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UCLA SCHOOL OF MEDICINE
HARBOR - UCLA MEDICAL CENTER
DEPARTMENT OF RADIOLOGY
1000 CARSON STREET
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Dec. 26, 1990

Samuel J. Chilk
Secretary, U.S. Nuclear Regulatory
Commission
11555 Rockville Pike
Rockville, MD 20852

Attn: Chief, Docketing and Service Branch

Dear Mr. Chilk:

This Petition is being submitted pursuant to 10 CFR Part 20.301(c) in order to authorize operating up to an annual dose to individual members of the public of 5 mSv (500 mrem). This has been undertaken after conferring with Mr. Hal Peterson of NRC. This Petition also requests a change in the present 10 CFR Part 35.75 because there is a closely related problem which merits being addressed. Last, this Petition requests deletion of 10 CFR 20.301(d), which could lead to absurd situations.

This Petition is being submitted by me personally in my capacity as an advisor to the NRC, because I see a potential problem. It is not being submitted on behalf of any organization or group. The fact that organizations to which I belong may support this Petition shall in no way be interpreted to mean that I am acting in any capacity as their agent. This is my idea and my work and I have not a priori requested their opinion or support.

The subject of this Petition is the radiation absorbed dose to members of the general public from patients receiving radiopharmaceuticals for diagnosis or therapy. At present, members of the general public are permitted absorbed doses of up to 5 mSv/y. When the new Part 20 goes into effect, the level of absorbed dose permitted will be reduced to 1 mSv/y. If members of the public who are closest to the patient may not receive more than 1 mSv/y, patients who are now hospitalized would require hospitalization for appropriately longer times than they are now and many outpatients would have to be made inpatients. This would be extremely expensive. It is difficult to imagine any benefit to the public by reducing dose to 1 mSv, as no one has demonstrated any risk from chronic doses of 5 mSv/y. Indeed, residents of portions of Colorado, who receive 2.5 mSv/y, and those in higher background areas, have never shown any adverse effects from these low levels of radiation. The new Part 20 continues to permit the fetus of a declared pregnant woman to accrue a dose of 5 mSv/9 mo.; it would be scientifically consistent to permit certain members of the general public to do the same.

The new Part 20.903 appears to have retained the concept of the 1110 MBq (30 mCi) limit, which is expressed in 35.75(a)(2). It is as though NRC omitted consideration of the basis of the 1110 MBq limit when the new Part 20 was written, because it is not at present scientifically consistent with the Part 20 absorbed dose change. In addition, 35.75(a)(2) is not scientifically sound

either, because it refers to all radionuclides instead of just I-131, for which the 1110 MBq activity limit was originally intended.

I propose to retain the 1110 MBq limit for I-131, vary the maximum activity of other radionuclides consistent with the calculation methodology employed in NCRP no. 37, and continue to permit members of the public to receive up to 5 mSv from patients. I wish 10 CFR 20.301(d) to be deleted because EPA's radionuclide NESHAPS will be a national standard on 19 May 91 and its more restrictive nature nullifies the present Part 20 standards. For Part 20 to hold us to EPA which nullifies Part 20, is an example of colossal regulatory absurdity.

ECONOMIC IMPACT

In 1989, there were approximately 150,000 administrations of NaI-131. Of these, about 100,000 were 3.7 MBq or less, and of no consequence in terms of public radiation absorbed dose. There were about 35,000 hyperthyroid treatments, 10,000 metastatic surveys, and 5000 remnant ablation and thyroid cancer therapy doses. Nearly all the hyperthyroid treatment and metastatic survey doses were administered to outpatients. About 40,000 of these patients would become inpatients, as the I-131 limit for administered activity to comply with a 1 mSv public dose would be dropped to 1110 MBq/5 = 222 MBq (6 mCi). Assuming that the typical dose for hyperthyroidism is 444-555 MBq, and the uptake is about 70% and the effective halflife about 4.3 days, the average patient would require hospitalization for 4 days:

$0.7 \times 500 = 350$ MBq in gland after 1 day.

$$\frac{222}{350} = e^{-\frac{0.693}{4.3}(t)}$$

$$0.634 = e^{-0.16\,t}$$

$$-0.456 = -0.16\,t$$

$$t = 0.456/0.16 = 2.85\text{d}$$

$1 + 2.85 = 3.85 \approx 4$ days

Assuming that half the metastatic survey patients receive 370 MBq, 5000 patients would require 1 day of inpatient admission.

Assuming that the 5000 thyroid remnant ablation and thyroid cancer therapy doses are 3700-7400 MBq, and that it takes 1-2 days to get to the 1110 MBq level now, it would take another 1-2 days to drop another 80% to 222 MBq, or an average of 1.5 days extra.

