POLICY ISSUE (Notation Vote)

November 30, 2004 SECY-04-0226

FOR: The Commissioners

FROM: Luis A. Reyes

Executive Director for Operations /RA/

<u>SUBJECT</u>: DENIAL OF PETITION FOR RULEMAKING (PRM-20-22) SUBMITTED

BY THE NORTHEAST OHIO REGIONAL SEWER DISTRICT

PURPOSE:

To request Commission approval to deny a petition for rulemaking submitted by the Northeast Ohio Regional Sewer District (the District or the petitioner).

SUMMARY:

The District filed a petition for rulemaking (dated August 2, 1993, Docket No. PRM-20-22), requesting that the U. S. Nuclear Regulatory Commission (NRC) amend its regulations to require licensees to provide no less than 24 hours advance notice to the appropriate sewage treatment plant prior to releasing radioactive material into the sanitary sewer system, and to exempt radioactive materials that entered the sanitary waste stream from the requirements regarding NRC approval for incineration. Because there were concerns raised on the broader issue of long-term effects of releases of radioactive materials into sanitary sewer systems, resolution of the petition was deferred until studies were conducted regarding potential radioactive contamination in sewage sludge. NRC took several initiatives including publishing an Advance Notice of Proposed Rulemaking (ANPR) in the *Federal Register* to solicit public comments and undertaking several studies on issues associated with the disposal of radioactive material into sanitary sewer systems. NRC has participated in the Interagency Steering Committee of Radiation Standards (ISCORS) and has co-chaired with the U.S.

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Environmental Protection Agency (EPA) the Sewage Sludge Subcommittee to facilitate a systematic and thorough study of the potential concerns related to radionuclides in sewage sludge, and to obtain data to support a technical basis for a potential regulatory decision. In November 2003, ISCORS issued a final report, entitled "ISCORS Assessment of Radioactivity in Sewage Sludge: Radiological Survey Results and Analysis," (NUREG-1775). ISCORS is in the process of finalizing two other reports, entitled "ISCORS Assessment of Radioactivity in Sewage Sludge: Modeling to Assess Radiation Doses" and "ISCORS Assessment of Radioactivity in Sewage Sludge: Recommendations on Management of Radioactive Materials in Sewage Sludge and Ash at Publicly Owned Treatment Works." The ISCORS reports concluded that no excessive concentrations of radioactive material were observed in the sewage sludge or ash and that no widespread concern to public health and safety was identified. Based on the findings, the staff is recommending that the Commission deny the petition.

BACKGROUND:

By letter dated August 2, 1993, the District submitted a petition requesting that NRC amend its regulations in 10 CFR 20.2003 to require that all licensees provide no less than 24 hours advance notice to the appropriate sewage treatment plant before releasing radioactive material into the sanitary sewer system. The District also requested that NRC amend 10 CFR 20.2004 to exempt radioactive materials that enter the sanitary waste stream under 10 CFR 20.2003 from the requirements regarding NRC approval for incineration.

The petitioner stated that the District's Southerly Wastewater Treatment Center has been contaminated from releases of radioactive material containing cobalt-60 into its sanitary sewer system, resulting in costly characterization and remediation. The petitioner also noted that NRC had documented radioactive contamination problems at other sewage treatment sites. A copy of the District's petition is provided as Attachment 1. No supplementary information nor supporting data were provided with the petition.

On October 20, 1993, NRC published a notice of receipt of the District's petition in the *Federal Register* (58 FR 54071). Twelve comment letters were received prior to January 3, 1994, when the comment period was closed. A full accounting of the public comments is presented in the *Federal Register* notice for denial of the petition (Attachment 2).

NRC changed the release criteria and reduced concentration limits for releases of licensed material into sanitary sewer systems as part of a major revision to 10 CFR Part 20 (56 FR 23360; May 21, 1991). The licensees were allowed to defer the implementation of the changes until January 1, 1993. The contamination at the District's facility was discovered in April 1991 prior to the revised concentration limits being fully implemented. NRC recognized the lack of data on the issue raised by the petitioner, and wanted to gain a nationwide perspective on the potential issue of the licensed material being concentrated in sewage sludge. More data were necessary to assess the effectiveness of the new regulation in protecting public health and safety, and in avoiding future radionuclide contamination in sewage sludge.

On February 25, 1994, NRC published an ANPR in the *Federal Register* (59 FR 9146) to solicit public input on whether NRC regulations needed to be amended regarding releases of radionuclides from NRC licensed facilities into sanitary sewer systems, based on current sewer

treatment technologies. The ANPR also noted the receipt of a petition submitted by the District and specifically solicited public comments on the two rulemaking changes requested in the petition. A total of 73 comment letters were received on the ANPR prior to May 26, 1994, when the comment period was closed. About one-third of the comment letters related to the District's petition.

DISCUSSION:

Public Comments from Notice of Receipt (58 FR 54071; October 20, 1993)

Twelve comment letters were received in response to the publication of the notice of receipt of the District's petition. Ten of the 12 comment letters addressed the District's request for NRC to amend its regulations to require that all licensees provide at least 24-hour advance notice to the appropriate sewage treatment plant before releasing radioactive material into a sanitary sewer system. Three commenters supported the amendment; one commenter supported the intent of the petition without endorsing a rulemaking; and the other six commenters did not support the amendment.

Eight of the 12 letters commented on the District's request for NRC to amend its regulation to no longer require NRC approval prior to treatment or disposal of licensed material by incineration, if those licensed materials have entered the sanitary sewage system under 10 CFR 20.2003. Two commenters were supportive of this part of the petition while the rest opposed a change in NRC's regulations.

Public Comments from ANPR (59 FR 9146; February 25, 1994) Related to PRM-20-22

Additional comments regarding the District's petition were received through the public comment process for the ANPR. Among 73 comment letters received, 21 included comments on the District's request for NRC to amend its regulations to require that all licensees provide at least 24-hour advance notice to the appropriate sewage treatment plant before releasing radioactive material into a sanitary sewer system. Six commenters supported some type of reporting requirements for licensees to inform the sewage treatment plant of releases of licensed materials into the sanitary sewer system; the other 15 commenters did not support the petitioner's proposed amendment.

There were six comment letters that addressed the District's request for NRC to amend its regulations to no longer require NRC approval prior to treatment or disposal of licensed material by incineration. Four commenters supported the petition, and two opposed the petitioner's proposed change.

