



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

NOV 15 1979

Ref: SA/ECA

Mr. Dayne H. Brown, Chief  
Radiation Protection Section  
Division of Facility Service  
Box 12200  
Raleigh, North Carolina 27605

Dear Mr. Brown:

Identified below is a licensee in North Carolina 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.

Duke University  
Durham, North Carolina

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,

A handwritten signature in cursive script, appearing to read "G. Wayne Kerr".

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

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