

NUCLEAR REGULATORY COMMISSION WASHINGTON, D. C. 20555

NOV 15 1979

Ref: SA/ECA

Marshall Parrott, D.Sc.
Manager
Radiation Control Service
Division of Health
Department of Human Resources
1400 South West Fifth Avenue
Portland, Oregon 97201

Dear Dr. Parrott:

Identified below is a licensee in Oregon who was 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. This State licensee was mentioned by Nuclear Pharmacy, Inc's. (NPI) response to an NRC Notice of Violation.

University of Oregon, Oregon Medical School Portland, Oregon

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.

This is a request for you to review the identified license 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 license you may want to initiate enforcement action against the licensee.

Sincerely.

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

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