[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 20

[RIN 3150-AE90]

Disposal of Radioactive Material by Release Into Sanitary Sewer Systems; Withdrawal of Advance Notice of Proposed Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Advance notice of proposed rulemaking: Withdrawal.

SUMMARY: The Nuclear Regulatory Commission (NRC) is withdrawing an advance notice of proposed rulemaking (ANPR) that presented possible changes to the regulations governing the release of radionuclides from licensed nuclear facilities into sanitary sewer systems. Changes were proposed to account for the potential for radionuclide concentration during some types of wastewater treatment processes. NRC is withdrawing this advance notice of proposed rulemaking because it has determined that there are no widespread public health and safety concerns due to potential radiation exposures associated with the handling, beneficial use, and disposal of sewage sludge containing radioactive materials. This notice of withdrawal acknowledges public comments sent in response to the ANPR.

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SUPPLEMENTARY INFORMATION:

On February 25, 1994 (59 FR 9146), NRC published an ANPR to seek information to determine whether an amendment to its regulations governing the release of radionuclides from licensed nuclear facilities into sanitary sewer systems was needed. NRC was considering revising the approach to limiting these releases because of the potential effects of newly-developed sewage treatment technologies on radionuclide reconcentration during wastewater treatment. The Commission requested advice and recommendations on several proposals and asked related questions regarding whether and in what way the regulations governing the release of radionuclides from licensed nuclear facilities into sanitary sewer systems should be changed. NRC received seventy-four comment letters in response to the ANPR. The comment period expired on May 26, 1994.

Because there were concerns raised on the broader issue of long-term effects of releases of radioactive materials into sanitary sewer systems, action on the ANPR was deferred until studies were conducted regarding potential radioactive contamination in sewage sludge. Since that time, NRC participated in the Interagency Steering Committee of Radiation Standards (ISCORS) and co-chaired, with the 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 regulatory decision.

Regulatory Framework Relevant to the Release of Radioactive Material into Sanitary Sewers

NRC regulations governing the release of licensed material into sanitary sewer systems can be found in 10 CFR 20.2003. This regulation was published in the *Federal Register* (56 FR 23360; May 21, 1991) as part of an overall revision of NRC standards for protection against radiation. Licensees were required to implement this regulation by January 1, 1993. As

part of the 1991 revision of 10 CFR Part 20 regulations, NRC removed the broad provision that allowed the release of non-biological insoluble materials into sanitary sewers because of the potential for this material to reconcentrate in sewers, publicly owned treatment works (POTWs), and sewage sludge. The current NRC regulations require that any licensed material discharged into a sanitary sewer system must be readily soluble in water or be readily dispersible biological material. In addition, the concentration limits for radionuclides released into a sanitary sewer system, listed in Table 3 of the Appendix B to Part 20, were reduced by a factor of 10 as part of an overall reduction in effluent release limits. In addition to the limits in 10 CFR 20.2003, NRC recommends that licensees should maintain doses as low as is reasonably achievable (ALARA) by setting goals for effluent concentrations and quantities to be only a modest fraction (10 to 20 percent) of their allowable limits, as described 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.

Surveys, Studies, and Reports Relevant to the Release of Radioactive Material into Sanitary Sewers

In May 1992, 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 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 the dose individuals receive from natural background radiation.

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 where contamination was found in sewage sludge or ash or in wastewater collection systems. GAO concluded that the full extent of contamination nationwide was unknown. 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." 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. At the hearing, NRC and EPA agreed to cooperate to 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, NRC published NUREG/CR-6289, "Reconcentration of Radioactive Material Released into Sanitary Sewers in Accordance with 10 CFR Part 20." A review of the literature demonstrated that some radioactive materials discharged into sanitary sewer systems reconcentrate in sewage sludge. 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 reconcentration in sewage sludge at levels which present significant risk to the public; nor is the available data sufficient to suggest strategies for changing the requirements.

In 1996, the Association of Metropolitan Sewerage Agencies (AMSA) conducted a limited survey of reconcentration 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 that there was no indication that radioactive material in sewage sludge 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. 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 had elevated concentrations of NORM, such as radium, and did not have elevated concentrations of radionuclides from manmade sources.

In February, 2005, the Sewage Sludge Subcommittee published a report, NUREG-1783, "ISCORS Assessment of Radioactivity in Sewage Sludge: Modeling to Assess Radiation Doses." This report contains dose modeling results for seven different sewage sludge management scenarios for POTW workers and members of the public. Results of the dose models and survey results indicated 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.

In February, 2005, the Sewage Sludge Subcommittee also published a report, "ISCORS Assessment of Radioactivity in Sewage Sludge: Recommendations on Management of Radioactive Materials in Sewage Sludge and Ash at Publicly Owned Treatment Works" (EPA 832-R-03-002B; ISCORS Technical Report 2004-04). This report provides guidance to: (1) alert POTW operators, as well as State and Federal regulators, to the possibility that radioactive materials may concentrate in sewage sludge and incinerator ash; (2) inform POTW operators how to determine whether there are elevated levels of radioactive materials in the POTW's sludge or ash; and (3) assist POTW operators in identifying actions for reducing potential radiation exposure from sewage and ash.

Reasons for Withdrawing the ANPR

The results of the survey and dose modeling work conducted by the ISCORS Sewage Sludge Subcommittee regarding radioactive materials in sewage sludge and ash provide a technical basis for withdrawing the ANPR. The survey demonstrated that the most significant levels of radioactive materials in POTWs are attributable to NORM. The dose modeling work indicated that, 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 modify the current restrictions regarding the release of radioactive materials into sanitary sewers (10 CFR 20.2003) as discussed in the ANPR. In addition, public comments indicated that several of the options discussed in the ANPR would be costly to implement and may not be consistent with efforts to maintain doses ALARA. For these reasons, NRC is withdrawing the ANPR.

Public Comments on the Potential Changes to 10 CFR Part 20

In the ANPR, NRC invited comment on the following aspects of the regulation of release of radionuclides into sanitary sewers: the form of materials suitable for disposal, the limits on the total radioactivity of materials that can be released by a licensee into sanitary sewers in a year, also called the "total quantity limit," the types of limits applied, and the exemption for medical patient excreta. The following is a summary of those comments and NRC responses.

(1) Form of Material for Disposal

The May 21, 1991, final rule (10 CFR 20.2003) allows soluble and readily dispersible biological material to be released but prohibits the release of any non-biological insoluble material. Because NRC recognized that new technologies for wastewater treatment, such as ion-exchange and some types of biological treatment, can reconcentrate radionuclides, NRC invited comments regarding whether and how regulations should account for the effects of different wastewater treatment technologies on radionuclide reconcentration. NRC also invited comments regarding the potential impacts that additional restrictions on the form of materials allowable for release into sanitary sewers would have on licensee operations. Public comments regarding the adequacy of the current restrictions also were received.

Comment: Nine commenters, including representatives of the New York State Energy Office, New York State Department of Environmental Conservation, AMSA, and the Department of Energy (DOE), expressed the view that the regulations should be reevaluated because of

new sewage treatment technologies or should account for the effects of new technologies used to treat sewage or sewage sludge. One commenter suggested that NRC limits should account for a variety of POTW-specific factors, including sludge handling processes, and sludge disposal methods, and restrictions on the POTW's treated water discharge. Another commenter suggested NRC should take new sewage treatment technologies into account only if the results of NUREG/CR-6289, which was incomplete at the time the comment was made, indicated that new sewage treatment technologies had the potential to cause significant reconcentration of radionuclides in sewage sludge. Two commenters recommended NRC develop technology-specific reconcentration factors to help POTW operators to design appropriate pretreatment plans. A representative of DOE suggested NRC should expect that advances in the sewage treatment process would result in increasing concentration of radionuclides in sewage sludge. Two commenters recommended NRC regulations account for synergistic health effects of radiation and pollutants in wastewater, and one suggested NRC evaluate the synergistic effects of radiation and the chlorine and fluoride used in drinking water treatment.

Response: NRC acknowledges the commenters' support for regulations that would account for the reconcentration of radionuclides by wastewater treatment processes. However, the regulations will not be changed because the ANPR is being withdrawn for the reasons previously explained.

Comment: Four commenters expressed the view that NRC regulations should not take sewage treatment technologies into account. Reasons included uncertainty that new technologies will be implemented and a lack of information about the effects of the new technologies on radionuclide reconcentration. A representative of the State of Illinois Department of Nuclear Safety suggested NRC should keep informed of technological developments, but should not implement additional restrictions without significant evidence that the current restrictions are not adequate. Two commenters suggested that, rather than revising

§ 20.2003 to account for new treatment technologies, NRC should consider placing additional restrictions on individual licensees to provide the necessary protection to the receiving POTWs in unusual cases where the number of licensees, size of the sewage treatment plant or nature of the technology used at the treatment plant may cause doses above 100 mrem/yr. One commenter stated that it is unnecessary for NRC regulations to account for sewage sludge treatment technologies because local POTWs have the authority and mandate to account for these technologies by developing industrial water discharge permits pursuant to 40 CFR 403.5(c)(1).

Response: NRC acknowledges the commenters' opposition to the proposed rule change, which supports NRC's decision to withdraw the ANPR. With respect to the comment that POTWs have the authority and mandate to impose limits on radioactive materials released into sanitary sewers, NRC notes that, as described in Section 4.7 of the ISCORS recommendations on management of radioactive materials in sewage sludge and ash (EPA 832-R-03-002B), POTWs may not have the same authority to regulate radioactive material as they do to regulate other materials released into sanitary sewers.

Comment: Eight commenters expressed the view that NRC regulations should account for the fact that several licensees may discharge to the same POTW, and, of those, five expressed the view that the regulations should also take the capacity of the POTW into account. Five commenters stated that restrictions on the release of nonradioactive pollutants established under EPA's National Pollutant Discharge Elimination System (NPDES) account for the capacity of the receiving POTW, the wastewater treatment systems used, and the number of industrial users discharging to a POTW, and suggested any new regulations governing the release of radioactive materials into sanitary sewers should take these factors into account. A representative of DOE expressed the view that changes to the regulations to account for multiple dischargers should be considered but may not be necessary because sanitary systems

serving multiple licensees would probably be large systems in which the licensees' effluent would be diluted by many other inputs to the sewer system. One commenter suggested that, if limits on the total amount of radioactivity individual POTWs could receive were developed, any cases in which the limits are being exceeded by licensees that were already discharging sewage into the sewer system before the limits were developed should be handled on a case-by-case basis.

Response: NRC acknowledges the commenters' support for regulations that would account for the capacity of individual POTWs and the number of licensees discharging to a single POTW. However, the proposed change will not be implemented for the reasons previously explained.

Comment: Twenty-seven commenters were opposed to additional restrictions on the forms of material suitable for release into sanitary sewers. Twenty-one stated that the potential for significant reconcentration of radionuclides during wastewater treatment probably had been addressed by the May 21, 1991 changes to Part 20 (56 FR 23360) that restricted the forms of materials that could be released into sanitary sewers and lowered concentration limits. Another commenter expressed the view that it was unclear whether contamination described in the case studies discussed in the ANPR occurred because of violations of the existing regulations, and also that it would be inappropriate for NRC to respond to individual violations of regulatory requirements by making changes to the regulations for all licensees. Representatives of six licensees indicated that additional restrictions on the forms of material appropriate for disposal would impose a significant burden on their operations. Commenters listed the costs of building new storage facilities, analyzing samples of waste to determine whether insoluble radionuclides were present, and establishing new collection, handling, and disposal procedures as well as retraining of personnel as expenses that would be incurred if additional restrictions were imposed. In addition, three commenters expressed the concern that further restricting the forms

of material appropriate for disposal in a sanitary sewer would not be consistent with NRC's policy that doses should be maintained ALARA because the additional waste handling that would be required would cause doses to workers that would not be justified based on the minimal dose to members of the public or POTW workers that might be avoided.

Response: NRC acknowledges the commenters' remarks, which support the withdrawal of the ANPR. However, the NRC staff notes the need to analyze samples of waste to determine if the waste contains insoluble radionuclides should not impose an additional burden because the restriction on releasing insoluble, non-biological wastes was already in place when the comment was made.