GAO Report and Congressional Interest

In May 1994, the U.S. General Accounting Office (GAO, now the U.S. Government Accountability Office) issued a report, "Nuclear Regulation: Action Needed to Control Radioactive Contamination at Sewage Treatment Plants," that described nine cases, including the District, where contamination was found in sewage sludge or ash or in wastewater collection systems (GAO/RCED-94-133). On the basis of the limited information available on radiation levels in sewage sludge and ash across the country, GAO concluded that the full extent of

contamination nationwide is unknown. The GAO also concluded that the "problem of radioactive contamination of sludge and ash in the reported cases was the result, in large part, of NRC's regulation, which was incorrectly based on the assumption that radioactive materials would flow through treatment systems and not concentrate." The GAO report did note that to address the problem of radioactive materials concentrating in sludge and ash, NRC has revised its regulation to reduce the concentration levels of the radioactive materials that licensees can discharge into sanitary sewer systems, although the GAO report also pointed out that "NRC does not know how effective this action will be." The GAO report said that health implications of the exposure of treatment plant workers and the public to contaminated sludge, ash, and related by-products are unknown because neither NRC nor EPA knows (1) how much radioactive material may be in these products and (2) how these products might affect people.

In June 1994, a joint U.S. House of Representatives and Senate hearing (June 21, 1994; S. Hrg. 103-1034) was held to officially release and address questions raised in the GAO report. These hearings were prompted by concerns associated with elevated levels of radioactivity in incinerator ash at the Cleveland treatment plant referenced in the District's petition. During the hearing, the testimony presented by both NRC and EPA noted that there was no indication of a widespread problem, and that the District's incident appeared to be an isolated event. However, at the hearing, NRC and EPA committed to jointly develop guidance for publicly owned treatment works (POTWs) and to collect more data on the concentration of radioactive materials in samples of sewage sludge and ash from POTWs nationwide.

Efforts Related to Sewage Sludge Studies

NRC examined doses to POTW workers and members of the public from exposure to radionuclides in sewage sludge in NUREG/CR-5814, "Evaluation of Exposure Pathways to Man from Disposal of Radioactive Materials into Sanitary Sewer Systems," dated May 1992. It was found that doses from licensed material were generally within regulatory limits. However, the 1992 analysis examined only a few known cases in which radioactive materials were detected at POTWs.

Between 1994 and 1997, Federal, State, and industry studies were conducted to assess reconcentration of radioactive materials that are released into sanitary sewer systems. The possibility of the reconcentration of radioactive materials within a wastewater treatment plant was assessed in a December 1994 report, NUREG/CR-6289, "Reconcentration of Radioactive Material Released to Sanitary Sewers in Accordance with 10 CFR Part 20." Although it was found that radioactive materials were reconcentrated as a result of wastewater treatment, the extent of the issue was difficult to determine because the degree of reconcentration was radionuclide-specific and was influenced by the wastewater treatment processes used. The report concluded that the available data were not sufficient to assess the adequacy of 10 CFR 20.2003 in preventing occurrences of radionuclide concentrations in sewage sludge at levels that presented an undue risk to the public; nor were the available data sufficient to suggest strategies for changing the regulations.

The Association of Metropolitan Sewerage Agencies (AMSA) conducted a limited survey of concentrations of radioactivity in sewage sludge and ash samples from some of its member POTWs in 1996. The AMSA survey of 55 wastewater treatment plants in 17 States found that the most significant sources of radioactivity were naturally occurring radioactive materials

(NORM). In 1997, the Washington State Department of Health issued a report, WDOH/320-013, "The Presence of Radionuclides in Sewage Sludge and Their Effect on Human Health." The report concluded that doses from radionuclides in sewage sludge are extremely low compared to background or to generally accepted regulatory dose limits; and that there is no indication that radioactive materials in sludge pose a public health and safety risk. Findings from these documents did not show any significant concerns of radioactive material in sewage sludge; however, their scope was limited. Therefore, an extensive, nationwide survey was needed to confirm the findings from these documents on a wider scale.

ISCORS Efforts Related to Sewage Sludge

ISCORS was formed in 1995 to address inconsistencies, gaps, and overlaps in current radiation protection standards among Federal, State, and local agencies. In 1996, ISCORS formed a Sewage Sludge Subcommittee to coordinate specific efforts concerning radioactive materials in sewage sludge and to address the recommendations in the 1994 GAO report. Several Federal, State, and local agencies participated in the Sewage Sludge Subcommittee. A representative from the District was and still is a member of the Sewage Sludge Subcommittee. The District representative participated in the development of survey and dose modeling and was involved in the preparation of the associated ISCORS reports.

Between 1998 and 2000, the Sewage Sludge Subcommittee conducted a voluntary survey of POTW sewage sludge and ash to help assess the potential need for NRC and/or EPA regulatory decisions. In November 2003, the results of the survey were published in a final report, NUREG-1775, "ISCORS Assessment of Radioactivity in Sewage Sludge: Radiological Survey Results and Analysis." The survey results indicated that the majority of samples with elevated radioactivity were attributable to NORM, such as radium, rather than man-made sources. With the exception of NORM, most of the radioactive materials in sewage sludge were at or near the detection limits. No excessive concentrations of radioactive materials were observed in sludge or ash.

The Sewage Sludge Subcommittee is in the process of finalizing two other reports. One draft report, NUREG-1783, "ISCORS Assessment of Radioactivity in Sewage Sludge: Modeling to Assess Radiation Doses," contains computer modeling information, sewage sludge management scenarios, and calculated doses. Using survey results with the dose modeling, the calculated doses showed that there is no widespread concern to public health and safety from potential radiation exposures associated with the handling, beneficial use, and disposal of sewage sludge containing radioactive materials including NORM. The other draft final report, EPA 832-R-03-002B, "ISCORS Assessment of Radioactivity in Sewage Sludge: Recommendations on Management of Radioactive Materials in Sewage Sludge and Ash at Publicly Owned Treatment Works," provides general guidance for a POTW if it encounters a concern with radioactive materials in its sewer systems. For example, the ISCORS is recommending that POTW operators take certain mitigative measures if radium gets concentrated to an elevated level in the sewage sludge. Both reports are expected to be finalized by the end of 2004.

Disposition of Petition's Request to Amend 10 CFR 20.2003

In its petition, the District argued that the regulations in 10 CFR 20.2003 should be amended to require licensees to notify the appropriate sewage treatment facility no less than 24 hours in advance before releasing radioactive materials into a sanitary sewer system. The staff has considered the petition and its stated rationale. For the reasons set forth in a draft *Federal Register* notice (Attachment 2) and summarized in this section, the staff recommends that the Commission deny the petition.

Although the revised Part 20 regulation (56 FR 23360, May 21, 1991) became effective on June 20, 1991, the licensees were allowed to defer the implementation of the changes until January 1, 1993. Therefore, the revised concentration limits for radionuclides released into a sanitary sewer system were not fully implemented at the time of discovery of the contamination at the District's Southerly Wastewater Treatment Center. NRC regulatory requirements including effluent limits from NRC-licensed activities are established to ensure public health and safety. In addition, NRC recommends that licensees should set "as low as is reasonably achievable" (ALARA) goals for effluents at a modest fraction of their allowable limits as stated in NRC Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," dated July 1993 to further reduce radionuclide concentrations released into a sanitary sewer system.

