

St Joseph's Hospital and Medical Center

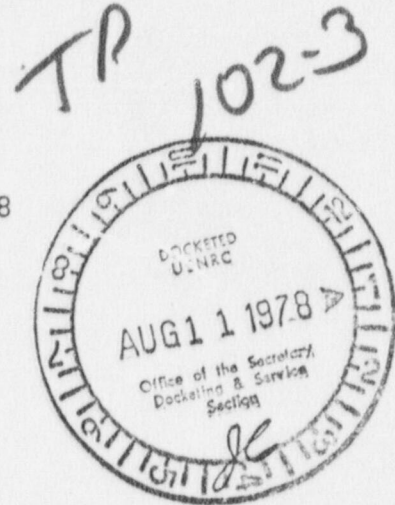
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Continuing Commitment to Care

DOCKET NUMBER
PROPOSED RULE

(18)
PR-35(43FR29292)

August 4, 1978



Bernard Singer, Chief
Radioisotopes Licensing Branch
Division of Fuel Cycle and
Material Safety

Dear Sir:

I have reviewed the proposed regulation dated July 20, 1978 from the Nuclear Regulatory Commission. I believe that this proposed rule while having merit, is in general, irresponsible. I take particular exception for the definition of misadministration where it refers to a diagnostic dose greater than 20% of the prescribed dose. To the best of my knowledge, notifying the patient, the patient's physician, and everyone in general is totally unnecessary. There is no proof that a dose of more than 20% of that usually given is in anyway damaging. Furthermore, there are many Isotope Departments who administer 50 to 100% more of a particular isotope than other departments. What does one do in a situation such as this?

I suggest that the NRC submit to a department, during an inspection period, an "unknown" to place in their dose calibrator for testing. If the calibrator is functioning correctly then I think we will have to assume that the technicians are giving the "usual prescribed dose". I would suggest that a dose of 5 to 10 times the usual diagnostic amount should be reported to the patient's physician but certainly not 20%.

The therapeutic dose range probably should be raised to about 25% rather than 10%. Again, there are many variations in the amount given for a specific illness depending on the radiation therapist. I also believe if a misadministration is discovered this should be reported to the patient's physician and perhaps to the patient if the overdose could result in tissue necrosis.

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Acknowledged by card.

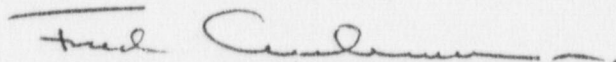
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Bernard Singer, Chief
8/4/78

The proposed rules, while important in attempting to correct misadministration, would prove to be a bonanza for malpractice lawyers. At the very least they would cause excessive concern on the part of the patient if we assume that all cases of misadministration would even be admitted.

Very truly yours,

A handwritten signature in dark ink, appearing to read "Fred Cushmore", with a horizontal line extending from the end of the signature.

Frederick N. Cushmore, M.D.

FNC/ss