

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By letter dated August 2, 1993, the District submitted a petition for rulemaking to amend 10 CFR 20.303 (superceded by 20.2003) and 20.305 (superceded by 20.2004).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 ($\mu\text{Sv}/\text{yr}$) (1 millirem per year (mrem/yr)) to 930 $\mu\text{Sv}/\text{yr}$ (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.