The rationale that public health and safety would be enhanced by the advance notification was not supported. The petitioner did not provide any supporting data on the need for such a notification requirement. Both the ISCORS survey report and the dose modeling report have shown that doses from radionuclides in sewage sludge are generally low compared to background and to generally accepted regulatory dose limits. On a national level, the most significant levels of radioactivity in POTWs are associated with NORM, rather than licensed material. The District's proposed amendment is not necessary to ensure protection of public health and safety and the environment from licensed activities. A regulatory burden that would impact thousands of licensees with no apparent benefit regarding public health and safety should not be imposed because of isolated occurrences of radioactive material detected at sewage treatment plants.

Furthermore, amending 10 CFR 20.2003 in the manner that the petitioner suggests would not be effective, efficient, or realistic. Several public comments stated that advance notification would be impractical, if not impossible, because most releases are continuous and involve very small quantities of radioactive material. In addition, a requirement for an advance notification would be considered as an information request burden under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). The regulatory burden proposed by the District would be significant, due to the large number of licensees that discharge into sanitary sewer systems. Such a requirement for advance notification would have significant cost impacts without commensurate health and safety benefits to the public.

Disposition of the Petition's Request to Amend 10 CFR 20.2004

In its petition, the District argues that the regulations in 10 CFR 20.2004 should be amended to no longer require NRC approval prior to incineration of licensed radioactive materials that enter the sanitary sewer system under 10 CFR 20.2003. The staff has considered the petition and its stated rationale. For the reasons set forth below, and in a draft *Federal Register* notice

(Attachment 2) addressing the petitioner's request, the staff recommends that the Commission deny the petition.

NRC regulations in 10 CFR 20.2004 apply to either an NRC or an Agreement State licensee and generally do not apply to a POTW or its operations. POTWs are not required to obtain NRC approval for incineration of their sewage sludge, unless the sewage sludge contains licensed material. Studies, surveys, and modeling efforts conducted to date indicate that releases of radioactive material from licensed facilities in accordance with 10 CFR 20.2003 generally do not reconstitute in sewage sludge in sufficient concentrations to pose risk to public health and safety. Therefore, a change to 10 CFR 20.2004 regulations is not needed.

If a licensee incinerates licensed material, the staff continues to believe that the NRC approval requirements are necessary to have reasonable assurance that the public health and safety are adequately protected. The major revision to 10 CFR Part 20 (56 FR 23360; May 21, 1991) did not include any changes in the regulations for treatment or disposal by incineration with the exception of certain waste oil. The "Statement of Considerations" for the final rulemaking stated that NRC considered relaxing the prior approval requirement but did not adopt such relaxation. Even though the discharge requirements for 10 CFR 20.2003 were set to adequately protect public health and safety and the environment, different human exposure scenarios apply to the disposal of licensed material by incineration, even if those materials are discharged in compliance with another section of the regulations. NRC found, when reviewing 10 CFR 20.2004, that the acceptability of incineration as a disposal option (except for exempted quantities of radioactive materials) must be determined on a facility- and site-specific basis. In reviewing this petition, the staff found that the staff's existing rationale for not amending 10 CFR 20.2004 is still sound: the acceptability of incineration as a disposal option must consider incinerator design, isotopic composition and activity of the material to be burned, and potential human exposure to effluents may require special computational methods because of complex meteorologic conditions and other factors.

Summary

Efforts from the ISCORS Sewage Sludge Subcommittee regarding radioactive materials in sewage sludge and ash provide a sufficient technical basis to resolve PRM-20-22. The survey demonstrated that the most significant levels of radioactive materials in POTWs are NORM. In general, the doses from licensed materials in sewage sludge present a sufficiently low health and safety risk to POTW workers and to the public under the current regulatory structure. Therefore, it is not necessary to require NRC licensees to provide advance notice to the appropriate sewage treatment plant prior to releasing licensed material into the sewer system as requested by the petitioner. Similarly, the current provision of NRC oversight of sewage incineration is necessary to ensure the protection of health and safety and the environment. This condition could not be safely relaxed in the manner suggested by the petitioner.

ISCORS survey and dose modeling found that no widespread public health and safety risk exists from releases of licensed materials into sanitary sewer systems under the current regulatory structure. Therefore, the NRC's strategic safety goal to "ensure protection of public health and safety and the environment" would be maintained while denying the PRM-20-22. The NRC's strategic goal to "ensure openness in our regulatory process" was accomplished by the openness demonstrated in the consideration of this petition. Public comments on the

petition were solicited on two separate occasions in the *Federal Register*. A representative from the District participated as a member of the ISCORS Sewage Sludge Subcommittee, was involved in the development of the survey and the dose modeling, and in preparation of the ISCORS reports. Additionally, availability and solicitation of public comments on the ISCORS reports were announced in the *Federal Register* (68 FR 66503; November 16, 2003), and posted at the ISCORS website: www.iscors.org. It is expected that denying this petition will further the NRC's effectiveness goal to "ensure that NRC actions are effective, efficient, realistic, and timely," because imposing such requirements as requested by the petition would have a significant regulatory burden on licensees without an apparent benefit to public health and safety. Additionally, it would be difficult, if not impossible, for licensees to implement such requirements proposed by the petition. For these reasons, the staff finds that the proposed amendments requested in PRM-20-22 do not support rulemaking to revise 10 CFR 20.2003 and 20.2004.

Other Related Actions

Separately, the staff will respond to the last remaining open recommendation of the GAO report (GAO/RCED-94-133), which recommends that NRC "establish acceptable limits for radioactivity in sludge, ash, and related byproducts to ensure the health and safety of the treatment workers and the public," through the summary report process as required by Section 236 of the "Legislative Reorganization Act of 1970." The summary report presents the NRC's progress made in addressing recommendations from GAO reports. Based on the last annual summary report date April 6, 2004, the staff intends to respond to the last remaining recommendation by issuing final reports on "ISCORS Assessment of Radioactivity in Sewage Sludge: Modeling to Assess Radiation Doses" and "ISCORS Assessment of Radioactivity in Sewage Sludge: Recommendations on Management of Radioactive Materials in Sewage Sludge and Ash at Publicly Owned Treatment Works." The next annual summary report is anticipated to be issued in early 2005.

By the Commission's approval of the staff's recommendation to deny the District's petition, the staff will take action to withdraw the 1994 ANPR (59 FR 9146) because no widespread contamination exists at sewage treatment facilities. The existing NRC regulations contain acceptable limits to ensure public health and safety. The staff plans to address public comments received on the 1994 ANPR and to prepare a withdrawal package by June 30, 2005.

RECOMMENDATIONS:

That the Commission:

- 1. <u>Approve</u> the denial of the petition for rulemaking and publication of the *Federal Register* notice announcing the denial;
- 2. <u>Inform</u> appropriate Congressional committees; and
- 3. <u>Note</u> that a letter is attached for the Secretary's signature (Attachment 3), informing the petitioner of the Commission's decision to deny the petition.

