy test

2.148 Positive urine drug screen (legal)



Presentation made on April 4, 1988

PROPERTY	POTABLE LIMIT	HYGIENE LIMIT	NIOSH	EPA	POTABLE LIMIT (Al₂)
PHYSICAL					
color					15
conductivity	TBD	TBD			
gas, dissolved	0	0			
gas, free	0	0			
particulates	40	40			
pH	6.0-8.0	5.0-8.0			
solids, total	<100	<500			
solids, diss.					500
surfactants					
taste, odor	<3	<3			
turbidity	TBD	TBD			<5
AESTHETICS	(minimum)	(mg/L)			
Cations	TBD<30	NA			
Anions	TBD<30	NA			
CO_2	TBD<15	NA			
INORGANIC					
METALLICS	(ppm)				
Aluminum	TBD	TBD			
Antimony	TBD	TBD			
Arsenic	0.01	0.01			0.05
Barium	1.00	1.00			1.00
Beryllium	TBD	TBD			
Boron	TBD	TBD			
Cadmium	0.01	0.01			0.01
Calcium	TBD	TBD			
Chromium	0.05	0.05			0.05
Cobalt	TBD	TBD			
Copper	1.00	1.00			1.00
Iron	0.30	0.30			0.30
Lead	0.05	0.05			0.05
Magnesium	0.05	0.05			
Manganese	0.05	0.05			0.50
Mercury	0.002	0.002			0.002
Molybdenum	TBD	TBD			
Nickel	0.05	0.05			
Potassium	TBD	TBD			
Selenium	0.01	0.01			0.01
Silver	0.05	0.05			0.05
Thallium	TBD	TBD			
Tin	TBD	TBD			
Titanium	TBD	TBD			
Zinc	5.00	5.00			5.00

DONOR SAFEGUARDS

Exposure and Risk

- **Sources**
  - **Hygiene Wastes**
    - **Shower**
    - **Clothes Washing**
    - **Dish Washing**
  - **Urine**
  - **Humidity Condensate**

- **Routes**
  - **Skin Contact including mucous membranes**
  - **Transdermal**
  - **Inhalation**
  - **Ingestion**
- **Exposure**
  - **Intermittent** for Grand Testing
  - ~~**Continuous**~~
- **Risks**
  - **Chemical**
  - **Biological**

TABLE 3-4

RECOMMENDATIONS FOR MONITORING

PHYSICAL

- CONDUCTIVITY
- COLOR
- pH
- TURBIDITY

INORGANIC

Non-Metals

- Ammonia
- Chloride
- Bromide
- Iodide
- Nitrate
- Phosphate
- Sulfate

Metals

- Arsenic
- Barium
- Cadmium
- Calcium
- Chromium
- Copper
- Iron
- Lead
- Magnesium
- Manganese
- Mercury
- Nickel
- Potassium
- Selenium
- Silver
- Zinc

ORGANICS

- Cyanide
- TOC
- Total Toxic Organics (TTO) (including P-Y.

MICROBIOLOGICAL

- Total Bacteria
- Total Coliforms
- Heterotrophs
- Non-Saprophytic
- Legionellae

TABLE 3-5

METHODS AND INSTRUMENTATION FOR WATER QUALITY VERIFICATION

PARAMETER	METHOD	INSTRUMENTATION
PHYSICAL		
CONDUCTIVITY	EPA 120.1	Cond. Meter
COLOR	EPA 110.3	UV-VIS
pH	EPA 150	pH Meter
TURBIDITY	EPA 180	Nephelometer
INORGANIC		
Non-Metals		
Ammonia	EPA 350.2	UV-VIS
Chloride	EPA 300.0	Ion Chromatograph
Bromide	EPA 300.0	Ion Chromatograph
Iodide	EPA 300.0	Ion Chromatograph
Nitrate	EPA 300.0	Ion Chromatograph
Nitrogen, Total	EPA 351.3	UV-VIS
Phosphate	EPA 300.0	Ion Chromatograph
Sulfate	EPA 300.0	Ion Chromatograph
Metals		
Arsenic	EPA 206.3	AAH
Barium	EPA 200.7	ICP
Cadmium	EPA 213.2	AAG
Chromium	EPA 200.7	ICP
Copper	EPA 200.7	ICP
Iron	EPA 200.7	ICP
Lead	EPA 239.2	AAG
Magnesium	EPA 200.7	ICP
Manganese	EPA 200.7	ICP
Mercury	EPA 245.1	Hg Analyzer
Nickel	EPA 249.2	AAG
Potassium	EPA 258.1	AAF
Selenium	EPA 270.3	AAH
Silver	EPA 272.2	AAG
Zinc	EPA 200.7	ICP
ORGANICS		
Cyanide	EPA 335.2	UV-VIS
Halogenated Hydrocarbon	EPA 612	GC/ECD
Organic Acids		HPLC
Organic Alcohols		HPLC
Pesticides	EPA 608	GC/ECD
Phenols	EPA 604	GC/FID
TOC	EPA 415.2	TOC Analyzer
Total Toxic Organics	EPA 624, 625	GC/MS

SECONDARY REQUIREMENTS (CONT.)

Compound	Source	Amt.	Toxicity
palmitic acid	7	10	ivn mus LD_{50} 57mg
pentane, 2,3-dimethyl-	1	50	
pentane, 2,2,4-trimethyl-	1	100	
4-methyl-2-pentanone	1	50	
2-methyl-2,4-pentanediol	1	410	
pentene, 4,4-dimethyl-1-	1	100	
phosphate, diethyl pentyl-	1	67	
phosphate, triethyl-	1	12	
phosphate, tertamethylpyro-	1	2	
phosphate, tetramethylpyro-	2	100	
1-propene	1	100	
propionic acid	1	6,000-17,222	orl rat LD_{50} 1510mg
propylene glycol	1	300	
Pyrrolidine			orl rat LD_{50} 800mg
pyrrolidine, N-methyl-	1	71	
pyrrolidone	1	100	
styrene	1	50	ihn hmn TCLo 376ppm
salicylic acid	6	350000	orl rat LD_{50} 891mg
thiophene, tetrahydro-1,1-dioxide	1	15	
thiourea	1	300-500	
thiourea, tetramethyl	1	35	
urea	1	<16,000	
Undecanoic Acid			ivn mus LD_{50} 140mg
n-undecane	4	200	
vanillan	6	200	orl rat LD_{50} 1580mg
Xylenol			orl mus LD_{50} 1070mg
xylenes, total	1	50	

SECONDARY REQUIREMENTS (CONT.)

Compound	Source	Amt.	Toxicity
caprylic acid	1	273ppb	ivn mus LD_{50} 600mg
cyanurate, triallyliso-	1	12ppb	
carboxylic acids	4	40,800ppb	
carboxylic acids	2	92,210ppb	
carboxylic acids	3	81,500ppb	
carboxylic acids (5)	7	3,500ppb	
carboxylic acid cmpds (4)	6	52,000ppb	
carboxylic acids (5)	1	43,000ppb	
unknown carboxylic acids	1	2,633ppb	
Caproic Acid			orl rat LDLo 3000mg
caprolactam	1	15,000ppb	
carbon disulfide	1	14-722ppb	
Decanal			orl rat LD_{50} 3730mg
decan cmpds (2)	4	280ppb	
Dodecyl alcohol			ipr rat LD_{50} 800mg
dodecanol	3	100ppb	
dibenzofuran	1	20	
dimethyl-benzene methanol	1	16ppb	
dioxolane cmpds	3	600ppb	
ether, ethyl propyl	1	34ppb	
ether, ethylene glycol monobutyl-	1	100ppb	
ether, p-chlorophenyl methoxyisobutyl	4	400ppb	
ethers, glycol (2)	1	550ppb	
	3	900ppb	
furfuryl alcohol	5	200	orl rat LD_{50} 275mg
Heptanoic Acid			orl mus LD_{50} 160mg
4-heptanone	6	100ppb	
heptanone cmpds (2)	4	60ppb	
Hexanol			orl rat LD_{50} 720mg
hexanol, 2-ethyl-1-	6	100ppb	
hexanol, 5-methyl-1-	1	150ppb	
2-hexanone	1	50ppb	
cyclohexanone	1	35ppb	
isophorone	1	3ppb	
lactone cmpds	3	130ppb	
morpholine, 4-ethyl	1	470ppb	
morpholine, n-ethyl	1	400ppb	
nonanedioate, bis(2-ethyl hexyl)-	1	1,100ppb	
nonanedioic acid	1	6ppb	
octanoate, methyl-	3	200ppb	

SECONDARY REQUIREMENTS

Compound	Source		Amt.	Toxicity
Acetic Acid	5		300	orl hmn TDLo 1470 ug GIT ihl hmn TDLo 816ppm/3min
acetic acid, phenyl	4		400	
acetate, ethanol ethoxy	1		180	
acetate, vinyl	1		50	
acetone	3		3300	orl hmn TCLo 500ppm Eye
diacetone alcohol	1		19ppb	
acetone cmpds (2)	4		250ppb	
acrylate, 3-methoxy-butyl	3		130ppm	
azepin-2-one, hexahydro	1	SL1	73ppb	
	1	SL3	4.3ppm	
aniline	1		20ppb	
2-nitroaniline	1		200ppb	
3-nitroaniline	1		200ppb	
4-nitroaniline	1		200ppb	
Adipic Acid				orl rat LDLo 3600mg
adipate, tetramethylene	1		6ppb	
amide, butyl benzenesulfon	1		6ppb	
amide, N,n-di-n-butylform-	1		60ppb	
amide, N-methyl-N-ethyl form-	1		1,103ppb	
4-chloroaniline	1		100ppb	
amide, N,n-dimethyl form-	1		541ppb	
amides (4)	1		3190ppb	
amides (2)	2		400ppb	
amine, dimethyl				orl rat LD_{50} 698mg
amine, N,n-dimethyl benzyl-	1		80ppb	
amine, di-n-butyl	1		74ppb	
amines (2)	1		200ppb	
alcohol cmpds (2)	3		5000ppb	
alkene ($C_{29}H_{58}$)	3		10ppb	
Butyric Acid				orl rat LD_{50} 2940mg
butyrates, 3-hydroxy -trimethylpentyliso	1		300ppb	
1-butanamine, n-butyl-	1		180ppb	
butanoate,2 methoxymethyl-2-	1		55ppb	
2-butanone	1		900ppb	
butanone, 3-methyl-2-	1		60ppb	
benzoic acid	1		500ppb	orl rat LD_{50} 3040mg
	3		848ppb	
benzoic acid cmpds (2)	4		3000ppb	
	6		150ppb	
benzaldehyde	3		1000ppb	orl rat LD_{50} 1300mg
benzaldehyde cmpds (3)	4		150ppb	
benzyl alcohol	1		4700ppb	orl rat LD_{50} 1330mg
benzisoxazole	1		100ppb	

PRIMARY REQUIREMENTS (CONT.)

