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FINAL REPLY:

Rep. Sonny Callahan

TO:

Rathbun, OCA

FOR SIGNATURE OF : \*\* GRN \*\*

CRC NO: 01-0411

Travers, EDO

DESC:

ROUTING:

Comments on Part 35, Medical Regulations  
(John T. Renz)

Travers  
Paperiello  
Kane  
Norry  
Craig  
Burns/Cyr

DATE: 08/17/01

ASSIGNED TO: CONTACT:  
NMSS Virgilio

SPECIAL INSTRUCTIONS OR REMARKS:

*Template Secy 017*

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**ACTION OFFICE:** EDO ✓

**AUTHOR:** REP Sonny Callahan  
**AFFILIATION:** REP  
**ADDRESSEE:** Dennis Rathbun  
**SUBJECT:** Concerns regulations (10 CFR Part 35) related to diagnostic nuclear medicine

**ACTION:** Signature of EDO  
**DISTRIBUTION:**

**LETTER DATE:** 08/13/2001  
**ACKNOWLEDGED:** No  
**SPECIAL HANDLING:** OCA to Ack

**NOTES:**  
**FILE LOCATION:** ADAMS

**DATE DUE:** 09/11/2001 **DATE SIGNED:**

EDO --G20010344

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Mr. Dennis K. Rathbun  
Director, Office of Congressional Affairs  
Nuclear Regulatory Commission  
Washington, DC 20555

RE: John T. Renz, M.D.  
P.O. Box 2144  
Mobile, AL 36652

Dear Mr. Rathbun:

The attached communication is submitted for your consideration.

If you will advise me of your action in this matter and have the letter returned to me with your reply, I will appreciate it.

With kindest regards, I am

Sincerely,

  
Sonny Callahan  
Member of Congress

SC:db

Enclosure

PLEASE RESPOND TO: CONGRESSMAN SONNY CALLAHAN  
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**August 9, 2001**

**The Honorable Sonny Callahan,  
Chairman  
House Appropriations Energy and  
Water Development Subcommittee  
2372 Rayburn House Office Building  
Washington, D.C. 20515**

**Dear Chairman Callahan:**

**It has come to my attention that the Nuclear Regulatory Commission (NRC) has adopted new and burdensome regulations (10 CFR Part 35) related to diagnostic nuclear medicine. I am concerned that the new regulations that the NRC is ready to implement will significantly increase the cost of important nuclear medicine procedures, and hinder my ability to treat patients.**

**I am a physician at the Mobile Infirmary Medical Center in Mobile, Alabama, and have been practicing nuclear medicine without incident for over 10 years. As a member of the nuclear medicine community and an Authorized User of byproduct materials, I am very concerned about the NRC's increasing regulation of diagnostic nuclear medicine and intrusion into the practice of nuclear medicine.**

**Current amendments to 10 CFR Part 35 are before OMB for review. In my opinion, the regulations only add to the cost of health care without improving safety of the patient or public. These regulations will unnecessarily increase the burden on nuclear medicine practitioners such as myself, and increase the costs to millions of patients who benefit from highly cost-effective procedures such as cardiac stress tests, lung and bones scans each year.**

**The National Academy of Science/Institute of Medicine noted in a 1996 NRC-funded study that the more detailed reporting and enforcement systems required for byproduct materials, as compared to the regulatory systems in place for most other ionizing radiation (such as x-rays) used in medicine, do not seem to reduce risk to providers, patients or members of the public.**

**The NRC has spent several years revising its regulations governing the use of byproduct materials in medicine. When the process began, the NRC stated its willingness to make the regulations more "risk-informed." This was based on the NRC's decision to decrease oversight of low-risk activities, such as diagnostic nuclear medicine, while retaining oversight of high-risk activities. It was also consistent with the NRC's ongoing recognition of the low risks associated with diagnostic nuclear medicine.**

**Unfortunately, the NRC has shifted away from this original focus and moved forward with specific regulations that will provide no increased safety to patients of the public but instead inhibit the practice of nuclear medicine.**

**The Honorable Sonny Callahan**  
**Page Two**  
**August 3, 2001**

**Shortly, the House and Senate will meet to conference the Energy and Water Development FY 2012 Appropriations bill. I am writing to urge you, as Chairman, to support the Senate-passed provision that will block the implementation of Part 35 and force the NRC to adopt a regulatory systems for diagnostic nuclear medicine that reflects the discipline's unparalleled and undisputed safety record.**

**Thank you for your consideration. If you or your staff have any questions, please do not hesitate to contact me.**

**Sincerely,**



**John T. Frenz, M.D.**  
**Radiologist**  
**Chairman of Nuclear Medicine**  
**Mobile Infirmiry Medical Center**

**JTR/cb**