UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

May 3, 1990

The Honorable Elizabeth J. Patterson
United States House of Representatives
Washington, DC 20515

Dear Congresswoman Patterson:

Thank you for your letter of April 10, 1990, regarding comments by Dr. Mark C. Bruels of Greenville, South Carolina on proposed amendments to 10 CFR Part 35.

The Nuclear Regulatory Commission published a proposed rule on January 16, 1990, on "Medical Use of Byproduct Material" that would require medical use licensees to implement a basic quality assurance program and that would modify the reporting and recordkeeping requirements. The public comment period closed April 12, 1990. To date, we have received 66 public comment letters, including Dr. Bruels' letter which was enclosed with your letter.

The issues raised by the public comments will be evaluated and used in developing a final rule. In addition, we are conducting a pilot program to try out the proposed performance based regulatory requirements using about 65 volunteer medical use licensees from across the United States. Their experience, evaluations, and suggestions will also be used in developing a final rule.

I want to assure you that Dr. Bruels' comments will be considered with the other public comments in developing a final rule.

I trust that the above information is responsive to your request.

Sincerely,

James M. Taylor
Executive Director
for Operations

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Congress of the United States
House of Representatives
Washington, DC 20515

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April 10, 1990

Mr. Kenneth Carr
Chairman
Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, Maryland 20852

Dear Mr. Carr:

I am writing on behalf of a constituent, Dr. Mark C. Bruels, regarding the Commission's proposed rules on quality assurance.

As you can see from the attached correspondence, Dr. Bruels raises a number of significant issues about the proposed rules. His comments focus on the burdensome nature of the regulations and the requirement of duplicative efforts by rare medical physics personnel. Dr. Buels is also concerned about the penalty provisions of the new rule.

I would appreciate your giving Dr. Buels' views careful consideration as the Commission considers issuing a final rule. If I can provide additional information, please do not hesitate to contact me or Eric Spitler of my staff.

Cordially,

Liz Patterson

Elizabeth J. Patterson
Member of Congress

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Mark C. Bruels, Ph.D.
500 Wenwood Road 1811
Greenville, SC 29607

April 4, 1990

Secretary
Nuclear Regulatory Commission
Washington, DC 20555

Attention: Docketing and Service Branch

Dear Mr. Secretary:

I have had the opportunity to review proposed rules 10 CFR - part 35 RIN 3150 - AC65. I am extremely upset because less than a year ago your personnel came to a professional American College of Medical Physics meeting and publicly stated that while there were proposed rules coming regarding Quality Assurance, these rules would simply state there should be a Quality Assurance Program. The rules in their current proposed form can hardly be taken as that. I find these rules to be unacceptable for many reasons, far more than I can put into one letter. First, according to your own information, there are only minimal numbers of risk events that you are attempting to control. Further, you are defining as medically significant such insignificant doses as 1 REM to any organ of the body from diagnosis or doses as low as 50 to 100 RAD for cancer therapy patients. These questions alone are far beyond your purview, and I feel that to encode such numbers in Federal law is extremely poor regulations policy. You state that you have the support of professional organizations in developing these rules. Could you please list such support? There is no professional support that I know of from the Physics community, rather total opposition.

In your introductory explanation to these, you claim you recognize that all medical use should be planned with the realization that individuals make mistakes. Yet in your enforcement you state clearly you view the occurrence of a misadministration or other reportable events as evidence of inadequate quality assurance in the medical use of by-product material and may subject the licensee to enforcement action. This pair of statements is totally inconsistent. This approach will cause a tendency to hide errors. This is an undesirable effect. Further, this will beg the legal question as to whether or not there is a matter of implied liability inherent in the actions of an individual. If an individual has done everything that a prudent man would do, he may generally be judged in a court of law to be found innocent of wrong doing. However, commission of a simple error will be adequate for his civil prosecution with fiscal fines and other regulatory penalties according to your intentions. To me this contradicts our basic Constitutional rights.

There are many questions of medical judgement that you enter into. As I am a physicist I will not comment on those, and I am certain that many physicians will comment on them. I will reserve my comments regarding your

attempts to codify good practice regarding acceptance testing of computer programs and your strange requirement for a mandatory second opinion regarding calibration of Cobalt Units. Any Physicist, who is functioning in the accepted manner, does acceptance testing on computer programs which are used in radiation therapy treatment planning. The program that you outline is good in so far as it goes. It does not go far enough, of course. If you were to attempt to codify an adequate check out procedure, you would fail totally. What you have done now is wrong in that once someone has done this much they will stop, and thus, you have encoded mediocrity into regulation again. You should forget trying to make this a requirement. Good practice requires that such programs be checked out by individual users. Since you feel you need an item to check on your inspections, then you might put in an item that states: "treatment planning programs have been checked out by a qualified expert". You have also doubled the expense to institutions and hence to patients in that you require a second independent calibration of a Cobalt Unit. This is not acceptable. Many institutions today are on NIH sponsored protocols, and independent evaluations of their programs automatically follow. To my knowledge, only one event has occurred that could have been prevented regarding cobalt miscalibration. Since that event, Physicists always double check their own work, if they are following good practice procedures, and it is this good practice standard which is set by the professional community. You can not codify that due to its changing nature. But this good practice standard is that which is checked against by Courts of Law.

In summation, while I could go on for many pages, I find that this regulation does not truly have the patient interest at heart. It is clear that you are attempting to develop an expanded laundry list of items so that you can check them off when you come in to do your inspections, thereby proving that you are doing something worthwhile. You are doing something necessary. But your approach is wrong. What this does is to add an increasing burden to already over burdened personnel. What that translates to is that we will spend our time doing these minimal requirements, double checking the minimal requirements, instead of doing our jobs as we define them. The use of radiation is one of the safest areas of endeavor in a hospital. What you should be doing is spending your budget trying to find ways of improving use of nuclear energy in non-medical environments. You should not be attempting to hobble an already restricted field where developments are being choked off by increasing federal burdens and decreasing available income.

Thank you for your time in reading this letter.

Sincerely,

Mark C. Bruels, Ph.D.