



DOW CHEMICAL U.S.A.

MIDLAND, MICHIGAN 48640

September 22, 1982

B. Mallett, Chief  
Region III Licensing Section  
U.S. Nuclear Regulatory Commission  
799 Roosevelt Road  
Glen Ellyn, Illinois 60137

Dear Dr. Mallett:

CONTROL NUMBER 06582

In response to your telephone request of August 24, 1982, the following information is to be used in support of Dow's NRC License 21-00265-06 amendment request dated June 30, 1982.

Amendment 1

Replace R. C. Kolesar, M.D., with J. S. Moore, M.D., as the active physician on the Dow Radiation Safety Committee.

Dr. Moore has had previous training with various radio-nuclides, including on-the-job experience. Please refer to his curriculum vitae which was enclosed with the amendment request letter dated June 30, 1982. More specifically, at the University of Texas Southwestern Medical School, Dr. Moore participated in a one-month rotation in a nuclear medicine department where experience was gained in diagnostic imaging, thyroid ablation therapy, brain and spleen scans and cardiac studies using radionuclides such as iodine, technetium, thallium and gallium. At the National Naval Medical Center in Bethesda, Maryland, Dr. Moore performed therapeutic radiology treatments using external radiation beams. Finally, Dr. Moore received training at the Naval Undersea Medical Institute in Groton, Connecticut, where the health effects of tritium contamination and exposure were studied as part of the class curricula.

Because of these activities and his academic background, Dr. Moore is qualified to be the medical representative on the Radiation Safety Committee.

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AN OPERATING UNIT OF THE DOW CHEMICAL COMPANY



SEP 27 1982

Amendment 2

Increase the license possession limit from 3 to 6 curies for carbon-14.

No additional information was requested.

Amendment 3

Amend the license to allow for human studies with carbon-14.

1. A check for \$150.00 to cover the amendment fee costs of reassignment to the human research category from the broad scope category has been sent to Ms. Glenda Jackson of the License Fee Management Branch.
2. The medical isotopes committee referred to in 10CFR35.11(b) is the Dow Radiation Safety Committee.
3. All studies involving the use of carbon-14 in humans would be contingent upon review and approval of the protocols by the Dow technical staff, the Dow Human Health Research Review Committee, the Dow Radiation Safety Committee, the University of Michigan Committee to Review Grants for Clinical Research and Investigation Involving Human Beings (IRB) and the University of Michigan RDRD No. 45.
4. You will find enclosed letters from R. C. Bishop, M.D., Chairman, RDRD No. 45, and W. W. Corn, M.D., Chairman, IRB, which authorize Dow to submit protocols to the RDRD No. 45 and to the IRB for review.
5. The Dow Radiation Safety Committee currently can meet and vote on all radiation issues provided a quorum is present. For committee actions regarding human studies, either J. S. Moore, M.D., or O. U. Anders, Ph.D., both Radiation Safety Committee members, will be present as a member of the voting quorum. Dr. Anders' curriculum vitae was forwarded to the NRC with the Dow license application dated June 14, 1978.
6. All studies involving carbon-14 and human volunteers will be conducted using the Dow Midland, Michigan, facilities. Dow possesses facilities for dose administration, sample collection and analysis, and clinical care of the human volunteers. Specific instructions regarding biological excreta collection, radiation safety precautions for the volunteers, diet, exercise, alcohol and pharmaceutical consumption will be presented to the human volunteers.

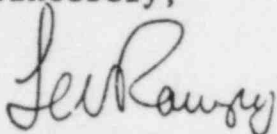
September 22, 1982

7. Employees, identified as the designated users of the radioactive material, will be selected based on the following qualification criteria.

- (a) Employee must have attended a Dow training class of at least Class II level.
- (b) Employee must have experience in the use, handling, and administration of nonradioactive or radioactive materials in human studies.
- (c) Employee must have supervised or conducted nonhuman studies involving the types and quantities of carbon-14 labeled compounds expected to be used in the human studies.

Please contact me if further information is required.