Comment: Twenty-three commenters encouraged NRC to continue to allow release of readily soluble wastes that met the quantity and concentration release criteria in 10 CFR Part 20. Twenty-one of those commenters indicated that they were unaware of any significant problems caused by the disposal of soluble radioactive material in sewer systems. Three commenters stated that they were not aware of any mechanisms that would reconcentrate the wastes typical of biomedical research in sewage sludge, and two of these stated that the activity levels were sufficiently low that reconcentration, even if it did occur, would not cause a significant dose.

Response: NRC acknowledges the commenters' support for the continuation of the current regulations which allow certain concentration and quantities of readily soluble radioactive material into sanitary sewers.

Comment: Two commenters suggested that NRC should change the regulation to re-establish disposal of dispersible non-biological materials. One commenter suggested disposal of non-biological dispersible materials should be allowed for materials that have half-lives of less than 100 days or are below the concentrations listed in 10 CFR Part 20 Appendix C.

Response: NRC acknowledges the commenters' suggestion that release of

non-biological dispersible material into sanitary sewers be allowed. NRC understands that reconcentration of a radionuclide in sewage sludge can be limited by its half life. However, NRC has chosen not to change the regulation governing the release of radioactive material into sanitary sewers for the reasons previously explained.

Comment: Six commenters, including a representative of DOE, noted that the chemical form of materials released into the sewer can change, and that materials that are soluble when released may precipitate or sorb to solid particles in the sewer or treatment plant. A representative of the New York State Department of Environmental Conservation suggested NRC study not only the effect of new technologies on radionuclide solubilities, but also how the solubility of radioactive materials change in sanitary sewers. A representative of DOE noted that precipitation and sorption could cause risks to individuals who work in POTWs, work in close contact with sewers, or who incinerate or use wastewater treatment sludge. In addition, the commenter remarked that, while it appeared to be reasonable to limit sewer releases to soluble and dispersible biological materials, NRC should realize that licensees could release insoluble or nondispersible materials to sewer systems inadvertently. One commenter expressed the view that NRC regulations should account not only for the form of material when released, but the form it was likely to take after being discharged.

Three commenters expressed the view that, because the form of a material discharged is likely to change when it reaches the sewer or POTW, the modification to 10 CFR 20 that eliminated disposal for non-biological "readily-dispersible" materials may not have removed the chance that radionuclides could reconcentrate in wastewater treatment sludge. Two commenters remarked that reconcentration of radionuclides probably would continue, in part because POTWs are designed to remove dissolved contaminants from wastewater. However, both commenters expressed the opinion that reconcentration is not necessarily a problem if the dose any individual is expected to receive from exposure to sewers, sewage, or sludge is low.

Response: NRC understands that materials that are released into the sewer in a soluble form can precipitate or sorb to solid materials in sewers or POTWs, as discussed in NUREG/CR-6289. Most of the commenters' concerns about the potential risk to POTW workers are addressed in the ISCORS dose modeling report (NUREG-1783), as previously explained. Although the ISCORS dose analysis (NUREG-1783) does not include an analysis of doses to workers that come into contact with sewers, those doses are expected to be limited because of the limited amount of time a worker would spend in close contact with a sewer and because of the relatively low doses predicted for most scenarios that involve contact with sewage sludge.

NRC acknowledges the concern that licensees may inadvertently dispose of insoluble non-biological material. NRC also acknowledges the suggestion that the regulations should account for changes in the form of materials that are likely to occur in sewers and POTWs and the concern about the efficacy of the 1991 revisions. For the reasons previously explained, NRC has decided not to change the regulations governing the release of radioactive material into sanitary sewers. However, NRC staff notes that, in addition to restrictions on form, NRC also has imposed annual limits in 10 CFR 20.2003 (a) (4) on the total amount of radioactivity that can be released into sanitary sewers to limit the potential for reconcentration of radioactive material in sanitary sewers, sewage sludge, and sludge ash.

Comment: Five commenters supported additional restrictions on the form of materials that can be released into sanitary sewers. One commenter expressed the view that the practice, used by some medical research laboratories, of releasing pureed tissue samples to the sanitary sewer was distasteful. Another commenter expressed the opinion that NRC should impose any requirement that would minimize the amount of radioactivity in the environment.

Response: NRC acknowledges the commenters' support for additional restrictions on the forms of material suitable for release into sanitary sewers but is not changing the regulations because it believes the current approach is sufficiently protective, as previously explained.

Comment: Three commenters requested clarification regarding the distinction between soluble and readily dispersible materials. One requested that an information notice be produced to address materials used in the biotech industry. Another commenter expressed the concern that it would be difficult to demonstrate compliance with the restriction that only soluble and readily-dispersible biological materials be released into sanitary sewers if colloids that flow through filters and resins are classified as non-biological dispersible material. The commenter proposed an operational procedure to distinguish between soluble and readily dispersible materials. A representative of the New York State Department of Environmental Conservation noted that traces of insoluble radioactive material could be released into sewers with soluble materials, and requested that NRC establish a lower limit of detection for insoluble material.

Response: NRC acknowledges the commenters' request for additional guidance on how licensees should demonstrate the solubility of radioactive material released to sanitary sewers. Although NRC does not have plans to provide additional guidance on this issue, the staff notes that, as discussed in NRC Information Notice 94-007, licensees are free to develop alternative methods of demonstrating the solubility of materials they wish to release into sanitary sewers and to submit these procedures to NRC for evaluation on a case-by-case basis.

(2) Total Quantity of Material

In the May 21, 1991 final rule, NRC did not change the total quantity limits, which allow a licensee to release 185 gigabecquerel (GBq) (5 curies (Ci)) of H-3, 37 GBq (1 Ci) of C-14, and 37 GBq (1Ci) of all other radioactive materials combined into sanitary sewers each year. The use of total quantity limits has been a long-standing requirement and was originally included in the rule (10 CFR 20.2003(a)(4)) to address concerns regarding the possibility for reconcentration of radionuclides. In the ANPR, NRC invited comments about the alternative approach of limiting the annual release of each radionuclide individually. NRC also invited comments about the current total quantity limits and the potential impacts that additional

restrictions on the annual releases into sanitary sewers would have on licensees.

Prior to publishing the ANPR, NRC received a petition for rulemaking to amend 10 CFR 20.303 (superseded by § 20.2003) and § 20.305 (superseded by § 20.2004) from the Northeast Ohio Regional Sewer District (PRM-20-22). A notice of receipt of the petition was published in the *Federal Register* (58 FR 54071; October 20, 1993). The petitioner requested that NRC amend its regulations to require that all licensees provide at least 24 hours advance notice to the appropriate POTW before releasing radioactive material to the sanitary sewer system. The petitioner also requested that NRC exempt materials that enter the sanitary waste stream from the requirements regarding Commission approval for incineration under NRC's current regulations. NRC solicited comments on the petition in the ANPR. The denial of the petition was noticed in the Federal Register on January 27, 2005 (70 FR 3898).

Comment: Six comments received in response to the ANPR supported annual total quantity limits. Two commenters, including a representative of DOE, suggested total quantity limits should be retained because they help prevent reconcentration of radionuclides in sewage sludge and two supported the total quantity limits because they are easy for licensees and regulators to understand and implement. Two commenters, including the representative of DOE, suggested it may be worthwhile for NRC to evaluate whether the regulation could be optimized by changing the annual release limits for some radionuclides. A representative of the Illinois Department of Nuclear Safety expressed the opinion that the relatively low doses calculated for the case studies described in the ANPR and predicted for other scenarios in NUREG/CR-5814 indicated that reconcentration of radionuclides in sewage sludge could be addressed on a case-by-case basis rather than by changing the total quantity limits in § 20.2003.

Response: NRC acknowledges support for the current approach of using annual limits on the total quantity of radioactive material that can be released into sanitary sewers by a

licensee. In accord with the commenters' suggestion, NRC performed a study to evaluate the reconcentration of various radiounuclides in POTWs, the results of which are discussed in NUREG/CR-6289.

Comment: A representative of the City of Oak Ridge made positive and negative statements about NRC annual total quantity limits. The commenter stated that both concentration and total quantity limits were necessary to ensure protection of workers and to ensure that traditional methods of sludge disposal remain acceptable. However, the commenter also expressed the view that the current values of the total quantity limits are too high and stated that disposal of 37 GBq (1 Ci) of Co-60 annually to the Oak Ridge POTW would result in unacceptably high concentrations of Co-60 in the POTW's sludge, especially if the material was released during a relatively short time period. The commenter also expressed the opinion that the total quantity limits are inappropriate for low specific activity radionuclides because of the large mass of the radionuclide that could be discharged. As an example, the commenter stated that release of 37 GBq (1 Ci) of U-238 to the city's POTW in a year would result in a mass concentration of uranium of more than 0.05 percent in the POTW's sludge, making the sludge licensable source material. In addition to these comments, the commenter suggested that, because the mean retention time of sludge at a POTW typically is one month or less, a monthly discharge limit would be more appropriate than an annual limit.

Response: NRC acknowledges the commenter's concern about the release of Co-60 to a POTW and the suggestion that quantity limits should be implemented on a monthly, rather than an annual, basis. The staff notes that the 1991 revision to 10 CFR Part 20 that eliminated the discharge of insoluble non-dispersible radioactive material into sanitary sewers was implemented to reduce the possibility of significant contamination of sewage sludge with insoluble radionuclides, such as Co-60. NRC has decided not to change the regulations governing sewer release of radioactive material for the reasons previously explained. NRC

acknowledges the commenter' concern about the applicability of the total quantity limit to low specific activity radionuclides. However, NRC does not agree that the accumulation of large masses of low-specific activity radionuclides in POTWs is likely to be problematic. In addition POTWs have some authority to impose limits on the release of material into sanitary sewers when the purpose of the limits is not radiation protection, as discussed in Section 4.7 of the ISCORS recommendations on management of radioactive materials in sewage sludge and ash (EPA 832-R-03-002B).

Comment: Twenty-three commenters described concerns about the current approach of limiting the total amount of radioactivity a licensee may release into a sanitary sewer system. Nineteen commenters expressed the opinion that it is not appropriate to apply the same total quantity limit to large and small facilities that discharge different amounts of sewage and therefore dilute radioactive materials to different extents. Another commenter stated that NRC should not attempt to impose total quantity limits on large facilities. Seventeen commenters expressed the view that NRC should consider relaxing the total quantity limits because of the new restriction on the form of material and lower release concentration limits implemented in the 1991 revision to 10 CFR Part 20. The commenters expressed the opinion that adherence to the new form and concentration limits may eliminate the need for total quantity limits. Three commenters suggested that, instead of limiting the total quantity of radioactivity a licensee could dispose of into a sewer, NRC should focus on the radionuclides and chemical forms of radionuclides that reconcentrate in POTWs to a significant extent. One commenter expressed the concern that a person could dispose of 37 GBq (1 Ci) of Cs-137 within a month while remaining in compliance with the current concentration and total quantity limits. Another commenter suggested concentration limits are sufficient and are superior to total quantity limits because concentration limits account for the total volume of water a licensee releases to the sanitary sewer system. The commenter noted that, although the nominal purpose of the total

quantity limits is to eliminate reconcentration, the total quantity limits do not appear to prevent reconcentration, as evidenced by the case studies described in the ANPR. The commenter suggested reconcentration could be avoided by reducing the allowable concentrations of those radionuclides that have shown a tendency to reconcentrate in sewage sludge.

Response: NRC acknowledges the comment about the application of the same total quantity limit to large and small facilities, but believes that the system is appropriate. Because the total quantity limit is designed to reduce the potential for reconcentration of radionuclides at POTWs, an appropriate total quantity limit is more dependent on the volume of sewage received by a POTW than it is on the volume of a licensee's effluent.

NRC acknowledges the comment that total quantity limits should be relaxed or eliminated, but does not agree that the limits on form and concentration eliminate the need for annual quantity limits. As discussed in NUREG/CR-6289, the form of radionuclides can change upon entering a sewer or POTW because of sorption and precipitation. NRC also acknowledges the concern that total quantity limits did not prevent the cases of contamination discussed in the ANPR. NRC believes that limiting both the form and total quantity of material released into sanitary sewers is the best way to limit the potential for significant reconcentration of radionuclides released by licensees into sanitary sewers.

