DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta GA 30333

May 28, 1985

U.S. Nuclear Regulatory Commission
Region II
101 Marietta Street, N.W.
Atlanta, Georgia 30323
ATTENTION: Carol A. Connell
Radiation Specialist
Nuclear Material Safety Section

Dear Ms. Connell:

We are submitting the enclosed documentation in response to your request for additional information concerning CDC's Material License Application, Control Number 18444.

Please contact use if you need additional information.

Sincerely,

David B. Weather for

Frank S. Lisella, Ph.D.
Director
Office of Biosafety

Enclosure

SUBJECT: Response to Request for Additional Information Concerning CDC's Material License Application, Control Number 18444

The following responses are provided as answers to questions concerning CDC's Material License Application:

1. Item 3 (Form NRC 313) - The specific address of the Lawrenceville facility is as follows:

   602 Webb Gin House Road
   Lawrenceville, GA 30246

2. Item 8 - Training

   A. On an as-needed-basis, a one-day course entitled "Radiation Safety in the Laboratory" is taught by Dr. William Wagner, a scientist employed with CDC's Laboratory Program Office (See Appendix A, Dr. Wagner's Curriculum Vitae).

   B. The major topics covered in the radiation safety course include: Basic Radiation Concepts, Biological Effects of Radiation, Personnel Protection Measures, Radiation Detection, Personnel Monitoring, and Contamination Control and Waste Disposal (See Appendix B, Typical Course Outline).

   C. The radiation safety course is usually scheduled whenever a minimum of twenty laboratorians have signed up to take the course. In other words, the frequency of the radiation safety course is determined by the needs of the laboratorians. Additionally, radiation workers are provided on-the-job training by the authorized users. Upon request, the Radiation Safety Officer is available to provide consultation and training on various radiation topics.

   D. The competency of radiation workers is evaluated by the authorized users. Noted deficiencies are communicated to the radiation worker, and subsequently, a plan of action is defined to assist the worker in gaining the education and/or experience needed to effectively perform his laboratory duties.

   E. After each radiation safety course, the Laboratory Program Office forwards to the Office of Biosafety a roster of the students who have completed the course. Rosters are kept in the files maintained by the Radiation Safety Officer.

   All laboratorians (authorized users and radiation workers) are encouraged to take the CDC 'Radiation Safety in the Laboratory' course regardless of their prior education and/or training in radiation safety. A refresher course is being organized to provide a review and update of radiation safety topics to laboratorians on a bi-annual basis.

3. Item 11 - Waste Management

A. Handling, Storing, and Disposing of Waste

All Nuclear Regulatory Commission regulations are followed in the disposal of radiological waste at CDC. Guidance to be followed by all laboratorians on the subject of handling, storing, and disposing of all radioactive waste is provided in the CDC Radiation Safety Manual (see Appendix C, Waste Disposal Policy). CDC does not presently incinerate any of its radiological waste and there are no future plans to incorporate incineration into the waste disposal program.

B. Radioactive Waste Removal From CDC

The principal radioactive isotopes used at CDC are H-3, C-14, I-125 (90% in RIA kits), and P-32. In the laboratory, solid waste with the exception of P-32 is stored in thin metal containers; only one isotope is stored per container. P-32 solid waste is stored in one-half inch wooden boxes. Liquid radioactive waste is stored in appropriate sized plastic bottles which are secured with bottle caps. P-32 liquid waste is placed in wooden radiation waste containers until it is picked up. When requested by telephone, radiation safety personnel from the Biosafety Office pick up radioactive waste from the laboratories in a timely manner. The waste is then transported from the laboratories to CDC's radiation storage area and is placed in 55-gallon steel drums until it is removed by ADCO, the licensed contract vendor located in Tinley Park, Illinois. ADCO services CDC four times per year and removes approximately 75 drums of liquid and solid waste annually. The radioactive storage area is a secure facility which is protected by perimeter fencing. Entry to the facility is via a gate which is kept locked except when authorized Office of Biosafety personnel require access.

4. Radiological Surveys

A. Laboratories in which radioactive materials are stored or used will be surveyed by the laboratorian as often as necessary to eliminate radioactive contamination. Data obtained when conducting surveys will be recorded on CDC Form 0.1002, Radiation Safety Report (see Appendix D, Radiation Survey Form) and will be kept in the CDC Radioisotope Log Book residing in each laboratory. The Office of Biosafety personnel will conduct a routine survey of all laboratories on a quarterly basis to ascertain whether laboratories are free of radioactive contamination; the findings of the OBS survey will also be kept in the log book.

