DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

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The Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555

JUN 2 1994

Attn: Docketing and Service Branch

Dear Sir,

The National Institutes of Health (NIH) wishes to provide the following comments regarding the Advanced Notice of Proposed Rulemaking for "Disposal of Radioactive Material by Release into Sanitary Sewer Systems", published in the Federal Register on February 25, 1994. NIH is a large facility conducting biomedical research and medical diagnosis and treatment. Disposal of radioactive materials to the sewer is performed in accordance with existing regulations and conditions of our license with the NRC. Radioactive materials are utilized in laboratory research, which generates a large quantity of aqueous radioactive waste, and in research with patients, which generates a large volume of radioactive excreta. TABLE 1 is a list of radioactive materials received at NIH from 1989-1993. Radionuclide usage fluctuates considerably for some isotopes. New research procedures may result in large increases or decreases in the use of certain radionuclides. Yet in spite of this, NIH has been able to successfully manage the radioactive liquid wastes in accordance with existing regulations and license conditions. Any changes to the regulations that would place new restrictions or further limit this method of disposal would have a significant negative impact on NIH's radioactive waste management program and the programs of other similar research facilities.

Existing license conditions and procedures at NIH require collection of all radioactive liquid wastes from laboratories for analysis and disposal at a centralized waste management facility. Once centrally collected, radioactive liquids may be discharged to the sewer system or placed in any one of nine holding tanks (total storage volume approximately 76,000 liters) prior to discharge. The primary use of the tanks is to hold short-lived radionuclides for decay, thus minimizing the radioactivity discharged. NIH has been granted an exception to the regulations governing the total quantity of materials that may be discharged. The exception allows a total annual release limit of 296 GBq (8 Ci) for all radionuclides. This exception has been extremely beneficial in allowing NIH to successfully manage the radioactive liquid wastes generated. For example, NIH utilizes a large quantity of S-35 in conducting biomedical research (see TABLE 1). The annual quantity of S-35 alone discharged to the sewer has consistently been above 37 GBq (1 Ci) each of the past five years. Discharge of this level of radioactive materials to the sewer would not be possible if the special exception were not authorized. However, the amount of H-3 discharged is well below the 185 GBq (5 Ci) limit in the regulations (see TABLE 4). It is important to note that all discharges from NIH have been below 1% of the maximum permissible concentrations (10 CFR 20, Appendix B, Table 1, Column 2) when annually averaged for the past 5 years.

It would be beneficial to further study the issue of reconcentration of radioactive materials at sewer treatment plants (STP's). It appears, from the case studies presented in the February 25, 1994 notice, that the primary radionuclides of interest are radioactive metals or wastes that were not soluble, not the majority of radionuclides typically used in biomedical research facilities such as NIH. A determination on whether or not to further restrict the total quantity of radioactive materials released should be based on a thorough study of the treatment technologies used and radiological impact to the public that results from reconcentration of radioactive materials at the STP's or use of the STP residue in some other fashion. It may be determined that the existing limits in 10 CFR 20.2003 are overly restrictive for some radionuclides and not restrictive enough for others. Adjustments could be made that would eliminate the need for special licensing approval for exceptions to the regulations, such as the one NIH has been granted, and allow greater flexibility to licensees whose use of radioactive materials changes over time.

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Reduction in the amount of radioactive material that may be released to the sewer may present a significant financial burden to large research facilities such as NIH. It may be necessary to solidify liquid wastes for land disposal, acquire additional storage facilities such as tanks, or identify other waste treatment systems to remove the radioactivity from the liquid waste stream. For example, solidification of liquid wastes would be tremendously expensive given the current cost of disposal of solid radioactive wastes. In 1993 NIH generated 140,299 liters of aqueous liquid radioactive waste. Solidification of this volume of liquid would generate approximately 1350 55-gallon drums of solid waste. At the current cost for disposal at Barnwell, SC for out of region waste, this would represent approximately $2.8 million. It would also increase the potential for spills involving radioactive liquids and higher radiation doses to the waste technicians due to increased handling of the liquid waste.

Radioactive excreta from patients is not collected and managed as other radioactive wastes at NIH. NIH has a 450 bed research hospital and admits a large number of patients for diagnostic and therapeutic procedures each year. The majority of patients admitted at NIH for research studies receive radiopharmaceutical doses below 1.11 GBq (30 mCi) and are released with no radiation safety restrictions pursuant to 10 CFR 35.75. Some of these patients may remain in the hospital for observation with no further radiation safety restrictions on their activities. A small number of patients are administered doses greater than 1.11 GBq (30 mCi) for therapeutic treatment, primarily thyroid cancer treatment using I-131. While these patients remain under radiation safety restrictions until released pursuant to 10 CFR 35.75, no excreta is collected and managed as radioactive waste. Collection of all the excreta as radioactive waste would present a substantially increased radiation hazard to NIH employees due to the large activity administered to the patients, typically 5.55-11.1 GBq (150-300 mCi). The current method of disposal is appropriate for maintaining radiation doses to patients, nurses, and waste handling personnel ALARA.