Compound	Source	Amt Det.
acenaphthene	1	100
acenaphthylene		
anthracene		
benzidine		
benzo-a-anthracene		
benzo-a-pyrene	1	100
benzo-b-fluoranthene		
3,4-benzofluoranthene		
benzo(g,h,i)perylene		
benzo(k)fluoranthene	1	40
bis(2-chloro ethoxy)methane		
bis(2-chloroethyl)ether		
bis(2-chloroisopropyl)ether		
bis(2-ethylhexyl)phthalate	8	103
4-bromophenyl phenyl ether		
butylbenzyl phthalate		
2-chloro naphthalene		
4-chlorophenyl phenyl ether		
chrysene	1	100
dibenzo(a,h)anthracene		
1,2-dichlorobenzene		
1,3-dichlorobenzene		
1,4-dichlorobenzene		
3,3'-dichlorobenzidine		
diethyl phthalate		
dimethyl phthalate		
di-n-butyl phthalate		
2,4-dinitro toluene		
2,6-dinitro toluene		
di-n-octyl phthalate		
1,2-diphenylhydrazine (as azobenzene)		
flouranthene		
fluorene		
hexachlorobenzene		
hexachlorobutadiene		
hexachlorocyclopentadiene		
hexachloroethane		
indeno(1,2,3-od)pyrene		
isophorone		
* 2-methyl naphthalene	1	40
naphthalene	1	100
nitrobenzene		
N-nitrosodimethylamine		
N-nitrosodi-n-propylamine		
N-nitrosodiphenylamine		
phenanthrene		
* phthalate, diethyl pentyl-	1	49
* phthalate esters (2)	6	350
* phthalate esters	1	140-15,000
* phthalate, bis(2-ethyl hexyl)-	8	103
pyrene		
1,2,4-trichlorobenzene		
2,3,7,8-tetrachlorodibenzo-p-dioxin		

PRIMARY REQUIREMENTS (CONT.)

	Compound	Source	Amt detected
	ACID COMPOUNDS		
	p-chloro-m-cresol		
	4,6-dinitrocresol		
	phenol		
	2-chlorophenol		
	2,4-dichlorophenol		
	2,4,6-trichlorophenol	1	200
	pentachlorophenol		
	4-chloro-3-methylphenol		
	2,6-dimethylphenol		
	2-nitrophenol		
	4-nitrophenol		
	2,4-dinitrophenol		
	2-methyldinitrophenol	1	40
•	2-methyl phenol	1	650
•	4-methyl phenol	1	10
•	phenol, 2,6-di -t-butyl-4-methyl-	1	16
•	phenol, 4-(1,1-dimethylethyl)	1	13
•	phenol cmpds	4	2,200
•	phenol cmpds (8)	6	600
•	phenol cmpds (6)	2	275
•	phenol,2,6-di -t-butyl-4-methyl-	8	150

SPECIFIC TOXICANTS

PRIMARY REQUIREMENTS

	Compound	Source	Amt detected
	VOLATILES		
•	Acetyl benzene	1	16
	Acrolein		
	Acrylonitrile		
	Benzene		
•	Bromochloromethane	1	500
•	Bromochloropropane	1	500
	Bromoform		
	Bromomethane	1	100
	Bromodichloromethane		
	Carbontetrachloride		
	Chlorobenzene		
	Chlorodibromomethane		
	Chloroethane		
	2-chloroethyl vinyl ether		
	Chloroform		
	Chloromethane	1	100
	Dibromochloromethane		
•	Dichlorobutane	1	500
	1,1-dichloroethane		
	1,2-dichloroethane		
	1,1-dichloroethylene		
	trans 1,2-dichloroethylene		
•	Dichlorofluoromethane	1	50
	1,2-dichloropropane		
	1,3-dichloropropene	1	100
	1,2-dichloropropylene		
•	Dimethylbenzene-methanamine	1	230
	ethyl benzene		
	methyl bromide		
	methyl chloride		
	methylene chloride		
	1,1,2,2-tetrachloroethane		
	tetrachloroethylene		
	toluene		
	1,2-trans-dichloroethylene		
	1,1,1-trichloroethane		
	trichloroethylene		
	trichlorofluoromethane	1	50
	vinyl chloride		

SPECIFIC TOXICANTS

Definition:

Primary

- **EPA Priority Pollutants and related compounds**
  - **Volatiles**
  - **Acid Extractables**
  - **Base/Neutral Extractables**
- **Pharmaceuticals**
  - **Metabolites**
  - **Oxidation Products**
- **Illicit Drugs**

Secondary

- **All Other**

~~**Mission Specific**~~

PROPERTY	POTABLE LIMIT	HYGIENE LIMIT	NIOSH	EPA	POTABLE LIMIT
INORGANIC					
NONMETALLICS	(ppm)				
Ammonia	0.50	0.50			
Bromide	TBD	TBD			
Chloride	250	TBD			
Chlorine	TBD	TBD			
Fluoride	1.00	1.00			
Iodide	15	TBD			
Nitrate	10	TBD			
Nitrite	TBD	TBD			
Nitrogen, total	TBD	TBD			
Phosphorous	TBD	TBD			
Sulfate	250	TBD			
Sulfide	0.05	0.05			
Sulfite	TBD	TBD			
ORGANICS	(ug/L)				
Cyanide	200	TBD			
Halogenated Hydrocarbons	TBD<10	TBD			
Oil & Grease	TBD	TBD			
Organic Alc.	TBD<500	TBD			
Organic acids	TBD<500	TBD			
Phenols	1	1			
Specific Toxicants	TBD	TBD			
TOC	TBD<500	TBD<10,000			
TTOC	TBD<100	TBD<1,000			
TOX	TBD	TBD			
MICROBIAL					
Bacteria					
Total	<1	TBD			
Anaerobes	<1	TBD			
Aerobes	<1	TBD			
Gram positive	<1	TBD			
Gram negative	<1	TBD			
E. coli	<1	TBD			
Enteric	<1	TBD			
Viruses (PFU)	TBD	TBD			
Yeast,molds	<1	TBD			
BACTERICIDE (mg/L)					
Residual halo.					
minimum	0.50	0.50			
maximum	4.00	6.00			
RADIOLOGICAL	(pCi/L)				
alpha 90 Sr	10	TBD			
alpha 226 Ra	3	TBD			
beta 3H	1,000	TBD			

CURRENT ISSUES

- **Detection Limits**
- **Accountability**
- **Drugs & Pharmaceuticals**

Expand on each of these

Proposed

TABLE 3-9

SAMPLING FREQUENCY REQUIRED FOR WATER QUALITY VERIFICATION

PARAMETERS	REAL-TIME	NEAR REAL TIME	DELAYED (24 HRS)
PHYSICAL			
Conductivity	X	X	X
Color		X	X
pH	X	X	X
Turbidity	X	X	X
INORGANIC			
Non-Metals			
Ammonia		X	X
Chloride		X	X
Bromide		X	X
Iodide		X	X
Nitrate		X	X
Phosphate		X	X
Sulfate		X	X
Metals			
Arsenic		X	X
Barium		X	X
Cadmium		X	X
Chromium		X	X
Copper		X	X
Iron		X	X
Lead		X	X
Manganese		X	X
Mercury		X	X
Selenium		X	X
Silver		X	X
Zinc		X	X
ORGANICS			
Cyanide		X	X
TOC	X	X	X
Total Toxic Organics (TTO)		X	X
BACTERIA			
Total Bacteria		X	X
Total Coliforms			X
Heterotrophs			X
Non-Saprophytic Legionellae			X
FUNGI AND YEAST			

Presentation made on May 19, 1988

ECLSS WATER RECOVERY TEST REVIEW

May 19, 1988
Building 4610, Room 2081

Agenda

o INTRODUCTION	DR. HUMPHRIES	9:30-9:45
o ECLSS TEST OVERVIEW	MR. SCHUNK	9:45-10:15
o WATER RECOVERY TEST OVERVIEW	DR. HUMPHRIES	10:15-10:45
o BREAK		10:45-11:00
o WATER RECOVERY TEST DESCRIPTION	MR. BAGDIGIAN MS. MORTAZAVI MS. MCGRIFF	11:00-12:00
o LUNCH		12:00-1:00
o MAN SYSTEMS SIMULATOR PROTOCOLS	MR. WHITMAN	1:00-1:45
o MAN SYSTEMS SIMULATOR EQUIPMENT	MS. TRAWEEK	1:45-2:30
o CHEMICAL SAMPLING AND ANALYSIS	MS. SERR	2:30-2:45
o MICROBIAL SAMPLING AND ANALYSIS	MS. RICHARD	2:45-3:00
o BREAK		3:00-3:15
o TEST SUBJECT SAFEGUARDS	MR. KILGORE	3:15-4:00
o SUMMARY/ACTIONS	DR. HUMPHRIES	4:00-4:15

ECLSS WATER RECOVERY TEST REVIEW

May 20, 1988
Building 4610, Room 5025

Agenda

o INTRODUCTION	DR. HUMPHRIES	8:30-8:40
o MEDICAL/LEGAL ASPECTS	DR. CRUMP	8:40-9:45
o BREAK		9:45-10:00
o MSFC/JSC INTERFACE DISCUSSION	DR. HUMPHRIES	10:00-10:30
o TECHNOLOGY DEMONSTRATION PROGRAM PLANS	MR. RAY	10:30-10:45
o PAST (PHASE II) TEST RESULTS	MR. WHITLEY	10:45-11:15
o SUMMARY/ACTIONS	DR. HUMPHRIES	11:15-11:30
o TEST FACILITY TOUR	MR. SCHUNK	11:30-12:30

ECLSS WATER RECOVERY TEST
TEST SUBJECT SAFEGUARDS

NASA

RECOMMENDATIONS FOR MONITORING

PHYSICAL
- CONDUCTIVITY
- COLOR
- pH
- TURBIDITY

INORGANIC
- Non-metals
  - Ammonia
  - Chloride
  - Bromide
  - Iodide
  - Nitrate
  - Phosphate
  - Sulfate
- Metals
  - Arsenic
  - Barium
  - Cadmium
  - Chromium
  - Copper
  - Iron
  - Lead
  - Manganese
  - Mercury
  - Selenium
  - Silver
  - Zinc

ORGANICS
- CYANIDE
- TOC
- TOX
  - Total Toxic Organics (TTO)
  - Specific Parmaceuticals

