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May 13, 1994

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DOCKETING & SERVICE

UCLA SCHOOL OF MEDICINE  
HARBOR - UCLA MEDICAL CENTER  
DEPARTMENT OF RADIOLOGY  
1000 CARSON STREET  
TORRANCE, CALIFORNIA 90509

Samuel Chilk  
Secretary, USNRC  
Washington, DC 20555

PR 20  
(59 FR 9146)

Attn: Docketing and Service Branch

Re: FR 59 (38), Feb. 25, 1994; pp 9146-9149: RIN 3150-AE90,  
10 CFR Part 20: Disposal of Radioactive Material by  
Release in Sanitary Sewer Systems

Dear Mr. Chilk:

I am surprised and disappointed to see the Advance Notice of Proposed Rulemaking about possible changes in the new 10 CFR Part 20 regarding radionuclide concentrations in sewage.

In the first place, the NRC demanded that all states accept the new Part 20 by 1 Jan. 94, quietly threatening to remove Agreement State status if a state was not in compliance by that date. Many states were hoping that NRC would fix the significant scientific problems with Part 20 before considering using it. However, that did not happen. Now, scarcely after the ink is dry, NRC is fiddling with an unimportant portion of Part 20 instead of directing its people to tackle the real problems they created by revising it.

In the second place, NRC has failed to show any "problems" or "concerns" worthy of corrective efforts in the area of sewage limits for which we will be charged User Fees. The NRC has discovered radioactive atoms in sewage. This is no surprise; we have been using artificial radionuclides since the 1930's. That is why there are limits published in part 20. The significant observation is not that radioactivity is in sewage, but that it is well within the levels set by NRC and is of no safety concern. In the few cases where public concern was expressed (although no hazards existed), the handful of manufacturers and service industries involved made some extra efforts to decrease emissions and all parties were satisfied. The NRC should be delighted that absolutely no need for any further efforts on its part is required. This is a wonderful opportunity to decrease NRC staff and thereby decrease our User Fees.

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In the third place, we do not understand why NRC is reviewing the issue of patient excreta after diagnostic and therapeutic nuclear medicine procedures have taken place. There is absolutely no evidence of any hazardous or near-hazardous situation anywhere when such patients produce radioactive excreta which enters ordinary sewer lines, and none has occurred since nuclear medicine began in 1936. What is the point of NRC's "interest", and why should we be asked to waste our valuable professional time producing data that NRC should have had for decades? In fact, these data were finally given to NRC by us on Feb. 14, 1990 when the last American production reactor went down and Richard Cunningham needed to know the total quantity of each reactor-produced radionuclide used by nuclear medicine per year in the United States. From those data, NRC could certainly be expected to derive general sewage levels. NCRP Commentary no. 7, which NRC paid for with our User Fees, tabulated numbers of procedures of different types as of 1989. That certainly should have been good enough for the type of estimate that NRC appears to "require". Why is NRC not using this information?

For the record, I am appending data from 1990 and 1992, and adding new data on Sr-89 therapy doses.

In the fourth place, the question of saving and decaying out patient excreta is moot. We are not going to save patient excreta. It is preposterously expensive, and medical institutions would simply stop offering nuclear medicine procedures. Licenses will be dropped, User Fee revenue would decrease, a few diehard licensees would not be able to afford the resulting astronomical User Fees and they will end their programs also. NRC would have to end its nuclear medicine program, because it will have ended nuclear medicine for all intents and purposes. However, I somehow think the Congress would stop NRC before patients are jeopardized by lack of services.

Just how expensive would it be? Well, let's get some "ballpark" estimates for therapy only. This year we will perform about 56,100 nuclear medicine therapy procedures, which includes about 6,000 metastatic surveys for thyroid carcinoma. Of all those procedures only about 6,000 patients need to be hospitalized (thyroid carcinoma therapies), for an average of about two days or a total of 12,000 hospital days. If patients were hospitalized for ten effective halflives, reducing radioactivity to 1/1024 of the original administered activity, the thyroid survey and therapy patients would require 4 days, the hyperthyroid patients would require 43 days, the Sr-89 patients would require 500 days, ( $T_B$  for bone = 2000d;  $T_B$  for exchangeable

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pool  $\approx 28d$ ; Teff for bony Sr-89 =  $T_p$ ) and the P-32 patients (sodium phosphate only) would require 143 days ( $T_B = 257d$ , so Teff =  $T_p$ ). That results in a total of 12,000 (4d) + 35,000 (43d) + 8000 (500d) + 550 (143d) = 48,000 + 1,505,000 + 4,000,000 + 78,650 = 5,631,650 = 5.6 million patient days more than we have now. At a cost of about \$800/day this comes to \$4.5 billion/year. This is for only 56,100 patients, and does not even cover the cost of new plumbing facilities. Each new set of plumbing would cost at least \$100,000.