B. To establish some specific guidelines for the radiation surveillance program, the Radiation Safety Committee appointed a Laboratory Radiation Surveillance Subcommittee. The resulting surveillance guidelines, which will be approved by the Radiation Safety Committee, will become CDC's policy for surveying laboratories by laboratorians and radiation safety staff. As soon as the surveillance guidelines are available, copies will be forwarded to the NRC.

5. Radioactive Materials/Use of Animals

At the present time, there are no CDC researchers utilizing radioactive materials in experiments with animals. In the future, if a researcher expresses a need to use radioisotopes in animal experiments, radiation safety personnel will collaborate with the individuals involved and jointly define all of the procedures necessary to protect the laboratorians and the animals from radiation exposures.

6. Draft Radiation Safety Manual

When approved by the Radiation Safety Committee, the Draft Radiation Safety Manual presently being edited and reformatted by CDC's Communication and Management Analysis Office will represent CDC's policy on radiation safety and protection. The final version of the CDC Radiation Safety Manual will be forwarded to NRC for inclusion as an appendix to CDC's Material License.

APPENDIX A

CURRICULUM VITAE

NAME: Dr. William M. Wagner

ADDRESS: 804 Hampton Place
Marietta, Georgia 30064
Home - (404) 422-6360
Work - (404) 329-3232

PERSONAL

Born: 1946, Cleveland, Ohio
Married: 1969, 2 children
Military Status: Active Duty, CDR, Scientist
05 Regular, U.S. Public Health Service

EDUCATION

1968 Emory University, Atlanta, Georgia
B.A. Degree, Physics

1969 Georgia Institute of Technology, Atlanta, Georgia
M.S. Degree, Physics

1976 Johns Hopkins School of Public Health and Hygiene, Baltimore, MD
Sc.D., Radiological Science (Radiobiology)

WORK EXPERIENCE

1980 - Present: Physical Science Consultant, Laboratory Training and Consultation Division, Laboratory Improvement Program Office, Centers for Disease Control, Atlanta, Georgia

1979 - 1980 Health Scientist Administrator, Structure and Function Branch, Division of Lung Diseases, National Heart, Lung, and Blood Institute, Bethesda, MD

1977 - 1980 Instructor, Graduate School at NIH, Foundation for Advanced Education in the Sciences, NIH, Bethesda, MD

1975 - 1979 Deputy Radiation Safety Officer, National Institutes of Health, Bethesda, MD
Assistant Chief for Operations, Radiation Safety Branch, Environmental Health and Safety Program, Division of Research Services, NIH, Bethesda, MD

1974 - 1977	Guest Researcher, Biochemical Section, Pulmonary Branch, National Heart, Lung, and Blood Institute, Bethesda, MD (Doctoral and Post Doctoral Research)
1974	Consultant, Radiation Physicist, Oyster Creek Nuclear Power Plant, Oyster Creek, NJ
1969 - 1975	Health Physicist, Radiation Safety Program, Department of Nuclear Medicine, Clinical Center, National Institutes of Health, Bethesda, MD

CERTIFICATION

1979 Hazard Control Manager, IHCMCB

HONORS

1968 Sigma Pi Sigma (Physics Honor Society)
1976 Certificate of Appreciation, North Carolina State Health Dept.
1977 Medal of Commendation, U.S. Public Health Service
1979 Letter of Commendation, American Lung Association

COMMITTEES

1980 - Present	Board of Examiners, Hazard Control Managers Certification Board
1980 - Present	Centers for Disease Control Radiation Safety Committee
1977 - 1980	National Institutes of Health Radiation Committee
1977 - 1978	Committee, Mid-Atlantic Chapter, American Association of Physicists in Medicine
1979 - 1980	President, Parent-Teacher Association, Fallsmead Elementary School

PROFESSIONAL TRAINING

A. Scientific

1970	USPHS-BRH	Reactor Safety and Hazard Evaluation
1970	FAES-NIH	Scientific German
1970	USPHS-BRH	Fundamentals of Non-Ionizing Radiation Protection
1970	American Board of Health Physicists - Certification Preparation Course	
1971	USPHS-BRH	Accelerator Radiation Protection
1972	USPHS-NIH-DCRT	Computer Training in CPS-IBM Language

1972	NIH-DCRT	CPS for Programmers
1974	FAES-NIH	Human Genetic Disease
1974	NIH-DCRT	Introduction to IBM-Time Sharing Options
1976	FAES-NIH	Organic Chemistry
1976	FCRC-NIH	Biological Safety Conference
1977	STEP-NIH	DNA Research Lecture
1977	DRS-NIH	Requirements for Sponsored Research in Higher Education
1977	Baker Chem. Corp.-NIH	Safe Handling of Chemical Carcinogens
1977	FCRC-NIH	Hazardous Chemical Safety
1980	Johns Hopkins Univ.-NIH	Control of Biological Hazards

