Lilly

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May 25, 1994

VIA FEDERAL EXPRESS

The Honorable Samuel J. Chilk
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
Attention: Docketing and Service Branch

Re: Comments or the Advance Notice of Proposed Rulemaking ("ANPR") as Published in 59FR 9146-9149 (February 25, 1994)

Dear Secretary Chilk:

Eli Lilly and Company ("Lilly") is a global, research based corporation that develops, manufactures, and markets pharmaceuticals, medical instruments, diagnostic products, and animal health products. Lilly is a Nuclear Regulatory Commission ("NRC") licensed research facility. Lilly is responding to the NRC's February 25, 1994, request for comments and information (the "Request") as it evaluates its options for providing additional or alternative means of regulatory control over radioactive material releases into sanitary sewers. See 59 FR 9147.

Lilly respectfully requests that the Commission consider and incorporate herewith the comments Lilly submitted on December 23, 1993, in response to the Northeast Ohio Regional Sewer District ("NORSD") petition published in the October 20, 1993 Federal Register (Lilly's comments are attached as Exhibit A). As explained within the following specific comments, it remains Lilly's position that it is not necessary, feasible or appropriate for the NRC to exercise additional means of regulatory control over disposal of radioactive material into sanitary sewers. See 10 CFR Part 20; Clean Water Act, 33 U.S.C. §1317(b) and (d) and §1319; See also EPA Clean Water Act Standards, 40 CFR Part 403 (national pre treatment standards for the control of pollutants which may adversely affect treatment processes). However, Lilly does support the alternative, sole use of concentration limits for measuring a licensee's limits for disposal of radioactive material into sanitary sewers.

1) Form of Material for Disposal

> The NRC invited comments on: (a) to what extent and how NRC regulations should take into account the technologies for processing sewage, and (b) the potential impacts on licensee's operations associated with any additional restrictions regarding the forms of materials suitable for dispersal [sic].

Based upon the arguments fully set forth in Exhibit A, it is Lilly's position that the NRC does not need to take into account the technologies for processing sewage. The Clean Water Act requires an NRC licensee to establish an appropriate pre treatment program if its pollutants may cause interference with the processing technology used by its waste water treatment plant. 40 CFR 403.8(a). Each local waste water treatment plant has the authority and mandate to ensure local industrial water permit limits are appropriately developed and enforced. 40 CFR 403.5(c)(1). As the NRC indicates in its Request, sewer treatment and sewer treatment technologies are very localized issues. These local issues have been and will continue to be fully regulated pursuant to the Clean Water Act. Further regulation by the NRC will be costly, confusing and unduly burdensome for the licensees that currently comply with existing NRC and EPA regulations.

If additional restrictions are imposed by the NRC regarding the forms of materials suitable for disposal, Lilly will experience (1) severe economic impact (new collection, storage, handling and disposal costs, retraining of personnel, etc.); and (2) increased personnel exposure due to the elimination of direct sewering disposal. In addition, although the NRC mentions its newly enforceable (1/1/94) standards found in 10 CFR Part 20 which narrow the forms of radioactive materials that may be permitted for disposal into sanitary sewers, the NRC fails to acknowledge that enforcement of the new standards may have eliminated the incidents described in the Request.

2-3) Total Quantity of Material/Type of Limits

> The NRC invited comments on: (a) the acceptability of the total quantity approach and whether a total quantity to be released should be specified or otherwise limited; and (b) whether it should consider limitation using a dose limit approach, and provide total quantity and concentration values in a Regulatory Guide to facilitate compliance with the dose limit.

It is Lilly's position that any efforts to further regulate sewer disposal of radioactive material must consider the dose to the public. Although the NRC has described a limited number of incidents where radioactive materials have concentrated, those situations (a) were not in compliance with the newly enforceable standards; (b) were not representative of the overwhelming majority of sewer disposal situations; and (c) did not recognize that the dose to the public from sewer disposal of H-3 and C-14 is a very small fraction of the dose already received from the natural presence of the two nuclides in the environment.

