TP 102-3

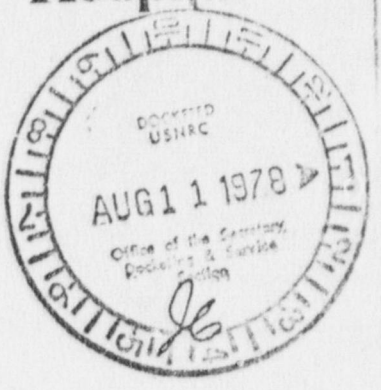
2900 West Oklahoma Avenue / Milwaukee, Wisconsin 53215 / Phone 414 647-6423

ST. LUKE'S Hospital

(19)

DOCKET NUMBER PROPOSED RULE PR-35 (43FR29297)

August 3, 1978



Secretary of Commission
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Sirs:

I most strongly object to the proposed regulation entitled, "Misadministration Reporting Requirements" (Rule 7590-01) for Nuclear Medicine. My objections are based on the following points:

1. The Regulation of Pharmaceuticals should not be performed by the NRC but more properly by the FDA, which at least has some familiarity with regulating pharmaceuticals.

2. The proposed rule is an example of gross over-regulation proposed by persons who apparently have little understanding of the processes they are attempting to regulate.

   a. There have been no large scale studies performed which demonstrate a serious problem in need of regulation.

   b. In the absence of hard data, reasonable and logical rules cannot be properly proposed.

3. The regulations proposed are illogical at face value.

   a. The proposed 20% tolerance on drug dosage is incredibly restrictive for example: In the nuclear medicine literature you will find acceptable Gallium-67 Citrate doses described from 3MCi to 10MCi for patients. It is incredible that with such a broad dosage range, you would require a report for a dosage variance of 20%. Furthermore, patients vary in size, shape, weight and height. They also vary markedly with respect to localization and excretion patterns for

7810170093

Acknowledged by card. 8/14

Secretary of Commission
U.S.N.R.C.

a given pharmaceutical. These individual variations alone could easily account for a 100 to 300% change in absorbed radiation dosage for a given dose administration.

Thus, the proposed rule would appear to be offensibly and needlessly restrictive in light of the normal patient variability and lack of demonstrated need for this type of regulation.

b. The proposed 10% tolerance on therapeutic radiation pharmaceutical dosage is even more incredible and again reflects the total lack of knowledge and understanding of clinical problems by the people involved in promogating this regulation. As an example, the accepted dosage for I^{131} therapy for hyperthyroidism is between 80 and 120 uCi per gram of estimated weight of thyroid (a 50% variation). Besides this broad therapeutic range, the I^{131} dose calculation depends upon the estimated weight of the thyroid gland which is often in error by at least 20%. Additional patient factors including varying thyroidal iodine turnover rate may cause an additional 100-300% variation in the therapeutic dose delivered to the patient. Thus, the proposed rule regarding a 10% tolerance for therapeutic doses is grossly over restrictive and unnecessary.

c. Studies of patients who have received therapy I^{131} for hyper thyroidism have not yet revealed any detectable long term radiation effects. Since the radiation exposure from diagnostic procedures are at least 1 - 2 orders of magnitude less than for a therapeutic procedure, there is no demonstrated need for this NRC regulation.

4. Nuclear Medicine Diagnostic procedures are among the safest of all diagnostic procedures that a patient can undergo as no radiation effects have been observed and because allergic and idiosyncreatic reactions to these materials are extremely rare. To propose a regulation which requires a telephone report within 24 hours to the NRC for inconsequential errors in dosage and to further require a follow-up written report to be made available both to the NRC and to patients is indeed making Mount Everest out of an ant hill. Furthermore, written notification to the patient will most certainly induce groundless fears of nuclear medicine procedure and may also result in needless law suits which are trouble enough in these litigious times.

Secretary of Commission
U.S.N.R.C.

In summary, I object to the regulation because it is unnecessary, unwise and will compound the mountain of paper work confronting physicians. Furthermore it may lead to needless law suits. The overall effect of this regulation will be to increase the inefficiency and costs of medical care without increasing the safety or efficiency of these procedures.

Sincerely,

David L. Yuille, M.D.

David L. Yuille, M.D.
Associate Director
Nuclear Medicine
St. Luke's Hospital
Milwaukee, Wisconsin

DLY/t