Another consideration in deciding the appropriateness for continuing the exemption for patient excreta is the fact that the majority of the radionuclides used in human research studies have very short half-lives, typically less than 9 days. Data from May 1993 through April 1994 shows that 4,365 radiopharmaceutical doses were prepared for patient studies at NIH (see TABLE 2). Excluding Xe-133 studies (which generate no solid or liquid waste) and Sr-89 therapies, the remaining 4240 doses were of radionuclides with half lives less than 9 days. These studies accounted for 96.8% of the radioactivity. Studies utilizing Tc-99m, the shortest lived radionuclide with a half-life of approximately 6 hours, accounted for 87.7% of the total radioactivity used during this period (see TABLE 3). If these radionuclides were found to accumulate in sludge or other water treatment facility residues, the radiological impact would be negligible due to rapid decay of the radioactivity.

Removal of the patient exemption would present significant problems in conducting a biomedical research and medical diagnosis and treatment program. Questions arise such as: "Would this result in changes to 10 CFR 35.75?", "Would a patient that receives <u>any</u> radiopharmaceutical dose have their activities restricted for radioactive waste management purposes?", "Is there a significant difference in patient excretion at a licensed facility as compared to excretion at a person's home or other public location?", "How will the licensee calculate the total radioactivity released by each patient and must this information be maintained in facility records?", and "Will this result in less effective medical diagnosis and treatment if use of smaller quantities of radioactive materials is required to comply with restrictive sewer discharge limits?" If the exemption for patient excreta is removed, a significant volume of radioactive waste will result. Assuming each dose, excluding Xe-133 doses, from TABLE 2 was administered to one patient and waste from each patient is collected for a minimum of one day, using the average values of approximately 1000 ml/day of urine excretion and 135 gram/day fecal loss (ICRP 26, October 1974), the minimum amount of additional radioactive waste that would have to be collected annually is 4244 liters of urine and 55,172 grams (over 0.6 tons) of feces.

The NRC will need to consider the impact on all patient care activities if the current exemption is removed from the regulations. It is recommended that the current exemption for patient excreta be continued without further restriction.

Another topic for the NRC to consider is the disposal of radioactive animal excreta. Use of radioactive materials in animals in biomedical research studies is ongoing. Collection and disposal of animal excreta is increasingly difficult due to restrictions placed on waste generators by commercial waste processors and disposal facilities. It is common that "biological" wastes, including animal excreta, are not accepted at waste processing and disposal facilities unless they are first treated. It is logical that disposal of animal excreta to the sewer should be considered exempt as the current disposal of patients excreta is. There is no significant difference in the waste forms other than the fact that studies involving animals may use longer-lived radionuclides such as H-3, C-14, and I-125. This will ease the burden of research facilities that use a large number of animals in biomedical research.

We hope that these comments are useful for your review of this topic. Please feel free to contact me at (301) 496-2254 if you have any questions regarding these comments.

William J. Walker, Ph.D.
Radiation Safety Officer, NIH

TABLE 1
NIH - Total Annual Radioisotope Receipts, by year - GBq (Ci).

