NRC Form 313 I (12-81) 10 CFR 30

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE
INDUSTRIAL

See attached instructions for details.

Completed applications are filed in duplicate with the Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety, and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555 or applications may be filed in person at the Commission's office at 1717 H Street, NW, Washington, D. C. or 7915 Eastern Avenue, Silver Spring, Maryland.

1. APPLICATION FOR: *(Check and/or complete as appropriate)*

	a. NEW LICENSE
X	b. AMENDMENT TO: LICENSE NUMBER 20-16890-01
	c. RENEWAL OF: LICENSE NUMBER

2. APPLICANT'S NAME *(Institution, firm, person, etc.)*

Allied/Instrumentation Laboratory

TELEPHONE NUMBER: AREA CODE – NUMBER EXTENSION
(617) 470-1790

3. NAME AND TITLE OF PERSON TO BE CONTACTED REGARDING THIS APPLICATION

F.X. Masse

TELEPHONE NUMBER: AREA CODE – NUMBER EXTENSION
(617) 245-6600

4. APPLICANT'S MAILING ADDRESS *(Include Zip Code)*
(Address to which NRC correspondence, notices, bulletins, etc., should be sent.)

1 Burtt Rd.
Andover, MA

5. STREET ADDRESS WHERE LICENSED MATERIAL WILL BE USED *(Include Zip Code)*

1 Burtt Rd. Andover, MA
113 Hartwell Ave. Lexington, MA

(IF MORE SPACE IS NEEDED FOR ANY ITEM, USE ADDITIONAL PROPERLY KEYED PAGES.)

6. INDIVIDUAL(S) WHO WILL USE OR DIRECTLY SUPERVISE THE USE OF LICENSED MATERIAL
(See Items 16 and 17 for required training and experience of each individual named below)

	FULL NAME	TITLE
a.	Arleen Chase, PhD.	Project Manager
b.	Mona Jensen, PhD.	Project Manager
c.		

7. RADIATION PROTECTION OFFICER & User
James C. Hengst, PhD. with consultation from F.X. Masse Associates

Attach a resume of person's training and experience as outlined in Items 16 and 17 and describe his responsibilities under Item 15.
yes

8. LICENSED MATERIAL

LINE NO.	A ELEMENT AND MASS NUMBER	B CHEMICAL AND/OR PHYSICAL FORM	C NAME OF MANUFACTURER AND MODEL NUMBER *(If Sealed Source)*	D MAXIMUM NUMBER OF MILLICURIES AND/OR SEALED SOURCES AND MAXIMUM ACTIVITY PER SOURCE WHICH WILL BE POSSESSED AT ANY ONE TIME
(1)	H-3	any	-	10 mCi
(2)	C-15	any	-	10 mCi
(3)	S-35	any	-	10 mCi
(4)	I-125 Cr-51	any	-	(fifty milliCuries) 50 mCi

	E DESCRIBE USE OF LICENSED MATERIAL
(1)	Research and Development
(2)	
(4)	

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9. STORAGE OF SEALED SOURCES

LINE NO.	CONTAINER AND/OR DEVICE IN WHICH EACH SEALED SOURCE WILL BE STORED OR USED. A.	NAME OF MANUFACTURER B.	MODEL NUMBER C.
(1)	not applicable		
(2)			
(3)			
(4)			

10. RADIATION DETECTION INSTRUMENTS

LINE NO.	TYPE OF INSTRUMENT A	MANUFACTURER'S NAME B	MODEL NUMBER C	NUMBER AVAILABLE D	RADIATION DETECTED (alpha, beta, gamma, neutron) E	SENSITIVITY RANGE (milliroentgens/hour or counts/minute) F
(1)	GM Survey meter	Ludlum	modle-3	2	B,r	0-20mR/hr
(2)	Liquied Scintillation counter	Beckman	-	2	B	0-10^6cpm
(3)	Gamma Counter	Beckman	-	2	r	0-10^6cpm
(4)	Portable Scintillation	Ctr. Ludlum	44.3	1	r	0-1 mR/hr

11. CALIBRATION OF INSTRUMENTS LISTED IN ITEM 10

☐ a. CALIBRATED BY SERVICE COMPANY

NAME, ADDRESS, AND FREQUENCY

☐ b. CALIBRATED BY APPLICANT

Attach a separate sheet describing method, frequency and standards used for calibrating instruments.

12. PERSONNEL MONITORING DEVICES

TYPE (Check and/or complete as appropriate.) A	SUPPLIER (Service Company) B	EXCHANGE FREQUENCY C
☒ (1) FILM BADGE ☐ (2) THERMOLUMINESCENCE DOSIMETER (TLD) ☐ (3) OTHER (Specify): _____	R.S. Landauer Jr., & Co.	☒ MONTHLY ☐ QUARTERLY ☐ OTHER (Specify): _____

13. FACILITIES AND EQUIPMENT (Check were appropriate and attach annotated sketch(es) and description(s).

- ☒ a. LABORATORY FACILITIES, PLANT FACILITIES, FUME HOODS (Include filtration, if any), ETC.
- ☐ b. STORAGE FACILITIES, CONTAINERS, SPECIAL SHIELDING (fixed and/or temporary), ETC.
- ☐ c. REMOTE HANDLING TOOLS OR EQUIPMENT, ETC.
- ☐ d. RESPIRATORY PROTECTIVE EQUIPMENT, ETC.

14. WASTE DISPOSAL

a. NAME OF COMMERCIAL WASTE DISPOSAL SERVICE EMPLOYED

Radiac Researth Corp.

b. IF COMMERCIAL WASTE DISPOSAL SERVICE IS NOT EMPLOYED, SUBMIT A DETAILED DESCRIPTION OF METHODS WHICH WILL BE USED FOR DISPOSING OF RADIOACTIVE WASTES AND ESTIMATES OF THE TYPE AND AMOUNT OF ACTIVITY INVOLVED. IF THE APPLICATION IS FOR SEALED SOURCES AND DEVICES AND THEY WILL BE RETURNED TO THE MANUFACTURER, SO STATE.

INFORMATION REQUIRED FOR ITEMS 15, 16 AND 17

Describe in detail the information required for Items 15, 16 and 17. Begin each item on a separate page and key to the application as follows:

15. RADIATION PROTECTION PROGRAM. Describe the radiation protection program as appropriate for the material to be used including the duties and responsibilities of the Radiation Protection Officer, control measures, bioassay procedures *(if needed)*, day-to-day general safety instruction to be followed, etc. If the application is for sealed source's also submit leak testing procedures, or if leak testing will be performed using a leak test kit, specify manufacturer and model number of the leak test kit.