NRC acknowledges the commenters' suggestion that, instead of imposing total quantity limits, it should focus on those radionuclides that have been shown to reconcentrate in sewers or sewage sludge. NRC also acknowledges the commenter's concern about the discharge of Cs-137 but believes the current approach to be sufficiently protective for the reasons previously explained.

Comment: One commenter expressed the view that additional limitations on the release of H-3 and C-14 into sanitary sewers would not produce any public health benefit because any dose an individual received from sewer-disposed H-3 and C-14 would be negligible in

comparison to the dose the individual would receive from naturally-produced H-3 and C-14.

Response: NRC acknowledges the commenter's view that additional restrictions on the quantities of H-3 and C-14 are unnecessary. The comment supports the withdrawal of the ANPR and the current total quantity limits which allow the annual release of 185 GBq (5 Ci) of H-3 and 37 GBq (1 Ci) of C-14 in addition to the release of 37 GBq (1 Ci) of all other radionuclides combined.

Comment: Eight licensees expressed the view that additional restrictions on the total quantity of radioactive material that could be released into sanitary sewers annually would have a severe negative impact on their facilities' operations. Representatives of a biomedical company, a university, and the National Institutes of Health (NIH) noted that a reduction in the total quantity limits would impose a significant financial burden on organizations involved in biotechnical research, development, or medical practice, especially if the limits were reduced to a point that liquid wastes would need to be solidified and disposed of as low level waste (LLW). The representative of NIH estimated that solidification and disposal of liquid wastes as LLW would cost NIH 2.8 million dollars annually, as of 1994. Two commenters remarked that companies would bear the additional expense of acquiring or building storage facilities or acquiring treatment technologies to remove radioactivity from liquid waste streams. One commenter noted that LLW disposal of many of the materials currently released into sanitary sewer systems would be a particularly unnecessary expense and inefficient use of LLW landfill space because, in many cases, the material would decay to negligible quantities before it reached the LLW landfill.

Five commenters associated with medical research facilities or companies that produce radiopharmaceuticals suggested additional restrictions on the total quantity of radioactive material that could be released into sanitary sewers annually could harm public health and safety by causing companies to limit biomedical research and development efforts. One of

these commenters stated that the amount of radioactivity released into sanitary sewers in association with medical research was insignificant as compared to the amount of radioactivity released to sewers in patient excreta and concluded that release of radioactive materials associated with biomedical research should be allowed as long as the exemption for patient excreta is continued. Two commenters expressed the opinion that additional restrictions on the total quantity of radioactivity a licensee could release into sanitary sewers annually would not be consistent with efforts to maintain doses ALARA because workers would be exposed to radioactive material while processing liquid waste to make it suitable for LLW disposal.

A representative of a company that offers health physics services stated that, for most of its clients who want to release radioactive material into sanitary sewers, the most limiting factor is the annual total quantity limits. A representative of the University of California expressed concern that the numerical limits in 10 CFR 20.2003 would be lowered, although the university typically releases only 11.1 Gbq (0.2 Ci) of radioactivity into sanitary sewers each year.

Response: NRC acknowledges the commenter's concerns about the potential impacts of additional restrictions on the total quantity of radioactive material that a licensee can release to sewers annually. As previously explained, the additional restrictions discussed in the ANPR will not be implemented.

Comment: A representative of AMSA stated that, although the organization understands that lowering total quantity limits could impose financial burdens on licensees, additional restrictions are appropriate if they are needed to prevent contamination of sewage sludge.

Response: NRC acknowledges the commenter's statement, but has decided not to change the total quantity limits because it believes the current approach is sufficiently protective for the reasons previously explained.

Comment: Twenty-one letters received in response to the ANPR included comments on the Northeast Ohio Regional Sewer District's request for NRC to amend its regulations to

require that all licensees provide at least 24 hours advance notice to the appropriate POTW 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, including the petitioner's request for a 24-hour advance notification before licensees release radioactive material, monthly or annual discharge reports, reports of releases that could be a threat to the POTW workers or the environment, or notification of large accidental releases. One commenter suggested licensees should analyze effluent samples and include the results in discharge reports. A representative of AMSA stated that advance notice of releases is necessary so that POTW operators can ensure worker health and safety and make appropriate decisions about sludge disposal and reuse.

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 without providing additional protection against radiation or dose reduction. These commenters expressed the view 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 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 there could be large cost implications and regulatory burdens associated with such notification. In addition, commenters were concerned

that data about releases of radioactive material could be misinterpreted if release reports were received and interpreted by sewage treatment plant personnel rather than radiation safety specialists. Several commenters stated 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.

Response: NRC has determined that a requirement for advance notification of each release of radioactive material to a sanitary sewer would impose an unnecessary regulatory burden on licensees without a commensurate health and safety benefit. Additional reasons for the denial of the petition are discussed in the *Federal Register* notice published on January 27, 2005 (70 FR 3898).

Comment: Six comment letters received in response to the ANPR included comments on the Northeast Ohio Regional Sewer District's request that NRC exempt materials that enter the sanitary waste stream from the requirement 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. These commenters suggested that, if release into a sanitary sewer system is to be considered disposal, the limits should be set so that no further regulation of the radioactive material is needed after release. One commenter did not support such an amendment and expressed the view that it would only serve to provide an open-ended system for radioactive material to pass into the environment and to the public without limitation or characterization.

Response: NRC approval to incinerating waste is required 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 depend on the specific characteristic of the sludge and the radionuclides that may be present. Additional reasons for the denial of the petition are discussed in the *Federal Register* notice published on January 27, 2005 (70 FR 3898).

(3) Type of Limits

The present approach to limiting releases of radioactive material into sanitary sewers is to specify limits on both the monthly average concentration of each radionuclide in a licensee's sewage and the total quantity of radioactive matter that a licensee can release annually. Table 3, Appendix B, of 10 CFR Part 20 lists the allowable monthly average concentration of each radionuclide in a licensee's release to sewers. Allowable concentrations are based upon a calculated dose of 5 mSv/yr (500 mrem/yr) due to ingestion of 2 liters per day of a licensee's effluent into the sanitary sewer.

In the ANPR, NRC invited comments on this regulatory approach. Specifically, NRC invited comment as to whether it should continue to base concentration limits on the assumption that an individual would drink 2 liters of the effluent from a licensee's facility each day, and whether exposure at other locations, such as at a POTW, should be considered in developing release limits. In addition, NRC invited comments about how other exposure scenarios, such as exposure to radionuclides in contaminated sludge, should be accounted for. NRC also invited comments as to whether it should establish limits in terms of dose instead of limits on the quantity and concentrations of radioactive material discharged. Included with the responses to these inquiries were several comments about monitoring, enforcement actions, and regulatory authority to set limits on releases of radioactive material into sanitary sewers that have been addressed with the General Comments.

Comment: Twenty-three commenters supported the current modeling approach of

assuming that an individual ingests 2 liters of water taken from the licensee's outfall to the sewer system each day. Nineteen of these commenters, representing hospitals, biomedical laboratories, and universities, noted that this assumption is conservative and easy for licensees to understand. A representative of DOE noted that the approach appears to be bounding, and has been "largely successful as a regulatory measure". The commenter also expressed the view that, because this type of consumption is not expected to be chronic, it is appropriate to base concentration limits on a calculated annual dose of 500 mrem instead of 100 mrem. One commenter did not specifically address the assumption that an individual would drink 2 liters of a licensee's discharge each day, but did support the use of a licensee's sewer outfall as an appropriate exposure location. Two commenters expressed the view that the modeling assumption was appropriate because individuals, including children, could drink or otherwise be exposed to water directly downstream of a sewer outfall. Another commenter that supported the current assumption expressed the view that modeling exposure at a licensee's outfall to a sewer system is consistent with modeling exposure at a licensee's fence line, as is done in other NRC assessments, and that considering a downstream location would be inconsistent with modeling exposure to the maximally exposed individual.

Response: NRC acknowledges support for the current modeling assumption. The staff notes that several commenters appeared to believe that the concentration limits were based on the assumption that an individual would consume 2 liters of sewage from a POTW outfall, rather than 2 liters of a licensee's effluent into the sewer system, each day. Staff notes that the assumption that an individual would consume a licensee's effluent is more conservative than the assumption that an individual would consume POTW effluent because the concentration of radionuclides in POTW effluent will have been diluted with effluent from all of the other residential and industrial dischargers to the POTW.

Comment: Three commenters expressed concern that the concentration limits are

based on an annual dose of 5 mSv (500 mrem) and stated that the concentration limits should be based on an annual dose of no more than 1 mSv (100 mrem), in accord with the 10 CFR 20.1301 limit on doses to members of the general public from licensed activities. One commenter expressed the view that the 1 mSv (100 mrem) annual public dose limit should be lowered. Two commenters expressed the view that the dose from ingesting a licensee's effluent should be included in the 1 mSv (100 mrem) TEDE annual public dose limit rather than being calculated separately and excluded from the 10 CFR 20.1301 limit. Another expressed the view that, if any activity were to be permitted to be discharged into sanitary sewers, the limiting dose for exposure to sewage sludge should be no greater than the dose limit for low level radioactive waste.

Response: NRC acknowledges the commenters' concern about the hypothetical dose used as the basis for the concentration limits. As discussed in the ANPR, the NRC staff believes the concentration limits based on an annual dose of 5 mSv (500 mrem) are reasonable because it is unlikely that an individual would have access to and would consume water at the point at which a licensee discharges water into the sanitary sewer and because dilution from additional discharges into the sewer is likely to reduce the expected dose to well below the 1 mSv (100 mrem) annual dose limit.

NRC also acknowledges the commenters' suggestion that the dose from consuming effluent released into the sanitary sewer be included in the TEDE from other licensee operations. However, in the case of sewer discharge, the point of exposure is expected to be remote from the licensee's facility. Because individuals that could be exposed to a facility's effluent are different individuals than those that live closest to the facility, it would be unrealistic to include the dose from exposure to a licensed facility's effluent in the total dose from all of the facility's activities. The staff notes that comments regarding the appropriate value of the annual dose limit for members of the public from licensed activities specified in 10 CFR 20.1301 are

beyond the scope of this rulemaking.

Comment: Ten commenters did not support the use of the current modeling approach of assuming that an individual ingests 2 liters of water taken from a licensee's sewer outfall each day. Almost all of these commenters expressed the view that the assumption is unrealistic. One commenter expressed the view that, while the assumption that an individual ingests 2 liters of water taken from a licensee's sewer outfall each day is a reasonably conservative basis for concentration limits, the assumption may not be a basis for total quantity limits because it would over-emphasize the potential impact of short-lived radionuclides.

Response: NRC acknowledges the commenters' opposition to the current modeling approach. However, it will be retained because the ANPR is being withdrawn for the reasons previously explained. With respect to the comment about the basis for total quantity limits, the staff notes that the assumption that an individual would consume a licensee's effluent is used as the basis of the concentration limits but is not used as the basis of the total quantity limits.

Comment: Ten commenters suggested alternate locations that NRC should consider when developing restrictions on the release radioactive materials into sanitary sewer systems. Of these, five suggested NRC consider the dose to a person ingesting water once it has reached or is leaving a POTW rather than at the licensee's sewer outfall. Three commenters suggested NRC consider locations downstream of a POTW that would be likely to be locations from which a municipality would extract drinking water, while one suggested doses in the nearest residential area should be considered. Another commenter suggested realistic models would incorporate a factor of at least one million between the point of discharge and a receptor locations, and suggested that, if NRC used a more realistic dose model, it would become clear that additional release restrictions are unnecessary. One commenter suggested that, in considering potential doses to members of the public, NRC should consider that sludge could be sent to a landfill, applied to agricultural land, or made into compost for sale to the public.

Five commenters, including representatives of POTWs and DOE, recommended NRC consider doses to sanitation workers and two commenters suggested NRC consider doses to workers that come into contact with sewage collection systems as well as POTW workers. One commenter noted the importance of matching exposure locations to appropriate pathways and suggested external radiation by gamma emitters may be an important pathway for POTW workers, whereas ingestion of beta emitters would be expected to be more important at a downstream drinking water source. Five commenters suggested NRC consider that the careful treatment given to sewage and sludge because of the other hazards it presents should limit doses to sanitary system workers. One commenter added that NRC regulations also should prevent contamination of sewers, POTWs, receiving waters, and sludge and ash disposal sites. Another commenter suggested NRC consider potential exposures to all POTW residuals, including sludge, screenings, grit, and ash. The commenter also pointed out that sewer pipes may leak and suggested NRC consider the potential for groundwater contamination.

