American Society of Hospital Pharmacists
4630 Montgomery Avenue
Bethesda, MD 20814

(301) 657-3000

(412)

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

'89 DEC 14 P2:03

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

December 12, 1989

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
Attention: Docketing and Service Branch

Re: Docket No. PRM 35-9

Dear Secretary:

The American Society of Hospital Pharmacists (ASHP) strongly supports the Petition for Rulemaking for the Nuclear Regulatory Commission (Docket No. PRM-35-9) as stated in the Federal Register on September 15, 1989.

ASHP is the national pharmacy organization representing over 23,000 members who practice in hospitals and other organized health-care settings. ASHP is dedicated to advancing rational drug therapy in organized health-care settings.

Nuclear Pharmacy has been a recognized specialty in pharmacy practice for the last 8 years. Many specialists in nuclear pharmacy practice in hospital or institutional settings. The proposed changes in the NRC regulations would greatly enhance the professional practice of many of these pharmacists.

Enclosed are copies of letters of support from some of our members who practice in nuclear pharmacy.

We urge your consideration of the revision of NRC regulations as stated in Docket No. PRM-35-9. If we can provide further information, please do not hesitate to contact us.

Sincerely,

Marie A. Smith

Marie A. Smith, Pharm.D.
Director, Clinical Affairs Department

MAS/mrs121200w
Enclosures

8912220025 891212
PDR PRM
35-9 PDR

DS10

The University of New Mexico

College of Pharmacy
Radiopharmacy
Albuquerque, NM 87131
Telephone 505: 277-6104

DATE: November 7, 1989

TO: Marie Smith, SPG Coordinator
American Society of Hospital Pharmacist

FROM: Selected University of New Mexico College of Pharmacy ASHP members: David G. Baughman, Resident-Graduate Student, Gary French, Resident-Graduate Student, William B. Hladik III, Associate Professor, Robert K. Leedham, Graduate Student, and Nancy Wolf, Resident-Graduate Student

SUBJECT: COMMENTS ON NRC PETITION FOR RULEMAKING

We have enclosed a page from the Journal of Nuclear Medicine which helps to explain the genesis of the proposed rules.

In addition, we have carefully reviewed the proposed rulemaking for Nuclear Regulatory Commission, 10CFR parts 30, 33, and 35, and are strongly in favor of the proposed changes. We feel a few comments should be strongly considered when the society makes their response.

Comment I: We believe the statement "nuclear pharmacists have been disenfranchised as a professional entity..." is very much accurate as stated in the proposed rulemaking. This disenfranchisement has particularly affected institutionally-based nuclear pharmacists because it has limited the opportunities for research and development of radiopharmaceutical agents and has made nuclear pharmacy less attractive as a career path for future pharmacists because of the limitations placed on us by the NRC.

Comment II: We also feel the statement "Nuclear medicine technologists reconstitute radiopharmaceuticals..." should be carefully explained. For technologists, the term "reconstitute" means that preparation of

Comment II (cont'd)

the product is in accordance with the package insert rather than compounding and dispensing as in the rulemaking.

Comment III: As you can infer from the enclosed letter to Dick Penna, NRC is trying to verify the qualifications of pharmacists with regard to their ability to alter existing radiopharmaceutical formulations or compound radiopharmaceuticals from raw materials. We believe that ASHP should represent pharmacists on this issue and explain to the NRC that pharmacists truly are qualified to perform these specific functions in addition to their many clinical responsibilities. As you know, at all pharmacy schools, students are required to successfully complete a series of pharmaceutics-related courses which involve topics such as pharmaceutical chemistry, pharmaceutical compounding, biopharmaceutics, pharmacokinetics, dosage forms, product formulation, sterile product preparation and aseptic technique, product stability, and other physicochemical properties of drugs. Moreover, those schools which offer a comprehensive training program in nuclear pharmacy also have a variety of courses that would further enhance the compounding expertise of these professionals. Such courses may include radiopharmaceutics, radiopharmaceutical chemistry, radiobiology, radiopharmacology, radiation protection, and internal dosimetry calculations, among others. Nuclear pharmacy training also involves biodistribution techniques, quality assurance measures, and research methodologies. Opportunities are also available for the student to apply the concepts learned in the above-stated courses before entering into professional practice, i.e., residencies, externships, etc.