16. FORMAL TRAINING IN RADIATION SAFETY. Attach a resume for each individual named in Items 6 and 7. Describe individual's formal training in the following areas where applicable. Include the name of person or institution providing the training, duration of training, when training was received, etc.

    a. Principles and practices of radiation protection.

    b. Radioactivity measurement standardization and monitoring techniques and instruments.

    c. Mathematics and calculations basic to the use and measurement of radioactivity.

    d. Biological effects of radiation.

17. EXPERIENCE. Attach a resume for each individual named in Items 6 and 7. Describe individual's work experience with radiation, including where experience was obtained. Work experience or on-the-job training should be commensurate with the proposed use. Include list of radioisotopes and maximum activity of each used.

18. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 2, certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Part 30, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

WARNING.–18 U.S.C., Section 1001; Act of June 25, 1948; 62 Stat. 749; makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

a. LICENSE FEE REQUIRED *(See Section 170.31, 10 CFR 170)*	b. CERTIFYING OFFICIAL *(Signature)*
	c. NAME *(Type or print)*
(1) LICENSE FEE CATEGORY:	d. TITLE
(2) LICENSE FEE ENCLOSED: $ 120.00	e. DATE

REQUIRED PROCEDURES FOR PROTEIN IODINATION

The following procedures will be followed when iodination of proteins is conducted:

1. Only persons who have prior experience or documented training in protein iodination will conduct such procedures.

2. The Radiation Safety Officer will be notified prior to each such process and will attend at least the first operation for each individual.

3. Room air samples will be conducted for such procedures until it is clearly established that the routine procedure results in airborne levels of less than 10% of MPC.

4. All such procedures will be conducted in a charcoal filtered minihood which is operated in a properly operating hood.

5. The hood exhaust air beyond the minihood will be sampled using a vacuum pump and in-line charcoal trap to determine the concentration of iodine that is not contained by either the original process controls or by the minihood during each iodination procedure. Air concentrations at the discharge point will be maiutained well within the average permissible concentrations for unrestricted areas with an ALARA goal of 10% of those levels.

6. Process will be carried to completion; all materials including columns and glassware will be decontaminated and washed or sealed and disposed; and all areas involved surveyed before process is considered to be complete.

7. All persons involved will have thyroid counts within two working days of procedure. Results will be permanently recorded.

8. Whenever possible, procedures shall be conducted in closed reaction vessels.

DUTIES OF RADIATION SAFETY OFFICER

The appointed Radiation Safety Officer shall assume the following duties:

1. Purchase and control all radionuclides used at Allied/Instrumentation Laboratory.

2. Coordinate all uses of radionuclides.

3. Control radioactive materials such that they are used only by properly trained and authorized individuals.

4. Coordinate personnel monitoring as necessary for those persons likely to receive more than 10% of maximum permissible exposures.

5. Provide initial training and annual retraining (with the help of FXM Associates) of all individuals working with radionuclides. Such training shall include:

   A. Review of license and conditions
   B. Review of 10CFR Parts 19 and 20
   C. Review of basics of radiation protection, radiation effects, and radiation measurements and calculations
   D. Required laboratory practices and procedures.

6. Provide initial orientation and annual reorientation for all ancillary personnel whose duties may require them to work in the vicinity of radioactive materials (e.g., janitors, guards). Such instruction will include an explanation of the potential radiation hazard, information on ways of controlling or avoiding unnecessary exposure, and emergency instruction.

7. Establish and conduct a radiation safety program (with the help of FXM Associates) which shall include:

   A. Routine surveys of all areas where radionuclides are used
   B. Inventory control procedures to guarantee adequate control of such materials
   C. Routine review of all radionuclides uses, including routine review of laboratory survey and use records
   D. Bioassay programs as necessary
   E. Air sampling programs as necessary
   F. Establishment and maintenance of an appropriate emergency program.

BIOASSAY PROGRAM FOR INTERNAL RADIATION MONITORING

I General

Appropriate internal radiation monitoring shall be conducted on any individual working with unsealed radioactive materials where a potential exists for receiving radiation doses and/or body burdens in excess of 20% of the limits established in 10 CFR 20. All records of such bioassays will be maintained by the Radiation Safety Office.

II Iodine-125 In-Vivo Thyroid Counting

A. All individuals routinely working with greater than 1 millicurie quantities of iodine-125 shall participate in the in-vivo thyroid counting program conducted by the Radiation Safety Officer.

B. The Radiation Safety Officer will arrange for routine monthly thyroid measurements for persons exposed as in (A) above. If the quantity handled exceeds 10 mCi, measurements will be performed weekly.

C. In addition to routine monthly thyroid monitoring, personnel involved in so-called "iodination" procedures will receive thyroid measurement preferably within 48 hours of performing the iodination procedure but in any case within one work-week.

D. The maximum permissible weekly increase of iodine-125 in the thyroid is established as 0.05 microcurie based upon the 40 hour per week maximum permissible air concentration.

E. If a thyroid measurement indicates the presence of greater than 0.05 microcuries of iodine-125 in the thyroid, the Radiation Safety Officer shall initiate an immediate investigation of the work place, local exhaust system, work practices, procedures, etc., to determine the cause of the increased iodine uptake. The investigation may include area and personal air monitoring and wipe testing of surfaces as well as visual observation of techniques. Depending on the actual thyroid level of radioiodine, the individual may also be temporarily restricted from further radioiodine work.

III Hydrogen-3 Urinalysis

A. All individuals routinely working with unsealed quantities of ^{3}H in excess of 10 mCi will participate in the urinalysis program conducted by the Radiation Safety Officer.

B. The Radiation Safety Officer will arrange for routine monthly urinalysis on all such individuals, the first measurement to be conducted within one week of the first use.

C. If radioassay indicates the presence of greater than 10% of the maximum permissible body burden (>3 uCi/liter) the Radiation Safety Office will initiate an immediate investigation of the work place, local exhaust system, work practices, procedures, etc., to determine the cause of increased H-3 uptake. Where appropriate, air samples and wipe tests of surfaces will be taken. Depending on the actual level of H-3 in the urine, the individual also may be temporarily restricted from further exposure.

EMERGENCY PROCEDURES

MINOR SPILLS

1. NOTIFY: Notify persons in the area that a spill has occurred.

2. PREVENT THE SPREAD: Cover the spill with absorbent paper.

3. CLEAN UP: Use disposable gloves and remote handling tongs. Carefully fold the absorbent paper and pad. Insert into a plastic bag and dispose of in the radioactive waste container. Also insert into the plastic bag all other contaminated materials such as disposable gloves.

4. SURVEY: With an appropriate low-range survey meter, check the area around the spill, hands, and clothing for contamination. For H-3 contamination, wipe testing followed by liquid scintillation counting will be necessary for such surveys.

5. REPORT: Report incident to the Radiation Safety Officer.

MAJOR SPILLS

1. CLEAR THE AREA: Notify all persons not involved in the spill to vacate the room.

2. PREVENT THE SPREAD: Cover the spill with absorbent pads, but do not attempt to clean it up. Confine the movement of all personnel potentially contaminated to prevent the spread.