Response: The alternate locations that the commenters suggested should be considered in dose models will not be used as a basis for a revision to the regulations because the ANPR is being withdrawn for the reasons previously explained. However, the NRC staff notes that several of the modeling scenarios suggested by the commenters, including sludge handling by POTW workers, sludge incineration, and exposure to land-applied sewage sludge, were considered in the ISCORS dose modeling project (NUREG-1783).

Comment: Six commenters, including representatives of POTWs and the New York State Department of Environmental Conservation, suggested that, in addition to protecting the general public and sanitation workers, NRC regulations should ensure that POTWs can continue to use traditional forms of use or disposal of biosolids (sewage sludge). One commenter noted that events that have not resulted in significant worker exposure have prevented POTWs from using or disposing of sewage sludge.

Response: Additional restrictions on the release of radioactive material into sanitary sewers will not be implemented for the reasons previously discussed. Section 7.2 of the ISCORS recommendations on management of radioactive materials in sewage sludge and ash (EPA 832-R-03-002B) provides guidance to assist POTW operators in reducing sources of radiation entering their treatment facilities.

Comment: Four commenters made suggestions about ways to account for complex exposure scenarios, such as exposure to contaminated sewage sludge. One commenter suggested that a variety of scenarios should be evaluated and that the scenario resulting in the highest dose should be used to establish limits on releases of radionuclides to sewers. Another commenter expressed the opinion that dose models should reflect limitations on access that are imposed to protect individuals from other health risks associated with sewage and sewage sludge. One commenter suggested no model could adequately represent complex exposure scenarios because dose modeling was not sufficiently well developed.

Response: The approaches the commenters suggested will not be used as a basis for new restrictions on the release of radioactive material into sanitary sewers because the ANPR is being withdrawn for the reasons previously explained. NRC staff acknowledge the commenter's statement about the capabilities of dose modeling.

Comment: Of the fourteen commenters that addressed dose limits, seven supported implementation of dose limits. One commenter expressed the view that dose limits are preferable to limits on concentration and quantity alone because dose limits are easier to relate to risk. The commenter suggested the assumptions used to evaluate compliance with dose limits should be realistic. The commenter also suggested the use of a tiered approach, in which simple bounding assumptions are first used to evaluate compliance, and more complex models and more site-specific data are used only if the simple bounding model does not demonstrate compliance. Another commenter suggested that, if the appropriate models were developed,

releases into sanitary sewers should be controlled under the requirements of 10 CFR 20.1302 and ALARA guidelines just as other facility effluents are. The commenter also noted that the potential doses calculated in NUREG/CR-5814 indicate that the current regulations governing the release of radionuclides into sanitary sewers are more restrictive than other NRC dose limits on facility effluents. Two commenters expressed the view that dose limits should be adopted only if the current limits were found not to be protective of the public or POTW workers. Four commenters agreed with the proposal in the ANPR that, if dose limits were adopted, NRC should publish a regulatory guide that included concentration and total quantity guidelines to facilitate compliance. One commenter asked if licensees would have a choice of complying with the dose limit or with the concentration and quantity guidelines published in a Regulatory Guide. Two commenters advocated dose limits, but expressed the view that the dose limits should be based on measured radionuclide concentrations from samples taken from sewer outfalls and intakes or on readings from dosimeters placed at POTWs rather than on concentrations calculated based on assumptions about releases to and dilution in sanitary sewers.

Response: NRC acknowledges the commenters' support for sewer release restrictions to be expressed as limits on dose rather than activity. NRC also acknowledges the commenters' suggestion that compliance with dose limits be made based on sample measurements. However, these options will not be implemented because the ANPR is being withdrawn for the reasons previously explained. No response is required to the commenter's question about compliance with dose limits because the ANPR is being withdrawn.

Comment: Of the fourteen commenters that addressed dose limits, six commenters opposed dose limits, and a representative of the New York State Department of Environmental Conservation noted potential problems with implementing dose limits but suggested NRC study the option. Almost all of the commenters that opposed dose limits commented on the uncertainty of assumptions about exposure pathways and the relative complexity of

implementing dose limits as compared to concentration and quantity limits. Three commenters predicted dose limits would require more regulatory oversight because NRC would need to review each licensee's dose model. One commenter expressed the concern that dose limits could make it necessary for licensees to require prior approval for releases of radioactive material into sanitary sewers. One commenter supported the current limits but suggested that, if dose limits were adopted, the dose limit should be 500 mrem/yr, realistic modeling assumptions should be made, and the modeling assumptions to be used in compliance calculations should be clearly defined. Another commenter advocated the use of limits expressed in "verifiable units of measure" rather than limits expressed as dose and expressed doubts about the capabilities of computer models used to calculate dose. Another commenter stated NRC should not limit the dose a patient could receive from a prescribed medical procedure.

Response: NRC acknowledges the commenters' opposition to dose limits, which will not be implemented because the ANPR is being withdrawn.

With respect to the commenter's concern that NRC should not limit the dose a patient could receive due to a medical procedure prescribed by his physician, the NRC staff notes the scope of the ANPR was limited to potential doses due to exposure to radioactive material in sewage or sludge. In general, NRC regulates the uses of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public and does not intrude into medical judgments affecting patients. Additional detail on this topic can be found in NRC's Final Policy Statement on the Medical Use of Byproduct Material, which was published in the *Federal Register* on August 3, 2000 (70 FR 3898).

Comment: Two commenters expressed concern that NRC would consider setting any non-zero dose limit for POTW workers. Both commenters expressed the view that any dose received by a POTW worker because of exposure to radionuclides released into sanitary

sewers by licensees would not be ALARA if the only reason such releases were allowed was to provide an inexpensive method of waste disposal to NRC licensees.

Response: NRC acknowledges the commenters' concern about sanitary system worker doses but disagrees with the view that only a dose of zero could be ALARA. The staff notes that the ISCORS dose modeling report (NUREG-1783) concludes that POTW worker doses typically are very low and are dominated by exposure to NORM. Additional restrictions on the release of radioactive material into sanitary sewers will not be implemented for the reasons previously discussed.

Comment: Three commenters expressed views on the appropriate time period over which releases should be averaged. A representative of a municipality suggested monthly averages should not be used because the practice encourages the use of dilution as a means of meeting the regulations. A representative of AMSA suggested daily averages should be used because POTW workers could be exposed to sewage and sludge on a daily basis. In contrast, a representative of a public utility district supported the use of weekly or monthly averages.

Response: NRC acknowledges the commenters' suggestions about appropriate time periods over which releases should be averaged. NRC believes monthly averages are appropriate because the effects of small quantities of radioactivity released during a month are not expected to depend on the time period over which the radioactive material is discharged. Monthly limits will be retained because the ANPR is being withdrawn for the reasons previously explained.

Comment: Ten commenters supported the development of annual release limits for individual radionuclides or groups of radionuclides. Eight commenters suggested limits for individual radionuclides should be based on the results of dose models. Specific factors that commenters suggested should be included in a dose model included a radionuclide's specific

activity, half-life, and solubility, and factors affecting the radionuclide's fate and transport in sewers, wastewater treatment process, and the environment. Two commenters recommended NRC consider imposing different discharge limits for those radionuclides and chemical forms that reconcentrate in POTWs to a significant extent and those that do not. Another commenter suggested NRC set limits for individual radionuclides based on whether they pose a risk primarily due to internal or external exposure and specifically suggested pathway modeling should include exposure to radionuclides that volatilize from sewage at a POTW, exposure to raw river water, and ingestion of treated river water. Another commenter suggested NRC consider the fate of radionuclides in engineered wetlands that are used by some POTWs as a final treatment step. One commenter predicted annual release limits for individual radionuclides would provide more flexibility to licensees and eliminate the need for special licensing exceptions to the current total quantity limits. A representative of DOE predicted that only a very few radionuclides would require reduced quantity limits even if the limits were conservative to bound variations in sewage plant designs and operating characteristics and to account for potential improvements in waste water treatment technology.

Four commenters suggested that annual release limits should be based on radionuclide half-life. A representative of the Texas Department of Health predicted it may be difficult for licensees to keep track of the quantity of each radionuclide released and suggested NRC impose one quantity limit for short-lived radionuclides that would be unlikely to reconcentrate in sewage sludge and a lower limit for long-lived radionuclides that have a greater potential to reconcentrate in sewage sludge.

A representative of the New York State Department of Environmental Conservation noted that it may not be appropriate to use Annual Limit of Intake (ALI) values as a basis for annual release limits for individual radionuclides, as suggested in the ANPR, because the ingestion pathway may not be the most significant exposure pathway and because the chemical

form of a radionuclide may be significantly different when it is released from a POTW than it was when it was originally discharged to the sewer. One commenter suggested both the total quantity of all radionuclides as well as quantities of individual radionuclides released should be limited, and that quantity limits for individual radionuclides should be based on fractions, rather than multiples, of ALI values. The commenter also suggested annual limits should assure the lowest possible rather than the lowest "reasonably achievable" exposure of members of the public to radionuclides.

Response: NRC acknowledges the commenters' support for the development of annual release limits for individual radionuclides or groups of radiounuclides. However, the proposed change will not be made because the ANPR is being withdrawn for the reasons previously explained.

Comment: Five commenters opposed the development of annual release limits for individual radionuclides. Two commenters suggested the low calculated doses received in the case studies discussed in the ANPR indicate the current regulations are adequate. Two commenters suggested that, if NRC were to change the annual quantity limits, it should focus on Co-60, Sr-90, Cs-137, Ir-192, and Am-241, because these radionuclides were identified in NUREG/CR-5814 as having the potential to result in a significant dose, based on the pre-1991 release limits. A representative of the State of Illinois Department of Nuclear Safety recommended NRC change the total quantity limits only if the releases of Co-60, Sr-90, Cs-137, Ir-192, and Am-241 that were determined to be potentially problematic in NUREG/CR-5814 would still be permitted, given the restrictions on form and lower concentration limits introduced in the 1991 revision to 10 CFR 20.

Another commenter noted that, although limiting the quantities of radionuclides released would not necessarily be difficult, the need to analyze batches of wastewater to determine the quantities of individual radionuclides being released would be a significant burden as compared

to the current method the company uses, which is to base releases on DOT shipping papers that identify the most limiting radionuclide in a batch. However, the commenter also noted that using limits based on multiples of ALI would be "on the right track" and would be similar to methods used in Europe.

One commenter expressed the view that the biokinetics of individual radionuclides could not be modeled well enough to provide a basis for limits on the quantity, concentration, or form in which a radionuclide could be discharged, especially because the models would not include the synergistic effects of radiation and other pollutants. The commenter also expressed the view that the exempt quantities published in 10 CFR Part 30 represented quantities "below regulatory concern" (BRC) and suggested it would be inappropriate to use multiples of the exempt quantity values as annual quantity limits.

Response: NRC acknowledges the commenters' opposition to annual release limits for individual radionuclides, which supports withdrawal of the ANPR.

(4) Exemption of Patient Excreta

The fourth topic on which NRC invited comment was the exemption of patient excreta from the regulations governing releases of radioactive material into sanitary sewers. NRC received fifty-two letters that addressed the exemption for patient excreta.

Comment: Forty-four commenters, including a representative of AMSA, recommended the exemption for patient excreta be continued and suggested it required no additional evaluation. Thirty-three of the commenters stated the exemption is necessary to maintain doses ALARA. Several commenters predicted that the radiological risks to health care workers, in the case of hospitalized patients, or family members, in the case of patients released from the hospital, associated with managing excreta would be far greater than any risk that the excreta would pose to POTW workers or members of the general public once released to the sewer system. Several commenters noted the possibility that excreta could be spilled or inadequately

shielded, especially in the case of patients that had been released from the hospital. One commenter expressed concern about radioactive materials volatilizing from containers of urine. Another commenter noted that children or pregnant women could be subject to increased risk from excreta stored in the home if the exemption were withdrawn. Seven commenters noted that, in addition to the radiological risks, collection and storage of patient excreta also could pose biological hazards.