MICROBIOLOGICAL
- TOTAL BACTERIA
- TOTAL COLIFORMS
- HETEROTROPHS
- NON-SAPROPHYTIC
- FUNGI AND YEAST
- LEGIONELLAE

METHODS AND INSTRUMENTATION FOR WATER QUALITY VERIFICATION

PARAMETER	METHOD	INSTRUMENTATION
PHYSICAL		
CONDUCTIVITY	EPA 120.1	Cond. Meter
COLOR	EPA 110.3	UV-VIS
pH	EPA 150	pH Meter
TURBIDITY	EPA 180	Nephelometer
INORGANIC		
Non-Metals		
Ammonia	EPA 350.2	UV-VIS
Chloride	EPA 300.0	Ion Chromatograph
Bromide	EPA 300.0	Ion Chromatograph
Iodide	EPA 300.0	Ion Chromatograph
Nitrate	EPA 300.0	Ion Chromatograph
Nitrogen, Total	EPA 351.3	UV-VIS
Phosphate	EPA 300.0	Ion Chromatograph
Sulfate	EPA 300.0	Ion Chromatograph
Metals		
Arsenic	EPA 206.3	AAH
Barium	EPA 200.7	ICP
Cadmium	EPA 213.2	AAG
Chromium	EPA 200.7	ICP
Copper	EPA 200.7	ICP
Iron	EPA 200.7	ICP
Lead	EPA 239.2	AAG
Magnesium	EPA 200.7	ICP
Manganese	EPA 200.7	ICP
Mercury	EPA 245.1	Hg Analyzer
Nickel	EPA 249.2	AAG
Potassium	EPA 258.1	AAF
Selenium	EPA 270.3	AAH
Silver	EPA 272.2	AAG
Zinc	EPA 200.7	ICP
ORGANICS		
Cyanide	EPA 335.2	UV-VIS
Halogenated Hydrocarbon	EPA 612	GC/ECD
Organic Acids		HPLC
Organic Alcohols		HPLC
Pesticides	EPA 608	GC/ECD
Phenols	EPA 604	GC/FID
TOC	EPA 415.2	TOC Analyzer
Total Toxic Organics	EPA 624, 625	GC/MS

Microbiological Concerns

1) MB Requirements & Spec for space station

Closed environmental control system
limited ability to remove biological agents

gravity vs microgravity

History -

Gemini Program - decrease in types of microorganis
- increase in numbers of microorganism
- microbial transfer reported

Apollo Program - illness not uncommon in early missio
- quarantine measures initiated (Apollo1
- urinary tract infection

Skylab - microbial flora studies
- transfer of pathogens
- microbial simplification for anaerobes
- microbial simplification not evident for aerobes
- air and surface samples showed gross contamination
- cellular immune response studies
- possibility of impairment of immune syste

Shuttle orbiter

moderate buildup on orbiter interior surfaces and air.

cross contamination among crew members

Space Station - 90 day rotation

alterations in microbial flora of crew

microbial flora of space station

microbiological monitoring

Health Stabilization Program

Pre - Flight

In flight (crew)

Post Flight (crew)

Space Station Subsystems

Pre flight

In flight

Surface samples (15 days)

Air samples (10 days)

Potable water (15 days)

Animal living quarters

Specifications -

Surface	100 CFU / 25 cm^2
Air	5,000 CFU / m^3
Water	0 CFU / 100 ml

1 Microbiology

2) Pseudomonas NH4 growth

3) Swimming pools
Favero, M.S. et. al. (1966) Factors influencing the occurrence of high numbers of iodine resistant bacteria in iodinated swimming pools
Appl. Microbiol. 14(4): 627.

4 Air AF 16

5) more presence of MO may not reveal anything about pathogenicity

6)

7) Dixon, B. (1986) Dangerous Thoughts, Science 7(3) p. 62.

(

Microbiology

DATA BASES (cultures) see file

DATA BASES (vendors)

DATA BASES (literature)

FATTY ACID System

NO NAMES <

2 NAMES DESCRIP.

FA system

Move ACL

METHODS AND INSTRUMENTATION FOR WATER QUALITY VERIFICATION

PARAMETER	METHOD	INSTRUMENTATION
PHYSICAL		
CONDUCTIVITY	EPA 120.1	Cond. Meter
COLOR	EPA 110.3	UV-VIS
pH	EPA 150	pH Meter
TURBIDITY	EPA 180	Nephelometer
INORGANIC		
Non-Metals		
Ammonia	EPA 350.2	UV-VIS
Chloride	EPA 300.0	Ion Chromatograph
Bromide	EPA 300.0	Ion Chromatograph
Iodide	EPA 300.0	Ion Chromatograph
Nitrate	EPA 300.0	Ion Chromatograph
Nitrogen, Total	EPA 351.3	UV-VIS
Phosphate	EPA 300.0	Ion Chromatograph
Sulfate	EPA 300.0	Ion Chromatograph
Metals		
Arsenic	EPA 206.3	AAH
Barium	EPA 200.7	ICP
Cadmium	EPA 213.2	AAG
Chromium	EPA 200.7	ICP
Copper	EPA 200.7	ICP
Iron	EPA 200.7	ICP
Lead	EPA 239.2	AAG
Magnesium	EPA 200.7	ICP
Manganese	EPA 200.7	ICP
Mercury	EPA 245.1	Hg Analyzer
Nickel	EPA 249.2	AAG
Potassium	EPA 258.1	AAF
Selenium	EPA 270.3	AAH
Silver	EPA 272.2	AAG
Zinc	EPA 200.7	ICP
ORGANICS		
Cyanide	EPA 335.2	UV-VIS
Halogenated Hydrocarbon	EPA 612	GC/ECD
Organic Acids		HPLC
Organic Alcohols		HPLC
Pesticides	EPA 608	GC/ECD
Phenols	EPA 604	GC/FID
TOC	EPA 415.2	TOC Analyzer
Total Toxic Organics	EPA 624, 625	GC/MS

K. Fig 13

Number key for the sources:

HCHE	1
HCHE BENDS	2
TIMES SHR	3
TIMES URINE RAW DISTILLATE	4
URINE RAW DISTILLATE (same as TIMES urine?)	5
VCD URINE RAW DISTILLATE	6
POST TREATED SHR RAW DISTILLATE	7
POST TREATED VCD/TIMES RAW DISTILLATE	8

Key to abbreviations:

Orl = oral
Ivn = intravenous
Ipr = intraperitoneal
Hmn = human
Mus = mouse

Key to toxicity information:

LDLo = Lowest published lethal dose (mg/Kg)
TCLo = Lowest published toxic concentration (mg/Kg)
TDLo = Lowest published toxic dose (mg/Kg)

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SECONDARY REQUIREMENTS (CONT.)

Compound	Source	Amt.	
octanol	4	1ppb	
octanoate, methyl-	3	200ppb	
oxalic acid	3	370ppb	orl hmn LDLo 700mg
octanoic acid	3	20000ppb	
octatetraene, formylcyclo	3	30ppb	
palmitic acid	7	10	ivn mus LD_{50} 57mg
	3	30ppb	
	8	10ppb	
pentane, 2,3-dimethyl-	1	50	
pentane, 2,2,4-trimethyl-	1	100	
4-methyl-2-pentanone	1	50	
2-methyl-2,4-pentanediol	1	410	
pentene, 4,4-dimethyl-1-	1	100	
phosphate, diethyl pentyl-	1	67	
phosphate, triethyl-	1	12	
phosphate, tertamethylpyro-	1	2	
phosphate, tetramethylpyro-	2	100	
1-propene	1	100	
propionic acid	1	6,000-35,400	orl rat LD_{50} 1510mg
	8	1500	
	3	840	
propylene glycol	1	300	
Pyrrolidine			orl rat LD_{50} 800mg
pyrrolidine, N-methyl-	1	71	
pyrrolidone	1	100	
styrene	1	50	orl mus LD_{50} 316mg
salicylic acid	6	350000	orl rat LD_{50} 891mg
sulfone, methyl-	4	20	
thiophene, tetrahydro-1,1-dioxide	1	15	
thiourea	1	300-500	
thiourea, tetramethyl	1	35	
thiourea cmpd (m.w. 174)	1	500 (est amt)	
toluonitrile	4	400ppb	
undecanoic acid	3	30	ivn mus LD_{50} 140mg
n-undecane	4	200	
urea	1	<16,000	
vanillan	6	200	orl rat LD_{50} 1580mg
	4	30	
Xylenol			orl mus LD_{50} 1070mg
xylenes, total	1	50	
xylene	4	8	

SECONDARY REQUIREMENTS (CONT.)

Compound	Source	Amt.	
ethyl alcohol	4	100ppb	orl man LDLo 50 mg
	1	86000ppb	
	3	5000ppb	
furfuryl alcohol	5	200	orl rat LD_{50} 275mg
	4	10ppb	
furan, 2,5-di-methyltetrahydro	4	10ppb	
formic acid	4	2678ppb	orl rat LD_{50} 1210mg
heptanoic acid	3	200ppb	orl mus LD_{50} 160mg
2-heptanone	4	5ppb	
4-heptanone	6	100ppb	
	4	25ppb	
heptanone cmpds (2)	4	60ppb	
heptyl alcohol	4	1ppb	
Hexanol			orl rat LD_{50} 720mg
hexanol, 2-ethyl-1-	6	100ppb	
hexanol, 5-methyl-1-	1	150ppb	
Hexanal			orl rat LD_{50} 4890mg
2-hexanone	1	50ppb	
hexanone, cyclo-	1	35ppb	
hexanoic acid	3	2000ppb	
hexanoic acid, 2-ethyl	1	750ppb	
hydrocarbon, unsaturated	4	30ppb	
2,5-hexanedione	3	50ppb	
3-hexene-2,5-dione	3	100ppb	
isophorone	1	3ppb	
lactic acid	3	1000ppb	
lactone cmpds	3	130ppb	
lactone, delta	3	10ppb	
lactone, gamma	3	60ppb	
lactone, gammahepta	3	30ppb	
levulinate, methyl	3	30ppb	
methyl alcohol	4	14000ppb	orl hmn LDLo 340 mg
	1	4000	
morpholine	4	5ppb	
morpholine, 4-ethyl	1	470ppb	
morpholine, n-ethyl	1	400ppb	
myristic acid	8	10ppb	ivn mus LD_{50} 43mg
nonanedioate, bis(2-ethyl hexyl)-	1	1,100ppb	
nonanedioic acid	1	6ppb	
nonanoic acid	3	2000ppb	orl rat LD_{50} 3200mg

SECONDARY REQUIREMENTS (CONT.)