3. SHIELD THE SOURCE: If possible, the spill should be shielded, but only if it can be done without further contamination or without significantly increasing your radiation exposure.

4. CLOSE THE ROOM: Leave the room and lock the door(s) to prevent entry.

5. PERSONNEL DECONTAMINATION: Contaminated clothing should be removed and stored for further evaluation by the Radiation Safety Officer. If the spill is on the skin, flush thoroughly and then wash with mild soap and lukewarm water.

RADIATION SAFETY OFFICER: Jim Hengst

OFFICE PHONE: 470-1790

HOME PHONE: 794-9436

ALTERNATE NAMES AND TELEPHONE NUMBERS DESIGNATED BY RADIATION SAFETY OFFICER:

A. Chase 861-0710

M. Jensen " "

F.X. Masse Assoc. 283-5200

G. Fallon 777-2419, 283-5200, 245-6600

AREA SURVEY PROGRAM

A. Individual users of unsealed radioactive materials are expected to perform routine area surveys of the work places and laboratories to insure that working surfaces, floor, equipment, etc. are free of removable contaminations and that external radiation exposures are maintained at a minimum.

B. In addition to self-evaluation, the Radiation Safety Officer will perform area surveys of radiation work areas at appropriate intervals to insure that external and internal exposure of personnel to radiation is maintained as low as reasonably achievable.

AREA SURVEY PROCEDURES

1. All radioactive materials handling areas will be surveyed on each day of use with an appropriate low-range survey meter and decontaminated if necessary. For daily surveys where no abnormal radiation levels are found, only the date, the identification of the person performing the survey, and the survey results need be recorded.

2. Laboratory areas where only small quantities of radioactive material are used (less than 200 uCi) will be surveyed monthly.

3. Waste storage areas and all other laboratory areas will be surveyed weekly.

4. The weekly and monthly surveys will consist of:

   a. A measurement of radiation levels with a survey meter sufficiently sensitive to detect 0.1 mR/hr.

   b. A series of wipe tests to measure contamination levels. The method for performing wipes will be sufficiently sensitive to detect 200 dpm per 100 cm^2 for the contaminant involved. For beta emitters such as P-32 or C-14, wipes may be measured by placing them in close proximity to the thin window of an A-M survey meter. A reading of 0.05 mR/hr is approximately equivalent to 200 dpm on the wipe. Wipes of preparation areas or other "high background" areas will be removed to a low background area for measurement.

5. A permanent record will be kept of all survey results, including negative results. The record will include:

   a. Location, date, and identification of equipment used, including the serial number and pertinent counting efficiencies.

   b. Name of person conducting the survey.

c. Drawing of area surveyed, identifying relevant features such as active storage areas, active waste areas, etc.

d. Measured exposure rates, keyed to location on the drawing (point out rates that require corrective action).

e. Detected contamination levels, keyed to locations on drawing.

f. Corrective action taken in the case of contamination or excessive exposure rates, reduced contamination levels or exposure rates after corrective action, and any appropriate comments.

6. Area will be cleaned if the contamination level exceeds 200 dpm/100 cm^2.

7. The Radiation Safety Officer will survey laboratories using less than 100 uCi at monthly intervals, and all other laboratories at weekly intervals. This survey will include a review of the laboratory monitoring records plus independent meaurements of radiation and contamination levels.

GENERAL SAFETY INSTRUCTIONS AND PRECAUTIONS FOR RADIOISOTOPE USERS

All individuals working with radioactive materials will adhere to the following minimum safety requirements.

1. Maintain daily exposure to radiation as low as possible.

2. No smoking, eating, drinking, use of cosmetics or storage of food or beverages will be permitted in any area where unsealed sources of radioactive materials are used, handled, transferred or stored.

3. No mouth pipetting of radioactive solutions will be permitted.

4. After handling unsealed radioactive material, hands shall be washed before leaving the laboratory and exposed skin, hair and/or clothing shall be surveyed for contamination.

5. When hand or clothing contamination is possible, protective gloves and lab-coat shall be worn.

6. Insure that containers of radioactive materials are appropriately marked and labeled indicating the contents, date, and responsible user.

7. Objects and equipment which may have been contaminated shall not be removed from the controlled area without appropriate prior survey for the presence of contamination. If contamination is detected, the object or piece of equipment must be satisfactorily decontaminated as directed by the Radiation Safety Officer.

8. Whenever practical, the user should perform a trial experimental run using a non-radioactive (or low activity) material to establish the adequacy of equipment and procedures.

9. All work which may result in significant airborne concentrations of radioactive materials (e.g. heating, evaporation to dryness etc.) shall be performed in a properly operating hood. Iodination of proteins shall be performed in a charcoal-filtered minihood operating inside a properly operating fume hood.

ORDERING AND RECEIVING OF RADIONUCLIDES

1. All Radioactive materials are ordered by the Radiation Safety Officer. Individuals desiring such materials must request same of the Radiation Safety Officer. Each authorized user will maintain an inventory record which must be checked before additional material is ordered. The Radiation Safety Officer must also check to ascertain that the supervisor requesting the material has been properly trained and registered to supervise this material.

2. The Radiation Safety Officer will receive all incoming shipments of radionuclides and will be responsible for assuring that they are contamination free before releasing them for active use within the facilities. Such monitoring will include measurement of the dose rate at the surface and at 3 ft. from the surface of the package, a wipe test on the surface (results must be less than 2000 d/m/100 cm^2), monitoring of packing material upon opening; and a wipe test on the inside container (again, contamination must be less than 2000 d/m/100 cm2). Gloves and a lab coat must be worn during this procedure, and an appropriate record kept of all such receipts. Therefore, the procedures listed under Appendix F of the medical section of this appplication will be used for all incoming shipments.

3. Upon release of the approved shipment to the authorized user, the Radiation Safety Officer will instruct the user in any special precautions to be employed (e.g. due to unusual conditions of the shipment), and of any additional montioring and/or handling care necessary when handling the primary container.

RADIOACTIVE WASTE DISPOSAL PROCEDURES

1. Each laboratory will be equipped with a closed-top waste container for the routine collection of dry radioactive waste, plus liquid waste containers for collection of segregated liquid waste as necessary.

2. Records will be kept by laboratory personnel of all activity placed in these containers.

3. When these containers are full, the Radiation Safety Officer will be notified and arrangements made to treat this activity as necessary and to transfer this material to a waste drum with appropriate record transfer.

