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

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MEMORANDUM FOR: Chairman Palladino
Commissioner Gilinsky
Commissioner Ahearne
Commissioner Roberts
Commissioner Asselstine

FROM: Joseph DelMedico
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Division of Fuel Cycle and Material Safety, NMSS

SUBJECT: EXPRESSION OF DISSENTING PROFESSIONAL OPINION CONCERNING SECY-83-62 (PROPOSED REVISION OF 10 CFR PART 35)

I wish to bring to your attention a General Accounting Office (GAO) report entitled "Management of the Licensing of Users of Radioactive Materials Should be Improved", dated February 1976 (Enclosure 1). Before the GAO investigation, the material licensing function conducted business in a fashion identical to that proposed in SECY-83-62. At that time, NRC did not require applicants to submit detailed procedures describing how they intended to meet the requirements in the regulations.

The GAO report was highly critical of NRC's Material Licensing Program. The report states in part:

> The licensing staff believes that it is not always necessary to evaluate detailed descriptions of applicants' radiation protection procedures and administrative controls, especially when regulatory requirements are clear and specific and methods for compliance are well known. . .
>
> [However]. . . The need to obtain and evaluate detailed descriptions of applicants' procedures and controls was demonstrated by material license inspection results which indicated that:

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--Many licensees had not developed and carried out procedures and controls necessary to comply with regulatory requirements.

--The users thought best able to use radioactive materials safely, and on whose qualifications NRC's licensing staff relied heavily, had experienced the highest rates of noncompliance, particularly in failing to develop adequate radiation safety programs.

In the proposed rule, the statement of consideration makes a vague reference to fully developed safety technology and the existance of professional board certifications. I can think of no safety technology or certification board that was not firmly established at the time of the GAO report. The real problem is that safety technology is expensive and board certified people are scarce, particularly in the less populated Western States, the Virgin Islands, Puerto Rico, Guam, etc.

Under the new licensing scheme, NRC would supposedly be concerned with whether the requirements in the regulations are being met, not with the details of the procedures used to meet them. This is putting the cart before the horse; GAO found that licensees were frequently not familiar with the regulations and therefore did not realize that their procedures were inadequate. I have found this to be especially true of physicians, whose primary concern is vital patient care.

The Value/Impact Statement decries the fact that the physician may hire a consultant to prepare the application. This fact is actually of little significance. The important point is that the application condenses all applicable requirements into a simple, concise document that the physician may keep at hand for ready reference. Whether or not Part 35 is changed, physicians and hospitals must still comply with applicable provisions in Parts 19, 20, 30, 35, and 71. From a compliance standpoint, a concise application is far preferable to dealing with the tiny print and the bulk of five separate Parts in 10 CFR.

Under our present system, the training and experience of each new physician is carefully evaluated by NRC staff before that physician is permitted to use byproduct material in or on humans. With the new application form in the proposed rule, physicians simply check a box and sign their name to indicate that they consider themselves to be qualified. Perhaps we should next extend this concept to reactor operator licensing! After all, reactor operators have never caused a death to a member of the public. There have been numerous patient deaths and serious accidental exposures caused by physicians' misuse of byproduct material. For examples, see Enclosures 2 and 3.

Under the proposed system, an NRC inspector could discover that a physician is, in fact, not qualified even though that physician has already performed hundreds of procedures! Worse yet, such a discovery could be connected with a major incident involving public and media interest. (See "The Riverside Radiation Tragedy", Enclosure 2.)

If Agreement States continue to perform a careful review of physician qualifications while NRC does not, the States may find themselves denying licenses to physicians who are already practicing in NRC areas. The proposed rule makes light of the fact that medical licensing would no longer be uniform among NRC and the Agreement States. Actually, this presents a serious problem for the nuclear medicine field as evidenced by Mr. Early's letter to Chairman Palladino (Enclosure 4).

The proposed rule places excessive reliance on a post licensing visit. Past experience has shown that these visits can be delayed indefinitely due to budget cuts and other problems. If NRC is to place so much reliance on this visit, I believe that it should be codified right into the rule so that we are forced to perform it in a timely fashion. What will NRC do if the visit reveals major deficiencies? Under the present system, we find deficiencies in the procedures submitted with applications. If procedures are no longer submitted, it follows that the inspections will reveal deficiencies. Will a return visit be necessary? If so, what about the cost?

When I mentioned these problems to the authors of the proposed rule, they seemed to think that NRC could stun the nuclear medicine field into compliance by imposing heavy civil penalties and revoking licenses. There are, however, serious political and moral implications involved when dealing with a highly organized group such as physicians and humanitarian institutions such as hospitals. It my experience, it is virtually impossible to revoke a nuclear medicine license once it has been issued because the physician can show that NRC has interfered with emergency medical procedures that are necessary to save patient lives.

Unscrupulous salespeople would have a field day under the proposed licensing scheme. At the present time, the cost of nuclear medicine imaging equipment starts at a hundred thousand dollars. A two or three percent commission on such a sum is quite a windfall. Of course, no physician or hospital wants to purchase equipment unless they can obtain a license to use it. Enter the salesman with NRC's new application in his hip pocket: "Just sign here, doctor. I'll check all the right boxes and mail it in for you. You'll have your license in no time." By the time NRC makes the first inspection, the salesman has his commission, the bewildered physician has a hefty list of violations, patients may have been mistreated and workers may have been overexposed.

The application form that we presently use for medical licensing is Form NRC 313M. For clearance under the Paperwork Reduction Act, NRC told OMB that the form required two hours for completion. Inexplicably, the Value/Impact statement for the proposed rule estimates that the same form requires two full days of professional nuclear medicine physician time and three secretarial days. This seems especially strange since all of the forms and procedures that must be submitted are available in preprinted form in Regulatory Guide 10.8 (Enclosure 5).

In FY 1981, NRC spent 1.2 million dollars to have Sandia National Laboratories analyze the materials licensing program. The Sandia study found that licensing delays were caused not by reviewing safety procedures, but by inefficiencies in typing, filing, and other clerical functions tangential to the review process. If we stop reviewing safety procedures in order to correct typing and filing problems we have, in my opinion, thrown the baby out with the bath water.

/S/

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Enclosures:
1. GAO report dtd. 2/11/76
2. "The Riverside Radiation Tragedy"
3. Report on Medical Misadministrations (11/82)
4. Ltr. from P. Early dtd. 8/11/82
5. Regulatory Guide 10.8