Compound	Source	Amt.	
benzoic acid	3	840ppb	
benzoic acid, 2-hydroxy	4	1000ppb	
	3	848ppb	
benzoic acid cmpds (2)	4	3000ppb	
	6	150ppb	
benzaldehyde	3	1000ppb	orl rat LD_{50} 1300mg
	4	20ppb	
benzaldehyde, 4-methyl	4	100ppb	
benzaldehyde cmpds (3)	4	150ppb	
benzyl alcohol	1	4700ppb	orl rat LD_{50} 1330mg
benzisoxazole	1	100ppb	
butyldihydroxybenzene	4	10ppb	
caprylic acid	1	273-410ppb	ivn mus LD_{50} 600mg
cyanurate, triallyliso-	1	12ppb	
carboxylic acids	4	40,800ppb	
carboxylic acids	2	92,210ppb	
carboxylic acids	3	81,500ppb	
carboxylic acids (5)	7	3,500ppb	
carboxylic acid cmpd	3	500ppb	
carboxylic acid cmpds (4)	6	52,000ppb	
carboxylic acids (5)	1	43,000ppb	
unknown carboxylic acids	1	2,633ppb	
Ca roic Acid			orl rat LDLo 3000mg
caprolactam	1	15,000ppb	
carbon disulfide	1	14-722ppb	
Dc anal			orl rat LD_{50} 3730mg
n-decane	4	150ppb	
decan cmpds (2)	4	280ppb	
decanoic acid	3	5000ppb	
Dodecyl alcohol	3	100ppb	ipr rat LD_{50} 800mg
dodecanol	3	100ppb	
dodecanoic acid	3	5000ppb	
decanol, ethoxy-de-1	3	50ppb	
decanol, hexa-	3	20ppb	
dibenzofuran	1	20	
dimethyl-benzene methanol	1	16ppb	
dioxalane cmpds	3	600ppb	
dioxalane, 2,4-dimethyl-1,3-	3	100ppb	
dioxalane, 2-ethyl-4-methyl-1,3-	3	500ppb	
ether, ethyl propyl	1	34ppb	
ether, ethylene glycol monobutyl-	1	100ppb	
	3	200ppb	
ether, p-chlorophenyl methoxyisobutyl	4	400ppb	
ethers, glycol (2)	1	550ppb	
ethers, glycol (2)	3	60ppb	
	3	900ppb	

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SECONDARY REQUIREMENTS

Compound	Source		Amt.	Toxicity
Acetaldehyde				orl rat LD_{50} 1950mg
acetaldehyde, trichloro-	4		20	
acetic acid	5		300-31200	orl hmn TDLo 1470 ug GIT
	3		35000	
	7		940	
acetic acid, phenyl	4		400	
acetate, ethanol ethoxy	1		180	
acetate, vinyl	1		50	
acetone	3		1800-3300	orl rbt LD_{50} 5300mg
hydroxyacetone	4		150	
diacetone alcohol	1		19ppb	
acetone cmpds (2)	4		250ppb	
acrylate, 3-methoxy-butyl	3		130ppm	
	1		200ppb	est amt
azepin-2-one, hexahydro	1	SL1	73ppb	
	1	SL3	4.3ppm	
aniline	1		20ppb	
2-nitroaniline	1		200ppb	
3-nitroaniline	1		200ppb	
4-nitroaniline	1		200ppb	
Adipic Acid				orl rat LDLo 3600mg
adipate, tetramethylene	1		6ppb	
amide, butyl benzenesulfon	1		6ppb	
amide, N,n-di-n-butylform-	1		60ppb	
amide, N-methyl-N-ethyl form-	1		1103ppb	
4-chloroaniline	1		100ppb	
amide, N,n-dimethyl form-	1		541ppb	
amides (4)	1		3190ppb	
amides (2)	2		400ppb	
amine, dimethyl				orl rat LD_{50} 698mg
amine, N,n-dimethyl benzyl-	1		80ppb	
amine, di-n-butyl	1		74ppb	
amines (2)	1		200ppb	
alcohol cmpds (2)	3		5000ppb	
alkene ($C_{29}H_{58}$)	3		18ppb	
dichloroalkyl	4		100ppb	
Butyric Acid	8		30ppb	orl rat LD_{50} 2940mg
butyrates, 3-hydroxy -trimethylpentylise	1		300ppb	
1-butanamine, n-butyl-	1		180ppb	
butanoate,2 methoxymethyl-2-	1		55ppb	
Butyraldehyde				orl rat LD_{50} 2490mg
2-butanone	1		900ppb	
butanone, 3-methyl-2-	1		60ppb	
benzoic acid	1		500ppb	orl rat LD_{50} 3040mg
	4		2000ppb	

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PRIMARY REQUIREMENTS (CONT.)

Compound	Source	Amt Det.
BASE/NEUTRALS (CONT.)		
* phthalate, diethyl pentyl-	1	49
* phthalate esters (2)	6	350
* phthalate esters	1	140-15,000
phthalate ester cmpds (4)	3	75
phthalate ester cmpds (3)	8	20
* phthalate, bis(2-ethyl hexyl)-	8	103
* phthalate, bis(2-ethyl hexyl)-	1	4600
pyrene		
1,2,4-trichlorobenzene		
2,3,7,8-tetrachlorodibenzo-p-dioxin		
PESTICIDE COMPOUNDS		
Aldrin		
alpha-BHC		
beta-BHC		
gamma-BHC		
delta-BHC		
chlorodane		
4,4'-DDD		
4,4'-DDE		
4,4'-DDT		
dieldrin		
endosulfan I		
endosulfan II		
endosulfan sulfate		
endrin		
endrin aldehyde		
heptachlor		
heptachlorepoxide		
toxaphene		
PCB-1016		
PCB-1221		
PCB-1232		
PCB-1242		
PCB-1248		
PCB-1254		
PCB-1260		

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PRIMARY REQUIREMENTS (CONT.)

Compound	Source	Amt Det.
BASE/NEUTRALS		
acenaphthene	1	100
acenaphthylene		
anthracene		
benzidine		
benzo-a-anthracene		
benzo-a-pyrene	1	100
benzo-b-fluoranthene		
3,4-benzofluoranthene		
benzo(g,h,i)perylene		
benzo(k)fluoranthene	1	40
bis(2-chloro ethoxy)methane		
bis(2-chloroethyl)ether		
bis(2-chloroisopropyl)ether		
4-bromophenyl phenyl ether		
butylbenzyl phthalate		
2-chloro naphthalene		
4-chlorophenyl phenyl ether		
chrysene	1	100
dibenzo(a,h)anthracene		
1,2-dichlorobenzene		
1,3-dichlorobenzene		
1,4-dichlorobenzene		
3,3'-dichlorobenzidine		
diethyl phthalate	1	200
dimethyl phthalate	1	240
di-n-butyl phthalate	1	9
2,4-dinitro toluene		
2,6-dinitro toluene		
di-n-octyl phthalate		
1,2-diphenylhydrazine (as azobenzene)		
flouranthene		
fluorene		
hexachlorobenzene		
hexachlorobutadiene		
hexachlorocyclopentadiene		
hexachloroethane		
indeno(1,2,3-cd)pyrene		
isopherone		
* 2-methyl naphthalene	1	40
naphthalene	1	100
nitrobenzene		
N-nitrosodimethylamine		
N-nitrosodi-n-propylamine		
N-nitrosodiphenylamine		
phenanthrene		

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PRIMARY REQUIREMENTS (CONT.)

	Compound	Source	Amt detected	
	ACID COMPOUNDS			
	0-cresol	8	160	
	p-chloro-m-cresol			
	4,6-dinitrocresol			
	phenol	8	150	
		3	3	
	2-chlorophenol			
	dichlorophenol	4	55	
	2,4-dichlorophenol			
	2,4,6-trichlorophenol	1	200	
		4	25	
	pentachlorophenol			
	chloromethylphenol	4	30	
	4-chloro-3-methylphenol			
	2,4-dimethylphenol			
	2-nitrophenol	4	265	
	4-nitrophenol			
	2,4-dinitrophenol			
	2-methyldinitrophenol	1	40	
	methylphenol	4	1000	
*	2-methyl phenol	1	650	
*	4-methyl phenol	1	10	
*	phenol, 2,6-di -t-butyl-4-methyl-	1	16	(20ppb est amt)
*	phenol, 4-(1,1-dimethylethyl)	1	13	
*	phenol cmpds	4	2,200	
*	phenol cmpds (8)	6	600	
*	phenol cmpds (6)	2	275	
*	phenol,2,6-di -t-butyl-4-methyl-	8	150	
	phenol (carbolic acid)	4	460	
	phenol, chloro- adduct	4	100	
	phenol, dichloromethyl	4	100	
	phenol, t-butyl	4	150	

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SPECIFIC TOXICANTS

PRIMARY REQUIREMENTS

	Compound	Source	Amt detected	
	VOLATILES			
*	Acetyl benzene	1	16	(20ppb est amt)
		3	30	
	Acrolein			
	Acrylonitrile			
	Alkylbenzene	4	50	
	Benzene			
*	Bromochloromethane	1	500	
*	Bromochloropropene	1	500	
	Bromoform			
	Bromomethane	1	100	
	dibromomethane	3	10	
	Bromodichloromethane			
	Carbontetrachloride			
	Chlorobenzene	3	5	
	Chlorodibromomethane			
	Chloroethane			
	2-chloroethyl vinyl ether			
	Chloroform	4	10	
		3	4	
	Chloromethane	1	100	
	Dibromochloromethane			
*	Dichlorobutane	1	500	
	1,1-dichloroethane			
	1,2-dichloroethane			
	1,1-dichloroethylene			
	trans 1,2-dichloroethylene			
*	Dichlorofluoromethane	1	50	
	1,2-dichloropropane			
	1,3-dichloropropene	1	100	
	1,2-dichloropropylene			
*	Dimethylbenzene-methanamine	1	230	
	ethyl benzene			
	methyl bromide			
	methyl chloride			
	methylene chloride	8	200	
	propa-di-ene chloride	4	30	
	1,1,2,2-tetrachloroethane			
	tetrachloroethylene			
	toluene			
	1,2-trans-dichloroethylene			
	1,1,1-trichloroethane			
	trichloroethylene			
	trichlorofluoromethane	1	50	
	vinyl chloride			

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Proposed Water Quality Requirements (cont'd)

PROPERTY	POTABLE LIMIT	HYGIENE LIMIT
INORGANIC		
NONMETALLICS	(mg/L)	(mg/L)
Ammonia	0.50	0.50
*Bromide	TBD	TBD
Chloride	250	TBD
*Chlorine	TBD	TBD
Fluoride	1.00	1.00
Iodide	15	TBD
Nitrate	10	TBD
*Nitrite	TBD	TBD
*Nitrogen, total	TBD	TBD
*Phosphorous	TBD	TBD
Sulfate	250	TBD
Sulfide	0.05	0.05
*Sulfite	TBD	TBD
ORGANICS	(ug/L)	(ug/L)
Cyanide	200	TBD
Halogenated Hydrocarbons	TBD<10	TBD
*Oil & Grease	TBD	TBD
Organic Alc.	TBD<500	TBD
Organic acids	TBD<500	TBD
Phenols	1	1
Specific Toxicants	TBD	TBD
TOC	TBD<500	TBD<10,000
TTOC	TBD<100	TBD<1,000
*Trihalomethanes	TBD	TBD
MICROBIAL		
Bacteria	(CFU/dL)	(CFU/dL)
Total	<1	TBD
Anaerobes	<1	TBD
Aerobes	<1	TBD
Gram positive	<1	TBD
Gram negative	<1	TBD
E. coli	<1	TBD
Enteric	<1	TBD
Viruses (PFU)	TBD	TBD
Yeast,molds	<1	TBD
BACTERICIDE	(mg/L)	(mg/L)
Residual halo.		
minimum	0.50	0.50
maximum	4.00	6.00
RADIOLOGICAL	(pCi/L)	(pCi/L)
alpha 90 Sr	10	TBD
alpha 226 Ra	3	TBD
beta 3H	1,000	TBD

PROPOSED WATER QUALITY REQUIREMENTS

PROPERTY	POTABLE LIMIT	HYGIENE LIMIT
PHYSICAL		
color	TBD	TBD
conductivity	TBD	TBD
gas, dissolved	0	0
gas, free	0	0
particulates	40	40
pH	6.0-8.0	5.0-8.0
solids, total	<100	<500
solids, diss.	TBD	TBD
surfactants	TBD	TBD
taste, odor	<3	<3
turbidity	TBD	TBD
AESTHETICS	(mg/L)	(mg/L)
Cations	TBD<30	NA
Anions	TBD<30	NA
CO_2	TBD<15	NA
INORGANIC		
METALLICS	(mg/L)	(mg/L)
*Aluminum	TBD	TBD
*Antimony	TBD	TBD
Arsenic	0.01	0.01
Barium	1.00	1.00
*Beryllium	TBD	TBD
*Boron	TBD	TBD
Cadmium	0.01	0.01
Calcium	TBD	TBD
Chromium	0.05	0.05
*Cobalt	TBD	TBD
*Copper	1.00	1.00
Iron	0.30	0.30
Lead	0.05	0.05
Magnesium	0.05	0.05
Manganese	0.05	0.05
Mercury	0.002	0.002
*Molybdenum	TBD	TBD
Nickel	0.05	0.05
Potassium	TBD	TBD
Selenium	0.01	0.01
Silver	0.05	0.05
*Thallium	TBD	TBD
*Tin	TBD	TBD
*Titanium	TBD	TBD
Zinc	5.00	5.00

Presentation made on May 20, 1988

NASA INSTITUTIONAL REVIEW BOARD - COMPOSITION

At least:

1. One NASA-employed Physician.
2. One NASA member of Chief Counsel's Office.
3. One NASA member of local Safety office.
4. One member with non-scientific expertise.
5. One member not affiliated with NASA.
6. Non-voting invited experts.

