



THE
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OF
ILLINOIS
AT
CHICAGO

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March 23, 1984

Bruce S. Mallett, Ph.D., Chief
Materials Licensing Section
U.S. Nuclear Regulatory Commission
Region III 799 Roosevelt Road
Glen Ellyn, IL 60137

re: Your letter dated March 5, 1984 concerning membership of Radiation Safety
and Radioactive Drug Research Committees for NRC License 12-00088-06.

REF: Control No. 76319

Dear Dr. Mallett:

We are submitting the information and/or clarification of items requested in your
above referenced letter, as follows:

1. The Radiation Safety Officer (RSO) should not have been listed as Ex-Officio on our Radiation Safety Committee membership list. The fact that our current RSO is temporary and is Acting Director of the Radiation Safety Office should not imply any reduced responsibility or authority. The RSO is a voting member of the Radiation Safety Committee.
2. We submitted our Radioactive Drug Research Committee (RDRC) membership list to the FDA on January 31, 1984. The FDA has not yet responded. We confirm that proposals for use of radioactive drugs in humans will be reviewed by a committee that has been approved as an RDRC. This means either the current proposed RDRC, once this FDA approval is obtained, or the previously approved RDRC in the interim.

We understand the IND applications accepted by the FDA do not require review and approval by an RDRC.

At this time we request two additional amendments to the 12-00088-06 license:

- A. Specify at least annual rather than semi-annual calibrations of survey meters. We perform quarterly operational checks on all survey meters and this would indicate any meters that would need repair and/or recalibration on interim schedules.

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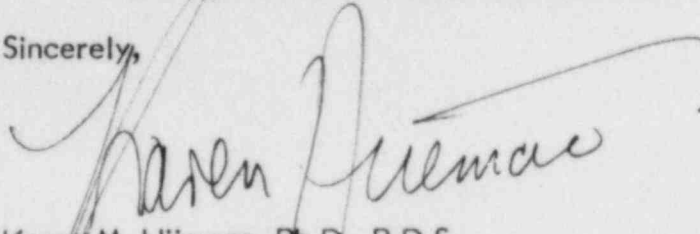
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- B. Our current license appears to specify the months of January, April and October for formal Radiation Safety "group" lectures to radioactive material users. We need to change such date restrictions to read "at least twice per year and as needed, as determined by the Radiation Safety Office". We believe this request is especially justifiable by the fact that our Radiation Safety Office interviews each license applicant (new user or those requesting changes) for each radionuclide proposal for usage. This in itself represents individual user radiation safety training.

Sincerely,

A handwritten signature in cursive script, reading "Karen Hiiemae". The signature is written in dark ink and is positioned above the typed name and title.

Karen M. Hiiemae, Ph.D., B.D.S.
Interim Dean of the Graduate College
Associate Vice Chancellor for Research
and Graduate Education

KMH:vnd