Sincerely,



L. W. Rampy, Chairman  
Radiation Safety Committee  
Industrial Hygiene Laboratory  
1803 Building  
517/636-6260

sjl

enclosures

cc: T. W. Parsons, Radiation Safety Officer

THE UNIVERSITY OF MICHIGAN  
Ann Arbor

October 12, 1978

Maynard B. Chenoweth, M.D.  
Research Scientist  
Bio-Medical Research  
Dow Chemical U.S.A.  
607 Building  
Midland, Michigan 48604

Dear Dr. Chenoweth:

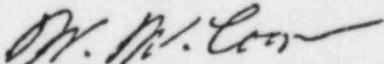
This letter is in reply to your request to the University of Michigan Human Research Review Committee to consider the review of protocols generated by the Dow Bio-Medical Research Laboratory. I have discussed this with Dr. George DeMuth in the Dean's office and with the members of my committee. We would be happy to review your protocols provided that there is not an inordinate number at any one time and provided that there is no time deadline for completion of the review process.

Enclosed in the accompanying envelope is a dozen or so of our research forms which we ask to be completed and submitted with a copy of the research protocol and the written informed consent documents.

I would be happy to meet with you and Dr. Saunders to discuss any of the procedural details. Perhaps the best time would be sometime early in November. If you would call my secretary we could arrange a time at our mutual convenience.

With very cordial regards,

Sincerely yours,



William W. Coon, M.D., Chairman  
Committee to Review Grants for  
Clinical Research and Investigation  
Involving Human Beings  
Phone: (313) 764-6121

WWC:s



UNIVERSITY HOSPITAL

June 15, 1982

Mr. Richard J. Nolan  
1803 Building  
Dow Chemical Company  
Midland, Michigan 48640

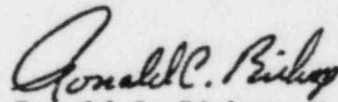
Dear Mr. Nolan:

Your request for review of research protocols in which radioisotopes are to be administered to human beings was discussed by this committee (Radioactive Drug Research Committee No. 45, University of Michigan) on May 28, 1982. We understand that these protocols will also be submitted to the University of Michigan Committee to Review Grants for Clinical Research and Investigation Involving Human Beings (IRB), Dr. William Coon, Chairman. We also understand that you will be sending us only one or two protocols per year.

We will be glad to help you with this matter. Please submit our copy of the protocols to:

Mr. Arthur Solari  
Radiation Control Service  
1101 North University Building  
University of Michigan  
Ann Arbor, Michigan 48109

Sincerely yours,

  
Ronald C. Bishop, M.D.  
Chairman, RDRC #45

cc: Dr. C. Overberger  
Mr. A. Solari

RCB/sv



## CONVERSATION RECORD

TIME

DATE

8/24/82

TYPE

☐ VISIT☐ CONFERENCE☐ TELEPHONE☐ INCOMING☒ OUTGOING

ROUTING

NAME/SYMBOL INT

Location of Visit/Conference:

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU

TRACY PARSONS

ORGANIZATION (Office, dept., bureau, etc.)

DOW CHEMICAL  
U.S.A. - MIDLAND, MI.

TELEPHONE NO.

SUBJECT

Amendment to NRC LIC. 21-00265-06.

CONTROL # 06582

SUMMARY

In order to complete review, need following:

ok 1. Concurrence from Univ. of MI to use committee.

ok 2. Application states committee will review - need to make clear that Rad. Saf. committee & RORC will approve & RORC will review efficacy, as well as, Rad. Safety concerns.

ok 3. Need general description of procedure will use for human use. (e.g. locations, precautions if allowed to go off-site, handling, etc.).

ok 4. Need criteria committee will use for facilities.

ok 5. Need criteria for approval of license (e.g. physicians, etc.).

ok 6. Need more fees. - need add. \$150 more. Since changing fee category.

ok 7. Need more fees. - need add. \$150 more. Since changing fee category.

ok 8. In order to add John S. Moore as member:

ok 1. Need to know types & quantities of nuclides (license) or clarify. - need will have someone from rad. safety present instead of only a single majority.

TEL. DEFICIENCY

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

Bruce S. Mallory

8/24/82

ACTION TAKEN

SIGNATURE

TITLE

DATE