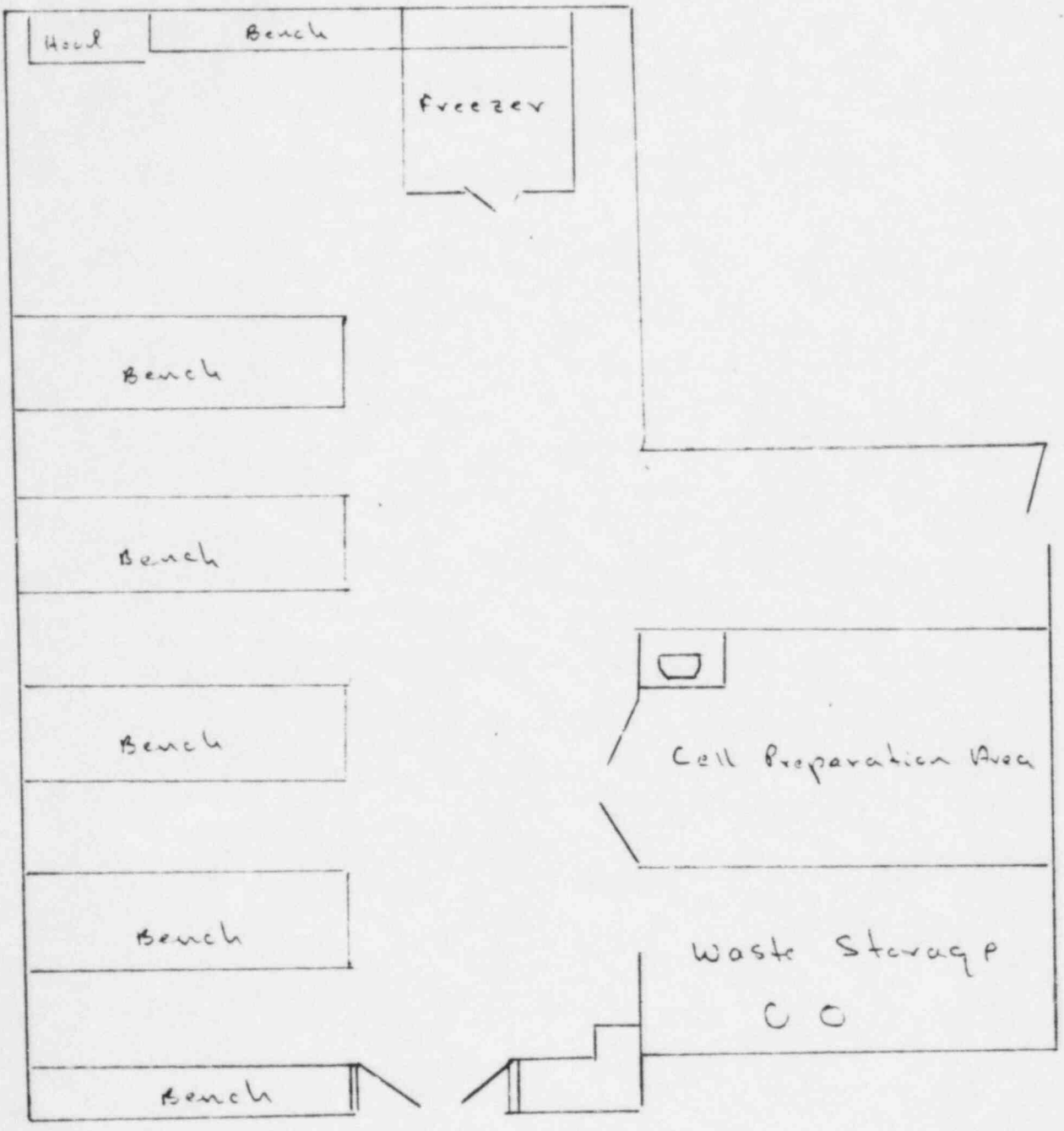
4. The liquid waste containers are unbreakable containers filled with absorbent material. These containers should not be overfilled with liquid, that is, they should not be filled to the extent that there is free-standing liquid above the absorbent.

5. Radionuclide wastes should be segregated according to half-life. For example, I-125 wastes, which may be stored for decay, should be collected separately from longer-lived materials.

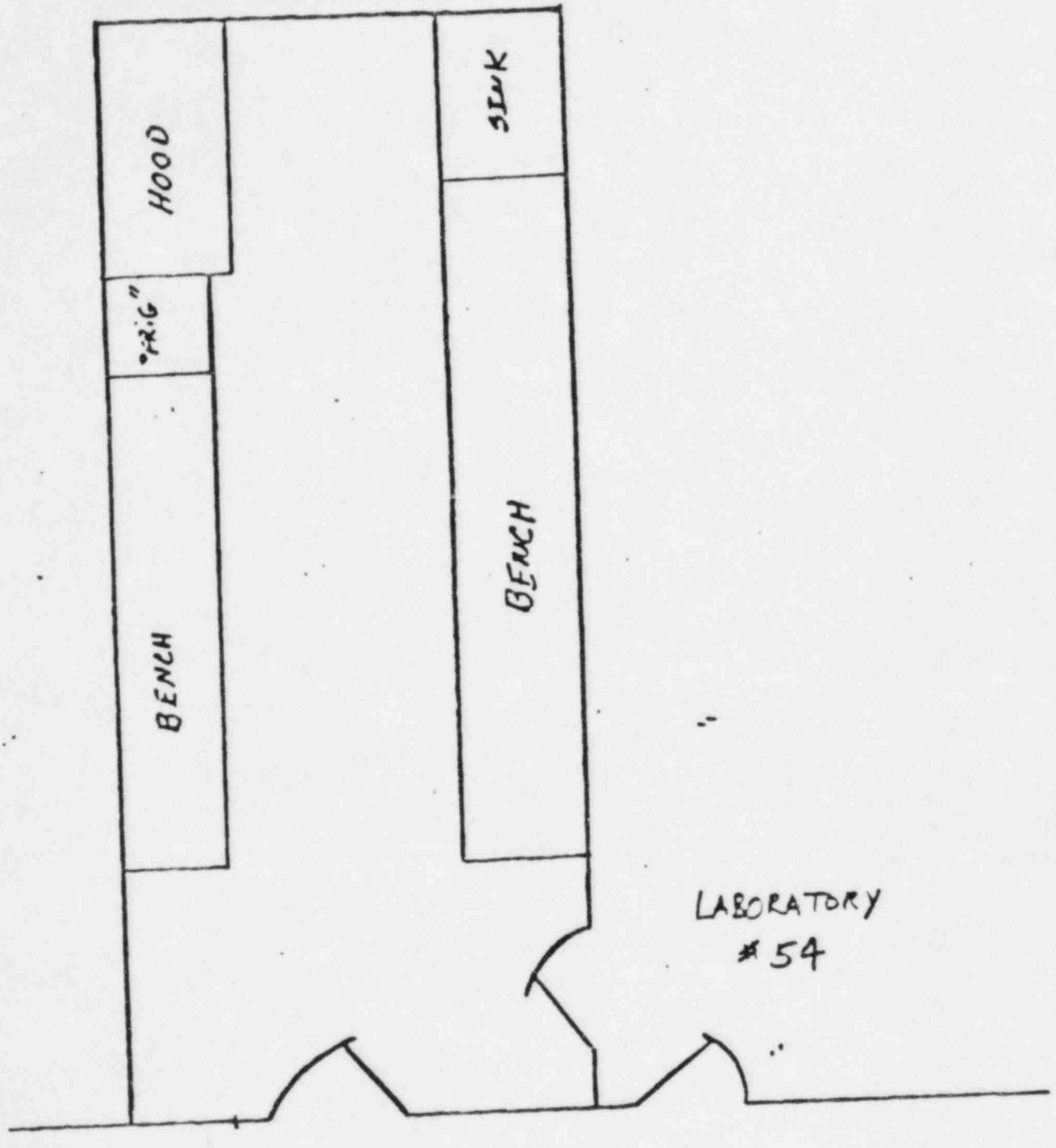
6. Wastes from short-lived materials such as I-125 may be segregated and stored for decay. At least 10 half-lives should elapse before disposal as normal trash is allowed, and all such waste must be surveyed with a thin-window survey meter without shielding in a low-background area before disposal. Waste reading background may be disposed as non-radioactive, and appropriate records must be retained.

