

MAR 05 1984

file

The University of Illinois
at Chicago
Office of the Dean
Graduate College
ATTN: Karen M. Hiemae, Ph.D., B.D.S.
Interim Dean of the Graduate
College, Associate Vice
Chancellor for Research
and Graduate Education
808 South Wood Street (60612)
Box 6998
Chicago, IL 60680

RE: Your letter dated February 14, 1984, concerning membership of your
Radiation Safety and Radioactive Drug Research Committees for NRC
License (No. 12-00088-06)

Dear Dr. Hiemae:

Since your letter indicates changes in the membership of these committees from that currently in your license file, we have considered your letter as a request to amend your NRC license. In order to complete our review and authorize these changes, we will need additional information on and/or clarification of the following items:

1. It appears that your Radiation Safety Officer (RSO), as an Ex-Officio member, may not have voting privileges on radiation safety issues. If our assumption is correct, please modify your committee membership to include the RSO as a voting member.
2. Please submit documentation indicating that your Radioactive Drug Research Committee (RDRC), as listed, has been approved by the Food and Drug Administration (FDA) for formal review purposes. If your RDRC has not been approved, you will need to provide us with evidence that proposals for the use of radioactive drugs in humans for research purposes will be reviewed by a committee that has been approved as an RDRC.

Please note that you may utilize radioactive drugs for diagnostic, therapeutic, or clinical trials for which a "Notice of Claimed Investigational Exemption of a New Drug" (IND) has been accepted by the FDA without a review and approval by an RDRC.

We will continue our review of your application upon receipt of this information. Please reply in duplicate, within 30 days, and refer to Control Number 76319.

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The University of Illinois
at Chicago

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If you have any questions or require clarification on any of the information stated above, you may contact us at (312) 932-2625.

Sincerely,

Bruce S. Mallett, Ph.D., Chief
Materials Licensing Section

RIII

Mallett/bl
03/02/84

CONVERSATION RECORD

TIME

DATE

2/29/84

TYPE

☐ VISIT☐ CONFERENCE☒ TELEPHONE☐ INCOMING☒ OUTGOING

ROUTING

NAME/SYMBOL

INT

Location of Visit/Conference:

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

Stan Huber, RSO

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

U. of Ill.

TELEPHONE NO.

996-7429

SUBJECT

Amendment Request to update & chg. Rad
Safety Committee. Control No. 76319. Lic. No. 12-
00088-06.

SUMMARY

B. Mallett called and stated there are 3 questions that need
to be answered prior to issuance of the amendment:

1. ~~Are~~ Are Drs. Bennett and Vany experienced with
types & quantities of radioactive materials in use. Stan Huber
stated yes; they have been on committee in the past.
2. Is RORC approved by the FDA?
3. Is RSD a voting member; he must be.

ACTION REQUIRED

B. Mallett agreed to write a letter addressing these
issues.

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

Bruce J. Mallett

DATE

2/29/84

ACTION TAKEN

SIGNATURE

TITLE

DATE