Senior level NASA employee appointed as Chairperson.

- NMI 7100.8A
  11/86

APPENDIX 6

CONSENT FORM
FOR APPROVED NASA HUMAN RESEARCH

1. I, the undersigned, do voluntarily give my informed consent for my participation as a test subject in the following test, experiment, or other evaluative procedure:

NAME OF EXPERIMENT _____

FLIGHT TO WHICH ASSIGNED _____

NAME OF DESIGNATED PRINCIPAL INVESTIGATOR _____

NAME OF RESPONSIBLE NASA PROJECT SCIENTIST _____

I understand that:

(a) This procedure is part of an experiment approved by NASA.

(b) I am performing these duties as a part of my employment, with _____.

(c) This procedure has been reviewed and approved by the JSC Human Research Policy and Procedures Committee (HRPPC) and determined that the procedure involves reasonable risk to the subject.

(d) "Reasonable risk" means that the risks of harm anticipated in the proposed research are greater than thos ordinarily encountered in daily life or during the performance of routine tests, but considered to be proper when weighing the anticipated benefits and the importance of the knowledge to be gained from the research.

(e) The procedure has been explained to me prior to the execution of this form. I was afforded an opportunity to ask questions, and all questions asked were answered.

(f) I am medically qualified to participate in the procedure.

(g) I may withdraw from the procedure at any time unless, as recommended by the Principal Investigator, or his/her designee, the withdrawal is dangerous or impossible.

(h) In the event of physical injury resulting from the procedure and calling for immediate action or attention that NASA will provide, or cause to be provided, the necessary treatment. I also understand that NASA will pay for any claims of injury, loss of life or property damage to the extent required by the Federal Employees' Compensation Act or the Federal Tort Claims Act. My agreement to participate shall not be construed as a release of NASA or any third party from any future liability which may arise from, or in connection with, the above procedures.

2. I, the undersigned, the Principal Investigator of the experiment designated above, certify that:

   (a) I have accurately described the procedure to the test subject.

   (b) The test set-up involves reasonable risk to the test subject. All equipment used has been inspected and certified for safe and proper operation.

   (c) The test subject is medically qualified to participate.

   (d) The test protocol has not been changed from that approved by the JSC Human Research Policy and Procedures Committee (HRPPC).

APPROVED:

Test Subject	Date
Principal Investigator	Date
Project Scientist	Date

This consent form is valid for a 60-day period from the date of signature by the subject and the Principal Investigator (which dates should be identical). A signed, dated copy of the form should be forwarded to the JSC Human Research Policy and Procedures Committee, Mail Code SA, Lyndon B. Johnson Space Center, Houston, Texas 77058.

ECLSS WATER RECOVERY TEST
MEDICAL ASPECTS

NASA

TEST SUBJECT PROTOCOL OUTLINE

2.11 INITIAL EVALUATION

- 2.111 NAME OF PERSONAL PHYSICIAN
- 2.112 RECENT ILLNESSES
- 2.113 PAST MEDICAL HISTORY
  - 2.1131 CHRONIC ILLNESSES (HYPERTENSION, DIABETES,ETC.)
  - 2.1132 REGULAR MEDICINES, INCLUDING OCP'S AND OTC
  - 2.1133 MENSTRUAL HISTORY
  - 2.1134 REGULAR CREAM, OINTMENT, OIL USE
  - 2.1135 OTHER DRUGS, ALCOHOL, TOBACCO
  - 2.1136 ACTIVE SKIN OR HAIR DISORDER
  - 2.1137 FREQUENCY OF MINOR INFECTIONS AND DISEASES
- 2.114 PHYSICAL EXAM
- 2.115 HEALTH PROFILE (DUHP)
- 2.116 LABORATORY
  - 2.1161 CBC
  - 2.1162 U/A AND CULTURE
  - 2.1163 WET PREP/GM STAIN (IF INDICATED)
  - 2.1164 SERUM PREGNANCY TEST
  - 2.1165 STOOL CULTURE
  - 2.1166 SPECIAL STUDIES
- 2.117 SKIN TEST ANERGY PACK AND PPD (READING REQ'D IN 48 HRS)
- 2.118 BEGIN SYMPTOM DIARY

2.12 DISQUALIFICATION CRITERIA FOR INITIAL EVALUATION

- 2.121 NO PERSONAL PHYSICIAN
- 2.122 ANY CHRONIC ILLNESS OR REGULAR MEDICINE INTAKE (OCP,OTC MEDS)
- 2.123 FREQUENT MINOR ILLNESSES
  - 2.1231 >4 COLDS/YR
  - 2.1232 > 2 GE /YR
  - 2.1233 > 1 UTI/YR
  - 2.1234 > 2 VAGINITIS /YR
  - 2.1235 > 1 ACTIVE SKIN INFECTION/YR
- 2.124 ABNORMAL PHYSICAL FINDING
- 2.125 POOR DUHP SCORE
- 2.126 ABNORMAL LAB
- 2.127 PREGNANCY
- 2.128 ANERGIC

ECLSS WATER RECOVERY TEST
MEDICAL ASPECTS

NASA

TEST SUBJECT PROTOCOL OUTLINE (cont'd)

2.13 IMMEDIATE PRETEST EVALUATION
- 2.131 REVIEW SYMPTOM DIARY
- 2.132 REVIEW RECENT MENSTRUAL HISTORY
- 2.133 REVIEW RECENT TOPICAL USE
- 2.134 BRIEF PHYSICAL EXAM
- 2.135 LABORATORY
  - 2.1351 U/A AND CULTURE
  - 2.1352 WET PREP/GM STAIN (IF INDICATED)
  - 2.1353 SERUM PREGNANCY TEST
  - 2.1354 URINE DRUG SCREEN (LEGAL RAMIFICATIONS)
  - 2.1355 SPECIAL STUDIES

2.14 DISQUALIFICATION CRITERIA FOR PRETEST EVALUATION
- 2.141 SIGNIFICANT NEW SYMPTOMS OF INFECTION
- 2.142 TESTING LIKELY TO OCCUR DURING MENSES (POLICY DECISION)
- 2.143 ANY TOPICAL USE ON PROHIBITED LIST
- 2.144 ABNORMAL PHYSICAL FINDING
- 2.145 POSITIVE URINE CULTURE (>10000/ML OF EACH ORGANISM)
- 2.146 POSITIVE WET PREP/GM STAIN
- 2.147 POSITIVE OR INDETERMINATE SERUM PREGNANCY TEST
- 2.148 POSITIVE URINE DRUG SCREEN (LEGAL)

TEST SUBJECT PROTOCOL OUTLINE (cont'd)

2.15 POST TEST EVALUATION

- 2.151 REVIEW SYMPTOM DIARY
- 2.152 REVIEW MENSTRUAL HISTORY
- 2.153 BRIEF PHYSICAL EXAM
- 2.154 REPEAT HEALTH PROFILE (BUMP)
- 2.155 LABORATORY
  - 2.1551 U/A AND CULTURE
  - 2.1552 WET PREP /GM STAIN (IF INDICATED)
  - 2.1553 SERUM PREGNANCY TEST
  - 2.1554 STOOL CULTURE

2.16 DETECTION OF SICK SUBJECTS

- 2.161 CONTINUE SYMPTOM DIARY
- 2.162 MONITOR VISITS TO PERSONAL PHYSICIAN (BY PERMISSION)
- 2.163 SUBJECT NOTIFIED

Presentation made to Luther Powell

TEST SUBJECT SAFEGUARDS

IMPORTANCE OF "MAN IN LOOP" TESTING

- Hard to separate input/output
- Biological Variability
- Maintains high standard of research at all times
- Never before accomplished

ADDITIONAL REQUIREMENTS FOR "MAN IN LOOP" TESTING

- Test Subject Safeguards
- Expanded Medical Support Program
- Increased Sampling and Analysis
- New Research Areas

EXPOSURE AND RISK

SOURCES

- HYGIENE WASTES
  - SHOWER
  - CLOTHES WASHING
  - DISH WASHING
- URINE
- HUMIDITY CONDENSATE

ROUTES

- SKIN CONTACT INCLUDING MUCOUS MEMBRANES
- TRANSDERMAL
- INHALATION
- INGESTION

EXPOSURE

- INTERMITTENT (FOR GROUND TESTING)

RISK

- CHEMICAL
- BIOLOGICAL

SPECIFIC TOXICANTS

DEFINITION
- PRIMARY
  - EPA PRIORITY POLLUTANTS AND RELATED COMPOUNDS
    - VOLATILES
    - ACID EXTRACTABLES
    - BASE/NEUTRAL EXTRACTABLES
  - PHARMACEUTICALS
    - METABOLITES
    - OXIDATION PRODUCTS

SECONDARY
- ALL OTHER

TIME REQUIREMENTS FOR MONITORING WATER QUALITY PARAMETERS

PARAMETERS	REAL-TIME (On Line)	NEAR REAL TIME (8 HRS)	DELAYED (24 HRS)
PHYSICAL			
Conductivity	X	X	X
Color		X	X
pH	X	X	X
Turbidity	X	X	X
INORGANIC			
Non-Metals			
Ammonia		X	X
Chloride		X	X
Bromide		X	X
Iodide		X	X
Nitrate		X	X
Phosphate		X	X
Sulfate		X	X
Metals			
Arsenic		X	X
Barium		X	X
Cadmium		X	X
Chromium		X	X
Copper		X	X
Iron		X	X
Lead		X	X
Manganese		X	X
Mercury		X	X
Selenium		X	X
Silver		X	X
Zinc		X	X
ORGANICS			
Cyanide		X	X
Phenols		X	X
TOC	X	X	X
TOX		X	X
Total Toxic Organics (TTO)		X	X
MICROBIOLOGICAL			
Total Bacteria		X	X
Total Coliforms			X
Heterotrophs			
Non-Saprophytic			X
Legionellae			
Fungi (Yeast & Molds)			
Viruses (TBD)			

