AUG 1 1 1988

Mr. Raymond C. Barrall
Director, Radiation Protection
The University of Illinois at Chicago
339 Clinical Sciences - North Wing
Box 6998
Chicago, IL 60680

Dear Mr. Barrall:

This is in response to your letter of May 23, 1988, to Donna-Beth Howe, Ph.D., asking if the NRC regulations permit or prohibit a licensee with a Type A specific license of broad scope from preparing and using their own radiopharmaceutical kits. Specifically, you asked whether an NRC licensee could fabricate and use kits that have neither an accepted "Notice of Claimed Investigational Exemption for a New Drug" (IND) nor an approved "New Drug Application" (NDA), but are based on the composition formulation found in US Food and Drug Administration (FDA) approved kits.

The NRC does not evaluate the safety and efficacy of drugs or approve drugs for human use. The FDA makes this determination. We refer all such matters to the FDA for clarification. We understand that you have written FDA to determine whether the situation you described complies with their regulatory requirements and "meets with FDA approval."

The NRC authorizes its licensees to prepare and use only reagent kits that are the subject of an accepted IND or an approved NDA. These kits are authorized for use under 10 CFR Part 35 regulations and need no further licensing action. The only non-IND and non-NDA reagent kits and radiopharmaceuticals NRC licensees may use are those used in studies that meet all the 21 CFR Part 361.1 FDA requirements and that are approved by the Radioactive Drug Research Committee. These are authorized in NRC License Item 9, "Authorized Use." Specifically, the authorization to "conduct medical research" is used to express this authorization in the broad-scope medical license.

Your non-IND and non-NDA reagent kits do not appear to be approved under 21 CFR 361.1. If you were an NRC licensee, you would not be permitted to use these reagent kits.

In the past, the NRC has been asked whether the Radiation Safety Committee of a NRC medical use licensee with a Type A specific license of broad scope can approve the medical use of the non-IND and non-NDA reagent kits and radiopharmaceuticals. We believe the answer to this question is pertinent to your request. The functions of the Committee are outlined in 10 CFR Parts 33 and 35. The Committee's primary responsibility is to oversee the organization's radiation safety program. Nothing in these regulations provides the Committee the authority to approve diagnostic imaging with non-IND or non-NDA reagent kits and radiopharmaceuticals.

I hope this information clarifies the NRC policy on this matter. If you have any questions feel free to contact Donna-Beth Howe, Ph.D., of my staff at (301) 492-0636.

Original Signed By
Norman L. McElroy

Norman L. McElroy, Section Leader
Medical and Academic Section
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety

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JUN 2 3 1988

MEMORANDUM FOR: Donald A. Nussbaumer, Assistant Director
for State Agreements Program
State, Local and Indian Tribe Programs, GPA

FROM: Richard E. Cunningham, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: APPROVAL OF NON-IND/NDA RADIOPHARMACEUTICALS

This is in response to your memorandum of April 19, 1988, concerning authorization to approve diagnostic imaging and therapy studies involving the use of radioactive drugs not covered by an accepted "Notice of Claimed Investigational Exemption for a New Drug" (IND) or an approved "New Drug Application" (NDA).

Radioactive Drug Research Committees (RDRC) serve a function under Food and Drug Administration (FDA) regulations. Radiation Safety Committees serve a function under Nuclear Regulatory Commission (NRC) regulations. ("Human Subjects Review Committees" are not covered in NRC regulatory requirements). It has been our understanding in the past that RDRC's can approve basic research studies only, and cannot approve diagnostic or therapy studies (see the FDA enclosed letter published in 1985). Your questions pertaining to the authority of the Human Subjects Review Committee and the Radioactive Drug Research Committee to approve diagnostic imaging and therapy studies for non-IND and non-NDA radioactive drugs is being referred to the FDA for clarification of their drug regulations.

The NRC only authorizes its licensees to use radioactive drugs in accordance with FDA requirements as a matter of administrative policy and as reflected in NRC regulations. Those drugs with an accepted IND or approved NDA are authorized for use under 10 CFR Part 35 regulations and need no further licensing action. Those non-IND and non-NDA drugs used in studies that meet all the 21 CFR Part 361.1 FDA requirements are approved by the RDRC and authorized by NRC License Item 9, "Authorized Use." Specifically, the authorization to "conduct medical research" is used to express this authorization in the broad-scope medical license, and a specific line item is used for other medical licenses.

The functions of the Radiation Safety Committee of a NRC medical use licensee with a Type A specific license of broad scope are outlined in 10 CFR Parts 33 and 35. The Committee's primary responsibility is to oversee the organization's radiation safety program. Nothing in these regulations provides the Committee the authority to approve diagnostic imaging or therapy studies involving the use of non-IND or non-NDA radioactive drugs.

JUN 2 3 1988

Donald A. Nussbaumer - 2 -

We will forward the FDA's response to you as soon as we receive it. If you have any questions feel free to contact Donna-Beth Howe, Ph.D., of my staff at (301) 492-0636.

Original Signed by
Richard E. Cunningham

Richard E. Cunningham, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

Enclosure:
As stated

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