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PROPOSED RULE PR-30,31 et al.
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In Reply Refer To: 598/115

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

Attn: Docketing and Service Branch

Re: Nuclear Regulatory Commission
10 CFR Parts 30, 31, 32, 35, and 40
Medical Use of Byproduct Material
Proposed Rule
FR 50 #144 pp. 30616 - 51.
July 26, 1985

Gentlemen:

Some general and specific comments are offered in consideration of the proposed rule cited above are given below.

Specific Comments

Para. 35.75: This proposed rule basically mandates an old licensing practice of allowing treatment on an out-patient basis when the therapeutic dose is less than 30mCi. It allows additionally either (1) 6 mr/hr at one meter or (2) the 30 mCi criteria to be used.

1. This rule disregards the National Council on Radiation Protection and Measurements (NCRP) Report No. 37, "Precautions the management of patients who have received therapeutic amounts of Radionuclides." Traditionally, the NRC has used NCRP recommendations as a basis for many of its regulations. This is one reason why the revised Part #20 has not been issued for public comment, i.e., NRC staff is waiting on issuance of NCRP guidance which will parallel ICRP 26 and 30.

2. Provisions of NCRP 37 use as a basis extrapolated exposure at 1 m for a variety of nuclides. Problems with the use of a single activity limit and correspondingly, a single exposure rate limit, are discussed on pp. 17 and 18 NCRP 37.

3. The rule is unclear on whether a patient is required to be hospitalized for the purposes of radiation safety if the treatment activity is 30 mCi or 6 mr/hr. The rule, as stated, only relates to when a patient may be released from confinement. Nevertheless, I would also object on NCRP 37 grounds, that these values be used for hospitalization.

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4. To provide more flexibility and be in accordance with NCRP 37, I would propose that the rule be modified to allow for the patient to be released or not admitted if, using patient-specific biological and physical measurement data (excretion rate, exposure rate) a member of the public will not likely receive more than 500 mrem as a result of the proximity of the therapy patient. Reasonable time and distance assumptions must be made in this assessment. The rule would then be similiar to 10 CFR 20.105 (a) and (b), in which considerations may be made in (a) to ameliorate the numerical criteria specified in (b).

5. This rule may not be ALARA in the sense of collective dose. From a dose standpoint, if a patient is hospitalized for a period of time greater than that recommended by NCRP 37 criteria, there will be many more people in the environs, **viz** hospital staff, than family members. Thus the collective dose will most likely be higher. From a monetary standpoint, the extra confinement will definitely increase health care costs. On an average of two extra days confinement, this will result in substantially increased costs. Other mitigating factors in a prolonged or unnecessary confinement, may be increased anxiety of staff and well being of patient since he is away from family.

6. It may be shown that in some circumstances that the 30 mCi or 6 mr/hr limit is less restrictive than necessary, again emphasizing the individual need for assessment.

General Comments

1. I question the need for specific regulations in which it is mandated how procedures are to be implemented. Regulations should provide goals to be achieved and not necessarily dictate what procedures are to be used to reach the goals. Nuclear Medicine, in particular, is such a diverse discipline that a large amount of latitude must be left up to the individual. Establishing strict regulations takes away initiative to improve practices as well as disregards established practices which are equally safe.

2. Regulations should be general in nature with more specific procedure left to the licensing guides. Public health and safety will be protected equally by enforcement of license conditions as by regulations.

3. It is a fallacy to assume that unless specific requirements are mandated, safe practices will not be observed. "Offenders" will continue to offend, and the "innocent" will be punished.

3.

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4. The rule will provide more uniformity in licensing of medical institutions. But uniformity is not necessarily an ideal goal except in the case of license reviewers. Some flexibility is desirable, even though it may lead sometimes to an uneven enforcement policy and review policy.

Lynn McGuire

LYNN McGUIRE
Radiation Safety Officer