

April 16, 2001

Donald A. Podoloff, M.D., President
American College of Nuclear Physicians
Government Relations Office
1850 Samuel Morse Drive
Reston, VA 20190-5316

SUBJECT: DENIAL OF PETITION FOR RULEMAKING (PRM-35-16) - AMERICAN
COLLEGE OF NUCLEAR PHYSICIANS / SOCIETY OF NUCLEAR MEDICINE

Dear Dr. Podoloff:

I am responding to the petition for rulemaking (PRM), dated January 3, 2001, jointly filed by you, on behalf of the American College of Nuclear Physicians (ACNP) and Jonathan M. Links, PhD, on behalf of the Society of Nuclear Medicine (SNM). The petition has been docketed as PRM-35-16.

The petition requests that the Commission: rescind its approval of the U.S. Nuclear Regulatory Commission (NRC) staff's draft final revision of the regulations at 10 CFR Part 35, "Medical Use of Byproduct Material," which was approved by the Commission in a Staff Requirements Memorandum dated October 23, 2000; revoke all of 10 CFR Part 35, except for specifically identified requirements; and institute a new rulemaking proceeding to adopt a regulatory scheme for the use of byproduct material, in diagnostic nuclear medicine, that reflects the discipline's safety record.

The NRC has considered the petition and the supporting rationale. For the reasons provided in the enclosed Federal Register notice, your petition is denied. In summary, the petition is being denied because the Commission approved the final rule after an extensive rulemaking process that provided an unprecedented level of enhanced public participation; the Commission believes that the ACNP/SNM had many opportunities to present their concerns and suggestions as part of that process; and, the petition does not appear to present any significant new information or recommendations that the Commission has not already considered.

The Federal Register notice denying the petition is being transmitted to the Office of the Federal Register for publication.

Sincerely,

/RA/

Annette Vietti-Cook

Enclosure: Federal Register notice

April 16, 2001

Jonathan M. Links, Ph.D., President
Society of Nuclear Medicine
Government Relations Office
1850 Samuel Morse Drive
Reston, VA 20190-5316

SUBJECT: DENIAL OF PETITION FOR RULEMAKING (PRM-35-16) - AMERICAN
COLLEGE OF NUCLEAR PHYSICIANS / SOCIETY OF NUCLEAR MEDICINE

Dear Dr. Links:

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

[Docket No. PRM-35-16]

American College of Nuclear Physicians and the Society of Nuclear Medicine;

Denial of a petition for rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Denial of a petition for rulemaking.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is denying a petition for rulemaking submitted by the American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM) (PRM-35-16). The petitioners request that the Commission: rescind its approval of the NRC staff's draft final revision of the regulations at 10 CFR Part 35 "Medical Use of Byproduct Material", which was approved by the Commission in a Staff Requirements Memorandum dated October 23, 2000; revoke all of Part 35, except for specifically identified requirements; and institute a new rulemaking proceeding to adopt a regulatory scheme for the use of byproduct material in diagnostic nuclear medicine that reflects the discipline's safety record. The NRC is denying the petition because: the Commission approved the final rule after an extensive rulemaking process that provided an unprecedented level of enhanced stakeholder and public participation; the Commission believes that the ACNP/SNM had many opportunities to present their concerns and suggestions as part of that process; and the petition

does not appear to present any significant new information or recommendations that the Commission has not already considered.

ADDRESSES: Copies of the petition for rulemaking and the NRC's letters to the petitioners are available for public inspection or copying in the NRC Public Document Room, 11555 Rockville Pike, Room 01-F21, Rockville, Maryland.

FOR FURTHER INFORMATION CONTACT: Catherine Haney, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6825, e-mail: cxh@nrc.gov.

The Petition

On January 11, 2001, the NRC docketed a January 3, 2001, letter from Donald A. Podoloff, MD, of the American College of Nuclear Physicians, and Jonathan M. Links, PhD, of the Society of Nuclear Medicine, to the Office of the Secretary, as a petition for rulemaking under 10 CFR 2.802 (PRM-35-16). The petitioners request that the Commission: rescind its approval of the NRC staff's proposed revision to 10 CFR Part 35, "Medical Use of Byproduct Material," which was approved by the Commission in a Staff Requirements Memorandum dated October 23, 2000; revoke all of 10 CFR Part 35, except for specifically identified requirements; and institute a new rulemaking proceeding to adopt a regulatory scheme for the use of byproduct material in diagnostic nuclear medicine that reflects the discipline's "unparalleled and undisputed safety record."

