

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

MOV 15 1979

Ref: SA/ECA

Mr. Joe Ward, Chief Radiologic Health Section Department of Health 714 P Street, Room 498 Sacramento, California 95814

Dear Mr. Ward:

Identified below are licensees in California who were confirmed to have received Xe-133 shipments from Oak Ridge National Laboratory (ORNL) during fiscal year 1978. ORNL is, among others, a non-FDA-approved Xe-133 supplier; i.e., it does not hold an FDA-issued IND or NDA for supplying Xe-133. These State licensees were mentioned by Nuclear Pharmacy, Inc's. (NPI) response to an NRC Notice of Violation.

Palmdale General Hospital Palmdale, California

Pleasant Valley Hospital Camarillo, California

St. John's Hospital Oxnard, California

St. Vincent Medical Center Los Angeles, California

It was noted during NRC's investigation of the NPI violation case, that apparently some ambiguity exists in the NPI License Condition No. 15 (Standard License Condition No. 55) which reads as follows:

Radioactive gases as free gas or in solution, to be administered to humans, shall be procured from a supplier who distributes the product indicated for human use in accordance with the Food, Drug and Cosmetic Act.

Further clarification or even replacement of this License Condition for involved licensees is expected soon.

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This is a request for you to review the identified licenses to determine if the above License Condition in the same wording, or similar wording, is used, and notify us of the results of your findings.

Based on your review of the licenses you may want to initiate enforcement action against the licensees.

Sincerely,

G. Wayne Kerr, Assistant Director for State Agreements Program Office of State Programs

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