

(vi) To allow inspectors to make unannounced inspections of the facility.

(d) Approval of an irradiation facility, and the compliance agreement required under paragraph (c)(2) of this section, are effective for one year, unless withdrawn or canceled under paragraph (e) of this section. In order to renew approval, irradiation facilities must, on an annual basis, renew the compliance agreement and undergo reinspection.

(e) Approval of an irradiation facility may be denied or withdrawn, and any compliance agreement entered into under this section may be canceled, orally or in writing, if:

(1) An inspector determines that a facility or its owner or operator does not meet or has not complied with the requirements of this section;

(2) The operator or a person responsibly connected with the business of the irradiation facility has committed any act involving fraud, bribery, extortion, smuggling, or any other act involving a lack of integrity needed for the conduct of operations affecting the irradiation of FBS, as determined by the Administrator.

(f) For the purposes of this section, a person shall be deemed to be responsibly connected with the business of the quarantine facility if such person has an ownership, mortgage, or lease interest in the facility's physical plant, or if such person is a partner, officer, director, holder or owner of 10 per centum or more of its voting stock, or an employee in a managerial or executive capacity.

(g) If the denial, cancellation, or withdrawal is oral, such action and the reasons for the action shall be confirmed in writing as promptly as circumstances allow. Any owner or operator whose facility has been denied approval, whose facility's approval has been withdrawn, or whose compliance agreement has been canceled, may appeal the decision, in writing, within 10 days after receiving written notification of the denial, withdrawal, or cancellation. The appeal must state all of the facts and reasons upon which the person relies to show that the approval was wrongfully denied or withdrawn, or that the compliance agreement was wrongfully canceled. As promptly as circumstances allow, the Administrator will grant or deny the appeal, in writing, stating the reasons for the decision. A hearing will be held to resolve a conflict as to any material fact. Rules of practice concerning the hearing will be adopted by the Administrator.

Done in Washington, DC, this 18th day of February, 1994.

Patricia Jensen,

Acting Assistant Secretary, Marketing and Inspection Services.

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 20

RIN 3150-AE90

Disposal of Radioactive Material by Release into Sanitary Sewer Systems

AGENCY: Nuclear Regulatory Commission.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Nuclear Regulatory Commission (NRC) is seeking information to determine whether an amendment to its regulations governing the release of radionuclides from licensed nuclear facilities to sanitary sewer systems is needed. The potential rulemaking would revise the approach to limiting the release of radioactive materials into sanitary sewer systems by licensed nuclear facilities based on current sewer treatment technologies. This advance notice of proposed rulemaking is being issued to invite comments, information, and recommendations from interested parties on the issues that have been identified as candidates for consideration as part of this rulemaking.

DATES: The comment period expires May 26, 1994. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Mail comments to: The Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

Deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:45 a.m. and 4:15 p.m. Federal workdays.

Examine copies of comments received at: The NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

Copies of NUREG/CR-5814, which supports this advance notice, may be purchased from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20013-7082. Copies are also available from the National Technical Information

Service, 5285 Port Royal Road, Springfield, VA 22161. A copy is also available for inspection and/or copying for a fee, at the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Dr. George E. Powers, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492-3747.

SUPPLEMENTARY INFORMATION:

Background

The Nuclear Regulatory Commission regulates the release of radioactive material by licensees into sanitary sewer systems under 10 CFR part 20. The basis for the NRC's sewer release requirements was established over 35 years ago. The NRC and Agreement States have become aware of instances where radioactive material has been detected in sewage treatment systems. Examination of several of these cases led the Commission to modify the requirements for disposal of radioactive materials into sanitary sewers as part of the revised standards for protection against radiation added to 10 CFR part 20 (56 FR 23360; May 21, 1991). In particular, the Commission removed the provision (except for the case of biologically dispersible materials) which allowed the disposal of dispersible materials into sewers because it appeared that dispersible, but insoluble materials, were generally implicated in the sewer sludge contamination cases. In addition, the concentrations allowed for various radionuclides released to sewers were reduced by a factor of 10, as part of an overall reduction in effluent release limits. The concentrations listed in Table 3 of appendix B to 10 CFR part 20 were calculated on the basis of a 5 mSv (500 mrem) dose via ingestion of material at the discharge point from the licensee. The concentrations listed in Table 3 were considered reasonable since it is unlikely that any individual would actually consume water at the point of discharge and since dilution from additional contributions within the sanitary sewer would likely reduce levels to well below the 1 mSv (100 mrem) annual dose limit for members of the public. The provisions permitting the release of soluble material and the total quantities of material which could be released in any one year were retained in the revision to 10 CFR part 20.