Lilly urges the NRC to compare the total quantity limit of 5 Ci per year sewer disposal for H-3 to its global (natural production) inventory per year of 70,000,000 Ci. See National Council for Radiation Protection and Measurement (NCRP) Report 62. Approximately 663,000,000 Ci of H-3 is projected to be released from natural production, atmospheric weapons testing, and nuclear power plants. NCRP Report 62 estimates the absorbed dose in tissue to man from the natural production of H-3 to be 0.0012 mrad/year. Based upon the current limits, any dose rate to the public from the sewer disposal of H-3 from NRC licensed facilities will be much less. In addition, compare the total quantity limit of 1 Ci per year sewer disposal for C-14 to the C-14 global inventory of 3,800,000 Ci. NCRP Report 81. The natural C-14 inventory corresponds to a annual dose of 1.25 mrad/year, or about one percent of the total annual background of 100 mrad/year. NCRP Report 81 also states that the dose from all C-14 waste sources other than naturally produced C-14 is insignificant. Therefore, any effort to lower the amount of permitted releases to sewers would have no measurable effect on the amount of H-3 or C-14 in the environment and/or the dose rate to the public.

The current method of total quantity limits ("TQL") is arbitrary and should be eliminated. The TQL method does not take into account the volume of sewer flow at a large facility. As the Request demonstrates, in unique situations, the TQL method has not prevented the concentration of radionuclides in certain sewage treatment facilities. In the alternative, the concentration limit method takes the volume flow of the sanitary sewer into consideration. Concentration limits for sewer disposal are specific to the radionuclide and could easily include modifying factors for radioactive materials that have been shown to be a problem for sewer treatment plants (i.e. heavy metals). Radioactive materials with no history of causing problems for the waste water treatment technology (e.g. H-3 and C-14) would be held to the concentration limit and would not need any modifying factors. Therefore, it is Lilly's position that the NRC should adopt the concentration limit method as the sole method used to limit the sewer disposal of radioactive material.

Conclusion

For the foregoing reasons, the NRC should not use national rulemaking to address isolated problems associated with industrial users' interference or pass through of radionuclides at waste water treatment plants. However, in order to better assist the localities as they develop and enforce the required local pre treatment limits/conditions, the NRC should move from the use of total quantity limits to concentration limits and concentration limits with modifying factors as the sole type of limits used for NRC permitted releases to the sanitary sewer.

Lilly would be pleased to discuss these comments at your convenience. Please contact Stanley Hampton, Assistant Radiation Safety Officer at (317) 276-7862 with any questions.

Sincerely,

ELI LILLY AND COMPANY

Martha Carter Bhatti, Ph.D.
Radiation Safety Officer

Eli Lilly and Company

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December 23, 1993

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
Attention: Docketing and Service Branch

Comments on the Petition for Rulemaking Presented by Northeast Ohio Regional Sewer District as Published in the October 20, 1993, Federal Register

Dear Secretary of the Commission:

In 58 Fed. Reg. 54071 (October 20, 1993), the Northeast Ohio Regional Sewer District's Southerly wastewater treatment plant ("Southerly") petitioned the Nuclear Regulatory Commission ("NRC") for a rulemaking, which it is allowed to do under the Administrative Procedures Act ("APA") and 10 C.F.R. 2.802. Specifically, Southerly requested that existing NRC regulations be revised:

1. to require 24-hour advance notice to the local wastewater treatment plant from all NRC licensees prior to discharging radioactive waste or materials containing radioactive waste into a sanitary sewer system; and

2. to exempt incineration of sanitary waste streams from NRC's current ban against incinerating radioactive waste without first obtaining NRC approval (i.e., a license).

Eli Lilly and Company ("Lilly") is responding to the NRC request for comments on the appropriateness of Southerly's petition. Lilly's comments pertain only to Southerly's request for 24-hour required notice prior to disposal of radioactive wastestreams, which we believe should be denied.

Implicit in Southerly's argument for rulemaking is that advance notice to wastewater treatment plants is necessary to protect the public and to ensure proper functioning of such plants. Southerly provides as support for this position its own experience of not knowing until recently that its wastewater treatment plant had been contaminated by years of exposure to accumulated industrial discharges containing Cobalt-60. As further support, Southerly cites a few plants elsewhere in the United States which may be experiencing similar problems. See 58 Fed. Reg. at 54071.