Twenty-seven of the commenters that supported the exemption noted the short half life of most radiopharmaceuticals, and most of these commenters hypothesized that the risk that radiopharmaceuticals could pose to sanitary system workers or members of the general public would be limited by their short half lives. Representatives of two hospitals indicated that approximately 90 percent of the radioactivity used at their hospitals was in the form of Tc-99m, which has a half life of 6 hours, and that most of the remaining radionuclides used have a half-life on the order of a few days. Twenty commenters noted the soluble or dispersible nature of patient excreta and five commenters suggested the dilution of patient excreta that occurs in the sewer system affords ample protection to the public and to the environment.

Four commenters remarked that, if NRC believes the regulation is adequate, as stated in the ANPR, there should not be a need to modify the exemption for patient excreta. Two commenters predicted restrictions on the release of patient excreta into sanitary sewers would not provide a significant benefit to public health and eleven commenters suggested the current exemption creates no environmental or public health hazard. One commenter remarked that none of the six case studies presented in the ANPR indicated that patient excreta released into sanitary sewers had caused a significant dose to any individual. A representative of a large health care organization noted that no complaints had been made about the sewage from any of the organization's hospitals, although the hospitals' effluents were tested by sanitary system staff routinely. Another hospital representative expressed the opinion that hospitals should not

be required to monitor patient excreta because the practice causes undue anxiety in the patients, creates additional burdens for nursing staff, and is unnecessary because survey readings generally are low.

Response: NRC acknowledges the commenters' support for the exemption for patient excreta, which supports the withdrawal of the ANPR.

Comment: Fourteen commenters stated that elimination of the exemption would impose significant burdens on their facilities' operations. Commenters expressed concern about the costs of building holding tanks for excreta, building separate plumbing systems, retraining workers, and employing additional workers to manage patient excreta. One commenter remarked that facilities would also incur the cost of hiring professionals to assess their current waste management practices and to recommend changes that would be needed to comply with new regulations. Three commenters remarked that medical facilities may also incur the costs of increased NRC licensing fees and inspections. Several commenters suggested any net health benefits associated with eliminating the exemption could not justify the costs of controlling the excreta, particularly for patients being treated on an out-patient basis.

Seven commenters predicted the costs of compliance with restrictions on release of patient excreta into sanitary sewers would cause a significant increase in health care costs for patients. Three commenters predicted that health care costs would increase both because of the increased infrastructure and labor required to manage patient excreta and because patients' hospital stays would be extended so that their excreta could be managed by hospital staff. A physician and member of the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) estimated that the national increase in health care costs would be approximately 4.5 billion dollars for patients undergoing therapeutic procedures and 62 billion dollars for patients undergoing diagnostic procedures, as of 1994. The American College of Nuclear Physicians and the Society of Nuclear Medicine jointly estimated that elimination of the

exemption would cause an increase in health care costs of 5.9 billion dollars annually.

One commenter expressed the concern that medical facilities may stop offering nuclear medicine services to avoid the legal consequences that could result if patients did not comply with restrictions on the release of excreta to sewer systems. Five commenters predicted that it would be difficult to compel patients being treated on an out-patient basis to store their excreta for decay or return it to a licensed facility. One commenter expressed the concern that strict controls over patients could infringe upon a patient's constitutional rights.

Several commenters expressed the concern that elimination of the exemption would impact patient care. Four commenters expressed the opinion that, if the exemption were eliminated, the costs or logistical difficulties associated with managing patient excreta would cause many facilities to discontinue offering nuclear medicine services and could cause the end of nuclear medicine in the United States. Three commenters expressed the concern that elimination of the exemption for patient excreta would limit patient access to diagnostic and therapeutic nuclear medicine services and five commenters expressed the view that inaccessibility of nuclear medicine services would be far more detrimental to public health than any adverse health effects that could be averted by eliminating the exemption for patient excreta. One commenter noted that many facilities already have eliminated some clinical procedures because of the lack of access to low level radioactive waste disposal facilities. Two commenters expressed the concern that eliminating the exemption for patient excreta would diminish the quality of care that patients received if facilities limited patient doses to comply with restrictions on the radioactivity of patient excreta released into sanitary sewers. One commenter expressed the concern that patients may decline beneficial medical procedures because of an objection to collecting or having someone else collect their excreta. One commenter noted that patient well-being would be compromised if patients needed to remain in the hospital so that their excreta could be managed because it would prolong the time away

from their families and jobs. Another commenter suggested the current exemption for patient excreta should be maintained until the impact on health care could be assessed.

Response: NRC acknowledges the commenters' concerns about the potential costs, legal implications, and impacts on patient care that may be caused by removing the exemption for patient excreta. The exemption will be maintained because the ANPR is being withdrawn for the reasons previously explained.

Comment: Three commenters suggested the effects of the exemption should be studied to determine if the exemption should be eliminated or modified. A representative of DOE recommended NRC maintain the exemption for the excreta of patients undergoing diagnostic procedures, but consider placing restrictions on the excreta of patients undergoing therapeutic procedures because they typically receive higher doses of radiopharmaceuticals. Another commenter remarked that it would be inconsistent of NRC to impose strict restrictions on the release of excreta by hospitalized patients if the excreta of patients being treated on an out-patient basis contributed more radioactivity to sanitary sewer systems. A representative of an association of POTWs in Minnesota stated that the organization is prepared to rely on NRC judgement about the appropriateness of the exemption once NRC has evaluated the amounts and types of radioactive materials released into sanitary sewers through patient excreta, but expressed concern that the ANPR indicated that the effects of the exemption had not been studied and would not be included in planned modeling efforts. The commenter also expressed the opinion that the safety of the exemption should be evaluated irrespective of the origin of the waste in medical uses. A representative of the New York State Department of Environmental Conservation suggested that a range of possibilities, including retaining the exemption, eliminating the exemption, and modifying the exemption, should be evaluated in an Environmental Impact Statement (EIS). The commenter stated an EIS would provide a "long-needed" record of the rationale for the decision to exempt patient excreta from the sewer

release restrictions and the expected impacts of the exemption on the environment and public health.

Response: NRC acknowledges the suggested modifications to the exemption of patient excreta and the suggestion that an EIS should be performed. However, those suggestions will not be implemented because the ANPR is being withdrawn for the reasons previously explained.

Comment: Two commenters suggested releases of radioactive materials into sanitary sewers should be regulated uniformly, irrespective of the origin of the wastes. One of the commenters questioned why the ANPR specifically stated that doses from patient excreta were expected to be "far below the NRC's dose limit" when this description was equally appropriate for the discharges from other licensees. Another commenter remarked that, although it may be difficult for medical institutions to meet restrictions on the release of patient excreta, the releases should be regulated because they have been shown to contaminate sewage sludge. Another commenter provided measurements of I-131 in sewage and sludge in one municipality's POTW and expressed the concern that I-131 could be a source of radiation exposure to sanitary system workers. The commenter also expressed the concern that, although it has a short half life, Tc-99m could cause significant radiation doses to workers exposed to sewage collection systems directly downstream of hospitals. In addition, the commenter expressed the concern that, because I-131 is very soluble, most of the I-131 that entered a POTW would be discharged in the treated effluent and that the POTW's effluent may, therefore, exceed NRC limits on the allowable releases of radioactivity to unrestricted areas. The commenter also expressed concern that many municipalities are not aware that releases of patient excreta are exempt from NRC restrictions and can be a significant source of radioactivity in wastewater.

Response: NRC acknowledges the commenters' suggestion that the release of

radioactive material should be regulated uniformly irrespective of its origin. However, NRC believes the exemption for patient excreta is appropriate because of the potential biological and radiological hazards associated with alternate methods of managing patient excreta. Additional limitations on the release of patient excreta into sanitary sewers are not being imposed for the reasons previously discussed. NRC appreciates the commenter's concern that municipalities may be unaware of the potential for patient excreta to contribute to the radioactivity of wastewater and sewage sludge. Section 3.2 of the ISCORS recommendations on managing radioactive material in sewage sludge and ash (EPA 832-R-03-002B) alerts POTW operators that a significant amount of the radioactivity discharged to POTWs that serve medical facilities can be discharged in the form of patient excreta.

Comment: Two commenters suggested the exemption for patient excreta should be eliminated to minimize the release of man-made radioactivity to the environment. One commenter expressed concern about NRC's policy on allowing patients who had received nuclear medicine treatments to leave the hospital (described in NRC Information Notice 94-009). The commenter also expressed concern about specific incidents in which, the commenter believed, patients had not been warned that high residual radioactivity would result from the medical procedures they had undergone or had been told that releasing excreta to a septic system would not cause adverse health effects. The commenter remarked that, although the radionuclides used in nuclear medicine procedures may be short-lived, each contribution of radioactivity to wastewater increased the potential dose to a member of the public. Another commenter noted that the contribution of radiopharmaceuticals to the radioactivity of wastewater increases as the number of procedures performed increases. The commenter also remarked that, if the half-lives of radioisotopes used in medical procedures typically are short, as NRC stated in the ANPR, the burden of storing the excreta until the radioactivity decays to background levels should not be large.

Response: NRC acknowledges the commenters' concerns about the potential effects of the release of patient excreta into sanitary sewers. However, NRC believes the current regulations are protective and has decided to retain the exemption and withdraw the ANPR for the reasons previously explained. The staff notes that comments about the regulations governing the release of nuclear medicine patients from the hospital are beyond the scope of this rulemaking.

Comment: One commenter suggested patient "vomitus" should be included in the exemption for the release of patient excreta into sanitary sewers explicitly. Two additional commenters mentioned sweat, saliva, blood, tears, and nasal fluids, but did not make any specific suggestions about how those fluids should be addressed in NRC regulations.

Response: The suggested change to the wording of the exemption will not be made because the ANPR is being withdrawn. However, NRC staff note that, in practice, the term "patient excreta" typically is understood to include situations when patients vomit.

Comment: A representative of a company that manufactures equipment that removes radionuclides from hospital waste noted German law requires that radioactive materials be removed from hospital effluent before it is released into sanitary sewers.

Response: NRC appreciates the information provided by the commenter. However, the exemption for patient excreta will be retained because the ANPR is being withdrawn for the reasons previously explained.

Comment: Three commenters asked questions about the regulatory implications of potential modifications to the exemption of patient excreta from sewer release restrictions. Two commenters asked whether patients would be required to store their excreta at home until it decayed to background levels of radioactivity or if they would be required to return it to the medical facility at which they were treated. Two commenters asked whether the homes of nuclear medicine patients would need to be monitored to ensure that proper waste disposal

procedures had been followed. One commenter asked if the elimination of the exemption would result in changes to 10 CFR 35.75. The commenter also asked whether restrictions would apply to all patients treated with radiopharmaceuticals, irrespective of the dose they had received. The commenter also asked how a licensee would calculate the radioactivity released by each patient and whether records of the releases would need to be maintained by the licensee.

Response: NRC acknowledges the many questions on this issue, but is not responding to them because the ANPR is being withdrawn.

Comment: One commenter suggested NRC should exempt the excreta of animals used in biomedical research from the restrictions governing the release of radioactive material into sanitary sewers.

Response: NRC notes that this comment is beyond the scope of this rulemaking.

(5) General Comments

In addition to comments on the topics discussed in the ANPR, NRC received a number of comments on other aspects of the release of radioactive material into sanitary sewers. These comments are addressed in this section.

Comment: Sixteen commenters expressed the opinion that the current regulations governing the release of radioactive materials into sanitary sewers are adequate and should not be changed. To support this view, commenters remarked that the number of incidents of contamination is small compared to the number of POTWs receiving radioactive materials and that the doses received in those instances are believed to be low. Commenters also suggested the regulations should not be changed in response to a small number of cases of contamination, especially if some of those cases involved violations of the applicable regulations. One commenter noted that modeling results described in NUREG/CR-5814 indicate that releases of radionuclides used in biomedical research are expected to result in

doses below the ALARA guidelines in NRC Regulatory Guide 8.37. A representative of the Texas Department of Health suggested the regulations should not be changed unless modeling results demonstrated that exposures other than ingestion could cause an annual dose greater than 5 mSv (500 mrem). Two commenters suggested the risk of adverse health effects associated with exposure to radioactive material released into sanitary sewers should be evaluated in comparison to the health risks associated with exposure to hazardous chemical and biological materials in sewage and sludge. One commenter suggested the current limits are appropriate because the quantities and concentrations of radionuclides at affected POTWs appear to be within 10 CFR Part 30 limits for general licensees.