These provisions have been effective since June 1991. However, licensees have until January 1, 1994, to comply with the requirements. In promulgating

4/2

the revised standards for protection against radiation, the NRC acknowledged that additional information was necessary regarding potential pathways of exposure and radiation doses that could result from releases into sanitary sewers, particularly in light of new sewerage treatment systems that further concentrate solids and are used by large municipalities. The NRC is publishing this advance notice to obtain public comment on a number of issues associated with the release of radioactive material to sewer systems. This information will be used in evaluating what additional changes to the requirements in 10 CFR part 20 may be necessary. This information will also be used in assessing the impacts of the various options that may be available for imposing any necessary additional requirements.

Discussion

There are approximately 15,000 sewer treatment plants (STPs) in the United States and 23,000 specifically licensed users of radioactive materials. It is not uncommon for several licensed radioactive materials users to discharge radioactive waste materials into the same sewerage system. Sewage treatment plants (STP) vary in size (capacity) from less than 1 million gallons per day (gpd) to over 1 billion gpd. A capacity of 1 million gpd would serve about 5000 people and a few small commercial users. A 1 billion gpd facility would accommodate a population of about 5 million people and a substantial industrial base. The sewage treatment process, the size of the sewage treatment facility, and the amount, as well as the physical and chemical form, of the radioactive materials released to the sewer system can have a significant effect on the fate of the radioactive materials in the process and the final concentrations of materials in the sewer sludge or ash.

A number of incidents of radioactive material contamination and reconcentration have occurred. A description of some of these cases is included at the end of this notice. It should be noted that each of these cases occurred prior to implementation of the revised part 20 limits for releases of radioactive material to sewer systems.

In 1989, the NRC contracted with Battelle, Pacific Northwest Laboratories (PNL), to study situations where radioactivity has been reported in sewer systems or sewer treatment sludge. The results of the PNL study were published in May 1992 as NUREG/CR-5814, "Evaluation of Exposure Pathways to Man from Disposal of Radioactive

Materials Into Sanitary Sewer Systems." NUREG/CR-5814 includes information on sewage treatment and disposal practices, and exposure pathways and scenario analysis, based on case studies of situations where radioactive contamination has been reported in sewer systems or in sewer treatment sludges.

The PNL study performed theoretical modeling of most types of licensee radioactive discharges, except for excreta from individuals undergoing medical diagnostic or therapeutic administrations of radioactive material, which are exempt from regulation under § 20.2003. Modeling scenarios estimated the exposure to individuals at the sewer treatment facility and as a result of various uses of sewage sludges resulting from treatment. The results of the study predicted doses of 0.2 to 93 mrem/yr total effective dose equivalent (TEDE). The assumptions used in the study were that all material was released at the part 20 limit and subsequently reconcentrated. Thus, the doses calculated represent an upper bound of possible doses to actual individuals.

Request for Information and Comment

The Commission requests comments and information on a number of issues related to requirements for disposal of radioactive material into sanitary sewers. This request for comments and information is in the context of evaluating the options which may be available to the Commission to provide additional or alternative means of regulatory control over releases into sanitary sewers. The comments and information which will be particularly useful are those related to the impacts of various alternatives for each issue, including impacts on various types of licensees such as biomedical and university research licensees.

(1) Form of the Material for Disposal

The standards for protection against radiation in 10 CFR part 20 permit the disposal of materials into the sanitary sewer if they are soluble or readily dispersible biological materials. Formerly, the release of dispersible non-biological material was permitted. At the time of publication of the 1986 proposed rule (51 FR 1992; January 9, 1986) for the revised standards for protection against radiation, the Commission had proposed that only soluble materials be permitted for disposal into sanitary sewers. The Commission received significant comment at that time regarding the practice of research institutions to use sewer disposal as the preferred alternative for disposal of tissue samples

over incineration. As a result, the May 21, 1991, final rule allows readily dispersible biological material to be released but prohibits the release of any non-biological insoluble material.

The Commission recognizes that new technologies for sewer treatment are currently under development, such as the emerging mesocosm-based treatments which use bioprocessors to neutralize sludge. These bioprocessors can be selected with unique abilities to selectively reconcentrate specific heavy metals and organics. In the consideration of new requirements, the Commission invites comments on to what extent and how the regulations should take into account the technologies for processing sewage including technologies such as bioprocessing or ion-exchange.