- 4. <u>Note</u> that the staff will take action to respond to GAO recommendations.
- 5. <u>Note</u> that, upon Commission's approval to deny this petition for rulemaking, the staff will take action to withdraw the ANPR.

COORDINATION:

The Office of the General Counsel has no legal objection to the denial of this petition.

/RA/

Luis A. Reyes Executive Director for Operations

Attachments:

- 1. Northeast Ohio Regional Sewer District petition dated August 2, 1993
- 2. Draft Federal Register Notice of Denial of Petition for Rulemaking
- 3. Letter to the Petitioner

ATTACHMENT 1

Northeast Ohio Regional Sewer

District Petition Dated August 2, 1993



Northeast Ohio Regional Sewer District

3826 Euclid Avenue • Cleveland, Ohio 44115-2504

216 • 881 • 6600

FAX: 216 • 881 • 9709

August 2, 1993



Mr. Samuel Chilk Secretary U.S. Nuclear Regulatory Commission Washington, D.C. 20555

Attention: Chief

Docketing and Service Branch

Re: 10 CFR 2.802 Petition for Rulemaking

Dear Secretary Chilk:

The Northeast Ohio Regional Sewer District's ("District") Southerly Wastewater Treatment Center has been contaminated by disposal of Cobalt-60 into the sanitary sewer system. The characterization and remediation of this contamination is ongoing and will cost the District, at a minimum, in excess of one million dollars. The remediation costs could rise into the billions of dollars if off-site disposal of the contaminated ash is required.

The District is not the first sewage treatment authority to experience radioactive contamination at a treatment plant. The NRC has previously documented problems at Tonawanda and Grand Island, NY, Lansing, MI, Oak Ridge, TN, Royersford, PA, and Washington, D.C. The NRC has also recently investigated an occurrence in Youngstown, Ohio. This list does not include all contaminated facilities in Agreement states. The possibility also exists that contamination exists undetected at other treatment plants, as it did at Southerly for nearly 10 years.

It is our understanding that the NRC is undertaking a general review of the regulatory scheme as it relates to this problem. Regardless of what other revisions may be made to the sanitary disposal rules, the District hereby petitions the NRC to revise 10 CFR 20.303 (and 10 CFR 20.2003) to require that all licensees provide not less than 24 hours advance notice to the appropriate sewage treatment plant prior to releasing radioactive material to the sanitary sewer system.

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Mr. Samuel Chilk U.S. Nuclear Regulatory Commission August 2, 1993 Page Two

The District also requests that 10 CFR 20.305 (and 10 CFR 20.2004), which prohibit the incineration of radioactive waste without NRC approval, be revised to explicitly exempt materials that enter the sanitary waste stream under 10 CFR 20.303 (and 10 CFR 20.2003). This revision would clarify that the NRC does not intend to inhibit the operation of over 200 sewage sludge incinerators across the nation due to the discharges of its licensees.

Your prompt response to this petition for rulemaking would be appreciated as this is a matter of great concern to the District.

very cruit yours

William B. Schatz General Counsel

WBS/td

cc: Richard Bangart
Philip Olson
John Martin
Ken Kirk
Senator Glenn
Senator Metzenbaum
Representative Hoke
Representative Stokes
Erwin Odeal
Thomas Lenhart
Barry Koh

(chilk)

ATTACHMENT 2

Federal Register Notice; Denial of Petition for Rulemaking (PRM-20-22)

NUCLEAR REGULATORY COMMISSION

10 CFR Part 20

[Docket No. PRM-20-22]

Northeast Ohio Regional Sewer District; Denial of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Denial of petition for rulemaking.

SUMMARY: The Nuclear Regulatory Commission (NRC) is denying a petition for rulemaking (dated August 2, 1993, Docket No. PRM-20-22) submitted by the Northeast Ohio Regional Sewer District (the District or the petitioner). The petitioner requested that NRC amend its regulations to require all licensees to provide no less than 24 hours advance notice to the appropriate sewage treatment plant before releasing radioactive material into a sanitary sewer system, and to exempt radioactive materials that enter the sanitary waste stream from the requirements regarding NRC approval for incineration. NRC is denying the petition because it has been determined that current NRC regulations for discharge of licensed material into sanitary sewer systems are adequate and that current regulations for NRC approval for treatment or disposal of licensed material by incineration are necessary to ensure the protection of public health and safety and the environment.

ADDRESSES: Copies of the petition for rulemaking, the public comments received, and the NRC's letter to the petitioner may be examined at the NRC Public Document Room, O1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland.

The NRC maintains an Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. These documents may be accessed through the NRC's Public Electronic Reading Room on the Internet at http://www.nrc.gov/reading-rm/adams.html. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room Reference staff at 1-800-397-4209, (301) 415-4737, or by e-mail to pdr@nrc.gov.

FOR FURTHER INFORMATION CONTACT: Lydia Chang, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone (301) 415-6319, e-mail lwc1@nrc.gov.

SUPPLEMENTARY INFORMATION:

The Petition

By letter dated August 2, 1993, the District submitted a petition for rulemaking to amend 10 CFR 20.303 (superceded by 20.2003) and 20.305 (superceded by 20.2004). The petitioner requested that NRC modify its regulations to require that all licensees provide no less than 24 hours advance notice to the appropriate sewage treatment plant before releasing radioactive material into a sanitary sewer system, and to exempt radioactive materials that enter the

sanitary waste stream from the requirements regarding NRC approval for incineration. The petitioner stated that their Southerly Wastewater Treatment Center had been contaminated from releases of radioactive material containing cobalt-60 into its sanitary sewer system, resulting in costly characterization and remediation. The petitioner stated that the District was not the first sewage treatment authority to experience radioactive contamination and noted that NRC had documented radioactive contamination problems at other sewage treatment sites. The petitioner also stated that contamination may exist undetected at other sewage treatment plants and requested that the regulations be amended.

Public Comments on the Petition

A notice of receipt of the District's petition was published in the *Federal Register* (58 FR 54071; October 20, 1993). The public comment period closed on January 3, 1994. NRC received twelve comment letters in response to the petition prior to the closing date. Ten of the twelve comment letters addressed the District's request for NRC to amend its regulations to require that all licensees provide at least 24 hours advance notice to the appropriate sewage treatment plant before releasing radioactive material into a sanitary sewer system. Three commenters supported the District's request for providing a notification to the sewage treatment plant, but one commenter said that licensees and sewage treatment plant staff could agree on the provision of a report without making it a requirement in the Federal regulations. Six commenters did not support the District's request for such an amendment. Several comments said that such a requirement would be an unnecessary burden that would neither increase radiation safety nor reduce radiation exposures. Another commenter noted that it would be difficult to schedule "batch" releases because radioactive materials are used in continuous drug

research and development processes, and, as such, discharges into the sanitary sewer are continuous as well. One commenter believed that no radioactive waste should be deposited in any sewer system by any licensee for any reason.