7. All normal trash leaving a radioisotope laboratory shall be monitored with an end-window survey meter before removing it from the laboratory. Materials exhibiting contamination above background levels shall be segregated as radioactive waste. Records shall be kept of the daily monitoring of the normal trash.

Radioisotope Laboratory - Andover



Radioisotope Laboratory - Lexington



Fiona D. Jensen
70 Main Street
Hampstead, N.H. 03841

Education:

1966	B.S.	Life Sciences	Massachusetts Institute of Technology
1966-67		Biochemistry	Tufts Medical School
1973	Ph.D.	Biochemistry	Cornell University
1984	M.B.A.	Finance	Babson College

Postdoctoral Training:

1972-1975 Department of Radiobiology, Tufts-New England Medical Center; Dr. D.F.H. Wallach

Employment:

1972-present Instrumentation Laboratory (now Allied Instrumentation Laboratory), Lexington, MA

Appointments and Honors:

1984 Graduated with High Honors, Babson College
1980,1981 Special Reviewer, In Vitro
1974,1976 Adjunct Faculty Member, W. Alton Jones Cell Science Center, Lake Placid, N.Y.

Memberships: American Chemical Society, American Association for Clinical Chemistry, Tissue Culture Association, American Association for the Advancement of Science

Job-related Skills:

Tissue Culture: Development of tissue culture methods and instrumentation for both anchorage-dependent and suspension cultures. Applications research on a wide variety of cells, viruses, and parasites both in-house and as a consultant to academic and industry researchers. Research included determination of optimal culture environment conditions and control methods; and effects of environment on cell growth, differentiation and metabolism.

Immunology: Development of mouse-mouse hybridomas secreting monoclonal antibodies against proteins and haptans.

Radioisotopes: Protein iodination, covalent linkage of enzyme with co-factor and substrate intermediates using NaBT4, metabolic labeling of proteins and nucleic acids.

Immunochemistry: Development of isotopic and non-isotopic assays for clinically significant proteins and coagulation factors. Techniques included RIA, nephelometry, turbidimetry, latex immunoassay, and electrophoresis. One basic technology patent submitted.

Protein Chemistry: Enzyme and antibody isolation, purification and concentration; protein sequencing; enzyme kinetic, substrate specificity and active site configuration studies

ABSTRACTS:

Jensen, M.D., Lin, P.S., Wallach, DFH. "Comparison of Cell Growth on Varions Surfaces". (1973). In Vitro, Vol. 8, Pp 415.

Fessia, S.L., Jensen, M.D., & Bruce, A.S. (1982). "Antibody Induced in Mice Using a Human Transitional Bladder Carcinonia Cell Line". 66th Annual Meeting FASEB #3906.

Huang, P.K., Fowle, E.S., Jensen, M.D. (1985). "Development of Nephelometric(Neph) and Turbidimetric(Turb) Immunoassays of IgG, IgA and IgM for IL Multistat Plus Centrifugal Analyzer". Submitted to American Association for Clinical Chemistry for 1985 Annual Meeting.

Huang, P.K., Fowle, E.S., Jensen, M.D. (1985). "Nephelometric and Turbidimetric Immunoassays for antitrypsin(AAT) and Haptoglobin (HPT) on IL Multistat Plus Centrifugal Analyzer". Submitted to American Association for Clinical Chemistry for 1985 Annual Meeting.

Huang, P.K., Fowle, E.S., Jensen, M.D. (1985). "Development of Complement 3 and Complement 4 Assay Kits for IL Multistat Plus Centrifugal Analyzer." Submitted to American Association for Clinical Chemistry for 1985 Annual Meeting.

Huang, P.K., Fowle, E.S., Jensen, M.D. (1985). "Nephelometric and Turbidimetric Immunoassays for Serum Transferrin using IL Multistat Plus Centrifugal Analyzer". Submitted to American Association for Clinical Chemistry for 1985 Annual Meeting.

ARTICLES:

Jensen, M.D. (1974). "Comparative Growth Characteristics of VERO Cells on Gas-Permeable and Conventional Supports". Experimental Cell Research, 84, Pp. 271-281.

Jensen, M.D. (1976). "Culturing on a Gas-Permeable Membrane". J. Tissue Culture Methods, Vol 2, Pp 265-268.

Jensen, M.D., Wallach, D.F. and Sherwood, P. (1976) "Diffusion in Tissue Cultures on Gas-Permeable and Impereable Supports". J. Theoretical Biology, Vol. 56, Pp 443-458.

Jensen, M.D. (1977). "Mass Cell Cultures in a Controlled Environment". in "Cell Culture and its Application" [R. Acton, ed]. Academic Press. New York, Pp 589-601.

Jensen, M.D. (1978). "The Automation of Cell-Culture Techniques". Pharmaceutical Technology, Vol. 2(2), Pp 22-29.

Jensen, M.D. (1979). "The Application of Environmental Control to Continuous Culture and Vaccine Production". Practical Tissue Culture Applications. Pp 115-136.

Jensen, M.D. (1981). "Production of Anchorage-Dependent Cells- Problems and their Possible Solutions". Biotechnology and Bioengineering, Vol. XXIII, Pp 2703-2716.

Jensen, M.D., Conley M. and Helstowski, L.C. "Culture of Plasmodium Falciparum: The Role of pH, Glucose, and Lactate". The Journal of Parasitology. Vol. 69(6), Pp 1060-1067.