Coincident with publication of this advance notice, the Commission has initiated contract support to analyze typical water treatment processes, which includes determining how the solubility of materials in influent to a treatment plant may be changed in a way that affects the potential dose to members of the public. One possible outcome of this analysis could result in modified restrictions regarding the forms of materials suitable for disposal. Comments on the potential impacts on licensee's operations associated with any additional restrictions regarding the forms of materials suitable for dispersal are solicited.

(2) Total Quantity of Material

In the May 21, 1991, final rule, the Commission did not change the total quantity of radioactive materials which could be released into sanitary sewers. In brief, the limits are 185 GBq (5 Ci) of ^3H , 37 GBq (1 Ci) of ^{14}C , and 37 GBq (1 Ci) of all other radioactive materials combined to be released into a sanitary sewer by a licensed nuclear facility in a year provided the licensee complies with the other requirements of 10 CFR 20.2003. The use of a total quantity limit has been a long-standing requirement and was originally included to address concerns regarding the possibility for reconcentration. The Commission solicits comments regarding the acceptability of this approach, and whether a total quantity to be released should be specified or otherwise limited. As an alternative, the Commission solicits comments on an approach which might limit the total quantity of each radionuclide, such as some multiple of the annual limit of intake values or the related exempt quantities published in 10 CFR part 30. This alternative approach could have the advantage of specifying a total

quantity limit, concentration and form requirement based upon the biokinetics and health risk for each radionuclide. In particular, the Commission solicits comments on the potential impacts on licensee's operations associated with further restrictions on the total quantity of radioactive material which could be released during a year.

The Commission also invites comments on whether the total quantity of radionuclides that may be released to a sanitary sewer by a licensed nuclear facility should take into consideration the capacity and treatment methods used by the water treatment plant that serves the licensee, and whether consideration should be given to the fact that many licensed facilities may discharge into the same sewer treatment plant. In this regard, the Commission is interested in comments on the practicality of these approaches.

The NRC has also received a petition for rulemaking submitted by the Northeast Ohio Regional Sewer District concerning the disposal of radioactive material into sanitary sewerage (PRM-20-22). A notice of receipt and request for comment on the petition was published in the *Federal Register* on October 20, 1993 (58 FR 54071). The petitioner requests that the NRC amend its regulations to require that all licensees provide at least 24 hours advance notice to the appropriate sewage treatment plant before releasing radioactive material to the sanitary sewerage system. The petitioner also requests that the NRC exempt materials that enter the sanitary waste stream from the requirements regarding Commission approval for incineration under the NRC's current regulations. Comments on the issues raised in this petition will be considered in any possible revision to NRC regulations.

(3) Type of Limits

The present method of limiting releases into sanitary sewers is to specify annual total quantity and concentration values of radioactive materials. Table 3, Appendix B, of revised 10 CFR part 20 lists the concentrations of radioactive materials which can be disposed of in sanitary sewers and is based upon a calculated dose of 5 mSv/yr (500 mrem/yr) via ingestion of the effluent as the total water intake of the individual (2 liters/day) at the point of release. These limits are based upon a model of exposure which assumes that an individual could be present at the sewer outfall of the licensee, and that the exposure pathway is the ingestion of water. The Commission invites comments on two

facets related to this regulatory approach.

First, should the Commission continue an approach of limitation based upon an individual being exposed by the ingestion of water from the sewer outfall? Alternatively, should the Commission consider other locations, such as at a treatment facility, in determining the level of protection to be provided? If so, what modeling assumptions would be appropriate? Further, how would these types of approaches deal with exposure scenarios such as contamination in sewage sludges, as has been the case in contamination incidents?

Second, should the Commission consider limitation using a dose limit approach, and provide total quantity and concentration values in a Regulatory Guide to facilitate compliance with the dose limit?

(4) Exemption of Patient Excreta

The present requirements exclude from sewer release limits the contribution of patient excreta which may contain radioactive materials as a result of nuclear medicine diagnosis or treatment. In general, the radioactive materials used in these types of procedures have short half-lives and decay rapidly after their production, use and subsequent release into the sanitary sewer. Thus, doses to individuals from this source are expected to be far below the NRC's dose limit for members of the public. The Commission currently believes that the present regulation is adequate but recognizes that radionuclides used in nuclear medicine have been detected in very low concentrations on occasion at treatment facilities. Therefore, the Commission invites comments regarding the appropriateness of continuing the exemption for patient excreta.