B. Management

1975	USPHS-NIH	Management for the 70's
1975	NIH	Advanced Supervisory Development
1976	DRS-NIH	Adverse Actions
1976	AMA-NIH	Time Management for Senior Federal Executives
1977	AMA-NIH	Management Style Self-Directed Growth
1977	NIH	Position Management

C. Administration

1976	USPHS-NIH	Federal Budget
1976	NIH	Program Planning, Evaluation & Analysis
1977-1978	NIH-DRG	NIH Grants Associates Seminar Series for Health Sciences Administrators
1978	NIH-STEP	Implementation in the NIH
1980	CDC	Teaching by Telephone

PROFESSIONAL AFFILIATIONS

American Association of Physicists in Medicine
Foundation for Advanced Education in the Sciences, NIH
Board of Certified Hazard Control Managers
Sigma Xi

PUBLICATIONS

1. Buchignani, J., Wagner, W., Howley, J. Radiation Dosimetry in Full Chest Tomography, Radiology, Vol. 99, No. 1, 175, 1971.

2. Wagner, W., Buchignani, J., Howley, J. Reduction of Patient Exposure by Body Positioning, Health Physics, Vol. 22, 398, 1972.

3. Wagner, W., Howley, J. Simultaneous Radiation Dosimetry During Routine Fluoroscopic Procedures in Diagnostic Radiology, Symposium Publication, DHEW, #(FDA) 73-8009 BRH/DMRE-73-1 Reduction of Radiation Dose in Diagnostic X-Ray Procedures, 161, 1972.

4. Hance, A., Crystal, R., Wagner, W., et al, Biochemical Approaches to Investigation of Fibrotic Lung Disease, Chest, 69, 2(Suppl), 1976.

5. Aamodt, R., Broseus, R., Swain, R., Wagner, W. Radiation and Radiobiology, Human Health and Disease, FASEB, 1977.

6. Wagner, W. Laboratory Used Radioactive Materials, Laboratory Update Series, Department of Health and Human Services, Public Health Service, Centers for Disease Control, (80-97), 1980.

THESIS

"The Effects of Varied X-Ray Energy and Absorbed Dose on the Production of Pulmonary Fibrosis in Rabbits." The Johns Hopkins University, 1979.

APPENDIX B

Radiation Safety in the Laboratory

Atlanta, Georgia
November 14, 1984

8:00	Registration	
8:30	Introduction	
8:40	"Nobody's Perfect" (Video tape)	
9:00	Basic Radiation Concepts	
9:45	Break	
10:15	Biological Effects of Radiation	
11:15	Personnel Protection	
11:45	Lunch	
12:45	Radiation Detection	
1:15	Radiation Safety Program, CDC	Dr. Frank Lisella, Director, CDC OBS
1:45	Personnel Monitoring	
2:15	Contamination Control	
2:30	Break	
2:45	Contamination Control(continued)	
3:15	Waste Disposal	
3:45	Outline of a Laboratory Radiation Safety Program	

Instructor: Dr. William M. Wagner
Centers for Disease Control
Bldg 3 Rm B15
Atlanta, GA 30333
(404) 329-3232

APPENDIX C

M. Waste Disposal

No radioactive material may be disposed of without the knowledge and consent of the OBS and the RSO. Methods for disposal must be approved before any actual disposal. No radioactive waste will be accepted for disposal by the Office of Biosafty unless it is labeled with the appropriate isotopic name, activity, date of assay and date of disposal.

The OBS will supply authorized users with a standardized radioactive waste container for each isotope used in the lab. Each container will be used for ONE isotope only. A separate can will be issued for materials contaminated with a mixture of isotopes and disposal procedures will be based on the longest half-life. Authorized users are expected to supply plastic bags to line the waste containers. The radioactive waste cans should be stored in an area within the laboratory where they will not be knocked over, used for other waste, or accidently mistaken as nonradioactive waste. The area where the waste is stored must be marked with a "radioactive waste/ Do Not Remove" sign. Authorized users are responsible for securing waste until it is removed by the OBS. They can arrange for pickup of waste by contacting the RSO. Scheduling should be done in advance to prevent waste overflow. Waste is housed in the radioactive waste storage area adjacent to building 5 until permanent disposal. Access is prohibited except for OBS personnel.

All individual bags and bottles of radioactive waste must be marked with a radioactive waste label that includes on it all isotopes, their quantities, date assayed, and physical form. Any chemical information that might be useful should also be included (for example strong acid). These individual containers must then be placed in the waste can provided for the particular isotope. The lid of each large waste can will have an inventory sheet attached and entries must be made for each bag of waste that is placed in the can. These sheets will be supplied by OBS and should be a complete list of the isotopes disposed of in the waste cans.