Thank you for the opportunity to comment on this important issue.

Enclosures

August 1989

The University of Iowa
Iowa City, Iowa 52242

previously assigned comment #29

COPY

The University of Iowa Hospitals and Clinics
Department of Radiology

319/356-2188
If no answer, 356-1616

1847

October 17, 1989

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
Attention: Docketing and Service Branch

RE: Docket No. PRM-35-9
Petition for Rulemaking, Nuclear Regulatory Commission, 10 CFR Parts 30, 33, 35

Dear Sirs:

I am writing to express my total, unequivocal support for the entire petition for rulemaking referred to above.

I am a practicing nuclear pharmacist working in the nuclear medicine department of a university hospital. I am a registered pharmacist licensed by the State Board of Pharmacy in my state and am board certified in Nuclear Pharmacy by the Board of Pharmaceutical Specialties.

All of my pharmacist colleagues who work in other practice settings are allowed to use their professional judgement and expertise to optimize the delivery and use of drugs for individual patients. Much of pharmacy practice, generally speaking, extends beyond the simple regulatory case of using FDA-approved drugs (i.e., NDA or IND) within the confines of package insert recommendations. For example, community pharmacists routinely compound and dispense skin lotions, emulsions, suppositories, etc., for individual patient use upon the receipt of a valid prescription. Similarly, hospital pharmacists routinely compound and dispense drugs in I.V. solutions, complex parenteral nutrition I.V.'s (e.g., TPN's), and other drug dosages for individual patient use upon the receipt of a valid medical order. Moreover, both community and hospital pharmacists frequently depart from package insert directions for preparation of drugs in order to provide a more desirable concentration, etc., for a particular patient. All of these actions are performed pursuant to the receipt of a valid prescription, are subject to state laws governing the practice of pharmacy, and are the result of the pharmacist's best professional judgement in each specific case.

The fact that NRC has severely restricted my professional practice in nuclear pharmacy is, to say the least, extremely disturbing. The fact that NRC has essentially ignored or denied my professional existence is, frankly, insulting. The fact that I am not allowed to use my professional judgement in compounding and dispensing certain drugs pursuant to the receipt of a valid prescription is, in the eyes of my pharmacist colleagues, appalling.

~~8910250307~~ 2pp

NRC's strict, narrow, and incomplete interpretation of FDA's role in drug approval and use as evidenced in current NRC regulations (viz. 10 CFR Part 35) is a severe impediment to optimal patient care. In my own practice, for example, I typically prepare and dispense NDA radiopharmaceuticals according to package insert instructions; on almost a daily basis, however, I am requested by one of my nuclear physician colleagues to prepare and dispense a "special" dose of radiopharmaceutical for a specific patient. As I stated earlier, I practice in a university hospital so we have an unusually high number of patients with unusual conditions. Thus to optimize the patient's medical care frequently requires a radiopharmaceutical that is specially prepared for that patient. Many of these special requests, however, are not allowed to be realized under current NRC regulations and a less desirable alternative is necessary by default. The inability to optimize individual patient studies using "customized" radiopharmaceuticals may result in the necessity of performing two or more alternate studies to get equivalent (or even inferior) information, more radiation dose to the patient, prolonged hospital stay, and other monetary or non-monetary costs.

The major concern surrounding extemporaneous compounding of drug doses or departing from package insert instructions is that it places a greater burden of liability on the pharmacist. The pharmacist must be willing to accept the professional and legal responsibility to assure that the "special" drug dose is safe and effective. This assurance may involve drug quality testing (e.g., purity, sterility, apyrogenicity), reference to reports in the scientific literature, and personal experience. Compliance with established drug standards (USP/NF) and drug use (USP-DI) monographs, if they exist, is generally recommended.

In summary, the FDA, in conjunction with State Boards of Pharmacy, allows several acceptable mechanisms for drug preparation and use, only two of which are NDA and IND designations. Furthermore, the philosophy of the FDA and State Boards of Pharmacy is that drugs should be safe and efficacious, and that drug use should be optimized for each patient. Thus the NRC should adopt the petition for rulemaking, thus allowing the delivery of optimal patient care; the appropriateness of radiopharmaceutical preparation and dispensing will be ensured by State Board of Pharmacy governance, profession-accepted standards of practice in nuclear pharmacy, competency recognition through certification and re-certification in nuclear pharmacy, and independent professional judgement.