CURRICULUM VITAE

Arleen R. Chase
Allied-Instrumentation Laboratory
113 Hartwell Avenue
Lexington, MA 02173
(617) 861-0710 x1487

4001 Stearns Hill Road
Waltham, MA 02154
(617) 899-1521

EDUCATION:

1967 - B.S. Chemistry, Boston State College, Boston, MA
1971 - M.S. Organic Chemistry, Northeastern University, Boston, MA
1974-6 Special Student, Harvard University, Boston, MA
1982 - Ph.D. Pharmacology, Boston University, Boston, MA

EMPLOYMENT:

11/80-present: Allied Instrumentation Laboratory, Inc., 113 Hartwell Avenue, Lexington, MA 02173. Project Manager. Directing the program for the development of state-of-the art, non-isotopic immunoassays for therapeutic drugs, hormones and vitamins for application to existing and future instrumentation. Three products now being transfered to manufacturing for release in 1985. Involved in developing a company safety manual. Part of a core group dedicated to teaching creative problem solving methods. Scientific consultant to the Hybridoma group. Supervise eight people including two Ph.D.'s.

1976-1982: Boston University School of Medicine, Boston, MA and E. N. Rogers Veterans Memorial Hospital, Gerontology Research, Education and Clinical Center, Bedford, MA. Conducted studies of possible changes in the receptors on vascular smooth muscle cells in hypertension. Determined the effects of selected vasoactive agents on cyclic nucleotide levels in cultured aortic smooth muscle cells of normotensive and spontaneously hypertensive rats. Investigated differences in the growth characteristics of the cells. Participated in an aging study at the Bedford V A by performing similar measurements on cultured aortic smooth muscle cells from nutritionally deprived and ad libitum fed rats as were done in the studies of vascular smooth muscle cells in hypertension. In other studies, determined levels of cyclic nucleotides in various brain regions of hypertensive and control rats. Developed a radioimmunoassay for bradykinin.

1972-1976: Collaborative Research, Inc., 1365 Main Street, Waltham, MA. Supervisor of New Product Development, Research Products Division. Involved in all aspects of radioimmunoassay development, from the production of antisera and the preparation of ^{125}I -labelled antigens to the final marketed

product. Developed the first, commercially-available radioimmunoassay for Δ9-tetrahydrocannabinol and its metabolites in urine. Completed the development of the first, commercially-available radioimmunoassay for LSD in body fluids. Developed a radioimmunoassay for digoxin. Prepared affinity chromatography supports and contributed to the improvement of separations methods used in the isolation of an enzyme from tissue culture media. Responsible for the radiation protection program.

1971-1972: Leary Laboratories, Inc., 43 Bay State Road, Boston, MA. Immunochemist. Qualitative and quantitative analysis of serum, urine, and other body fluids using immunological methods. Research involved primarily assay development and optimization, with some protein isolation work.

1967-1970 Department of Chemistry, Northeastern University, Boston, MA. Synthesis of short-lived sulfur mustards containing an antigenic grouping for use in an immunological approach to cancer chemotherapy. Teaching Assistant. Teaching included general chemistry, analytical, organic chemistry laboratories and problem-solving sessions.

Awards: Predoctoral Fellowship from the Pharmaceutical Manufacturers Association Foundation, Inc., Jan. 1979 to Dec. 1980.

Societies: American Chemical Society, Medicinal Chemistry Division.
New England Clinical Ligand Society.
American Association for Clinical Chemists.

PUBLICATIONS:

Chase, A., Soloway, A. H., and Agranat, I.: Compounds for the chemoimmunotherapy of cancer. Presentation at the Second Northeast Regional Meeting of the American Chemical Society, 1970.

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Soloway, A. H., Chase, A. R., Hernandez, R. E., Kimball, E. S., and Cascieri, T., Jr.: Chemoimmunotherapy of Cancer I. J. Med. Chem., 17, 9, 1974.

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Hartz, T. P., Jr., Polgar, P., Ducomb, M., Chase, A., and Volicer, L.,: Effects of vasoactive agents on cyclic nucleotide levels of normotensive and spontaneously hypertensive rat smooth muscle cells. Fed. Proc., 37, 350, 1978.

Volicer, L., O'Donnell, A., Chase, A., and Gavras, H.: Cyclic nucleotide levels in brains of control and hypertensive rats. Life Sci., 24, 131-136, 1979.

Chase, A., and Volicer, L.: The differential growth of cultured aortic arch smooth muscle cells derived from spontaneously hypertensive (SHR), Wistar Kyoto (WKY), and Wistar Charles River (WCR), normotensive rats. The Pharmacologist, 22(3), 163, 1980.

Chase, A., and Volicer, L.: Effects of vasoactive agents on cyclic nucleotide levels in cultured smooth muscle cells from SHR and control rats. Presentation at the Eleventh Annual Meeting of the New England Pharmacologists, 1981.

Volicer, L., O'Donnell, A., and Chase A.: Acoustic startle response and brain cyclic nucleotides in spontaneously hypertensive and control rats. Adv. Cyclic Nucl. Res., 9, 744-745, 1978.

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Volicer, L., and Chase, A.: Effect of dietary restriction on growth and beta adrenergic receptors in vascular smooth muscle cells in culture. Presentation at the Eleventh Annual Meeting of the New England Pharmacologists, 1981.

Chase, A., and Volicer, L.: Bradykinin receptors in isolated intestinal smooth muscle. Drug Dev. Res., 2, 1-16, 1982.

Volicer, L., West, C., Chase, A., and Greene, L.: Beta adrenergic receptor sensitivity in cultured vascular smooth muscle cells; effect of age and of dietary restriction. Mech. Aging Dev., 21, 283-293, 1983.

Chase, A., Volicer, L., and Greene, L.: Aortic smooth muscle cells from spontaneously hypertensive, Wistar Kyoto, and Wistar Charles River rats.: 1. The differential growth of cultured cells. In preparation.

Chase, A., and Volicer, L.: Aortic smooth muscle cells from spontaneously hypertensive, Wistar Kyoto, and Wistar Charles River rats: 2. The effect of vasoactive agents on cyclic nucleotide levels. In preparation.

Date: December, 1984

CURRICULUM VITAE

James C.D. Hengst, Ph.D.