The petitioners provide a history of the Commission's statutory authority and nuclear medicine regulation from their perspective. The petitioners state that the NRC regulates the medical use of reactor-generated radioactive materials to protect the public health under Section 81 of the Atomic Energy Act (AEA) (42 U.S.C. 2111) and that its responsibilities include the regulation of radiopharmaceuticals and sealed sources. The NRC does not regulate machine-produced x-rays nor naturally occurring or accelerator-produced radioisotopes (such as those used in positron emission tomography). The petitioners also described the relationship between NRC and State regulatory authority and the impacts of NRC's program on State regulatory programs.

The petitioners characterize the use of radioactive material as a highly regulated activity. All uses and possession of radioactive material are prohibited, except those uses and possessions that are authorized by an individual license. The petitioners believe that as medical uses of radioactive materials expanded with the development of new technologies, the licensure process quickly became complex, often involving lengthy documents with little consistency from one license to another license. The petitioners state that in the late 1970's, the NRC placed all common license conditions into regulations. The petitioners believe that this regulatory action was the NRC's attempt to simplify the licensing process and to allow greater consistency in uses and possession of radioactive materials.

The petitioners believe that the NRC's regulations applicable to diagnostic nuclear medicine eclipse the regulatory controls imposed on other dramatically more dangerous medical products and procedures by a wide margin. The petitioners state that the goal of this petition is to end that unsupportable and extraordinarily expensive program. The petitioners

also state that their proposed regulatory scheme would assure the continued extremely safe use of diagnostic nuclear medicine products and procedures while saving the nation millions of dollars a year.

The Requested Actions

The petitioners request that the NRC amend its regulations to match the regulatory scheme to the minimal risks presented. Specifically, they request that NRC regulate the use of byproduct material in diagnostic nuclear medicine solely by:

1. Protecting workers, the general public, and the environment through the radiation protection standards of 10 CFR Part 20;
2. Ensuring the protection for patients, workers, the public, and the environment by enforcing comprehensive education, and training and experience requirements for the use and possession of byproduct materials;
3. Relying on health care professionals with the required education, training, and experience in nuclear medicine, nuclear pharmacy, and basic nuclear and radiation science to protect the health and safety of their patients under the supervision of their respective State Medicine and Pharmacy Boards;
4. Revoking all of Part 35, except for requirements concerning comprehensive education, training, and experience of authorized users, coupled with a new provision that would require evidence of mastery of basic nuclear and radiation sciences by passage of an examination given in this field by a board certified by the American Board of Medical Specialties

or a single alternate examination equivalent in scope and depth to that covered in the certified boards and approved by the Advisory Committee on the Medical Uses of Isotopes (ACMUI);

5. Ceasing the subdivision of diagnostic nuclear medicine into smaller and smaller fragments. After completing comprehensive education, training, and experience in basic nuclear and radiation sciences, and passing an appropriate comprehensive examination in these areas, as defined in (4) above, an authorized user may subspecialize in any portion of diagnostic nuclear medicine he/she wishes without further Commission restriction;

6. Removing all license conditions except for simple identification. This includes the name, address, e-mail address, telephone, and fax numbers of the institution, the responsible administrator, and the Radiation Safety Officer (RSO). The license should simply state, "This license permits the possession, use, transport, and disposal of any byproduct material, in any physical or chemical form, in any quantity, for diagnostic nuclear medicine use including clinical use, research, quality control, teaching, and related diagnostic nuclear medicine professional activities." In the case of presently limited licenses, such as in nuclear cardiology, "diagnostic nuclear cardiology" should replace "diagnostic nuclear medicine." The license should also state that, "This license does not cover diagnostic uses of radiopharmaceuticals containing more than 30 microcuries of I-131."

7. Inspecting diagnostic medical licensees only in those rare situations of likely over exposures of workers, the general public, or the environment. The routine inspections now being conducted are an invitation to document meaningless paperwork "deviations" and which impose substantial unnecessary costs on licensees. As far as patients are concerned, cases of

possible malpractice will be handled under existing State law by the Boards of Medicine and/or Pharmacy and the courts, without NRC involvement unless specifically requested by the Board or the court.