No radioactive waste will be accepted for disposal if nonradioactive waste such as lunch bags or other trash is mixed with the radioactive waste. Also each individual bag must be properly labeled and the inventory form on the top of the container must be complete.

Containers bearing a radioactive label but that no longer contain radioactive material must be disposed of as ordinary trash but only after the radioactive label is defaced or removed.

1. Solid Waste

Solid waste includes test tubes, beakers, absorbent paper, gloves, pipettes and other dry material contaminated with radioactive material. This material must be placed in plastic bags sealed with tape. Hypodermic needles, capillary pipettes and other sharp objects must be placed in puncture proof containers before being put into the large waste cans.

Any radioactive material contaminated with a biological organism (virus, fungus or bacteria) must be autoclaved or chemically treated in a manner that destroys all living organisms before disposal. Care should be taken to protect autoclaves from any radioactive contamination.

Before beginning animal experiments using radioisotopes, the OBS must be consulted so that proper arrangements can be made for disposal of radiologically contaminated and/or infectious carcasses. Animals that contain less than .05 microcuries of tritium or carbon-14 per gram should be treated as other biological waste. At concentrations higher than this or for other isotopes, the animal or tissues must be disposed of as radioactive waste. Carcasses or tissues should be wrapped securely and labeled as radioactive waste. The OBS should be contacted when this type of disposal is expected to that they can make arrangements to freeze these tissues until time for final disposal.

2. Liquid Waste

a. Organic

Scintillation vials should not be disposed of as radioactive waste IF they contain LESS then 0.05 microcuries tritium or carbon-14 per gram of scintillation medium. These vials will be disposed of as chemical waste. All other scintillation vials containing radioactivity must be labeled as radioactive waste. Scintillation fluid and radioactive waste must be left in their original vials for disposal. These vials should be placed upright in their shipping trays rather than in the large waste cans.

Solvents, which are insoluble, flammable or toxic must be collected in inert, airtight plastic bottles and must never be disposed of in the sink.

b. Aqueous

No liquid radioactive waste shall be disposed of by sewage system unless:

1) The liquid is readily soluble or dispersible in water and

2) The material is diluted to the concentrations shown in column 2, Appendix B, Table I, column II before disposal or flushed simultaneously with measured amounts of water sufficient to achieve those concentrations.

(For example wash water from glassware that has been used for processing radioactive materials could be disposed of down the sewer.)

Only one sink in each laboratory shall be used for this purpose and shall be appropriately labeled. After each disposal the sink shall be flushed with copius amounts of water. Authorized Users shall keep a record of quantities and isotopes disposed of in this manner and include such disposals on quarterly inventory reports. Chemicals normally treated as hazardous waste cannont be disposed of using this method.

Liquid radioactive waste must be stored in unbreakable, airtight bottles or in double containers with enough absorbent material in the outer container to absorb any spillage. Radioimmunoassay (RIA) kits containing I-125 should be treated as radioactive waste and will be disposed of by OBS.

(note: get diagram of radioactive and chemical hazard labels to put on next page.)

N. Specific Instructions

1. Cobalt-60 Irradiator

Only persons listed on the NRC license as users shall operate the Gammacell irradiator without personal supervision. All others must have one of the listed Authorized Users present. The room housing the irradiator must be locked at all times, and a TLD must be worn when using the Gammacell. Each user must also sign and date a logbook before using the irradiator. All notices from NRC concerning the Gammacell irradiator must be provided to each user.

The Gammacell will be tested for contamination and leakage at least once every 6 months. This test must be capable of detecting 0.05 microcurie of contamination. If 0.05 microcurie of removable contamination is found, the Gammacell will be removed from operation immediately.

RADIATION SURVEY REPORT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL
ATLANTA, GEORGIA 30333

Authorized User No.			
Authorized Investigator	Telephone No.	Organization	Date
Surveyor	Telephone No.	Building/Room No.	Radionuclides Used

COUNTING EQUIPMENT

L.S.C. ____ EFF _____ %

GAMMA ____ EFF _____ %

COMPLIANCE ITEMS

- Room and Storage Posted ☐
- Personnel Monitoring ☐
- Inventory, Disposal Records Adequate ☐
- Personnel Training ☐
- Containers & Equipment Labeled ☐
- Survey Records ☐
- Waste Handling Practices ☐
- Shielding ☐
- Hoods and Ventilation ☐
- Other ☐
- Survey Instruments ☐

SMEAR SURVEY RESULTS

SAMPLE NO.	LOCATION	CPM NUCLIDE		SAMPLE NO.	LOCATION	CPM NUCLIDE	

COMMENTS

AREA DIAGRAM AND SAMPLING SITES