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

OFFICE OF THE
CHAIRMAN

COMM.
CORR.

June 6, 1979

The Honorable Henry Bellmon
United States Senate
Washington, D.C. 20510

Dear Senator Bellmon:

This letter responds to your April 12, 1979 inquiry, which included a letter from your constituent, Rodney D. Ice, Ph.D, regarding the impact of the Nuclear Regulatory Commission's (NRC) regulations on the practice of pharmacy. We appreciate this opportunity to explain NRC's role in the regulation of nuclear pharmacies.

NRC has legislative authority to license and regulate all aspects of the possession and use of byproduct (i.e., reactor-produced) materials, including radiopharmaceuticals, in order to protect health and minimize danger to life or property. The Food and Drug Administration (FDA) has legislative authority to regulate the manufacture, sale and distribution of drugs, including radiopharmaceuticals, in order to provide reasonable assurance of safety and effectiveness. In the case of radioactive drugs, both FDA and NRC have regulatory responsibilities.

In 1975 FDA terminated an existing exemption for those radiopharmaceuticals previously regulated by the Atomic Energy Commission (AEC). At that time, AEC withdrew from regulation of the safety and effectiveness of radiopharmaceuticals with respect to the patient in order to prevent dual regulation. Since then, NRC medical licensees have been authorized to receive only FDA-approved radiopharmaceuticals. In the context of this letter, the phrase "FDA-approved" refers to FDA's approval of a "New Drug Application" (NDA) or FDA's acceptance of a "Notice of Claimed Investigational Exemption for a New Drug" (IND).

NRC has issued licenses to nuclear pharmacies authorizing them to provide FDA-approved radioactive drugs to NRC and Agreement State medical licensees. Basically, NRC's regulations have very little effect on State control of the practice of pharmacy. NRC will not license a nuclear pharmacy unless it has already been licensed by the State for the practice of pharmacy. It should be noted that the primary consideration of the State is whether pharmacy personnel have adequate training and experience to compound drugs. The state generally does not consider the same issues as does NRC (i.e., radiation safety).

NRC will license a nuclear pharmacy to prepare and distribute only those radiopharmaceuticals that have been approved or accepted by FDA. In most instances, the nuclear pharmacy purchases FDA-approved radiopharmaceuticals or FDA-approved radionuclide generators and reagent kits, and then prepares individual patient doses that are ready for injection or oral administration. Less frequently, the nuclear pharmacy may obtain FDA-approval for its own preparations or it may prepare radiopharmaceuticals for individual physicians who have obtained FDA-approval for their own products.

FDA will approve a radiopharmaceutical for routine use (i.e., approve an NDA) if the sponsor meets quality control standards and the sponsor has demonstrated substantial evidence of safety and effectiveness of a radiopharmaceutical. When the safety and effectiveness of a radiopharmaceutical have not been established, FDA will accept the radioactive drug for investigational use (i.e., accept an IND) if the sponsor has established certain criteria for safeguarding patients.

FDA approval of products distributed by nuclear pharmacies has always been a condition of the pharmacy's NRC license. NRC has recently published a statement of general policy on the medical use of isotopes (copy enclosed) which is consistent with this regulatory approach to nuclear pharmacies. The second part of the statement reads:

> The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

In summary, we do not believe that NRC's regulation of the nuclear portion of a State-approved pharmacy is too restrictive. Nuclear pharmacies may distribute FDA-approved radioactive drugs. We do not believe that it would be in the best interest of public health and safety to authorize nuclear pharmacies to distribute radioactive drugs that have not been approved or accepted by FDA because FDA is the Federal agency responsible for drug safety and effectiveness.

I trust that I have answered your inquiry. If you have further questions please contact me again or call Mr. Vandy L. Miller, Chief of the License Management Branch, Office of Nuclear Material Safety and Safeguards, at (301) 427-4232.

Sincerely,

Joseph M. Hendrie
Chairman

Enclosure: 44 FR 8242