8. Decreasing the size of the staff assigned to the medical use program to adequately reflect the limited role the Commission plays in assuring diagnostic nuclear medicine safety. This staff adjustment has been long overdue. As the number of NRC medical licensees decreases because of the increase in Agreement States, the number of employees assigned to the medical program paradoxically increases. Because Congress requires that the NRC recover its costs from licensees, fewer and fewer licensees are supporting an increasingly bloated NRC program. A properly sized staff alone would dramatically reduce the escalating cost of holding an NRC license.

Supporting Information

The petitioners state that they are not asking for a “deregulation” of diagnostic nuclear medicine in the usual meaning of the word, which implies a decrease in safety standards; they are requesting that NRC remove prescriptive regulations and license conditions. The petitioners believe that qualified professional authorized users have significantly more training and real-life experience than regulators in providing the highest level of protection and safety for their patients and others.

The petitioners believe that the Commission has never adopted a regulatory scheme that matches its requirements to the acknowledged minimal risks posed by diagnostic nuclear medicine. The petitioners characterize the revisions to 10 CFR Part 35 approved by the Commission on October 23, 2000, as offering little meaningful change from the existing

regulations. The petitioners believe that, combined with NRC's increased use of "license conditions" to impose requirements that do not appear in its regulations, the new supposedly "risk-informed" regulations mark a step backward, not forward and that these new regulations bear no relationship to the risk sought to be protected against, and which will, by its substantial unnecessary costs, adversely impact health care.

The petitioners state that in the 64-year history of nuclear medicine in the United States, about one-third of a billion radiopharmaceutical doses have been administered. There was one case, in the 1950's, of a radiation death due to a diagnostic radiopharmaceutical. This event occurred before there was board certification in nuclear medicine, nuclear pharmacy, and nuclear medicine technology. The petitioner states that this mistake was due to human error and would not have been avoided with NRC's current regulations and license conditions.

The petitioners believe that the entire predicate of the NRC's regulation of diagnostic nuclear medicine appears to be that radiation from byproduct materials poses significant risks to patients, workers and the public and that this predicate is demonstrably untrue. The petitioners believe that diagnostic nuclear medicine is extremely safe, and its use by properly trained health care professionals poses no undue risks. The petitioners cite the conclusion of the Institute of Medicine of the National Academy of Science that the regulatory structure imposed on diagnostic nuclear medicine by the NRC is a costly and unnecessary burden that yields no benefit to patients, workers, or the public.

Although this petition deals solely with diagnostic nuclear medicine, the petitioners believe that essentially the same arguments can be made to reduce the burden on the practice of therapeutic nuclear medicine.

The petitioners state that the NRC should become involved in regulating patient safety only when justified by the risk and where voluntary standards are inadequate. The petitioners believe that the NRC has steadily increased its regulations of nuclear medicine despite minimal changes in the materials used, their applications in medicine, and the absence of any evidence of significant problems.

Petitioners' Cost Estimate

On October 21, 1998, the petitioners presented a preliminary cost estimate of the impact of the proposed revisions of Part 35 to the NRC at a public meeting. The analysis, entitled "Preliminary Estimate of the Cost of the Proposed Part 35 for a Typical Hospital Nuclear Medicine Service; Spread Sheet Analysis," was prepared by Mark Rotman, a former Visiting Medical Fellow at the NRC. The petitioners state that the analysis did not include the cost of most of 10 CFR Parts 19 and 20, NUREG-1559 Volume 9 (the new guidance for medical use licensing, including nuclear medicine); typical license conditions; radioactive waste disposal; user fees; or any costs to any Agreement State nuclear medicine licensees. The petitioners state that the total cost of the NRC's regulatory scheme alone came to just over \$100,000,000/year and assuming Agreement States will be forced by NRC to have similar programs, which is happening now, the cost, including Agreement State licenses, is \$500,000,000. The petitioners believe that the total costs could easily reach \$1 billion per year, even with uncertainties. The petitioners request that the NRC discard its own cost analysis,

which was sent to OMB, and work with the petitioners to produce a realistic cost estimate. The petitioners assert that the Commission has refused to recognize the existence of the analysis produced by the ACNP/SNM and has refused to discuss it, comment on it, or address the issues on it in any manner. The petitioners believe that if this petition is granted, most of these costs would disappear. The petitioners believe that it is likely that nuclear pharmacy costs would also decrease and, therefore, radiopharmaceutical costs would decrease as well.

Conclusion

The petitioners believe that the requested changes would benefit the public in two ways. First, substantial requirements for physicians' education, training, and experience, and appropriate evidence of mastery by testing would improve the knowledge and abilities of physicians offering diagnostic nuclear medicine. Second, costs to the health care system would decrease without any decrease in safety.