How many sets of plumbing would we need? In my 500 bed hospital this year, based on first quarter extrapolation, I will perform 32 thyroid cancer therapies, 12 metastatic thyroid cancer surveys, 72 hyperthyroid therapies, 8 Sr-89 therapies, and no P-32 therapies. That is 44 (4d) + 72 (43d) + 8 (500d) = 176 + 3096 + 4000  $\approx 7300$  patient days/year for 124 patients. With optimal bed efficiency, I would need a minimum of 1 + 9 + 11 = 21 dedicated sets of plumbing; 30 would be a bare practical minimum because optimization of bed efficiency is not possible with these patients. That comes to \$3 million for new plumbing in my hospital alone.

And where would we store all this radioactive urine and stool? Each year my hospital would collect about 4,000 gallons of radioactive urine and about 750 gallons of radioactive stool. We have insufficient storage facilities at present, and it would be very costly to build a new one.

We have not even begun to discuss diagnostic studies, of which we had 10,700,000 in 1992. Figure that about 45% of these patients are inpatients and 55% are outpatients. Eighty percent of procedures use Tc-99m, and depending on  $T_B$ , patients could leave at up to 2 1/2 days following administration, say at an average of 2 days. Gallium-67, indium-111, and thallium-201 patients would remain for about a month, and I-123 patients for 5 days, if states were foolish enough to adopt NRC's byproduct regulations for accelerator-produced radiopharmaceuticals. Very roughly, this comes to 78 million patient days at a cost of \$62 billion/year. There are about 30 million inpatients a year in the U.S.A.; we would have to add another 4.8 million for excretion collection. Essentially all the hospitals sewage would have to be held for decay. We have not even begun to discuss other contaminated body fluids, such as lacrimal and nasal fluid, saliva, sweat, and blood.

NRC had better clear this with President Clinton's healthcare reform people. I think they're going to have a problem with it.

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In the fifth place, if NRC still isn't satisfied, it could request data from sewage treatment plants in enlightened Agreement States that have been monitoring for radioactive material for years. Probably many of those "inadequate and incompatible" states have had the foresight to collect the data that NRC lacks; certainly California and New York do so. Then, when the expected GAO "exposé" is released, NRC could actually answer the GAO with valid scientific data instead of shrugs.

In the sixth place, I don't think NRC should do anything with the sewer standards because EPA will probably do it when it gets around to it, and of course override NRC. Why should we pay any User Fees to NRC at all for this when we are already paying taxes to support EPA, and will have to live with EPA's standards anyway?

In conclusion, I would suggest that before NRC litters the Federal Register with any more nuclear nonsense impacting its already severely dysfunctional "medical" program, that it review the material first with its Advisory Committee on Medical Uses of Isotopes.

Thank you for the opportunity to comment on this Advance Notice of Proposed Rulemaking.

Sincerely,



Carol S. Marcus, Ph.D., M.D.  
Director, Nuclear Med. Outpt. Clinic  
and  
Assoc. Prof. of Radiological Sciences  
UCLA  
and  
Member, USNRC Advisory Committee on Medical  
Uses of Isotopes  
and  
Chair, USFDA Advisory Panel on Radiologic Devices  
and  
Vice-President-Elect, Society of Nuclear Medicine