ECLSS WATER RECOVERY TEST
TEST SUBJECT SAFEGUARDS

NASA

CURRENT ISSUES

DETECTION LIMITS
- SPECIFIC METHODS
- TURNAROUND TIME

ACCOUNTABILITY

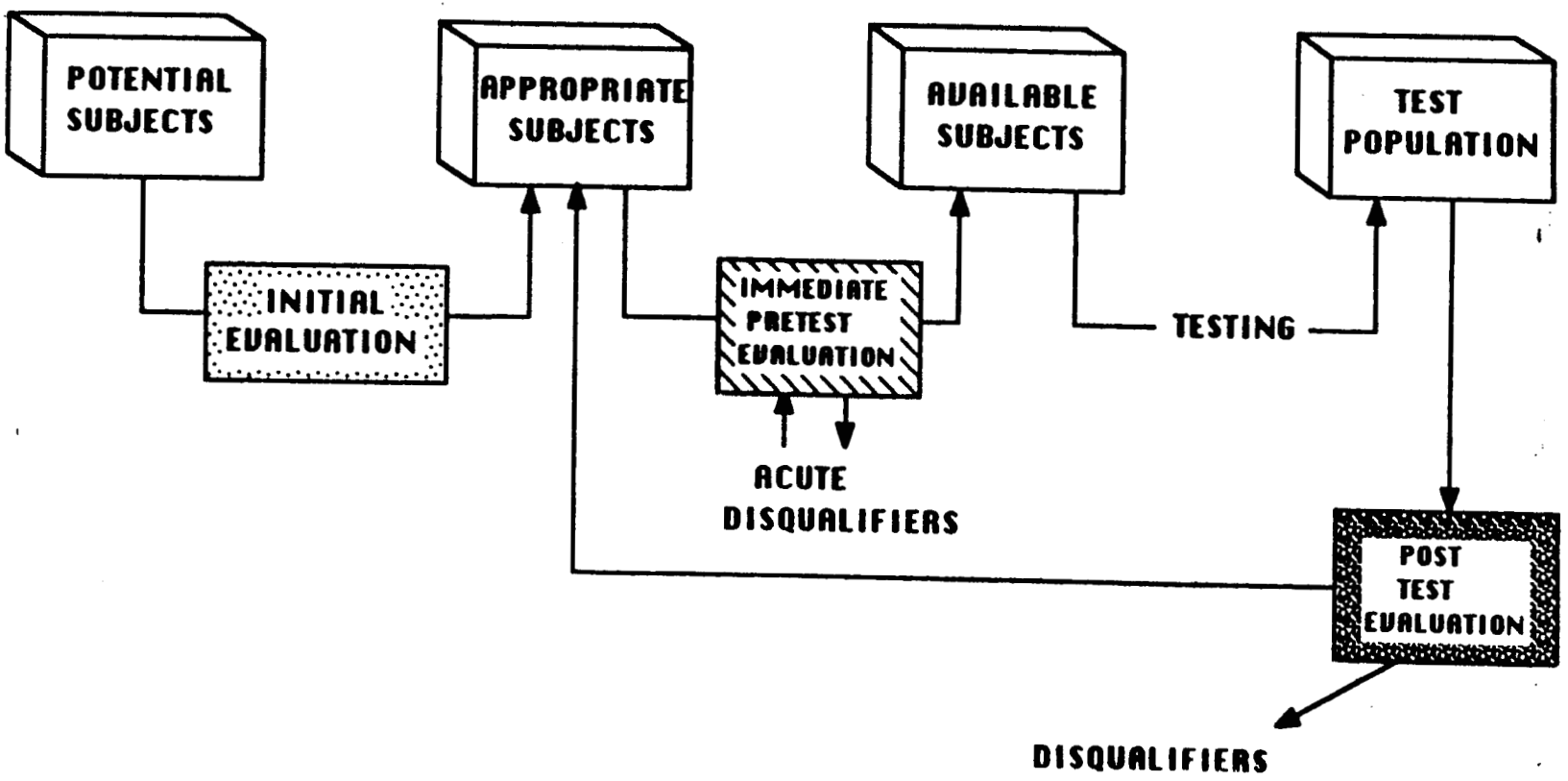
DRUGS AND PHARMACEUTICALS

MEDICAL AND LEGAL ASPECTS

ECLSS WATER RECOVERY TEST
MEDICAL ASPECTS

NASA

TEST SUBJECT PROTOCOL OUTLINE



ECLSS WATER RECOVERY TEST
MEDICAL ASPECTS

NASA

MEDICAL ISSUES

- DETERMINATION OF ACTUAL HUMAN RISK OF SKIN, MUCOUS MEMBRANE, AND INGESTION EXPOSURE TO:
  - CHEMICAL CONTAMINANTS
  - MICROBIAL CONTAMINANTS (UNUSUAL PATHOGENS)
  - URINARY METABOLITES OF PHARMACEUTICALS AFTER PRETREATMENT
- SAMPLING PROBABILITIES
  - NECESSARY AND SUFFICIENT DATA POINTS
  - TYPE II ERROR (FALSE NEGATIVE)
- GROUND TESTING STRATEGY FOR PHARMACEUTICALS
  - ALL DRUG INTAKE BY SUBJECTS PROHIBITED, OR
  - ONLY HMF FORMULARY ALLOWED
    - SUBJECT POPULATION SIZE
    - FEDERAL VS. PRIVATE TORT SYSTEM

INSTITUTIONAL REVIEW BOARD - COMPOSITION

1. The use of human subjects in research committee (UHSRC) shall be composed of at least five (5) members, with diverse backgrounds possessing the professional competence to promote complete and adequate review of research activities and ascertain acceptability in terms of institutional commitments and regulations, applicable law and standards or professional conduct and practice.

2. Representation on the UHSRC shall include:

   a. Men and women.
   b. Representation of more than one profession.
   c. At lease one member whose primary concerns are non-scientific, i.e., lawyer, ethicist, clergy member.
   d. At least one member who is not affiliated with the institution, either personally or by immediate familial relationship.

3. No person shall serve as a member of the UHSRC where such service would constitute a conflict of interest involving the proposed research project under review.

4. The UHSRC will invite individuals with specific competencies to assist in its review of complex issues. Within the scope of their invitation, these invited individuals will serve as full members of the UHSRC, except that they shall not have a vote.

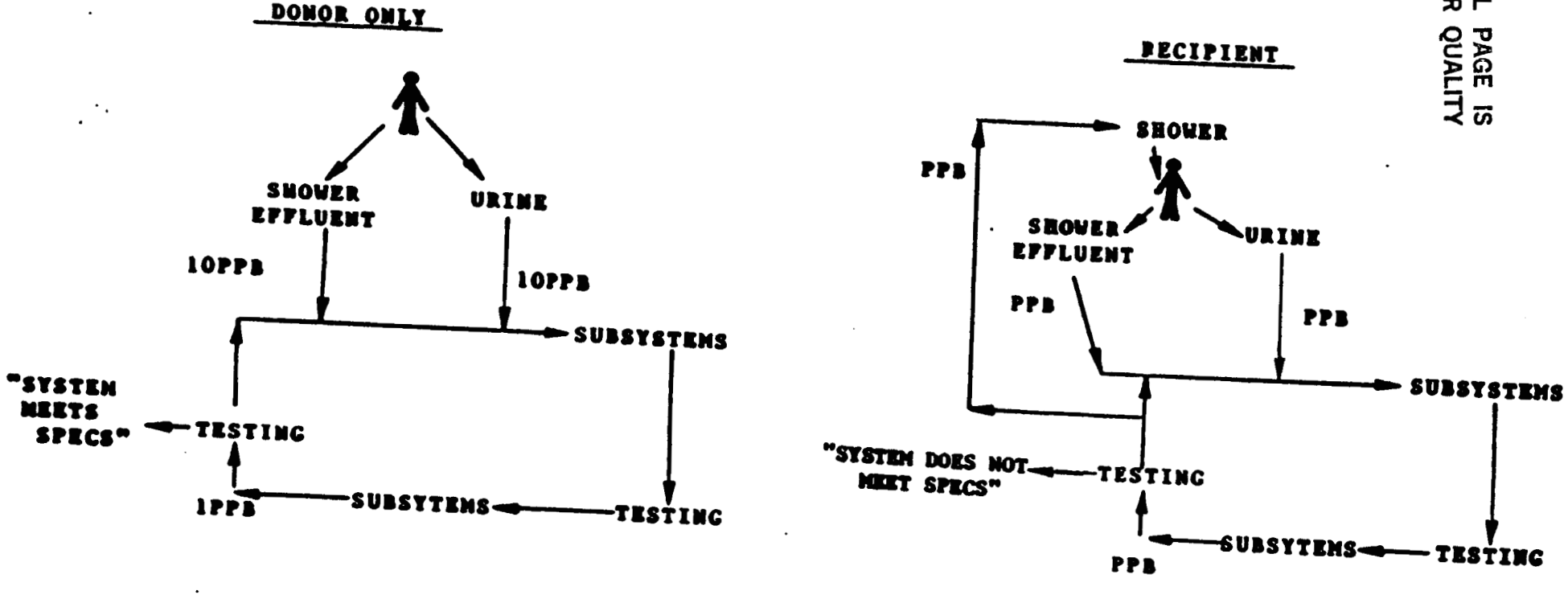
Model Federal Policy
Office of Science
and Technology Policy (OSTP)
6/86