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EXHIBIT A

Lilly believes that Southerly's petition is nothing more than a veiled attempt to get the NRC to fix a problem that Southerly by law was supposed to previously investigate and guard against and which Southerly could have corrected and still can correct on its own through existing regulatory authority regardless of whether NRC denies Southerly's request for additional rulemaking. Lilly's position derives from the following arguments: the Clean Water Act requires (and has always required) Southerly to prohibit discharges of radioactive waste that cause environmental problems, meaning Southerly not only has the means currently to prevent or limit further discharges of Cobalt-60 but that Southerly's problem was caused by Southerly's failure to follow Clean Water Act requirements and not because the NRC's rules do not require advance notice of radioactive discharges; in any event, the Clean Water Act already requires industrial discharges to provide notice to wastewater treatment plants upon discovery of potential problems or excessive discharges; the discharges which Southerly wants notice concerning are made only pursuant to NRC licenses containing limits that protect public health; and Southerly's petition, if granted, would result in a national rulemaking as a solution to a local problem that should be corrected instead through case-by-case licensing. Furthermore, Southerly's petition, if granted, would impose unnecessary yet significant burdens on those industrial dischargers and wastewater treatment plants which, through compliance with existing Clean Water Act and NRC regulations, are not experiencing the problems which Southerly and, at most, a few other plants have endured.

A. Implications for Southerly's Petition Created by the Clean Water Act

1. Pretreatment Programs

Under 40 C.F.R. Part 403, wastewater treatment plants must implement EPA's national pretreatment standards in a way to control pollutants that are discharged by industrial users of a sanitary sewer system from adversely affecting these plants' treatment processes. Pursuant to 40 C.F.R. 403.5, under any circumstance, "a user may not introduce into a [wastewater treatment plant] any pollutants which cause pass through or interference" or which might contaminate the plant or the sewage sludge that is generated. Each plant, such as Southerly, which handles a total design flow of greater than 5 million gallons/day[1] and which receives from industrial users pollutants that might cause interference is required by the Clean Water Act to establish a pretreatment program. 40 C.F.R. 403.8(a). In order to fulfill this obligation, the wastewater treatment plant "shall" develop local water permit limits for the appropriate industrial dischargers or users of the sanitary sewers. If the plant, in working with the local permitting agency, does not impose such limits then it is required to demonstrate that such limits are unnecessary. 40 C.F.R. 403.8f(4). Each

[1]The Southerly treatment plant is designed to handle 175 million gallons/day of wastewater.

wastewater treatment plant required to develop a pretreatment program "shall . . . enforce specific limits to implement the prohibition against interference." 40 C.F.R. 403.5(c)(1). In fact, the wastewater treatment plant is required to continue developing local industrial water permit limits and to provide for more effective enforcement "as necessary." Id. Thus, plants not creating and enforcing such pretreatment programs contravene Clean Water Act requirements and subject those plants to administrative or judicial action by EPA for penalties and/or an injunction. See 33 U.S.C. §1317(b) and (d); §1319.

The fact that Southerly has a Cobalt-60 problem is probably due to Southerly's failure to create a sufficient pretreatment program. If Southerly had an effective program and had done sufficient research into the wastestreams of its industrial users, or required those users to provide the necessary data, then the Cobalt-60 contamination should never have occurred. Thus, it appears Southerly is trying to get the NRC to adopt nationwide procedures that Southerly should have already instituted on a local level under the Clean Water Act.

Regardless of why the Cobalt-60 problem exists, it is clear that Southerly under 40 C.F.R Part 403 possesses sufficient legal authority to require its users to provide advance notice. In fact, this authority is broader--Southerly can (and probably should) impose appropriate limits on Cobalt-60 discharges and check to see whether those disposing it are licensed by the NRC.[2] Thus, there is no need for Southerly's petition for rulemaking.

2. Notice

Sufficient requirements for notice to wastewater treatment plants are currently contained in EPA's Clean Water Act rules, which is yet another reason Southerly's request for an NRC rulemaking is unnecessary. EPA requires "immediate notice to the local wastewater treatment plant when an industrial user suspects (not knows of) an ongoing or immediate violation of its water permit. See 40 C.F.R. 403.12f (users "shall notify the [wastewater treatment plant] immediately of all questions that could cause problems to the [plant], including any slug loadings"). Furthermore, EPA requires industrial users who learn of a previous violation to contact the wastewater treatment plant within 24 hours of becoming aware of such violation. 40 C.F.R. 403.12g(2).

