

NOVEMBER 18, 1989

DOCKET NUMBER  
PETITION RULE PRM-35-9  
(54FR 38239)

284

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DOCKETING  
BRANCH

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SECRETARY OF THE COMMISSION  
US NUCLEAR REGULATORY COMMISSION  
WASHINGTON, DC 20555

OFFICE OF  
DOCKETING & SERVICE  
BRANCH

ATTN: DOCKETING AND SERVICE BRANCH

RE: DOCKET #: PRM-35-9

LADIES AND GENTLEMEN:

I AM WRITING THIS LETTER IN SUPPORT OF THE AMERICAN COLLEGE OF NUCLEAR PHYSICIANS AND THE SOCIETY OF NUCLEAR MEDICINE! PETITION FOR RULE MAKING.

NUCLEAR PHARMACISTS PREPARE, COMPOUND AND DISPENSE RADIOPHARMACEUTICALS IN ACCORDANCE WITH A LICENSED NUCLEAR PHYSICIANS ORDERS. THE NUCLEAR PHYSICIAN DETERMINES WHAT RADIOPHARMACEUTICAL IS NECESSARY ON AN INDIVIDUAL CASE BASIS AND THEN THE NUCLEAR PHARMACIST HAS THE EXPERTISE AND TRAINING TO PREPARE EXACTLY WHAT THE PHYSICIAN HAS ORDERED. THIS RELATIONSHIP IS CLEARLY DEFINED AND REGULATED AT THE STATE LEVEL BY THEIR RESPECTIVE LICENSING BOARDS. NRC REGULATION OF THIS RELATIONSHIP CLEARLY HAMPERS THE PHYSICIANS AND PHARMACISTS ABILITY TO DELIVER QUALITY CARE.

AT ISSUE IS THE NRC RECENT REINTERPERATION OF LICENSE CONDITION FOR NUCLEAR PHARMACIES STATING THAT A NUCLEAR PHARMACIST MUST BE STRICTLY ADHERE TO PACKAGE INSERTS. WHILE THE MANUFACTURES PACKAGE INSERT SHOULD SERVE AS A GUIDELINE FOR THE PREPARATION OF ANY PRODUCT, THE NUCLEAR PHARMACIST MUST HAVE THE ABILITY TO USE HIS EXPERTISE AND PROFESSIONAL JUDGEMENT IN COMPOUNDING A PRODUCT TO ASSURE THE PHYSICIAN RECEIVES THE MOST EFFICACIOUS PRODUCT FOR THEIR PATIENT.

PHYSICIANS MUST ALSO BE ABLE TO USE THEIR EXPERTISE TO PRESCRIBE PRODUCTS WHICH ARE MOST APPROPRIATE FOR AN INDIVIDUAL PATIENT. STRICT ADHERENCE TO THE PACKAGE INSERT DOES NOT ALLOW FOR A PHYSICIAN TO USE HIS JUDGEMENT ON AN INDIVIDUAL BASIS. THIS MAY RESULT IN A DELAY OR FAILURE TO PROPERLY DIAGNOSIS A DISEASE IN A PATIENT.

THIS PETITION FOR RULE MAKING IS NECESSARY TO CLARIFY THAT THE USE OF RADIOPHARMACEUTICALS IS WITHIN THE SCOPE OF A PHYSICIANS PROFESSIONAL JUDGEMENT AND WILL ALLOW FOR THE PREPARATION BASED ON AN INDIVIDUAL ORDER FOR AN INDIVIDUAL CASE.

I STRONGLY URGE YOU TO CONSIDER THIS PETITION FOR RULE MAKING.

SINCERELY,

*Joseph A. Fery*

JOSEPH A. FERY, R.PH.  
NUCLEAR PHARMACIST

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