Reason for Denial

NRC is denying the petition because:

(1) The Commission approved the final rule addressing the issues raised in the petition after an extensive rulemaking process that provided an unprecedented level of enhanced stakeholder and public participation;

(2) The Commission believes that the ACNP/SNM had many opportunities to present their concerns and suggestions as part of that process and did so; and

(3) The petition does not appear to present any significant new information or recommendations that the Commission has not already considered.

In general, the proposed rule amendments, comments, and supporting information presented by the petitioners were previously submitted by the ACNP/SNM in the following documents that provided comments on the rulemaking to revise Part 35:

- Document entitled “A Framework for the Regulation of Nuclear Medicine” ACNP/SNM Government Relations Office, dated December 18, 1997 (docketed by the NRC on January 13, 1998, as comment number 239). This document presents information on the important and challenging issues that face the NRC as it reviews and revises 10 CFR Part 35.

- Letter dated November 10, 1998, to James Smith, NRC, jointly signed by David C. Nichols, ACNP/SNM; Roy Brown, Council on Radionuclides and Radiopharmaceuticals; Felix Killar, Nuclear Energy Institute; and Rich White, Council on Radionuclides and Radiopharmaceuticals (docketed by the NRC as comment number 498 on December 4, 1998). The signatories raise the matter of regulating diagnostic nuclear medicine through Part 35, combined with training and experience requirements.

- Letter dated December 16, 1998, from Robert L. MeckelInburg, M.D., President, ACNP and James W. Fletcher, M.D. President, SNM, to the Secretary, U.S. Nuclear Regulatory Commission (docketed by the NRC on December 16, 1998, as comment number 505). This letter discusses limiting the requirements for diagnostic nuclear medicine to the provisions of Part 20, combined with specific training and experience requirements.

- Letter dated September 3, 1999, to Greta Joy Dicus, then Chairman, NRC, from Robert F. Carretta, M.D., President, SNM, and James M. Woolfenden, M.D., President, ACNP (docketed by the NRC on November 8, 1999, as comment number 604). This letter discusses limiting the requirements for diagnostic nuclear medicine to the provisions of Part 20, combined with specific training and experience requirements.

The NRC has already responded to comments similar to those presented by the petitioners in their January 11, 2001, petition for rulemaking. Responses to these comments are provided in SECY-00-0118, "Final Rules -10 CFR Part 35, 'Medical Use of Byproduct Material' and 10 CFR Part 20, 'Standards for Protection Against Radiation'," dated May 31, 2000. In this document, the NRC staff presented the Commission with a draft final rule that would revise the regulations governing the medical use of byproduct material as well as related supporting and guidance documents. This document contains an exhaustive analysis of the comments received on the proposed revision to Part 35 that was noticed for public comment on August 13, 1998 (63 FR 43516); the NRC's response to these comments; and the changes made to the proposed rule in response to these comments. The Commission subsequently approved the draft final rule in a Staff Requirements Memorandum, dated October 23, 2000.

The following addresses Requested Actions 1-5, as listed under the heading "The Requested Actions" as well as cost figures, discussed under the heading, "Petitioner's Cost Estimate" of this notice. Requested Actions 6 through 8, as listed under the heading "The Requested Actions," raise issues not amenable to rulemaking such as removal of conditions from NRC diagnostic nuclear medicine licenses, inspection, and NRC personnel levels. As such, these issues are not further addressed here. However, the NRC staff has responded to

comments on related issues such as licensing and inspection of diagnostic nuclear medicine in SECY-00-0118, Attachment 6, SUPPLEMENTARY INFORMATION:, III. Summary of Public Comments and Responses to Comments, **Part II - General Issues**, B. Licensing (Issue 1) and C. Inspection (Issues 2 and 3).

The NRC staff has already responded to Requested Action 1 regarding the approach of regulating diagnostic nuclear medicine solely under Part 20 by explaining the need for certain specific provisions in Part 35 in SECY-00-0118, Attachment 6, SUPPLEMENTARY INFORMATION:, III. Summary of Public Comments and Responses to Comments, **Part II - General Issues**, A. Risk, Issue 4, as follows:

The final rule includes requirements that are needed to protect occupationally exposed individuals, patients, and the public. Certain radiation protection-related requirements unique to medical use are needed in Part 35 because of their contribution to risk reduction. For example, the final rule retains requirements to calibrate instrumentation used to measure the radioactivity of patient dosages before they are administered (§ 35.60). For this reason and because the NRC believes that these requirements are essential to the safe handling of byproduct material ...

