

DOCKETED

DOCKET NUMBER
PETITION RULE PRM 35-9
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OFFICE OF THE SECRETARY
DOCKETING & SERVICE
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SECRETARY OF THE COMMISSION
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555

ATTENTION: DOCKETING AND SERVICE BRANCH, RE: DOCKET NO. PRM-35-9

LADIES AND GENTLEMEN:

I HAVE BEEN A LICENSED PHARMACIST FOR 8 YEARS AND
I AM WRITING THIS LETTER IN SUPPORT OF THE AMERICAN COLLEGE OF
NUCLEAR MEDICINE SOCIETY OF NUCLEAR MEDICINE; PETITION
FOR RULEMAKING IS NECESSARY TO
ALLOW PHARMACISTS TO PRACTICE PHARMACY

PHARMACISTS COMPOUND AND DISPENSE
OFFICIAL PRESCRIPTIONS OF A LICENSED NUCLEAR
PHARMACIST WITH NUCLEAR PHARMACEUTICALS AND PHYSICIANS ARE TRAINED
PROFESSIONALS. A NUCLEAR PHARMACIST HAS THE EXPERTISE TO
COMPOUND THE RADIOPHARMACEUTICALS THE PHYSICIAN ORDERS. THE
PRACTICE OF MEDICINE AND PHARMACY IS CLEARLY GOVERNED BY THE
STATES REGARDLESS OF SPECIALTY. NRC REGULATION OF THE PRACTICE OF
THESE PROFESSIONALS MUST BE AVOIDED SINCE IT WILL HAMPER THE
PHYSICIANS AND PHARMACISTS ABILITY TO DELIVER QUALITY PATIENT
CARE.

OF PARTICULAR INTEREST IS THE NRC'S REINTERPRETATION OF
LICENSE CONDITIONS FOR NUCLEAR PHARMACIES AND REGULATIONS FOR
NUCLEAR MEDICINE LICENSEES. AT ISSUE IS A REQUIREMENT TO STRICTLY
FOLLOW THE MANUFACTURER'S INSTRUCTIONS FOR PREPARATION OF RADIO-
PHARMACEUTICALS AS PRINTED IN THE MANUFACTURER'S PACKAGE INSERT.
THE PACKAGE INSERT INFORMATION SHOULD BE CONSIDERED AS A GUIDELINE
IN THE PREPARATION AND USE OF ANY PRODUCT, BUT PHARMACISTS MUST
HAVE THE ABILITY TO USE PROFESSIONAL JUDGEMENT IN COMPOUNDING TO
ASSURE THE PRESCRIBING PHYSICIAN RECEIVES THE MOST EFFICACIOUS
PRODUCT FOR HIS/HER PATIENT. IN FACT, ADDITIVES CAN OFTEN BE
COMBINED WITH RADIOPHARMACEUTICAL PREPARATIONS TO ENHANCE THEIR
QUALITY OR STABILITY EVEN THOUGH THESE ADDITIVES ARE NOT IN THE
PACKAGE INSERT PREPARATION INSTRUCTIONS. THIS HAS BEEN A COMMON
PRACTICE OF PHARMACISTS FOR HUNDREDS OF YEARS.

PHYSICIANS MUST ALSO PRESCRIBE PRODUCTS WHICH ARE MOST APPROPRIATE
FOR THEIR INDIVIDUAL PATIENTS. A STRICT FOLLOWING OF THE PACKAGE
INSERT WOULD DELAY OR PREVENT DIAGNOSIS OF DISEASE IN SOME
PATIENTS. THE QUALITY OF CARE FOR THESE PATIENTS COULD BE
GREATLY INCREASED IF THESE PRACTICES WERE SUPPLEMENTED WITH
NUCLEAR MEDICINE STUDIES.

THIS PETITION FOR RULEMAKING IS NECESSARY TO CLARIFY THAT
PHYSICIANS AND PHARMACISTS HAVE THE FLEXIBILITY TO USE RADIO-

PHARMACEUTICAL PRODUCTS AS NECESSARY AND APPROPRIATE IN THE
DIAGNOSIS AND TREATMENT OF PATIENTS. DEATH, INJURY, OR
INAPPROPRIATE TREATMENT OF PATIENTS MAY RESULT FROM ANY MANDATED,
VERBATIM FOLLOWING OF THE PACKAGE INSERT INSTRUCTIONS.

I URGE YOU TO STRONGLY CONSIDER THE ACNP/SNM'S PETITION FOR
RULEMAKING. ITS ADOPTION WOULD CLARIFY THE ABILITY OF NUCLEAR
MEDICINE PHYSICIANS AND NUCLEAR PHARMACISTS TO GIVE THE BEST
PATIENT CARE.

SINCERELY,

Stephen L. Repit

NUCLEAR PHARMACIST