Presentation made on June 20, 1988

ECLSS WATER RECOVERY TEST
MEDICAL ASPECTS

NASA

RECIPIENT CRITICALITY
EXAMPLE - BENZENE



BIOACCUMULATION

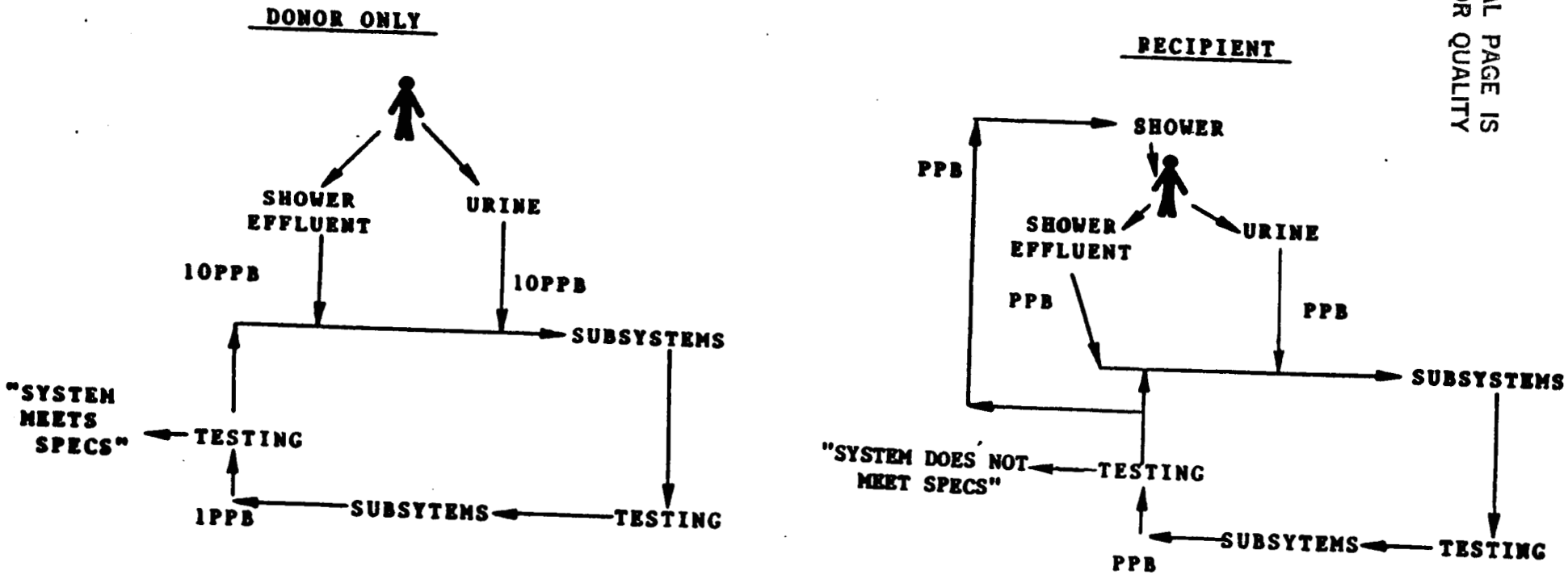
National Aeronautics and
Space Administration

George C. Marshall Space Flight Center
Science and Engineering Directorate

ECLSS WATER RECOVERY TEST
MEDICAL ASPECTS

NASA

RECIPIENT CRITICALITY
EXAMPLE - BENZENE



BIOACCUMULATION

ECLSS WATER RECOVERY TEST
MEDICAL ASPECTS

NASA

PHASED HUMAN SUBJECT WATER RECOVERY TEST

	DONOR		RECIPIENT	
	HYGIENE	URINE	HYGIENE	POTABLE
PHASE 1 DATA	X			
↓				
PHASE 2 DATA	X	X		
↓				
HUMAN SUBJECTS REVIEW				
↓				
PHASE 3 DATA	X	X	X	
↓				
HUMAN SUBJECTS REVIEW				
↓				
PHASE 4	X	X	X	X
↓				
DATA				
↓				
KNOWN SYSTEM PERFORMANCE				

ECLSS WATER RECOVERY TEST
MEDICAL ASPECTS

NASA

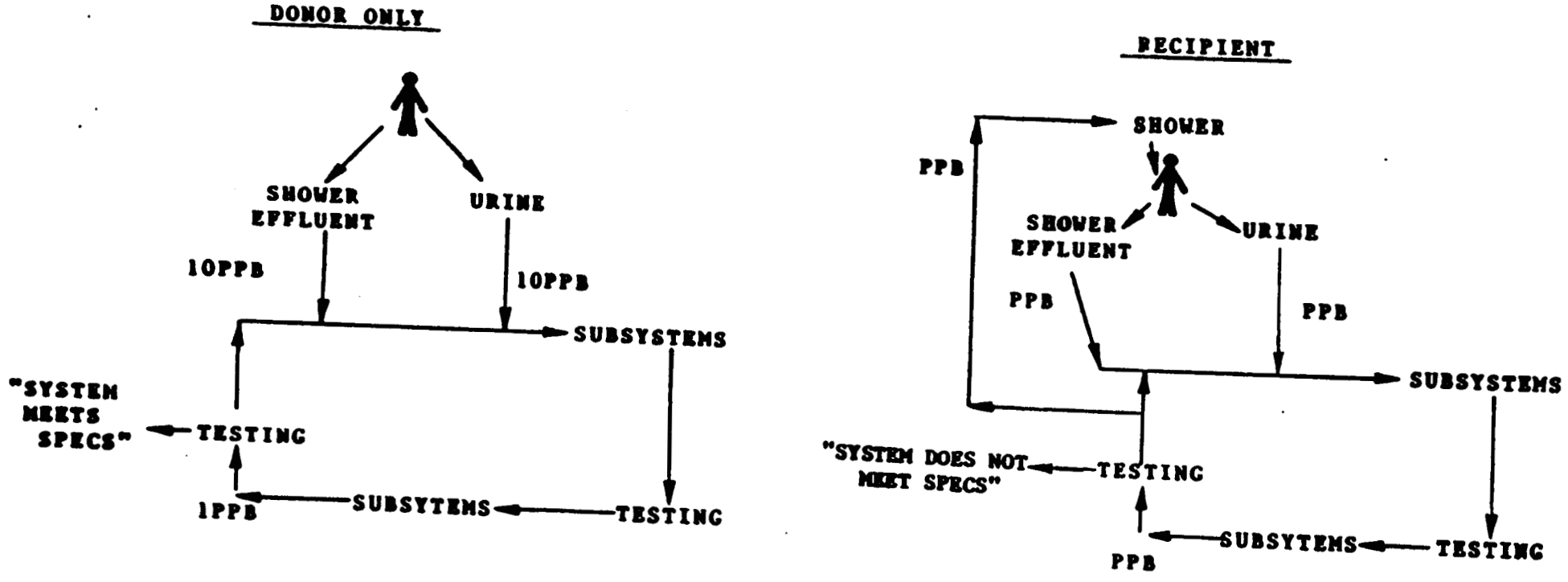
PHASED HUMAN SUBJECT WATER RECOVERY TEST

	DONOR		RECIPIENT	
	HYGIENE	URINE	HYGIENE	POTABLE
PHASE 1 DATA	X			
↓				
PHASE 2 DATA	X	X		
↓				
HUMAN SUBJECTS REVIEW				
↓				
PHASE 3 DATA	X	X	X	
↓				
HUMAN SUBJECTS REVIEW				
↓				
PHASE 4	X	X	X	X
↓				
DATA				
↓				
KNOWN SYSTEM PERFORMANCE				

ECLSS WATER RECOVERY TEST
MEDICAL ASPECTS

NASA

RECIPIENT CRITICALITY
EXAMPLE - BENZENE



BIOACCUMULATION

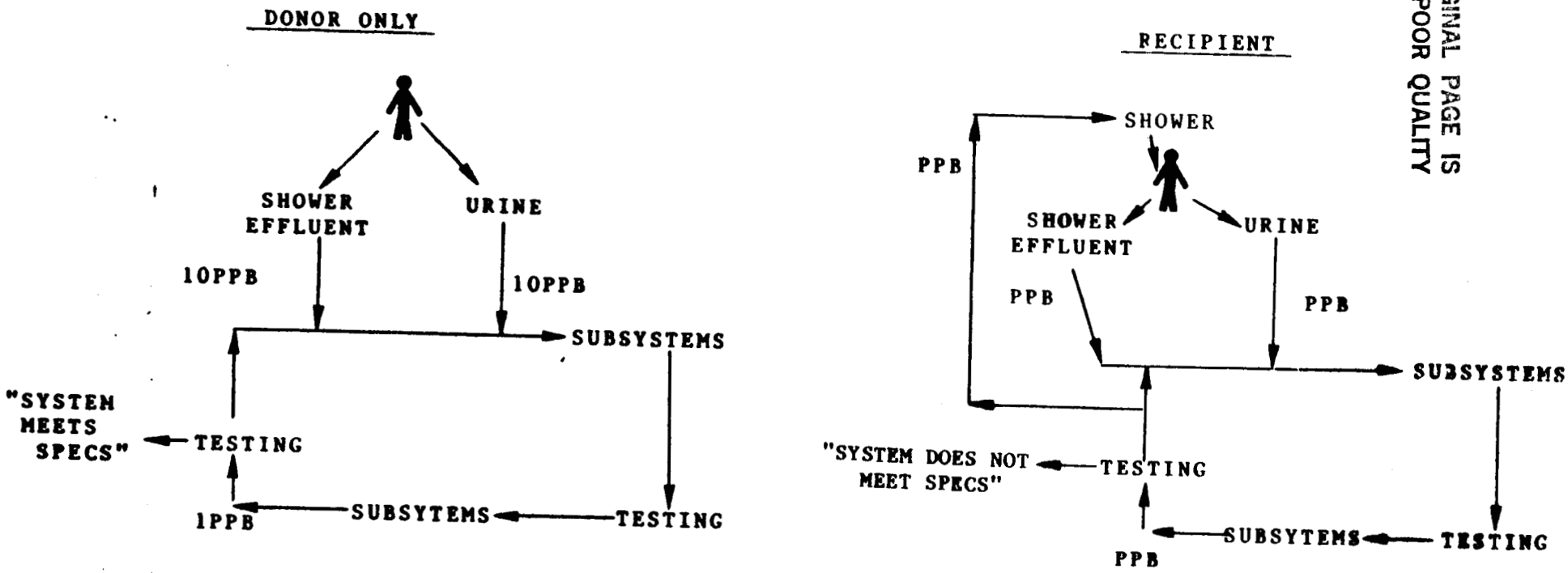
Presentation made on June 30, 1988 and July 5, 1988

National Aeronautics and
Space Administration
George C. Marshall Space Flight Center
Science and Engineering Directorate

ECLSS WATER RECOVERY TEST
MEDICAL ASPECTS

NASA

RECIPIENT CRITICALITY
EXAMPLE - BENZENE



BIOACCUMULATION

BIOTRANSFORMATION

National Aeronautics and Space Administration
George C. Marshall Space Flight Center
Science and Engineering Directorate

ECLSS WATER RECOVERY TEST
MEDICAL ASPECTS

NASA

PHASED HUMAN SUBJECT
WATER RECOVERY TEST

	DONOR		RECIPIENT	
	HYGIENE	URINE	HYGIENE	POTABLE
PHASE 1 DATA	X			
↓				
PHASE 2 DATA	X	X		
↓				
HUMAN SUBJECTS REVIEW				
↓				
PHASE 3 DATA	X	X	X	
↓				
HUMAN SUBJECTS REVIEW				
↓				
PHASE 4	X	X	X	X
↓				
DATA				
↓				
KNOWN SYSTEM PERFORMANCE				

Specific Toxicants

Definition

- Demonstrated toxicity
- Demonstrated occurence in water (air)
- Known industrial product or degradation product

Primary

- EPA Priority Pollutants and related compounds (60)

Secondary (170)