Eight of the twelve letters commented on the District's request to exempt radioactive materials that entered the sanitary waste stream from the requirements regarding NRC approval for incineration. Two commenters were supportive of this part of the petition. Four commenters were opposed to this request because they believed that it was another attempt to declare radioactive materials entering sanitary sewer systems as being "Below Regulatory Concern," as the exemption would only increase contamination as in the already documented cases, and it would pose a serious threat to the health and safety of populations surrounding facilities that incinerate radioactive materials. Two commenters cited the need for additional NRC review/guidance on this issue in order to clarify at what point radioactive material is no longer under regulatory control.

NRC published an advance notice of proposed rulemaking (ANPR) in the *Federal Register* (59 FR 9146; February 25, 1994) to determine whether an amendment to its regulations governing the release of radioactive material from licensed facilities into sanitary sewer systems was needed, based on current sewage treatment technologies. The ANPR noted receipt of the petition for rulemaking submitted by the District (PRM-20-22) and specifically requested comments on the two issues raised in the petition.

Twenty-one letters received in response to the ANPR included comments on the District's request for the NRC to amend its regulations to require that all licensees provide at least 24 hours advance notice to the appropriate sewage treatment plant before releasing radioactive material into a sanitary sewer system. Six of the twenty-one commenters supported a requirement for licensees to provide the sewage treatment plant with some type of reporting on the radioactive materials released into the sanitary sewer system. These commenters

supported a wide range of reporting requirements – from the petitioner's request for a 24-hour advance notification before licensees release radioactive material, to monthly or annual discharge reports, to reports of releases that could be a threat to the publicly-owned treatment works (POTW) workers or the environment, to notification of large accidental releases.

Fifteen of the twenty-one commenters did not support such a requirement for licensees to provide at least 24-hour advance notice to the appropriate sewage treatment plant before releasing radioactive material into a sanitary sewer system. Several commenters said that a 24-hour advance notification would result in an unnecessary regulatory burden, with no additional radiation safety protection nor dose reduction. These commenters indicated that the existing regulations for discharges of licensed material maintain doses at or below the existing dose limits for members of the public and if licensees meet the "as low as reasonably achievable" (ALARA) goals, the 24-hour advance notification would be unnecessary. Several commenters noted that such notification would be impractical because most releases are continuous and involve very small quantities of radioactive material. For example, discharges from hospitals and medical facilities would change daily depending on the number of patients treated and types of treatment used.

Several commenters also noted that potentially there would be large cost implications and regulatory burdens associated with such notification. In addition, commenters were concerned about having these reports received and interpreted by sewage treatment plant personnel, rather than radiation safety specialists, resulting in potential misinterpretation of the data. Several commenters offered that such an NRC requirement for licensees to provide a 24-hour advance notification was unnecessary because local municipalities have authority over their local sewer district, already have requirements to follow the Clean Water Act, and may establish a pretreatment program for wastewater acceptance. One commenter noted that the usefulness of a 24-hour advance notification should be assessed after the new limits for sewer

discharges are in place.

Six comment letters received in response to the ANPR included comments on the District's request that the NRC exempt materials that enter the sanitary waste stream from requirements for NRC approval prior to treatment or disposal of licensed material by incineration. Four commenters supported such an amendment because, given the radioisotopes and activities involved, the pathways for human exposure from radioactive wastes seem no more or less significant if the wastes are dispersed into water or air. If release into a sanitary sewer system is to be considered disposal, these commenters indicated, the limits should be set so that no further regulation of the radioactive material is needed after release into a sanitary sewer. One commenter did not support such an amendment because it would only serve to provide an open-ended system for radioactive material to pass into the environment and to the public without limitations or characterization. Another commenter supported sole use of concentration limits for measuring a licensee's limits for disposal of radioactive material into sanitary sewer systems.

Discussion

Regulatory Framework Relevant to the Petition

NRC regulations governing the discharge of licensed material by release into sanitary sewer systems and the treatment or disposal of licensed material by incineration can be found in 10 CFR 20.2003 and 20.2004, respectively. These regulations were published in the *Federal Register* (56 FR 23360; May 21, 1991) as part of an overall revision of NRC's standards for protection against radiation. The licensees were required to implement these regulations by January 1, 1993. Although the District filed its petition after the implementation date of the

1991 revision of 10 CFR Part 20 regulations, the sewage sludge and ash from the District's Southerly Wastewater Treatment Center were contaminated prior to the implementation date.

As part of the 1991 revision of 10 CFR Part 20 regulations, NRC examined several instances where radioactive material was detected in sewage treatment systems. The results of this examination led to modifications of the requirements for disposal of licensed material by release into sanitary sewer systems in 10 CFR 20.2003. Specifically, NRC removed the broad provision that allowed the disposal of dispersible materials into sanitary sewer system. The disposal of non-biological insoluble materials is no longer permitted because of potential reconcentration of these materials in the sanitary sewer system, sewage treatment plants, and sewage sludge. The current NRC regulations require that any licensed material discharged into a sanitary sewer system must be readily soluble (or is readily dispersible biological material) in water. In addition, the concentration limits for radionuclides released into a sanitary sewer system were reduced by a factor of 10 as part of an overall reduction in effluent release limits. The concentration limits were reduced because of past contamination incidents involving cobalt-60 and americium-241. The revised concentration limits, listed in Table 3 of the Appendix B to Part 20, were an effort to reduce the public's exposure to radionuclides released into the sanitary sewer system. In addition, NRC recommends that licensees should set ALARA goals for effluents at a modest fraction (10 to 20 percent) of their allowable limits as stated in NRC Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," dated July 1993. NRC also conducts periodic inspections to ensure that licensees are in compliance with NRC regulations.

A number of comments, received during the 1991 revision of 10 CFR Part 20, questioned the need for the requirements that incineration of radioactive material requires specific prior NRC approval. After these comments were analyzed and considered in developing the final rule, NRC did not revise the provision regarding Commission approval for

treatment or disposal by incineration except for waste oil. In the "Statements of Consideration" for the final rule, NRC stated:

Relaxation of the prior approval requirement for incineration was considered in connection with the amendments to part 20 of this final rule. The requirements for prior NRC approval of incineration remains in the amendments to part 20 in this final rule because the acceptability of incineration as a disposal option, except for exempted quantities of radioactive materials, must be determined on a site-specific basis considering: (1) incinerator design, (2) the variable isotopic composition and activity of the material to be burned, and (3) potential human exposure to effluents, which may require special calculational methods because of complex meteorologic conditions and other factors.