Sincerely,

James A. Ponto, MS, RPh, BCNP
Chief Nuclear Pharmacist
Division of Nuclear Medicine
Department of Radiology
University of Iowa Hospitals & Clinics
Iowa City, IA 52242

JAP/pd

Marie

OCT 30 1989

previously assigned comment #94

Beaumont

William Beaumont Hospital Nuclear Medicine

October 25, 1989

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Docketing and Service Branch, Docket # PRM-35-9
Washington, D.C. 20555

Dear Mr. Secretary:

I write at this time to express my strong support for the Petition for Rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. I practice nuclear pharmacy at William Beaumont Hospital in Royal Oak, Michigan. I am concerned over the revised 10 CFR 35 regulations (effective April, 1987) governing the medical use of byproduct material as they significantly impact our ability to practice high quality nuclear medicine and have in several instances prevented us from providing optimized care to individual patients.

If manufacturers' instructions as presented in the package insert were followed strictly, I would no longer be able to prepare a gastric emptying meal with sulfur colloid meal, would no longer be able to use macroaggregated albumin for the detection of patency of a Levine shunt, and I would no longer be able to prepare white blood cells labeled with HMPAO technetium-99m. In addition, high specific activity MAA is required for the performance of right-to-left cardiac shunt studies, and if the manufacturers' instructions are strictly adhered to, large amounts of technetium-99m could not be placed on the MAA, thus causing some hazard to the patient.

The NRC should recognize that the FDA does allow, and often encourages, other clinical uses of approved drugs and actively discourages the submission of physician-sponsored INDs that describe new indications for approved drugs. The package insert in my opinion was never intended to prohibit physicians from deviating from it in prescribing for other indications, nor pharmacists from preparing and dispensing pursuant to a bona fide prescription, when these other indications are in the patient's best interest. Such deviations are necessary for growth in developing new diagnostic and therapeutic agents. In many cases, manufacturers will not go back to the FDA to revise their package insert to include new indications because it is not required by the FDA, and there is simply no economic incentive to do so. This latter point is extremely important in the radiopharmaceutical field.

continued...

3601 West Thirteen Mile Road Royal Oak, Michigan 48072 (313) 551-4100

~~8911020088~~ 2pp

VHA. Member of Voluntary Hospitals of America, Inc.

Currently, the regulatory provisions in Part 35 (35.100, 35.200, 35.300 and 33.17[a][4]) do not allow practices which are legitimate and legal under FDA regulations and State medicine and pharmacy laws. These regulations, therefore, inappropriately interfere with the practice of pharmacy as I practice it, which directly contradicts the NRC's medical policy statement against such interference.

I would like to point out that highly restrictive NRC regulations will only jeopardize public health and safety by: restricting access to appropriate nuclear medicine procedures; exposing patients to higher radiation absorbed doses from alternate legal, but non-optimal, studies; and exposing hospital personnel to higher radiation absorbed doses because of unwarranted repetition of procedures. The NRC should not strive to construct proscriptive regulations to cover all aspects of medicine, nor should it attempt to regulate radiopharmaceutical use. Instead, the NRC should rely on the expertise of the FDA, State Boards of Pharmacy, State Boards of Medical Quality Assurance, the Joint Commission on Accreditation of Health Care Organizations, radiation safety committees, institutional Q/A review procedures, and most importantly, professional judgement of physicians and pharmacists who have been well-trained to administer and prepare these materials.

Since the NRC's primary regulatory focus appears to be based on the unsubstantiated assumption that misadministrations, particularly those involving diagnostic radiopharmaceuticals, pose a serious threat to the public health and safety, I strongly urge the NRC to pursue a comprehensive study by a reputable scientific panel, such as the National Academy of Sciences or the NCRP, to assess the radiobiological effects of misadministrations from nuclear medicine diagnostic and therapeutic procedures. I firmly believe that the results of such a study will demonstrate that the NRC's effort to impose more and more stringent regulations are unnecessary and not cost-effective in relation to the extremely low health risks of these studies.

I strongly urge the NRC to adopt the ACNP/SNM Petition for Rulemaking as expeditiously as is possible.

Sincerely,

William Porter Pharm.D. BCNP

William Porter, Pharm.D.

HJD:cg
(Oc2389.L1)

cc: Marie Smith