



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

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Ref: SA/LA3

Gerard C. Wong, Ph.D., Chief
Radiation Management Section
Radiologic Health Branch
State Department of Health Service
714 P Street, Office Building, #8
Sacramento, California 95814

JUL 11 1988
SACRAMENTO

Dear Dr. Wong:

This is in response to your April 15, 1988 letter regarding the extent of authority placed by the Food and Drug Administration (FDA) to the local Radioactive Drug Research Committees (RDRC).

I am enclosing our memo to the NMSS group and their reply. Basically, the RDRC can approve projects utilizing microcurie quantities of radioactive material for research studies only. Diagnostic and therapeutic studies utilizing non-IND or NDA radioactive material may only be approved by the FDA.

If you have any further questions please let us know.

Sincerely,

Donald A. Nussbaumer

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

Enclosure:
As stated