As part of the 1991 revision of 10 CFR Part 20, it was authorized that a licensee may treat or dispose of licensed material contained in certain waste oil by incineration without prior NRC approval. In making this regulatory change, the NRC staff analyzed the type of radionuclides and their potential concentrations in waste oil, performed atmospheric dispersion modeling to characterize potential hazards from incineration, and evaluated the potential environmental impact. The regulatory basis for requirements in obtaining NRC approval prior to incineration is to ensure that NRC may evaluate the potential impact to the public health and safety and the environment on a case-by-case and site-specific basis. Hazards associated with incineration of sewage sludge will highly depend on the specific characteristic of the sludge such as the presence of radioactive materials, which could potentially have a broad spectrum of radionuclides and a wide range of concentration levels. The petitioner's request to incinerate sewage sludge without prior NRC approval is not supported by any detailed data, and has the

potential to be inconsistent with the petitioner's basis for requesting an amendment to 10 CFR 20.2003. If petitioner is concerned with potential contamination of radioactive material in the sewage sludge, incineration of such sewage sludge without prior NRC approval would potentially not be protective to the public health and safety and the environment.

Surveys, Studies, and Reports Relevant to the Petition

In May 1992, the NRC issued the results of a scoping study in NUREG/CR-5814, "Evaluation of Exposure Pathways to Man from Disposal of Radioactive Materials into Sanitary Sewer Systems," which evaluated the potential radiological doses to POTW workers and members of the public from exposure to radionuclides in sewage sludge. The first part of the analysis estimated the potential doses to workers for five known cases in which radioactive materials were detected at POTWs (Tonawanda, NY; Grand Island, NY; Royersford, PA; Oak Ridge, TN; and Washington, DC). Doses from the case studies were estimated to range from less than 10 microsieverts per year (µSv/yr) (1 millirem per year (mrem/yr)) to 930 µSv/yr (93 mrem/yr) for members of the public, using a deterministic scenario analysis and the reported radionuclide concentrations and/or discharges. The second part of the study estimated the maximum radiation exposures to POTW workers and others who could be affected by low levels of man-made radioactivity in wastewater. The quantities of radionuclides released into the sewer systems were assumed to be the maximum allowed under NRC regulations at the time. Estimates of the hypothetical, maximum exposures to workers ranged from zero to a dose roughly equal to natural background.

In May 1994, the U.S. General Accounting Office (GAO, now U.S. Government Accountability Office) issued a report, GAO/RCED-94-133, "Nuclear Regulation: Action Needed to Control Radioactive Contamination at Sewage Treatment Plants," that described nine cases, including the District, where contamination was found in sewage sludge or ash or in wastewater

collection systems. On the basis of the limited information available on radiation levels in sewage sludge and ash across the country, GAO concluded that the full extent of contamination nationwide is unknown. The GAO also concluded that the "problem of radioactive contamination of sludge and ash in the reported cases was the result, in large part, of NRC's regulation, which was incorrectly based on the assumption that radioactive materials would flow through treatment systems and not concentrate." The GAO report did note that to address the problem of radioactive materials' concentrating in sludge and ash, the NRC has revised its regulation to reduce the concentration levels of the radioactive materials that licensees can discharge into sanitary sewer systems although the GAO report also pointed out that "NRC does not know how effective this action will be." The GAO report stated that health implications of the exposure of treatment plant workers and the public to contaminated sludge, ash, and related by-products are unknown because neither the NRC nor the United States Environmental Protection Agency (EPA) knows (1) how much radioactive material may be in these products and (2) how these products might affect people.

In June 1994, a joint U.S. House of Representatives and Senate hearing (June 21, 1994; S. Hrg. 103-1034) was held to officially release and address questions raised in the GAO report. These hearings were prompted by concerns associated with elevated levels of radioactivity in incinerator ash at the Cleveland treatment plant referenced in the District's petition. The testimony presented by both NRC and EPA during the hearing noted that there was no indication of a widespread problem, and that the District's incident appeared to be an isolated event. However, at the hearing, NRC and EPA committed to jointly develop guidance for POTWs and to collect more data on the concentration of radioactive materials in samples of sewage sludge and ash from POTWs nationwide.

Between 1994 and 1997, Federal, State, and industry studies were conducted to assess reconcentration of radioactive materials that are released into sanitary sewer systems. In

December 1994, the NRC published NUREG/CR-6289, "Reconcentration of Radioactive Material Released to Sanitary Sewers in Accordance with 10 CFR Part 20." The objectives of this study were to: (1) assess whether radioactive materials that are released into sanitary sewer systems undergo significant reconcentration within the wastewater treatment plant, and (2) determine the physical and/or chemical processes that may result in their reconcentration within the wastewater treatment plant. A review of the literature clearly demonstrated that some radioactive materials discharged into sanitary sewer systems are reconcentrated in sludge produced as a result of wastewater treatment. However, the report concluded that the available data were not sufficient to assess the adequacy of the requirements in 10 CFR 20.2003 in preventing occurrences of radionuclide concentrations in sewage sludge at levels which present undue risk to the public; nor is the available data sufficient to suggest strategies for changing that requirements.

In 1996, the Association of Metropolitan Sewerage Agencies (AMSA) conducted a limited survey of concentrations of radioactivity in sewage sludge and ash samples from some of its member POTWs. Samples were obtained from 55 wastewater treatment plants in 17 States. The most significant sources of radioactivity were potassium and radium isotopes, which are naturally occurring radioactive materials (NORM).

In December 1997, the Washington State Department of Health issued a report WDOH/320-013, "The Presence of Radionuclides in Sewage Sludge and Their Effect on Human Health," that was based on sludge samples taken at six POTWs in the State. The report concluded that doses from radionuclides in sewage sludge are extremely low compared to background or to generally accepted regulatory dose limits, and that there is no indication that radioactive material in biosolids in the State of Washington poses a health risk.

The Interagency Steering Committee on Radiation Standards (ISCORS) was formed in 1995 to address inconsistencies, gaps, and overlaps in current radiation protection standards.

In 1996, the Sewage Sludge Subcommittee of ISCORS was formed to coordinate efforts to address the recommendations in the 1994 GAO Report. Between 1998 and 2000, the EPA and NRC (through the ISCORS) jointly conducted a voluntary survey of POTW sewage sludge and ash to help assess the potential need for NRC and/or EPA regulatory decisions. Sludge and ash samples were analyzed from 313 POTWs, some of which had greater potential to receive releases of radionuclides from NRC and Agreement State licensees, and some of which were located in areas of the country with higher concentrations of NORM. Although the survey and sampling were biased towards facilities with greater potential for the presence of licensed material and NORM, ISCORS did not make a conclusion about the bias of the results. In November 2003, the results of the survey were published in a final report, NUREG-1775 "ISCORS Assessment of Radioactivity in Sewage Sludge: Radiological Survey Results and Analysis." No widespread or nationwide public health concern was identified by the survey and no excessive concentrations of radioactivity were observed in sludge or ash. The results indicated that the majority of samples with elevated radioactivity were attributable to NORM, such as radium, rather than man-made sources. With the exception of NORM, most of the other samples were at or near the limit of detection. The results of this survey are consistent with the AMSA survey noted above.