The NRC staff has already responded to Requested Actions 2-4 regarding training and experience requirements for the medical use and possession of byproduct material. See SECY-00-0118, Attachment 6, SUPPLEMENTARY INFORMATION:, III. Summary of Public Comments and Responses to Comments, **Part II - General Issues**, E. Training and Experience, Issue 7 , as follows:

The NRC believes that the training and experience requirements in the final rule for authorized medical physicists (AMP), authorized nuclear pharmacists (ANP), authorized users (AU), and Radiation Safety Officers (RSO) are sufficient to assure that the radiation safety of the public, patients, human research subjects, and workers is maintained. Therefore, we deleted the requirement for an examination from all the training and experience sections. Instead of an examination, we will rely on the preceptor's certification that an individual has completed the required training and

experience and has achieved a level of competency sufficient to function independently as an AMP, ANP, AU, or RSO.

Further, under the revised 10 CFR Part 35, NRC will continue to rely on health care professionals who are required to meet certain NRC training and experience criteria to protect the health and safety of the public and patients.

The NRC staff has already responded to Requested Action 5 regarding the structure of regulations for the medical use of byproduct material in nuclear medicine (i.e., there are different requirements for training of AU's under §§35.100, 35.200 and 35.300) in SECY-00-0118, Attachment 6, SUPPLEMENTARY INFORMATION:, III. Summary of Public Comments and Responses to Comments, **Part II - General Issues**, E. Training and experience, 2. Training and experience - unsealed byproduct material, Issue 5, as follows:

The NRC recognizes that there is a certain degree of basic radiation safety knowledge that is common among all the types of use, e.g., use of the decay formula and decontamination techniques. However, we also believe that there are some basic differences between the uses of byproduct material under §§ 35.100, 35.200, and 35.300 that warrant additional training and experience, e.g., increased potential for exposures in excess of Part 20 limits and the potential for adverse biological effects. For example, AUs [authorized users] handling byproduct material for imaging and localization studies, as compared to uptake, dilution, and excretion studies, are generally handling larger quantities and many different radionuclides. Also, AUs meeting the training and experience requirements in § 35.190 are not authorized to prepare radioactive drugs using generators and reagent kits, but AUs under § 35.290 are authorized to prepare drugs using generators and reagent kits. Finally, AUs under § 35.390 are handling material in quantities that can cause deterministic effects.

The NRC staff has already addressed the cost figures (i.e., over \$100,000,000/ year to \$1 billion/year) presented by the petitioners in SECY-00-0118, Attachment 6, SUPPLEMENTARY INFORMATION:, III. Summary of Public Comments and Responses to Comments, **Part II - General Issues**, G. Costs of the revision, Issue 5, as follows:

In evaluating the costs of regulatory compliance and implementation, the NRC has used detailed information whenever it is available. We have sought data from a number of sources, including medical speciality groups, manufacturers, members of the ACMUI, the National Institutes of Health, and various published sources. However, certain necessary data are treated as proprietary. Other data are not collected or are available only in a disaggregated form. Many of the compliance costs will vary substantially from licensee to licensee, depending on the number and type of modalities and procedures that they use and perform. Other compliance costs will be dependent on numerous interrelated variables. We believe that an effort to collect the necessary data and/or develop necessary models to provide substitutes for missing or unavailable data would require very considerable time and expense. We are concerned that at the conclusion of such an effort, because of many remaining gaps and uncertainties in the underlying data, an estimate of the total cost of the regulations would still fall within such broad confidence bounds that it would be fundamentally flawed.

In addition, the NRC has prepared a regulatory analysis for the final rule which shows a net decrease in the cost to licensees of implementing the final rule as compared to the current rule. NRC has also submitted an estimate of the cost associated with the recordkeeping and reporting to OMB for its approval. This document, currently under review by OMB, shows a decrease of approximately 30 percent in costs associated with the recordkeeping and reporting requirements as compared to the current Part 35.

For the reasons cited in this document, the NRC denies the petition in its entirety.

Dated at Rockville, Maryland, this 16th day of April, 2001.

For the Nuclear Regulatory Commission.

/RA/

Annette Vietti-Cook,
Secretary of the Commission.