Thus, Southerly should be receiving sufficient notices to address its Cobalt-60 problem. As seen above, it can certainly require these notices if they have not been forthcoming.

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[2]If these industrial users do not possess appropriate NRC licenses, then Southerly (and the NRC) under existing law can enforce against these users. No new rulemaking would be needed from the NRC to accomplish this.

The only notices that Southerly needs are those already required by EPA. EPA requires industrial users to alert their treatment plants to possible problems immediately and to report all violations. There is no general need[3] to require advance notice of discharges that otherwise comply with both the user's water permit effluent limits and the user's NRC license. These permits are required to have limits that are safe. If the wastewater treatment plant is concerned about discharges complying with these limits, it ought to reopen the permit and establish new limits rather than impose a notice requirement on every industrial discharger in the United States.

B. Implications for Southerly's Petition Presented by NRC Rules

The NRC is required by its enabling legislation to regulate generators and disposers of radioactive materials and wastes such that public health and the environment are adequately safeguarded. See, e.g., 58 Fed. Reg. at 54071 (NRC admits it is charged with establishing standards for protection against ionizing radiation resulting from the activities conducted by [NRC] licensees."). In 10 C.F.R. 20.303 and 10 C.F.R. 20.2003, the NRC imposes extremely stringent requirements on those who would discharge radioactive wastes into a sanitary sewer system (i.e., one year total may not exceed one curie per pollutant). These limits even account for a source's daily, monthly, and yearly sewer flows. And before these discharges can be made, the source must obtain prior approval from the NRC in the form of a license.

Clearly, Southerly's petition requests advance notice of only licensed discharges; unlicensed discharges of radioactive waste are not allowed by the NRC (or EPA) and no one would argue that the legal means to prevent such discharges does not already exist. Given that only licensed discharges are focused on by Southerly, there is no need for advance notice for discharges that meet the conditions of the NRC license. Through public notice and comment, that license with all of its conditions was legally issued for the source and it represents a safe allowable loading. In fact, there is no real benefit from requiring advance notice of discharges that comply with the source's license. The local wastewater treatment plant operators are not likely to possess the expertise to evaluate the risk of a source's radioactive discharge. Undoubtedly, they would defer to what the NRC said is safe in the source's license.

Furthermore, the NRC overprotects public health and the environment when it issues licenses to sources disposing of radioactive materials. For

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[3]The only time advance notice would be appropriate would be if the wastewater treatment plant, in order to adequately handle certain radioactive discharges, needs to take precautionary measures or alter its normal treatment processes. Southerly's request is not limited in this regard. Even if these facts did exist for Southerly, it would be due to a local problem not justifying a national rulemaking.

example, in NRC Regulatory Guide 8.37 "ALARA Levels for Effluents from Materials Facilities" (July 1993), the NRC sets as a goal that sources discharge no more than 10-20 percent of their otherwise allowable limits. These ALARA (as low as reasonably achievable) goals are often included as enforceable conditions in NRC licenses.

Consequently, the only notice needed by Southerly is notice of a violation or imminent violation of a NRC license or water permit, and this notice is already required under the Clean Water Act.

C. Implications for Southerly's Petition Due to Application of General Administrative Legal Principles

In denying Southerly's petition for rulemaking, nothing in the APA or NRC's own regulations would require the NRC to act further. Courts do not, except in unusual circumstances, such as an agency being arbitrary and capricious, question an agency's denial of rulemaking. See e.g., Arkansas Power & Light Co. v. ICC, 725 F.2d 716 (D.C. Cir. 1984) (stated that courts will compel agencies to institute rulemakings only in an "extremely rare instance"). As long as the NRC in denying Southerly's petition explains the facts and policy the denial relies upon and shows that the facts have some basis in the record, courts will defer to the NRC's decision. See also Heckler v. Chaney, 470 U.S. 821 (1985) (Supreme Court refused to reopen the FDA's decision not to enforce against a potential violator).

