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DOCKET NUMBER PR 50
PROPOSED RULE

45FR67099

34



November 25, 1980

DOCKET NUMBER PR 2
PROPOSED RULE
45FR66754

37



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

Re: Request for Comments, 45FR 66754

Sir:

This letter is a response to your request for specific comments regarding items identified in the document identified as 45FR 69077.

1. The policy is not fair and equitable. My experience has been that most inspections have been carried out in an atmosphere which offers constructive criticism tempered by an appreciation for the nuances of medical practice which require some flexibility. However, there has been sufficient variability in the conduct of the examinations to give me concern that your stated policy of achieving compliance by "aggressive enforcement strategy that seeks more frequent use of stronger enforcement measures" will absolve the occasional inspector with a punitive bent.

I trust that the mandate to raise the limits of the civil fines will not be misconstrued to mean that the more frequent use of fines is a desirable enforcement method. As a relatively small user of by-product material, I am sensitive to your statement that non-compliance should be more expensive than compliance. Legal defense of a disputed non-compliance violation might very well be far more expensive than the fine. Ultimately, the cost of the fines will be borne by the public. It seems strange that at a time when the public appears to be decrying the high cost of medical care, you would choose to become more aggressive in your enforcement strategy and simultaneously raise the level of fines.

2. The policy may be understandable but that does not justify it. There is absolutely no indication that alternative methods of increasing compliance have been explored. It appears that the Commission is becoming more punitive in addition to becoming increasingly aggressive. This policy will detract from the enthusiasm with which nuclear medicine is practiced.

Handwritten signature/initials

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Acknowledged by card... 12/5/80

Donald W. Fundingsland, President

3. The policy indicates that a Violation of Severity V or VI that is reported by the licensee will not generate a notice of violation. The Severity levels are not defined so well that I am sure that you and I will always be in agreement as to the level of violation. By reporting a level V violation, I might be testifying against myself at level IV, III or II even though my reporting of a level V violation was prompted by my desire to avoid generating a notice of violation.

4. I am fearful that despite adequate definition of levels of activities, it is the small user who will suffer most from your new policy. We are vulnerable because we cannot afford legal defense nor do we have other resources which would identify us as an opponent so formidable that you would proceed with caution before imposing a considerable fine. Verification of the success (or failure) of your new policy undoubtedly will be measured by the use of numbers and charts. I am fearful that the small user will be seen as the one who can provide sufficient statistical data to justify the new policy.

5. I am disturbed by being categorized as "all other licensees and persons subject to civil penalties". It leaves me with the impression that the policy was developed because of enforcement problems with the other three categories of licensees. If that is the case, what guarantees are provided that the major impact of this new policy will not be on "all other licensees"?

6. No comment.

7. The amount of discretion to be allowed the Office Directors is not easily decided. I have no qualms about allowing good people as much discretion as they need. Quite obviously the question is not so much one about the amount of discretion to be allowed, but rather one about the capabilities of the individual Directors.

8. No comment.

9. No comment.

This completes my itemized list of comments addressed to the specific items you identified. I am anxious to share my thoughts on some items which you did not specify.

The time between October 28, 1980 and the public hearings scheduled for the first week in December is too short for me to alter other plans which will preclude me from attending. At this time few of my colleagues are aware of the October 28, 1980 letter.

I suspect that the NRC Staff has already decided what the policy will be and that the request for comments is just so much window-dressing. There is no reason given for why the policy needed change. There is no statement about consideration given to alternative means of ensuring compliance. In short, all that is asked for is comment about a few items which will not affect policy at all.

A fine schedule based upon the levels of Severity and the licensees "ability to pay" indicates to me that although you are concerned about the seriousness of the violation, you are unsure about how much harassment the licensees will tolerate. I question your right to judge my ability to pay.

The intent of The Regulatory Flexibility Act of 1980 was to protect the small entities from regulations which would affect them adversely and disproportionately because of their size. I feel that your new policy has ignored the intent and perhaps the letter of P.L. 96-354.

Sincerely,



R. C. Feulner, M. D.

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