Response: NRC acknowledges the commenters' support for the current regulations, which supports withdrawal of the ANPR.

Comment: Nine commenters, including a representative of DOE, suggested the changes made to 10 CFR Part 20 in 1991 may have significantly reduced the potential for reconcentration of radionuclides in POTWs, and that resources should not be expended to address a problem that may have already been solved. Of these, five commenters noted that the ANPR did not include any information about contamination problems that had occurred since the modification of 10 CFR Part 20 and two commenters noted that most of the contaminants in the case studies presented in the ANPR were insoluble non-biological materials and would not meet current release criteria. Several commenters recommended NRC evaluate the effects of the lower discharge concentration limits and prohibition against discharging insoluble, non-biological materials into sanitary sewers before making additional changes to 10 CFR Part 20. One commenter expressed the opposite view and stated that the NRC should not assume that the changes made to 10 CFR Part 20 in 1991 would eliminate contamination of POTWs with licensed radioactive materials.

Response: NRC acknowledges the commenters' recommendation that it study the

effect of the changes made to 10 CFR Part 20 in 1991 on the amount of radioactive material at POTWs. The NRC staff notes that the ISCORS sewage sludge survey and dose modeling work were performed several years after the January 1, 1993, deadline for licensees to meet the revised requirements and should reflect the effects of the 1991 revision of the regulation.

Comment: Five commenters expressed the view that additional restrictions on the release of radioactive materials into sanitary sewers would not be consistent with efforts to keep doses ALARA. Several of the commenters predicted that doses to workers that were required to collect or prepare waste for disposal would be far greater than the collective dose that could be averted by more restrictive sewer release limits.

Response: NRC acknowledges the commenters' opposition to additional restrictions on the release of radioactive materials into sanitary sewers, which supports the withdrawal of the ANPR.

Comment: Four commenters stated that any additional restrictions on the release of radioactive material into sanitary sewers would have a significant negative impact on the facilities they represented. One commenter expressed the view that banning the release of radioactive material into sewers would impose a large financial burden on all biological research facilities and estimated that, as of 1994, alternative disposal methods would cost his company $150,000 to $300,000 annually. A representative of a nuclear laundry stated that additional restrictions on the release of radioactive material into sanitary sewers could have a serious detrimental effect on his company and its customers if nuclear laundries could no longer operate. Another commenter suggested new restrictions should be implemented gradually by adding new restrictions during license renewals.

One commenter expressed concern that additional restrictions on the release of radioactive material to sewers would encumber facilities that perform medical research, and requested that educational and medical research institutions be exempted from the regulations

because the long-lived radionuclides that had been detected in the cases described in the ANPR typically are not used by medical research facilities. The commenter also requested that, if medical research facilities were not exempted, more explicit guidance about the implications of the regulations on specific practices used in medical research facilities be provided by NRC. Another commenter proposed that the regulation should explicitly permit disposal of medical diagnostic products in aqueous mixtures that contain less than 370 kBq (10 microcuries) of radioactivity and which are composed of isotopes with half-lives less than 61 days.

Response: NRC acknowledges the commenters' information about the burdens that could be caused by additional restrictions on the release of patient excreta into sanitary sewers, which supports the withdrawal of the ANPR. The staff notes that requests for exemptions of certain classes of facilities or types of waste are beyond the scope of this rulemaking. NRC acknowledges that guidance written specifically for medical research facilities would be helpful to some licensees, but does not have plans or resources to develop such guidance.

Comment: A representative of DOE expressed the view that the current rules are protective of public heath and safety and the environment, and noted that, if the provision for release of radioactive materials into sanitary sewers was not available, risks to the public would result from other waste management options. As an example, the commenter predicted elimination of the release of radioactive material into sewers would cause an increase in traffic accidents because of the need to transport more waste to LLW disposal facilities. However, the commenter also recommended NRC increase inspections of licensees' releases into sanitary sewers and perform additional analyses of potential doses to members of the public and sanitary system workers to ensure that adequate safety provisions are in place to preclude accidental discharge of large quantities of radioactive material. The commenter also recommended NRC contact AMSA and industry trade groups to obtain additional information about variations and trends in wastewater treatment technologies, practices, and regulations.

Response: NRC acknowledges the commenter's remarks regarding the risks that could result from additional restrictions on the release of radioactive material into sanitary sewers, which support the withdrawal of the ANPR. In accord with the commenter's suggestions, NRC participated in the ISCORS sewage sludge survey (NUREG-1775) and dose modeling report (NUREG-1783), the results of which provide a technical basis for withdrawing the ANPR. The staff acknowledges the suggestion regarding NRC inspection activities but notes the topic is beyond the scope of this rulemaking.

Comment: A representative of NIH stated that, although NIH is a large facility conducting both biomedical research and medical diagnosis and treatment, and its usage of some isotopes fluctuates considerably, NIH has been able to manage its radioactive liquid wastes in compliance with NRC regulations. The commenter also stated that NIH uses large, centrally-located tanks to hold short-lived radionuclides for decay, and that NIH has been granted an exception to the total quantity limits that allows it to discharge a total of 296 GBq (8 Ci) annually.

Response: NRC acknowledges the commenter's information regarding the adequacy of the current regulations governing the release of radioactive material into sanitary sewers.

Comment: A commenter who was a member of ACMUI as well as a physician and professor of Radiological Sciences at the University of California, Los Angeles, expressed several concerns regarding the possible changes described in the ANPR. The commenter expressed the opinion that NRC resources would be better spent changing other parts of 10 CFR Part 20 than by making the changes proposed in the ANPR. The commenter also stated that Agreement States had been reluctant to adopt the changes made to 10 CFR Part 20 in 1991 because of unspecified problems with the revised rule. The commenter expressed concern that user fees were used to support a National Council on Radiation Protection study of the number of various types of nuclear medicine procedures performed annually as of 1989.

The commenter also expressed concern that any change in NRC regulations governing the release of radioactive materials into sewers would later be changed by an EPA rule, and that NRC licensees would, in effect, pay for a rule twice by paying both NRC user fees and paying taxes to support EPA.

The commenter asked why the NRC had published the ANPR and expressed concern that NRC wasted licensees' time by asking for data regarding various nuclear medicine procedures. The commenter stated that the data had been given to NRC in 1990 and asked why NRC did not used these data to derive concentrations of various radionuclides in sanitary sewage. The commenter also suggested NRC could request data regarding concentrations of radioactive materials in wastewater and sewage sludge from POTWs in Agreement States. In addition, the commenter suggested NRC review any proposed changes related to medical uses of isotopes with the ACMUI and expressed an unfavorable opinion about NRC's program to regulate medical uses of radionuclides.

Response: NRC acknowledges the commenter's statements about the 1991 revision to 10 CFR Part 20 but notes that other parts of the regulation are beyond the scope of this rulemaking. A response to the commenter's displeasure at paying licensing fees to support this rulemaking is not needed because the ANPR is being withdrawn. The same applies to the commenter's concern that EPA would impact a change in NRC's regulations. Because the ANPR is being withdrawn, that concern is no longer applicable to this issue.

NRC published the ANPR to invite comments and recommendations from interested parties on potential changes in the regulations governing the release of radioactive materials into sanitary sewers. In response to the commenter's concern about the time licensees may have spent responding to the ANPR, NRC notes that the ANPR invited comment but did not require a response. In addition, NRC notes that the ANPR invited comment on a variety of issues and was not limited to a request for information to support the derivation of

concentrations of radionuclides in sewage.

NRC acknowledges the commenter's suggestion that potential changes to the rule be discussed with the ACMUI, and the commenter's statements about NRC's program to regulate medical uses of radionuclides.

Comment: Three commenters expressed the view that cases of contamination at POTWs demonstrate that the current regulations governing the release of radioactive material into sanitary sewers is inadequate. All three commenters expressed the concern that the regulations did not adequately protect the health and safety of POTW workers. In addition, a representative of AMSA expressed the concern that the current regulations could jeopardize the ability of POTWs to fulfill their environmental objectives. The commenter also expressed concern about NRC's involvement with existing cases of contamination and urged NRC to take a more active role in protecting POTWs from contamination with radionuclides.

Each of the three commenters expressed the opinion that the current regulations also fail to protect POTWs from the legal and financial consequences of contamination of POTWs and POTW biosolids with radionuclides. Two commenters noted that the public ultimately bears the costs associated with contamination of POTWs and one estimated that billions of dollars of public funds could be required to dispose of contaminated sludge and decontaminate POTWs. A representative of the City of Oak Ridge outlined the history of contamination of the Oak Ridge POTW with Co-60, Cs-137, uranium isotopes, and I-131 from 1984 to 1994. The commenter noted that, as of 1994, disposal of wastewater treatment sludge cost the City of Oak Ridge approximately $100,000 per year, primarily because of radioactive contamination. The commenter stated that, because of this expense, the city is in the process of implementing its own limits to control releases of radioactive materials into the sanitary sewers and provided a reference that describes the approach that has been taken to control radioactive materials through the municipality's industrial pretreatment program.

A representative of the Northeast Ohio Regional Sewer District noted that, although no significant health or safety problems had been found to result from the contamination at the district's Southerly Facility, the district has had to manage difficult regulatory issues and concerns from the public and from workers that had cost the district, as of 1994, $1.5 million to resolve. The commenter remarked that the sanitary district had over one hundred thousand cubic meters (4 million cubic feet) of Co-60 contaminated ash at its Southerly Facility and had recently discovered contamination at another one of its POTWs. The commenter expressed the view that the District's problems were attributable to inadequate regulations or ineffective enforcement by NRC and suggested that major revisions to both 10 CFR Part 20 and to NRC's enforcement program were overdue.

Response: NRC acknowledges the commenters' concerns about cases of contamination and protection of POTW workers. However, NRC believes that the restrictions on the forms of material suitable for release and lower concentration limits established in the 1991 revision to 10 CFR Part 20 have reduced the potential for significant contamination of POTWs or sewage sludge with radionuclides. Although additional restrictions on the release of radioactive material into sanitary sewers will not be implemented, Section 7.2 of the ISCORS recommendations on management of radioactive materials in sewage sludge and ash (EPA 832-R-03-002B) provides guidance to assist POTW operators in reducing sources of radiation entering their treatment facilities. Comments about NRC's enforcement program are beyond the scope of this rulemaking.

NRC acknowledges the information provided by the City of Oak Ridge regarding the POTW's industrial pretreatment program. Information about the program is summarized in Appendix F of the ISCORS recommendations on management of radioactive materials in sewage sludge and ash (EPA 832-R-03-002B).

Comment: A representative of a sanitary district stated that, contrary to the position

taken by NRC in the ANPR, many cases of contamination of POTWs are the result of relatively basic wastewater treatment technologies. In addition, the commenter expressed the view that NRC's emphasis on the concept of "reconcentration" as the cause of contamination problems is misleading and noted that, at one POTW in the district, it appeared that particles of Co-60 were removed from the sewage through settling, as other solids are removed, rather than through reconcentration of dissolved cobalt or agglomeration of fine particles. The commenter expressed the view that the new restrictions on the forms of materials suitable for release into sanitary sewers may prevent many problems with insoluble materials such as Co-60 if the regulations are properly enforced.

Response: NRC acknowledges the commenter's concern that the term "reconcentration" was used in the ANPR to describe all processes by which the concentration of radionuclides in sewage sludge or ash could be increased on volumetric basis. NRC understands that radioactive materials may be concentrated by common wastewater treatment processes, as discussed in NUREG/CR-6289.

Comment: Seven commenters expressed the view that discharges of radioactive materials into sanitary sewers should be regulated locally. Two commenters suggested that, because relatively few cases of contamination had been observed, it appeared that the cases could be resolved without NRC involvement. One commenter expressed the view that local control would be easiest to implement if the problematic discharges involved other hazardous, nonradioactive materials.