More importantly, courts are clear that it is inappropriate to convert a local problem into the need for a national rulemaking and that an agency will always be justified in denying a petition to do so. In Arkansas Power & Light, the ICC denied such a petition and was upheld by the court. The court stated that the "case for deference to the agency's decision not to undertake rulemaking is made even stronger where the alternative is not maintenance of the status quo but the formulation of standards via case-by-case adjudication." 725 F.2d at 723. Thus, rulemaking should be initiated, and, even in those rare cases where an agency ignored its responsibilities, will only be required when a national issue is presented which necessitates uniform, widespread and binding enforcement.

Southerly may argue that its petition does not involve case-by-case considerations and that notice should always be required. But, to the contrary, Southerly's petition is merely a mask for what is a localized problem affecting that plant.[4] Southerly does state that in seven other locales wastewater treatment plants have encountered problems similar to

[4]In fact, Southerly's problem is with the discharge of a single pollutant not generally generated by most NRC licensees: Cobalt -60. This is further reason not to engage in a national rulemaking for all pollutants and all industrial users.

its own. 58 Fed. Reg. at 54071. However, Southerly fails to point out that the hundreds of other wastewater treatment plants in the United States do not experience this problem of contamination. There are significant burdens associated with requiring advance notice as desired by Southerly. The overwhelming majority of wastewater treatment plants (and their industrial users) who have effective pretreatment programs should not be forced to incur additional time-consuming responsibilities in order to provide federal assistance to a minority of plants who have failed to establish effective pretreatment programs. The Arkansas Power & Light court, in part, upheld the ICC's denial of rulemaking because of this concern. 725 F.2d at 722 ("development of a nationwide database [here] is unnecessarily cumbersome because it would require numerous railroads, operating both efficiently and inefficiently, to provide data that might never be used.") (emphasis added)

Just as in Arkansas Power & Light, Southerly's petition for rulemaking would result in sources reorganizing their business to provide notices to wastewater treatment plants that will not provide meaningful information; the notices will only inform the plants that a discharge in compliance with the source's water permit and NRC license is forthcoming. Some of the burdens and consequences associated with this unnecessary rule include the following:

1. the wastewater treatment plant will have to devote resources to process and review notices that are submitted;

2. the industrial user will no longer be able to sewer directly in compliance with its permit but will instead need to take steps to collect and store the radioactive material until 24 hours have passed;

3. storage and handling will be time-consuming and expensive (Lilly would need to hire one more full time employee and spend over $30,000 for storage containers);

4. requiring the industrial user to collect its effluent containing radioactive material prior to discharge will serve to concentrate the radiation involved and expose more people to the material than would otherwise be exposed if direct sewering had occurred; and

5. if in order to avoid dealing with a mandatory notice requirement, the wastewater treatment plant decides to prohibit all discharges of radioactive waste, Lilly estimates it would incur $425,000/year more in disposal fees and would have to hire and train two new employees in order to convert the liquid waste into absorbed solids placed in disposable drums.

Finally, EPA has been clear that the details of any problems associated with industrial users' interference or pass through of pollutants at wastewater treatment plants should not be dealt with through a national rulemaking. Instead, EPA requires states and wastewater treatment plants to develop local pretreatment limits and conditions on an individualized basis. See, e.g., 55 Fed. Reg. 30082, 30105 (July 24, 1990) ("EPA's experience in developing and overseeing the pretreatment program has led it to believe that individual control mechanisms are the best way to ensure compliance with applicable pretreatment standards, requirements [and prohibitions].")

Conclusion

For the foregoing reasons, the NRC should deny the Southerly petition for a rulemaking that would require all wastewater treatment plants to impose an obligation on industrial users to provide 24-hour advance notice of discharge of radioactive materials to sanitary sewer systems. If the NRC nonetheless decides to initiate rulemaking, even though the Clean Water Act already provides the legal protection Southerly says it needs, then the rule finally adopted by the NRC should only allow (not require) wastewater treatment plants to obtain advance notice if, in their discretion, a local situation justifies it.

Lilly would be pleased to discuss these comments at the Secretary of the Commission's convenience. Please contact the undersigned at (317) 276-3753 with any questions.

Sincerely,

ELI LILLY AND COMPANY

David R. McAvoy

David R. McAvoy
Attorney

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