Isotope	1989	1990	1991	1992	1993
H-3	786.1 (21.245)	1207.5 (32.636)	477.6 (12.908)	451.4 (12.199)	478.3 (12.928)
C-14	9.5 (0.256)	9.9 (0.267)	10.5 (0.285)	8.2 (0.221)	8.6 (0.232)
S-35	653.6 (17.664)	708.3 (19.143)	619.1 (16.733)	663.0 (17.920)	597.2 (16.141)
P-32	799.3 (21.604)	866.7 (23.425)	892.4 (24.118)	961.0 (25.974)	899.0 (24.297)
I-125	239.2 (6.466)	244.9 (6.620)	205.1 (5.543)	176.5 (4.771)	157.9 (4.268)
I-131	453.0 (12.242)	375.7 (10.155)	291.4 (7.875)	341.0 (9.216)	217.0 (5.864)
Ga-67	72.4 (1.958)	68.0 (1.838)	77.2 (2.086)	54.8 (1.481)	67.3 (1.819)
Tc-99m	533.8 (14.426)	501.7 (13.560)	594.4 (16.066)	752.5 (20.339)	643.0 (17.378)
Ca-45	7.4 (0.201)	5.5 (0.149)	5.1 (0.138)	3.8 (0.104)	4.8 (0.129)
Cr-51	226.6 (6.123)	249.5 (6.742)	221.4 (5.983)	186.2 (5.033)	162.2 (4.383)
In-111	17.9 (0.483)	18.8 (0.507)	26.3 (0.712)	26.2 (0.708)	19.9 (0.537)
Lu-177	0.1 (0.002)	0.0 (0.0)	0.6 (0.017)	87.0 (2.350)	7.0 (0.189)
Tl-201	48.0 (1.296)	58.9 (1.593)	75.9 (2.051)	90.5 (2.445)	110.4 (2.985)
Cu-67	11.8 (0.319)	12.0 (0.323)	6.4 (0.172)	1.8 (0.049)	3.0 (0.082)
Y-90	109.3 (2.953)	153.1 (4.139)	118.0 (3.190)	59.9 (1.620)	43.3 (1.170)
Mo-99	12767.6 (345.07)	12736.9 (344.24)	12987.7 (351.02)	12549.7 (339.18)	12195.9 (329.62)
Other	327.0 (8.837)	413.1 (11.165)	407.8 (11.021)	274.4 (7.416)	273.8 (7.401)
Total	17062.3 (461.144)	17630.6 (476.502)	17017.0 (459.918)	16687.9 (451.023)	15888.65 (429.423)

TABLE 2
Radiopharmaceutical Doses Prepared - May 1993-April 1994

STUDY	DOSES	TOTAL ACTIVITY GBq (Ci)
Adrenal MIBG I-131	12	0.2 (0.006)
Bone Tc-99m	1,688	1,561.4 (42.200)
Brain Tc-99m	8	3.0 (0.080)
Cisternagram In-111	2	0.04 (0.001)
Gallium Absess/Tumor Ga-67	158	56.8 (1.535)
Venogram Tc-99m	1	0.9 (0.025)
Gastric Emptying Tc-99m/In-111	13	0.3 (0.008)
GI Bleed Tc-99m	16	14.8 (0.400)
Heart(TcO_4/PYP) Tc-99m	1,189	1,099.8 (29.725)
Heart (Sestamibi)Tc-99m	35	67.0 (1.810)
Heart Tl-201	491	72.7 (1.964)
Hepatobiliary Tc-99m	15	2.9 (0.078)
Liver/Spleen Tc-99m	22	4.9 (0.132)
Lung V/Q Xe-133	121	103.6 (2.800)
Lung MAA Tc-99m	118	17.5 (0.472)
Meckle's Tc-99m	3	1.1 (0.030)
Parotid Tc-99m	1	0.3 (0.007)
Parathyroid(TcO_4) Tc-99m	57	42.2 (1.140)
Parathyriod Tl-201	4	0.4 (0.012)
Renogram Tc-99m	31	1.1 (0.031)
Renogram I-131	51	0.3 (0.007)
Renogram MAG3 Tc-99m	37	13.7 (0.370)
Thyroid Uptake I-123	96	0.7 (0.018)
Whole Body I-131	73	13.5 (0.365)
Therapy I-131	20	149.9 (4.050)
Limb perfusion I-131	66	0.5 (0.0145)
Renal (DMSA) Tc-99m	4	0.4 (0.012)
Lymphoscintigraphy Tc-99m	16	0.6 (0.016)
Breast (Sestamibi) Tc-99m	13	9.6 (0.260)
Therapy Sr-89	4	0.6 (0.016)
Totals	4,365	3,240.6 (87.585)

TABLE 3
Radiopharmaceutical Doses
BREAKDOWN BY ISOTOPE

ISOTOPE	DOSES	ACTIVITY GBq (Ci)
Tc-99m	3263	2841.6 (76.800)
Tl-201	495	73.1 (1.976)
In-111	6	0.05 (0.0014)
Ga-67	158	56.8 (1.535)
Xe-133	121	103.6 (2.800)
I-131	222	164.4 (4.442)
I-123	96	0.7 (0.018)
Sr-89	4	0.6 (0.016)
Totals	4365	3240.2 (87.572)

TABLE 4
Annual Radioactive discharges from NIH - GBq (Ci)

Nuclides	1990	1991	1992	1993
H-3	109.4 (2.956)	91.5 (2.473)	101.0 (2.730)	112.2 (3.032)
C-14	2.1 (0.056)	1.2 (0.032)	1.0 (0.026)	1.2 (0.032)
All others	107.8 (2.914)	152.2 (4.114)	131.1 (3.543)	79.2 (2.141)