The Sewage Sludge Subcommittee is in the process of finalizing a draft report, NUREG-1783, "ISCORS Assessment of Radioactivity in Sewage Sludge: Modeling to Assess Radiation Doses." This report contains computer modeling information, seven different sewage sludge management scenarios, and doses calculated by using modeling process that converts known activity concentrations in sludge to potential doses to individuals. Using survey results with the dose modeling, the calculated doses showed that no widespread concern to public health and safety from potential radiation exposures associated with the handling, beneficial use, and disposal of sewage sludge containing radioactive materials, including NORM.

The Sewage Sludge Subcommittee is also in the process of finalizing a draft final report, EPA 832-R-03-002B, "ISCORS Assessment of Radioactivity in Sewage Sludge:

Recommendations on Management of Radioactive Materials in Sewage Sludge and Ash at Publicly Owned Treatment Works," November 2003. This report provides guidance to: (1) alert POTW operators, and State and Federal regulators to the possibility of radioactive materials concentrating in sewage sludge and incinerator ash; (2) inform them how to determine whether there are elevated levels of radioactive materials in their sludge or ash; and (3) assist them in identifying actions for reducing potential radiation exposure from sewage and ash.

Reasons for Denial

NRC is denying the petition because it has been determined that current NRC regulations in 10 CFR 20.2003 and 20.2004 adequately ensure the protection of public health and safety and the environment.

With regard to the petitioner's request to amend 10 CFR 20.2003, NRC has reviewed the petitioner's rationale, the public comments on the petition and on the ANPR, and a number of relevant activities, surveys, and reports to determine whether there was a health and safety issue due to the reconcentration of radioactive materials in sewage sludge and ash, and if so, was the requested amendment for 24 hours advance notifications necessary to help prevent excessive exposures to workers and the public.

The current requirements in 10 CFR 20.2003 were not fully implemented at the time of contamination at the District's Southerly Wastewater Treatment Center. The NRC significantly decreased the concentration limits for radionuclides discharged into sanitary sewer systems as part of the 1991 revision of 10 CFR Part 20, and licensees were required to comply with the

regulatory changes as of 1993. In addition to lowering the concentration limits, the disposal of non-biological insoluble materials was prohibited because of potential reconcentration of these materials in sanitary sewer systems, treatment plants, and sludge. NRC also has issued guidance to further reduce the effluent limits through use of ALARA goals. In addition, NRC conducts periodic inspections to ensure that licensees are in compliance with NRC regulations. Under this current regulatory framework, NRC expects that doses from release of licensed material into a sanitary sewer system are within regulatory limits.

The available data do not support the District's assertion that health and safety protection would be enhanced by advance notification from all licensees to the appropriate sewage treatment plant. The ISCORS final survey report shows that NORM constitutes the most significant levels of radioactive materials in POTWs, and therefore any notification requirement imposed on licensees will not effectively reduce the level of radioactive materials in POTW facilities. Effluent levels from NRC-licensed activities are established in order to maintain doses to the public at or below a pre-determined protective level. The ISCORS draft dose modeling report shows that calculated doses to POTW workers and the public are sufficiently low from discharge of the licensed material into sanitary sewer systems, based on radionuclide concentrations in the sewage sludge and the associated sewage sludge management practices.

NRC has determined that a requirement for an advance notification would impose an unnecessary regulatory burden on licensees, without a commensurate health and safety protection of the public. Such a requirement for advance notification would also be considered as an information request burden under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). This burden is broadly defined, and any method of notification imposed by an Agreement State or the NRC, including telephonic or electronic, is applicable. The regulatory burden proposed by the District is large, due to the large number of licensees that discharge to

sanitary sewer systems. In addition, there is no justification on how the notification would be used at the wastewater treatment plant to affect treatment operations in response to a discharge of licensed material to ensure protection of health and safety.

Finally, several commenters stated that it would be impractical, if not impossible, for all licensees to provide advance notices to the appropriate sewage treatment plant because of the nature of the process involved. Very small quantities of radioactive materials are continuously used at certain licensed facilities, such as drug research and development companies, and these radioactive materials are continuously discharged into sanitary sewer systems.

Discharges from clinics and hospitals would have many fluctuations depending on the number of patients treated and the types of treatment used. It would be unreasonable to expect licensees to notify the sewage treatment facility prior to each discharge. It would also be equally unreasonable, in some cases, to expect licensees to collect discharges in order to schedule for a batched discharge.

In summary, NRC has concluded that the petitioner's rationale, public comments, data, analyses, and reports do not support the petitioner's request for a rulemaking to amend the regulations in 10 CFR 20.2003 to require that all licensees provide no less than 24 hours advance notification to the appropriate sewage treatment plant before releasing radioactive material into a sanitary sewer system. Such a rulemaking would impose unnecessary regulatory burden on licensees and does not appear to be warranted for the adequate protection of public health and safety and the common defense and security. Therefore, NRC is denying the petitioner's request to amend 10 CFR 20.2003.

With respect to the petitioner's request to amend 10 CFR 20.2004, NRC has reviewed the petitioner's rationale, the public comments on the petition, and the regulatory history on the requirements for NRC approval for incineration. NRC regulations in 10 CFR 20.2004 apply to either an NRC or an Agreement State licensee and generally do not apply to a POTW or its

operations. POTWs are not required to obtain NRC approval for incineration of their sewage sludge, unless the sewage sludge contains licensed radioactive material. Studies, surveys, and modeling efforts conducted to date indicate that releases of radioactive material from licensed facilities in accordance with 10 CFR 20.2003 generally do not reconstitute in sewage sludge in sufficient concentrations to pose risk to public health and safety. Therefore, a change to 10 CFR 20.2004 regulations is not needed.

If a licensee incinerates licensed material, the staff continues to believe that the NRC approval requirements are necessary to have reasonable assurance that the public health and safety are adequately protected. Hazards associated with incinerating licensed material will highly depend on the specific characteristic of the matrix containing the licensed material. If a licensee incinerates the licensed material contained in the sewage sludge, many factors would have to be considered because the sewage sludge could potentially have a broad spectrum of radionuclides from various sources and a wide range of concentration levels. The potential hazards also highly depend on the case-specific incinerator design and site-specific exposure to the public and the environment. Even though the discharge requirements for 10 CFR 20.2003 were set to adequately protect public health and safety and the environment, different human exposure scenarios apply to the disposal of licensed material by incineration, even if those materials are discharged in compliance with another section of the regulations. NRC found that the acceptability of incineration as a disposal option, except for exempted quantities of radioactive materials, must be determined on a facility- and site-specific basis. NRC continues to believe that prior NRC approval for incineration is necessary to have reasonable assurance that the public health and safety are adequately protected. Therefore, NRC is also denying the petitioner's request to amend 10 CFR 20.2004 to explicitly exempt radioactive materials that enter the sanitary waste stream under 10 CFR 20.2003 from the requirements regarding NRC approval for incineration.