The preliminary views expressed in this notice may change in light of comments received. In any case, there will be an opportunity later for additional public comment in connection with any proposed rule that may be developed by the Commission.

Case Studies

Case 1—Tonawanda, New York

A manufacturer of smoke detectors, which used Americium-241 (^{241}Am) foils, operated in the 1970s and early 1980s in Tonawanda, New York. When the facility was being decommissioned in 1983, ^{241}Am contamination of the sewer lines leading from the facility was detected. Similar contamination was subsequently detected in the STP sewage sludge and incinerated sludge

ash residue. It is believed that the contamination occurred over a period of several years. Tests performed by the State of New York in 1984 showed levels up to 27.75 Bq/g (750 pCi/g) of ^{241}Am in ash taken from a sludge incinerator. Levels of 5.92 Bq/g (160 pCi/g) were detected in landfill samples. The levels in the sludge at the time of the investigation were up to 3.7 Bq/g (100 pCi/g). Following the termination of licensed activities in 1983, these levels decreased to less than .037 Bq/g (1 pCi/g) by 1986. Bioassays of STP workers and landfill workers detected no radioactivity over background levels in their lungs or bones.

Case 2—Grand Island, New York

Because of the ^{241}Am contamination at the Tonawanda STP, the New York Department of Health also collected sludge samples in 1984 at the Grand Island STP, which received effluent from another manufacturer that produced devices that used ^3H , ^{210}Po , and ^{241}Am . This manufacturing facility discharged about 0.925 MBq/yr (25mCi/yr) of ^{241}Am into the sanitary sewer that fed into the Grand Island STP. The Grand Island STP uses tertiary treatment prior to discharging effluent, with a sludge production averaging 450 ton/yr. Tertiary treatment removes material from the effluent that has not been removed through primary and secondary treatment. Tertiary treatment may include the use of microscreens, filtration through specific media such as activated charcoal, precipitation, and coagulation prior to discharging effluent. The sludge is digested and pressed to increase the solids content to about 20%, and it is subsequently buried in a landfill. The average ^{241}Am concentration in the dry sludge was about 3.7 Bq/g (100 pCi/g) dry weight when first studied. At the request of the New York State Department of Labor, the manufacturer reduced the ^{241}Am concentration in its liquid discharges after the contamination was identified. By adding filtration to the licensee's holding tank, concentrations of ^{241}Am in sludge were decreased to about 1.48 Bq/g (40 pCi/g). Using information provided by the State of New York, calculations of the annual average concentration of ^{241}Am in the wet sludge were based on the assumption that all ^{241}Am entering the plant was concentrated in the sludge. Wipe samples taken within the STP did not detect ^{241}Am above levels allowed for unrestricted use (20 dpm/100cm² removable alpha contamination and 100 dpm/100cm² total removable and fixed alpha contamination). Some of the workers used dried sludge as a soil

supplement in their home gardens, and one garden showed measurable amounts of ^{241}Am . Based on the sampling data, it was concluded that there did not appear to be a radiation hazard to the STP employees or landfill employees and that no specific safety measures beyond those normally taken by employees would be required of these facilities.

Case 3—Royersford, Pennsylvania

A commercial laundry for radioactively contaminated protective clothing discharged approximately 15,000 gallons of wastewater per day to the local sanitary sewer system. The wastewater from the laundry was temporarily stored, treated to adjust the pH, and analyzed for gross alpha and gross beta activity before the contents were released to the sanitary sewer system. Inspections by the NRC in late 1985 revealed no violations by the licensee. Subsequently, an inspection of the Royersford STP revealed radiation levels up to 12 $\mu\text{Sv/h}$ (1.2 mR/h) above background at the secondary digester. Because of these elevated levels, the NRC evaluated the impacts of the radionuclides released to the sanitary sewer system by the laundry facility. The evaluation encompassed not only the STP, but the potential radiological impact of sludge applications to agricultural areas as well. The results indicated that the highest potential doses would be received by farmers working the fields where the sludge had been applied. However, potential doses were less than 50 $\mu\text{Sv/yr}$ (5 mrem/yr). Radiation levels on the outside of a tank truck, used to carry the sludge to application sites, ranged up to 3 $\mu\text{Sv/h}$ (0.3 mR/h), well within the range allowed for transport by the Department of Transportation.