Five commenters, including a representative of AMSA, expressed the opinion that POTWs should have the legal authority to establish local limits for the release of radioactive material into sanitary sewers. Three of the commenters expressed the concern that, although municipalities are held responsible for the disposal or beneficial use of POTW sludge, the municapalities have no control over the radioactivity of materials discharged to the sewer

system that affect sludge quality. One commenter expressed the concern that the existing regulatory framework is inadequate because NRC maintains that the party in possession of the radioactive material is responsible for remediation, offers no assistance to POTWs that have been contaminated by a licensee's effluent, and states that the AEA indicates that its regulations preempt more restrictive local regulations. The commenter expressed concern that NRC has indicated that this position would not change even if NRC had proof that material was illegally discharged by a licensee and that a POTW's only recourse to recover remediation costs is to take legal action against the discharger. One of the commenters suggested NRC should either assume responsibility for disposing of radioactive sludge generated in POTWs as a result of "errant discharge" from NRC licensees or allow POTWs to regulate the discharge of radioactive materials into sewer systems. The other commenter suggested that, in cases in which the reuse or disposal of sludge is restricted because of its radiological contamination, NRC should cooperate with EPA to help affected POTWs establish local discharge limits to protect the traditional method of disposal or reuse of the biosolids.

Another commenter stated that it was not necessary, feasible, or appropriate for NRC to develop new regulations that would limit the disposal of radioactive material into sanitary sewers because POTWs already had the legal authority and mandate to establish and enforce appropriate pretreatment standards that would prevent contamination of POTWs or sewage sludge, pursuant to the Clean Water Act (33 U.S.C. 1317(b) and (d) and 1319) and EPA Clean Water Act Standards (40 CFR Part 403).

Response: NRC acknowledges the commenters' concern about the power that local authorities have to regulate the release of radioactive material to their POTWs. The U.S. Supreme Court has held that, for certain activities covered by the AEA, Federal authority preempts other regulatory authorities whose purpose is radiation protection. It is difficult to predict whether unusual cost to the POTW caused by radioactive effluent discharges would be

a sufficient reason to impose more restrictive discharge limits than those permitted under Federal law because there are no Federal cases in which the specific facts corresponded to the scenarios faced by local POTW authorities. More information on this issue is presented in Chapter 4 and Section 7.2 of the ISCORS recommendations on management of radioactive materials in sewage sludge and ash (EPA 832-R-03-002B).

Comments regarding NRC's responsibility for the disposal of contaminated sludge are beyond the scope of this rulemaking. As discussed in Chapter 7 of the ISCORS recommendations (EPA 832-R-03-002B), in individual cases of contamination, legal counsel should be consulted to determine if dischargers may be liable for portions of remediation costs.

Comment: One commenter recommended NRC exempt POTWs from any regulations that would apply to material released into their systems because the potential benefits of regulating POTWs would not justify the costs.

Response: This suggestion is beyond the scope of this rulemaking.

Comment: Five commenters, including a representative of AMSA, expressed the view that POTWs should be able to apply the same type of pretreatment standards to radionuclides in licensees' effluent that are applied to toxic materials discharged into sewer systems by industrial dischargers as part of EPA's NPDES program. Commenters noted that local limits can account for the number of licensees discharging to a single POTW, the total flow into a POTW, and the effects of various treatment process on radionuclide reconcentration. Three commenters noted that, in general, local restrictions on discharges of pollutants to POTWs are established by determining an allowable load of a pollutant to a POTW that will not create a violation of the POTW's effluent limit and not interfere with disposal or reuse of the POTW's biosolids, and then allocating that limit among industrial facilities that discharge effluent to the POTW. Two commenters expressed the view that the same process should be used to develop individual limits for each radionuclide, taking into account each radionuclide's specific activity,

half-life, and solubility. One commenter noted that this procedure cannot be followed with radioactive materials because no "acceptable" levels of radionuclides in sludge have been established. Another commenter recommended NRC coordinate any future regulations affecting sanitary sewer discharges with EPA requirements for Clean Water Act discharges, including Categorical Standards, NPDES permits, and regulations pertaining to sewage sludges.

Two commenters suggested that, because setting limits for radioactive materials will be new to many POTWs, NRC should provide guidance on establishing local limits on the release of radioactive materials into sanitary sewers. A representative of AMSA suggested a number of topics that the recommended guidance should address and recommended NRC consider two EPA resources used to develop limits on industrial discharges to POTWs.

Response: This comment includes detailed recommendations about the creation of a program in which the release of radionuclides into sanitary sewers would be regulated by local, rather than Federal, authorities, and is beyond the scope of this rulemaking. Although guidelines for the development of local limits under such a program have not been developed, many of the topics the commenters requested be included in such guidance are included in the ISCORS recommendations on management of radioactive materials in sewage sludge and ash (EPA 832-R-03-002B), as is information about local pretreatment programs established in Albuquerque, NM, St. Louis, MO, and Oak Ridge, TN.

Comment: One commenter was concerned that system-specific discharge limits could be difficult to implement if, as is done in the NPDES process, discharge limits are based on the "waste assimilative capacity" of the receiving waterway, which, the commenter stated, could be difficult to determine. The commenter also expressed concern that licensees would need to obtain prior approval for sewer discharges, and that regulatory agencies would need to keep track of separate discharge allotments for each licensee and any changes to each POTW's

treatment processes. The commenter noted that an alternative to establishing system-specific discharge limits would be to set activity limits so low that regulatory limits or ALARA goals for public doses would be met, irrespective of the wastewater treatment process used, the capacity of the receiving POTW, or the number of dischargers discharging to the POTW. The commenter noted that this approach would not require as much regulatory oversight and suggested these approaches should be evaluated in an EIS.

Response: NRC acknowledges the commenter's concerns about the difficulties involved with implementing system-specific discharge limits. An EIS that evaluates the alternatives will not be developed because the ANPR is being withdrawn for the reasons previously discussed.

Comment: One commenter asked for clarification as to how the revised rule would relate to NRC decommissioning standards and various EPA rules and suggested NRC hold public hearings on the issue.

Response: NRC is not responding to the request for clarification on the relationship between the proposed rule and EPA or NRC standards because the ANPR is being withdrawn.

Comment: Ten commenters expressed the view that any change to the regulations governing the release of radioactive materials into sanitary sewers should have a solid technical basis. Three commenters recommended NRC delay decisions about the need for modifications to the regulation until NUREG/CR-6289, which was incomplete at the time, was made available to licensees. Two commenters expressed concern that the ANPR was offered without a significant risk assessment. Six commenters recommended that any proposed change in the regulation should be based on a realistic assessment of either the collective dose or the risks to members of the public and POTW workers that the new regulations would avert. Two commenters expressed the concern that changes to the regulations would be made for reasons other than technical reasons, including regulatory convenience, a perception of public opinion, or political pressure.

A representative of the New York State Department of Labor remarked that some of the regulatory changes proposed in the ANPR would be complex for both licensees and regulatory agencies to implement and, therefore, should not be undertaken without a without a firm technical basis. The commenter expressed the view that, except for the exemption of patient excreta, all of the options discussed in the ANPR required more analysis before NRC would have sufficient information on which to base a decision. The commenter expressed the opinion that frequent changes in the same regulation are especially burdensome for licensees and urged NRC to perform the necessary analyses before changing the rule again. Representatives of the New York State Energy Office and New York State Department of Environmental Conservation encouraged NRC to develop an EIS to evaluate the options discussed in the ANPR. The representative of the New York State Department of Environmental Conservation remarked that the current regulations, including the revisions made in 1991, had never undergone a full environmental review.

Two commenters expressed the concern that the current limits on the discharge of radioactive material to sewers do not reflect the hazards radioactive materials could pose in a POTW or after release to the environment. The commenters recommended NRC initiate a study that would include a POTW hazard identification and assessment, exposure and toxicity assessments, and a risk characterization. The two commenters also recommended NRC study the fate and transport of radionuclides in sewers, POTWs, and the environment. A representative of the City of Oak Ridge provided a reference that discussed the fate and transport of radionuclides in the municipality's POTW. A representative of AMSA recommended NRC cooperate with EPA, POTWs, and affected industries to assess the exposure and contamination pathways of radionuclides, and the impact of radioactive materials on wastewater treatment processes.

Response: NRC acknowledges the commenters' view that the 1991 revision to the

regulations governing the release of radioactive materials into sanitary sewers should have been based upon detailed risk analyses. As discussed previously, NRC cooperated with representatives of EPA and POTWs in developing the ISCORS survey and dose modeling project to assess the radioactive contamination in POTWs and pathways for exposure of POTW workers and members of the general public to radionuclides released into sanitary sewers. The results of these analyses served as the technical basis for the withdrawal of the ANPR. An EIS for the rulemaking will not be performed because the ANPR is being withdrawn for the reasons previously discussed.

Comment: Three commenters, including a representative of AMSA, recommended NRC study the extent of the use of sewer discharges and contamination of POTWs around the country. The representative of AMSA suggested that, because NRC had acknowledged that it did not know how many POTWs in the country were contaminated with radionuclides and because it would be inappropriate to develop national standards based on contamination in a few isolated cases, NRC should establish a task force composed of NRC and EPA staff as well as representatives of POTWs and licensees to study the nature and extent of radioactive contamination of POTWs nationally. Three commenters recommended NRC determine which licensees release radioactive material into sanitary sewers and two of these commenters recommended NRC make the information available in a national database. Of these commenters, one suggested the database should be similar to the EPA's Toxic Release Inventory and the other suggested the database should include information about the mass of each radionuclide discharged per year by each licensee, the volume of the licensee's discharge, and the licensee's POTW service area. A representative of one utility district expressed concern that, as of 1994, the NRC had not been able to provide a list of the licensees discharging into the district's sewer system and that the district had, therefore, been unable to initiate an appropriate monitoring program.

Response: NRC acknowledges the commenters' request for a national database, but notes that a database that contains information about releases of radioactive material into sanitary sewers by licensees is not being developed. As discussed in Section 5.1 of the ISCORS recommendations on management of radioactive materials in sewage sludge and ash (EPA 832-R-03-002B), POTW operators are encouraged to contact the applicable NRC Regional Office, appropriate State Radiation Safety Office, and any nearby DOE facilities if they have questions about the sewer releases of facilities in the POTW's service area that use radioactive materials.

Comment: One commenter requested that, because NRC had just begun to study the fate of radionuclides in POTWs and because NRC did not know which of its licensees discharged materials into sanitary sewers, a moratorium be imposed on the disposal of radioactive material into sanitary sewers until NRC had the information necessary to help POTWs develop protective limits.

Response: NRC notes that this comment is beyond the scope of this rulemaking.

Comment: One commenter expressed concern that the assumptions used in 10 CFR Part 20 ignored exposures to children, fetuses, elderly, people with existing body burdens of radioactive material, and individuals in other sensitive groups. The commenter expressed concern that the risk of birth defects from ionizing radiation had been limited to only two generations in NRC analyses and stated that the greatest number of birth defects will be seen in generations beyond the next two. The commenter also expressed the view that NRC should consider non-cancer and nonfatal cancer health effects in risk calculations and expressed concern that these effects were not considered in the promulgation of 10 CFR Part 20.

Response: The commenter's remarks about NRC's development of standards for the protection against radiation are beyond the scope of this rulemaking.

Comment: Three commenters recommended NRC perform a cost/benefit analysis of

alternatives to the release of radioactive materials into sanitary sewers before proceeding with a rulemaking and two of those commenters expressed the view that the proposed changes could not be justified by either a risk analysis or cost/benefit analysis. One commenter urged NRC to apply the backfit provisions that apply to power reactors to a broader scope of rulemaking decisions, and expressed the view that the alternatives suggested in the ANPR could not be justified in a backfit analysis.

Response: NRC is not performing a cost/benefit analysis or risk analysis because the ANPR is being withdrawn for the reasons previously discussed. The staff note that the commenter's opinions about NRC's backfit provisions are beyond the scope of this rulemaking.

Comment: One commenter expressed the concern that limits based on overly-simplified dose models could be overly-restrictive and could cause unintended harm to the public by limiting beneficial uses of radioactive materials. The commenter suggested NRC consider the "total societal impact" of its release limits, and expressed the view that NRC and other regulatory agencies typically perform inadequate assessments of the financial impacts of their rules. The commenter added that NRC should not avoid this responsibility by claiming that the AEA does not give it the responsibility to evaluate the total societal impact of its rules, because evaluation of cost, benefit, and total societal impact is inherently included in the concept of maintaining doses ALARA.

