ACS PHARMACEUTICALS INC.
5245 Edina Industrial Blvd
Edina, Minnesota 55435
612-835-3446

August 17, 1982

Mr. George Michael McCann
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

Dear Mike;

I enjoyed meeting with you on Wednesday and I was glad for the opportunity to answer some of your questions while you and your colleague were here. This letter should clarify the remaining points.

The first point was intended use of radiolabelled material. We will use radioisotopes for analysis of correct sequencing in the synthesis of peptides and for labelling of small amounts of immunoglobulin for tracer studies in our labs. No labelled material will ever leave the premises. We will use between 1 and 5 microCuries of 125I in each labelling experiment and all of the work except for counting will be performed under the radioisotope labelling hood. If it is necessary to separate free reagent from labelled protein, this will be done under the hood in a disposable column which will be discarded with other non-flammable radioactive waste when the experiment is finished. All materials will be disposed of properly. A small tabletop centrifuge and a fraction collector will be designated for the radioisotope room and will remain there permanently for use in these experiments. No radiolabelled material or isotopes will be injected into animals; our animal studies involve no use of radioactive material. No sealed sources of radiation will be used except as counting standards.

Another matter we discussed concerns the training and experience of approved users. You will find enclosed a table of intended users which specifies their qualifications.

All new employees wil go through an informal orientation by the radiation safety officer. Technicians who are not approved users and ancillary personnel will be informed of areas where access is controlled and instructed to avoid these areas. They will be instructed briefly on radiation safety and the significance of signs marking controlled access areas and symbols on tape, etc. Approved users and potential users will receive a broader orientation and will learn procedures for receipt, use, and disposal of radioactive materials and emergency procedures in case of spills, etc. These users and potential users will be asked to read the company radiation safety manual and invited to consult the safety officer on any questions they have. All employees will have a refresher session with the safety officer annually. No handling of radioactive material will take place in the absence at the company of an approved user.

Some clarification may be helpful concerning our instrumentation. Sometime in the next year ACS will purchase a liquid scintillation

counter with standards. This instrument will be calibrated at each use with standards as will our gamma counter. These standard readings will be recorded and records will be reviewed periodically by the safety officer. Wipe tests will be done by the laboratory manager in all areas of the labelling room and around and inside the counters. Surfaces will be wiped with circles of Whatman #1 filter paper by the lab manager. Each bench will be wiped and the paper circle will be inserted into a scintillation vial with 5 ml. of scintillation fluid and counted in the B-counter for 10 minutes. The cut-off level for decontamination will be 200 cpm; any area with counts above this will be cleaned with Count-off or some other decontamination form. When tracer experiments are being done with B-emitters wipe tests will be done monthly. When labelling with B-emitters is done, areas used will be wiped after each labelling experiment. When iodine isotopes are used, the same schedule will be followed for monitoring with the GM probe, and this will be done by the lab manager. Records of these tests will be kept by the lab manager and reviewed annually by the radiation safety officer. The GM probe used for radiation safety monitoring of all areas where radioactive material will be used will be calibrated by the manufacturer at least annually.

In the case of personnel monitoring, no pocket dosimeters will be used. Access to all areas where radioisotopes will be used will be strictly controlled. All users will wear lab coats when handling isotopes and film badges or rings will be worn at all times. While radioactive materials are being handled under the hood, the front panel of the hood will be kept well below face level so that the breathing zone will not be exposed. If more than the specified 10% of maximum radioactivity will be involved in an iodine labelling or tracer experiment, the user will receive a thyroid scan before and after the experiment at St. Paul-Ramsey Medical Center in St. Paul.

The areas in which radioactive materials may be used and to which access will be controlled are the labelling room where the hood is located, the instrument room where the counters will be located, and the tissue culture room. All these areas will be clearly marked, and personnel will have been instructed on those who may not have access to these spaces. Maintenance personnel will be told about radioactive waste disposal and asked not to clean restricted areas.

Records concerning waste disposal will be kept by the lab manager and reviewed by the radiation safety officer annually. The same will be true concerning receipt of radioisotopes. All deliveries of radioactive materials will be made to the back entrance, directly into the lab, and the lab manager will receive and inspect all material. The lab manager will wear gloves for this and will monitor the surface of parcels and at three feet with the GM probe. Each final container will be wipe-tested by the lab manager. The radiation safety officer will do all ordering of isotopes and will handle decontamination of any parcels where tests show spillage has occurred.

Unused iodine isotopes will be held in their lead containers until they have decayed as judged by probe monitoring, and then discarded as ordinary waste. Small amounts of tritium in scintillation vials with scintillation fluid will be disposed of according to section 20.303 of the U.S. N.R.C. Rules and Regulations.

If there are any other questions I can answer, please call me. Again, it was a pleasure to meet with you, and I look forward to receiving our license soon.

Sincerely,

Susan A. Stern

Susan A. Stern, Ph.D.
Radiation Safety Officer
ACS Pharmaceuticals, Inc.

Training and Experience of Radioisotope

Users at ACS Pharmaceuticals, Inc.

Users	Training	Experience
Susan A. Stern, Ph.D. Radiation Safety Officer	1976-1979 Informal training in radiation safety. 1980-U of Minnesota Radiation Training Course	1976-1980 200 Tracer experiments: 100uCi tritium/experiment. 1980-82 100 Tracer experiments: 100uCi tritium/experiment. 8 protein iodine-125 labelling experiments: 4-5uCi/experiment. 2 protein carbon-14 labelling experiments: 25uCi/experiment
Dee M. McManus, B.S., A.S.M.T. Lab Manager	1974-75 Informal training in radiation 1976-U of Minnesota Radiation Protection Training Course	1974-1976 500 tracer experiments (Insulin I125) of 50uCi/assay 1977-1978 100 tracer experiments 100uCi tritium/experiment 1978-1982 50 tracer experiments/100uCi tritium/experiment
Alan R. Day, D. Phil.	1968-three month course in radiochemistry, radiation safety, modern atomic theory and isotopes	1973-74 2 iodine labelling experiments: 2uCi/experiment. 1976-5 labelling experiments: 10uCi/experiment.

Dr. Day will work under supervision for the first year to gain more recent experience before becoming an approved user.