cc: Interested parties

CSM:sfd

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## NUCLEAR MEDICINE THERAPY PROCEDURE ESTIMATES, 1993

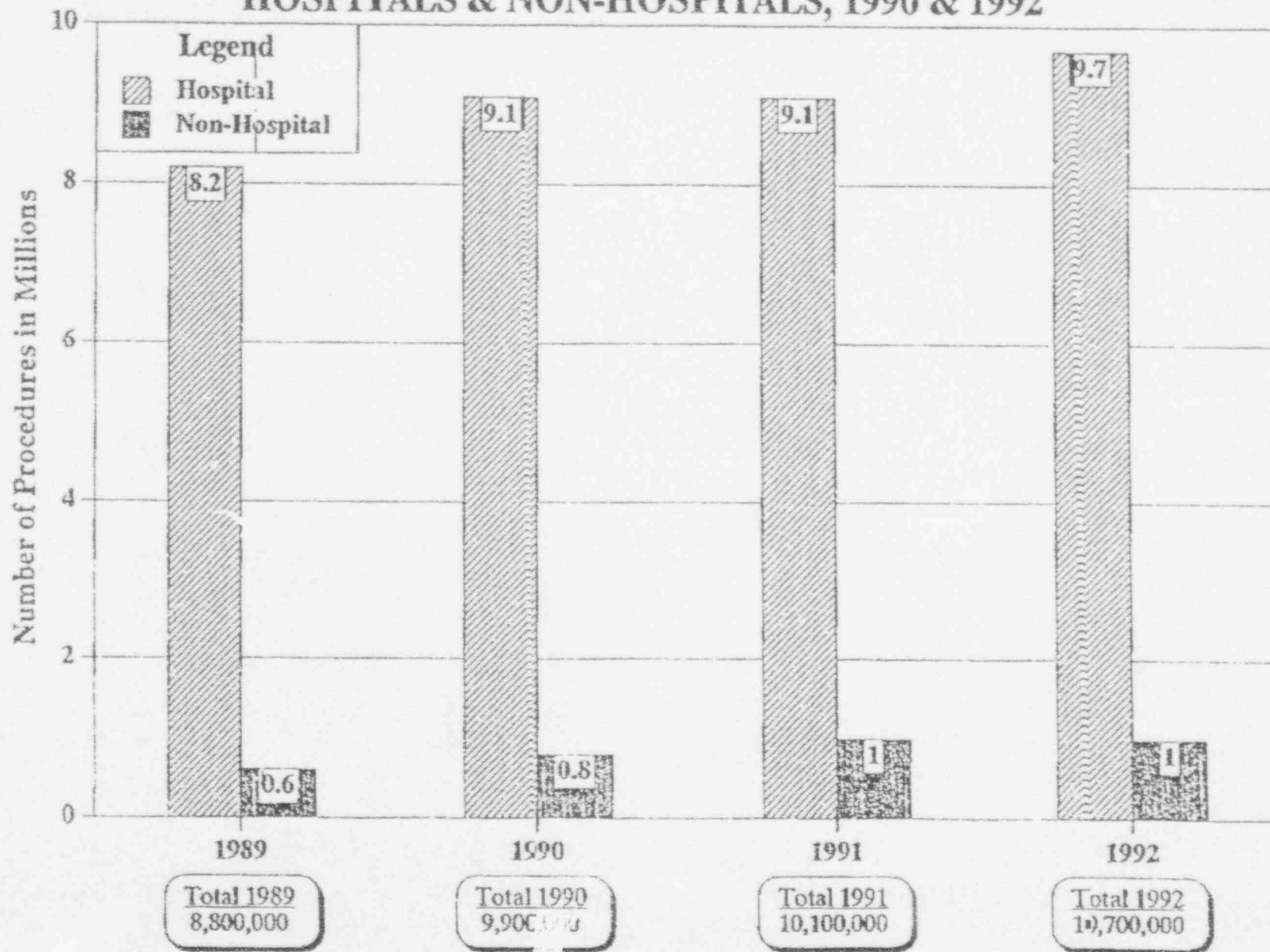
P-32: 1100/yr. For purposes of calculations in these comments I assumed that half were P-32-sodium phosphate and half were P-32-chromic phosphate.

I-131-sodium iodide: 6000 thyroid cancer ablations, 6000 metastatic surveys, and 35,000 hyperthyroid therapies. ( The total quantity of I-131 used in nuclear medicine in the United States each year is about 1 kilocurie.)

Sr-89-chloride: 8000/yr and rising to about 10,000-11,000/yr.

# TOTAL PROCEDURE VOLUMES

## HOSPITALS & NON-HOSPITALS, 1990 & 1992





Procedure Category	1988*	1989*	1990	1992
<b>HOSPITALS</b>				
Bone	2,231	2,377	3,464	3,457
Brain	68	94	120	100
Cardiovascular	2,062	2,288	2,539	3,232
Liver	446	412	474	346
Renal/Hepatobiliary	667	754	810	845
Respiratory	1,223	1,170	1,085	998
Monoclonal	0	0	0	20
Other	1,059	1,147	607	741
Total	7,756	8,242	9,099	9,739
<b>INDEPENDENTS</b>				
Bone			332	387
Brain			9	4
Cardiovascular			338	488
Liver			41	35
Renal/Hepatobiliary			40	37
Respiratory			19	17
Monoclonal			0	1
Other			60	61
Total	423**	596**	839	1,030
<b>GRAND TOTAL</b>				
Bone			3,796	3,844
Brain			129	104
Cardiovascular			2,877	3,720
Liver			515	381
Renal/Hepatobiliary			850	882
Respiratory			1,104	1,015
Monoclonal			0	21
Other			667	802
Total	8,179**	8,838**	9,938	10,769

\* Based on sampling of 350+ sites in study conducted for NEMA/SNM  
 \*\* Independent data by procedure category is not available for 1988 and 1989