

POLICY ISSUE (Notation Vote)

November 30, 2004

SECY-04-0226

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations /RA/

SUBJECT: 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. Approve the denial of the petition for rulemaking and publication of the *Federal Register* notice announcing the denial;
2. Inform appropriate Congressional committees; and
3. Note 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. Note that the staff will take action to respond to GAO recommendations.
5. Note 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

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

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

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