It costs about $500/day in a private room for these radioactive patients.

The new Part 20 would therefore cost:

$[35{,}000(4) + 5000(1) + 5000(1.5)]\ 500 =$

152,500 (500) = $76,250,000/year for NaI-131 patients.

Assuming that the number of outpatients receiving over 1110 MBq Tc-99m in various forms by Jan., 1993 is about 600,000 (using 1989 numbers), and that each requires 1 day as an inpatient, we have another 600,000(1)(500) = $300,000,000/y.

The above calculation assumes that the maximum administered activity for an outpatient stated in 35.75(a)(2) will not go down by a factor of 5; if it did, an extra 3,500,000 patients a year would become inpatients, at about $1,750,000,000/y.....!

In summary then, the new Part 20 as it stands will cost $76,250,000/y for NaI-131 patients. The old 35.75(a)(2) will cost, within 2 years, $300,000,000/y. If the old 35.75(a)(2) were upgraded to reflect the Part 20 philosophy, it would cost an additional $1,750,000,000/y.

If NRC requires us to accept EPA standards, that amounts to well over $100,000,000/y (CIRRPC Report of June 26, 1990).

If this Petition is granted, there will be zero additional costs.

We may still have additional costs if EPA decides that NRC standards are not high enough to assure public health and safety and we have dual regulation. For NRC to capitulate without firing single torpedo (20.301(d)) is sad indeed.

35.75(a)(2): CALCULATIONS FOR TC-99m

In order to calculate the actual activity of Tc-99m inside a patient that will result in excessive radiation absorbed dose to members of the public in close contact with the patient, I will use the NCRP no. 37 model:

$$D(t) = \frac{34.6\ \Gamma Q_o\ T_{\frac{1}{2}}\ (1-e^{-0.693t/T_{\frac{1}{2}}})}{r^2}$$

Where D(t) = accumulated exposure at time t, in roentgens.

Γ = specific gamma-ray constant for a point source (R/mCi-h at 1 cm). In its use, no account is taken of scattering or absorption of the gamma-rays in the body of the patient.

Q_o = initial activity of the point source in millicuries.

$T_{\frac{1}{2}}$ = physical halflife in days.

r = distance from the point source to the point of interest, in cm.

t = exposure time, in days.

The model assumes that a member of the public remains 1 meter from the patient continuously until total radionuclide decay. It assumes that there is no excretion of the radionuclide from the patient.

Γ for Tc-99m = 0.8; $T_{\frac{1}{2}}$ = 6.02h = 0.25d

r = 1 meter = 100 cm

$t = \infty$

D = 0.5R

$$0.5 = \frac{34.6\ (0.8)(Q_o)(0.25)(1-e^{-0.693(\infty)/0.25}}{10,000}$$

$$0.5 = \frac{6.92\ Q_o}{10,000}$$

$$Q_o = \frac{0.5(10,000)}{6.92} = 722 \text{ mCi}$$

In other words, a member of the public standing 1 m from a patient containing 722(37) = 26,700 MBq of Tc-99m would receive 5 mSv radiation absorbed dose.

The corresponding number for I-131 is 8 mCi; the NRC limit of 30 mCi recognized the fact that one need not spend full time next to the patient. Using the factor of 30/8 = 3.75 for Tc-99m, the patient could have 722(3.75) = 2710 mCi = 100,000 MBq inside him. That is a lot more than the present limit of 1110 MBq.

The present limit for Tc-99m is roughly 2 orders of magnitude too low. No one is going to give more than about 2200 MBq to a patient. We don't need a published limit. You just need to change 35.75 to refer to I-131 only or to set the limit at that which gives an absorbed dose of 5 mSv to a member of the public.

20.301(c) REQUIREMENTS/ANSWERS

(1) Demonstration of the need for and the expected duration of operations in excess of the limit in paragraph (a) of this section.

The need has been demonstrated. The duration is indefinite.

(2) The licensee's program to assess and control dose within the 0.5 rem (5 mSv) annual limit.

Patients given 1110 MBq of I-131 or more will be hospitalized and released in accordance with NCRP no. 37 guidelines. The more a patient can reasonably be expected to stay away from others, the more I-131 he may leave with. It would be rare for a member of the public to be exposed more than once a year to patients containing high activities of I-131. Should that be expected to occur, the licensee would keep the patient in the hospital longer.

(3) The procedures to be followed to maintain doses as low as is reasonably achievable.

Education of patient and care-giver to minimize time and contamination and maximize distance.

Thank you for your attention and consideration.

Sincerely,

C S Marcus

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CSM:dt