Response: NRC acknowledges the commenter's concern about the adequacy of financial impact analyses performed by NRC and other regulatory agencies. NRC staff agree that, as defined in 10 CFR Part 20.1003, the term "ALARA" indicates consideration of societal and socioeconomic impacts.

Comment: Five commenters expressed the opinion that, in general, any changes to the regulations should allow less radioactive material to be released into sanitary sewers. Reasons for this position included new information about the adverse effects of chronic exposure to low

levels of ionizing radiation, information about the synergistic effects of radiation and chemical pollutants, and concern about the cumulative effects of multiple sources of radiation on public health and the environment. Two commenters suggested that all radioactive waste should be isolated in secure storage or disposal facilities. Another commenter stated that NRC should not allow environmental build-up of multiple sources of radiation even if each, individually, could be dismissed as being minimal. One commenter stated that his organization had commented on the revision of 10 CFR Part 20 repeatedly and that it remains concerned that the allowable concentrations of many radionuclides in air and water increase.

Response: The ANPR is being withdrawn for the reasons previously explained. Comments about the basis for NRC's standards for the protection against radiation are beyond the scope of this rulemaking.

Comment: Four commenters expressed the opinion that the potential burden that additional restrictions on the release of radioactive material into sanitary sewers would impose on licensees is secondary to the primary goal of protecting public health and safety and should be given little weight in the evaluation of whether additional restrictions should be established. Two commenters expressed concern that, in the ANPR, NRC made several inquiries about the impacts of new restrictions on licensees without expressing a similar interest in the potential impacts of the release of radioactive material into sanitary sewers on other parties. One of the commenters expressed the view that the concern for licensees may be misplaced because it is municipalities, and not licensees, that ultimately bear the costs of disposal of contaminated sludge and POTW decontamination. The commenter also remarked that it appeared to be more appropriate for licensees, rather than the public, to bear the expense of the disposal of radioactive materials used by licensees. The other commenter suggested NRC should have solicited comments regarding the potential impact of the regulations on public health, healthcare costs, contamination of agricultural land, restriction of land uses, and environmental

degradation. Two commenters stated that it would be inappropriate for NRC to allow any risk to members of the public to lessen economic or regulatory burden on licensees. Another commenter noted that, in cases in which contamination of a POTW has been discovered, licensees must recognize that safety of the community is more important than the desire for a licensee to use its current disposal options.

Response: NRC acknowledges the commenters' concerns regarding the specific requests for comment in the ANPR. With regard to the consideration given to the potential effects of changes in the regulation on public health and the environment as compared to potential burdens on licensees, the NRC staff notes that a significant effort was made to study the potential effects of the release of radioactive material into sanitary sewers on the public and POTW workers in conjunction with the ISCORS reports that were described previously. Comments about the basis for NRC's standards for the protection against radiation are beyond the scope of this rulemaking.

Comment: Six commenters suggested that detection of radionuclides at a few POTWs is an insufficient reason to impose additional restrictions on the release of radioactive material to sanitary sewers. These commenters stated that radioactivity can be measured at very low levels that are not expected to cause a significant adverse health effect for any individual. One commenter stated that lowering release limits to values that are significantly lower than limits needed to protect the public makes it more difficult for licensees to assure compliance of medical research and clinical staff with radiation safety procedures and undermines the public's confidence in realistic exposure or activity standards. Another commenter recommended NRC acknowledge that the risks caused by radioactivity in sewage sludge are small compared to the risks associated with the extra handling and transportation of waste that would occur if releases of radioactive material to sanitary sewers were eliminated.

One commenter also suggested that, because radioactivity can exist in sewer systems

and POTWs without causing a significant dose to any individual, and because there are beneficial uses of radioactive materials, that it might be better to attempt to build public acceptance of the current practices than it would be to lower release limits or eliminate sewer discharge. Another commenter suggested incidents of contamination should be handled in a consistent, routine way without undue alarm. A representative of DOE predicted that any discovery of radioactive contamination of sewage pipes or sewage treatment plants is likely to result in regulatory concern, even if the possible doses are tiny, because it may take time to determine whether the contamination poses a threat to public health and safety.

Response: NRC acknowledges the commenters' opinions, which support the withdrawal of the ANPR. The staff acknowledges the commenters' recommendations about proper treatment of cases of contamination, but notes they are beyond the scope of this rulemaking.

Comment: Three commenters addressed the potential for accidental releases of radioactive material into sanitary sewers. One commenter hypothesized that the case studies presented in the ANPR may have been the result of abnormal events and expressed the opinion that no amount of regulation, planning or notification can prevent inadvertent releases that result from system failures or other errors. Another commenter suggested NRC should realize that, irrespective of its regulations, an individual is likely to find a way to defeat "reasonable safeguards." Another commenter expressed concern that the modeling results described in the ANPR did not account for the potential for accidental releases in excess of the 10 CFR Part 20 limits and suggested the reported calculated doses may be underestimates.

Response: NRC acknowledges the commenters' statements about the possibility of accidental releases. NRC staff note that its inspections are designed to ensure licensees' operations are conducted safely and in accordance with good practices and license conditions. With respect to the commenter's concern that the dose modeling results discussed in the ANPR do not include the effects of accidental releases, NRC staff note that the doses estimated in

NUREG/CR-1548 did not include the potential effects of accidental releases; however, the doses reported in the ISCORS dose modeling report (NUREG-1783) were based on observed levels of radioactivity measured in conjunction with the ISCORS sewage sludge survey (NUREG-1775) and, therefore, reflect any accidental releases that may have been made to the 313 POTWs surveyed.

Comment: Seven commenters addressed LLW disposal. Four commenters noted that additional restrictions on the release of radioactive materials to sewers would increase the amount of low level radioactive waste that would need to be disposed of in some other way. Two commenters recommended NRC evaluate the options proposed in the ANPR in the context of the risks associated with the disposal of low level nuclear waste and the limited capacity of LLW disposal facilities. Two commenters noted that many licensees had, as of 1994, very limited or no access to LLW disposal facilities and one of the commenters noted that licensees without access to a LLW disposal facility would need to store waste on site indefinitely. Three commenters noted that additional restrictions on the release of radioactive materials into sanitary sewers would be especially burdensome because the facilities they represented lacked access to LLW disposal sites. One commenter stated that sewer disposal is the primary way that many medical research and biotechnology laboratories minimize generation of LLW.

One commenter expressed the concern that the use of sanitary sewer disposal of radioactive material would increase because of the high cost and limited availability of LLW disposal. The commenter noted that the release of radioactive material into sanitary sewers itself can lead to the creation of large volumes of LLW by contaminating sludge. Another commenter opposed the implication that sanitary sewer disposals would be used as a means of relief from the relative inaccessibility of LLW disposal and noted that most types of LLW do not meet the requirements for release into sanitary sewers.

Response: NRC acknowledges the commenters' concerns regarding the impact that the

proposed changes would have because of some licensees' lack of access to LLW disposal facilities. These comments support the withdrawal of the ANPR.

NRC also acknowledges the commenter's concern that limitations on LLW disposal could lead to an increase in the release of radioactive material to sanitary sewers. The NRC staff notes that the results of the ISCORS sewage sludge survey (NUREG/CR-1775) do not indicate that the frequency of POTW contamination incidents has increased since the commenters' remarks were made in 1994.

Comment: Five commenters expressed the opinion that licensees should bear all costs associated with waste disposal. One commenter suggested NRC's descriptions of case studies should include a description of the financial costs associated with the contamination and should indicate the party paying the remediation costs. Two commenters stated that NRC licensees should bear the costs of data collection, data reporting, and worker training needed to implement any new NRC studies or regulations needed to protect POTWs from contamination. Two commenters expressed the view that licensees should pay to have monitoring equipment installed at POTWs.

Response: NRC acknowledges the commenter's suggestion that NRC's descriptions of case studies should include information about the economic aspects of the contamination and notes that some information about remediation costs is provided in Section 1.2 of the ISCORS recommendations on management of radioactive materials in sewage sludge and ash (EPA 832-R-03-002B). Comments regarding the costs associated with implementation of new sewer release restrictions are moot because the ANPR is being withdrawn.

Comment: Six commenters expressed opinions about NRC enforcement actions. A representative of DOE stated that it was unclear whether one or more of the incidents described in the ANPR involved violations of the regulations, and suggested enhanced inspections, and not additional rulemaking, would be the most appropriate way to eliminate contamination of

POTWs. Three commenters suggested NRC or POTWs should verify licensee's reported discharges into sanitary sewers and one commenter suggested compliance with NRC regulations should be demonstrated at the licensee's outfall into the sanitary sewer system so that POTWs would not be impacted and would not need to implement special controls. Two representatives of POTWs noted that POTWs routinely sample the effluent of major industrial users as part of their industrial pretreatment programs. Another commenter suggested NRC should assist POTWs with monitoring of licensee's effluents and enforcement of the discharge limits.

Response: NRC notes that suggestions about inspection and enforcement activities are beyond the scope of this rulemaking.

Comment: Six commenters made specific suggestions about monitoring. Two commenters suggested licensees' outfalls and potable water intakes should be monitored, and three commenters suggested monitoring also should occur at POTWs. One of the commenters that advocated monitoring at POTWs expressed the view that monitoring would limit uncertainty in model results and would facilitate the study of the effects of influent radionuclide form and quantity on POTW worker doses. The commenter also suggested licensees should be encouraged to provide dosimetry and elementary radiation safety training to POTW workers. One commenter expressed the opinion that radionuclides in licensees' effluents should be monitored to record the highest concentrations discharged and facilitate a regulator's ability to link discharges with their sources. Three commenters suggested the radioactivity of sewage sludge should be monitored. One commenter expressed concern about the radioactivity of an engineered wetland used to treat wastewater in his town.

Response: Recommendations regarding locations for monitoring a licensee's effluent are beyond the scope of the proposed rulemaking.

Comment: A representative of the New York State Department of Environmental

Conservation recommended that the Notice of Proposed Rulemaking for any change to the regulation governing the release of radioactive material into sanitary sewers notice, for public comment, the compatibility category NRC intends to apply to each provision so that Agreement States and other interested parties can participate in decisions about compatibility requirements. The commenter stated that, as of 1994, Agreement States were required to develop regulations that were compatible with the revised 10 CFR Part 20 without NRC having determined compatibility requirements and stated that this type of situation must not recur.

Response: NRC acknowledges the commenter's recommendation that intended compatibility categories be included in Notices of Proposed Rulemaking. Compatibility categories for the options discussed in the ANPR are moot because the ANPR is being withdrawn.

Comment: One commenter expressed a number of concerns about the case studies described in the ANPR. Concerns raised by the commenter included specific exposure pathways that may not have been included in the dose analyses, the appropriateness of NRC's comparison of doses with background radiation, and the concern that calculated doses to individuals could have been higher if the sludge to which they were exposed included radiation from multiple sources. The commenter expressed the view that radioactivity in the environment may increase because of human activity, and that it would be inappropriate to consider manmade contributions of radioactivity to the environment in the calculation of "background" radiation, or to allow releases because they would be minimal in comparison to background radiation. The commenter also remarked that the cases of contamination that had occurred in Washington, DC, and Cleveland, OH, indicated the potential for contamination to be significant to large populations. In addition, the commenter asked specific questions about the assumptions used to calculate the doses resulting from the case studies discussed in the ANPR and what sources of radiation NRC included in its calculation of "background radiation".

Response: The commenter's concerns about the doses calculated in the case studies are no longer applicable because more recent studies served as the technical basis for the withdrawal of the ANPR. NRC acknowledges the commenter's concern regarding contamination at POTWs. The commenter's specific questions about the modeling assumptions used to calculate doses for the case studies discussed in the ANPR are addressed in NUREG/CR-1548. NRC notes that its definition of "background radiation", provided in 10 CFR Part 20.1003, excludes contributions of radioactivity from source, byproduct, or special nuclear materials regulated by NRC.

For the reasons cited in this document, NRC withdraws this ANPR.

Dated at Rockville, Maryland, this 11 day of Oct, 2005.

For the Nuclear Regulatory Commission.

Luis A. Reyes
Executive Director for Operations.