For the reasons cited in this document, NRC denies this petition.	
Dated at Rockville, Maryland, this_	day of, 2004.
	For the Nuclear Regulatory Commission.
	Annette Vietti-Cook Secretary of the Commission.

ATTACHMENT 3

Letter to the Petitioner; Denial of Petition for Rulemaking (PRM-20-22) Mr. William B. Schatz, General Counsel Northeast Ohio Regional Sewer District 3826 Euclid Avenue Cleveland, OH 44115-2504

Dear Mr. Schatz:

I am responding to the petition for rulemaking that you submitted to the U.S. Nuclear Regulatory Commission (NRC) on August 2, 1993, on behalf of the Northeast Ohio Regional Sewer District (hereafter, the District). Your petition, docketed as PRM-20-22, requested that the NRC amend its regulations to: (1) require that all licensees provide no less than 24 hours advance notice to the appropriate sewage treatment plant before releasing radioactive material to the sanitary sewer system, and (2) explicitly exempt materials that enter the sanitary waste stream under 10 CFR 20.2003 from the requirements regarding obtaining NRC approval for incineration. Your rationale for the first amendment is that the District's Southerly Wastewater Treatment Center has been contaminated by disposal of radioactive wastes into the sanitary sewer system, resulting in costly characterization and remediation. You stated that the second amendment would clarify that NRC does not intend to inhibit the operation of over 200 sewage sludge incinerators across the nation due to discharges from NRC licensees.

On October 20, 1993, NRC published a notice of receipt of the District's petition for rulemaking in the *Federal Register* (58 FR 54071), to which 12 public comment letters were received. Ten of the 12 comment letters received addressed the District's request for no less than 24 hours advance notice requirement. Three commenters supported the petition; one commenter supported the intent of the petition without endorsing a rulemaking; and the other six commenters did not support such rulemaking citing unjustified regulatory burden and potential problems in implementing the proposed notification requirement. Eight of the 12 comment letters received related to the District's request regarding removal of the approval requirement for incineration. Two supported the petitioner's proposal, two requested clarification, and four opposed the petition because of undue risk placed upon the communities surrounding the incinerator.

On February 25, 1994, NRC published an advance notice of proposed rulemaking (ANPR) in the *Federal Register* (59 FR 9146) to seek information whether an amendment to its regulations governing the release of radionuclides from licensed nuclear facilities to sanitary sewer systems was needed based on then current sewer treatment technologies. The ANPR also noted the receipt of a petition submitted by the District and specifically solicited public comments on the two rulemaking changes requested in the petition. Through the public comment process for the ANPR, there were 21 comments related to the District's petition. The majority of comments opposed the reporting requirement proposed by the petitioner. Six commenters supported some type of reporting requirements. There were six comments that addressed the District's request regarding prior approval for incineration. Four commenters supported the petition, and two opposed the petitioner's proposed changes. Public comments on the two Federal Register notices are discussed in detail in the attachment to this letter.

Since there were concerns raised on a broader issue of long-term effects of releases of radioactive materials into sanitary sewer systems, resolution of the petition was deferred until studies are conducted regarding potential radioactive contamination in sewage sludge. Since 1994, NRC conducted several studies and participated in the Interagency Steering Committee on Radiation Standards (ISCORS). NRC has co-chaired, with the Environmental Protection Agency, the ISCORS Sewage Sludge Subcommittee to coordinate and facilitate a systematic and thorough study of potential concerns related to radioactive materials in sewage sludge. Mr. Tom Lenhart from the District is a member of the ISCORS Sewage Sludge Subcommittee. He has participated in meetings, evaluated survey data, reviewed dose modeling, and assisted in preparing the associated reports.

In November 2003, the results of the survey were published in NUREG-1775, "ISCORS Assessment of Radioactivity in Sewage Sludge: Radiological Survey Results and Analysis." Based on the survey report, most of the survey samples collected were at, or near, the detection limits, with the exception of naturally occurring radioactive materials (NORM). Draft report, NUREG-1783, "ISCORS Assessment of Radioactivity in Sewage Sludge: Modeling to Assess Radiation Doses" and draft final report, EPA 832-R-03-002B, "ISCORS Assessment of Radioactivity in Sewage Sludge: Recommendations on Management of Radioactive Materials in Sewage Sludge and Ash at Publicly Owned Treatment Works" were made available to the public for comment as announced in the Federal Register (68 R 66503; November 16, 2003). ISCORS is currently finalizing these two reports. There are no widespread public health and safety concerns identified by the survey and dose modeling due to releases of licensed material into sanitary sewer systems. The results indicated that radioactivity was primarily attributable to NORM rather than licensed material. These findings are significant because regulatory requirements for NRC licensees do not pertain to NORM. In addition, the concentrations found in sewage sludge were generally low compared to background and dose limits; they do not pose an undue risk to the public health and safety.

NRC is denying your request to amend 10 CFR 20.2003 to require that all licensees provide no less than 24-hour advance notification to the appropriate sewage treatment plant before releasing radioactive material to the sanitary sewer system because a review of the relevant data, analyses, comments, and reports does not support such a requirement. Radioactive materials discharged to sanitary sewer systems are already adequately controlled and managed as a result of the 1991 changes to 10 CFR 20.2003 and by NRC guidance. The majority of detectable radionuclides at sewage facilities are attributable to NORM and are not subject to NRC regulations proposed in this petition. In addition, any advance notice is impractical, especially for continuous or frequent batched discharges. NRC has concluded that the requested rulemaking would neither increase radiation safety nor reduce radiation exposure; therefore, the rulemaking would result in a significant regulatory burden, with no additional protection of health or safety.

NRC is also denying your request to amend 10 CFR 20.2004 to no longer require prior NRC approval for incineration of licensed radioactive materials that enter the sanitary waste stream under 10 CFR 20.2003. NRC regulations in 10 CFR 20.2004 apply to either an NRC or an Agreement State licensee and generally do not apply to a POTW or its operations. POTWs are not required to obtain NRC approval for incineration of their sewage sludge, unless the sewage sludge contains licensed radioactive material. Studies, surveys, and modeling efforts conducted to date indicate that releases of radioactive material from licensed facilities in accordance with 10 CFR 20.2003 generally do not reconstitute in sewage sludge in sufficient

concentrations to pose risk to public health and safety. Therefore, a change to 10 CFR 20.2004 regulations is not needed. If a licensee incinerates licensed material, NRC continues to believe that the NRC approval requirements are necessary to have reasonable assurance that the public health and safety are adequately protected.

NRC has considered your petition and the stated rationale. For the reasons provided in the attached *Federal Register* notice, NRC is denying your petition. The *Federal Register* notice for denying the petition is being transmitted to the Office of Federal Register for publication.

Sincerely,

Annette Vietti-Cook Secretary of the Commission

Enclosure: Federal Register Notice