Home Address: 30 Mount Vernon
North Andover, MA 01845

Business Address: Allied Health and Scientific Products
Instrumentation Laboratory
Department of Life Sciences
1 Burtt Road
Andover, MA 01810

Social Security No.: 321-48-7208

Date of Birth: October 3, 1953

Place of Birth: New York, New York

Marital Status: Married - 1975 - Karen L. Hengst

Education: 1981 Ph.D. (Immunology) University of Illinois at the Medical Center, Chicago, Illinois

1975 B.S. cum laude (Chemistry) Eureka College, Eureka, Illinois

Appointments: Senior Scientist, Allied Health and Scientific Products, Department of Life Sciences, 7-1-84 to present

Research Associate, University of Southern California School of Medicine, Department of Microbiology, 1-1-83 to 6-30-84

Member, Melanoma Site Team, Los Angeles County, University of Southern California Medical Center, 10-5-83 to 6-30-84

Research Scholar, University of Southern California School of Medicine, Department of Microbiology, 10-1-80 to 12-31-82

Bank of America - Giannini Foundation Postdoctoral Fellow, 10-1-81 to 9-30-82

National Institutes of Health Immunology Trainee, 10-1-80 to 9-30-81 (T32 AI 07078)

Appointments (cont): U.S. Public Health Service Oncology Trainee, 4-1-76 to 6-30-78 (PHS CA 05291)

Research Assistant; 7-1-78 to 6-30-79
(PHS CA 18241)
7-1-79 to 9-30-80
(RO1 CA 26480)

Memberships in Professional and Scientific Societies:

American Association for Cancer Research
American Institute of Biological Sciences
Sigma Zeta
Society for Analytic Cytology

Research Interests:

Fffects of Immunomodulators and Chemotherapeutics on Immune Functions

Reviewer for Scientific Journals:

Cancer Research
Cancer Immunology and Immunotherapy
Journal of the National Cancer Institute
Biochemical Pharmacology

James C.D. Hengst, Ph.D.

Publications

1. Braun, D.P., Hengst, J.C.D., Mokyr, M.B. and Dray, S. Antitumor immunity in strain 2 guinea pigs immunized with potassium chloride extracts of L2C tumor cells. J. Natl. Cancer Inst., 60:899, 1978.

2. Mokyr, M.B., Hengst, J.C.D., Przepiorka, D. and Dray, S. Augmentation of antitumor cytotoxicity of MOPC-315 tumor bearer spleen cells by depletion of dinitrophenol-adherent cells prior to in vitro immunization. Cancer Res., 39:3928, 1979.

3. Mokyr, M.B., Bennett, J.A., Braun, D.P., Hengst, J.C.D., Mitchell, M.S. and Dray, S. Opposite effects of different strains or batches of the same strain of BCG on the in vitro generation of syngeneic and allogeneic antitumor cytotoxicity. J. Natl. Cancer Inst., 64:339,1979.

4. Hengst, J.C.D., Mokyr, M.B. and Dray, S. Importance of timing in cyclophosphamide therapy of MOPC-315 tumor-bearing mice. Cancer Res., 40:2135, 1980.

5. Hengst, J.C.D., Mokyr, M.B. and Dray, S. Cooperation between cyclophosphamide tumoricidal activity and host antitumor immunity in the cure of mice bearing large MOPC-315 tumors. Cancer Res., 41:2163, 1981.

6. Mokyr, M.B., Hengst, J.C.D. and Dray, S. Role of antitumor immunity in cyclophosphamide-induced rejection of subcutaneous nonpalpable MOPC-315 tumors. Cancer Res., 42:974, 1982.

7. Kempf, R.A., Hengst, J.C.D., Pham, A.T.H., Ferraresi, R.W., Greiner, J., Rudnick, S. and Mitchell, M.S. Immunological effects of recombinant alpha-2 interferon in a phase I clinical study. 13th Int. Congress Chemother. Proc., 13:41, 1983.

8. Hengst, J.C.D., Kempf, R.A., Kan-Mitchell, J., Pham, A.T.H., Grunberg, S.M., Kortes, V.L. and Mitchell, M.S. Immunological effects of recombinant interferon alpha-2 in cancer patients J. Biol. Response Modifiers., 2:516, 1883.

9. Hengst, J.C.D. and Kempf, R.A. Immunomodulation by cyclophosphamide. Clin. Allergy Immunol., 4:1, 1984.

10. Bertram, J.H., Hengst, J.C.D. and Mitchell, M.S. Staph Protein A immunoadsorptive column induces mitogenicity in perfused plasma. J. Biol. Response Modifiers, 3:1, 1984.

11. Hengst, J.C.D. and Mitchell, M.S. Principles of combining biological response modifiers with cancer chemotherapy. In: Principles of Cancer Chemotherapy. Eds. S.K. Carter and K. Hellmann, New York: McGraw-Hill Book Co. (In Press).

12. Hengst, J.C.D., Chan, K.K. and Mitchell, M.S. Inhibition of proliferation without affecting the generation of cytotoxicity in the human mixed lymphocyte reaction. Cell. Immunol. (In Press).

13. Kan-Mitchell, J., Hengst, J.C.D., Kempf, R.A., Rothbart, R.K., Simmons, S.M., Adelson, L.J., Sharma, O.P., Brooker, A.S. and Mitchell, M.S. Immunological functions of human pulmonary alveolar macrophages. Cancer Res. 45:453, 1985.

14. Hengst, J.C.D, Kan-Mitchell, J., Kempf, R.A., Strumpf, I.J., Sharma, O.P., Kortes, V.L. and Mitchell, M.S. Correlation between cytotoxic and suppressor activities of human pulmonary alveolar macrophages. Cancer Res. 45:459, 1985.

15. Hengst, J.C.D. and Mitchell, M.S. Methods of measuring drug-induced immunosuppression. In ASM Handbook of Clinical Immunology, 3rd Edition, (In Press).

16. Kan-Mitchell, J., Imam, A., Kempf, R.A., Taylor, C.R., Pham, A.T.H., Rao, V.S., Owens, J.D., Hengst, J.C.D. and Mitchell, M.S. Identification of melanoma tumor-associated antigens with human monoclonal antibodies. Int. J. Cancer (Submitted).

17. Bertram, J.H., Grunberg, S.M., Kunkel, L., Hengst, J.C.D., Boquieren, D., Shulman, I., Apuzo, M., Waugh, W.J., Plotkin, D. and Mitchell, M.S. Correlation of mitogenic activity in plasma perfused over staphylococcal protein A column with clinical reaction and response. N. Eng. J. Med. (Submitted).

18. Rao, V.S., Hengst, J.C.D., Kan-Mitchell, J. and Mitchell, M.S. Isolation and characterization of n-butanol-extracted antigens of human melanoma. (In Preparation).

19. Bertram, J.H., Hengst, J.C.D., Talpos, D.E. and Mitchell, M.S. The Staphylococcal protein A column. I. Mitogenicity of column perfused plasma. (In Preparation).

20. Bertram, J.H., Hengst, J.C.D., Boquieren, D.T. and Mitchell, M.S. The Staphylococcal protein A column. II. Suppressogenic materials in column-activated plasma. (In Preparation).

21. Hengst, J.C.D., Rosenbaum, C.A., Chan, K.K. and Mitchell, M.S. Effect of different exposure conditions on the immunomodulatory activity of phosphoramide mustard. (In Preparation).

Abstracts

1. Hengst, J.C.D. and Braun, D.P. Opposite effects of different batches of BCG in the in vitro generation of antitumor cytotoxicity. Presented at the Am. Assoc. Cancer Res. meetings, New Orleans, 1979.