Case 4—Oak Ridge, Tennessee

A company in Oak Ridge which specialized in decontaminating nuclear power plant materials disposed of a small amount of radioactive material by release to the city sanitary sewer system. When a new STP was put into operation by the city of Oak Ridge, contamination of the sewer lines leading from the company was discovered. In addition, radionuclides were detected in the sludge being processed at the sewage treatment facility. The contamination was found at the STP in both its primary and secondary digesters. This sludge had subsequently been applied to deforested land at a government facility, resulting in radiation levels of about 0.1 $\mu\text{Sv/h}$ (0.01 mR/h) (2 to 3 times background) in the area. Stricter radioactive material release guidelines

were set by Tennessee's Division of Radiological Health, to limit the amount of radioactive material released to the sewer system. Additionally, the licensee was allowed to release only soluble material, because it was suspected that some of the material previously released had been insoluble.

A study was conducted by the State of Tennessee to evaluate the risk to the general public from the radionuclides released into the sanitary sewer systems at Oak Ridge and Erwin, Tennessee. The study estimated that there were four radionuclides of concern in the sludge, of which ^{137}Cs was the primary contaminant, with lesser quantities of ^{60}Co , ^{134}Cs and ^{54}Mn . It was determined that the primary risk would be through consumption of vegetables grown in a garden fertilized with sludge from the STP at an estimated dose rate of approximately 60 $\mu\text{Sv/yr}$ (6 mrem/yr).

Case 5—Washington, DC

The Blue Plains Wastewater Treatment Plant processes waste from the metropolitan Washington area, including a number of Federal research facilities that use a relatively broad spectrum of radionuclides. Some liquid effluents are released directly to the sanitary sewer system, while others are retained in temporary holding tanks to permit decay of short-lived isotopes before release. Inspections of two research facilities and the STP were conducted in early 1986, with no violations of Federal regulations or licenses noted. Samples were obtained at both facilities from holding tanks and effluent discharge points and at the STP for influent, liquid effluent, and sludge. Radionuclide concentrations in facility effluents were 2% or less of the limits specified for maximum daily release concentrations in Appendix B, Table I, Column 2 of the version of 10 CFR part 20 in effect at that time. Analysis of the STP samples revealed that concentrations of soluble isotopes, such as ^{137}Cs and beta-emitters in general, were on the same order of magnitude for liquid influent and effluent, and that concentrations in sludge were about 10% of those in the liquid samples. In contrast, for insoluble materials (primarily alpha-emitters), the influent concentrations were about 10 times higher than those of the liquid effluent samples.

Since the publication of the NUREG/CR-5814, additional incidents concerning the reconcentration of radioactive isotopes in sewerage sludge have been identified, and one is presented below.

Case 6—Cleveland, Ohio

During an aerial monitoring survey of an NRC licensee in the Cleveland metropolitan area, ^{60}Co contamination was identified in a STP that is part of the Northeast Ohio Regional Sewer District (NEORS) and services a large portion of Cuyahoga County. The source of the radioactivity may have originated from a sealed source manufacturer which had previously discharged to the STP. Analysis of treated sewerage sludges samples revealed ^{60}Co concentration averages from approximately 2.96 to 14.8 Bq/g (80 to 400 pCi/g). The STP is currently proceeding to remediate the site. In October 1993, the NRC has received two Requests for Modification of a License under 10 CFR 2.206 from NEORS. The first 2.206 Petition, notice of receipt published in the *Federal Register* on April 13, 1993 (58 FR 19282), requested modification to a license to require the licensee (1) to assume all costs resulting from the off-site release of cobalt-60 that had been deposited at a District treatment plant, and (2) to decontaminate the sewer line connecting the licensee's facility and the District's treatment plant. The second 2.206 Petition, notice of receipt published in the *Federal Register* on December 6, 1993; 58 FR 64341, requested modification to a license to require that the licensee provide adequate financial assurance to cover public liability pursuant to section 170 of the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2210. The NRC is taking appropriate action on the two 2.206 Petitions as separate matters.

List of Subjects in 10 CFR Part 20

Byproduct material, Criminal penalties, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Special nuclear material, Source material, Waste treatment and disposal.

The authority citation for this document is: Sec. 161, 58 Stat. 948, as amended (42 U.S.C. 2201); Sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

Dated at Rockville, MD, this 18th day of February, 1994.

For the Nuclear Regulatory Commission,
Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 94-4294 Filed 2-24-94; 8:45 am]

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