Pharmaceuticals

- Metabolites
- Oxidation Products
- Illicit Drugs

Exposure and Risk

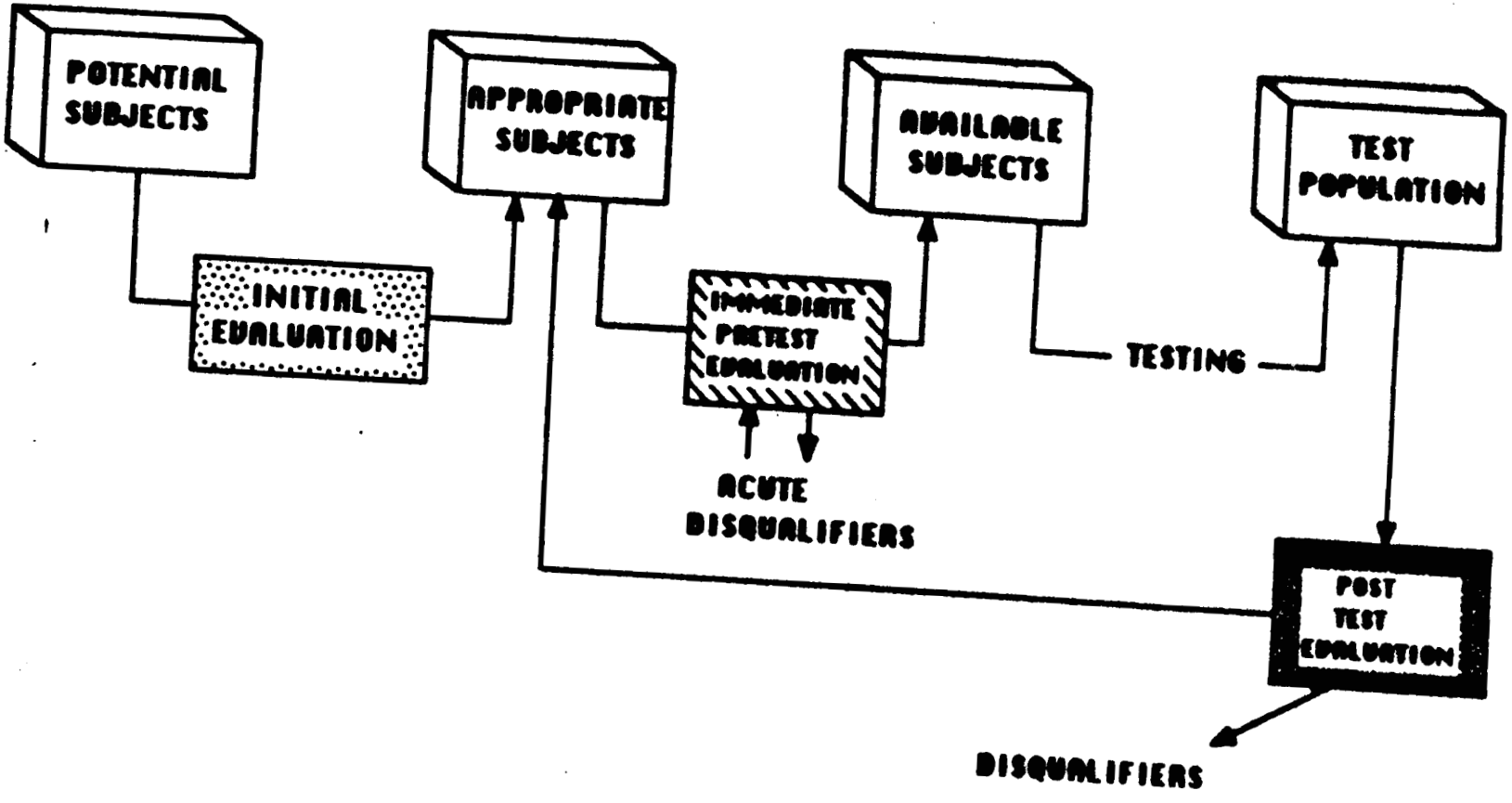
- Sources
  - Hygiene Wastes
    - Shower
    - Clothes Washing
    - Dish Washing
  - Urine
  - Humidity Condensate

- Routes
  - Skin Contact including mucous membranes
  - Transdermal
  - Inhalation
  - Ingestion
- Exposure
  - Intermittent (for ground testing)
- Risks
  - Chemical
  - Biological
- Liability Exposure

ECLSS WATER RECOVERY TEST
MEDICAL ASPECTS

NASA

TEST SUBJECT PROTOCOL OUTLINE



Presentation made on September 7, 1988

INITIAL SCREENING (R.N.)

1) Informed consent
2) Health questionnaire (HQ)
3) Health profile (DUHP)
4) Begin symptom dairy
5) Appointment with examining physician (EP)

INITIAL EXAM (M.D.)

1) History and physical

2) Lab drawn

3) Skin tests placed

4) EP indicates opinion to environmental health physician (EHP)- 48 hour delay

SUBJECT LAB

Complete Blood Count

Urinalysis

Wet Preparation

Serum Pregnancy

Stool

Urine Drug Screening
(Qualitative)

HIV

HEP Profile

APPENDIX E

2.12 Disqualification Criteria for Initial Evaluation

- 2.121 No personal physician
- 2.122 Any chronic illness or regular medicine intake
- 2.123 Frequent minor illnesses
  - 2.1231 > 4 colds/yr
  - 2.1232 > 2 GE/yr
  - 2.1233 > 1 UTI/yr
  - 2.1234 > 2 Vaginitis/yr
  - 2.1235 > 1 Active Skin Infection/yr
- 2.124 Abnormal physical finding

2.14 Disqualification Criteria for Pre-test Evaluation

- 2.141 Significant new symptoms of infection
- 2.142 Testing likely to occur during menses (phase dependent)
- 2.143 Any topical use (phase dependent)
- 2.144 Abnormal physical finding
- 2.145 Positive urine culture (>10,000/ml of each organism)
- 2.146 Positive wet prep/GM stain
- 2.147 Positive or indeterminate serum pregnancy test
- 2.148 Positive urine drug screen

PRE-TEST EXAM (M.D.)
(ONE-WEEK PRIOR TO INVOLVEMENT)

1) Brief history and physical

2) Lab drawn

3) EP indicates opinion to EHP- 48 hour delay

SUBJECT HEALTH SURVEILLANCE

1) Symptom diary continued

2) Brief history and physical at 1 week, 6 and 12 months after first participation.

3) Monthly review of any MD visits for 24 months by EHP.

INITIAL EVALUATION (CONTINUED)

	NL	ABNL	COMMENTS
HEART	___	___	_____
ABD	___	___	_____
GU	___	___	_____
NEURO/MS	___	___	_____
HEALTH PROFILE	___	___	_____
LABORATORY			
ROUTINE	___	___	_____
SPECIAL	___	___	_____
SKIN TEST			
PPD	___	___	_____
ANERGY	___	___	_____
SYMPTOM DIARY	___	___	_____

I have examined the above named subject and believe he/she (is) (is not) qualified to be involved in the water recovery test at MSFC.

_____ M.D. ___/___/___
DATE

APPENDIX D
MEDICAL EVALUATION, SUBJECTS FOR WATER RECOVERY TEST, MSFC

NAME: _____ _____ _____
LAST FIRST MIDDLE

ADDRESS _____

_____

AGE_____ DATE OF BIRTH_____

WORK AREA_____ WORK PHONE_____

HOME PHONE_____ MAIL CODE_____

IN CASE OF EMERGENCY, CONTACT:_____

_____ PHONE_____

PERSONAL PHYSICIAN_____

ADDRESS_____ PHONE_____

INITIAL EVALUATION

	NL	ABNL	COMMENTS
PMH	___	___	_____
CHRONIC ILLNESSES	___	___	_____
MEDS	___	___	_____
MENSTRUAL HISTORY	___	___	_____
RECENT ILLNESSES	___	___	_____
TOPICAL USE	___	___	_____
HABITS (D, T, A)	___	___	_____
SKIN/HAIR DISORDER	___	___	_____
MINOR ILLNESS FREQUENCY	___	___	_____
PHYSICAL EXAM			
SKIN	___	___	_____
HEENT	___	___	_____
LUNGS	___	___	_____

APPENDIX D
MEDICAL EVALUATION, SUBJECTS
FOR WATER RECOVERY TEST, MSFC

NAME: _____ _____ _____
LAST FIRST MIDDLE

ADDRESS_____

_____

AGE_____ DATE OF BIRTH_____

WORK AREA_____ WORK PHONE_____

HOME PHONE_____ MAIL CODE_____

IN CASE OF EMERGENCY, CONTACT:_____

_____ PHONE_____

PERSONAL PHYSICIAN_____

ADDRESS_____ PHONE_____

PRE-TEST EVALUATION

	NL	ABNL	COMMENTS
SYMPTOM DIARY	___	___	_____
MENSTRUAL HISTORY	___	___	_____
TOPICAL USE	___	___	_____
PHYSICAL EXAM			
_____	___	___	_____
_____	___	___	_____
_____	___	___	_____
LABORATORY			
ROUTINE	___	___	_____
SPECIAL	___	___	_____

I have examined the previous named subject and believe he/she (is) (is not) qualified to be involved in the water recovery test at MSFC.

_____ M.D. ___/___/___
DATE

Detailed Test Activities

1. Insert Microbiological sampling section, including methodologic information similar to Appendix C and D of Garcia Shower Proposal.

2. Insert chemical sampling section, including information similar to Appendix C and D of Garcia Shower Proposal.

3. Insert pharmaceutical sampling section, including information similar to Appendix C and D of Garcia Shower Proposal.

4. Insert overview of sampling schedule, including frequency and volumes necessary with mass balance estimate.

5. Insert section of Human Subject pool selection/evaluation process (Crump's Outline).

6. Insert incremental plan for adding creams, drugs, menstrual blood.

7. Insert Boeing's plan for orientation, pre-involvement education.

8. Insert water certification process similar to NASA-JSC SAE Shower Publication, updated for more frequent sampling schedule.

OH

LAST EPISODE - SOME -
REMAINING ?'S

PROTOCOL OUTLINE

INITIAL SCREEN

LAB - DISCUSS LATER

INITIAL EXAM

REASON FOR DELAY < SKIN LAB

"BASIS OF OPINION"

DISQUAL CRITERIA

MENSES/CREAM PHASE DEPENDENT

PRE TEST

REASON FOR DELAY - LAB

SURVEILLANCE

DRUG SCREEN - YES
HIV - YES
HEP PROFILE - YES

SUBJECT LAB

FORMS

INITIAL EVAL - 1
" " - 2

PIPETEST

MY JUNE REL FOR
SECTION 8 OF MASTER

DETAILED TEST ACTIVITY

APPENDIX H
Budget Summary

FINANCIAL REPORT SUMMARY

CONTRACT: FNAS Environmental Control Medical Support Team

ACCOUNT NUMBER: 5-31806

REPORT PERIOD: 12/7/87 - 9/30/88

		Budget	Expended	Encumbered	Balance
I.	Salary & Wages	47,889.00	46,651.43	300.00	937.57
II.	Fringe	10,057.00	9,656.89	0.00	400.11
III.	Operating Expenses	1,625.00	5,663.25	0.00	<4,038.25>
IV.	Laboratory Supplies	0.00	0.00	0.00	0.00
V.	Travel	4,754.00	594.23	1,431.00	2,728.77
VI.	Facility Useage	0.00	0.00	0.00	0.00
VII.	Indirect	30,876.00	29,892.26	686.88	296.86
	TOTAL:	95,201.00	92,458.06	2,417.88	325.06

Date: 10/31/88
Prepared by: M.V. Kilgore, Jr.