2. Hengst, J.C.D. and Dray, S. Augmenting antitumor cytotoxicity of tumor bearer spleen cells. Presented at the Tissue Culture Assoc. (Midwest Branch) meetings, Chicago, 1979.

3. Hengst, J.C.D., Mokyr, M.B. and Dray, S. Importance of timing cyclophosphamide therapy for curing MOPC-315 tumor-bearing mice. Presented at the Am. Assoc. Cancer Res. meetings, San Diego, 1980.

4. Dray, S., Hengst, J.C.D. and Mokyr, M.B. Synergy between antitumor immunity and tumoricidal activity of cyclophosphamide for curing MOPC-315 tumor-bearing mice. Presented at the 4th Int. Congress Immunol. meetings, Paris, 1908.

5. Dray, S., Hengst, J.C.D. and Mokyr, M.B. Cooperation between cyclophosphamide cytotoxic effects and host antitumor immunity in the cure of mice bearing large size s.c. MOPC-315 tumors. Presented at the Am. Assoc. Cancer Res. meetings, Washington, D.C., 1981.

6. Kan-Mitchell, J., Hengst, J.C.D., Kempf, R.A., Brooker, A.S., Adelson, L.J., Rothbart, R.K., Simons, S.M. and Mitchell, M.S. Cytotoxicity of human pulmonary alveolar macrophages from patients with lung cancer. Presented at the Am. Assoc. Cancer Res. meetings, St. Louis, 1982.

7. Hengst, J.C.D., Kan-Mitchell, J., Kempf, R.A., Rothbart, R.K., Simons, S.M., Brooker, A.S., Adelson, L.J. and Mitchell, M.S. Antitumor cytotoxicity of human alveolar macrophages in lung cancer. Presented at the 13th Int. Cancer Congress, Seattle, 1982.

8. Hengst, J.C.D., Kempf, R.A., Kan-Mitchell, J., Pham, A.T.H., Grunberg, S.M., Kortes, V.L. and Mitchell, M.S. Immunological effects of recombinant interferon-alpha in cancer patients. Presented at the 3rd Int. Congress for Interferon Res., Miami, 1982.

9. Hengst, J.C.D., Kan-Mitchell, J., Kempf, R.A., Strumpf, I.J., Sharma, O.P., Adelson, L.J., Rothbart, R.K., Simons, S.M., Swart, T.L,, Kortes, V.L. and Mitchell, M.S. Correlation between cytotoxic and suppressor activities of human pulmonary alveolar macrophages. Presented at the Am. Assoc. Cancer Res. meetings, San Diego, 1983.

10. Kempf, R.A., Hengst, J.C.D., Pham, A.T.H., Ferraresi, R.W., Greiner, J., Rudnick, S. and Mitchell, M.S. Immunological effects of recombinant alpha 2 interferon in a phase I clinical study. Presented at the 13th Int. Congress Chemother. meetings, Vienna, 1983.

11. Hengst, J.C.D., Chan, K.K. and Mitchell, M.S. Inhibition of lymphocyte proliferation by concentrations of phosphoramide mustard that do not affect the generation of cytotoxic lymphocytes. Presented at the Am. Assoc. Cancer Res. meetings, Toronto, 1984.

12. Bertram, J.H., Boquieren, D., Hengst, J.C.D., Grunberg, S.M. and Mitchell, M.S. On the mechanism of action of Staph protein A column. Presented at the Am. Assoc. Cancer Res. meetings, Toronto, 1984.

RELEVANT TRAINING AND EXPERIENCE WITH RADIOISOTOPES

Formal Training:

Eureka College, Eureka, Illinois
Physical Chemistry - 8 Semester Hours

University of Illinois Medical Center, Chicago, Illinois
Methods in Biological Research - 5 Semester Hours
Department of Biological Chemistry
Seminar in Radiation Safety - Noncredit
Radiation Safety Committee

University of Southern California
School of Medicine
Seminar in Radiation Safety - Noncredit
Health Safety Office

Experience:

University of Illinois Medical Center, 1975 to 1980
Department of Microbiology and Immunology
Summary: 3H purines and pyrimidines as well as 51Cr (sodium chromate salt) used extensively in graduate thesis research work under supervision of Sheldon Dray, M.D., Ph.D.

University of Southern California
School of Medicine
Department of Microbiology and the Cancer Center, 1980 to 1984
Summary: 3H purines and pyrimidines, 51 Cr (sodium chromate salt), and 125I (carrier free NaI) used extensively in postdoctoral research work under supervision of Malcolm S. Mitchell, M.D. Was responsible for maintaining radiation safety files and radioactive materials records for the laboratory.

FORM NRC-313M-SUPPLEMENT A (8-78)

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES *(Hours)* C	SUPERVISED LABORATORY EXPERIENCE *(Hours)* D
a. RADIATION PHYSICS AND INSTRUMENTATION	EUREKA COLLEGE, EUREKA, IL PHYSICAL CHEMISTRY UNIVERSITY OF ILLINOIS MED CENTER CHICAGO, IL, METHODS IN BIOL RESEARCH	40h 16h	64h 128h
b. RADIATION PROTECTION	UNIVERSITY OF ILLINOIS MED CENTER SEMINAR IN RADIATION SAFETY UNIVERSITY OF SOUTHERN CALIFORNIA SEMINAR IN RADIATION SAFETY	10h 6h	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	EUREKA COLLEGE CALCULUS UNIVERSITY OF ILLINOIS MED CENTER STATISTICS	80h 192h	
d. RADIATION BIOLOGY	UNIVERSITY OF ILLINOIS MED CENTER MOLECULAR BIOLOGY	64h	128h
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
^{3}H	10 mCi	UNIVERSITY OF ILLINOIS UNIVERSITY OF SOUTHERN CALIFORNIA	1975-80 1980-84	IN VITRO
^{51}Cr	10 mCi	U. I. USC	1975-80 1980-84	"
^{125}I	10 mCi	USC	1980-84	"

BETWEEN: William O. Miller, Chief
License Fee Management Branch
Office of Administration

John E. Glenn, Chief
Nuclear Materials Section B
Division of Engineering and
Technical Programs

LICENSE FEE TRANSMITTAL

A. REGION 1 Fee Needed

1. APPLICATION ATTACHED

Applicant/Licensee: Allied/Instrumentation Laboratory

Application Dated: 5/28/85

Control No.: 03922

License No.: 20-16890-01

2. FEE ATTACHED

Amount: ~~$~~ #120

Check No.: ~~X~~ 18127

3. COMMENTS

Signed Brenda Platchek

Date 6/7/85

03620 6/86

B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount: 3M - #120

2. Correct Fee Paid. Application may be processed for:

Amendment ✓

Renewal

License

Signed K Jackson

Date 6/17/85

REGION I FORM 213
(MARCH 1983)